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Bill Gates Had a Q Clearance and a Private Editor at NIH

Across nearly twenty years, the Bill & Melinda Gates Foundation built a relationship with the federal government that ran on personal access as much as formal partnership. Newly released emails show the country's most senior public health officials treating one of the world's richest men as a colleague and a collaborator.

WHAT THE DOCUMENTS SHOW

1. **Bill Gates held a Department of Energy "Q" security clearance for seven years, spanning the height of the COVID-19 pandemic.** Responding to Chairman Paul's June 23, 2026 letter, DOE confirmed that Gates's "DOE Q security clearance was reciprocally granted on June 11, 2014, and subsequently terminated on December 6, 2021." A DOE "Q" security clearance permits access to Top Secret Restricted Data of the U.S. Government.

2. **Anthony Fauci served as Bill Gates's private editor, with the help of David Morens.** In April 2020, Gates requested Fauci's feedback on a memo titled "Pandemic I: The First Modern Pandemic" which set out how Gates was thinking about the COVID pandemic. In January 2022, Gates asked Fauci to edit his book "How to Prevent the Next Pandemic" before it was sent to the publisher. Fauci returned tracked changes, then wrote:

> **"I gave the manuscript in close confidence to a trusted colleague who destroyed it after reading it. His name is Dr. David Morens."**

3. **When the NIH Director urgently asked what his agency's ties to the Gates Foundation were, the answer came back that the foundation had been funding pieces of NIH.** On Friday, May 25, 2018, Francis Collins emailed Fauci and senior staff: "For reasons I can't currently explain, I need answers to the following: 1) are we giving any grants to BMGF (I assume no) 2) what are our current collaborative projects with BMGF?" He wanted it by Saturday afternoon. NIH's internal review reported that the foundation had never applied for an NIH grant, but that "BMGF has funded various components of NIH." That Sunday, Collins wrote again. Called to an Oval Office meeting with no stated agenda, he reported that Gates had been promoting a universal flu vaccine directly to the President, and asked:

> **"Is this coordinated in some way, or is Bill going rogue?"**

4. **DARPA gave the Gates Foundation a private briefing on four military biological threat programs.** On May 3, 2022, DARPA's Biological Technologies Office convened a ninety-minute session at agency headquarters for the foundation's Bioinnovation Accelerator, covering INTERCEPT, PREEMPT, Friend or Foe, and ReVector. PREEMPT's stated aim is "targeting viruses in animals before they emerge in humans." Its projects include bat sampling across four countries and a transmissible Lassa vaccine "with internal off switch," which the briefing lists for potential deployment in Sierra Leone, Guinea, and other West African countries.

5. **Collins told Melinda French Gates he had spent his tenure bringing NIH and the foundation closer together.** On October 8, 2021, days after announcing his resignation, Collins wrote: "It has been a privilege to work with the Bill and Melinda Gates Foundation over these 12 years, and I am glad to have had the chance to bring our global health efforts even closer together than ever."

It looks like you're trying to secretly run a federal health agency. Would you like help?

OK Cancel

Released by Chairman Rand Paul

Entered into the record by Chairman Rand Paul at the July 29, 2026 HSGAC Hearing titled, "Testimony of Anthony Fauci".

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United States Senate
COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510–6250

June 23, 2026

The Honorable Chris Wright
Secretary
Department of Energy
1000 Independence Avenue, SW
Washington, DC 20585

Dear Secretary Wright,

As you know, the Committee on Homeland Security and Governmental Affairs is conducting an investigation into the origins of COVID-19 and taxpayer-funded life sciences research. Through the course of the investigation, I have obtained information that leads me to believe that Bill Gates may have held a Department of Energy "Q" clearance.

For this reason, I request you provide written responses to the following questions no later than 5:00 PM on June 30, 2026:

1. Has William Henry Gates III (DOB: October 28, 1955) ever held a Department of Energy "Q" clearance or access authorization?
    a. If yes, please provide the date(s) upon which his "Q" clearance or access authorization became active and the corresponding termination date, if applicable.

Thank you for your attention to this matter.

Sincerely,

Rand Paul, M.D.
Chairman
U.S. Senate Committee on Homeland
Security and Governmental Affairs

Released by Chairman Rand Paul

Entered into the record by Chairman Rand Paul at the July 29, 2026 HSGAC Hearing titled, "Testimony of Anthony Fauci".

CUI

Department of Energy
Washington, DC 20585

June 30, 2026

The Honorable Rand Paul
Chairman, Senate Committee on Homeland
Security and Governmental Affairs
Washington, DC 20510

Dear Mr. Chairman:

The United States Department of Energy (DOE) has received your request for information regarding the DOE "Q" access authorization security clearance for Mr. William Henry Gates, III. Your inquiry was referred to the Office of Environment, Health, Safety and Security for a response.

The DOE Office of Headquarters Security Vetting [redacted] was the office responsible for processing Mr. Gates' security clearance. Mr. Gates' DOE Q security clearance was reciprocally granted on June 11, 2014, and subsequently terminated on December 6, 2021.

This information is subject to the Privacy Act of 1974 and is being provided pursuant to the exception in 5 U.S.C. § 552a(b)(9). DOE requests that this information be maintained in confidence and not for public release.

If you have any questions, you may contact me at [redacted] or [redacted]@doe.gov, , or [redacted] Deputy Assistant Secretary for Senate Affairs, Office of Congressional and Intergovernmental Affairs, at [redacted]

Sincerely,

[redacted]

Digitally signed by [redacted]
Date: 2026.06.30 17:19:51 -04'00'

[redacted]
Director
Office of Departmental Vetting and Assistance
Office of Environment, Health, Safety
and Security

cc: [redacted]

Released by Chairman Rand Paul

From: Bill Gates [redacted]@gatesventures.com>
To: "afauci@niaid.nih.gov" <afauci@niaid.nih.gov>
Cc: Trevor Mundel [redacted]@gatesfoundation.org>
Subject: Pandemic Innovation memo
Date: Wed, 22 Apr 2020 23:46:37 -0400
Importance: Normal
Attachments: Pandemic_I_-_The_First_Modern_Pandemic.pdf

Tony,

The attached memo sets out how I'm thinking about the COVID pandemic in its various aspects.

I plan on sharing it in its full length with some key audiences (like WHO, policymakers) and might do a shorter version for the broader public.

It's been great getting your feedback over the last few weeks, so if you think changes or additions are needed, please let me know.

Bill

Released by Chairman Rand Paul

Pandemic I: The First Modern Pandemic

BILL GATES

Released by Chairman Rand Paul

The coronavirus pandemic pits all of humanity against the virus. The damage to health, wealth, and well-being has already been enormous. This is like a world war, except in this case, we're all on the same side. Everyone can work together to learn about the disease and develop tools to fight it. I see global innovation as the key to limiting the damage. This includes innovations in testing, treatments, vaccines, and policies to limit the spread while minimizing the damage to economies and well-being.

This memo shares my view of the situation and how we can accelerate these innovations. The situation changes every day, there is a lot of information available—much of it contradictory—and it can be hard to make sense of all the proposals and ideas you may hear about. It can also sound like we have all the scientific advances needed to reopen the economy, but in fact we do not. Although some of what's below gets fairly technical, I hope it helps people make sense of what is happening, understand the innovations we still need, and make informed decisions about dealing with the pandemic.

Exponential growth and decline

In the first phase of the pandemic, we saw an exponential spread in a number of countries, starting with China and then throughout Asia, Europe, and the United States. The number of infections was doubling many times every month. If people's behavior had not changed, then most of the population would have been infected. By changing behavior, many countries have gotten the infection rate to plateau and start to come down.

Exponential growth is not intuitive. If you say that 2 percent of the population is infected and this will double every eight days, most people won't immediately figure out that in 40 days, the majority of the population will be infected. The big benefit of the behavior change is to reduce the infection rate dramatically so that, instead of doubling every eight days, it goes down every eight days.

We use something called the reproduction rate, or R0 (pronounced "are-nought"), to calculate how many new infections are caused by an earlier infection. R0 is hard to measure, but we know it's below 1.0 wherever the number of cases is going down and above 1.0 wherever the number of cases is going up. And what may appear to be a small difference in R0 can lead to very large changes.

If every infection goes from causing 2.0 cases to only causing 0.7 infections, then after 40 days you have one-sixth as many infections instead of 32 times as many. That's 192 times fewer cases. Here's another way to think about it: If you started with 100 infections in a community, after 40 days you would end up with 17 infections at the lower R0 and 3,200 at the higher one. Experts are debating now just how long to keep R0 very low to drive down the number of cases before opening up begins.

Exponential decline is even less intuitive. A lot of people will be stunned that in many places we will go from hospitals being overloaded in April to having lots of empty beds in July. The whiplash will be confusing, but it is inevitable from the exponential nature of infection.

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As we get into the summer, some locations that maintain behavior change will experience exponential decline. However, as behavior goes back to normal, some locations will stutter along with persistent clusters of infections and some will go back into exponential growth. The picture will be more complex than it is today, with a lot of heterogeneity.

Have we overreacted?

It is reasonable for people to ask whether the behavior change was necessary. Overwhelmingly, the answer is yes. There might be a few areas where the number of cases would never have gotten large numbers of infections and deaths, but there was no way to know in advance which areas those would be. The change allowed us to avoid many millions of deaths and extreme overload of the hospitals, which would also have increased deaths from other causes.

The economic cost that has been paid to reduce the infection rate is unprecedented. The drop in employment is faster than anything we have ever experienced. Entire sectors of the economy are shut down. It is important to realize that this is not just the result of government policies restricting activities. When people hear that an infectious disease is spreading widely, they change their behavior. There was never a choice to have the strong economy of 2019 in 2020.

Most people would have chosen not to go to work or restaurants or take trips, to avoid getting infected or infecting older people in their household. The government requirements made sure that enough people changed their behavior to get the reproduction rate below 1.0, which is necessary to then have the opportunity to resume some activities.

The wealthier countries are seeing reduced infections and starting to think about how to open up. Even as a government relaxes restrictions on behavior, not everyone will immediately resume the activities that are allowed. It will take a lot of good communication so that people understand what the risks are and feel comfortable going back to work or school. This will be a gradual process, with some people immediately doing everything that is allowed and others taking it more slowly. Some employers will take a number of months before they require workers to come back. Some people will want the restrictions lifted more rapidly and may choose to break the rules, which will put everyone at risk. Leaders should encourage compliance.

Differences among countries

The pandemic has not affected all countries equally. China was where the first infection took place. They were able to use stringent isolation and extensive testing to stop most of the spread. The wealthier countries, which have more people coming in from all over the world, were the next to be affected. The countries that reacted quickly to do lots of testing and isolation avoided large-scale infection. The benefits of early action also meant that these countries didn't have to shut down their economies as much as others.

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The ability to do testing well explains a lot of the variation. It is impossible to defeat an enemy we cannot see. So testing is critical to getting the disease under control and beginning to reopen the economy.

So far, developing countries like India and Nigeria account for a small portion of the reported global infections. One of the priorities for our foundation has been to help ramp up the testing in these countries so they know their situation. With luck, some factors that we don't understand yet, like how weather might affect the virus's spread, will prevent large-scale infection in these countries.

However, our assumption should be that the disease dynamics are the same as in other countries. Even though their populations are disproportionately young—which would tend to mean fewer deaths from COVID—this advantage is almost certainly offset by the fact that many low-income people's immune systems are weakened by conditions like malnutrition or HIV. And the less developed a country's economy is, the harder it is to make the behavior changes that reduce the virus's reproduction rate. If you live in an urban slum and do informal work to earn enough to feed your family every day, you won't find it easy to avoid contact with other people. Also, the health systems in these countries have far less capacity, so even providing oxygen treatment to everyone who needs it will be difficult.

Tragically, it is possible that the total deaths in developing countries will be far higher than in developed countries.

What we need to learn

Our knowledge of the disease will help us with tools and policies. There are a number of key things we still don't understand. A number of studies are being done to answer these questions, including one in Seattle done with the University of Washington. The global collaboration on these issues is impressive, and we should know a lot more by the summer.

- **IS THE DISEASE SEASONAL OR WEATHER DEPENDENT?**
  Almost all respiratory viruses (a group that includes COVID) are seasonal. This would mean there are fewer infections in the summer, which might lull us into complacency when the fall comes. This is a matter of degree. Because we see coronavirus spreading in Australia and other places in the Southern hemisphere, where the seasons are the opposite of ours, we already know the virus is not as seasonal as influenza is.

- **HOW MANY PEOPLE WHO NEVER GET SYMPTOMS HAVE ENOUGH OF THE VIRUS TO INFECT OTHERS? WHAT ABOUT PEOPLE WHO ARE RECOVERED AND HAVE SOME RESIDUAL VIRUS—HOW INFECTIOUS ARE THEY?**
  Computer models show that if there are a lot of people who are asymptomatic but infectious, it is much harder to open up without a resurgence in cases. There is a lot of disagreement about how much infection comes from these sources, but we do know that many people with the virus don't report symptoms, and some portion of those might end up transmitting it.

- **WHY DO YOUNG PEOPLE HAVE A LOWER RISK OF BECOMING SERIOUSLY ILL WHEN THEY GET INFECTED?**
  Understanding the dynamics here will help us weigh the risks of opening schools. It is a complicated subject because even if young people don't get sick as often, they might still spread the disease to others.

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- **WHAT SYMPTOMS INDICATE YOU SHOULD GET TESTED?**
  Some countries are taking the temperature of lots of people as an initial screening tool. If doing this helps us find more potential cases, we could use it at airports and large gatherings. We need to target the tests we have at the people at greatest risk since we don't have enough tests for everyone.

- **WHICH ACTIVITIES CAUSE THE MOST RISK OF INFECTION?**
  People ask me questions about avoiding prepared food or door knobs or public toilets so they can minimize their risk. I wish I knew what to tell them. Judgments will have to be made about different kinds of gatherings like classes or church going and whether some kind of spacing should be required. In places without good sanitation, there may be spread from fecal contamination since people who are infected shed the virus.

- **WHO IS MOST SUSCEPTIBLE TO THE DISEASE?**
  We know that older people are at much greater risk of both severe illness and death. Understanding how gender, race, and comorbidities affect this is a work in progress.

The Gates Foundation's role

In normal times, the Gates Foundation puts more than half of its resources into reducing deaths from infectious diseases. These diseases are the reason why a child in a poor country is 20 times more likely to die before the age of five than one in a rich country. We invest in inventing new treatments and vaccines for these diseases and making sure they get delivered to everyone who needs them. The diseases include HIV, malaria, tuberculosis, polio, and pneumonia. Whenever there is an epidemic like Ebola, SARS, or Zika we work with governments and the private sector to help model the risks and to help galvanize resources to create new tools to stop the epidemic. It was because of these experiences that I spoke out about the world not being ready for a respiratory epidemic in my 2015 TED talk. Although not enough was done, a few steps were taken to prepare, including the creation of the Coalition for Epidemic Preparedness Innovation, which I will discuss below, in the vaccine section.

Now that the epidemic has hit, we are applying our expertise to finding the best ideas in each area and making sure they move ahead at full speed. There are many efforts going on. More than 100 groups are doing work on treatments and another 100 on vaccines. We are funding a subset of these but tracking all of them closely. It is key to look at each project to see not only its chance of working but also the odds that it can be scaled up to help the entire world.

One urgent activity is to raise money for developing new tools. I think of this as the billions we need to spend so we can save trillions. Every additional month that it takes to get the vaccine is a month when the economy cannot return to normal. However, it isn't clear how countries will come together to coordinate the funding. Some could go directly to the private sector but demand that their citizens get priority. There is a lot of discussion among governments, the World Health Organization, the private sector, and our foundation about how to organize these efforts.

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Innovation to beat the enemy

During World War II, an amazing amount of innovation, including radar, reliable torpedoes, and code-breaking, helped end the war faster. This will be the same with the pandemic. I break the innovation into five categories: treatments, vaccines, testing, contact tracing, and policies for opening up. Without some advances in each of these areas, we cannot return to business as usual or stop the virus. Below, I go through each area in some detail.

TREATMENTS

Every week, you will be reading about new treatment ideas that are being tried out, but most of them will fail. Still, I am optimistic that some of these treatments will meaningfully reduce the disease burden. Some will be easier to deliver in rich countries than developing countries, and some will take time to scale. A number of these could be available by the summer or fall.

If in the spring of 2021 people are going to big public events—like a game or concert in a stadium—it will be because we have a miraculous treatment that made people feel confident about going out again. It's hard to know precisely what the threshold is, but I suspect it is something like 95 percent; that is, we need a treatment that is 95 percent effective in order for people to feel safe in big public gatherings. Although it is possible that a combination of treatments will have over 95 percent effectiveness, it's not likely, so we can't count on it. If our best treatments reduce the deaths by less than 95 percent, then we will still need a vaccine before we can go back to normal.

One potential treatment that doesn't fit the normal definition of a drug involves collecting blood from patients who have recovered from COVID, making sure it's free of the coronavirus and other infections, and giving the plasma to people who are sick. The leading companies in this area are working together to get a standard protocol to see if this works. They will have to measure each patient to see how strong their antibodies are. A variant of this approach is to take the plasma and concentrate it into a compound called hyperimmune globulin, which is much easier and faster to give a patient than unconcentrated plasma. The foundation is supporting a consortium of most of the leading companies that work in this area to accelerate the evaluation and, if the procedure works, be ready to scale it up. These companies have developed a Plasma Bot to help recovered COVID patients donate plasma for this effort.

Another type of potential treatment involves identifying the antibodies produced by the human immune system that are most effective against the novel coronavirus. Once those antibodies have been found, they can be manufactured and used as a treatment or as a way to prevent the disease (in which case it is known as passive immunization). This antibody approach also has a good chance of working, although it's unclear how many doses can be made. It depends on how much antibody material is needed per dose; in 2021, manufacturers may be able to make as few as 100,000 treatments or many millions. The lead times for manufacturing are about seven months in the best case. Our grantees are working to compare the different antibodies and make sure the best ones get access to the limited manufacturing capacity.

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There is a class of drugs called antivirals, which keep the virus from functioning or reproducing. The drug industry has created amazing antivirals to help people with HIV, although it took decades to build up the large library of very effective triple drug therapies. For the novel coronavirus, the leading drug candidate in this category is Remdesivir from Gilead, which is in trials now. It was created for Ebola. If it proves to have benefits, then the manufacturing will have to be scaled up dramatically.

The foundation recently asked drug companies to provide access to their pipeline of developed antiviral drugs so researchers funded by the Therapeutics Accelerator can run a screen to see which should go into human trials first. The drug companies all responded very quickly, so there is a long list of antivirals being screened.

Another class of drugs works by changing how the human body reacts to the virus. Hydroxychloroquine is in this group. The foundation is funding a trial that will give an indication of whether it works on COVID by the end of May. It appears the benefits will be modest at best. Another type of drug that changes the way a human reacts to a virus is called an immune system modulator. These drugs would be most helpful for late-stage serious disease. All of the companies that work in this area are doing everything they can to help with trials.

VACCINES

Vaccines have saved more lives than any other tool in history. Smallpox, which used to kill millions of people every year, was eradicated with a vaccine. New vaccines have played a key role in reducing childhood deaths from 10 million per year in 2000 to fewer than 5 million per year today.

Short of a miracle treatment, which we can't count on, the only way to return the world to where it was before COVID showed up is a highly effective vaccine that prevents the disease.

Unfortunately, the typical development time for a vaccine against a new disease is over five years. This is broken down into: a) making the candidate vaccine; b) testing it in animals; c) safety testing in small numbers of people (this is known as phase 1); d) safety and efficacy testing in medium numbers (phase 2); e) safety and efficacy testing in large numbers (phase 3); and f) final regulatory approval and building manufacturing while registering the vaccine in every country.

Researchers can save time by compressing the clinical safety/efficacy phases while conducting animal tests and building manufacturing capacity in parallel. Even so, no one knows in advance which vaccine approach will work, so a number of them need to be funded so they can advance at full speed. Many of the vaccine approaches will fail because they won't generate a strong enough immune response to provide protection. Scientists will get a sense of this within three months of testing in humans by looking at the antibody generation. Of particular interest is whether the vaccine will protect older people, whose immune systems don't respond as well to vaccines.

The issue of safety is obviously very important. Regulators are very stringent about safety, to avoid side effects and also to protect the reputation of vaccines broadly, since if one has significant problems, people will become more hesitant to take any vaccines. Regulators worldwide will have to work together to decide how large the safety database needs to be to approve a COVID vaccine.

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One step that was taken after the foundation and others called for investments in pandemic preparedness in 2015 was the creation of the Coalition for Epidemic Preparedness Innovations (CEPI). Although the resources were quite modest, they have helped advance new approaches to making vaccines that could be used for this pandemic. CEPI added resources to work on an approach called RNA vaccines, which our foundation had been supporting for some time. Three companies are pursuing this approach. The first vaccine to start human trials is an RNA vaccine from Moderna, which started a phase 1 clinical safety evaluation in March.

An RNA vaccine is significantly different from a conventional vaccine. A flu shot, for example, contains bits of the flu virus that your body's immune system learns to attack. This is what gives you immunity. With an RNA vaccine, rather than injecting fragments of the virus, you give the body the genetic code needed to produce lots of copies of these fragments. When the immune system sees the viral fragments, it learns how to attack them. An RNA vaccine essentially turns your body into its own vaccine manufacturing unit.

There are also at least five leading efforts that look promising and that use other approaches to teach the immune system to recognize and attack a viral infection. CEPI and our foundation will be tracking efforts from all over the world to make sure the most promising ones get resources. Once a vaccine is ready, our partner GAVI will make sure it is available even in low-income countries.

A big challenge for vaccine trials is that the time required for the trials depends on finding trial locations where the rate of infection is fairly high. While you are setting up the trial site and getting regulatory approval, the infection rate in that location could go down. And trials have to involve a surprisingly large number of people. For example, suppose the expected rate of infection is 1 percent per year and you want to run a trial where you would expect 50 people to be infected without the vaccine. To get a result in six months, the trial would need 10,000 people in it.

The goal is to pick the one or two best vaccine constructs and vaccinate the entire world—that's 7 billion doses if it is a single-dose vaccine, and 14 billion if it is a two-dose vaccine. The world will be in a rush to get them, so the scale of the manufacturing will be unprecedented and will probably have to involve multiple companies.

I am often asked when large-scale vaccination will start. Like America's top public health officials, I say that it is likely to be 18 months, even though it could be as short as nine months or closer to two years. A key piece will be the length of the phase 3 trial, which is where the full safety and efficacy are determined. When the vaccine is first being manufactured, there will be a question of who should be vaccinated first. Ideally, there would be global agreement about who should get the vaccine first, but given how many competing interests there are, this is unlikely to happen. The governments that provide the funding, the countries where the trials are run, and the places where the pandemic is the worst will all make a case that they should get priority.

TESTING

All of the tests to date for the novel coronavirus involve taking a nasal swab and processing it in a Polymerase Chain Reaction (PCR) machine. Our foundation invested in research showing that having patients do the swab themselves, at the tip of the nose, is as accurate as having a doctor push the swab further down to the back of your

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throat. Our grantees are also working to design swabs that are cheap and able to be manufactured at large scale but work as well as ones that are in short supply. This self-swab approach is faster, protects health care workers from the risk of exposure, and should let regulators approve swabbing in virtually any location instead of only at a medical center. The PCR test is quite sensitive—it will generally show whether you have the virus even before you have symptoms or are infecting other people.

There has been a lot of focus on the number of tests being performed in each country. Some, like South Korea, did a great job of ramping up the testing capacity. But the number of tests alone doesn't show whether they are being used effectively. You also have to make sure you are prioritizing the testing on the right people. For example, health care workers should be able to get an immediate indication of whether they are infected so they know whether to keep working. People without symptoms should not be tested until we have enough tests for everyone with symptoms. Additionally, the results from the test should come back in less than 24 hours so you quickly know whether to continue isolating yourself and quarantining the people who live with you. In the United States, it was taking over seven days in some locations to get test results, which reduces their value dramatically. This kind of delay is unacceptable.

There are two types of PCR machines: high-volume batch processing machines and low-volume machines. Both have a role to play. The high-volume machines provide most of the capacity. The low volume machines are better when getting a result in less than an hour is beneficial. Everyone who makes these machines, and some new entrants, are making as many machines as they can. Adding this capacity and making full use of the machines that are already available will increase the testing capacity. The foundation is talking to the manufacturers about different ways to run the big machines that could make them more than twice as productive.

Another type of test being developed is called a Rapid Diagnostic Test (RDT). This would be like an in-home pregnancy test. You would swab your nose the same way as for the PCR test, but instead of sending it into a processing center, you would put it in a liquid container and then pour that liquid onto a strip of paper that would change color if it detects the virus. This form of test may be available in a few months. Even though it won't be as sensitive as a PCR test, for someone who has symptoms it should be quite accurate. You would still need to report your test result to your government since they need visibility into the disease trends.

A lot of people talk about the serology test, where you give blood and it detects whether you have antibodies against the virus. If you do, it means you have been exposed. These tests only show positive results late in your disease, so they do not help you decide whether to quarantine. Also, all the tests done so far have problems with false positives. Until we understand what level of antibodies is protective and have a test with almost no false positives, it is a mistake to tell people not to worry about their exposure to infection based on the serology tests that are available today. In the meantime, serology tests will be used to see who can donate blood and to understand the disease dynamics.

A lot of countries did a good job focusing the PCR capacity on the priority patients. Most countries had their government play a central role in this process. In the United States, there is no system for making sure the testing is allocated rationally. Some states have stepped in, but even in the best states, the access isn't fully controlled.

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Testing becomes extremely important as a country considers opening up. You want to have so much testing going on that you see hot spots and are able to intervene by changing policy before the numbers get large. You don't want to wait until the hospitals start to fill up and the number of deaths goes up.

Basically, there are two critical cases: anyone who is symptomatic, and anyone who has been in contact with someone who tested positive. Ideally both groups would be sent a test they can do at home without going into a medical center. Tests would still be available in medical centers, but the simplest is to have the majority done at home. To make this work, a government would have to have a website that you go to and enter your circumstances, including your symptoms. You would get a priority ranking, and all of the test providers would be required to make sure they are providing quick results to the highest priority levels. Depending on how accurately symptoms predict infections, how many people test positive, and how many contacts a person typically has, you can figure out how much capacity is needed to handle these critical cases. For now, most countries will use all of their testing capacity for these cases.

There will be a temptation for companies to buy testing machines for their employees or customers. A hotel or cruise ship operator would like to be able to test everyone even if they don't have symptoms. They will want to get PCR machines that give quick results or the rapid diagnostic test. These companies will be able to bid very high prices—well above what the public health system would bid—so governments will have to determine when there is enough capacity to allow this.

One assumption is that people who need to get tested will isolate themselves and quarantine those in their household. Some governments police this carefully, whereas others simply assume people will follow the recommendation. Another issue is whether a government provides a place for someone to isolate themselves if they can't do it at their home. This is particularly important if you have older people in close quarters at your house.

CONTACT TRACING

I mentioned in the testing section that one of the key priorities for testing is anyone who has been in close contact with someone who has tested positive. If you can get a list of these people quickly and make sure they are prioritized for a test like the PCR test (which is sensitive enough to detect a recent infection), then these people can isolate themselves before they infect other people. This is the ideal way of stopping the spread of the virus.

Some countries, including China and South Korea, required patients to turn over information about where they have been in the last 14 days by looking at GPS information on their phone or their spending records. It is unlikely that Western countries will require this. There are applications you can download that will help you remember where you have been; if you ever test positive, then you can voluntarily review the history or choose to share it with whoever interviews you about your contacts.

A number of digital approaches are being proposed where phones detect what other phones are near them. (It would involve using Bluetooth plus sending a sound out that humans can't hear but that verifies that the two

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phones are reasonably close to each other.) The idea is that if someone tests positive then their phone can send a message to the other phones and their owners can get tested. If most people voluntarily installed this kind of application, it would probably help some. One limitation is that you don't necessarily have to be in the same place at the same time to infect someone—you can leave the virus behind on a surface. This system would miss this kind of transmission.

I think most countries will use the approach that Germany is using, which requires interviewing everyone who tests positive and using a database to make sure there is follow-up with all the contacts. The pattern of infections is studied to see where the risk is highest and policy might need to change.

In Germany, if someone is tested and confirmed positive, the doctor is legally required to inform the local government health office. The doctor must provide all personal data—name, address, phone number—so that the health office can contact the person and ensure they isolate themselves.

Then the local health office begins the process of contact tracing. They interview the infected person, find out how to contact all the people he or she has met in the past couple of weeks, and contact those people to ask them to self-isolate and get a test.

This approach relies on the infected person to report their contacts accurately, and also depends on the ability of the health authorities to follow up with everyone. The normal health service staff can't possibly do all this work even if the case numbers are fairly low. Every health system will have to figure out how to staff up so that this work is done in a timely fashion. Everyone who does the work would have to be properly trained and required to keep all the information private. Researchers would be asked to study the database to find patterns of infection, again with privacy safeguards in place.

OPENING UP

Most developed countries will be moving into the second phase of the epidemic in the next two months. In one sense, it is easy to describe this next phase. It is semi-normal. People can go out, but not as often, and not to crowded places. Picture restaurants that only seat people at every other table, and airplanes where every middle seat is empty. Schools are open, but you can't fill a stadium with 70,000 people. People are working some and spending some of their earnings, but not as much as they were before the pandemic. In short, times are abnormal but not as abnormal as during the first phase.

The rules about what is allowed should change gradually so that we can see if the contact level is starting to increase the number of infections. Countries will be able to learn from other countries that have strong testing systems in place to inform them when problems come up.

One example of gradual reopening is Microsoft China, which has roughly 6,200 employees. So far about half are now coming in to work. They are continuing to provide support to employees who want to work at home. They insist people with symptoms stay home. They require masks and provide hand sanitizer and do more intensive

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cleaning. Even at work, they apply distancing rules and only allow travel for exceptional reasons. China has been conservative about opening up and has so far avoided any significant rebound.

The basic principle should be to allow activities that have a large benefit to the economy or human welfare but pose a small risk of infection. But as you dig into the details and look across the economy, the picture quickly gets complicated. It is not as simple as saying "you can do X, but not Y." The modern economy is far too complex and interconnected for that.

For example, restaurants can keep diners six feet apart, but will they have a working supply chain for their ingredients? Will they be profitable with this reduced capacity? The manufacturing industry will need to change factories to keep workers farther apart. Most factories will be able to adapt to new rules without a large productivity loss. But how do the people employed in these restaurants and factories get to work? Are they taking a bus or train? What about the suppliers who provide and ship parts to the factory? And when should companies start insisting their employees show up at work?

There are no easy answers to these questions. Ultimately, leaders at the national, state, and local levels will need to make trade-offs based on the risks and benefits of opening various parts of the economy. In the United States it will be tricky if one state opens up too fast and starts to see lots of infections. Should other states try to stop people moving across state boundaries?

Schools offer a big benefit and should be a priority. Large sporting and entertainment events probably will not make the cut for a long time; the economic benefit of the live audience doesn't measure up to the risk of spreading the infection. Other activities fall into a gray area, such as church services or a high school soccer game with a few dozen people on the sidelines.

There is one other factor that is hard to account for: human nature. Some people will be naturally reluctant to go out even once the government says it is okay. Others will take the opposite view—they will assume that the government is being overly cautious and start bucking the rules. Leaders will need to think carefully about how to strike the right balance here.

Conclusion

Melinda and I grew up learning that World War II was the defining moment of our parents' generation. In a similar way, the COVID pandemic—the first modern pandemic—will define this era. No one who lives through Pandemic I will ever forget it. And it is impossible to overstate the pain that people are feeling now and will continue to feel for years to come.

The heavy cost of the pandemic for lower-paid and poor people is a special concern for Melinda and me. The disease is disproportionately hurting poorer communities and racial minorities. Likewise, the economic impact of

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the shutdown is hitting low-income, minority workers the hardest. Policymakers will need to make sure that, as the country opens up, the recovery doesn't make inequality even worse than it already is.

At the same time, we are impressed with how the world is coming together to fight this fight. Every day, we talk to scientists at universities and small companies, CEOs of pharmaceutical companies, or heads of government to make sure that the new tools I've discussed become available as soon as possible. And there are so many heroes to admire right now, including the health workers on the front line. When the world eventually declares Pandemic I over, we will have all of them to thank for it.

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Casco, Tony (NIH/NIAID) [C]

From: Gail Carson <[redacted]@ndm.ox.ac.uk>
Sent: Wednesday, October 15, 2014 9:04 AM
To: Tatiana Verdon; [redacted]@imperial.ac.uk; [redacted]@virginia.edu; Peter Horby; wbrooks3@jhu.edu; [redacted]@who.int; [redacted]@who.int; [redacted]@gmail.com; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int; [redacted]@med.navy.mil; [redacted]@phac-aspc.gc.ca; Kobinger, Gary (Public Health Agency of Canada); [redacted]@linkp.com; Larry Zeitlin; [redacted]@sbcglobal.net; [redacted]@icloud.com; [redacted]@tekmirapharm.com; [redacted]@mail.mil; [redacted]@mail.mil; Higgs, Elizabeth (NIH/NIAID) [E]; Olinger, Gene (NIH/NIAID) [C]; Jahrling, Peter (NIH/NIAID) [E]; Hensley, Lisa (NIH/NIAID) [E]; Davey, Richard (NIH/NIAID) [E]; [redacted]@replicor.com; [redacted]@replicor.com; [redacted]@Sarepta.com; [redacted]@Sarepta.com; [redacted]@utoronto.ca; [redacted]@accella-advisors.com; [redacted]@kgu.de; Uyeki, Timothy M. (CDC/OID/NCIRD); Fischer, William A. II; Michelle Berrey; [redacted]@medivector.com; [redacted]@toyama-chemical.co.jp; Christopher, George (DOD); [redacted]@mail.mil; Randall Lanier; [redacted]@uhnres.utoronto.ca; [redacted]@its.jnj.com; Calum Semple ([redacted]@liverpool.ac.uk); [redacted]@its.jnj.com; [redacted]@gatesfoundation.org; Steiner Mag. Thomas; [redacted]@BIOCRYST.com; Peter Horby
Cc: Kajsa-Stina Longuere; Raul Pardinaz-Solis; Hayden, Frederick G *HS ([redacted]@hscmail.mcc.virginia.edu); Rebecca Howell-Jones ([redacted]@hotmail.com); Sigfrid Louise (EAST SUSSEX HEALTHCARE NHS TRUST) ([redacted]@nhs.net); [redacted]@chimerix.com; Gail Carson
Subject: RE: Agenda and dial in numbers _ Ebola Therapeutics WG Teleconference on Thursday October 16th at 15:00 BST
Attachments: Draft Minutes Ebola WG TCC [redacted] Draft v1_fgh.docx; isaricnumbers.pdf; WHO slides Oct 16 final version.pdf

Dear All,

We are looking forward to speaking to you again tomorrow at 15:00 BST.

Raul will host the call for ISARIC.

The agenda for the TCC is:

Welcome- FH
New introductions- Medivector, Fuji/Toyama
WHO update- DW, MF, AMHR, NS
US CDC Update- TU
Favipiravir (T705)- CE, HK
Discussion
AOB

I have attached the draft minutes, the dial in numbers and one presentation.

Released by Chairman Rand Paul

PIN number: [redacted]#

Best wishes
Gail

Dr Gail Carson (formerly Thomson)

Clinical Coordinator & Consultant in Infectious Diseases
International Severe Acute Respiratory & emerging Infection Consortium (ISARIC)
University of Oxford, Nuffield Department of Medicine Research Building,
Old Road Campus, Headington, OX3 7FZ, UK

[redacted]
www.isaric.org

From: Gail Carson
Sent: 29 September 2014 21:27
To: Tatiana Verdon; [redacted]@imperial.ac.uk; [redacted]@virginia.edu; Peter Horby; [redacted]@jhu.edu; [redacted]@who.int; [redacted]@who.int; [redacted]@gmail.com; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int; [redacted]@med.navy.mil; [redacted]@phac-aspc.gc.ca; [redacted]@phac-aspc.gc.ca; [redacted]@linkp.com; [redacted]@mappbio.com; [redacted]@sbcglobal.net; [redacted]@icloud.com; [redacted]@tekmirapharm.com; [redacted]@mail.mil; [redacted]@mail.mil; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@niaid.nih.gov; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@replicor.com; [redacted]@replicor.com; [redacted]@Sarepta.com; [redacted]@Sarepta.com; [redacted]@utoronto.ca; [redacted]@accella-advisors.com; [redacted]@kgu.de; [redacted]@cdc.gov; Fischer, William A. II; Michelle Berrey; [redacted]@mail.mil; [redacted]@mail.mil; Randall Lanier; [redacted]@uhnres.utoronto.ca; [redacted]@its.jnj.com; Calum Semple ([redacted]@liverpool.ac.uk); [redacted]@its.jnj.com; [redacted]@gatesfoundation.org
Cc: Kajsa-Stina Longuere; Raul Pardinaz-Solis; Hayden, Frederick G *HS ([redacted]@hscmail.mcc.virginia.edu); Rebecca Howell-Jones ([redacted]@hotmail.com); Sigfrid Louise (EAST SUSSEX HEALTHCARE NHS TRUST) ([redacted]@nhs.net)
Subject: Reminder: Ebola Therapeutics WG Teleconference on Thursday October 2nd at 15:00 BST

Dear All,

We look forward to speaking to you on Thursday at 15:00 BST.
The agenda and dial in numbers are to follow.

Thank you.
Gail

Dr Gail Carson (formerly Thomson)

Clinical Coordinator & Consultant in Infectious Diseases
International Severe Acute Respiratory & emerging Infection Consortium (ISARIC)
University of Oxford, Nuffield Department of Medicine Research Building,
Old Road Campus, Headington, OX3 7FZ, UK

[redacted]
www.isaric.org

From: Gail Carson
Sent: 17 September 2014 15:40
To: Tatiana Verdon; [redacted]@imperial.ac.uk; [redacted]@virginia.edu; Peter Horby; [redacted]@jhu.edu; [redacted]@who.int; [redacted]@who.int; [redacted]@gmail.com; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int; [redacted]@med.navy.mil; [redacted]@phac-aspc.gc.ca; [redacted]@phac-aspc.gc.ca; [redacted]@linkp.com; [redacted]@mappbio.com; [redacted]@sbcglobal.net; [redacted]@icloud.com; [redacted]@tekmirapharm.com; [redacted]@mail.mil; [redacted]@mail.mil; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@niaid.nih.gov; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@replicor.com; [redacted]@replicor.com; [redacted]@Sarepta.com; [redacted]@Sarepta.com; [redacted]@utoronto.ca; [redacted]@accella-advisors.com;

Released by Chairman Rand Paul

[redacted]@kgu.de; [redacted]@cdc.gov; Fischer, William A. II; Michelle Berrey; [redacted]@mail.mil; [redacted]@mail.mil; Randall Lanier; [redacted]@uhnres.utoronto.ca; [redacted]@its.jnj.com; Calum Semple ([redacted]@liverpool.ac.uk); [redacted]@its.jnj.com; [redacted]@gatesfoundation.org
Cc: Kajsa-Stina Longuere; Raul Pardinaz-Solis; Hayden, Frederick G *HS ([redacted]@hscmail.mcc.virginia.edu); Rebecca Howell-Jones ([redacted]@hotmail.com); Sigfrid Louise (EAST SUSSEX HEALTHCARE NHS TRUST) ([redacted]@nhs.net)
Subject: Updated agenda: Ebola Therapeutics WG Teleconference on Thursday September 18th at 15:00 BST _ Agenda and dial in numbers

Dear All,

There has been a change to the agenda. Please note that there will be a presentation on Brincidofovir (CMX001).

Best wishes
Gail Carson on behalf of Fred Hayden

From: Gail Carson
Sent: 17 September 2014 14:42
To: Tatiana Verdon; [redacted]@imperial.ac.uk; [redacted]@virginia.edu; Peter Horby; [redacted]@jhu.edu; [redacted]@who.int; [redacted]@who.int; [redacted]@gmail.com; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int; [redacted]@med.navy.mil; [redacted]@phac-aspc.gc.ca; [redacted]@phac-aspc.gc.ca; [redacted]@linkp.com; [redacted]@mappbio.com; [redacted]@sbcglobal.net; [redacted]@icloud.com; [redacted]@tekmirapharm.com; [redacted]@mail.mil; [redacted]@mail.mil; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@niaid.nih.gov; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@replicor.com; [redacted]@replicor.com; [redacted]@Sarepta.com; [redacted]@Sarepta.com; [redacted]@utoronto.ca; [redacted]@accella-advisors.com; [redacted]@kgu.de; [redacted]@cdc.gov; Fischer, William A. II; Michelle Berrey; [redacted]@mail.mil; [redacted]@mail.mil; Randall Lanier; [redacted]@uhnres.utoronto.ca; [redacted]@its.jnj.com; Calum Semple ([redacted]@liverpool.ac.uk); [redacted]@its.jnj.com
Cc: Kajsa-Stina Longuere; Raul Pardinaz-Solis; Hayden, Frederick G *HS ([redacted]@hscmail.mcc.virginia.edu); Gail Carson; Rebecca Howell-Jones ([redacted]@hotmail.com); Sigfrid Louise (EAST SUSSEX HEALTHCARE NHS TRUST) ([redacted]@nhs.net)
Subject: RE: Ebola Therapeutics WG Teleconference on Thursday September 18th at 15:00 BST _ Agenda and dial in numbers
Importance: High

Dear All,

We look forward to speaking with you on Thursday at 15:00 BST.

The agenda is:

- Welcome- FGH
- New Introductions- All
- WHO Update- MF, DW, VS, NS
- Report from USCDC-WHO Clinical Teleconference- TU
- Convalescent plasma/WB transfusion- DW, CS, TL
- Animal model studies- LH, GO, , SB, GK
- Brincidofovir (CMX001)- RL

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- Andeovirus-MVA vaccine strategy- BC (JNJ)
- Next steps

The dial in numbers are attached.
The PIN is: [redacted]#

There are 4 attachments: the dial in numbers, a review on Selenium by Billy Fischer and two sets of minutes.

If you have any queries please contact either Fred or me.

Best wishes
Gail

Dr Gail Carson (formerly Thomson)
ISARIC Clinical Coordinator

From: Tatiana Verdon
Sent: 05 September 2014 14:55
To: [redacted]@imperial.ac.uk; [redacted]@virginia.edu; Peter Horby; [redacted]@jhu.edu; [redacted]@who.int; [redacted]@who.int; [redacted]@gmail.com; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int; [redacted]@med.navy.mil; [redacted]@phac-aspc.gc.ca; [redacted]@phac-aspc.gc.ca; [redacted]@linkp.com; [redacted]@mappbio.com; [redacted]@sbcglobal.net; [redacted]@icloud.com; [redacted]@tekmirapharm.com; [redacted]@mail.mil; [redacted]@mail.mil; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@niaid.nih.gov; [redacted]@nih.gov; [redacted]@nih.gov; [redacted]@replicor.com; [redacted]@replicor.com; [redacted]@Sarepta.com; [redacted]@Sarepta.com; [redacted]@utoronto.ca; [redacted]@accella-advisors.com; [redacted]@kgu.de; [redacted]@cdc.gov; Fischer, William A. II; Michelle Berrey; [redacted]@mail.mil; [redacted]@mail.mil; Randall Lanier
Cc: Kajsa-Stina Longuere; Raul Pardinaz-Solis; Gail Carson; Hayden, Frederick G *HS ([redacted]@hscmail.mcc.virginia.edu)
Subject: Ebola Therapeutics WG Teleconference on September 18th at 15:00 BST

Dear All,

Professor Fred Hayden would like to invite you to the next Ebola Therapeutics WG Teleconference on September 18th at 15:00 BST.

The minutes from the last call and the dial in numbers will follow in due course.

Best wishes,
Tatiana
ISARIC Coordination Centre, Oxford

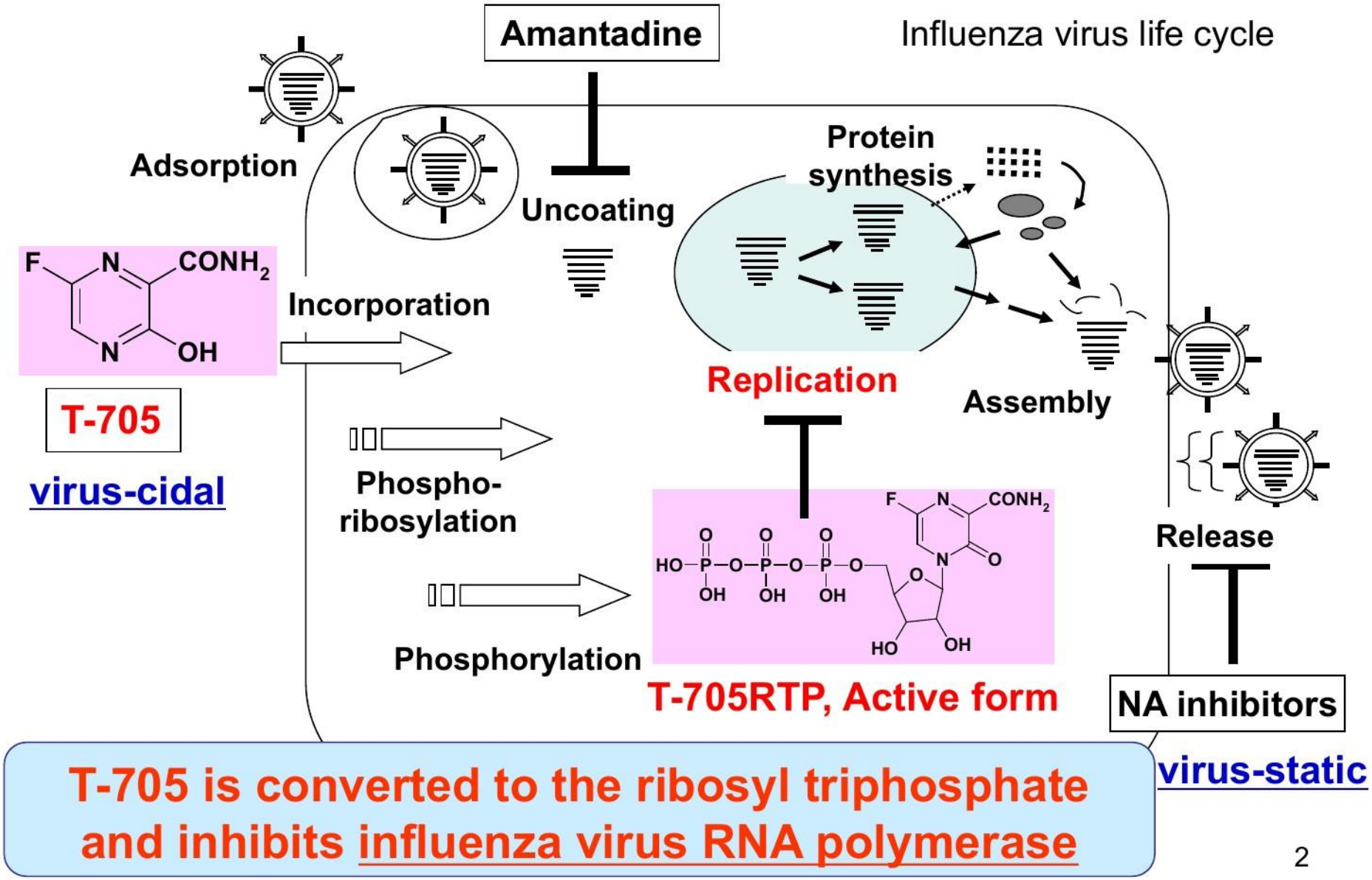
Released by Chairman Rand Paul

Favipiravir for Ebola

October 16, 2014
Fujifilm Pharmaceuticals
Fujifilm Holdings
Toyama Chemical
MediVector

Released by Chairman Rand Paul

Mechanism of Action for Favipiravir



Released by Chairman Rand Paul

New Drug Application Approval favipiravir in Japan
AVIGAN® Tablet 200mg

- March 24, 2014
- Indications
  - Novel or re-emerging influenza virus infections (limited to cases in which other anti-influenza virus agents are not effective or insufficiently effective)
- Contraindications
  - Women known or suspected to be pregnant
- Dosage and Administration (for adults in Japan)
  - 1600 mg orally twice for 1 day followed by 600 mg orally twice daily for 4 days. The total administration period is five days.

AVIGAN® is a drug the use of which is considered only when there is an outbreak of novel or re-emerging influenza virus infections in which other anti-influenza virus agents are not effective or insufficiently effective, and the government decides to use the drug as a countermeasure against such influenza viruses.
It is manufactured upon request by the Minister of Health, Labor, and Welfare.

Released by Chairman Rand Paul

Availability, Manufacturing Capability

- Toyama currently has a stock of 2.8 million tablets in terms of the 200mg tablet. They correspond to 56,000 treatment courses under the dose regimen for the on-going Phase 3 clinical studies for influenza (1,800mg BID on Day 1 followed by 800 mg BID on Day 2 to 5). Please note the dose regimen for Ebola treatment could be different than influenza.
- Upon request by the Minister of Health, Labor, and Welfare, our monthly manufacturing capacity is around 8 million tablets.

Released by Chairman Rand Paul

In vitro antiviral activity of favipiravir against EBOV

1) Successful treatment of advanced Ebola virus infection with T-705 (favipiravir) in a small animal model

Oestereich L et al. *Antiviral Res.* 2014 105:17-21.

IC_{50} = 10.5 μg/ml

IC_{90} = 17 μg/ml

IC_{99} = 29 μg/ml

- Zaire EBOV Mayinga 1976
- Vero E6 cells

2) Post-exposure efficacy of oral T-705 (Favipiravir) against inhalational Ebola virus infection in a mouse model.

Smither SJ et al. *Antiviral Res.* 2014 104:153-155.

EC_{50} EC_{90}= 31 - 63 μg/ml

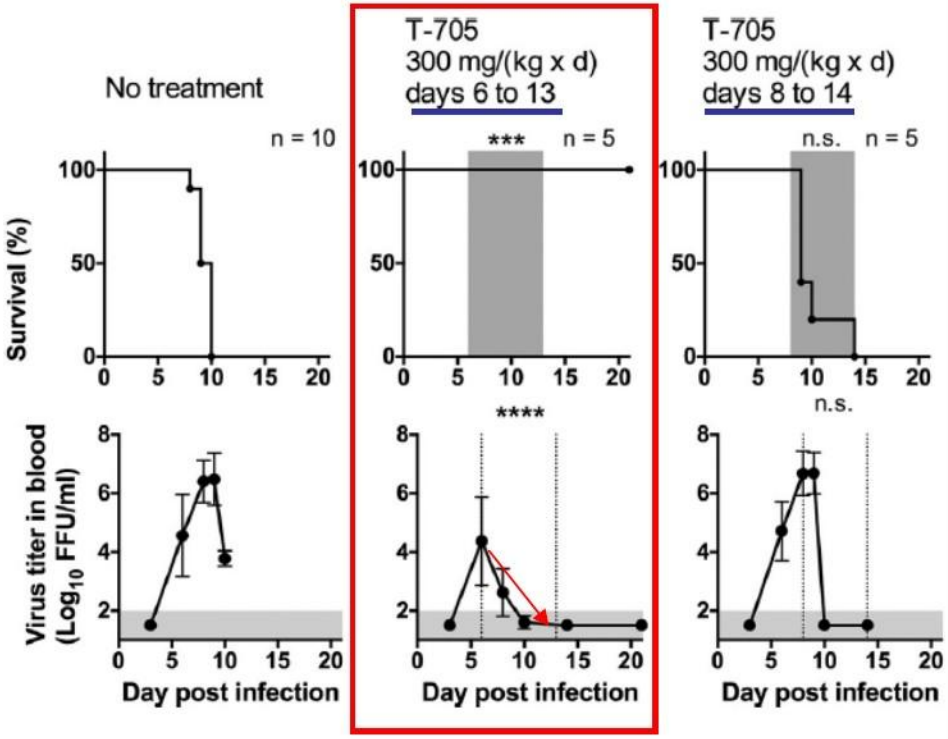
- EBOV E718, Kikwit
- Vero C1008 cells

Released by Chairman Rand Paul

Efficacy of favipiravir in mice infected with EBOV

1) Successful treatment of advanced Ebola virus infection with T-705 (favipiravir) in a small animal model

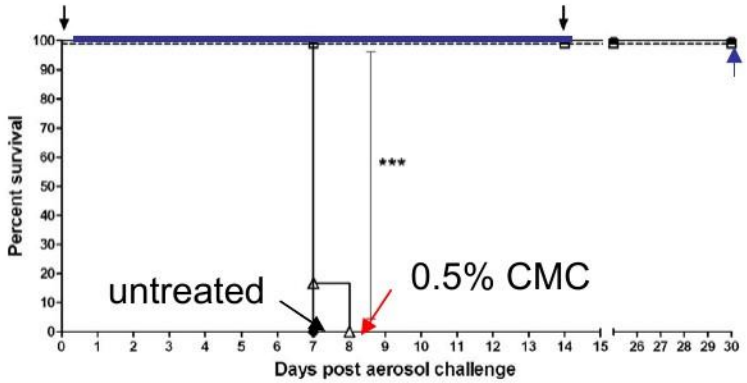
Oestereich L et al. *Antiviral Res.* 2014 105:17-21.



- Zaire EBOV Mayinga 1976
- IFNAR-/- C57BL/6 mice
- Dose regimen: 150mg/kg BID, 8 days
- Treatment was initiated at Day 6 or 8 post infection

2) Post-exposure efficacy of oral T-705 (Favipiravir) against inhalational Ebola virus infection in a mouse model.

Smither SJ et al. *Antiviral Res.* 2014 104:153-155.



- EBOV E718
- IFNAR-/- A129 mice
- Dose regimen: 150mg/kg BID, 14 days
- Treatment was initiated 1 hr after the infection

In lethal mouse models, favipiravir gave 100% protection against EBOV infection at 150mg/kg BID.

Released by Chairman Rand Paul

Phase 3 Global Program Influenza

- Global study dose regimen 1800mg BID Day 1, 800mg BID Days 2-5
- Elevations of uric acid (asymptomatic)
- Blinded studies include Asians (56), blacks from US, Europe and Australia (294), and South African blacks (colored) (13)
- Approximately 1,000 subjects on active regimen in the flu program
- No safety signals detected
- Funded by US DoD (drug supplies in the US are property of DoD)

Released by Chairman Rand Paul

NHP Study Results

- Conducted at USAMRIID in BSL-4
- First time any study done with oral medication (oral gavage) for Ebola
- First time BID dosing (with BID sedation) done
- Preliminary
- Confidential
- Unaudited

Released by Chairman Rand Paul

First NHP Study Results - Preliminary

- Two arm, vehicle controlled study administering favipiravir once a day by oral gavage
- Favipiravir 400 mg/kg/d once followed by 200mg/kg/d for 13 days
- Animals sedated once a day to protect technician
- EBOV challenge four days after beginning favipiravir
- Control monkeys died within the expected timeframe
- One test animal survived to Day 28, the others lived longer than controls
- Viral titers suggested antiviral effect
- Suggestion of GI abnormalities
- Histology, PK pending
- Audit of study pending

Confidential

Released by Chairman Rand Paul

Second NHP Study Results – Preliminary - 1

- Three arm, vehicle controlled study administering favipiravir twice a day
- 250 mg/kg favipiravir BID on Day 0, maintenance dose regimen of 150 mg/kg BID on Days 1-13.
- 125 mg BID on Day 0 followed by 75 mg BID on Days 1-13 (expected similar exposure to influenza regimen)
- EBOV challenge the day favipiravir started
- Favipiravir administered BID by oral gavage
- Animals sedated twice a day

Confidential

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Second NHP Study Results – Preliminary - 2

- Control monkeys died within the expected timeframe
- No animal survived to Day 28
- Statistically significant increase in time to death
- Statistically significant decrease in viral titers
- GI abnormalities that contributed to morbidity and mortality, not consistent with Ebola
- Histology, PK pending
- Audit of study pending

Confidential

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GI Lesions

- Gastrointestinal (GI) lesions that are not typically associated with filoviral disease in NHPs
- Lesions not seen in healthy NHP toxicology studies
- The lesions were more severe and occurred nearly exclusively in animals from the groups that received favipiravir
- Distal small intestine, cecum, colon
- Foci and transmural areas of hemorrhage and necrosis, adhesions, stringy white material
- Hard feces
- Material in stomach and intestines that appeared similar to favipiravir
- Potential complicating factors
  - Dehydration
  - Opioid effect of sedation on GI tract
  - Stress of BID sedation

Confidential

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Ebola Patients Receiving Favipiravir

- 38 year old German male
- 29 year old French female
- (Possible unknown French female patient)
- 32 year old Norwegian female
- 44 year old Spanish female
- 56 year old German male * preexisting liver failure

- Dose regimens varied
- Combination therapy in some
- Uncontrolled inconsistent treatment.

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Favipiravir Plasma Levels in Healthy Volunteers and Influenza Patients

Intensive Blood Sampling - Healthy Volunteers

Study	N	Dose Regimen (Loading / Maintenance)	D1 Cmax (ug/ml)	D5 Cmax (ug/ml)	D5 Cmin (ug/ml)	D5 AUC24hr (ug*hr/ml)
US213a	6	1200 TID / 600 TID	35.9	51.0	25.5	915.9
US213a	6	2400-600-600 / 600 TID	82.5	56.4	33.6	1086.0
US107	20	1200 BID / 800 BID	43.2	68.6	28.9	1120.6

Population PK (Sparse Sampling) – Influenza Patients

Data Sources	N	Dose Regimen (Loading / Maintenance)	D1 Cmax (ug/ml)	D5 Cmax (ug/ml)	D5 Cmin (ug/ml)	D5 AUC24hr (ug*hr/ml)
US213 US204	-	2400-600-600 / 600 TID	94.7 (89.5-101)	103 (94.9-113)	47.0 (42.7-53.7)	1410 (1290-1560)
US213 US204	-	1800 BID / 800 BID	99.5 (91.2-107)	88.7 (79.4-98.1)	30.1 (24.9-35.4)	1100 (953-1270)

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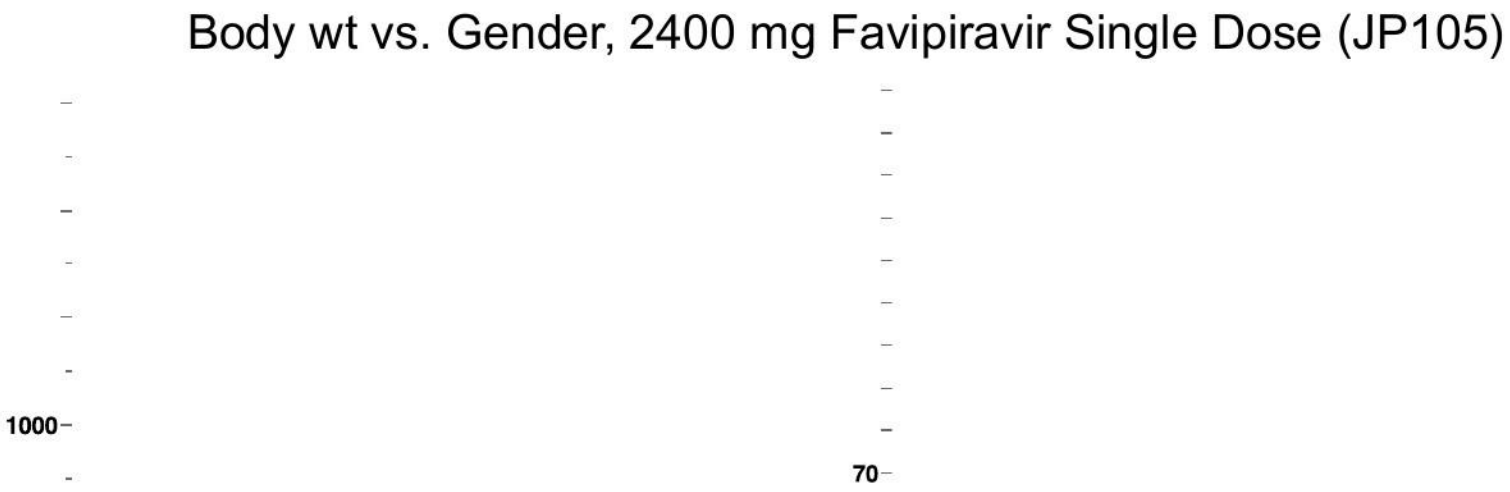
Favipiravir PK, Additional Considerations

Liver impairment

- Child-Pugh (5-6): 1.7 to 2.3 fold increase AUC_{inf}
- Child-Pugh (7-9): 1.7 to 2.1 fold increase AUC_{inf}
- Child-Pugh (10-15): 2.3 to 4.5 fold increase AUC_{inf}

Body Weight



Confidential

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Further Considerations

- Ongoing discussions with FDA
  - NHP results
  - Safety
  - Future trial design
- Ongoing discussions with DoD
  - Possibility of performing studies
- Discussions with USAMRIID regarding performing PK analyses from patient samples

Confidential

Released by Chairman Rand Paul

Casco, Tony (NIH/NIAID) [C]

From: Hayden, Frederick G *HS <[redacted]@hscmail.mcc.virginia.edu>
Sent: Wednesday, August 06, 2014 12:02 PM
To: Olinger, Gene (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Jahrling, Peter (NIH/NIAID) [E]; Kobinger, Gary (Public Health Agency of Canada)
Cc: Pierre Formenty; [redacted]@who.int; Shindo, Nikki; [redacted]@who.int; [redacted]@who.int; [redacted]@who.int
Subject: RE: Ebola WG Teleconference Thursday 10 am EDT; 15:00 BST

Importance: High

It would be very helpful to know in advance of tomorrow's teleconference about the timelines or actual results of the repeat testing of favipiravir (T-705) in the EBOV rhesus model. This drug is approved for very restricted influenza indications in Japan and has been offered to WHO for potential use in EVD. Thanks for any insights, fgh

---

From: Gail Carson [[redacted]@ndm.ox.ac.uk]
Sent: 06 August 2014 11:17
To: Hayden, Frederick G *HS; [redacted]@who.int; [redacted]@linkp.com; [redacted]@who.int
Cc: Trina Racine; [redacted]@who.int; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; [redacted]@who.int; Larry Zeitlin; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; [redacted]@who.int; deborah scott; Shindo, Nikki; [redacted]@gmail.com; Tara Nyhuis; [redacted]@WELLCOME.AC.UK; [redacted]@med.navy.mil; Mike Hensley; Marshall Hoke; [redacted]@mac.com; Brooks, Abdullah; [redacted]@imperial.ac.uk; Kajsa-Stina Longuere; Gail Carson
Subject: RE: Ebola WG Teleconference Thursday 10 am EDT; 15:00 BST

Dear All,

We are looking forward to speaking with you tomorrow Thursday August 7th at 11am EDT.
I have attached the minutes of the last call (thank you Gene) and an article that Tom/Fred wished to share.
A few new people will join us tomorrow & I am sure they will introduce themselves then.

The agenda is below. Professor Hayden will chair.
I have also attached the dial in numbers. The participant PIN is [redacted]#

1.Welcome- FH
2.Roll-call and introduction of new participants- FH 3.WHO Perspectives- David Wood, Martin Friede 4.Update on siRNA- Ian MacLachlan (Tekmira) 5.Update on rVSV-GP vaccine- Jay Ramsey (Bioprotection Systems) 6.Screening of FDA-approved Drugs- Gene Olinger (NIH) 7.Development of draft HCW protocols- Mike Hensley AOB 8. Discussion and future actions- All

Best wishes
Gail
Dr Gail Carson
Clinical Coordinator ISARIC
Consultant in Infectious Diseases
Centre for Tropical Medicine and Global Health Oxford University, UK Honorary Consultant Public Health England

https://isaric.tghn.org/

Released by Chairman Rand Paul

-----Original Message-----
From: Hayden, Frederick G *HS [mailto:[redacted]@hscmail.mcc.virginia.edu]
Sent: 05 August 2014 15:19
To: Kajsa-Stina Longuere; Gail Carson
Cc: Trina Racine; [redacted]@who.int; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; [redacted]@who.int; Larry Zeitlin; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; [redacted]@who.int; deborah scott; Shindo, Nikki; [redacted]@gmail.com; Tara Nyhuis; [redacted]@WELLCOME.AC.UK; [redacted]@med.navy.mil; Mike Hensley; Marshall Hoke
Subject: RE: Ebola WG Teleconference

Resending with call-in numbers.

_____
From: Hayden, Frederick G *HS
Sent: 05 August 2014 06:40
To: kajsa-[redacted]@ndm.ox.ac.uk ; [redacted]@ndm.ox.ac.uk
Cc: Trina Racine; [redacted]@who.int; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; [redacted]@who.int; Larry Zeitlin; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; [redacted]@who.int; deborah scott; Shindo, Nikki; [redacted]@gmail.com; Tara Nyhuis; [redacted]@WELLCOME.AC.UK; [redacted]@med.navy.mil; Mike Hensley; Marshall Hoke
Subject: RE: Ebola WG Teleconference

ISARIC through its Coordinating Centre at U Oxford will be pleased to host a follow-up teleconference this Thursday at 10:00 EDT (15:00 BST). The attachment provides toll-free call-in numbers. For others, the international number is: 0044 203 059 2627. The code is 3119150#.
If you plan to participate, please send a confirmation to Kajsa kajsa-[redacted]@ndm.ox.ac.uk<mailto:kajsa-[redacted]@ndm.ox.ac.uk> with your contact details, so that we can make list. If you have a specific topic to discuss, please forward that information to me, Kajsa, and Gail Carson. Thanks, fgh

_____
From: Marshall Hoke [[redacted]@cbrintl.com]
Sent: 04 August 2014 23:37
To: Mike Hensley
Cc: Hayden, Frederick G *HS; Trina Racine; [redacted]@who.int; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; [redacted]@who.int; Larry Zeitlin; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; [redacted]@who.int; deborah scott; Shindo, Nikki; [redacted]@gmail.com; Tara Nyhuis
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

Apologies,

That last email was meant to read: we hope to be available to discuss further development of the phase 1 protocol in the coming weeks, but would defer to the rest of the group at this time so as to prevent any delays on our end. Thank you for the opportunity to take part in the development of this protocol, and we apologize for any inconvenience this may have caused.

Thank you,
Marshall

Marshall Hoke, B.A.
Technical Associate

Released by Chairman Rand Paul

CBR International Corp. (r)
[redacted]
www.cbrintl.com<http://www.cbrintl.com/>

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On Aug 4, 2014, at 8:42 AM, "Mike Hensley" <[redacted]@icloud.com<mailto:[redacted]@icloud.com>> wrote:

Was late getting the document because of some e-mail issues but finally received. I have no additions or deletions and would consider it a fair and objective assessment of what is available on the therapeutic side of the ledger. Working on references as I'm still at Lisa's home and need to locate a couple on line. Thanks for including me.

Mike Hensley
On Aug 3, 2014, at 11:38 AM, "Hayden, Frederick G *HS"
<[redacted]@hscmail.mcc.virginia.edu<mailto:[redacted]@hscmail.mcc.virginia.edu>> wrote:

Apologies but I left the last reference off by mistake. Please add this very helpful review article:

Feldmann H, Geisbert TW. Ebola haemorrhagic fever. Lancet 377: [redacted]

From: Trina Racine [[redacted]@phac-aspc.gc.ca<mailto:[redacted]@phac-aspc.gc.ca>]
Sent: 03 August 2014 10:30
To: Hayden, Frederick G *HS
Cc: [redacted]@who.int<mailto:[redacted]@who.int>; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov<mailto:[redacted]@nih.gov> [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; Mike Hensley; [redacted]@who.int<mailto:[redacted]@who.int>; Larry Zeitlin; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; Marshall Hoke; [redacted]@who.int<mailto:[redacted]@who.int>; deborah scott; Shindo, Nikki; [redacted]@gmail.com<mailto:[redacted]@gmail.com> ; Tara Nyhuis
Subject: RE: Combining the existing Phase 1 with a Therapeutic Portion

Hello Frederick,

Please find attached an edited version of the document (only very minor edits). The document is very well done and provides a nice overview of what is available. The document I received however did not contain sections 5 and higher as listed in the Content section (not sure if this was intentional or not).

Thanks,

Trina

From: "Hayden, Frederick G *HS" <[redacted]@hscmail.mcc.virginia.edu<mailto:[redacted]@hscmail.mcc.virginia.edu>>

Released by Chairman Rand Paul

To: Marshall Hoke <[redacted]@cbrintl.com<mailto:[redacted]@cbrintl.com>>, Larry Zeitlin <[redacted]@mappbio.com<mailto:[redacted]@mappbio.com>>, Trina Racine <trina.racine@phac-aspc.gc.ca<mailto:trina.racine@phac-aspc.gc.ca>>, deborah scott <[redacted]@sbcglobal.net<mailto:[redacted]@sbcglobal.net>>
Cc: "Gary (Public Health Agency of Canada) Kobinger" <[redacted]@phac-aspc.gc.ca<mailto:[redacted]@phac-aspc.gc.ca>>, "[redacted]@nih.gov<mailto:[redacted]@nih.gov> [C] Olinger" <[redacted]@nih.gov<mailto:[redacted]@nih.gov>>, "Peter (NIH/NIAID) [E] Jahrling" <[redacted]@niaid.nih.gov<mailto:[redacted]@niaid.nih.gov>>, Mike Hensley <[redacted]@icloud.com<mailto:[redacted]@icloud.com>>, "Lisa (NIH/NIAID) [E] Hensley" <[redacted]@nih.gov<mailto:[redacted]@nih.gov>>, Miles Brennan <[redacted]@cbrintl.com<mailto:[redacted]@cbrintl.com>>, Tara Nyhuis <[redacted]@cbrintl.com<mailto:[redacted]@cbrintl.com>>, "Shindo, Nikki" <[redacted]@who.int<mailto:[redacted]@who.int>>, "[redacted]@gmail.com<mailto:[redacted]@gmail.com> " <[redacted]@gmail.com<mailto:[redacted]@gmail.com>>, "[redacted]@who.int<mailto:[redacted]@who.int>" <[redacted]@who.int<mailto:[redacted]@who.int>>, "[redacted]@who.int<mailto:[redacted]@who.int>" <[redacted]@who.int<mailto:[redacted]@who.int>>, "[redacted]@who.int<mailto:[redacted]@who.int>" <[redacted]@who.int<mailto:[redacted]@who.int>>
Date: 2014-08-03 03:12 AM
Subject: RE: Combining the existing Phase 1 with a Therapeutic Portion

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Dear Colleagues, I am writing on behalf of the Ebola clinical management team at WHO and am forwarding this working version of a document on potential therapeutics. Comments, corrections, and additions are welcome- forward these to Aaruni Saxena, Nikki Shindo, and me at your earliest opportunity. Please note that this document is a draft and should be held in confidence. Thanks for your help, fgh

---

From: Marshall Hoke [[redacted]@cbrintl.com<mailto:[redacted]@cbrintl.com>]
Sent: 31 July 2014 22:24
To: Larry Zeitlin; Trina Racine; deborah scott
Cc: Hayden, Frederick G *HS; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov<mailto:[redacted]@nih.gov> [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; Mike Hensley; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; Tara Nyhuis
Subject: RE: Combining the existing Phase 1 with a Therapeutic Portion

Dear All,

Due to limited availability tomorrow, we would like to postpone our discussion until next Tuesday (8/5/14) at 7 AM PDT/ 8 AM MDT/ 9 AM CDT/ 10 AM EDT/ 4 PM CEST. We will distribute an agenda and dial-in information on Monday, and please let us know of any questions or requests in the meantime.

Thank you,
Marshall

Marshall Hoke, B.A.
Technical Associate
CBR International Corp. (r)
[redacted]

Released by Chairman Rand Paul

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From: Marshall Hoke
Sent: Wednesday, July 30, 2014 11:25 AM
To: 'Larry Zeitlin'; Trina Racine; deborah scott
Cc: Frederick G *HS Hayden; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov> [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; Mike Hensley; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; Tara Nyhuis
Subject: RE: Combining the existing Phase 1 with a Therapeutic Portion

Dear All,

At the request of Dr. Zeitlin in the email below, we would like to propose a teleconference this Friday (8/1/2014) at 7 AM PDT/ 8 AM MDT/ 9 AM CDT/ 4 PM CEST. Alternatively, we would propose a teleconference next Tuesday (8/5/2014) at 7 AM PDT/ 8 AM MDT/ 9 AM CDT/ 4 PM CEST if Friday is not an option for the group. Please let us know your availability and we will draft a preliminary agenda and distribute it to everyone along with dial-in information.

Thank you,
Marshall

Marshall Hoke, B.A.
Technical Associate
CBR International Corp. (r)
[redacted]

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From: Larry Zeitlin [mailto:[redacted]@mappbio.com]
Sent: Wednesday, July 30, 2014 10:55 AM
To: Trina Racine; deborah scott
Cc: Frederick G *HS Hayden; Gary (Public Health Agency of Canada) Kobinger; [redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov> [C] Olinger; Peter (NIH/NIAID) [E] Jahrling; Mike Hensley; Lisa (NIH/NIAID) [E] Hensley; Miles Brennan; Tara Nyhuis; Marshall Hoke
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

Hi all,

Released by Chairman Rand Paul

This is coming together very nicely. I'd like to suggest a follow-up call to discuss this in more detail and have cc'd our colleagues at CBR who have been leading the regulatory and clinical planning effort for ZMapp.

Assuming everyone agrees a call would be worthwhile, can I trouble CBR to arrange it?

Best,
Larry

From: Trina Racine [redacted]@phac-aspc.gc.ca<mailto:trina.racine@phac-aspc.gc.ca><mailto:trina.racine@phac-aspc.gc.ca>>
Date: Wednesday, July 30, 2014 at 8:43 AM
To: deborah scott
<[redacted]@sbcglobal.net<mailto:[redacted]@sbcglobal.net><mailto:[redacted]@sbcglobal.net>>
Cc: Frederick G *HS Hayden
<[redacted]@hscmail.mcc.virginia.edu<mailto:[redacted]@hscmail.mcc.virginia.edu><mailto:[redacted]@hscmail.mcc.virginia.edu>>, Gary Kobinger <gary.kobinger@phac-aspc.gc.ca<mailto:gary.kobinger@phac-aspc.gc.ca><mailto:gary.kobinger@phac-aspc.gc.ca>>, Gene Olinger <[redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov>>, Peter Jahrling <[redacted]@niaid.nih.gov<mailto:[redacted]@niaid.nih.gov><mailto:[redacted]@niaid.nih.gov>>, Mike Hensley <[redacted]@icloud.com<mailto:[redacted]@icloud.com><mailto:[redacted]@icloud.com>>, Larry Zeitlin <[redacted]@mappbio.com<mailto:[redacted]@mappbio.com><mailto:[redacted]@mappbio.com>>, Lisa Hensley <[redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov>>
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

Hello all,

I too have made a number of comments and edits. Please let me know if you would like to discuss.

Trina

From: deborah scott
<[redacted]@sbcglobal.net<mailto:[redacted]@sbcglobal.net><mailto:[redacted]@sbcglobal.net>>
To: Mike Hensley <[redacted]@icloud.com<mailto:[redacted]@icloud.com><mailto:[redacted]@icloud.com>>, Larry Zeitlin <[redacted]@mappbio.com<mailto:[redacted]@mappbio.com><mailto:[redacted]@mappbio.com>>
Cc: Frederick G *HS Hayden
<[redacted]@hscmail.mcc.virginia.edu<mailto:[redacted]@hscmail.mcc.virginia.edu><mailto:[redacted]@hscmail.mcc.virginia.edu>>, "Peter \(NIH/NIAID\) \[E\] Jahrling"
<[redacted]@niaid.nih.gov<mailto:[redacted]@niaid.nih.gov><mailto:[redacted]@niaid.nih.gov>>, "Lisa \(NIH/NIAID\) \[E\] Hensley" <[redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov>>, "[redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov> \[C\] Olinger"
<[redacted]@nih.gov<mailto:[redacted]@nih.gov><mailto:[redacted]@nih.gov>>, "Gary \(Public Health Agency of Canada\) Kobinger" <gary.kobinger@phac-aspc.gc.ca<mailto:gary.kobinger@phac-aspc.gc.ca><mailto:[redacted]@phac-aspc.gc.ca>>, Trina Racine <[redacted]@phac-aspc.gc.ca<mailto:[redacted]@phac-aspc.gc.ca><mailto:[redacted]@phac-aspc.gc.ca>>
Date: 2014-07-30 12:39 AM
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

---

Released by Chairman Rand Paul

I've inserted comments and discussion points. please see attached

Deb

On Tuesday, July 29, 2014 1:53 PM, Mike Hensley
<[redacted]@icloud.com<mailto:[redacted]@icloud.com><mailto:[redacted]@icloud.com>> wrote:

As discussed toward the end of the call today, I took a shot at combining the objectives of your phase 1 protocol submitted to FDA with the objective of separating the vaccine and ZMapp products into two separate protocols. See attached. I've done nothing more with the vaccine portion but I like Deb's suggestion of doing a vaccine study in Canada or as someone suggested today, in Geneva. Logical, since Health Canada apparently controls the drug product.

In combining the two objectives I constructed an initial phase to be done in HCW's not yet deployed. In this group we can do the pK and immunogenicity work needed. Assuming we get reasonable data there we cold move into HCW's deployed and exposed. I could sympathize with a larger group in the first phase but was taking into account limited supplies of ZMapp when I made my choices. Some details I calculated from or extrapolated from your pre-IND package. Doses I chose based on the NHP trials.

Once again this is a clinical synopsis but gives us a set of talking points and probably anticipates most issues. Lots of detail missing but easy to complete with a little q&a if this looks reasonable

Mike Hensley
[attachment "Revised Phase 1 ZMapp Study Protocol Synopsis jb ds(2).docx" deleted by Trina Racine/HC-SC/GC/CA]
[attachment "TREATMENT_OF_EBOLA_Report_for_Clinicians_ver_4_External.docx" deleted by Trina Racine/HC-SC/GC/CA]

Released by Chairman Rand Paul

Casco, Tony (NIH/NIAID) [C]

From: Hensley, Lisa (NIH/NIAID) [E]
Sent: Friday, August 15, 2014 3:09 PM
To: Kobinger, Gary (Public Health Agency of Canada); Olinger, Gene (NIH/NIAID) [C]
Subject: RE: Your Perspectives

Nice email

BTW I got an email trying to send IFN's to SL – They send me my own paper that said it didn't work on it's own... there is some other company that has silver nanparticles that they are supposedly using in Nigeria...

All crazy

I am going on leave next week but will be on emails etc. If you need me my personal cell is [redacted] and email is [redacted]@gmail.com. I will have my b berry of course but just in case.

Lisa E. Hensley
Associate Director, Science
NIH/NIAID/IRF
Ft Detrick MD

[redacted]

From: Kobinger, Gary (Public Health Agency of Canada)
Sent: Thursday, August 14, 2014 3:13 PM
To: Hayden, Frederick G *HS
Cc: Olinger, Gene (NIH/NIAID) [C]; [redacted]@who.int; Hensley, Lisa (NIH/NIAID) [E]; Shindo, Nikki; [redacted]@who.int
Subject: Re: Your Perspectives

Dear Frederick
Sorry I am a bit late here,

Yes I have followed also some of this. As I have responded to one of this group, I think that there is real damages that can come out of testing some of these drugs indeed approved but for other indications. Some were shown to worsen Ebola disease in animals, others had no apparent effects. My point of view is that testing drugs that have not shown at least partial efficacy in animal species modelling at least some of the clinical sequelae of EVD is taking an undue risk. At best nothing will happen but then this means that hope that will be arising from these tests will be crushed and bring a negative impact that will affect the entire response, including on the evaluation of drugs or vaccines that have shown efficacy (and there is many more than what is listed in this letter).

At the minimum, experts like Gene and Heinz who have been looking at FDA approved drugs should be brought in that process.

The use of the MAbs in a few cases in the field has opened an important door due to what may be important benefits (confirming similar findings in nonhuman primates). Hopefully this will be managed carefully for other approaches as to not end up with angry populations that will set everything back.

Lastly as now disclosed the first to be considered for the ZMapp was Dr Kahn, an MD from Sierra Leone. Currently Liberia has the remaining of the ZMapp doses because they made the request.

Released by Chairman Rand Paul

Thank you very much for all you are doing to move this file ahead, this is to all of us an extremely important period.
Best wishes

Gary

"Hayden, Frederick G *HS" ---2014-08-07 03:35:38 PM---Since we did not have time to discuss on today's telecon, I would really appreciate your thoughts on

From: "Hayden, Frederick G *HS" <[redacted]@hscmail.mcc.virginia.edu>
To: "[redacted]@nih.gov" <[redacted]@nih.gov>, "[redacted]@nih.gov" <[redacted]@nih.gov>, Gary Kobinger <[redacted]@phac-aspc.gc.ca>
Cc: "[redacted]@who.int" <[redacted]@who.int>, "Shindo, Nikki" <[redacted]@who.int>, "[redacted]@who.int" <[redacted]@who.int>
Date: 2014-08-07 03:35 PM
Subject: Your Perspectives

Since we did not have time to discuss on today's telecon, I would really appreciate your thoughts on the proposed treatment strategy outlined in the attached email from David Fedson to WHO. Based on your understanding of Ebola disease pathogenesis in NHPs and humans, does this make sense? Are there any data with these agents in filovirus models? If not, might you be willing to undertake a small study? Thanks in advance for your opinions, fgh
[attachment "Email from David Fedson to WHO.pdf" deleted by Gary Kobinger/HC-SC/GC/CA]

Released by Chairman Rand Paul

Casco, Tony (NIH/NIAID) [C]

From: Lane, Cliff (NIH/NIAID) [E]
Sent: Friday, October 17, 2014 9:20 PM
To: Higgs, Elizabeth (NIH/NIAID) [E]
Subject: RE: Geneva meeting

Thanks - we can talk virtually any time over the weekend. The main thing is to make sure that you and Ed and Lu are aligned. As per your note I think it is fine to hold off on specifics and focus discussion on the Bayesian approach. For the discussion regarding placebo controls I am not sure the water is as clear as it was to me for vaccines. While it is my preference and I know the preference of FDA I am not sure there is adequate equipoise within the investigator community. As an aside we do have a commitment from ZMapp to receive product for a stander RCT. In my ideal world the first paring in the RCT would be SOC v.s ZMAPP. with 40 doses of ZMapp you can treat 40 open label trial not be sure of what you have done or 80 in an RCT and have a chance at determining efficacy.

From: Higgs, Elizabeth (NIH/NIAID) [E]
Sent: Friday, October 17, 2014 6:03 PM
To: Lane, Cliff (NIH/NIAID) [E]
Subject: FW: Geneva meeting

Hi Cliff,
You must be exhausted. I am available if you want to talk by phone. My office phone in Rockville has changed (though I'm appeal to a return of the old number [redacted]. My work cell is [redacted]. Personal cell is [redacted].

I know you wanted to touch base with me on the Geneva meeting. Having looked at the agenda I don't see where we (the USG) are supposed to specifically present the therapeutics protocol design. It looks like generic study design presentations followed by discussion. May be better not to discuss specifics beyond the basic Bayesian adaptive study design and we are not in a position to share a specific protocol as all there are still many decisions remaining on the protocol.
I have reached out to colleagues in Geneva but I haven't had a response, but hope they will follow up tomorrow. My travel is set including the Oct. 23 Vaccine Development and Availability meeting.

If tonight doesn't work, we can talk tomorrow or Sunday. I'm flying Sunday night.
Best
Libby

-----Original Message-----
From: Cox, Edward M (FDA/CDER)
Sent: Friday, October 17, 2014 7:52 AM
To: Lane, Cliff (NIH/NIAID) [E]; Borio, Luciana (FDA/OC)
Cc: Higgs, Elizabeth (NIH/NIAID) [E]; McNay, Laura (NIH/NIAID) [E]
Subject: RE: Geneva meeting and we are not in a position to share a specific protocol as all the partners have not

Just received agenda (in attached e-mail).
-Ed

Released by Chairman Rand Paul

-----Original Message-----
From: Lane, Cliff (NIH/NIAID) [E] [mailto:[redacted]@niaid.nih.gov]
Sent: Friday, October 17, 2014 7:28 AM
To: Borio, Luciana
Cc: Higgs, Elizabeth S (NIH); McNay, Laura A (NIH); Cox, Edward M
Subject: Re: Geneva meeting

Let's discuss - given his involvement in the development of the protocol it might make more sense to have it be Ed but I understand the FDA sensitivities. Do you have an agenda?

> On Oct 17, 2014, at 7:22 AM, "Borio, Luciana (FDA/OC)" <[redacted]@fda.hhs.gov> wrote:
>
> Sounds good. Would be nice for NIH to present the protocol.
>
> ----- Original Message -----
> From: Lane, Cliff (NIH/NIAID) [E] [mailto:[redacted]@niaid.nih.gov]
> Sent: Friday, October 17, 2014 07:20 AM
> To: Higgs, Elizabeth S (NIH)
> Cc: McNay, Laura A (NIH); Cox, Edward M; Borio, Luciana
> Subject: Geneva meeting
>
> Thanks - I have copied Ed Cox and Lu Borio. I think they are both going and should be able to provide details. Laura can help facilitate getting the travel orders. Cliff
>
> On Oct 17, 2014, at 6:57 AM, "Higgs, Elizabeth (NIH/NIAID) [E]"
<[redacted]@niaid.nih.gov<mailto:[redacted]@niaid.nih.gov>> wrote:
>
> Sure
>
> Sent from my iPhone
>
> On Oct 17, 2014, at 2:33 AM, "Lane, Cliff (NIH/NIAID) [E]"
<[redacted]@niaid.nih.gov<mailto:[redacted]@niaid.nih.gov>> wrote:
>
> Any chance you would want to go back to Geneva next week? I think Lu and Ed Cox are attending.
> _____
> From: Kurilla, Michael (NIH/NIAID) [E]
> Sent: Thursday, October 16, 2014 3:49 PM
> To: Lane, Cliff (NIH/NIAID) [E]; Davey, Richard (NIH/NIAID) [E]
> Cc: Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]
> Subject: Status of Master Protocol & Geneva meeting
>
> Cliff & Rick,
>
> On the Ebola Medical Countermeasures Senior Steering Group (EMC-SSG) this afternoon, Nicki asked about the status of Master Protocol and whether the intention is to present a Master Protocol at the Geneva

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meeting next week, as well as who from NIH is planning on attending. She's interested in arriving at a common USG policy position prior to the meeting.
>
> I'm sure you're tied up with Clinical Center activities at the moment. Nicki is somewhat anxious. Anything I can relate?
>
> Michael G Kurilla, MD-PhD
> Director, Office of BioDefense, Research Resources, and Translational
> Research Associate Director for BioDefense Product Development DMID,
> NIAID, NIH, DHHS
> 5601 Fishers Lane 8G61
> Rockville, MD 20852
> [redacted]
> The truly unusual day would be a day when nothing unusual happens.
> - Persi Diaconis
>

Released by Chairman Rand Paul

October 17, 2014

The Honorable Rob Portman
United States Senate
Washington, DC 20510

Dear Senator Portman:

Thank you for your letter to President Obama regarding the opportunity to further strengthen the U.S. government's efforts to contain the spread of the Ebola virus disease (Ebola) in the U.S. and stop the Ebola outbreak at its source in West Africa. Your letter was forwarded to the U.S. Department of Health and Human Services (HHS) for a response. As you are aware, the U.S. government is accelerating response efforts to the outbreak, both domestically and abroad, through multiple channels. Like you, I am committed to ensuring an efficient and productive collaboration among all federal agencies involved, as we work together toward the shared goal of controlling this epidemic.

In response to your recommendation to appoint one agency leader to serve as a central point-of-contact for all U.S. efforts related to Ebola, President Obama has named Mr. Ron Klain, to coordinate a whole-of-government response and to lead a regular series of meetings and calls with all federal agencies involved. Under his leadership, these agencies will continue to work together to stop the spread of Ebola both at home and abroad.

Domestically, involved federal agencies are working together to prepare and fortify our national public health infrastructure to prevent entry of and respond quickly and effectively to Ebola cases in the United States. Most specifically, the Centers for Disease Control and Prevention (CDC) acted quickly based on its response plan to support state and local efforts to treat the U.S. index case in Dallas, Texas. CDC has updated these plans based on lessons learned, and details on these plans are enclosed for your reference.

Globally, the U.S. government is collaborating to achieve four main goals related to the outbreak in West Africa, as declared by President Obama:

- Control the outbreak.
- Address the ripple effects of local economies and communities to prevent a truly massive humanitarian disaster.
- Coordinate a broader global response.
- Urgently build up a public health system in these countries for the future.

The United States Agency for International Development continues to lead the U.S. overseas response to the outbreak, while the Department of Defense (DoD), CDC, the U.S. Department of State, the National Institutes of Health, the U.S. Food and Drug Administration, and the Office of the Assistant Secretary for Preparedness and Response are supporting the whole-of-government approach led by Mr. Klain and the National Security Council. Detailed information about the

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roles of each of these agencies in the whole-of-government U.S. response is enclosed for your reference.

The U.S. government has been in contact with the affected countries in West Africa since March and immediately engaged in the response—providing assistance and resources at the level requested by each country's government. The U.S. government already has committed more than $350 million toward fighting the outbreak in West Africa, including more than $111 million in humanitarian aid. DoD is prepared to devote more than $1 billion to the whole-of-government Ebola response effort. As a further indication of our prioritization of this response, the United States convened a special United Nations (UN) Security Council session on the epidemic, and President Obama called the world to action during a subsequent UN session called by Secretary-General Ban Ki-moon. These U.S. actions have galvanized millions of dollars in international funding and in-kind support.

We believe this whole-of-government approach is the best way to assist the ministries of health in the affected West African countries and protect the lives of the citizens of the United States. However, it is important to acknowledge that we cannot fight this epidemic alone. Continued collaboration with these countries and the international community is critical to stopping the spread of Ebola at home and abroad.

The Ebola outbreak reminds us that our global efforts to build the capacity to prevent, detect, and rapidly respond to infectious disease threats like Ebola have never been more vital. In February, we came together with nations around the world to launch the Global Health Security Agenda (GHSA) as a five-year effort to accelerate action. On September 26, 2014, President Obama met with leaders of 40 nations as well as top Administration officials to advance progress in the GHSA.

Over the next five years the United States has committed to working with at least 30 partner countries to invest in model systems to advance the GHSA. CDC and DoD will work with other U.S. agencies and partner countries to establish emergency operations centers, build information systems, and strengthen laboratory security to mitigate biological threats and build partner capacity.

Thank you again for your letter and for your support of the U.S. government's response to the current Ebola epidemic. Please do not hesitate to contact me with any further thoughts or concerns.

Sincerely,

Sylvia M. Burwell

Enclosure

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Details on Federal Agency Roles in the U.S. Response to the Ebola virus disease Outbreak

The United States Agency for International Development (USAID)

USAID is leading the international response to the Ebola outbreak in West Africa. In August, USAID deployed a Disaster Assistance Response Team (DART) to the region to coordinate and prioritize the U.S. government's response to the outbreak. The DART assesses and identifies priority needs and coordinates key areas of the response, such as planning, operations, and logistics. The 28-member DART team comprises staff from USAID, the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), and the U.S. Forest Service.

The DART has airlifted more than 16 tons of medical supplies and emergency equipment to West Africa, including personal protective equipment, water treatment units, portable water tanks, body bags, infrared thermometers, and plastic sheeting to be used in the construction of treatment units. The DART is also in the process of procuring generators that will provide electricity to Ebola treatment units and other response facilities.

In addition, USAID is supporting a Community Care Campaign, which will provide communities and households with protection kits, appropriate information and training on how to protect themselves and their loved ones. In partnership with the United Nations Children Fund, the Paul Allen Family Foundation, and other key partners, USAID is targeting the 400,000 most vulnerable households in Liberia. The package will subsequently be scaled to cover the country and the broader region.

USAID also recently launched "Fighting Ebola: A Grand Challenge for Development," with a call to innovators around the world to submit ideas focused on improving the tools used by frontline health care workers in the fight against Ebola in West Africa. The initial focus of the Challenge, as announced by President Obama on September 26, 2014, is to generate pioneering solutions to improve the personal protective equipment and tools used by health care workers battling Ebola.

Centers for Disease Control and Prevention (CDC)

Domestically, CDC has been working with state and local governments to strengthen health care and community preparedness for infectious diseases in general, and specifically improving readiness for identifying and responding to U.S. Ebola cases. Since the Ebola outbreak in West Africa was identified in March 2014, CDC has been working with domestic partners to anticipate and prepare for the first case of Ebola in the United States. To this end, CDC has been:

- Enhancing surveillance and laboratory testing capacity in states to detect cases.
- Developing guidance and tools for health departments to conduct public health investigations.
- Providing recommendations for health care infection control and other measures to prevent disease spread.
- Providing guidance for flight crews, Emergency Medical Services units at airports, and Customs and Border Protection officers about reporting ill travelers to CDC.

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- Disseminating up-to-date information to the general public, international travelers, and public health partners.

The recent laboratory confirmation of three cases of Ebola in Dallas, Texas, have revealed the complexities in responding to a highly lethal and infectious pathogen such as Ebola virus. CDC's four decades of experience with Ebola in Africa demonstrate that that the agency knows how to control the disease through thorough case finding, isolation of ill people, contacting people exposed to each ill person, and further isolation of contacts if they develop symptoms. This process also must include proper infection control procedures by those caring for ill persons.

While we do not yet know the source of the exposure of the infected health care workers in Dallas, and the investigation is ongoing, CDC has taken immediate steps to improve processes and procedures known to reduce risk to health care personnel. Care for a patient with Ebola requires meticulous attention to detail, and refining these steps makes it safer and easier.

CDC's protocol offers a range of choices for implementation. In Dallas, CDC is making specific improvements in the following process and procedures:

- **Personal protective equipment (PPE)**
  - PPE suits will be standardized, to include a specific type of suit to ensure consistency in both training and use, possibly using only full-body suits. This is consistent with current CDC recommendations.
  - Use of a model of hood that protects health care workers' necks, so necks will not be exposed.
  - Removing PPE now includes an enhanced and detailed step-by-step disinfection of hands process, with specific sequencing for removal of each piece of equipment and the hand washing.

- **Oversight and monitoring**
  - The single most important aspect of safe care of Ebola is to have a site manager at all times who oversees the putting on and taking off of PPE and the care given in the isolation unit. A site manager is now in place and will be at Texas Presbyterian Hospital 24/7, as long as Ebola patients are receiving care.

- **Enhanced training**
  - CDC is providing additional onsite intensive infection control training and education with heath care workers in Dallas. In addition, two infection control nurses from Emory who have experience treating Ebola patients are in Dallas to provide peer-to-peer training and support.

CDC is also actively engaged with health care systems nationwide to prepare all providers, hospitals, state and local health departments, and others involved in public health preparedness and response for the identification and management of a patient with Ebola in the United States. These efforts include providing more opportunities for U.S. health care providers to receive

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additional training and to get their questions answered from CDC experts. Clinicians can get updates on these events at www.cdc.gov/Ebola. Training and educational sessions over the next month will include at least seven regional or national meetings/conferences calls, a major national web-based training event, and ongoing calls and webinars with partners to promote improved understanding of appropriate protocols and practices for the safe management of patients with Ebola in U.S. hospitals.

Additionally, CDC is setting up a dedicated CDC Response Team that could be on the ground within a few hours at any hospital that receives a confirmed patient with Ebola. The CDC Response Team would provide in-person, expert support and training on infection control, healthcare safety, medical treatment, contact tracing, waste and decontamination, public education and other issues. The CDC Response Team would help ensure that clinicians, and state and local public health practitioners, consistently follow strict standards of protocol to ensure safety of the patient and health care workers.

CDC is providing Public Health Emergency Preparedness cooperative agreement funding and assistance to state and local health departments for all-hazards preparedness, including infectious disease outbreaks. This funding and assistance helps public health departments develop capabilities that are applicable to responding to many public health threats, including Ebola.

In regard to travel safety, CDC is working closely with the U.S. Department of Homeland Security's Customs and Border Protection (CBP) and other partners at U.S. ports of entry—primarily international airports—to use enhanced screening measures to identify travelers who show signs of infectious disease. CBP is now conducting entry screening at five U.S. airports that receive over 94 percent of travelers from the Ebola-affected nations of Guinea, Liberia, and Sierra Leone. Additionally, CDC has been working with the U.S. Department of Transportation on guidance for the transportation and handling of Ebola-infected medical waste.

The U.S. Food and Drug Administration (FDA)

FDA is actively working to help advance the development of treatments, vaccines, and diagnostic tests with the potential to help bring the Ebola epidemic under control as quickly as possible. These efforts include providing scientific and regulatory advice to U.S. government agencies that support medical product development—including the National Institutes of Health, the Office of the Assistant Secretary for Preparedness and Response, CDC, and DoD—to help accelerate product development programs. Specific activities include:

- Working with medical product sponsors to clarify regulatory requirements, review and provide input on pre-clinical and clinical trial designs (including studies that can potentially be conducted in West Africa), and expediting the regulatory review of data as it is received from product developers. This includes expediting the review of Investigational New Drug (IND) applications, which are required for FDA-regulated clinical trials of drugs and vaccines to proceed. For example, FDA rapidly reviewed IND applications for two investigational Ebola vaccines and, after such review, allowed them to proceed.
- Collaborating with the World Health Organization (WHO) and other international regulatory counterparts—including the European Medicines Agency, Health Canada, and others—to

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exchange information about investigational products for Ebola in support of international response efforts. FDA is also providing technical support and scientific advice to WHO on the potential for the development and use of convalescent plasma in affected countries.

- Issuing an Emergency Use Authorization for use of a diagnostic test—developed by DoD—to detect the Ebola virus in laboratories designated by DoD. This test has been made available to 14 laboratories within the United States that are located close to ports-of-entry where travelers from West Africa frequently arrive in the United States, which will support the rapid diagnosis of any suspected cases of Ebola.
- Monitoring for fraudulent products that claim to prevent or treat Ebola infection and taking actions, as warranted, to protect public health. For example, FDA recently issued warning letters to three firms marketing products that claim to prevent, treat, or cure infection with the Ebola virus.

National Institutes of Health (NIH):

The NIH's National Institute of Allergy and Infectious Diseases (NIAID) is accelerating ongoing research efforts and partnering with governments and private companies throughout the world to speed the development of medical countermeasures that could help control the current Ebola epidemic and future outbreaks. NIAID research is focusing on understanding how Ebola causes illness in animals and in people, and researchers are also working on the development of Ebola diagnostic tools, vaccines, and therapeutics. Specific activities include:

- Providing support to and collaborating with Mapp Biopharmaceutical, Inc., to develop MB-003—a combination of three antibodies that prevents Ebola in monkeys when administered as late as 48 hours after exposure. NIAID is also evaluating therapeutics licensed or in development for the treatment of other diseases for their potential activity against Ebola.
- Advancing development of novel diagnostic tools that are capable of detecting Ebola and other viruses or antiviral antibodies.
- Providing technical diagnostic support on-the-ground in Liberia.
- Testing Ebola vaccine candidates. The NIAID Vaccine Research Center has a robust viral hemorrhagic fever vaccine development program. Two Ebola vaccine candidates are undergoing Phase 1 clinical testing this fall. NIAID will play a critical role in advancing these Ebola vaccine candidates. The results of these Phase 1 studies will inform essential discussions about whether and how such vaccines could be of use in the current epidemic or future Ebola outbreaks.

Office of the Assistant Secretary for Preparedness and Response (ASPR)/ Biomedical Advanced Research and Development Authority (BARDA)

Commented [DES/IMAC1]: Note to HHS: ASPR has their own Congressional open regarding their role in the response; will be important to make sure the two responses are consistent.

ASPR/BARDA is supporting large-scale production of medical countermeasures as a response measure to the Ebola epidemic. Specific activities include:

- Providing funding and technical assistance for the development and scaled-up manufacturing of the ZMapp monoclonal antibody therapeutic.
- Working with DoD/DTRA and industry partners to scale up the manufacturing of one of several promising investigational Ebola vaccine candidates to commercial scale.

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- Coordinating with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and other partners—including the affected West African countries, WHO, the Bill and Melinda Gates Foundation; and others—to efficiently allocate resources and efforts to address the Ebola epidemic.

Department of Defense (DoD)

DoD is providing military support and funding to help control the Ebola epidemic. Specific efforts include:

- Sending a field-deployable hospital to Liberia and providing more than 10,000 Ebola test kits to the Liberian Institute of Biological Research and to Sierra Leone's Kenema Government Hospital.
- Overseeing the construction of and facilitating staffing for at least 17 100-bed Ebola treatment units across Liberia.
- Reprogramming $500 million in Fiscal Year 2014 Overseas Contingency Operations funds for humanitarian assistance, a portion of which will be used to fulfill requirements identified by CDC, USAID, the Joint Staff, and U.S. Africa Command to provide military air transportation of DoD and non-DoD personnel and supplies; medical treatment facilities (e.g. isolation units), personnel protective equipment, and medical supplies; logistics and engineering support, and; subject matter experts in support of sanitation and mortuary affairs.
- Redirecting $25 million to provide personal protective equipment and laboratory reagents, support for technical advisors, and other requests as validated by the DART. DoD has also requested to reprogram an additional $60 million to enable the Cooperative Threat Reduction program to address urgent biosafety, biosecurity, and biosurveillance needs in the three countries most affected by the Ebola outbreak, as well as bolster the capabilities of neighboring countries and other partners in Africa.
- Scaling-up the DoD presence in West Africa with the planned deployment of 3,200 troops, including 700 from the 101st Airborne Division headquarters element to Liberia. These forces will deploy in late October and become the headquarters staff for the Joint Forces Command.

Commented [JB2]: Isn't the reprogramming supposed to total $1B?

Note to HHS: CDC doesn't have the information to confirm this.

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Casco, Tony (NIH/NIAID) [C]

From: Hu-Primmer, Jean (FDA/OC)
Sent: Friday, July 25, 2014 10:13 AM
To: Olinger, Gene (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Honko, Anna (NIH/NIAID) [E]
Subject: RE: today's Ebola MCM working group

Hotly debated here at FDA too – this is part of the reason why DAVP does not want to comment on the already approved drugs for re-purposing because most are oral and they say that oral is not the way to go because as you say – cases arrive late and will not tolerate oral doses. And we know that MSF is using IV therapies (ie IV rehydration).....

Already approved drugs don't mean anything if we are changing route of administration of doses (because the some of the therapeutic windows are too narrow for EBOV).... If we change the dose or route the existing human safety information is questionable (may not be applicable).

From: Olinger, Gene (NIH/NIAID) [C] [mailto:[redacted]@nih.gov]
Sent: Thursday, July 24, 2014 11:39 AM
To: Hu-Primmer, Jean; Hensley, Lisa E (NIH); Honko, Anna N (NIH)
Subject: RE: today's Ebola MCM working group

Honestly, at this point, cleaning the area is difficult. So there are many logistical/clinical issues. Injections, needles, etc. are an issue but IV is commonly done with Lassa cases (is how they administer ribavirin). Limited physical contact is preferred. In other conversations, oral administration is likely not ideal either as cases arrive late in disease and may not tolerate doses by oral route.

Lisa or Anna may want to comment on this topic as this is a hotly debated area. May even want some of the clinicians who have been there or there to comment as I am sure there are local differences.

Gene

From: Hu-Primmer, Jean (FDA/OC)
Sent: Thursday, July 24, 2014 10:07 AM
To: Olinger, Gene (NIH/NIAID) [C]; Hensley, Lisa (NIH/NIAID) [E]; Honko, Anna (NIH/NIAID) [E]
Subject: RE: today's Ebola MCM working group

I will circulate your thoughts within the Division, as well as the excel spreadsheet – see if they have any ideas.

I will also ask Gary to consider convalescent IVIG since this Friday's conversation will be CBER-related and polyclonals are in their shop.

I understand that because the field "hospital" conditions are very austere, there is a concern about the feasibility for any IV treatment with concerns of ancillary supply availabilitiy and potential for needlesticks etc.... was that raised during the WHO call?

Thanks,
Jean

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From: Olinger, Gene (NIH/NIAID) [C] [mailto:[redacted]@nih.gov]
Sent: Thursday, July 24, 2014 9:55 AM
To: Hu-Primmer, Jean; Hensley, Lisa E (NIH); Honko, Anna N (NIH)
Subject: RE: today's Ebola MCM working group

Here are a few comments to consider:

With unlimited funds, we would take as many "shots on goal" as possible, however, my experience is that there is limited funding and we will have prioritize. Anna made a wonderful comment the other day about rushing to use something that has potential too soon and killing it because of the rush! It is something we should all consider.

Dr. Kobinger has demonstrated neutralization with two of the mabs in the cocktail and binding with all three mabs to the current isolate (unpublished, personal communication). 13C6 does not neutralize and all evidence suggest it works through ADCC and thus binding is the key aspect for this mab. Binding kinetics are similar to Zaire. The biggest issue past funding and time, will be scale up of the process to produce large lots of the drug (estimate 1-3 months). They are planning dose sparing studies in Sept. which could alter production and offer 2X, 5X or 10X production/doses numbers. That study could be expedited.

BCX4430 has published data against Marburg and Ebola for guinea pigs but only Marburg virus for NHPs. Maybe there is unpublished data, but I expect (given my experience) there was less efficacy observed for EBOV versus MARV. It is also encouraging to see that the noted issues with toxicity, immune suppression, and high risk potential in phase I is listed for this product. I did see where NIH NIAID provided additional support for this product a few weeks ago.

The recommendation for UV4 makes no sense as written. If UV4 is going to be listed, there really should be many other compounds listed that have demonstrated efficacy against Ebola in vitro, rodents, and in some cases NHPs. The work Lisa and Peter did with various drugs with efficacy should be considered. In addition, while at RIID we screened all of the approved drugs and there are many drugs that could be repurposed/given off-label with efficacy in mice (they are working on NHP studies; short list attached but many others). Most of the drugs I mention here are approved and could be given off label.

We are also still missing vaccination. Both Dr. Sullivan's and the VSV platform should be considered as there are preclinical and clinical data available. The WHO has plans with the University of Geneva to use VSV (a cGMP lot) for those exposed and mabs for those that develop symptoms.

Anna and I were on the telcon for Lisa the last few days with WHO. Would love to share some of the discussions. There was a lot of discussion on convalescent serum and how quickly a process could be developed to pursue that approach.

Gene

From: Hu-Primmer, Jean (FDA/OC)
Sent: Thursday, July 24, 2014 9:09 AM
To: Hensley, Lisa (NIH/NIAID) [E]; Honko, Anna (NIH/NIAID) [E]; Olinger, Gene (NIH/NIAID) [C]
Subject: Fw: today's Ebola MCM working group

FYI - Please take a look at the document Jules put together.

I also asked them to include Tekmira after receiving this document.

Please let me know if you know of anywhere we can get more information on the gaps Jules discussed - as well as if you

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have any questions which we should consider.

Thanks!!
Jean

From: O'Rear, Julian
Sent: Thursday, July 24, 2014 07:51 AM
To: Hu-Primmer, Jean; Roberts, Rosemary; Leissa, Brad G; Mullick, Charu; Miele, Peter; Donaldson, Eric; Choi, Su-Young
Cc: Armstrong, Kimberly; Maher, Carmen
Subject: RE: today's Ebola MCM working group

Eric's document is not relevant here as there weren't any good candidate drugs for MERS-CoV so we were starting from square 1.

I've attached my thoughts on the proposed candidates. Most of the information is in the public domain (links to references included).

Jules O'Rear, Ph.D.
Lead Clinical Virologist
FDA\OMPT\CDER\OND\OAP\Division of Antiviral Products
[redacted]

From: Hu-Primmer, Jean
Sent: Wednesday, July 23, 2014 8:46 PM
To: Roberts, Rosemary; Leissa, Brad G; O'Rear, Julian; Mullick, Charu; Miele, Peter; Donaldson, Eric; Choi, Su-Young
Cc: Armstrong, Kimberly; Maher, Carmen
Subject: Fw: today's Ebola MCM working group

FYI....see email below RE the non-disclosure agreement.

To extent that we can provide any comments on the "frontrunner" MCMs indicated by our HHS partners including what data gaps need to be filled before we would consider use for US troops/CDC EIS officers and other US citizens in affected areas, that would be great.
I understand that those MCMs are:
1. MappBio's ZMab
2. Toyama's T-705
3. Biocryst's BCX4430
4. Unither Virology's UV4 (which is listed in clinicaltrials.gov for a dengue therapeutic study)
Any thoughts on these specific therapeutics would be great to include.

Gary has already sent an email to the lead POCs of each agency/institution that says we cannot share our document until we have everyone who is participating in the WG sign off on the MOU's NDA.

Rosemary - I passed on your suggestion of looping NIAID/IRF into the discussions; I hope they will comply.

Thanks all for your participation and help in today's discussions!!
Jean

From: Hu-Primmer, Jean
Sent: Wednesday, July 23, 2014 06:25 PM
To: Disbrow, Gary (OS) ([redacted]@hhs.gov) <[redacted]@hhs.gov>
Cc: Maher, Carmen
Subject: today's Ebola MCM working group

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Dear Gary,

Great call – thanks for facilitating the discussions.

I wanted to circle back with you and make sure I understand what FDA's current action item is with respect the outcome of our discussions.

We are prepared to draft a document that is more generic with respect to regulatory considerations for Ebola therapeutics, and will also include some product-specific thoughts/recommendations. However, before we send that to you, we need to make sure that we invoke the PHEMCE MOU and have all participants of the WG sign the attached non-disclosure agreement so that we can share non-public information for the purpose of this WG's deliberations.

Please see the attached document which is the PHEMCE MOU NDA "blessed" by ESC/EEC (if you need the actual MOU signed by all PHEMCE partners, please let me know).

<<! ICC Form - 2014 PHEMCE MOU.PDF>>

Also before we start the any discussion which will include non-public information, we need to state the following per the MOU SOP:

"This discussion may include trade secret or confidential commercial information protected from disclosure to the public under the Freedom of Information Act, the Trade Secrets Act, the Federal Food, Drug, and Cosmetic Act, or FDA regulations. Each participant must have signed an individual PHEMCE Confidentiality Commitment to participate today, and information provided may only be shared with employees or contractors who sign a PHEMCE Confidentiality Commitment. Please identify yourself if you have not yet signed this agreement and we will provide one to allow for your continued participation today. Participants should not further disclose or otherwise make public the information that is shared."

Finally, am happy to be the liaison for our FDA group, and appreciate that you go through me for all of your needs and concerns. One recommendation that our FDA group would like me to convey to you is that we strongly believe that NIAID/IRF should be included in the Ebola/Marburg MCM WG – specifically Lisa Hensley and/or her staff as they are engaged in much of the early research and even have boots on the ground in Africa and are in a position to share data that are critical to our deliberations.

Thanks,

Jean

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Casco, Tony (NIH/NIAID) [C]

From: Larry Zeitlin
Sent: Wednesday, July 30, 2014 12:55 PM
To: Trina Racine; deborah scott
Cc: Frederick G *HS Hayden; Kobinger, Gary (Public Health Agency of Canada); Olinger, Gene (NIH/NIAID) [C]; Jahrling, Peter (NIH/NIAID) [E]; Mike Hensley; Hensley, Lisa (NIH/NIAID) [E]; Miles Brennan; Tara Nyhuis; Marshall Hoke
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

Hi all,

This is coming together very nicely. I'd like to suggest a follow-up call to discuss this in more detail and have cc'd our colleagues at CBR who have been leading the regulatory and clinical planning effort for ZMapp.

Assuming everyone agrees a call would be worthwhile, can I trouble CBR to arrange it?

Best,
Larry

From: Trina Racine <[redacted]@phac-aspc.gc.ca>
Date: Wednesday, July 30, 2014 at 8:43 AM
To: deborah scott <[redacted]@sbcglobal.net>
Cc: Frederick G *HS Hayden <[redacted]@hscmail.mcc.virginia.edu>, Gary Kobinger <[redacted]@phac-aspc.gc.ca>, Gene Olinger <[redacted]@nih.gov>, Peter Jahrling <[redacted]@niaid.nih.gov>, Mike Hensley <[redacted]@icloud.com>, Larry Zeitlin <[redacted]@mappbio.com>, Lisa Hensley <[redacted]@nih.gov>
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

Hello all,

I too have made a number of comments and edits. Please let me know if you would like to discuss.

Trina

From: deborah scott <[redacted]@sbcglobal.net>
To: Mike Hensley <[redacted]@icloud.com>, Larry Zeitlin <[redacted]@mappbio.com>
Cc: Frederick G *HS Hayden <[redacted]@hscmail.mcc.virginia.edu>, "Peter \(NIH/NIAID\) \[E\] Jahrling" <[redacted]@niaid.nih.gov>, "Lisa \(NIH/NIAID\) \[E\] Hensley" <[redacted]@nih.gov>, "[redacted]@nih.gov \[C\] Olinger" <[redacted]@nih.gov>, "Gary \(Public Health Agency of Canada\) Kobinger" <[redacted]@phac-aspc.gc.ca>, Trina Racine <[redacted]@phac-aspc.gc.ca>
Date: 2014-07-30 12:39 AM
Subject: Re: Combining the existing Phase 1 with a Therapeutic Portion

---

I've inserted comments and discussion points. please see attached

Deb

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On Tuesday, July 29, 2014 1:53 PM, Mike Hensley <[redacted]@icloud.com> wrote:

As discussed toward the end of the call today, I took a shot at combining the objectives of your phase 1 protocol submitted to FDA with the objective of separating the vaccine and ZMapp products into two separate protocols. See attached. I've done nothing more with the vaccine portion but I like Deb's suggestion of doing a vaccine study in Canada or as someone suggested today, in Geneva. Logical, since Health Canada apparently controls the drug product.

In combining the two objectives I constructed an initial phase to be done in HCW's not yet deployed. In this group we can do the pK and immunogenicity work needed. Assuming we get reasonable data there we cold move into HCW's deployed and exposed. I could sympathize with a larger group in the first phase but was taking into account limited supplies of ZMapp when I made my choices. Some details I calculated from or extrapolated from your pre-IND package. Doses I chose based on the NHP trials.

Once again this is a clinical synopsis but gives us a set of talking points and probably anticipates most issues. Lots of detail missing but easy to complete with a little q&a if this looks reasonable

Mike Hensley
[attachment "Revised Phase 1 ZMapp Study Protocol Synopsis jb ds(2).docx" deleted by Trina Racine/HC-SC/GC/CA]

Released by Chairman Rand Paul

Casco, Tony (NIH/NIAID) [C]

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Friday, August 08, 2014 4:26 PM
To: Kurilla, Michael (NIH/NIAID) [E]
Cc: Heilman, Carole (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]; Lane, Cliff (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]
Subject: Task
Attachments: Ebola MCM Time lines 08-07-14 v2.docx

Mike:

I just got off the phone with Robin Robinson and expressed to him my concern that the attached document was put together and distributed rather widely within the Department without any verification whether the timelines and objectives are feasible. He felt badly about how this rolled out. He confirmed our suspicion that this is really a "patchwork" of initiatives that have been collected at Nicki's instructions by contacting various people from various agencies and then this "timeline" was put together. He is as concerned as we are. One example is that he spoke with Larry Zeitlin from MAPP and Larry is not certain that they can even make enough zMapp to do a phase I/II trial during the timeline indicated. There are also other issues in the timeline.

Robin then asked me to go over the document and indicate with tracked comments what we think is incorrect and/or what we think is not feasible. Could you please go over the document and do this and then send it to me to see before we send it back to Robin. Please copy everything to Hilary.

Thanks,

Tony

Released by Chairman Rand Paul

DRAFT-DRAFT-DRAFT-DRAFT

Time-Line of Events for the Current Out-Break

- March 2014 – the first cases of Ebola virus in West Africa were reported
- August 7, 2014 – Number of infected individuals exceeded 1,711 with 932 reported deaths

THERAPEUTICS:

Mapp Biopharmaceutical – ZMapp monoclonal antibody

- May 2005 – NIAID funded Mapp Biopharmaceutical for discovery and early development of monoclonal antibodies (mAbs) for treatment of Ebola virus infections (2006-2011)
- September 2007 – NIAID funded Mapp Biopharmaceutical additionally for early development of MB003 mAb cocktail for treatment of Ebola virus infections (2007-2014)
- February 2013 – Defense Threat Reduction Agency funded Mapp Biopharmaceutical for early development of ZMapp mAb cocktail produced in tobacco plants for treatment of Ebola virus infections
    - Activities covered in year one included non-clinical evaluation and production of non-clinical investigational lots at pilot scale
- Late July 2014 – Medicins Sans Frontieres (MSF) requested product at PHAC lab to be shipped from Sierra Leone, where a stability study of ZMapp was on-going, to the University of Geneva for possible treatment of Dr. Khan, who become infected with Ebola
- July 29, 2014 – Samaritan's Purse, which had two American healthcare providers infected with Ebola virus in Liberia, requested ZMapp from PHAC and Mapp Biopharmaceutical, as PHAC had brought a treatment course of ZMapp to West Africa previously for other purposes. CDC and NIAID assisted the NGO in finding the right contact persons at PHAC and the company. DTRA released ZMapp product to Mapp Biopharmaceuticals.
- July 31, 2014 – Initial treatment efforts including transfusions with convalescent sera was administered to Patient 1 in Liberia.
- August 2, 2014
    - The first treatment course of ZMapp was administered to the two American patients in Liberia. Improvement was noted in both patients.
    - Emory University Hospital requested ZMapp from Mapp Biopharmaceutical for treatment of the returning American patients.
    - Emory University Hospital requested from FDA an emergency IND (eIND) for use of ZMapp; one treatment course was shipped to Emory University Hospital
    - NIAID began toxicology studies on ZMapp to assist the DTRA project and support an IND submission
- August 5, 2014 – FDA granted an eIND to Emory University Hospital for use of ZMapp to treat the returning Ebola-infected Americans from Liberia. They each received additional doses on arrival.
- August 2014 –

  - DTRA exercises option on contract with Mapp Biopharmaceutical to develop ZMapp further in coordination with NIAD and BARDA
  - BARDA will award a contract to Mapp Biopharmaceutical for advanced development of ZMapp including optimization, expansion, & validation of product manufacturing, pivotal non-clinical animal challenge studies, and clinical studies towards FDA licensure
- September 2014 –
  - Kentucky BioProcessing will commence manufacturing of ZMapp for Mapp Pharmaceutical under BARDA contract to support additional non-clinical and Phase 1/2 clinical studies
  - Additional manufacturing runs will occur to optimize manufacturing process immediately after previous manufacturing runs have been completed
  - Tech transfer of manufacturing process to other tobacco-based manufacturing sites
  - Mapp Biopharmaceutical with DTRA, NIAID, and BARDA will meet with FDA in a pre-IND meeting to discuss data and any outstanding questions or concerns
- Anticipated December 2014 – Mapp Biopharmaceutical will release ZMapp for Phase 1 clinical study
- Anticipated January 2015 – Mapp Biopharmaceutical will submit IND to FDA
- Anticipated February/March 2015 – NIAID will initiate Phase 1 in healthy adults in U.S. and Phase 1/2 clinical study in Ebola-infected human subjects in West Africa

BioCryst – BCX4430 antiviral drug

- September 2013 - NIAID started funding BioCryst (Cary, NC) for early development of BCX4430, an adenosine analogue, as an antiviral drug for treatment of Ebola infections in September 2013.
- August 2014 – Biocryst completed initial studies with product candidate in a murine Ebola challenge model and developed a pilot scale product manufacturing process
- September 2014 –
  - USAMRIID will evaluate the efficacy of BCX4430 in NHP challenge studies with Ebola virus.
  - Biocryst will commence manufacturing of BCX4430 for clinical trials. Manufacturing could be scaled up to 5kg from current 1kg if warranted.
- Anticipated November 2014 – Biocryst will make available 10 treatment courses for clinical evaluation and other usages.
- Anticipated December 2014
  - Biocryst will make available an additional 10 treatment courses for clinical evaluation and other usages.
  - Biocryst will file an IND with the FDA to conduct a Phase 1 clinical trial.
- January 2015 – Biocryst will initiate enrollment into a Phase 1 clinical trial for safety.

Medivector – Favipiravir antiviral drug

- March 2012 – JPM-TMI (DoD) began funding to Medivector (Boston, MA) for development of Favipiravir (T-705) for influenza infection; project is in Phase 3 clinical studies
    - Approximately 32,000 influenza treatment courses available for purchase from Medivector
    - DoD has recently awarded contracts for domestic manufacturing but has not initiated manufacturing
- July 2014 – DoD showed the initial evaluation of this drug in Ebola-infected non-human primates had no efficacy; however suboptimal dosing may have occurred.
- September 2014 – DoD will evaluate drug again in Ebola-infected in non-human primates at higher dose to determine efficacy
- October 2014– If non-human primate studies are successful, then Medivector will request FDA to determine if clinical bridging study(s) will be required for Ebola infections.

VACCINES:

Vaccine Research Center (VRC) and GSK – Adenovirus-vector Ebola vaccine

- 2009 - NIAID/VRC started early development of their chimp Ad3 Ebola vaccine
- August 2014 - NIAID/VRC will submit an IND to FDA for their vaccine candidate
- September 2014 - NIAID will conduct a dose-ranging safety Phase 1 clinical study in the U.S. in healthy adults in
- January 2015 - NIAID will conduct a Phase1/2 safety and immunogenicity study in neighboring countries of those West African countries with Ebola outbreaks
- NIAID/VRC will work GlaxoSmithKline to optimize and scale up manufacturing of the vaccine candidate in 2014-2015

Newlink Genetics and Public Health Agency Canada (PHAC) - Recombinant Vesicular Stomatitis Virus (rVSVΔG) Ebola Vaccine

- August 7, 2014 - DoD/DTRA awarded contract to PHAC and Newlink Genetics (Ames, IA) for development of a rVSV Ebola ΔG vaccine, which PHAC began developing in 2006
- GMP material was produced at IDT in Germany
- August 2014 – PHAC indicated they had 1400 doses of vaccine on hand
    - 10 doses were sent to University of Geneva
    - ~1400 doses at PHAC
        - 600 reserved for non-clinical studies to support Clinical Trial Application (CTA – USA IND equivalent) and Phase 1 trial
        - 800 doses available
- Anticipated September 2014
    - Preclinical toxicology studies utilizing product from PHAC
    - Manufacture GMP lot at IDT in Germany to support non-clinical and Phase 1 clinical study
- Anticipated January 2015 – Newlink Genetics will submit IND to FDA.

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- Anticipated February 2015 – Newlink Genetics will initiate Phase 1 clinical study in U.S. for safety.

USG Interagency Coordination

- July 18, 2014 = ASPR commissioned a PHEMCE Working Group to provide a landscape of MCMs for treatment and prevention of Ebola and determine which product candidates could be expedited in their development to address the current Ebola outbreaks in West Africa
- July 23, 2014 – PHEMCE Interagency Working Group deliberated on Ebola therapeutics under development
- July 25, 2014 – PHEMCE Interagency Working Group deliberated on Ebola vaccines under development
- August 1, 2014 – PHEMCE Interagency Working Group deliberated on how PHEMCE partners can coordinate efforts and develop recommendations for potential use of products
- August 6, 2014 – DTRA, NIAID, and BARDA met to discuss development of ZMapp and coordination of efforts
    - DTRA, NIAID, and BARDA will meet weekly to coordinate efforts and share information
- August 2014 – DTRA, NIAID and BARDA will meet with the FDA under the PHEMCE MOU to ensure that all necessary studies for ZMapp have been completed, are ongoing or planned for IND submission by Mapp Pharmaceutical

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CEPI

Coalition for Epidemic Preparedness Innovations

Concept Note for the Start-Up Phase

Overview

The 2014-2015 Ebola outbreak in West Africa highlighted significant gaps in the world's ability to prepare for and respond to infections of epidemic potential, and a particularly urgent need for a new approach to stimulating, coordinating and financing the development of vaccines. Similar challenges have been demonstrated by other recent epidemics and pandemics, including SARS, H1N1 flu, MERS-CoV and Lassa.

Following the leadership of Chancellor Merkel as chair of G7 and the meeting of experts in Berlin in March 2015, chaired by Bill Gates, there is now broad international and cross-sector agreement that current models for supporting vaccine development in advance of and during epidemics is failing, and that a new system is needed. The four reports into the Ebola epidemic – from WHO, LSHTM/The Lancet, NAM/Global Health Risks Framework and the UN Secretary General's High Level Panel – all reached the same conclusion and created a clear mandate for change.

In response to this demand, stakeholders from international organisations, governments, industry, public and philanthropic R&D funders, academia, NGOs and civil society groups agreed at the World Economic Forum in Davos, 2016, to explore new ways of working to drive vaccine innovation to address public health threats, in alignment with the WHO Blueprint for R&D. This initiative is known as 'CEPI'.

Vision

CEPI's vision is that vaccines play the fullest possible part in managing outbreaks of infectious diseases with epidemic potential, at the earliest possible stage, so that they do not become public health emergencies. This will contain loss of life, limit damage to social and economic development, and prevent humanitarian crises.

CEPI aims to do this by creating an innovative partnership between the public, private, philanthropic and civil society sectors, to take an "end-to-end" approach to vaccine development, predominantly in cases where there is no commercial market. It will:

- Advance the development of specific, effective vaccines to the stage where there is proof of principle of efficacy and safety, ready for full trials or emergency use in the event of an epidemic.
- Plan and execute the manufacture and stockpiling of such vaccines, and resolve issues such as indemnity and trial design, so vaccines can be deployed swiftly in the event of an epidemic.
- Provide a 'hub' for global coordination of efforts around development of vaccines for preparedness.
- Partner with the organizations that have the potential to reach vaccination target populations, so that development success translates into immunization.

Product

CEPI is in its start-up stage and will evolve through multi-sectorial dialogue between its stakeholders. The aim is to have a completed Strategic and Business Plan outlining the vision, partnership model and operational and funding requirements of a new innovative partnership, and to secure initial funding commitments in the fall of 2016, and to launch at the World Economic Forum in January 2017. **Stakeholders are asked to work together to provide input to these plans.**

Governance

During its planning phase, CEPI has been governed through a temporary structure designed to ensure that all stakeholders can contribute their perspectives. This has been co-ordinated by an interim Secretariat provided by the Norwegian Government, working closely with members of the Core Team (Bill & Melinda Gates Foundation, Wellcome Trust, the Government of India's Department of Biotechnology and the World Economic Forum) to manage the operational aspects of CEPI. Stakeholders to date have been contributing through a three-tier system divided into the Leadership Group (full list available in Annex), a Chairs Group and three Task Teams.

An interim chief executive officer, John-Arne Røttingen of the Norwegian Institute of Public Health, was appointed in June 2016, to oversee the start-up phase through to late 2017. An interim board of directors including representatives of likely funders, private sector and governmental and non-governmental organizations, scientific advisory committee, will be appointed imminently. A group of CEPI champions consisting of high level advocates will be engaged with the aim to mobilize political and financial capital to support CEPI's mission. A CEPI Joint Coordination Group will serve as a platform for coordination with affiliated partners. **Interested stakeholders should contact the Secretariat to discuss the most appropriate areas for engagement.**

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Progress to Date

A series of high-level interactive workshops and teleconferences have been held since January 2016 to develop initial proposals for the science and regulation, partnership models and financing considerations of CEPI.

Next Steps

The following next steps are envisioned:

- Finalize task team recommendations for integration into the Strategic and Business Plans
- Establish a cross task team cost modeling group
- Formalize interim governance arrangements
- Convene Leadership Group Meeting in London to present agreed Integrated Strategic/ Business Plan
- Tender the concept with G7 Health Ministers in Japan
- Broaden advocacy and secure initial funding commitments for launch at the Annual Meeting at Davos in January 2017

Interaction

- **30 August**
  Stakeholder Meeting in London
- **31 August**
  First Interim Board Meeting
- **September/October (TBD)**
  First Scientific Advisory Committee Meeting
- **11-12 September**
  G7 Health Ministers' Meeting Side Event
- **10 November**
  Interim Board Meeting in India
- **17-20 January, 2017**
  Launch Partnership at the World Economic Forum Annual Meeting in Davos

Leadership Group Members

Name	Role	Organisation
Peter Piot (Chair)	Director	London School of Hygiene and Tropical Medicine
Arnaud Bernaert	Head of Global Health and Healthcare Industries, Member of the Executive Committee	World Economic Forum
Olivier Brandicourt	Chief Executive Officer	Sanofi
Christian Brechot	Directeur General de l'Institut Pasteur et President de la Fondation Paster Suisse	Institut Pasteur
Seth Berkley	Chief Executive Officer	GAVI
Borge Brende	Minister of Foreign Affairs	Ministry of Foreign Affairs, Norway
Francis S. Collins	Director	National Institute of Health
Steve Davis	President and Chief Executive Officer	PATH
Victor Dzau	President	National Academy of Medicine
Ruxundra Draghia-Akli	Director of the health Directorate at the Research DG	EU Commission
Jeremy Farrar	Director	Wellcome Trust
Anthony Fauci	Director	NIH
Mark Feinberg	President and Chief Executive Officer	IAVI
Thomas Frieden	Director	CDC
Julie Gerberding	Vice-President, Strategic Communications, Global Public Policy and Population Health	MSD
Tore Godal	Special Advisor	MFA Norway
Peter Hale	Executive Director	Foundation for Vaccine Research
Jane Halton	Secretary	Department of Finance, Australia
Richard Hatchett	Director	BARDA
Marie-Paule Kieny	Assistant Director-General, Health Systems and Innovation	WHO
Joanne Liu	International President	MSF
Adel Mahmoud	Director	Princeton University
Susan McAdams	Director of Multilateral and Innovative Financing	World Bank Group
Trevor Mundel	President, Global health Programme	Gates Foundation
Ngozi Okonjo-Iweala	Chair	GAVI
Stanley Plotkin	Emeritus Professor	UPENN
Adar Poonawalla	Chief Executive Officer	Serum Institute of India
Vijay Raghavan	Secretary	DBT India
John-Arne Rottingen	Executive Director, Infection Control and Environmental Health	NIPH
Susan Silbermann	President, Pfizer Vaccines	Pfizer
Paul Stoffels	Worldwide Chairman, Pharmaceuticals; Chief Scientific Office	Johnson & Johnson
Christophe Weber	President and Chief Executive Officer	Takeda
Andrew Witty	Chief Executive Officer	GlaxoSmithKline

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CEPI - COALITION FOR EPIDEMIC PREPAREDNESS INNOVATIONS

Program

CEPI Stakeholders Meeting

Wellcome Trust
215 Euston Road
London NW1 2BE, UK

The objectives of this meeting:

1. Sharing/Internal Launch CEPI Business plan and Communications plan or (for discussion)
2. CEPI announcing its full interim structure including: interim Board, Scientific Advisory Committee and other committees

10:00 – 10:15	**Welcome & Introduction** Announcement: Interim Board, SAC, Joint Coordination Group, CEPI Champions Peter Piot, Director, London School of hygiene and tropical medicine
10:15 – 11:15	**Panel: Presentation and discussion of Business Plan** John-Arne Røttingen, CEPI Interim Director Selected Panelists
11:15 – 12:15	**Q&A on Business Plan** Nancy Lee, Wellcome Trust Penny Heaton, Bill and Melinda Gates Foundation Panel: John-Arne Røttingen, Jeremy Farrar, Peter Piot
12:15 – 13:00	**Lunch**
13:00 – 14:00	**Updates from other processes** Selected Panelists
14:00 – 14:30	**Coffee Break**
14:30 – 15:30	**Panel (special call in session for those not being able to participate in person):** Challenges ahead and departing advice for the Interim Board Selected Panelists from the Leadership Group
15:30 – 16:00	**Communications and Advocacy** Mark Henderson, Wellcome Trust Samia Saad, Bill and Melinda Gates Foundation Nancy Lee, Wellcome Trust Gabrielle Fitzgerald, GPS Strategy Inc. **Conclusion / wrapping-up / Next Steps** John-Arne Røttingen, CEPI Interim Director
16:30 – 18:00	**Networking reception with drinks**

DRAFT

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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: CEPI invitation
Date: Fri, 19 Aug 2016 06:26:29 -0400
Importance: Normal
Attachments: CEPI_ConceptNote_Aug2016_(003).pdf; August_30_2016_draft_program_20160815.docx
Embedded: RE:_Invitation:_Panel_Presentation,_CEPI_Stakeholder_Meeting,_30_August_2016_at_the_Wellcome_Trust,_London

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fyi

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, August 19, 2016 5:31 AM
To: Glass, Roger (NIH/FIC) [E]; Kilmarx, Peter (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]
Subject: FW: CEPI invitation

Hi Roger and Peter,

Please see attachments. Roger represented NIH at the last CEPI meeting in DC in May. Neither Tony nor I can attend this next meeting in London on August 30. With apologies for the very short notice, we're hoping that one of you might be able to attend – is that possible?

We'll need to have a quick pow-wow in advance of the meeting, to be sure we're all on the same page about CEPI.

Francis

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From: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "'Helgeland, Astrid'" <[redacted]@fhi.no>
Cc: Røttingen, John-Arne <[redacted]@fhi.no>, "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" <[redacted]@nih.gov>
Subject: RE: Invitation: Panel Presentation, CEPI Stakeholder Meeting, 30 August 2016 at the Wellcome Trust, London
Date: Mon, 15 Aug 2016 09:40:57 -0400
Importance: Normal
Inline-Images: image001.png

Dear Astrid:
Thanks for your note and invitation. Unfortunately, due to prior commitments neither Francis Collins nor I will be able to attend the CEPI Stakeholder Meeting in London on August 30. We will work on getting a senior NIH person to represent the NIH at this meeting. Many thanks.
Best regards,
Tony

From: Helgeland, Astrid [mailto:[redacted]@fhi.no]
Sent: Monday, August 15, 2016 8:16 AM
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Røttingen, John-Arne
Subject: Invitation: Panel Presentation, CEPI Stakeholder Meeting, 30 August 2016 at the Wellcome Trust, London

Dear Tony,

The Coalition for Epidemic Preparedness Innovations (CEPI) is holding a Stakeholder Meeting on 30 August 2016 in advance of its inaugural Board Meeting on 31st August 2016.

The purpose of the Stakeholder Meeting is to launch CEPI as an entity, announce CEPI governance structures including its Board and Scientific Advisory Committee and present the initial Business Plan (and Communications Plan) to stakeholders acknowledging their commitment and participation in the CEPI set up phase.

As a part of the day, we are reaching out to key individuals in the field of vaccine development for epidemics as potential panellists able to provide updates on initiatives in their individual organisations.

We would be delighted if you would be willing to participate as a panellist in "*Updates from other processes*" session scheduled between 13.00 and 14.00 (BST). The format for the panel will be a three minute presentation by each member of a six person panel followed by an open discussion session from the floor.

The Stakeholder Meeting will be attended by a representatives from organisations who have actively participated in the initial phase of CEPI; its Leadership Group, Chairs Group, Core Group and three key Task Teams.

We have attached a summary document outlining the CEPI concept and process to date together with a draft Agenda to facilitate your decision-making and scheduling.

We will be delighted to support you with logistics arrangements for the day should you be able to join us.

I looking forward to receiving your response at your earliest convenience.

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Kind regards,

Astrid

Astrid Helgeland
Senior advisor
CEPI – Coalition for Epidemic Preparedness Innovations
c/o Norwegian Institute of Public Health
Postal address: PO Box 4404, N-0403 Oslo, Norway
Visiting address: Lovisenberggt 8, Oslo, Norway
[redacted]
www.fhi.no

folkehelseinstituttet

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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>
Subject: FW: Support on Ebola
Date: Fri, 08 Aug 2014 08:56:24 -0400
Importance: Normal
Inline-Images: image001.png

Francis:
I will forward to you in another e-mail the response of John Mascola when I asked him if Gates could help. Stay tuned.
Tony

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, August 07, 2014 9:49 PM
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Support on Ebola

I have allocated enough money to do the VRC vaccine trial and so we do not need Gates money. I believe that BARDA has enough money to accelerate the zMapp production. I will give John Mascola a call and find out if he can think of any way that Gates can help with his trial.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, August 07, 2014 9:20 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: Support on Ebola

I was thinking exactly the same thing. Do you see ways that BMGF could be helpful?

FC

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, August 07, 2014 7:37 PM
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Support on Ebola

We should discuss how we are going to respond to Trevor

From: Trevor Mundel [mailto:[redacted]@gatesfoundation.org]
Sent: Thursday, August 07, 2014 7:17 PM
To: Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]
Subject: Support on Ebola

Dear Francis and Tony,

It is clear that the problem, concern and media attention surrounding the treatment of the two individuals now in Atlanta add further weight to the Ebola outbreak concerns, which we have discussed by email over the past week or so. Although the overall burden of disease due to Ebola is not of the magnitude of the conditions we address strategically, we recognize that the current situation calls for action and places considerable pressure on your agency and WHO and others of our key

Released by Chairman Rand Paul

partners. For these reasons we have provided emergency funds to WHO and UNICEF to support public health measures as well as on the ground human resources in the target countries as one in kind contribution to the problem.

We would also like to be supportive of your efforts, if doing so can add value. One challenge is that we believe that interventions that could help to interdict the current epidemic are needed the most. Interventions that are not ready to give to patients in the relatively near term will not be of help for this emergent situation.

We understand that there are efforts with GSK and the VRC to scale up the lot of the ChAd3 vaccine, which is due to go into FIH studies this fall and for which additional doses might be available for evaluation in at risk individuals by early 2015; we believe that Wellcome may be interested in supporting this effort.

We also understand that there are very limited supplies of ZMapp (~12 courses of therapy). Assuming an appropriate approach can be designed with input from relevant stakeholders (i.e., one which provides for equity in opportunity for participation in an interventional trial that extends beyond foreign health workers to include indigenous individuals), we would be willing to assist with partial funding to generate more product in partnership with NIH and other relevant agencies. We can also provide in-kind CMC expertise through two MAb manufacturing experts with considerable industry experience on our team. Please let us know if this would be useful to you.

We appreciate your frontline efforts to address this problem and look forward to helping where we might.

Warm regards,

Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Amissa Cormier
Senior Program Assistant
Global Health Office of the President
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>
Subject: FW: Support on Ebola
Date: Fri, 08 Aug 2014 08:57:08 -0400
Importance: Normal
Inline-Images: image001.png

As per my prior e-mail.

From: Mascola, John (NIH/VRC) [E]
Sent: Friday, August 08, 2014 8:49 AM
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Koup, Richard (NIH/VRC) [E]
Subject: Re: Support on Ebola

Tony,
Several relevant items.

1. We heard from GSK that Welcome trust is willing to help support expanded international trials and this is being pursued. Rip Ballou of GSK is coordinating with Rick Koup.
2. We discussed with Nelson Michael and colleagues yesterday, a trial in Uganda that would be run by African investigators and generate data in African volunteers. Some funding to support this may be helpful., but there may be existing NIAID/DoD funds existing to support this.
3. GSK is close to final decision about making larger lot of vaccine. BARDA or Gates funding could play a role here.

There are many moving parts here and several fairly imminent decisions. Rick has been on all the calls with BARDA, GSK, WHO etc. A first key step in to find out what BARDA plans to do, and based on that, decide if there are other funding gaps.

Rick, do you know when we will hear specifically what BARDA will fund, how much and when this will be announced. Will they support some GSK manufacturing activities?

John

Apple iPad

On Aug 7, 2014, at 9:50 PM, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov> wrote:

John:
See e-mail string below. Is there any way that you can think of where Gates can be of assistance to us in the ChimpAd Ebola vaccine development?
Tony

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, August 07, 2014 9:49 PM
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Support on Ebola

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We appreciate your frontline efforts to address this problem and look forward to helping where we might.

Warm regards,

Released by Chairman Rand Paul

Trevor

<image001.png>
Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Amissa Cormier
Senior Program Assistant
Global Health Office of the President
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Koup, Richard (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Mascola, John (NIH/VRC) [E]" <[redacted]@mail.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: Support on Ebola
Date: Fri, 08 Aug 2014 13:25:34 -0400
Importance: Normal

Thanks, Rick. Very helpful.

From: Koup, Richard (NIH/VRC) [E]
Sent: Friday, August 08, 2014 9:15 AM
To: Mascola, John (NIH/VRC) [E]; Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: Support on Ebola

John and Tony:

Here is the latest I know. We have been getting a lot of additional clarifying questions from BARDA subsequent to our telecom, so I am fairly confident they will fund production of 1 "lot" of vaccine, but I remain unclear as to when we will hear definitively. Wellcome Trust seems willing to provide half the funds for another lot, but only if GSK or some other source partners for the other half of the funds. GSK leadership is not interested, but Rip Ballou is checking with MRC and others to see what can be done. WHO is anxious to start additional small phase 1 trials in Africa (20 subjects per country, at MRC sites). We currently have adequate vaccine stock for our NIH-based phase 1, an expanded phase 1 in Uganda (100 subjects with MHRP), and 1 or 2 other African phase 1 trials.

Whether the funding comes to us or GSK, we will both use a contract mechanism to have the vaccine produced at Advent, which is the Okairos facility that made the first lot for us under contract. Our pilot plant would do the vialing and lot release would be shared by us and Okairos.

Maybe more info than you wanted.

Rick

Richard A. Koup, MD
Chief, Immunology Laboratory
Deputy Director
Vaccine Research Center, NIAID, NIH
40 Convent Drive, MSC 3022
Building 40, Room 3502
Bethesda, MD 20892
Tel: [redacted]
Fax: [redacted]
[redacted]@mail.nih.gov

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From: Mascola, John (NIH/VRC) [E]
Sent: Friday, August 08, 2014 8:49 AM
To: Fauci, Anthony (NIH/NIAID) [E]

Released by Chairman Rand Paul

Cc: Koup, Richard (NIH/VRC) [E]
Subject: Re: Support on Ebola

Tony,
Several relevant items.

1. We heard from GSK that Welcome trust is willing to help support expanded international trials and this is being pursued. Rip Ballou of GSK is coordinating with Rick Koup.
2. We discussed with Nelson Michael and colleagues yesterday, a trial in Uganda that would be run by African investigators and generate data in African volunteers. Some funding to support this may be helpful., but there may be existing NIAID/DoD funds existing to support this.
3. GSK is close to final decision about making larger lot of vaccine. BARDA or Gates funding could play a role here.

There are many moving parts here and several fairly imminent decisions. Rick has been on all the calls with BARDA, GSK, WHO etc. A first key step in to find out what BARDA plans to do, and based on that, decide if there are other funding gaps.

Rick, do you know when we will hear specifically what BARDA will fund, how much and when this will be announced. Will they support some GSK manufacturing activities?

John

Apple iPad

On Aug 7, 2014, at 9:50 PM, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov> wrote:

John:
See e-mail string below. Is there any way that you can think of where Gates can be of assistance to us in the ChimpAd Ebola vaccine development?
Tony

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, August 07, 2014 9:49 PM
To: Collins, Francis (NIH/OD) [E]
Subject: RE: Support on Ebola

I have allocated enough money to do the VRC vaccine trial and so we do not need Gates money. I believe that BARDA has enough money to accelerate the zMapp production. I will give John Mascola a call and find out if he can think of any way that Gates can help with his trial.

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, August 07, 2014 9:20 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: Support on Ebola

I was thinking exactly the same thing. Do you see ways that BMGF could be helpful?

FC

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, August 07, 2014 7:37 PM

Released by Chairman Rand Paul

To: Collins, Francis (NIH/OD) [E]
Subject: FW: Support on Ebola

We should discuss how we are going to respond to Trevor

From: Trevor Mundel [mailto:[redacted]@gatesfoundation.org]
Sent: Thursday, August 07, 2014 7:17 PM
To: Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]
Subject: Support on Ebola

Dear Francis and Tony,

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To: "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Fw: October 7 visit of Bill Gates
Date: Thu, 26 Sep 2013 22:37:09 -0400
Importance: Normal
Attachments: NIH_Visit_of_Bill_Gates_..docx; Wilson_Young_bios.docx

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From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric ([redacted]@state.gov) <[redacted]@state.gov>
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Best regards, Francis

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PROGRAM OF ACTIVITY
NIH VISIT OF BILL GATES
OCTOBER 7, 2013

10:15 AM – 11:00 AM Media Roundtable at Clinical Center (room TBD)

11:05 AM – 11:15 AM Meeting with Dr. Collins (room TBD)

11:15 AM – 12:30 PM Roundtable Discussion with NIH Senior Leadership

Medical Board Room, Clinical Center

Opening remarks: Francis Collins and Bill Gates

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12:00 PM – 12:30 PM **Working Lunch**

Masur Auditorium, Clinical Center

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1:40 PM – 2:00 PM Q's and A's

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Clif Barry

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Wilson is a pediatrician and immunologist. He joined the faculty at the University of Washington in 1979 in the Infectious Diseases Division of the Department of Pediatrics and later served as head of the Division of Infectious Diseases, Immunology and Rheumatology. In 1989, he became one of the founding faculty members in the new Department of Immunology, and served as Chairman of the Department of Immunology and head of the graduate program in immunology from 1999-2009.

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To: "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 08:47:36 -0400
Importance: Normal
Attachments: NIH_Visit_of_Bill_Gates_..docx; Wilson_Young_bios.docx

---

Gray,

Are there materials we can send Eric on the implementation science partnership ? Would Melanie Bacon by the person to reach out to

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To: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
Cc: "Bacon, Melanie (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:35:45 -0400
Importance: Normal

A-OK. I would check with Melanie and will copy her here just to save time.

Melanie can you pull something off the shelf to help Rob out or would you like some help from OGR?

Thanks. Gray

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 12:12 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: RE: October 7 visit of Bill Gates

He does have time with Bill prior to the media roundtable, and then again prior to the leadership roundtable I will be updating the agenda to reflect

There have been a few instances where the background OGAC staff have provided is outdated, so I'm just trouble shooting in case we have information we could provide

---

From: Handley, Gray (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 12:08 PM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: October 7 visit of Bill Gates

I would have assumed that Eric's own staff would provide these materials since the activities are funded by OGAC. Melanie would be the person to ask about this as she keeps track of these initiatives….but very informally because multiple ICs are actually in charge of their bits and pieces.

On the revised visit schedule, wouldn't it make more sense for Francis to have his one-on-one before the press event rather than after?

G

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Released by Chairman Rand Paul

From: "Bacon, Melanie (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:40:01 -0400
Importance: Normal
Attachments: PEPFAR_update_2013.xlsx

Hi Gray,

I wasn't really sure what he needed, but I just sent this…. Let me know if you think there is something else I should provide.

Melanie

From: Bacon, Melanie (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 1:21 PM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: October 7 visit of Bill Gates

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From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 12:18 PM
To: Bacon, Melanie (NIH/NIAID) [E]

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Subject: FW: October 7 visit of Bill Gates
Importance: High

Hi Melanie,

I hope things are well Dr Collins will ask Eric Goosby to say a few words about the implementation science partnership, during the roundtable discussion with Bill Gates on Oct 7

I'm staffing Dr Collins for this May I ask, is there any information on progress, from our end, that we might pass to Eric that may help him prepare? Thanks for any assistance you might be

Best

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric ([redacted]@state.gov) <[redacted]@state.gov>
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Best regards, Francis

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HPTN 071: PopART								
NIAID	Hayes		LSHTM	PopART	South Africa/ Zambia	$10,000,000 PEPFAR	PEPFAR, NIAID, NIMH, BMGF	Randomized study of combination prevention interventions involving 21 communities in Zambia and South Africa. The intervention, taking place in PEPFAR-funded clinics in the intervention communities, is scheduled to begin by September 30. Enrollment in the population cohort (which will be used to measure the HIV incidence outcome)will begin next month.
Project SEARCH								
NIAID	Havlir	CTU suppl	UCSF	SEARCH	Uganda/Kenya	$2,000,000 PEPFAR	PEPFAR, WB, NIAID	POC CD4 testing with streamlined initiation of care in Uganda.
RFA AI-11-003: NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation (R01)								
IC	**PI**	**Grant #**	**Institution**	**Title**	**Country**	**1st year amount (=request -3.5%)**	**$ Source**	**AIM**
NIAID	Farquhar	99974	UW	Assisted partner notification to augment HIV treatment an prevention in Kenya	Kenya	$650,587.56	OAR	introduce assisted partner notification services (aPS) into 18 facilities in Kenya and estimate its capacity to promote HIV testing, identify partners with HIV infection, and link these partners to care
NIAID	Gray	100031	JHU/Rakai	Male Circumcision for HIV Prevention	Uganda	$964,670.94	PEPFAR	To increase MC uptake in a rural setting, particularly in higher risk men, using enhanced messaging, targeted outreach, task shifting, task sharing and mobile camps, and to compare MC uptake, coverage, and client sociodemographic/behavioral characteristics and cost-effectiveness in static clinics versus mobile camps; and conduct a randomized study of the acceptability and safety of EIMC provided by clinical officers (COs) who currently perform adult MC, compared with nurse-midwives (NMWs) who are not currently licensed to perform the procedure
NIAID	Stringer	100053	UAB/CIDRZ	Point-of-care virologic testing to improve outcomes of HIV-infected children	Zambia	$964,980.70	PEPFAR	a cluster-randomized trial of the SAMBA POC virologic test to improve outcomes of HIV-infected children in Zambia
NIAID	Braithwaite	99970	NYU/Ampath	Implementation science to optimize HIV prevention in East Africa PEPFAR programs.	Uganda/Kenya/ Tanzania	$889,221.45	PEPFAR	create a model that will simulate the HIV epidemic in east Africa, taking into account person-to-person HIV transmission, in order to evaluate the benefit and value of retention-in-care interventions in east Africa
NIAID	Havlir	99959	UCSF	Initiate ART: Sreamlined ART Start Strategy (START)	Uganda	$963,331.52	PEPFAR	evaluate the effectiveness of a multi-component Streamlined ART Start Strategy (START) based on an empirically validated model of change that deploys 1) portable point of care (POC) CD4 testing and adapted counseling to enable ART start, 2) dissemination of information through education that predisposes provider behavior and 3) feedback reporting on FTIs that reinforces uptake of ART
NIAID	Frenkel	100037	Seattle Child	Drug resistance testing in Kenya to improve ART suppression of HIV replication	Kenya	$934,684.53	PEPFAR	An inexpensive simple assay [oligonucleotide ligation assay (OLA)] to detect HIV drug-resistance will be implemented in Kenya. We will study the benefits conferred by this assay to improving infected individuals health, and compare the overall cost of using to not using this test.
NIAID	El Sadr	100059	Columbia	Link4Health: a combination strategy for linkage and retention: Swaziland	Swaziland	$962,976.40	OAR	two-arm cluster site-randomized trial to compare the effectiveness of a novel combination package of evidence-based interventions, the combination intervention strategy (CIS), compared to standard of care (SOC) on linkage and retention of HIV-positive patients from point of testing to retention in care
NIAID	Bailey	99953	U-IL/UNIM	integration of infant male circumcision with community health services in Kenya	Kenya	$964,748.14	PEPFAR	To provide the evidence-base necessary to guide implementation of IMC services, we propose a simultaneous, prospective comparison of two sustainable, scalable models of IMC service delivery
NIAID	Rosen	100015	Boston U	Rapid initiation of ART to promote early HIV/AIDS treatment in	South Africa	$331,692.70	OAR	The study is designed as an unblinded randomized strategy trial comparing the current standard of care to a rapid ART initiation strategy for outpatient adults and pregnant women who come to a South African clinic for an HIV test and are eligible for ART
NIAID	Howard	100044	Columbia	A combination intervention package for Isoniazid preventive therapy in Ethiopia	Ethiopia	$632,048.95	PEPFAR	ENhance Initiation and Retention in IPT Care for HIV Study (ENRICH Study), which aims to evaluate the effectiveness of a combination intervention package (CIP) versus standard of care (SOC), to improve IPT initiation, adherence, and completion among HIV-infected individuals enrolled in HIV care at health centers in Ethiopia
NCI	Campbell	100026	U CO	Strategies to improve KS Outcomes in Zimbabwe	Zimbabwe	$965,000.00	PEPFAR	develop evidence-based, cost-efficient approaches to improve detection and management of AIDS-KS and its related symptoms in low resource environments, and to evaluate the implementation of these approaches in primary care settings in urban and rural communities in Zimbabwe
NICHD	Abrams	99951	Columbia	ART in pregnant women in SA	South Africa	$768,676.54	PEPFAR	"fast tracking" ART initiation in pregnancy, combines strategies to address the key health systems, clinical, and patient education and adherence issues that currently act as barriers to rapid ART initiation in pregnancy - HIV viral suppression at the time of delivery as the primary outcome. Secondary aims include the transmission of HIV from mother-to-child and retention in care through 6 months postpartum, as well as the acceptability and cost-effectiveness of this intervention
NICHD	Pfeiffer	99987	UW	Among HIV-positive pregnant women in central MZ	Mozambique	$593,311.92	PEPFAR	develop and test a pilot intervention in central Mozambique to implement the new WHO guidelines and increase the proportion of HIV-positive pregnant women in target ANC clinics who start ART prior to delivery, without reducing ART adherence. The intervention will emphasize a "test and treat" approach.
NIMH	Blattner	100101	UMD	TRUST	Nigeria	$964,909.29	PEPFAR	TRUST is that Network-based recruitment to expand engagement of Nigerian MSM that links clients to combination prevention and comprehensive HIV and medical services delivered at community-trusted venues achieves measurable behavioral change, and durable high quality clinical outcomes
NIMH	Wagner	99884	RAND	Task shifting model of depression treatment to unleash HIV Public Health Benefits		$392,755.00	PEPFAR	We will test an algorithm-based, nurse-driven model for managing antidepressant treatment.
TOTAL per YEAR						**$11,943,595.64**		
OAR Funds						$1,945,256.66		
PEPFAR Funds						$9,998,338.98		
RFA HD-12-210: NIH/PEPFAR Collaboration for Advancing Implementaton Science in Prevention of Maternal-Child HIV Transmission (PMTCT) R01								
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IC	**PI**	**Grant #**	**Institution**	**Title**	**Country**			

Released by Chairman Rand Paul

NICHD	Sherr	75057			Systems analysis and improvement to optimize pMTCT: A cluster randomized Trial	Cote d'Ivoire/ Kenya/ Mozambique			
	Aliyu	75075			Optimizing integrated PMTCT services in rural North Central Nigeria	Nigeria			
	Yotebeing	75171			Conditional cash transfers to increase uptake and retention of PMTCT services	Democratic Republic of Congo			
	Israel-Ballard	75090			Effect of feeding buddies on adherence to WHO PMTCT guidelines in South Africa	South Africa			
	Abrams	75163			Mother and infant retention for health (MIR4Health)	Kenya			
	Chi	75131			Validation of a community survey methodology formeasuring PMTCT impact	Zambia			
	Ezeanolue	75050			Comparative effectiveness of congregation and clinic based approaches to PMTCT	Nigeria			
	Davies	75156			Closing the gaps in PMTCT program coverage, early infant diagnosis and treatment	South Africa			
	Farquhar	75108			HIV testing and educating male partners to improve maternal and infant outcomes	Kenya			
TOTAL per YEAR							**$3million**		
PEPFAR Funds							$2.5million		
NICHD Funds							$500,000		
RFA DA-12-002: HIV/AIDS Implemenation Science Targeting Drug Using Populations: A Collaboration with PEPFAR (R01)									
NIDA	Altice	33679			Expanding Medication Assisted Therapies in Ukraine				
NIDA	Owczarzak	33644			A Novel, Bottom Up Approach to Promote Evidence Based HIV Prevention for IDUs				
NIDA	Goldsamt	33673			Implementation of a Sexual Health Intervention for YMSM in Two Vietnamese Cities				
NIDA	Page	33672			Cambodia Integrated HIV and Drug Prevention Implementation Program				
NIDA	Li	33609			Enhancing the Role of Commune Health Workers in HIV and Drug Control in Vietnam				
NIDA	O'Brien	33671			A Pilot Implementation Project of Methadone and Suboxone for Injecting Drug Users				
NIDA	Woody	33670			Opioid Relaps & HIV Risk: 48 vs. 24 Weeks of ER Injectable Naltrexone Opioid Relaps & HIV Risk: 48 vs. 24 Weeks of ER Injectable Naltrexone				
No PEPFAR funding was supplied - all of these grants funded through NIDA									
FOGARTY INTERNATIONAL CENTER									
Medical Education Partnership Initiative (MEPI)									
FIC	multiple				Medical School Training/Education	multi	~$10m/yr	OGAC	
						multi	$6 - 7m/yr	FIC	

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From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Bacon, Melanie (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:45:43 -0400
Importance: Normal

Seems just right to me. Rob will let you know if he has any other questions. He is a good guy and we want to help him. Sorry for the duplication. I did not know he had written you already. Many thanks. g

---

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To: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 14:09:17 -0400
Importance: Normal

As always...>Thanks.

Can I call you?

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Sent: Thursday, September 26, 2013 10:37 PM
To: Handley, Gray (NIH/NIAID) [E]
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From: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: NIAID OD AM <[redacted]@niaid.nih.gov>
Subject: FW: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013
Date: Tue, 05 Nov 2013 22:18:19 -0500
Importance: Normal
Inline-Images: image001.png

Let us discuss tomorrow and I will also separately discuss with Hillery Harvey.

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Tuesday, November 05, 2013 11:20 AM
To: NIAID OD AM
Subject: FW: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Additional guidance on Gates visit from Dr. Collins:

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From: Eiss, Robert (NIH/FIC) [E]
Sent: Tuesday, November 05, 2013 11:14 AM
To: Harvey, Hillery (NIH/NIAID) [E]; Wood, Gretchen (NIH/OD) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Burklow, John (NIH/OD) [E]; Doepel, Laurie (NIH/NIAID) [E]; Handley, Gray (NIH/NIAID) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hi Hillery,

Absolutely, that was our intention since both of the lab visits involve NIAID. The one positive in having to cancel the event due to the shutdown, is the availability of Dr. Fauci to participate on the rescheduled date.

With regards to the format of the roundtable discussion, below is the note that Dr. Collins sent to the IC Directors and Deputies participating in the roundtable, prior to the cancellation I hope this is instructive and would be happy to provide any additional background and clarifications.

The costs of the catered lunch will be supported out of the representational fund – covering both the guests and IC Directors.

Best,

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Dear colleagues,

I am delighted you are able to join the roundtable discussion with Bill Gates on Monday, October 7, from 11:15 AM-12:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with staff from the Global Health Program at the BMGF.

I had an opportunity to review the agenda briefly with Bill at the Lasker Awards ceremony (where he and Melinda received the Lakser~Bloomberg award) last week. He is very much looking forward to the discussion.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I also ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to relate the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD), and Kathy Young, Senior Project Manager for Strategic Planning and Engagement in Bill's office. Their bios area attached.

We are delighted and honored that Eric Goosby (a former Barmes Lecturer) will join the roundtable. I am asking Eric to comment on the NIH/PEPFAR partnership in implementation science.

We will include a working lunch as part of the roundtable discussion Details on the lunch are forthcoming.

Prior to the discussion, we also will send a background summary of current IC (and FNIH) activities with the Gates Foundation.

Rob Eiss of the FIC has assisted with the planning and organization of this visit. Please feel free to contact Rob with any questions you or your staff may have surrounding the visit.

Best regards, Francis

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Tuesday, November 05, 2013 10:08 AM
To: Wood, Gretchen (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Burklow, John

Released by Chairman Rand Paul

(NIH/OD) [E]; Doepel, Laurie (NIH/NIAID) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Thank you Gretchen. Very helpful.

ROB: Dr. Fauci would like to be included in the tour of Bldg. 33 with Clif Barry and Kathy Zoon. As the schedule evolves, can you incorporate this modification?

Many thanks again to you both.
Hillery

From: Wood, Gretchen (NIH/OD) [E]
Sent: Tuesday, November 05, 2013 9:57 AM
To: Harvey, Hillery (NIH/NIAID) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hi Hillery,

Sorry to be late in responding. We will actually be re-working the agenda to have the media briefing at the end of the day's agenda so Mr. Gates will have the opportunity to hear from Senior Leadership and be better prepared for questions from the media. I do not believe that we were intending for ICD to use slides, but rather have an open dialogue with Mr. Gates. Given the time allotted, it would appear that each topic would have between 12 and 15 minutes, and I imagine that the opening comments for each would be up to the lead discussant. I have cc'd Rob Eiss here on this e-mail as he has been working on the format and can relay any ideas that he has received from Dr. Collins.

Please do not hesitate to contact me should you need anything further. Rob and I are hoping to hear from remaining ICD before the end of the week to pin down a more accurate agenda.

Best wishes,

Gretchen

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 04, 2013 1:01 PM
To: Wood, Gretchen (NIH/OD) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hello Gretchen—

In discussing Dr. Fauci's preparation for his role in Mr. Gates' visit December 2nd, several questions arose regarding the agenda discussion on HIV, malaria, and TB:

- What is the general discussion format? e.g., opening slides or comments followed by organic discussion?
- For the 11:45am-1pm agenda items, how much time is allotted for each? For the lead discussant's opening comments?
- Should Dr. Fauci plan to use slides?

And any other information on how Dr. Collins envisions this roundtable/working lunch would be helpful.
Many thanks for your help!
Best wishes,
Hillery

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Hillery A. Harvey, Ph.D.
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From: Wood, Gretchen (NIH/OD) [E]
Sent: Friday, November 01, 2013 2:26 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Green, Eric (NIH/NHGRI) [E]; Mascola, John (NIH/VRC) [E]; Barry, Clifton (NIH/NIAID) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Good afternoon,

We have received confirmation from the Gates Foundation that Mr. Gates is available to deliver the Barmes Global Health Lecture and meet with NIH Senior Leadership on Monday, December 2, 2013. Attached please find a preliminary draft of the day's agenda which mirrors the one from October and now includes a scientific tour of the VRC. It has not been approved by the Foundation. Please review and indicate whether you have any conflict that would prevent or delay your participation on the agenda as it is currently presented.

Please do not hesitate to contact me should you have any questions or concerns.

Best wishes,

Gretchen

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Celebration of Science at NIH: *watch how medical research saves lives and improves health*

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From: "Jin, Daozhong (NIH/OD) [C]" <[redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Article about Bill Gates
Date: Wed, 13 Nov 2013 11:58:12 -0500
Importance: Normal

Hello Dr. Tabak,

Here's an article about Bill Gates from the Financial Times that Robert Eiss in FIC passed along.

Daozhong

From: Eiss, Robert (NIH/FIC) [E]
Sent: Wednesday, November 13, 2013 11:45 AM
To: Jin, Daozhong (NIH/OD) [C]
Subject: RE: October 7 visit of Bill Gates

If of interest to Dr Tabak, the following was published in the Financial Times the Friday before last. It's well done
http://www.ft.com/cms/s/2/dacd1f84-41bf-11e3-b064-00144feabdc0.html#axzz2je9a7qXd
November 1, 2013 11:05 am

An exclusive interview with Bill Gates

By Richard Waters

The internet is not going to save the world, says the Microsoft co-founder, whatever Mark Zuckerberg and Silicon Valley's tech billionaires believe. But eradicating disease just might.

<< OLE Object: Picture (Device Independent Bitmap) >> ©Amanda Friedman

Gates photographed at the Bill & Melinda Gates Foundation in Seattle in September

Bill Gates describes himself as a technocrat. But he does not believe that technology will save the world. Or, to be more precise, he does not believe it can solve a tangle of entrenched and interrelated problems that afflict humanity's most vulnerable: the spread of diseases in the developing world and the poverty, lack of opportunity and despair they engender. "I certainly love the IT thing," he says. "But when we want to improve lives, you've got to deal with more basic things like child survival, child nutrition."

These days, it seems that every West Coast billionaire has a vision for how technology can make the world a better place. A central part of this new consensus is that the internet is an inevitable force for social and economic improvement; that connectivity is a social good in itself. It was a view that recently led Mark Zuckerberg to outline a plan for getting the world's unconnected 5 billion people online, an effort the Facebook boss called "one of the greatest challenges of our generation". But asked whether giving the planet an internet connection is more important than finding a vaccination for malaria, the co-founder of Microsoft and world's second-richest man does not hide his irritation: "As a priority? It's a joke."

Then, slipping back into the sarcasm that often breaks through when he is at his most engaged, he adds: "Take this malaria vaccine, [this] weird thing that I'm thinking of. Hmm, which is more important, connectivity or malaria vaccine? If you think connectivity is the key thing, that's great. I don't."

At 58, Bill Gates has lost none of the impatience or intellectual passion he was known for in his youth. Sitting in his office on the shore of Seattle's Lake Washington, the man who dropped out of Harvard University nearly four decades ago and went on to build the world's first software fortune is more relaxed than he was. He has a better haircut and the more pronounced air of self-deprecation that comes with being married and having children who have reached adolescence. But, with the relentless intellectual energy he has always brought to bear on whatever issue is before him, he still can't resist the jibes at ideas he thinks are wrong-headed. After the interview, his minders call to try and persuade me to not report his comments on Zuckerberg: as a senior statesman of the tech and philanthropic worlds, it doesn't help these days to pick fights.

There is no getting round the fact, however, that Gates often sounds at odds with the new generation of billionaire technocrats. He was the first to imagine that computing could seep into everyday life, with the Microsoft mission to put a PC on every desk and in every home. But while others talk up the world-changing power of the internet, he is under no illusions that it will do much to improve the lives of the world's poorest. "Innovation is a good thing. The human condition – put aside bioterrorism and a few footnotes – is improving because of innovation," he says. But while "technology's amazing, it doesn't get down to the people most in need in anything near the timeframe we should want it to".

It was an argument he says he made to Thomas Friedman as The New York Times columnist was writing his 2005 book, *The World is Flat*, a work that came to define the almost end-of-history optimism that accompanied the entry of China and India into the global labour markets, a transition aided by the internet revolution. "Fine, go to those Bangalore Infosys centres, but just for the hell of it go three miles aside and go look at the guy living with no toilet, no running water," Gates says now. "The world is not flat and PCs are not, in the hierarchy of human needs, in the first five rungs."

It is perceptions such as this that have led Gates to spend not just his fortune but most of his time on good works. Other billionaires may take to philanthropy almost as a mark of their social status but, for Gates, it has the force of a moral imperative. The decision to throw himself into causes like trying to prevent childhood deaths in the developing world or improving education in the US was the result of careful ethical calculations, he says. Quoting from an argument advanced by moral philosopher Peter Singer, for instance, he questions why anyone would donate money to build a new wing for a museum rather than spend it on preventing illnesses that can lead to blindness. "The moral equivalent is, we're going to take 1 per cent of the people who visit this [museum] and blind them," he says. "Are they willing, because it has the new wing, to take that risk? Hmm, maybe this blinding thing is slightly barbaric."

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Gates, aged 25, photographed in 1981 with Microsoft co-founder Paul Allen

Through the stroke of pen on cheque book, Gates probably now has the power to affect the lives and wellbeing of a larger number of his fellow humans than any other private individual in history. The Bill & Melinda Gates Foundation, which he set up with his wife in 1997 and where he has been working since leaving his full-time role at Microsoft five years ago, gives away nearly $4bn a year. Much of the money goes toward improving health and fighting poverty in developing countries by tackling malaria or paying for vaccination drives against infectious diseases. This is nearly half as much as the US government spent on global health initiatives in 2012.

In many ways, Gates was the archetype for the successful tech entrepreneur, the driven nerd who created an industry with little more than foresight and drive. But to the generation of aspiring techno-visionaries who have followed, the arc of his career no longer has the allure it once did, even if his iconic status is assured. These include people such as Peter Diamandis, a serial entrepreneur who founded the X Prize, which in 1996 offered a $10m award for the first private sector organisation that could create a suborbital space rocket. He likes to think big, and his latest brainstorm involves trying to mine minerals on passing asteroids.

According to Diamandis, the Gates Foundation, with its focus on alleviating the suffering of the poorest, smacks of the early 20th-century philanthropy of the robber barons – men such as Andrew Carnegie and John D Rockefeller, who built and then milked monopolies before spending their later years doling out cash to worthy causes. The latest wave of techno-visionaries, he says, is focused instead on creating whole new industries capable of changing the world.

At the height of its powers, the way that Microsoft wielded its PC monopoly to maximise profits from the computing industry made it feared and hated by rivals and start-ups alike. Now, with the PC world on the wane and the company's leadership and direction in doubt, it is spoken of almost with disdain in Silicon Valley – even though it remains the third biggest tech company based on stock market value, behind Apple and Google.

Gates Foundation project

Partnering with Coca-Cola and Ghana's health services

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Coca-Cola is found in the remotest places on the planet. The foundation is working with the multinational beverage company to use their supply chain expertise to help Ghana's health service improve delivery of vaccines to the most difficult-to-access patients, including more efficient management of refrigeration systems.

Gates fends off questions about Microsoft, though he says – contrary to persistent speculation – that he is not about to step back in to run it as Steve Jobs once returned to revive Apple. He also admits that the company is taking up a much bigger slice of his time than the one day a week to which he signed up after he left. As

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chairman and a member of the committee searching for a replacement to Steve Ballmer as chief executive, Gates says he still holds regular meetings with some of the company's product groups and that he expects to spend considerable time working with the next boss after an appointment is made.

To Diamandis's argument that there is more good to be done in the world by building new industries than by giving away money, meanwhile, he has a brisk retort: "Industries are only valuable to the degree they meet human needs. There's not some – at least in my psyche – this notion of, oh, we need new industries. We need children not to die, we need people to have an opportunity to get a good education."

It takes more than money to rid the world of a scourge such as polio – though having buckets of cash certainly helps. Also needed are ambitious thinking, organisational knowhow and the ability to bring new ideas to bear on old problems. These are also the kind of things that go into creating a successful technology company. This time around, though, Bill Gates the CEO has had to take a back seat to a less familiar persona: Bill Gates the diplomat.

When the Gates Foundation made polio eradication a priority five years ago, the global anti-polio effort was running into the sand. More than 10 years of progress had given way, at around the turn of the millennium, to a stalemate as vaccination efforts in the countries still harbouring the disease failed to reach the coverage levels needed to push it into extinction. The organisations behind the existing drive – such as Rotary International, the business group that had long led the effort – "had sort of naively assumed it was on track, but it wasn't", Gates says. "The idea that business as usual was going to get us there – it had to be broken out of that, because it wasn't going to succeed. It probably would have been better to just give up than do business as usual. But that would have been horrific."

Gates seems to relish nothing more than challenging business as usual, often by applying a dose of more ambitious thinking. It was the same impetus that led him to rethink familiar approaches to philanthropy, throwing his money into the urgent pursuit of solutions to big problems rather than attempting a drip-feed of donations that would amount to little more than a Band-Aid. While the foundations started by the likes of Howard Hughes and pharmaceuticals boss Sir Henry Wellcome are still among the handful of the world's richest decades after their founders' deaths, the Gates Foundation has been programmed to dole out all its cash and wind itself up 20 years after their deaths.

The instinct to shake up the complacent and challenge the intellectually lazy doesn't always win Gates friends. Putting his personal money and reputation on the line to eradicate a disease has also risked accusations of vanity – a case of the "ego philanthropy" that can distort goals when the super-rich get involved. Wiping out a disease has only happened once before, when the World Health Organisation declared in 1980 that smallpox had been eliminated. Helping to finance and organise a second eradication would cap the Gates Foundation's emergence as the most significant private charity in the world of global health. It would also set the stage for the next items on the list of diseases it hopes eventually to wipe out, starting with malaria.

<< OLE Object: Picture (Device Independent Bitmap) >> ©AP

Gates with his wife Melinda, at a meeting in 2011 with members of the Mushar community in Jamsot, near Patna, India

Gates brushes off questions about the merits of the eradication effort and whether other initiatives might be a better investment in terms of the immediate number of lives saved. "Eradications are special," he says. "Zero is a magic number. You either do what it takes to get to zero and you're glad you did it; or you get close, give up and it goes back to where it was before, in which case you wasted all that credibility, activity, money that could have been applied to other things."

Since he threw his organisation behind the effort, polio has been eradicated in India. But it remains rooted in Afghanistan, Nigeria and Pakistan, spilling over sporadically into their neighbours. That these three countries remain among the world's most difficult to operate in – in Pakistan, the Taliban has taken to bombing vaccination teams, accusing them of being in cahoots with the CIA – provides a clue about why, nearly 30 years after the eradication campaign began, polio persists. Eradication has little to do with making advances in science and technology – though work on new vaccines targeted more directly at the strains of the disease that remain has helped in the fight.

Take one of the biggest challenges to managing immunisation campaigns against polio and other diseases in the developing world: getting vaccines to where they're required while keeping their temperature in a narrow 2C-8C range to prevent them spoiling. Running the so-called "cold chain" needed for this to happen – from big refrigerators in regional distribution centres to the cases vaccinators carry into the field – requires painstaking logistical organisation. Often, kerosene or other fuels used in refrigeration are in short supply or antiquated

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equipment fails due to lack of maintenance. According to Gates, problems like these are too low-tech to attract the world's best brains. "Unfortunately, it's a very mundane, practical thing," he says. "It's not sexy from a scientific point of view."

A businessman's understanding of incentives helps. The number of fridges needed is not large enough to provide a profitable market for manufacturers so the foundation has had to make financial commitments in advance. The business model of the vaccine makers gives them little reason to lower their manufacturing costs to make their products more affordable, he adds. Their high costs are more than covered by prices they can charge in the developed world and any mistakes they might make as a result of tampering with their carefully regulated production processes would jeopardise that existing business. "That's not science – that's, how the hell do you make 50 cent vaccines?"

Gates Foundation project

Needle-free immunisation

The disposable-syringe jet injector (DSJI) is a needle-free immunisation system developed by Path, a non-profit organisation, with funding from the foundation. Using a pressurised liquid stream to push through the skin, it prevents cross-contamination and injuries to medical staff.

Management methods that would be immediately familiar to anyone involved in the fast-moving technology world are also being brought to bear. These include employing the rapid cycle of trial and error that new tech companies engage in before pouring money into a formula that works – a process known as "scaling", which takes place as they race to capitalise on a new market before rivals emerge.

Apoorva Mallya, a senior program officer who works on country implementation, puts the success in stamping out the disease in India partly down to pouring money into local initiatives that had the potential to be effective across the country, but which were being conducted on too small a scale to make a difference. These included assigning community mobilisers to individual districts and neighbourhoods before vaccination drives began in order to organise meetings of women and overcome distrust or resistance. "We went in and funded them for a massive expansion across India," he says.

Another method familiar from the tech world involves more effective data collection and analysis. Vaccination drives fail if too many children fall through the net. To get a better understanding of effectiveness, the foundation has paid for teams of researchers to use statistical sampling to see if adequate coverage levels have been reached.

Measurement is also being brought to bear to build a more detailed understanding of how costs are incurred in vaccination drives. Without that data, it's hard to know where to focus attention to make global health programmes more effective, says Orin Levine, who runs the foundation's vaccination efforts. "We don't necessarily differentiate where the costs are in the system yet, so it makes it harder to say an innovation in [a particular area] will be something we really want," he explains.

This kind of rigour would be familiar inside an engineering-centric company such as Microsoft, where rationality reigns. But in the more chaotic world of global aid, with its loose alliance of government agencies, NGOs and charities – many of them operating with only partial information – it does not pay to assume such disciplines. Learning to work in that world is one of the greatest adjustments.

"The fact that people don't understand numbers and systems thinking and science and logic, that's OK," Gates says – though his famous impatience might belie such a claim. "I only need a half of the people who contribute to really think in a way where I can say, hey, come on, there's a theory of change here, do you get it, do you get if that piece doesn't happen, it completely messes up that piece?"

Like many self-made business people, Gates is wary about the ability of governments to deal with some of society's most pressing problems. Personal experience might have something to do with it. More than a decade ago, his fight with the US Department of Justice over whether Microsoft had acted illegally to defend its PC software monopoly ended in defeat, though a settlement with the George W Bush White House saved the company from the forced break-up that a judge had ordered.

Gates describes himself as a natural optimist. But he admits that the fight with the US government seriously challenged his belief that the best outcome would always prevail. With a typically generalising sweep across history, he declares that governments have "worked pretty well on balance in playing their role to improve the human condition" and that in the US since 1776, "the government's played an absolutely central role and something wonderful has happened". But that doesn't settle his unease.

"The closer you get to it and see how the sausage is made, the more you go, oh my God! These guys don't even actually know the budget. It makes you think: can complex, technocratically deep things – like running a healthcare system properly in the US in terms of impact and cost – can that get done? It hangs in the balance."

Released by Chairman Rand Paul

Gates Foundation project

Creating a vaccine that can survive at room temperature

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In 2010, the Serum Institute of India, with funding from the Gates Foundation Meningitis Vaccine Project, developed MenAfriVac, the first meningitis vaccine to be pre-qualified by the World Health Organisation for use at temperatures of up to 40C for up to four days. This made distributing the medication in rural areas much easier.

It isn't just governments that may be unequal to the task. On this analysis, the democratic process in most countries is also straining to cope with the problems thrown up by the modern world, placing responsibilities on voters that they can hardly be expected to fulfil. "The idea that all these people are going to vote and have an opinion about subjects that are increasingly complex – where what seems, you might think … the easy answer [is] not the real answer. It's a very interesting problem. Do democracies faced with these current problems do these things well?"

Compared with fixing the US healthcare system, the issues of global health and development taken on by Gates' foundation are, by his own estimate, relatively straightforward. But the work has required him to develop new skills: a willingness to engage with politicians and to develop reserves of diplomacy and persuasiveness. With more than 1,000 staff members and the ambition to shape the broad strategies directed at solving the problems it takes on, the foundation does much more than simply hand over money. It relies on partnerships with a wide range of government agencies and other bodies to have any effect – and that has forced Gates, the uncompromising and impatient tech leader, to apply the human touch.

Workers at the foundation say that he has been closely involved even at a regional and district level in winning the needed political backing. Gates, for instance, says he personally "bonded with" Nitish Kumar, the highly rated chief minister of the Indian state of Bihar, over the latter's strong backing for vaccination efforts.

Sometimes in the field of global development, however, it is enough simply to be Bill Gates: the fame and wealth work their own magic. "If … I need to go to the Indian parliament and say, 'Let's get serious about vaccines,' then yes – since I'm giving my own money [on a] large scale and spending my life on it and I'm a technocrat – yes, that can be quite valuable."

If this brand of international development diplomacy has required new skills, however, some things haven't changed. Talk to almost anyone who has worked with Gates and they have a story about his intensity. On trips to the developing world his tirelessness wears out those around him. Inside the foundation, he shows the kind of endurance that once inspired and exhausted Microsoft product managers. "He wants to do the work with us at the most granular level. He will sit in four-hour meetings with us going over slide page after slide page," says Raja Rao, who heads the foundation's work on perfecting the cold chain. "I've seen him sit in a room for 11 hours nonstop just talking about technology, eating snacks and drinking Diet Coke."

Gates Foundation project

Re-thinking the child health record

Paper health records are one of the most reliable sources of medical information. Yet they are often less useful than they might be: lacking enough space to include all relevant information and made of cheap paper which can disintegrate. In June, the foundation launched the $50,000 Records for Life Contest in search of a more durable format to increase usage and the accuracy of information recorded.

Many of the works on the bookshelves in Gates' office overlooking Lake Washington are scientific tomes on the diseases that he is combating – of which, with characteristic diligence, he now has a deep personal understanding, according to others at the foundation. A voracious reader – he has always taken periodic breaks from his regular routine to read about and ponder the biggest problems he has taken on – his conversation is littered with references to authors. Given the smallest excuse, he plunges into a description of the different types of polio and vaccines – and then into the genetic tests that show how the disease once persisted and spread in areas like Uttar Pradesh even when full outbreaks were rare.

This is the Gates who once ruled Microsoft with a command of detail and intellectual intensity that led to the kind of culture that was capable of dominating the tech world – even as it tipped over into behaviour that brought a regulatory backlash. "I was a kind of hyper-intense person in my twenties and very impatient," he says. "I don't think I've given up either of [those] things entirely. Hopefully it's more measured, in a way."

If the manner has mellowed, though, the uncompromising attitude is still very much in evidence. It is at once one of the strongest assets and one of the biggest hindrances in his plan to save some of the world's poorest from the

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fate to which a sometimes oblivious world has left them. Knowing how to pursue an unflinching personal logic without alienating people remains a work in progress for him.

"When we had a meeting a couple of years ago, when people weren't thinking through the polio thing very well, I was pretty critical," he says. His message to the assembled workers: "'Hey, this is not good thinking, this is not good, this is not going to get us there.'"

The new Gates, though, was not prepared to leave it at that. After the meeting was over, he did what husbands the world over are liable to do at such times: "I said to Melinda, was I too tough on that, who should I send mail to, was that motivational, de-motivational? It's all a matter of degree."

Richard Waters is the FT's West Coast editor.

To comment on this article, please email [redacted]*@ft.com*

This article was amended on November 4 2013. An argument forwarded by Australian moral philosopher Peter Singer was wrongly attributed to hedge fund manager Paul Singer.

Released by Chairman Rand Paul

From: "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Varmus, Harold (NIH/NCI) [E]" <[redacted]@nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Zoon, Kathryn (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Pineda, Mark (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Hedje, Judith (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: MRTC in Bamako
Date: Thu, 11 Apr 2013 14:11:52 -0400
Importance: Normal
Attachments: History_NIAID_USTTB_collaboration_11_Apr_2013.docx; Gates_Foundation_Call_for_Global_Health_Case_Studies_11_28_08_gh_edits_no_tracked_changes-map.doc; LABORATORY_CAPACITY_AND_INFRASTRUCTURE_April2013.doc

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Dr. Varmus:

Attached is background information on the ICER in Mali. I am sending what I have gathered so far – two documents prepared for different purposes, which describe this long-term engagement. So far, I am still pulling together information about overall funding, although the "History" piece includes some recent information. Gathering this data is challenging because much of the early support was from a variety of sources including Foundations and USAID. I will send at least a ball-park figure next week.

Yesterday, the ICER programs all presented on their current studies so I will also try to share the slides related to the Mali program. These well illustrated some aspects of the history and the current breadth of our scientific engagement there.

I have also attached a short paper on our ICER in Uganda. Another very productive partnership where many sources of funding have helped build a robust infrastructure used by both extramural and intramural scientists. We also have an NIAID scientist posted there to oversee this program.

On the Lahore involvement, I was able to learn a little of the back-story from Dr. Karl Western, our knowledgeable historian. From 1959-1981 the University of Maryland, Baltimore had an International Center for Medical Research (and Training) [ICMR(T)] in Lahore, Pakistan. This program was one of NIAID's earliest tools to help build research capacity overseas. When the International Centers for Infectious Disease Research (ICIDR) program was competed for the first time (it was envisioned as a replacement for the ICMR(T)), none of the ICMR's were competitive and so funding was slated to end for the Lahore program. The UMd Dean and US PI for the Lahore ICMR(T) visited NIAID with a Maryland Congressional Delegation to seek reversal of the decision not to fund Lahore as an ICIDR. This was about the time that the Soviets invaded Afghanistan so the State Department was eager not to have anything offend Pakistan (sounds familiar). The compromise was for UMd to submit the best components of their ICIDR application as individual R01 applications. One got funded but then later did not re-compete successfully; so the UMd ICMR faded out.

On PEPFAR, I would be happy to share my point of view about how NIH researchers formed the foundation for early PEPFAR success, particularly in South Africa and Uganda, if that would be helpful at some point.
Hope this is useful; more to come.

Gray

From: Varmus, Harold (NIH/NCI) [E]
Sent: Monday, April 08, 2013 5:20 PM

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To: Handley, Gray (NIH/NIAID) [E]
Subject: Re: MRTC in Bamako

Thanks on both counts.

For Mali, I just seek some approximate values so that I can say roughly how much the operation---and particular parts of the operation---depended on NIH funds.

I haven't though much about your point about PEPFAR because the narrative was heading elsewhere for the kind of audience I expect. But I'd like to learn more about this if it is in a short form.

On 4/8/13 5:12 PM, "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov> wrote:

Dr. Varmus:

No problem. We have some information on Mali, but it needs to be updated and not sure about the budget questions. I will do my best to get back to you this week but obviously want to be careful to send only what can be verified.

As you talk about PEPFAR, I hope you will note how the program was able to accomplish so much so fast (in some key countries like South Africa) because it built on expertise and capacity that had been fostered through NIH supported research for a decade before the advent of PEPFAR service delivery programs. It's a good story.

More to come.

Gray

F. Gray Handley
Associate Director for International Research Affairs
National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
(O) [redacted]

From: Varmus, Harold (NIH/NCI) [E]
Sent: Monday, April 08, 2013 2:30 PM
To: Handley, Gray (NIH/NIAID) [E]
Cc: Wiszneauckas, Joy (NIH/NCI) [E]
Subject: MRTC in Bamako

Gray, as you may have heard, I am developing a series of lectures to be given in the UK about three examples of US involvement in medical science and health abroad: the Uganda Cancer Center, PEPFAR, and the Malian MRTC. To help gather information for these lectures, I've been doing interviews with some of the people involved. In talking with some people in Bamako, I realized that I don't have facts and figures about the extent and duration of support that NIAID has provided there. Is it possible for you to summarize the history of our spending at the MRTC from 1990 to the present? I don't need many details, just overall all levels and perhaps a couple of categories (salaries, grants, other support).

I have also learned that NIAID has supported other programs like the MRTC, even some (like the one in Lahore) that have been called MRTC. Do you have any information about them and how they related to the efforts in Mali?

Thanks for whatever you can provide.

Harold

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Research for Health: The Experience of the US/ Mali International Center for Excellence in Research

Background

The reasons for initiating efforts for improving the research capacity in developing countries are many and varied. In some cases, it may be the policy of a national foreign assistance program or international agency to sponsor institutional strengthening. In such programs the goal is usually to improve a countries capacity to better solve those health problems that are of greatest concern. In such programs the involvement of partners and/or experts from more developed institutions may be transient or long lasting, but in the end, the goal is the improvement of a national capacity. These partners are usually functioning as contractors to the donor and basically are providing a service to the recipient.

Other programs may be stimulated by the need for a research institution to develop a mechanism for extending its programs into areas where diseases are endemic, not just academic. Such programs are intrinsically less altruistic, but in the end can often serve not only their own needs, but effectively work to strengthen the research capacities of the country in which they have chosen to work.

In the late 1980s it became clear that the medical entomology program of the Division of Intramural Research (DIR) of the National Institute of Allergy and Infectious Diseases of the US National Institutes of Health required a field research component to complement its laboratory based research efforts on the development of transgenic mosquitoes. The implementation of a strategy for malaria control based on altering the capacity of vector populations to transmit the malaria parasite required a better understanding of the population genetics of these populations in the field. Mali was selected as the site to establish such a program because of the presence in that country of Dr.
Yeya Toure and a recognized team of Malian researchers already working on the genetics and cytogenetics of Anopheles gambiae. An. gambiae is the primary vector of malaria in sub-Saharan Africa and was the mosquito targeted by the NIH for genetic manipulation. Dr. Toure had achieved an international reputation for his work on mosquito populations and for his skill in managing and implementing medical research programs. Indeed, in 1989, in addition to his faculty position as Professor of Biology and Genetics at the National School of Medicine and Pharmacy (ENMP) of Mali, Dr. Toure was serving as Director-General of the National Center for Scientific Research and Technology of the Republic of Mali.

The medical entomology program at the ENMP was part of the unofficial department (DEAP) started by the French under the direction of Dr. Phillipe Ranque. In the 1980s, Dr. Ranque selected a number of outstanding Malian scientists to be trained in Europe. In addition to Dr. Toure, the group included Dr. Anatole Tounkara (now deceased), who

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subsequently became Dean of the Medical School in Bamako and Head of the NIAID ICER HIV/AIDS (SEREFO) research program, Dr. Constance Souko a senior scientist in the ICER Leishmaniasis program, and Dr. Amadou Diallo, previous Rector of the University of Bamako.

The research program which proved to be the basis of the NIH/Mali collaboration was initially focused on the role of the mosquito vector in the epidemiology of malaria and was funded by the WHO (TDR) / Rockefeller Foundation partnership program. Dr. Yeya Toure was the PI in Mali, Dr. Mario Coluzzi headed the Rome component of the program and Dr. Robert Gwadz was responsible for the NIH segment.

To provide a structure to manage this research effort, the Malaria Research and Training Center (MRTC) was established in 1989 by agreement between the Dean of the University of Bamako Faculty of Medicine and the Director of the Division of Intramural Research, NIAID. Dr. Yeya Toure was named the first Director of the MRTC and was the person primarily responsible for working with the NIH in developing the MRTC infrastructure and new laboratories. When Dr. Toure took a posting with the WHO in Geneva in 2001, Drs. Ogobara Doumbo and Sekou Traore were named co-Directors of the MRTC by the Dean of the Medical School.

Based on the success of the WHO/RF program additional support was solicited from a number of donor agencies. With funding from the US Agency for International Development (USAID), the program was expanded to include clinical and epidemiological studies of malaria and Dr. Richard Sakai was posted at the MRTC as the NIH Resident Scientist in Mali. Dr. Sakai had a wealth of international experience before going to Mali and since 1990 has been responsible for coordinating NIH activities at the Center. His efforts for the program and the people of Mali have become legendary and he has been honored by the President of Mali with the award of “Chevalier of the Nation.”

From the inception of the MRTC, significant support has been obtained from a number of USAID programs including the USAID Mission, Bamako, and from the Combating Childhood Communicable Diseases (CCCD) and Health and Human Resources Analysis for Africa (HHRAA) programs of the AID Africa Bureau in Washington.

Beginning in 1992, USAID funds allowed the expansion of the scope of work in Mali to include studies of the genetic basis of malaria parasite resistance to anti-malarial drugs and the effects of various human hemoglobinopathies on the pathogenesis of malaria. USAID funds were also used to significantly expand and improve the research laboratories and support facilities at the MRTC. USAID can justifiably take credit for much of what constitutes the infrastructure of the MRTC today.

Additional support for the MRTC was obtained from the International Atomic Energy Agency (IAEA), the WHO, NASA and the MacArthur, SatelLife and Dreyfus Health Foundations.

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In 1997, USAID ended direct support of MRTC activities, but in March 1998, President Clinton in a speech in Kampala, Uganda, singled out the MRTC of Mali for recognition and made the promise of continued support. Since 1998, virtually all activities in Mali have been supported by NIAID.
In September 2000, laboratory space within the MRTC was more than tripled with the opening of a new laboratory building and the renovation of laboratories adjacent to the original laboratories. These new laboratories are focused on supporting work associated with the development and evaluation of malaria vaccine candidates.

In 2001, the MRTC became part of the ICER (International Center for Excellence in Research) program, an initiative launched by NIAID to recognize a select group of overseas research facilities, make them part of the regularized budget process of the Institute, and develop and sustain research programs through partnerships with local scientists. All administrative functions of the various ICER programs including payroll for Malian staff and support of day to day operations were placed under the direction of the Core ICER staff. The Mali ICER is one of three ICERs in the world. The other two are located in Uganda and India.

The ICER is involved in all aspects of research on malaria. All work at the Mali ICER is directed at the development and testing of appropriate strategies for the eventual control of malaria and the reduction of the burden of disease in the people of Mali, the region, and all of Africa. The ICER program is based on the clear understanding that not enough is known today to control malaria in Africa, and most current programs are failing because of a lack of adequate tools and techniques. The ICER seeks to bring to bear the best methodologies for understanding and attacking this difficult problem. Newer programs have been initiated within the Mali ICER including basic and clinical studies in leishmaniasis and its vectors, mosquito proteomics and bioinformatics, filariasis, acarology and tick borne diseases, and Lassa fever.

It is important to note that the Mali ICER serves as the primary research and training arm of the Malian Ministry of Health. The ICER works closely with the Director of the National Malaria Control Program.

In 2002, the NIH through the NIAID Division of Clinical Research (DCR) and the NIAID Division of AIDS initiated a major research program on HIV/AIDS and TB named SEREFO (the Center for Research and Training on HIH/TB). This project was created with the objective of investigating the relationship between HIV infection and Tuberculosis and shares administrative and communication facilities with the Mali ICER.

[**Off note:** Since January 2013, part of the SEREFO research program and associated BSL 3 lab was transitioned from intramural to extramural funding, and is now under the responsibility of Northwestern University. The intramural program retained one of the HIV/TB laboratories and associated personnel and converted it into an immunology core laboratory that will collaborate with the other existing intramural research programs.]

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In 2004, NIAID established the Mali Service Center (MSC), which serves as the NIAID's financial arm for intramural and extramural activities.

In 2006, the NIAID appointed an NIH staff member to serve as the Director of the NIAID/NIH Mali office and overall manager of NIAID ICER activities in Mali.

NIAID's total investment in Mali in FY12 was approximately $9.4 million.

Evolution of the ICER Mali

1. Research facilities

When the program was initiated in 1989, research facilities at the medical school were virtually non-existent and research programs limited primarily to field based entomological and epidemiological studies. Under the supervision of Drs. Toure and Sakai, the NIH embarked on a major program of laboratory development. Initially, existing laboratories and classrooms were renovated and equipped. Later, new facilities were constructed. Construction was managed by either the US Embassy or the Office of the Dean of the medical school. Over 20 new laboratories were constructed or renovated and fully equipped.

The Mali ICER facilities are located in five buildings on the campus of ENMP, now called the University of Sciences, Techniques, and Technologies of Bamako (USTTB).

The following is a summary of laboratories and facilities added as part of the NIH program:

<u>Medical Entomology Program</u>

- Molecular Entomology with 2 large insectaries
- Cytogenetics
- Molecular Ecology
- GIS/Remote Sensing
- Vector Proteomic
- Vector Bioinformatics
- Malaria Immunology
- Malaria Pathogenesis
- Leishmaniasis
- Acarology
- Filariasis
- Lassa fever

<u>Parasitology / Vaccine Development Unit</u>

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- Vaccine research center
- Vaccine trial data Center
- Vaccine trial field sites
- Drug research
- Insecticide resistance

HIV/AIDS TB Program

- BSL-3 TB
- 6 HIV/TB laboratories

Core facilities (managed by the NIAID/NIH Mali office)

- Clinical Analysis Laboratory
- Library/conference room (seats 60)
- Lunch room
- Freezer room
- Motor Pool with 23 vehicules
- Storage facility (laboratory supplies)
- Guest House - Chez Gwadz (can house up to 12 guests, with dining facility and computer room)
- Administrative offices
- Emergency power system
- VSAT communication satellite system with links to the internal NIH IT systems and to the study sites in Bancoumana and Ouelessebougou

Field sites

The Mali ICER maintains several field and clinical research sites in many regions of Mali, including sites for field testing of candidate vaccines and drug testing. The center has conducted major studies in Mopti, Koro, Niono, Bandiagara, Bancoumana, Soutuba, Donegeubougou, Kenieroba, Tienegoubougou, Kambila, Kalifabougou, and Ouelessebougou.

2. Staff

The current staff consists of close to 140 researchers, administrative staff and support personnel. All Malian staff is supported through a contract with the USTTB. The Center also hosts several senior Malian medical/pharmacy students from the Faculty of Medicine and the Faculty of Pharmacy who are doing hands on research in the center's projects for their MD and PhD theses, as well as students from neighboring African countries. The ICER does collaborative research with researchers worldwide. Yearly the center hosts more than 200 visiting collaborative researchers.

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3. Training

The Malian staff is continuously undergoing training in cutting edge technologies to transfer the newest research tools to the Center

Since the beginning of the program in Mali, the NIH has been cooperating in the training of Malian students, in Mali, in the US and at various Canadian and European research centers. Three students, all with Malian doctorates, have received Ph.Ds. from Tulane. Two Malians, while Research Fellows under Dr. Wellems at the NIH have completed training at the University Of Maryland School Of Medicine. One was awarded a PhD in molecular biology, the second an MSc in vaccinology. Two MRTC staff completed PhDs at the University of Notre Dame in Indiana in molecular entomology.

One Malian doctorate while a Research Fellow (VP) in the LMVR was the first student participant in the NIAID / London School of Hygiene and Tropical Medicine Doctoral Training Program in Tropical Medicine. He completed his academic course work in London and his research at the NIH and in Mali and was awarded a PhD in 2007.

A number of Malian graduate students at the MRTC are working with mentors from US universities including the University of California (Davis), the University of Minnesota, and UCLA. For the past several summers, Malian students have been enrolled in the Graduate Summer Institute of Epidemiology and Biostatistics at The Johns Hopkins University. Many of these are playing crucial roles in the vaccine testing effort. Several have completed bioethics training courses in the US.

The Mali ICER has also provided a unique venue for training scientists from the US and other countries.

For example, in 1998, the NIH launched a training program which provided training opportunities for undergraduate, graduate and medical students with emphasis on students from disadvantaged and underrepresented backgrounds. This program was supported by the NIH Office of Minority and Woman's Health through the Fogarty International Center with administration by the University Of Maryland School Of Medicine. From 1999 to 2003, a total of 74 students spent from 2 to 12 months in Mali.

4. NIAID/NIH Mali Office Development

NIAID's Research Support Office was developed in 2005 after NIAID decided to unilaterally approach the Mali site having both extramural and intramural involved. The idea of the NIAID/NIH Mali Office was to develop an organized office structure which would unify all of DIR's scientific management and administrative functions into one office. This office would be headed by a Director which would serve as the official NIAID-NIH Senior Resident Representative in Mali. The first Director of the office and Senior Res Rep was Dr. Y'Drissa Sow who formerly worked with the NIAID HIV/TB program in Mali. In 2012 Dr. Sow was succeeded by Dr. Mame Khouredia Niang. Dr.

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Niang liaises with US and Malian government and NGO entities, the MSC, the intramural program, and extramural grantees.

The NIAD/NIH Mali staff is composed of the following individuals:

1. Dr. Mame Niang, Director of the NIH/NIAID Mali Office, Country Representative
2. Dr. Richard K. Sakai, Resident Scientist
3. Dr. Kassambara Hamadoun, Scientific Programs Manager
4. Mr. Souleymane Karambe, Senior Support Supervisor (FSN)
5. Ms. Neneh Tabara Diallo, Administrative Assistant (FSN)
6. Ms. Koumbas Maiga, Administrative Assistant

5. Mali Service Center development

In 2004 a Decree was signed by the University of Bamako and NIAID stating that there was agreement on the development of a Mali Service Center (MSC), supported by NIAID, to assist Mali in their management of extramural funds with the idea of training and developing capacity for the MSC to be fully owned by Malians and the University of Bamako in the near future. The MSC is currently located on the campus of the Faculty of Medicine close to all of NIAID's programs and is run by an NIAID contractor, the Mitchell Group. All extramural grants with monies going to Mali are required to use the MSC.

6. Ongoing NIH funded projects at the ICER Mali

The Table below summarizes the different NIH projects or protocols currently ongoing at the ICER Mali.

PROJECT NAME	DATES	STUDY SITE(S)	ON GOING PROTOCOL
Malaria vector ecology	2004 to present	Thierola and surrounding villages	Studies all aspects of malaria vector ecology with the aim of uncovering ecological factors which may be exploited to help control malaria transmission.
Malaria Transmission Assay Development and Gametocyte Carriage	2011 to present	Bacoumana	Development of an assay to evaluate the potential of a candidate malaria transmission-blocking vaccine.
Immuno-Epidemiology	2011 to present	Oulessebougou	A study of host and parasite factors that influence susceptibility to malarial infection and disease during pregnancy and early childhood.
Lymphatic Filariasis	2004 to	Tieneguebougou	Study of mass drug administration, assessment of new drugs and

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	present		treatment strategies, co-infection with malaria
Longitudinal Study of Healthy Volunteers to Determine if Malaria Resistance is Associated with Acquisition of Specific Memory B-Cells	2010 to present	Kambila	A study designed to test the hypothesis that resistance to malaria is associated with the acquisition of B memory cells specific to P. falciparum
Lassa Fever	2009 to present	Soromba and surrounding villages	Study to map the prevalence of Lassa fever in Mali by analyzing rodent reservoirs
Longitudinal Systems Biological Analysis of Naturally-Acquired Malaria Immunity	2011 to present	Kalifabougou	Identify gene expression profiles induced by *P. falciparum* infections associated with malaria immunity
Leishmaniasis	2004 to present	Baraoueli	Surveillance of cutaneous leishmanaiasis vector studies and vaccine development
SEREFO	2004 to present	Multiple sites	Study to assess the relationship of co-infection with HV and tuberculosis: 1. Establishment of normal parameters for blood and sputum with samples obtained from volunteers in Bamako. 2. Sensitivity and Specificity of Oral Urea Breath Testing for Presumptive Diagnosis and Treatment Response in Pulmonary Tuberculosis in Bamako, Mali 3. Strategic Timing of Anti-Retroviral Treatment (START). 4. Utility of MODS (Microscopic - Observation Drug resistant) for the Diagnosis of MDR-TB and Second-Line Antituberculous Drug-Susceptibility Testing in Mali
Tick-bourne Relapsing Fever in Mali	2009 to present	Multiple sites	Surveillance of various sites in Mali for tick-borne relapsing fever, vector studies and isolation of the parasite
PMI Collaborations with USAID			
IRS Monitoring in 3 District Sentinel Site	2008 to present	Bla, Koulikoro and Baraoueli	Monitoring of vector populations, biting behavior, malaria transmission dynamics and determining insecticide resistance status
Strengthening National Malaria Control Capability			Training health workers in malaria diagnostics (microscopy and RDT) and

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in Case Management			malaria surveillance trough case management

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Title of project: The Mali – NIH Partnership: A Model of Research Collaboration in Africa

Nature of the organizations (e.g. non-profit, government, university, industry) involved in the project:

This project involves primarily a U.S. Government organization and a Malian Academic institution. Historically, it has benefited from the engagement of various non-governmental partner organizations, including philanthropic and multilateral organizations.

Government:
National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) within the U.S. Department of Health and Human Services (HHS)

University:
Faculty of Medicine, Pharmacy, and Odonto-Stomatology (FMPOS) at the University of Bamako, Mali

The project is primarily funded by NIAID/NIH intramural and extramural program dollars. (FMPOS laboratories have received past and some current funding from several other international and U.S. agencies and organizations, as noted below).

Summary of the project (including timeline, progress and future plans):

One of NIAID's most successful international collaborations involves the International Center for Excellence in Research (ICER) based in Bamako, Mali. NIAID's long-standing relationship with Mali began in 1989 when NIAID and Malian scientists from the National School of Medicine and Pharmacy, the Ecole Nationale de Medicine et de Pharmacie et d'Odontostomatologie du Mali (which later became the Faculty of Medicine, Pharmacy, and Odonto-Stomatology (FMPOS) at the University of Bamako) began a collaborative study of the mosquitoes (*Anopheles gambiae)* that transmit malaria. The collaboration was originally funded by the WHO (TDR)/Rockefeller Foundation partnership program with emphasis on the role of the mosquito vector in the epidemiology of malaria. To provide a stronger base for research, in 1991 NIAID joined with the National School of Medicine and Pharmacy to create the Malaria Research and Training Center (MRTC). The intent of the MRTC was to conduct world-class malaria research and to build Mali's research capabilities.

From its inception, the MRTC received significant support from USAID programs. Beginning in 1992, USAID funds allowed the expansion of the scope of work in Mali to include studies of the genetic basis of malaria parasite resistance to anti-malarial drugs. USAID funds also were used to significantly expand and improve the research laboratories and support facilities at the MRTC. Additional support was obtained from the International Atomic Energy Agency, the World Health Organization (WHO), and the MacArthur, SatelLife, and Dreyfus Health Foundations. In 1996, the MRTC successfully competed for the NIAID extramural Tropical Medical Center (TMRC) award. Since 1997, new laboratories and support facilities have been added to the MRTC. These include Vaccine Development, Clinical, and Medical Entomology laboratories that conduct research collaborations in Leishmaniasis, filariasis, and malaria pathogenesis.

Since 1998 NIAID has provided most of the financial support, primarily through the Institute's Division of Intramural Research with increasing Extramural Program involvement and supplemental support. In 2001 the MRTC became part of the new NIAID-funded International Center for Excellence in Research (ICER) in Mali, along with the Entomology Unit of the Faculty of Medicine of FMPOS/University of Bamako (FMPOS). The Centre of Recherche et Formation (SEREFO) was established in 2002 as part of the Mali ICER. It expands the scientific scope of the ICER to include HIV and tuberculosis research. A key component of the Mali ICER is its establishment of several highly-developed rural field sites that are locally supported and linked to community leadership.

Like other ICERs being established in Uganda and India, the Mali ICER is mandated to develop and sustain research and training programs in resource-poor countries through partnerships with NIAID intramural laboratories, NIH-funded investigators, and other organizations that support biomedical research excellence in developing countries. Research conducted through the ICERs is focused on infectious diseases of local public health importance, including HIV, TB, malaria and other vector-borne and respiratory diseases. The emphasis is on basic laboratory and field research to develop new drugs, vaccines, and diagnostics; translational research with engagement of local public health officials; infrastructure development (including IT); and training of successive generations of local scientists. Each ICER program meets the

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following criteria: an established relationship with promising local scientists; involvement of local community leaders in decision-making; long-term commitment of NIAID staff, including potential in-country postings; training opportunities for local scientists at NIH and in-country; and the ability to attract NIH extramural or other funding.

With support from NIAID and FMPOS, the Mali ICER has become a unique organization and a model for research centers in developing countries. It is a truly African operation where the work is directed and executed by Malian staff. In addition to providing support for research, the program also provides a robust training program to help form the new generation of Malian scientists critical to the success and sustainability of the program. Current training includes programs in vector and parasite biology, tropical medicine, medical entomology, and epidemiology. NIAID also continues to help build the University of Bamako's key scientific infrastructure—expanding and modernizing laboratories, upgrading information technologies, and helping to improve grant-management and scientific communication skills. With this infrastructure in place, scientists from Mali, the United States, and other countries have a strong base of operations at the Mali ICER from which to continue to work together on some of the world's most pressing infectious disease problems.

Type of transaction(s) involved (i.e. contracts, collaborative agreements, etc):

Inter-governmental agreement, cooperative agreements, contracts and grants

A brief description of the time spent in negotiating and finalizing (if applicable) the collaboration or transaction:

This is a longstanding collaboration that has engaged the staff at NIAID and at the University of Bamako in many complex interactions and negotiations over a period of 20 years. As the program has evolved new collaborative mechanisms have been developed and initiated as needed with very few bureaucratic delays.

The expertise and resources necessary to complete the collaboration or transaction (i.e. human resources, capacity):

The MRTC/Mali ICER collaborations over time have involved many key administrative, management, scientific, and technical staff at both NIAID/NIH and the University of Bamako, including the research field sites.

Management and oversight structure for the project:

In 2004, an NIH-sponsored management center, the Mali Service Center (MSC), was created in partnership with the University of Bamako, to provide administrative, technical, and financial support to the ICER in the management of international research grants and contracts. In 2005, the Mali Research Support Office (RSO) was established to consolidate and coordinate NIH/NIAID representation in Mali. While continuing to support NIAID engagement in the ICER, the MSC has the capability and potential to service other grant and contract supported programs at the University of Bamako.

A brief statement of the objectives and rationale of project from the perspective of each organization involved:

NIAID/NIH: The mission of the ICER program is to generate high-quality, collaborative international infectious disease research and, through that research, to facilitate the building of institutional and human research capacity. Underlying principles of the program include engaging local scientists as equal partners, involving local community leaders in decision making, and building sustainable research capacity.

University of Bamako/Mali: The Mali ICER and the previously established Malaria Research Training Center, were established to develop and maintain a critical mass of well-trained Malian and other African scientists in infectious disease research; to build world-class research infrastructure; and to train scientists in the context of infectious disease-related research.

Overview of challenges and/or critical issues from the project from the perspective of each organization involved:

Over the 20-year history of collaboration that has resulted in the Mali ICER, there have been many management and administrative challenges. The creation of both the Mali Service Center and the Mali Research Support Office, referred to

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above, have contributed to the resolution of many of these challenges. The opportunity accorded by the Mali ICER for Malian researchers to conduct and publish relevant scientific work in first class facilities, and to receive ongoing support and training, has limited the loss of skilled scientists to other organizations and has helped address issues related to retention of staff and long-term sustainability.

Results and/or achievements (whether goals have been met or progress towards goals):

Scientific Achievements:
Collaborative research activities have included malaria vaccine research, clinical, and field-based research on malaria, malaria vectors, and pathogenesis. Multiple malaria vaccine trials have been conducted with the results of the first trials published in 2006 and 2007. Other research collaborations include laboratory and clinical research on immunology and biology of HIV, and *Mycobacterium tuberculosis* and research on other parasitic diseases and their vectors, including Leishmaniasis, filariasis and relapsing fever. These collaborative studies have resulted in more than 100 peer-reviewed research articles that have been published in leading journals such as *Science, Nature,* the *New England Journal of Medicine*, and *Lancet.*

Impact on Health Policy and Programs:
The Mali ICER Program and its affiliate scientists collaborate with several national programs in Mali to have an impact on the country's health policies and programs:

- The MRTC/ICER serves as the primary research and training arm of the National Malaria Control Program in Mali
- The Geographic Information System (GIS) team predicts malaria epidemics and sends information to decision makers at the Ministry of Health (MOH)
- MRTC/ICER and NIAID, in cooperation with the MOH, USAID, and the U.S. President's Malaria Initiative (PMI), are developing strategies for reduction of malaria transmission.
- The Mali ICER HIV/TB program collaborates with the National TB Program in training and technical and laboratory support
- The Mali ICER provides support for the National Program for the Elimination of Lymphatic Filariasis to help monitor interruption of transmission
- ICER-supported research has resulted in introduction of a skin test to describe the epidemiology and inform national policy on control of cutaneous Leishmaniasis.

Capacity Building/Infrastructure Development:
The Mali ICER Program has established and maintains a significant number of state-of-the-art research laboratories and facilities that perform research in the following areas: Vaccine Development, Drug Resistance, Core Clinical Laboratory, HIV/TB laboratories (including a Biosafety Level 3 laboratory), Medical Entomology, Malaria Immunology and Pathogenesis, Filariasis, Leismaniasis, and Vector Informatics. The MRTC/ICER has developed the capacity to apply Geographic Information System (GIS) techniques to studies of malaria epidemiology and the impact of vaccines on target populations. Studies using remote sensing information and climate prediction are aimed at predicting future malaria outbreaks. The ICER also has developed comprehensive support facilities that include a library with conference space and international videoconferencing capability; sophisticated and reliable telecommunications and computer networking capabilities; administrative and storage facilities and a freezer repository; a guest house and a motor pool. Malaria vaccine trials are conducted at well-established and staffed clinical research field sites in Bandiagara, Doneguebougou, and Bancoumana.

Training:
Since the beginning of the program in Mali, the NIH has cooperated in the training of Malian students in Mali, in the United States, and at various Canadian and European research centers. The ICER has provided a unique venue for training scientists from the United States and other countries. For example, from 1999 to 2003, the NIH Office of Minority and Women's Health through the NIH Fogarty International Center and in collaboration with the University of Maryland School of Medicine provided training opportunities for U.S. undergraduate, graduate, and medical students that involved 2 to 12 months of experience in Mali. The launch of the SEREFO project has brought together physicians and researchers from Mali and the United States to study HIV/AIDS and tuberculosis and to provide training for African scientists.

Lessons Learned (actual and potential):

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Several key factors contribute to the success of the Mali-NIAID collaboration:

1) A strong scientific basis for collaboration that involves shared scientific interests by capable, well-trained Malian and U.S. investigators and motivated students who produce high quality research outcomes. It should be noted that Mali priorities drive the research effort.
2) Malian Government and university support
3) Involvement of local community leaders in decision making
4) Long-term commitment of NIAID staff to research collaboration and mentoring
5) Training of the next generation of local scientists, with opportunities for them to engage in scientific leadership
6) Human, physical, and technological capacity building
7) Ability to attract NIH and other funding, i.e., multiple sources of support
8) Establishment of research administration structure at the MSC and RSO
9) On-going personal relationships and trust developed over a long period of interactions

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International Center for Excellence in Research (ICER) in Uganda

The International Centers for Excellence in Research (ICER) program was launched in 2002 to develop and sustain research programs in low-income countries through partnerships between NIH intramural scientists and local scientists. The Rakai ICER program is focused on clinical research in infectious diseases. The Division of Intramural Research (DIR), through long-term collaborations with colleagues in Uganda, has developed a core research program supporting the expansion of research capabilities including improvement of laboratory and clinical infrastructure and enhancement of information technology capability.

The International Center for Excellence in Research (ICER) Program in Uganda began in 2002. The primary goal of the program was to develop a sustained research program of excellence in the areas of high infectious disease burden, through international partnerships. The office is composed of Dr. Steven Reynolds, M.D., M.P.H., Scientific Director, and four Ugandan Nationals (two Administrators and two Drivers). The U.S. PI of the Ugandan ICER is Dr. Tom Quinn and the Ugandan PIs are Drs. Nelson Sewankambo and David Serwadda.

In 2003 a 4000 square foot laboratory facility was renovated as part of the NIAID ICER collaboration with Rakai Health Sciences Program (RHSP) in Kalisizo, The laboratory opened in late 2004 and currently supports both basic bench and clinical research and provides clinical laboratory support for the RHSP antiretroviral treatment program. This is a state-of-the art full service laboratory equipped with hematology (Coulter ACT-5 Diff), chemistry (Roche Cobas), Flow cytometry (Facscalibur), microbiology and molecular diagnostics (HIV viral load, Hepatitis B viral load, GUD diagnostics). The laboratory participates in and has been fully successful in the external quality assurance programs of the College of American Pathologists (CAP) and the Virology Quality Assurance (VQA) programs.

The Rakai Health Sciences Program Laboratory supports several intramural and extramural NIAID research protocols as well research funded by the Gates Foundation and a large PEPFAR funded HIV treatment program providing services to 8000 HIV infected individuals in Rakai district. The facility also provides training and technology transfer. ICER also enhanced RHSP data facilities through provision of computer networks and satellite broad band internet access, videoconferencing and datafax.

LABORATORY CAPACITY AND INFRASTRUCTURE

Basic Laboratory

RHSP is a state of the art biohazard II level laboratory. The facility includes four 6' laminar flow biosaftey cabinets, a fume hood and a water purification system. Samples collected from the field or obtained from the clinic are processed and sorted in the accession lab. Biologic samples are then sent to the microbiology lab for malaria or

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tuberculosis testing. Samples needing a viral load test are sent to the molecular lab and those requiring a CD4 test are sent to flow cytometry lab. HIV antibody testing is performed in the serology lab. Besides laboratory testing in support of patient care, the RHSP facility has a research mandate which the facility is fully capable to pursue.

Lab accession

Clinical Microbiology

Molecular Capacity

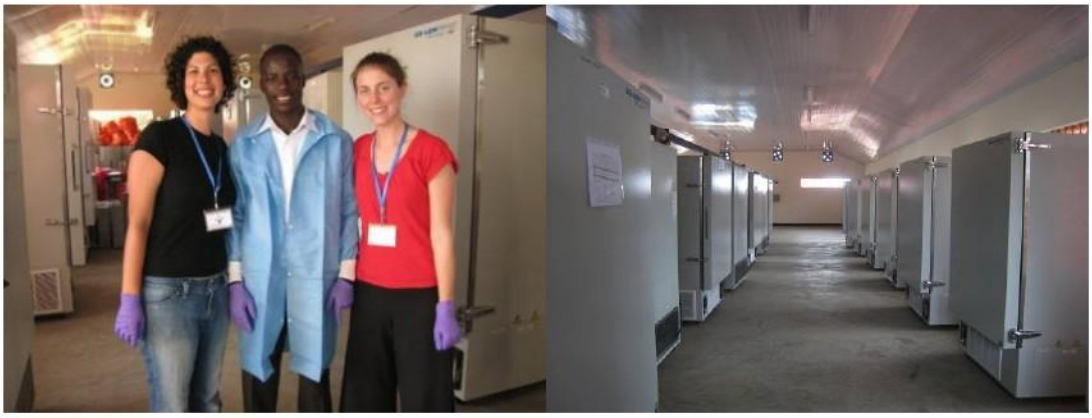
The RHSP molecular biology capacity is demonstrated by the more than 18,000 HIV viral load tests have been performed within the facility in support of ARV treated patients. Additionally the facility is equipped with real time PCR capacity. An ABI 7900 has been maintained for years and is currently used for protocols for the quantitation of HBV and detection of etiologic agents causing GUDs. Basic research can be conducted with gel electrophoresis systems, UV-Vis spectrophotometry with NanoDrop 2000 and gel documentation using a gel logic 100 system.

Flow Cytometry and Blood Chemistry

Two BD four color FACSCALIBER flow cytometers have generated more than 30,000 CD4 counts in support of ARV treated patients in the RHSP. Blood chemistry instrumentation to monitor ARV related blood toxicity.

Freezer Storage

Sample repositories are maintained with Freezerworks system. More than 30 -80°C freezers are currently on line.



Additional support: Electrical, Waste Disposal and Communications

Three 200 KVA diesel generators are currently on line with one spare operational generator. Power inverters and electrical stabilization are in place to maximize the use of locally generated electrical power. Additional support includes incineration for the disposal of biologic waste and satellite communication to support both research and data transfer

Incinerator

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From: "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Varmus, Harold (NIH/NCI) [E]" <[redacted]@nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Pineda, Mark (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Hedje, Judith (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: MRTC in Bamako
Date: Wed, 17 Apr 2013 15:13:57 -0400
Importance: Normal

Dr. Varmus:

Since 1990, NIAID has spent about $2.1 M in partnership with the University in Mali to upgrade the infrastructure that is on the FMPOS campus and five field sites – which constitutes the Mali ICER/MRTC. These funds have come from NIAID, the Rockefeller Foundation and the US Embassy. USAID also provided a small amount of support for this program in its early years. In all cases, resources helped support both infrastructure and program costs. Considerable investment has been made by the FMPOS itself, but we have no way to document that.

In addition, we have invested in essential IT infrastructure to support multiple projects and ICER operations. Since 2000, this investment has been about $1.7 M. This includes maintenance, services, hardware, software, local human capital investment, and travel. This figure does not capture elements of the Mali ICER IT system that were part of services and systems provided to the entire ICER network. Obviously, in all these expenditure estimates, there is no capture of NIH staff costs.

In addition, utilizing and sustaining this infrastructure, NIAID has expended about $141 M over the last 21 years to support research projects and programs at the Mali ICER - $57 K in extramural grants and contracts and $84 K in intramural research project support. In addition, NIMH, FIC and the OD also have funded ICER-associated research projects. This has been only a few million dollars, but still has been significant.

Please let me know if this data does not meet your need or if you have other questions.

Gray

From: Varmus, Harold (NIH/NCI) [E]
Sent: Thursday, April 11, 2013 4:07 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: Re: MRTC in Bamako

Gray, many thanks. I'll be reviewing these items over the weekend and will look forward to the numbers next week.

On 4/11/13 2:11 PM, "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov> wrote:

Dr. Varmus:

Attached is background information on the ICER in Mali. I am sending what I have gathered so far – two documents prepared for different purposes, which describe this long-term engagement. So far, I am still pulling together information about overall funding, although the "History" piece includes some recent information. Gathering this data is challenging because much of the early support was from a variety of sources including Foundations and USAID. I will send at least a ball-park figure next week.

Yesterday, the ICER programs all presented on their current studies so I will also try to share the slides related to the Mali program. These well illustrated some aspects of the history and the current breadth of our scientific engagement there.

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I have also attached a short paper on our ICER in Uganda. Another very productive partnership where many sources of funding have helped build a robust infrastructure used by both extramural and intramural scientists. We also have an NIAID scientist posted there to oversee this program.

On the Lahore involvement, I was able to learn a little of the back-story from Dr. Karl Western, our knowledgeable historian. From 1959-1981 the University of Maryland, Baltimore had an International Center for Medical Research (and Training) [ICMR(T)] in Lahore, Pakistan. This program was one of NIAID's earliest tools to help build research capacity overseas. When the International Centers for Infectious Disease Research (ICIDR) program was competed for the first time (it was envisioned as a replacement for the ICMR(T)), none of the ICMR's were competitive and so funding was slated to end for the Lahore program. The UMd Dean and US PI for the Lahore ICMR(T) visited NIAID with a Maryland Congressional Delegation to seek reversal of the decision not to fund Lahore as an ICIDR. This was about the time that the Soviets invaded Afghanistan so the State Department was eager not to have anything offend Pakistan (sounds familiar). The compromise was for UMd to submit the best components of their ICIDR application as individual R01 applications. One got funded but then later did not re-compete successfully; so the UMd ICMR faded out.

On PEPFAR, I would be happy to share my point of view about how NIH researchers formed the foundation for early PEPFAR success, particularly in South Africa and Uganda, if that would be helpful at some point.

Hope this is useful; more to come.

Gray

From: Varmus, Harold (NIH/NCI) [E]
Sent: Monday, April 08, 2013 5:20 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: Re: MRTC in Bamako

Thanks on both counts.

For Mali, I just seek some approximate values so that I can say roughly how much the operation---and particular parts of the operation---depended on NIH funds.

I haven't though much about your point about PEPFAR because the narrative was heading elsewhere for the kind of audience I expect. But I'd like to learn more about this if it is in a short form.

On 4/8/13 5:12 PM, "Handley, Gray (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov> wrote:
Dr. Varmus:

No problem. We have some information on Mali, but it needs to be updated and not sure about the budget questions. I will do my best to get back to you this week but obviously want to be careful to send only what can be verified.

As you talk about PEPFAR, I hope you will note how the program was able to accomplish so much so fast (in some key countries like South Africa) because it built on expertise and capacity that had been fostered through NIH supported research for a decade before the advent of PEPFAR service delivery programs. It's a good story.

More to come.

Gray

F. Gray Handley
Associate Director for International Research Affairs

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National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
(O) [redacted]

From: Varmus, Harold (NIH/NCI) [E]
Sent: Monday, April 08, 2013 2:30 PM
To: Handley, Gray (NIH/NIAID) [E]
Cc: Wiszneauckas, Joy (NIH/NCI) [E]
Subject: MRTC in Bamako

Gray, as you may have heard, I am developing a series of lectures to be given in the UK about three examples of US involvement in medical science and health abroad: the Uganda Cancer Center, PEPFAR, and the Malian MRTC. To help gather information for these lectures, I've been doing interviews with some of the people involved. In talking with some people in Bamako, I realized that I don't have facts and figures about the extent and duration of support that NIAID has provided there. Is it possible for you to summarize the history of our spending at the MRTC from 1990 to the present? I don't need many details, just overall all levels and perhaps a couple of categories (salaries, grants, other support).

I have also learned that NIAID has supported other programs like the MRTC, even some (like the one in Lahore) that have been called MRTC. Do you have any information about them and how they related to the efforts in Mali?

Thanks for whatever you can provide.

Harold

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From: "Wood, Gretchen (NIH/OD) [E]" <[redacted]@od.nih.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Somerman, Martha (NIH/NIDCR) [E]" <[redacted]@nih.gov>, "Mascola, John (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Guttmacher, Alan (NIH/NICHD) [E]" <[redacted]@mail.nih.gov>, "Germino, Gregory (NIH/NIDDK) [E]" <[redacted]@niddk.nih.gov>, "Pettigrew, Roderic (NIH/NIBIB) [E]" <[redacted]@mail.nih.gov>, "Austin, Christopher (NIH/NCATS) [E]" <[redacted]@mail.nih.gov>, "Varmus, Harold (NIH/NCI) [E]" <[redacted]@nih.gov>, "Gibbons, Gary (NIH/NHLBI) [E]" <[redacted]@nih.gov>, "Insel, Thomas (NIH/NIMH) [E]" <[redacted]@mail.nih.gov>, "Green, Eric (NIH/NHGRI) [E]" <[redacted]@nhgri.nih.gov>, "Barry, Clifton (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Zoon, Kathryn (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>

Cc: "Cantrel, Katherine (NIH/NIAID) [C]" <[redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Stover, Kathleen (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Qiao, Mo (NIH/NIDCR) [C]" <[redacted]@nih.gov>, "Brown, Crystal (NIH/NICHD) [C]" <[redacted]@nih.gov>, "Wilkerson, Anita D. (NIH/NIDDK) [E]" <[redacted]@niddk.nih.gov>, "Poole, Charlene (NIH/NIDDK) [E]" <[redacted]@EXTRA.NIDDK.NIH.GOV>, "Brawley, David (NIH/NIDDK) [E]" <[redacted]@nih.gov>, "Izzard, Tom (NIH/NIBIB) [C]" <[redacted]@mail.nih.gov>, "Finnegan, Sean (NIH/NCATS) [C]" <[redacted]@nih.gov>, "Wiszneauckas, Joy (NIH/NCI) [E]" <[redacted]@od.nci.nih.gov>, "Togashi, Mieko (NIH/NCI) [E]" <[redacted]@exchange.nih.gov>, "Wells, Connie (NIH/NHLBI) [E]" <[redacted]@nhlbi.nih.gov>, "Earle, Melody (NIH/NHLBI) [E]" <[redacted]@nhlbi.nih.gov>, "Sante, Annette (NIH/NHGRI) [C]" <[redacted]@mail.nih.gov>, "Holt, Tracy (NIH/NIMH) [E]" <[redacted]@mail.nih.gov>, "Guzman, Marlene (NIH/NIMH) [E]" <[redacted]@mail.nih.gov>, "Rodela, Gloria (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Suhana, Tina (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Lebron, Janette (NIH/NIAID) [C]" <[redacted]@niaid.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" <[redacted]@od.nih.gov>, "Burklow, John (NIH/OD) [E]" <[redacted]@OD.NIH.GOV>, "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" <[redacted]@od.nih.gov>

Subject: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December

Date: Fri, 29 Nov 2013 09:56:46 -0500

Importance: High

Attachments: Revised_NIH_Visit_of_Bill_Gates_December_2_fsc.docx; NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding_NIAID_final_c_.docx; 2013_BMGF_AL_English.pdf

Inline-Images: image001.png

Good morning,

Attached please find the final agenda for Mr. Gates' visit this Monday, 2 December. For your review we have also included a briefer on the NIH/BMGF partnerships in Global Health and the BMGF Annual Letter. If you have any questions or concerns, please do not hesitate to contact me and Rob Eiss. Many thanks and enjoy your weekend.

Best wishes,

Gretchen

Gretchen S. Wood

Released by Chairman Rand Paul

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PROGRAM OF ACTIVITY
NIH VISIT OF BILL GATES
DECEMBER 2, 2013

8:45 AM Dr. Francis Collins and colleagues arrive at VRC

9:00 AM Mr. Gates and colleagues arrive (The Dale and Betty Bumpers Vaccine Research Center (VRC)

9:05 AM – 9:10 AM Dr. Francis Collins one-on-one with Bill Gates (room 1107, building 40)

9:10 AM – 9:50 AM Scientific Tour of the VRC

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. John Mascola, Director, VRC

9:50 AM – 10:00 AM Dr. Collins, Mr. Gates, and colleagues travel to Clinical Center, South entrance (building 10)

10:00 AM – 10:45 AM Media Roundtable (Library Conference Room, Clinical Center)

- Associated Press
- New York Times
- Wall Street Journal
- Washington Post

10:45 AM – 11:00 AM Dr. Collins and Mr. Gates go to Masur Auditorium's Green room

11:00 AM – 12:00 PM David E. Barmes Global Health Lecture (Masur Auditorium, Clinical Center)

- 11:00 AM – 11:05 AM Introduction by Dr. Francis Collins
- 11:05 AM – 11:40 AM "Why the Future Needs Biomedical Innovation"
- 11:40 AM – 12:00 PM Q's and A's

12:00 PM – 12:15 PM Dr. Collins, Mr. Gates, and colleagues travel from Masur Auditorium to Medical Board Room

12:15 PM – 1:20 PM Roundtable Discussion with NIH Senior Leadership and Working Lunch
Select priorities in global health: state of the science, questions to resolve
(Medical Board Room, Clinical Center)

- **Opening remarks:** *Dr. Francis Collins and Mr. Bill Gates*

- **HIV, malaria, TB and other infectious disease priorities**
  Lead discussant: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
  Dr. Roger Glass, Director, Fogarty International Center

- **Understanding the molecular basis of growth and nutrition**
  Lead discussant: Dr. Alan Guttmacher, Director, Eunice Kennedy Shriver, National Institute of Child Health and Human Development
  Dr. Gregory Germino, Deputy Director, National Institute of Diabetes and Digestive and Kidney Diseases

- **Point-of-care diagnostics and therapeutics for neglected diseases**
  Lead discussant: Dr. Roderic Pettigrew, Director, National Institute of Biomedical Imaging and Bioengineering
  Dr. Martha Somerman. Director, National Institute of Dental and Craniofacial Research
  Dr. Christopher Austin, Director, National Center for Advancing Translational Sciences

- **Integrating NCD research into global health**
  Lead Discussant: Dr. Harold Varmus, Director, National Cancer Institute
  Dr. Gary Gibbons, Director, National Heart Lung and Blood Institute
  Dr. Thomas Insel, Director, National Institute of Mental Health

- **New partnerships in discovery science and capacity building: H3Africa and the Medical Education Partnership Initiative**
  Lead Discussant: Dr. Eric Green, Director, National Human Genome Research Institute
  Dr. Francis Collins, Dr. Roger Glass

1:20 PM – 1:30 PM Dr. Collins, Mr. Gates, and colleagues travel to Building 33

1:30 PM – 2:20 PM Innovations in TB Drug Development (The C.W. "Bill" Young Center)
Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. Clif Barry, Chief, Tuberculosis Research Section, National Institute of Allergy and Infectious Diseases
Dr. Kathryn Zoon, Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases

2:20 PM – 2:30 PM Wrap up discussion (The C.W. "Bill" Young Center)
Dr. Collins and Mr. Gates

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NATIONAL INSTITUTES OF HEALTH (NIH) – BILL & MELINDA GATES FOUNDATION (BMGF) ACTIVE FUNDED PARTNERSHIPS IN GLOBAL HEALTH

1. The Foundation for the National Institutes of Health (FNIH), which leverages the resources of the NIH with the public and private sectors, has the following initiatives.

- Global Health
    - *Grand Challenges in Global Health (GCGH)* aims to create "deliverable technologies" – health tools that are not only effective, but also inexpensive to produce, easy to distribute, and simple to use in developing countries ($201M; 2003-2015).
    - *Vector-Based Control of Transmission: Discovery Research (VCTR)* aims to extend GCGH research and establish a pipeline of innovative new tools that will be safe, easily deployed, effective, and sustainable for use in the control of mosquito-borne diseases such as malaria and dengue ($52M; 2009-2016).
    - *Etiology, Risk Factors & Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health & Development (MAL-ED)* aims to understand the interactions between enteric infections and malnutrition in association with poor health outcomes, including physical growth, cognitive development deficits, and poor immunological responses to childhood vaccines, in order to design better intervention strategies ($40M; 2008-2014) (Partner: Fogarty International Center (FIC).
    - *Identification of High-Quality HITs for Tuberculosis (HIT-TB)* aims to produce high-quality chemical hit series with defined, tractable targets as drug leads for tuberculosis ($2.9M; 2010-2013) (Partner: National Institute of Allergy and Infectious Diseases (NIAID).
    - *Rapid Identification of Individuals with Viable Adult Worms of Onchocerca volvulus: A Means to an End (pending)* aims to identify host and parasite specific biomarkers in human subjects of adult female *O. volvulus* and develop rapid point of care methods to detect these biomarkers ($1.5M; 2013-2015) (Partner: NIAID).
- Collaboration for AIDS Vaccine Discovery (CAVD)
    - *T-Cell Vaccine Immune Monitoring Consortium (CTC-VIMC)* provides standardized T cell assays for both non-human primate and clinical vaccine trials and facilitates comparison of efficacy data from different vaccine development efforts across the CAVD ($50M; 2006-2016) (Partner: NIH).
    - *Centralized Envelope Comparative Immunogenicity Phase I Study (CECI)* aims to understand how best to design T-cell immunogens in order to develop a vaccine that addresses the broad genetic diversity of HIV-1 ($4.5M; 2009-2014) (Partner: NIAID).
    - *Development of a Second Generation Broadly Neutralizing Antibody Product to Prevent HIV-1 Infection* aims to develop a second generation broadly neutralizing antibody product to prevent HIV-1 infection, with improved potency and longer half-life ($1.2; 2011-2016) (Partner: NIAID).

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2. NIAID, in addition to the work it is doing in partnership with FNIH, is involved in the following activities with the support of the BMGF:

- Testing whether "unnatural immunity" (antibodies that are not generated in natural infection) against structures that form a capsule uniquely on the surface of infecting Leishmania promastigotes can prevent infection in the mammalian host, as well as block the development of infectious promastigotes in the sandfly vector (~$310K)

- Working to produce additional amounts of HIV clade C gp145 envelope protein, for use as a research reagent and potential HIV vaccine immunogen. Additional protein would be produced at a reduced cost and shortened development time due to the decrease in the number of production runs and associated release and stability testing ($2.9M)

- NIAID is also involved as a sub-grantee on the following BMGF-funded projects:

    - Application of clinical imaging modalities to tuberculosis treatment and transmissions: whole body imaging technology as a means of facilitating development of new drugs that may shorten chemotherapy duration. ($5M, University of Pittsburg)

    - Coordinating and administering collaborative research in chemistry and microbiology for advancement of new TB medicines ($690K, Infectious Disease Research Institute)

    - Ascertaining the adjuvant effects, when combined with HIV/SIV immunogens, on innate/adaptive immunity in tissue sites and on protection from SIV challenge using the *in vivo* macaque model (~614K, Fred Hutchinson Cancer Research Center)

    - Supporting development of biomarkers for TB that can be used in treatment evaluation and disease diagnosis (~893K, Catalysis Foundation)

    - Assessing neutralizing antibody responses against HIV-1 in human clinical trials in a Good Clinical Laboratory Practices (GCLP) compliant manner and working on developing a second generation broadly neutralizing antibody product to prevent HIV-1 infection in humans through participation in the CAVD/Comprehensive Antibody Vaccine Immune Monitoring Consortium (CAVIMC) ($1.42M, Duke University)

    - Working in Cameroon to develop and test a strategy to extend mass drug treatment for lymphatic filariasis and hyperendemic onchocerciasis to areas endemic for loiasis ($324K, Institut Bouisson Bertrand)

    - Screening 80,000 diversity-oriented synthesis (DDS) molecules against *Mycobacterium tuberculosis* (TB) and developing a whole body imaging technology as a means of facilitating development of new drugs that may shorten the duration of chemotherapy in patients with TB ($110K, Broad Institute)

    - Working to develop a global HIV-1 incidence assay through determination of cell-associated viral load in CD4 T cells ($130K, Duke University)

3. NICHD has done extensive global work with the support of the BMGF.

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- The establishment of NICHD's Global Network for Women's and Children's Health Research was the first public-private partnerships between NIH and the BMGF. The BMGF provided $15M over the first 3 years and was instrumental in laying the foundation for the Global Network's numerous achievements over the past 12 years. Achievements include, but are not limited to:
    - Initial large-scale individual site studies conducted during the first cycle, which found that training birth attendants in neonatal resuscitation and essential newborn care reduced neonatal mortality and morbidity from birth asphyxia and neonatal infections and that oral misoprostol reduced postpartum hemorrhage
    - The development of "common" trials, conducted by at least 3 sites, which led to increased collaboration and scientific capacity building, and to numerous findings, including that local instructor-training in newborn resuscitation and essential newborn care significantly reduced perinatal deaths and was cost-effective
    - A current Global Network comprised of 7 multidisciplinary research units existing in India, Pakistan, Zambia, the Democratic Republic of the Congo, Kenya and Guatemala with the aim of addressing the three major causes of perinatal morbidity and mortality: asphyxia, prematurity, and infection
    - The maintenance of a detailed birth registry, which enrolls mothers early in pregnancy and has provided outcome data on 340,000 mother-infant pairs
    - Publishing of 170 manuscripts in 10 years, almost half with a scientist from the developing world as first author
    - Tremendous independent research capacity evidenced by funding of global collaborators by the World Health Organization, the World Bank, the government of France, the Thrasher Foundation, and the Church of the Latter Day Saints, among others
- NICHD, with the support of the BMGF, is currently working on an integrated approach to infection, noncommunicable diseases, food insecurity, and the dual burden of over- and under-nutrition through the following projects:
    - The *Biomarkers of Nutrition for Development* (*BOND)* program, which aims to develop a unified, scientific approach to select biomarkers for assessing the function and effect of diet and nutrition on health and diseases in individuals and populations (~$450K)
    - The *Iron and Malaria* project, which aims to identify safe and effective interventions (such as iron supplementation) to prevent iron deficiency and related health problems in areas where malaria and other infections are common ($9.4M)

4. Fogarty International Center (FIC) is supported by the BMGF as well.

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- In a collaborative effort with NICHD, FIC is working to obtain clinical outcome results of an experimental Vi-conjugate vaccine and to produce a human sera reference standard to be used to accelerate the development of commercialized Vi-conjugate vaccines ($586K).

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Heads of International (Biomedical) Research Organisations

2nd July 2014

Item 3: Update from members on recent organisational developments

Organisation	Page
Bill & Melinda Gates Foundation	2
Biomedical Research Council, Singapore	4
Canadian Institutes of Health Research (CIHR)	5
Chinese Academy of Medical Sciences (CAMS)	7
Council for Science and Technology Policy, Government of Japan	9
Deutsche Forschungsgemeinshaft (DFG)	10
European Commission (EC)	12
Indian Council of Medical Research (ICMR)	15
Institut national de la santé et de la recherché médicale (INSERM), France	17
Institut Pasteur	19
Medical Research Council (MRC), UK	20
National Health & Medical Research Council (NHMRC), Australia	21
National Institutes of Health (NIH), USA	23
National Science Foundation (NSF), USA	24
South African Medical Research Council	26
Swedish Research Council (Medicine and Health)	27
Wellcome Trust, UK	29
ZonMw, Netherlands	31

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Update from the Bill & Melinda Gates Foundation

Organizational update

Susan Desmond-Hellmann, M.D., M.P.H. started as CEO of the foundation on May 1, 2014. An oncologist by training, Desmond-Hellmann is a recognized leader on issues of higher education, public health, drug development, regulatory innovation, and health policy. Prior to joining the foundation, Dr. Desmond-Hellman was chancellor of University of California, San Francisco. She was appointed to that position in August 2009 – the first woman to serve as the university's chancellor, overseeing all aspects of the university and medical center's strategy, academic programs and operations. She has extensive experience in product development, and a deep understanding of how to bridge applied research to delivery of product. Prior to her tenure at UCSF, she was President of Product Development at Genentech, where she led the development and introduction of two of the first gene-targeted therapies for cancer, Avastin and Herceptin.

Program update(s)

Grand Challenges in Global Health

The 2014 Grand Challenges Meeting will take place from October 5-8 in Seattle. The 2014 meeting is a significant milestone, marking the 10th anniversary of the annual gathering and more than a decade of grant-making using the Grand Challenges approach. Based on a decade of lessons learned and a growing network of funders, we plan to re-launch Grand Challenges with an announcement of new opportunities to accelerate development of interventions for global health and create a more systematic approach to ensure that every child is thriving. We welcome the opportunity to engage with additional partners on these new initiatives.

Cross-cutting surveillance initiative

Beginning this year, the foundation will fund the development of the Sentinel Epidemiology and Etiology Data (SEED) network of 20-25 sites that will measure the burden of infectious disease associated with diarrhea, pneumonia and febrile illness among children under 5 years of age across sub-Saharan Africa and South Asia. Geospatial analysis will be used to ensure a representative cross section of sites, and laboratory and epidemiologic methods will be standardized. This will result in the collection of population-based data that can be used to gain situational awareness of specific geographies, measure trends over time, and assess the impact of global health interventions and programs. A sophisticated data transmission scheme will allow the data to be used within 3 months of collection, under a data governance structure that will ensure country ownership of the data. This network will also serve as a platform for research, allowing the global health community to maximally leverage the SEED infrastructure.

Global Burden of Disease (GBD) 2.0

The foundation funded the Institute for Health Metrics and Evaluation (IHME) at the University of Washington to support a continuously updated and expanded Global Burden of Disease platform to

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track health around the world. The goal is to provide up-to-date evidence of patterns and trends worldwide. Estimates will be produced at least annually and probably at more frequent intervals to reflect new evidence as it accumulates. An independent review committee chaired by Prof. Peter Piot (London School of Hygiene and Tropical Medicine) will assess the strengths and weaknesses of different results and methods—particularly to identify opportunities to improve estimates using new data collection and analysis solutions. The review committee will also advise IHME about opportunities for strengthening collaboration and ownership of GBD 2.0, engage in dialogue around other efforts on global health estimates, and formulate guidelines for access to and use of the GBD databases globally, regionally, and nationally. One of the most important challenges for governments and global health funding agencies is to relate investments to results. By creating a comprehensive approach with uniform methods to track health data at the national level, GBD 2.0 will be an invaluable resource for the understanding of whether actions have changed health trends.

Other updates

Open access policy

The foundation is close to adopting an open access publication policy that is consistent with peer organizations, including:

- Publications that are discoverable and accessible online. Publications will be deposited in specified repository(s) with proper tagging of metadata.
- Publication will be on “Open Access” terms. All publications shall be published under the Creative Commons attribution 2.0 generic license (CC BY 2.0)
- Foundation will pay necessary fees.

We are in the process of reviewing other aspects related to embargo periods and possible requirements for making the data underlying the published results available as well.

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NATIONAL INSTITUTES OF HEALTH (NIH) – BILL & MELINDA GATES FOUNDATION (BMGF) ACTIVE FUNDED PARTNERSHIPS IN GLOBAL HEALTH

1. The Foundation for the National Institutes of Health (FNIH), which leverages the resources of the NIH with the public and private sectors, has the following initiatives.

- Global Health
    - *Grand Challenges in Global Health (GCGH)* aims to create "deliverable technologies" – health tools that are not only effective, but also inexpensive to produce, easy to distribute, and simple to use in developing countries ($201M; 2003-2015).
    - *Vector-Based Control of Transmission: Discovery Research (VCTR)* aims to extend GCGH research and establish a pipeline of innovative new tools that will be safe, easily deployed, effective, and sustainable for use in the control of mosquito-borne diseases such as malaria and dengue ($52M; 2009-2016).
    - *Etiology, Risk Factors & Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health & Development (MAL-ED)* aims to understand the interactions between enteric infections and malnutrition in association with poor health outcomes, including physical growth, cognitive development deficits, and poor immunological responses to childhood vaccines, in order to design better intervention strategies ($40M; 2008-2014) (Partner: Fogarty International Center (FIC).
    - *Identification of High-Quality HITs for Tuberculosis (HIT-TB)* aims to produce high-quality chemical hit series with defined, tractable targets as drug leads for tuberculosis ($2.9M; 2010-2013) (Partner: National Institute of Allergy and Infectious Diseases (NIAID).
    - *Rapid Identification of Individuals with Viable Adult Worms of Onchocerca volvulus: A Means to an End (pending)* aims to identify host and parasite specific biomarkers in human subjects of adult female *O. volvulus* and develop rapid point of care methods to detect these biomarkers ($1.5M; 2013-2015) (Partner: NIAID).
- Collaboration for AIDS Vaccine Discovery (CAVD)
    - *T-Cell Vaccine Immune Monitoring Consortium (CTC-VIMC)* provides standardized T cell assays for both non-human primate and clinical vaccine trials and facilitates comparison of efficacy data from different vaccine development efforts across the CAVD ($50M; 2006-2016) (Partner: NIH).
    - *Centralized Envelope Comparative Immunogenicity Phase I Study (CECI)* aims to understand how best to design T-cell immunogens in order to develop a vaccine that addresses the broad genetic diversity of HIV-1 ($4.5M; 2009-2014) (Partner: NIAID).
    - *Development of a Second Generation Broadly Neutralizing Antibody Product to Prevent HIV-1 Infection* aims to develop a second generation broadly neutralizing antibody product to prevent HIV-1 infection, with improved potency and longer half-life ($1.2; 2011-2016) (Partner: NIAID).

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2. NIAID, in addition to the work it is doing in partnership with FNIH, is involved in the following activities with the support of the BMGF:

- Testing whether "unnatural immunity" (antibodies that are not generated in natural infection) against structures that form a capsule uniquely on the surface of infecting Leishmania promastigotes can prevent infection in the mammalian host, as well as block the development of infectious promastigotes in the sandfly vector (~$310K)

- Working to produce additional amounts of HIV clade C gp145 envelope protein, for use as a research reagent and potential HIV vaccine immunogen. Additional protein would be produced at a reduced cost and shortened development time due to the decrease in the number of production runs and associated release and stability testing ($2.9M)

- NIAID is also involved as a sub-grantee on the following BMGF-funded projects:

    - Application of clinical imaging modalities to tuberculosis treatment and transmissions: whole body imaging technology as a means of facilitating development of new drugs that may shorten chemotherapy duration. ($5M, University of Pittsburg)

    - Coordinating and administering collaborative research in chemistry and microbiology for advancement of new TB medicines ($690K, Infectious Disease Research Institute)

    - Ascertaining the adjuvant effects, when combined with HIV/SIV immunogens, on innate/adaptive immunity in tissue sites and on protection from SIV challenge using the *in vivo* macaque model (~614K, Fred Hutchinson Cancer Research Center)

    - Supporting development of biomarkers for TB that can be used in treatment evaluation and disease diagnosis (~893K, Catalysis Foundation)

    - Assessing neutralizing antibody responses against HIV-1 in human clinical trials in a Good Clinical Laboratory Practices (GCLP) compliant manner and working on developing a second generation broadly neutralizing antibody product to prevent HIV-1 infection in humans through participation in the CAVD/Comprehensive Antibody Vaccine Immune Monitoring Consortium (CAVIMC) ($1.42M, Duke University)

    - Working in Cameroon to develop and test a strategy to extend mass drug treatment for lymphatic filariasis and hyperendemic onchocerciasis to areas endemic for loiasis ($324K, Institut Bouisson Bertrand)

    - Screening 80,000 diversity-oriented synthesis (DDS) molecules against *Mycobacterium tuberculosis* (TB) and developing a whole body imaging technology as a means of facilitating development of new drugs that may shorten the duration of chemotherapy in patients with TB ($110K, Broad Institute)

    - Working to develop a global HIV-1 incidence assay through determination of cell-associated viral load in CD4 T cells ($130K, Duke University)

3. NICHD has done extensive global work with the support of the BMGF.

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- The establishment of NICHD's Global Network for Women's and Children's Health Research was the first public-private partnerships between NIH and the BMGF. The BMGF provided $15M over the first 3 years and was instrumental in laying the foundation for the Global Network's numerous achievements over the past 12 years. Achievements include, but are not limited to:
    - Initial large-scale individual site studies conducted during the first cycle, which found that training birth attendants in neonatal resuscitation and essential newborn care reduced neonatal mortality and morbidity from birth asphyxia and neonatal infections and that oral misoprostol reduced postpartum hemorrhage
    - The development of "common" trials, conducted by at least 3 sites, which led to increased collaboration and scientific capacity building, and to numerous findings, including that local instructor-training in newborn resuscitation and essential newborn care significantly reduced perinatal deaths and was cost-effective
    - A current Global Network comprised of 7 multidisciplinary research units existing in India, Pakistan, Zambia, the Democratic Republic of the Congo, Kenya and Guatemala with the aim of addressing the three major causes of perinatal morbidity and mortality: asphyxia, prematurity, and infection
    - The maintenance of a detailed birth registry, which enrolls mothers early in pregnancy and has provided outcome data on 340,000 mother-infant pairs
    - Publishing of 170 manuscripts in 10 years, almost half with a scientist from the developing world as first author
    - Tremendous independent research capacity evidenced by funding of global collaborators by the World Health Organization, the World Bank, the government of France, the Thrasher Foundation, and the Church of the Latter Day Saints, among others
- NICHD, with the support of the BMGF, is currently working on an integrated approach to infection, noncommunicable diseases, food insecurity, and the dual burden of over- and under-nutrition through the following projects:
    - The *Biomarkers of Nutrition for Development* (*BOND)* program, which aims to develop a unified, scientific approach to select biomarkers for assessing the function and effect of diet and nutrition on health and diseases in individuals and populations (~$450K)
    - The *Iron and Malaria* project, which aims to identify safe and effective interventions (such as iron supplementation) to prevent iron deficiency and related health problems in areas where malaria and other infections are common ($9.4M)

4. Fogarty International Center (FIC) is supported by the BMGF as well.

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Notes from meeting Bill Gates
Tuesday, October 8th

Meeting with Dr. Collins, Director, National Institutes of Health (NIH)
Time: 9:00am-10:00am
Location: BMGF Office, Houston Conference Room
Foundation Participants: Bill Gates, Chris Wilson (by phone), Nageeb Sumar
External Participants:

- Dr. Francis Collins, Director, National Institutes of Health (NIH)
- Dr. Anthony Fauci, Director National Institute of Allergy and Infectious Diseases (NIAID)
- Dr. Harold Varmus, Director, National Cancer Institute (NCI)

Notes by: Chris Wilson/Nageeb Sumar

Purpose: Learn more about the activities of NIH, NIAID and NCI, and overlapping interests with the foundation's priorities

Summary:
The group discussed the current federal budget impasse and how sequestration had already hurt R&D.

Polio:
On polio, Bill discussed supporting research to create safer OPV and the regulatory pathway that might be done for licensure via China.

P5:
Fauci introduced the P5 work and noted progress was on-track. He reiterated the biggest problem is the delay in manufacturing the protein and that the Barouch/Walker Ad26 will be part of the phase I group in the research trial; J&J Crucell will fund production of the vector for that trial. Bill asked a question related to adenoviral vectors-- Fauci made the point that induces influx and/or activation of mucosal T cells by Ad5 may be the culprit and that an Ad that does not do this may be safe(r).

Fauci related that bNAb inducing immunogen work is on track between NIH and Gates, and funding of Nussenzweig to do POC studies that bNAbs can have a biological impact with NIH supporting parallel studies through the VRC candidates.

Bill talked about potential use of bNAbs in therapy, less difficult/less frequent intermittent maintenance therapy and potentially functional cure. Fauci raised the possibility that vaccination in a fully suppressed person might be able to induce protective immunity, even if frequent boosters would be needed. They agreed that until an effective active vaccine is in hand, that passive immunoprophylaxis trials are an important activity that we should/will both pursue.

Fauci discussed the VRC01 PMTCT trial to block breast milk transmission – the phase I PK/PD is soon to launch in the US, and then to test benefit in African infants - to try and block the breakthrough that occurs in infants on ART prophylaxis. Fauci acknowledged that VRC01 is probably not the top bNAb for other studies. Bill talked about his enthusiasm for the AAV vectored delivery of bNAbs, acknowledging the regulatory pathway is a challenge.

Malaria:

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Fauci was positive about the Sanaria vaccine efficacy study. Bill talked about the limitations for use in low income settings of the Sanaria irradiated sporozoite vaccine, and by contrast the value of this approach to learn about protective immunity and how it might be induced by a vaccine that is more practical for low income settings.

Fauci suggested that the mechanism is likely to be predominantly CD8 T cell mediated immunity in the liver. He indicated that the NIH will do durability and heterologous protection studies at the NIH and Steve Hoffman has funding to do an initial POC study in Africa.

Bill reiterated that the deliverability of the current Sanaria vaccine is a big barrier given the need for liquid nitrogen storage, putting aside the ability to manufacture at scale and affordable cost. Bill then talked about issues of RTS,S deployment given the limited efficacy of the current vaccine and that we do not see wide deployment of RTS,S given its relatively limited efficacy. He noted our commitment to a second generation vaccine with either better efficacy for the individual or with sexual stage-gametocyte component that would block onward transmission. The discussion turned to drug therapy, the importance of drugs that can clear gametocytes, and the potential with highly effective test and treat that included a drug that cleared gametocytes to drive elimination.

Cancer:
Varmus discussed infection-related cancers in the developing world, in particular talking about HPV and HepB related cancers.

He focused on the potential to scale HPV vaccination with fewer than 3 doses potentially providing meaningful benefit, referencing a GAVI study in Costa Rica which indicated that 2 rather than 3 doses could be equally effective when focusing on 9-11 year old adolescents.. Bill talked about Serum Institute of India HPV vaccine candidate that could come in at <$1/dose. Varmus also referenced a nonavalent vaccine by Merck which would cover 90 percent of cervical cancer. The group discussed some of the myth and controversy around HPV administration in India leading to deaths.

Varmus turned to Epstein-Barr virus (jaw-related disease) related malignancies, the geographical association between high malaria incidence and greater risk for Burkitt's lymphoma. Varmus also talked about MedImmune EBV vaccine candidate abandoned for uncertain reasons around the time they were acquired by Astra Zeneca; the vaccine was not aimed at preventing infection but appeared to have an ~80% reduction in Infectious Mononucleosis; it is unclear whether it would have a similar impact on Burkitt's lymphoma.

The topic of RNA vaccines came up as a possible approach to rapidly test antigenic constructs, including the Novartis approach and one from CureVac. Diagnostic tools to detect these and other infections were discussed. Bill talked about nucleic acid based diagnostics – the promise of a low cost, platform has not yet been met (e.g., the GenXpert for TB) but might get there in the next 10 years. The discussion turned to which countries are most nimble and efficient to develop and test practical and scalable diagnostics and intervention testing, and the potential value of emerging economies (Brazil, Mexico, China) rather than the lowest income countries to this end.

Cookstoves/Indoor air pollution:
Collins acknowledged the challenges of getting something that would be properly taken up and used and the weakness of the data showing benefit. Bill noted that we need data – what do we need to remove to have a health benefit and can this best be achieved with a new stove or an

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alternative intervention that would remove the problematic pollutants. He also noted a healthy skepticism regarding the actual attributable burden of disease and the cultural challenges of using a new system. Collins agreed that simply counting numbers of delivered stoves is not the right metric and that we need the science to demonstrate the potential utility of any intervention.

Collins then referenced the MEPI program jointly to build capacity in sub-Saharan African universities which is currently an NIH partnership with OGAC, HRSA, CDC. Bill stated “we feel badly” that we don’t fund this capacity building. He noted the potential value of K-RITH. He said we should look at this and consider if and if so how and to whom we should contribute and what the metrics for success would be.

Bill suggested that MOOCs might be able to target high-end nurses or low-end doctors and really generate net benefit in knowledge to the medical system in developing countries.

Collins proposed that we should look to have an annual meeting between key leaders at all the relevant NIH institutes (not just NIAID in whom we have already been doing this) and BMGF leaders to learn from each other and foster more effective collaboration. Bill endorsed this idea.

Follow-up:

- Chris W. to follow-up on meeting with all relevant NIH institutes (similar to NIAID)

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From: "Collins, Francis (NIH/OD) [E]" </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=COLLINSFR>
To: "[redacted]@fda.hhs.gov" <[redacted]@fda.hhs.gov>
Cc: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>, "Baker, Rebecca (NIH/OD) [E]" <[redacted]@od.nih.gov>
Subject: Upcoming meeting with Gates Foundation and NIH
Date: Fri, 19 May 2017 18:22:14 -0400
Importance: Normal
Attachments: DRAFT_agenda_BMGF-NIH_meeting_2017_5_12_(003).docx

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Dear Scott,

Over the past several years, the scientific leadership of the NIH and Bill & Melinda Gates Foundation has met annually to review progress of joint activities and plan future projects. Bill Gates will personally join our next workshop, to take place Friday, June 2, at the John Porter Neuroscience Research Center on the NIH campus, beginning at 8:30 AM I will co-chair the meeting with Dr. Trevor Mundel, President of the Global Health Division at the Bill & Melinda Gates Foundation.

Though I am sure your schedule is packed, we'd be delighted if you could join part or all of the morning session, given the relevance of the topics. Discussion will include:

- State-of- the-art developments in global health vaccine R&D , with emphasis on therapeutic vaccines and structure-based immunogen design;
- New concepts in cell-phone enabled point-of-care diagnostics, including development of open interface standards, and
- Strategies to create a durable network of African sites capable of licensure for standard trials, among other clinical and translational research capacity needs to be addressed by a new partnership called the Coalition for African Research and Innovation.

We are finalizing an agenda, which I will share once available, with logistical details. In the interim, I attach the current draft agenda. We have engaged several FDA colleagues in developing the panel session on POC diagnostics, including Alberto Gutierrez.

I hope you can make it. Your perspectives would be of great value, and the discussion will give you a close sense of some of the global health product development priorities and pathways pursued jointly by NIH and the Gates Foundation.

Best regards, Francis

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Bill & Melinda Gates Foundation- National Institutes of Health
Fourth Annual Consultative Workshop
June 2, 2017

John Edward Porter Neuroscience Research Center
35 Convent Drive
Bethesda, MD

DRAFT

8:30 A.M. – 8:35 A.M.	**Welcome** Francis S. Collins, MD, PhD, Director, National Institutes of Health (NIH) Trevor Mundel, MD, PhD, President, Global Health Division, Bill & Melinda Gates Foundation (BMGF)
8:35 A.M. – 8:45 A.M.	**Opening Remarks** Bill Gates, Co-Chair and Trustee, Bill & Melinda Gates Foundation
8:45 A.M. – 9:30 A.M.	**Panel 1: Vaccine R&D developments: Challenges and opportunities in therapeutic and preventive vaccine R&D for HPV and other cancer causing viruses** Douglas R. Lowy, MD, Acting Director, National Cancer Institute (NCI), NIH Jeffrey Cohen, MD, Chief, Laboratory of Infectious Diseases, NIAID, NIH Peter Dull. MD, Deputy Director, Integrated Clinical Vaccine Development, Bill & Melinda Gates Foundation Kirsten Vogelsong, PhD, Senior Program Officer, Contraceptive Development, Family Planning; Bill & Melinda Gates Foundation
9:30 A.M. – 10:15 A.M.	**Panel 2: Vaccine R&D developments: Structure-based immunogen design** Anthony S. Fauci, MD, Director, National Institute of Allergy and Infectious Diseases (NIAID), NIH John Mascola, MD, Director, Vaccine Research Center and Chief, Virology Laboratory, NIAID, NIH Lynda Stuart, MD, PhD, Deputy Director, Vaccines and Host-Pathogen Biology, Discovery and Translational Sciences Division, Bill & Melinda Gates Foundation Amy Weiner, PhD, Senior Program Officer, Discovery and Translational Sciences Division, Bill & Melinda Gates Foundation
10:15 A.M. – 10:45 A.M.	**Coffee Break**
10:45 A.M. – 11:30 P.M.	**Panel 3: Point-of-care diagnostics for low-resource settings** Daniel J. Wattendorf, MD, Director, Innovative Technology Solutions, Bill

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& Melinda Gates Foundation
Roderic I. Pettigrew, PhD, MD, Director, National Institute of Biomedical Imagining and Bioengineering, NIH
Rob Taylor, Program Officer, Global Health Integrated Development, Bill & Melinda Gates Foundation
Ram D. Sriram, PhD, Chief, Software and Systems Division, Information Technology Laboratory, National Institute of Standards and Technology
Apple HealthKit representative (TBD)
Alberto Gutierrez, PhD, Director, Office of In Vitro Diagnostic Device Evaluation and Safety, Food and Drug Administration
Or
Jeffrey Shuren, MD, Director, Center for Devices and Radiological Health, Food and Drug Administration

Discussion to include:

- Achieving open interface standards for smartphones to read Dx tests (without additional hardware)
    - Developing an influenza diagnosis through a lateral flow test
    - Regulatory concerns and strategy
- Opportunities to strengthen core diagnostic lab networks/services in LMICs

11:30 A.M. – 12:15 P.M. **Panel 4: The Emergence of the Coalition for African Research and Innovation**

Francis S. Collins, MD, PhD, Director, National Institutes of Health (NIH
Tom Kariuki, MD, Director Alliance for Accelerating Excellence in Science in Africa (AESA) and Interim Executive Director, African Academy of Sciences
Trevor Mundel, MD, PhD, President, Global Health, Bill & Melinda Gates Foundation
Kedest Tesfagiorgis, Program Officer, Bill & Melinda Gates Foundation
Penny, Heaton, M.D., Director of Vaccine Development, Bill & Melinda Gates Founsation

Discussion to include:

- Strengthening clinical and translational research and training to accelerate the current and emerging pipeline of investigational products
- Creating greater "demand" for research among national leaders in Africa, and engaging corporate investors

12:15 P.M. – 2:15 P.M. **Working Group Lunch and Breakout Sessions**

HIV/AIDS
Co-chairs: Emilio Emini, Nina Russell and Carl Dieffenbach

Malaria
Co-chairs: Lee Hall and Dan Hartman

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TB
Co-chairs: Gilla Kaplan, Christine Sizemore and Clif Barry

Maternal, Neonatal and Child Health
Co-chairs: Sindura Ganapathi and Diana Bianchi

Pneumonia, enteric diseases, and indoor air pollution
Co-chairs: Keith Klugman (for Gail Rodgers), Josh Rosenthal and Linda Lambert

Contraceptive research
Co-chairs: Nomi Fuchs-Montgomery and Dan Johnston

HPV/cervical cancers
Co-chairs: Peter Dull and Aimee Kreimer (for Doug Lowy)

Point of care diagnostics
Co-chairs: Cristina Giachetti and Roderic Pettigrew

2:15 P.M. – 3:50 P.M. **Open Session**
Moderators: Francis S. Collins, MD, PhD, Director, NIH
Trevor Mundel, MD, PhD, President, Global Health Division, BMGF

- Reports of the Working Groups
- Proposed new areas of cooperation with discussion

3:50 P.M. -4:00 P.M. **Wrap-up and Review of Next Steps**
Francis S. Collins, MD, PhD, Director, NIH
Emilio A. Emini, Ph.D.,Director, HIV Program,
Bill & Melinda Gates Foundation

4:00 P.M. **Adjourn**

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From: STEWART SIMONSON <[redacted]@icloud.com>
To: Cliff Lane <[redacted]@niaid.nih.gov>
Subject: Fwd: attached four or so pages will bring you up to speed as of Tuesday
Date: Fri, 03 Apr 2020 14:04:14 -0400
Importance: Normal
Attachments: Wartime_Six_Month_Vaccine_Program_v2.docx

Please keep confidential, Cliff.

STEWART SIMONSON
[redacted]@icloud.com

Begin forwarded message:

From: Richard Danzig <[redacted]@gmail.com>
Subject: attached four or so pages will bring you up to speed as of Tuesday
Date: April 2, 2020 at 10:12:04 AM EDT
To: Stewart Simonson <[redacted]@icloud.com>
Cc: Richard Hatchett <[redacted]@cepi.net>

Please treat as confidential.
We have moved further.
You will get an email re tomorrow's call - 12:30 Eastern.
Excellent to talk with you as always. Will be even better working with you.*
Richard
* Especially if you do most of the work.

--
Richard Danzig
3670 Upton St. NW
Washington DC 20008

[redacted]@gmail.com
[redacted]

Released by Chairman Rand Paul

Draft – Not for Further Circulation Without Author's Approval

A Six Month "Wartime" Vaccine Program v2 (March 29, 2019)

Contact: Richard Danzig – [redacted]@gmail.com

A vaccine is the single most important tool now missing in our fight against the corona virus. As many as 100[i] separate efforts are proceeding with unprecedented speed and resources to develop one or more vaccines. Though in the recent past it has taken at least a decade to move from conception to widespread distribution, these efforts are on an ambitious trajectory to produce a vaccine in 12-18 months.

This paper proposes that a previously unrealistic goal of six months should be pursued and this can be done with justifiable risk. Peacetime constraints inhibited the 12-18 month plan from being accelerated further. A wartime effort can move twice as fast by embracing three innovations:

- previously unthinkable government support in the form of underwriting costs, indemnification, maximum speed FDA review, acceptance of additional clinical and manufacturing risk appropriate to the enormous benefit, engagement of reluctant actors, and, if necessary, use of the Defense Production Act;
- evaluation by a cohort study or human challenge trials rather than traditional clinical trials;
- identification, funding and preparation of manufacturing assets before trials demonstrate success.

These ideas have been vetted in discussion with leaders in the vaccine industry. This path can get us there if an overarching strategic plan is developed immediately, government actors embrace it, and initial actions are taken in the first half of April. The reward warrants the effort: **wide availability of an effective vaccine in October could invaluably protect health care workers and other essential personnel, would greatly diminish a second cold weather wave of COV-19, permit economic recovery by assuring immunity to workers and consumers who receive it, and, through sharing globally, create immense goodwill and respect for America**.

A meeting will be held on March 31 at 8am California time to assess these ideas and no doubt to develop others that would contribute to a six-month vaccine. The agenda for a two and a half-hour meeting is:

I. 20 minutes: brief general reactions, including expressions of enthusiasm and skepticism.

II. 60 minutes: participants construct the basics of a six-month plan, identifying the major initiatives that would need to occur to make the plan viable. This discussion will proceed without respect to whether participants are persuaded such a plan is likely to succeed.

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III. 30 minutes: discussion of whether participants view the plan as plausible enough to be worth the opportunity costs (distraction, etc.) and risks it will entail.

IV. 40 minutes: If the plan is considered to be worth further effort, the group will discuss how to progress, including engagement of the US, European, India, and the PRC.

Attachment 1 provides a Q&A on some key points about the plan along with footnotes pointing to some relevant reading. [Footnote not provided in this draft.]

Attachment 2 lists those with whom the plan has been discussed. It does not imply endorsement. An asterisk indicates those who should be invited to the planned teleconference. It further lists a small number of others are proposed for invitation to the teleconference. Suggestions are welcome for others who might be especially important contributors. This meeting will not involve government participants after this first meeting. One question to be discussed is also when and how to engage governments

Attachment 1

1. *Isn't it very possible that present initiatives will not yield a good vaccine candidate in which case this strategy will not be rewarding?* Yes. Decades after starting the search for an AIDS vaccine, we have not secured one. This strategy does not increase the odds of discovering a vaccine, it merely --- but if successful hugely beneficially --- accelerates the availability of that vaccine if it is discovered.

2. *How substantial is the likelihood that mutations in Covid-19 will undercut the utility of a vaccine?* That is distinctly possible, but most assessments have concluded that the virus is particularly stable, suggesting that immunity from infection or vaccine is likely to be long-lasting. The possibility of mutation argues for the six-month strategy. A longer period between development and distribution exposes us to greater risks from mutation.

3. *What is the six-month goal?* To have production at the level of tens of millions of doses per week by October 15, rapidly ramping up to hundreds of millions of doses per week using multiple facilities.

4. *Can we put in place production capabilities without knowing which of a number of vaccines might establish their value in as yet uncompleted clinical trials?* An RNA vaccine is in a class by itself in both its challenges and its potential. It needs to be addressed separately. Putting that vaccine aside for purposes of this discussion, modern front-end production equipment (vessels, etc.) has high fungibility between the three main forms of production: bacteria, mammalian cells and yeast. Requirements for GMP can in the main be met in advance, particularly if regulators participate in real time rather than review afterwards. Purification requirements are more varied. Fill/finish is relatively straightforward (though there is a risk that capacity could become limiting). A critical first step would be to survey the CMC (chemical, manufacturing and control) executives

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at the enterprises now investigating vaccine candidates to ascertain their intended mode of manufacture. Manufacturing plans could be made accordingly, with a great deal initiated immediately.

5. *Drug companies frequently build production capability before they have an approved product. How is this different?* The principle is the same and the precedent is instructive. But this effort would be unprecedented in scale, scope and timing. The scale required is a production capacity for two to three hundred million doses for just the United States and more than two to three billion doses globally. Moreover, a drug company knows the specific products and processes for which it is building. This effort will have to prepare for manufacture of at least the leading 10 or so candidates and perhaps for many more. Finally, to meet a six-month target, investments will have to be made much earlier in the development cycle than is customary for companies.

6. *Can production capacity be found or created at the scale required?* Some can be created and for an RNA vaccine an entirely new infrastructure would be required. For other types of vaccine, existing infrastructure would have to be reallocated. Some unused capability is readily identifiable. A majority of capacity, however, is likely to come from reallocation of existing facilities from a significant number of companies. Reallocation requires planning and discussion about financial costs and risks (e.g., if flu vaccine capabilities were reallocated to COVID-19). CEPI (Richard Hatchett) has pointed out that early recognition of potential reallocation demands could have the benefit of stimulating some present product to 24/7 production, thereby softening the effects of later reallocation. Discussion and planning is also necessary to establish a regime for sharing IP, financial reward, etc. and for standardizing production. It seems evident, however, that the capacity is there.

7. *Is it possible to assess the safety and efficacy of a vaccine candidate within six months?* It is possible, though not by any means certain. Meeting that target might involve a month for determining a compound and manufacturing it in small quantities for initial trials; two months for initial trials (perhaps a combined Phase 1 and Phase 2) titrating the compound by administering it in varying doses and analyzing blood serum results; and three months for a cohort study or challenge study in lieu of a typical Phase 3 trial. The resulting vaccine might only be approved for certain populations pending a bridge study of, for example, other age groups and a Phase 4 study drawn from evaluation of those who are inoculated.

8. *How would a cohort study work?* Inoculation would be provided to a subset of health care workers in some high attack environments, while a control group would receive a placebo. Statistical analysis would compare results from exposure.

9. *How would human challenge trials work? Are they morally defensible?* We have substantial experience with challenge trials.[ii] Volunteers would have to be informed of the risks and probably would be concentrated in age ranges where risks were lowest.

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The volunteers for this effort would likely be rather like our military servicemembers --- and we regularly accept the morality of putting military volunteers at risk. The most salient hurdle might be in determining the infectious dose with which volunteers would be exposed.

10. *Would this program be international?* That seems highly desirable as a matter of efficiency, production capacity, morality, and US international standing. Even by a narrow definition of American interest, it is in our interest to suppress the disease everywhere. The mechanisms of international cooperation, however, demand attention.

11. *Has a vaccine ever been developed as fast as now proposed?* Yes. During World War II the US developed more than 20 vaccines, some of them at speeds comparable to this. A wartime mentality catalyzes accomplishment by reevaluating risks and investments that are not well advised in peacetime.

12. *Doesn't the World War II experience highlight the risks of speed?* Yes. Notably, for example, an adjuvant for a Yellow Fever vaccine caused 50,000 people to develop jaundice.[iii] Care will need to be taken to minimize risk, but risks must always be weighed against rewards.

13. *Can we generalize to the broader population from challenge trials with a limited range of volunteers?* Efficacy and safety with a healthy younger population may suggest, but would not demonstrate, efficacy in other segments of the population, but it would warrant vaccine production for the population that is tested and intense testing with older populations.

Attachment 2

This document has benefited from discussions with the following. I am grateful for their help, but no one listed below is responsible for this paper's conclusions or errors. The individuals with asterisks next to their names are invited to the March 31 meeting. Those not asterisked can be invaluable participants. It is imperative though to strain to reduce the numbers in an on-line conference call.

1. **Barry Buckland – Executive Director of NIIMBL - former Merck head of BioProcess Development***
2. **Robert Califf, Former Director of FDA and Former Director, Center for Actionable Health Data Science (Duke)***
3. **Michael Callahan – Mass General Hospital, former DARPA Program Manager ***
4. **Richard Danzig – Johns Hopkins Applied Physics Laboratory***
5. **Emilio Emini – Gates Foundation, Previously Director of Wyeth Vaccine Programs (as an observer)***
6. John Erickson – Senior Fellow at NIIMBL – former GSK manufacturing
7. Mark Feinberg – head of IAVI*

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8. **Richard Hatchett – CEPI***
9. Kendall Hoyt – Dartmouth
10. **Marc Lipsitch – Harvard Prof of Public Health Epidemiologist***
11. Dave Robinson – Gates Foundation, Director, CMC Vaccines Development and Surveillance (as an observer)
12. **James Robinson – indep consultant, former Merck, working with CEPI***
13. David Stump – Genentech and Human Genome director of Clinical Trials*
14. **Rajeev Venkayya – Takeda Pharma; respiratory physician***
15. Dick Wilder – CEPI (retired)

Additional people invited to participate in Tuesday call.

1. Luciana Borio, InQTel, former director of National Security Council Directorate for Medical and Biodefense Preparedness; former Chief Scientist at FDA
2. Tom Inglesby, Director, Johns Hopkins Center for Health Security
3. **Tom Kalil, Schmidt Futures (former Deputy Director, Office of Technology Policy)**
4. **Chris Kirchhoff, Schmidt Futures (author of NSC Ebola Review)**
5. **Jason Matheny, former head of the Intelligence Advanced Research Projects Activity)**
6. Mike Osterholm, Director, Center for Infectious Disease Research & Policy, University of Minnesota

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[i] WHO and the Milken Institute have compiled lists of over forty initiatives. CEPI is compiling a more comprehensive list on the order of twice that number.

[ii] See Thomas C. Darton, et al., "Design, Recruitment and Microbiological Considerations in Human Challenge Studies," The Lancet Infectious Diseases (May 2015).

[iii] Kendall Hoyt, Long Shot p. 73.

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From: "Lane, Cliff (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: STEWART SIMONSON <[redacted]@icloud.com>
Subject: Re: attached four or so pages will bring you up to speed as of Tuesday
Date: Sat, 04 Apr 2020 09:25:09 -0400
Importance: Normal

Thanks – the heads-up is helpful.

From: Stewart Simonson <[redacted]@icloud.com>
Date: Saturday, April 4, 2020 at 7:43 AM
To: "Lane, Cliff (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Re: attached four or so pages will bring you up to speed as of Tuesday

Sure thing, Cliff. I spoke with Jeremy Farrar late afternoon yesterday and Victor and he plan to reach out to Tony this weeding, I believe,

S

STEWART SIMONSON
[redacted]@icloud.com

On Apr 3, 2020, at 9:39 PM, Lane, Cliff (NIH/NIAID) [E] <[redacted]@niaid.nih.gov> wrote:

Thanks – I will likely not review with Tony until it is closer to some "event". I did a congressional brief today where this was discussed. I am not sure what type of significant impact this type of document would have.

I really appreciate you reaching out to us.

Cliff

From: Stewart Simonson <[redacted]@icloud.com>
Date: Friday, April 3, 2020 at 2:05 PM
To: "Lane, Cliff (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Fwd: attached four or so pages will bring you up to speed as of Tuesday

Please keep confidential, Cliff.

STEWART SIMONSON
[redacted]@icloud.com

Begin forwarded message:

Released by Chairman Rand Paul

From: Richard Danzig <[redacted]@gmail.com>
Subject: attached four or so pages will bring you up to speed as of Tuesday
Date: April 2, 2020 at 10:12:04 AM EDT
To: Stewart Simonson <[redacted]@icloud.com>
Cc: Richard Hatchett <[redacted]@cepi.net>

Please treat as confidential.
We have moved further.
You will get an email re tomorrow's call - 12:30 Eastern.
Excellent to talk with you as always. Will be even better working with you.*
Richard
* Especially if you do most of the work.

--
Richard Danzig
3670 Upton St. NW
Washington DC 20008

[redacted]@gmail.com
[redacted]

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From: "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Automatic reply: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:07:58 -0400
Importance: Normal

Thanks for your message. I am out of the office until June 4 and will have limited access to email until then. In case of urgency, please call [redacted].

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From: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" <[redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:05:32 -0400
Importance: Normal
Attachments: Select_Recent_Highlights.docx

Hi Larry,

In reviewing the spreadsheet and links, here are two additions:

- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

- NIH and the Gates Foundation also are co-supporting an African Post-Doctoral Training Initiative (APTI) within the intramural program. The Gates Foundation commitment over six years is $2 million. The NIH commitment over that timeframe is $2.2 million

I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] <[redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] <[redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Schwetz, Tara (NIH/NIAID) [E] <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

From: Anthony Fauci <[redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Garbarini, Nicole

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(NIH/OD) [E]" <[redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov> wrote:

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov> wrote:

For reasons I can't currently explain, I need answers to the following:
1) are we giving any grants to BMGF (I assume no)

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2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?

Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.

Questions? Call [redacted]. Getting on a plane in 10 minutes

FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

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Select Recent Highlights
NIH-Bill & Melinda Gates Foundation Cooperation

- **Efficacy studies of two HIV vaccines moving forward**
  - The P5 vaccine efficacy study (HVTN 702), which launched in November 2016 in South Africa, is the first HIV vaccine efficacy study in 7 years
  - The Imbokodo (HVTN 705) study, which launched in November 2017, is a Phase 2b proof-of-concept study evaluating the safety and efficacy of a Ad26 mosaic vaccine and Clade C gp140. The vaccine regimen is based on "mosaic" immunogens — vaccine components designed to induce immune responses against a wide variety of global HIV strains.

- **Evaluation of a novel, long acting injectable antiviral for HIV Prevention**
  - In November 2017, launched Phase III efficacy study (HPTN 084) to compare long-acting cabotegravir to daily Truvada for pre-exposure prophylaxis in HIV-uninfected women.

- **TB Drug development and clinical endpoints**
  - NIAID intramural collaborations with BMGF have contributed to novel clinical markers for treatment response (PET/CT, NexGenNCT02371681) that are now further evaluated in the "PREDICT TB" trial (NCT02821832) to identify patients who may benefit from shortened therapy.
  - NIAID intramural, in collaboration with pharmaceutical partners (GSK, Merck) through the BMGF funded "TB Drug Accelerator" are co-developing novel anti-TB agents that are now entering clinical evaluation.
  - NIAID extramural programs are continuing to contribute to the establishment of best practices and preclinical/clinical evaluation of new drug candidates that are advanced through BMGF funded PDPs.

- **Single-dose HPV vaccine**
  - In early November, NCI participated in high-level meetings at the Gates Foundation to discuss ongoing efforts to evaluate single-dose protection of the HPV vaccines**.**
  - If the hypothesis that one dose can confer strong protection is verified by the results of the trial, these results should enable this approach to be the standard of care and greatly increase HPV vaccination uptake – which currently stands at around 3% of eligible girls in LMICs - throughout the world.
  - In late November, the new Costa Rica Vaccine Trial ("ESCUDDO") started-- the first girls have now been immunized.
  - Additional studies planned to complement Costa Rica Trial; one immunogenicity study built to harmonize with the Costa Rica trial has already been initiated.

- **Contraception**
  - A comprehensive analysis of publicly available gene expression and protein expression data has been performed to identify reproductive-tract specific transcripts/proteins to serve as potential non-hormonal targets for male and/or female contraceptive development.
  - A web-based contraceptive target database containing all pertinent information is in development for public access with a beta version released early to mid-2018.

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- Results from early collaborations in two Grand Challenges Explorations topics related to contraceptive research and development for either men or women anticipated in 2018 and 2019.
  - Successful projects may be integrated into a small, focused program
  - Research resulting from these awards is expected to have a large positive impact on the quality of applications to the NIH in the near-term future

- **Indoor air pollution**

  - Jointly launched RCT of liquefied petroleum gas (LPG) cookstoves and fuel in four LMICs (India, Rwanda, Guatemala and Peru).
  - First large-scale trial to investigate whether home use of cookstoves that run on LPG improve air quality sufficiently to offer measurable health benefits.
  - Enrollment began February 1, 2018.
  - Increased BMGF interest in endpoint of severe pneumonia confirmed by the study team with consolidations in the lungs and/or hypoxemia is leading to potential new designs, including proceeding with the trial as initially proposed, and in parallel, developing local pneumonia surveillance systems in the same localities.

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" <[redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:21:12 -0400
Importance: Normal

Many thanks

Sent from my iPhone

On May 25, 2018, at 9:05 PM, Eiss, Robert (NIH/FIC) [E] <[redacted]@mail.nih.gov> wrote:

Hi Larry,

In reviewing the spreadsheet and links, here are two additions:

- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

- NIH and the Gates Foundation also are co-supporting an African Post-Doctoral Training Initiative (APTI) within the intramural program. The Gates Foundation commitment over six years is $2 million. The NIH commitment over that timeframe is $2.2 million

I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] <[redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] <[redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Schwetz, Tara (NIH/NIAID) [E] <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

Released by Chairman Rand Paul

From: Anthony Fauci <[redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" <[redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

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Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov> wrote:

Dropping FC off.

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With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
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NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

Released by Chairman Rand Paul

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On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov> wrote:

For reasons I can't currently explain, I need answers to the following:
1) are we giving any grants to BMGF (I assume no)
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Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.

Questions? Call [redacted]. Getting on a plane in 10 minutes

FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

<Select Recent Highlights.docx>

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:28:50 -0400
Importance: Normal

Many thanks Rob

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From: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
Date: Friday, May 25, 2018 at 9:05 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>, Anthony Fauci <[redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" <[redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" <[redacted]@nih.gov>
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Released by Chairman Rand Paul

(NIH/NIAID) [E] <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

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https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
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Released by Chairman Rand Paul

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larry

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FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>, "Glass, Roger (NIH/FIC) [E]" <[redacted]@mail.nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 13:36:50 -0400
Importance: Normal

Hi Francis,

I did review and the only additions I offered were the HPV post licensure vaccine trial and the new African postdoctoral fellowship program, to bring more African trainees to our intramural labs.

The group relied on the Gates Foundation awards data base to identify the Foundation's publicly accessible funding commitments for joint projects with NIH. Also, I'm digging out info on the Gates contribution to the WorldReport database maintenance (although this would be modest expenditure compared to the collaborative projects Larry has outlined)

The Gates Foundation and ICs have made parallel investments surrounding some of the NIH/BMGF working group initiatives, but the funding is not easily sourced (e.g., the contraceptive targets database). We would need to confer with ICs to assemble reliable estimates

Based on the intent of the request, I would be happy to provide any additional info that might be of use in your response. As one example, NIH and the Gates Foundation have cooperated in the development of such transformative global health interventions as MenAfriVac and the rapid TB diagnostic- Xpert MTB/RIF. NIH cooperation with the Foundation extends to eleven ICs, etc

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: sábado, 26 de mayo de 2018 12:06 p.m.
To: Eiss, Robert (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Glass, Roger (NIH/FIC) [E]
Subject: RE: Need info on BMGF — Urgent

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] <[redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Released by Chairman Rand Paul

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

Sent from my iPhone

> On May 25, 2018, at 6:46 PM, Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov> wrote:
>
> Looking into this. They provide support for world report along with Wellcome, UK MRC, Canada, European Union. We don't give to Gates.
>
> In past , they fully supported FNIH for malnutrition enteric disease project led by FIC.
>
>
>
> Sent from my iPhone
>
>> On May 25, 2018, at 5:01 PM, Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov> wrote:
>>
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>>
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>>>
>>> FC
>>>
>>> Sent from my iPhone

Released by Chairman Rand Paul

Released by Chairman Rand Paul

From: "Haskins, Melinda (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Automatic reply: POTUS meeting
Date: Mon, 28 May 2018 17:56:00 -0400
Importance: Normal

I am out of the office with only limited access to email. If you require assistance, please contact Sara Selgrade, Ph.D., NIAID OCGR LACMB.

Released by Chairman Rand Paul

From: "Selgrade, Sara (NIH/NIAID) [E]" <[redacted]@nih.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>

Cc: "Haskins, Melinda (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" <[redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" <[redacted]@mail.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>

Subject: Re: POTUS meeting

Date: Mon, 28 May 2018 18:23:24 -0400

Importance: Normal

Dr. Fauci,

Will do.

Have a great evening,
Sara

> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov> wrote:
>
> Melinda/Sara:
> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
> Thanks,
> Tony
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Monday, May 28, 2018 5:40 PM
> To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
> Subject: RE: POTUS meeting
>
> Hi Tony,
>
> Still no more information about the agenda for tomorrow's WH meeting.
>
> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>
> Francis
>
> -----Original Message-----
> From: Fauci, Anthony (NIH/NIAID) [E]
> Sent: Sunday, May 27, 2018 9:31 AM
> To: Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>
> Subject: RE: POTUS meeting
>
> Francis:

Released by Chairman Rand Paul

> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
> Best regards,
> Tony
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Sunday, May 27, 2018 8:52 AM
> To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>
> Subject: POTUS meeting
>
> Hi Tony,
>
> Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.
>
> Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)
>
> Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.
>
> What's the answer to that?
>
> Glad to speak by phone if that would make this easier. [redacted]
>
> Francis
>
> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:02 PM
> To: Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] <[redacted]@nih.gov>
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To: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 19:46:09 -0400
Importance: Normal

Yes. We need someone (? Sara) to go over to VRC in the AM to pick up the prop and then we deliver it to Dr. Collins in Room 126 in Building 1.

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E]
Sent: Monday, May 28, 2018 7:45 PM
To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting

Sorry not sure I understand. I think this is for Francis Colin's to take to the WH meeting. I think we can get someone to pick it up. Is that what you mean?

Sent from my iPhone

> On May 28, 2018, at 6:43 PM, Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov> wrote:
>
> Thanks, Barney.
>
> -----Original Message-----
> From: Graham, Barney (NIH/VRC) [E]
> Sent: Monday, May 28, 2018 6:29 PM
> To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
> Cc: Haskins, Melinda (NIH/NIAID) [E] <[redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] <[redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] <[redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] <[redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
> Subject: Re: POTUS meeting
>
> I'll be in my office by 7 am tomorrow and have them packed.
>
> Barney
>
>
>
> Sent from my iPhone
>
>> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov> wrote:
>>
>> Melinda/Sara:
>> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
>> Thanks,
>> Tony
>>
>> -----Original Message-----

Released by Chairman Rand Paul

>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Monday, May 28, 2018 5:40 PM
>> To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Hi Tony,
>>
>> Still no more information about the agenda for tomorrow's WH meeting.
>>
>> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>>
>> Francis
>>
>> -----Original Message-----
>> From: Fauci, Anthony (NIH/NIAID) [E]
>> Sent: Sunday, May 27, 2018 9:31 AM
>> To: Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Francis:
>> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
>> Best regards,
>> Tony
>>
>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Sunday, May 27, 2018 8:52 AM
>> To: Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>
>> Subject: POTUS meeting
>>
>> Hi Tony,
>>
>> Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.
>>
>> Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)
>>
>> Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.
>>
>> What's the answer to that?
>>
>> Glad to speak by phone if that would make this easier. [redacted]
>>

Released by Chairman Rand Paul

>> Francis
>>
>> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
>>
>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Friday, May 25, 2018 5:02 PM
>> To: Glass, Roger (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] <[redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <[redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] <[redacted]@nih.gov>
>> Subject: Re: Need info on BMGF — Urgent
>>
>> Just spoke with Larry, he has the full scoop
>>
>> Sent from my iPhone
>>
>>> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov> wrote:
>>>
>>> For reasons I can't currently explain, I need answers to the following:
>>> 1) are we giving any grants to BMGF (I assume no)
>>> 2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?
>>>
>>> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.
>>>
>>> Questions? Call [redacted]. Getting on a plane in 10 minutes
>>>
>>> FC
>>>
>>> Sent from my iPhone

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2009-0021	CTA - Clinical Trial Agreement	7/1/2009		Baxter Healthcare Corporation	Steven Holland
2009-0207	CRADA	7/13/2009		Chimerix, Inc.	Jeffrey Cohen
2009-0229	CRADA	8/22/2009	8/22/2023	Lexicon Pharmaceuticals, Inc.	Thomas Leto
2009-0547	CTA - Clinical Trial Agreement	10/26/2009		Ception Therapeutics (acq Cephalon/Teva Pharmaceutical Industries) [US]	Amy Klion
2009-0573	CTA - Clinical Trial Agreement	10/19/2009		Genentech, Inc.	Melody Carter
2009-0577	Letter of Intent/MOU	8/17/2009		Massachusetts General Hospital (MGH; General Hospital Corp.)	
2009-0577	Letter of Intent/MOU	8/17/2009		Massachusetts General Hospital (MGH; General Hospital Corp.)	
2009-0624	Research Collaboration Agreement	6/19/2012	8/18/2016	University of Texas Health Center at Tyler	Adrian Zelazny
2009-0763	CTA - Clinical Trial Agreement	11/30/2009		NexBio, Inc.	Richard Davey
2009-0910	Letter of Intent/MOU	12/18/2009		Stanford University (Leland Stanford Junior University), University of Rochester	Kanta Subbarao
2009-0929	Gift	3/9/2010		Center for Infectious Disease Research (CID) (Formerly Seattle Biomed) (Merged w	Patrick Duffy
2009-0953	Gift	2/29/2016	7/31/2016	Massachusetts General Hospital (MGH; General Hospital Corp.)	Clifton Barry
2009-0953	Gift	2/29/2016	7/31/2016	Massachusetts General Hospital (MGH; General Hospital Corp.)	Clifton Barry
2010-0133	Research Collaboration Agreement	6/15/2010		Australian Nuclear Science and Technology Organisation [AU]	
2010-0133	Research Collaboration Agreement	6/15/2010		Australian Nuclear Science and Technology Organisation [AU]	
2010-0151	Research Collaboration Agreement	6/12/2015	6/21/2018	University of Wisconsin-Madison [US]	Heinrich Feldmann
2010-0278	CRADA	9/30/2010	9/30/2018	Hawaii Biotech, Inc.	Stephen Leppla
2010-0291	Gift	4/28/2010		Bill & Melinda Gates Foundation (BMGF)	
2010-0291	Gift	4/28/2010		Bill & Melinda Gates Foundation (BMGF)	
2010-0432	Research Collaboration Agreement	8/15/2014	8/23/2018	National Institute of Agricultural Technology (INTA; Instituto Nacional de Tecno	
2010-0432	Research Collaboration Agreement	8/15/2014	8/23/2018	National Institute of Agricultural Technology (INTA; Instituto Nacional de Tecno	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2010-0434	Gift	2/15/2012	6/30/2017	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry
2010-0443	CTA - Clinical Trial Agreement	8/20/2010		Adamas Pharmaceuticals, Inc.	Richard Davey
2010-0488	Research Collaboration Agreement	2/26/2014	7/27/2017	Medical Research Council (MRC) [GB]	Patrick Duffy
2010-0612	CTA - Clinical Trial Agreement	1/26/2011		Genzyme (acq by Sanofi 2/16/2011) [US]	David McDermott
2010-0612	CTA - Clinical Trial Agreement	1/26/2011		Genzyme (acq by Sanofi 2/16/2011) [US]	David McDermott
2010-0639	CRADA	1/7/2011	1/7/2020	Amgen Inc.	Ulrich Siebenlist
2010-0676	CTA - Clinical Trial Agreement	10/8/2010		Romark Laboratories, L.C.	Shyamasundaran
2010-0751	CRADA	12/12/2011	12/12/2018	PaxVax, Inc. (aquired by Emergent BioSolutions 10/04/2018)	Mark Connors
2010-0754	Gift	11/12/2010		National Psoriasis Foundation	
2010-0754	Gift	11/12/2010		National Psoriasis Foundation	
2010-0806	Gift	11/3/2010		Bill & Melinda Gates Foundation (BMGF)	Harlan Caldwell
2011-0072	Research Collaboration Agreement	6/21/2010		Netherlands Cancer Institute (NKI) [NL]	Jonathan (Jon) Ye
2011-0143	CTA - Clinical Trial Agreement	4/22/2011		NexBio, Inc.	Richard Davey
2011-0290	CTA - Clinical Trial Agreement	10/6/2011		Pharmasset (bought by Gilead 11/2011)	Shyamasundaran
2011-0381	CRADA	5/4/2015	7/21/2017	Microbiotix, Inc.	Sanjay Desai
2011-0419	CTA - Clinical Trial Agreement	6/2/2011		Jenner Institute [GB], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Ruth Ellis
2011-0468	Research Collaboration Agreement	8/9/2011	8/9/2024	Walter Reed Army Institute of Research (WRAIR) (DoD)	
2011-0468	Research Collaboration Agreement	8/9/2011	8/9/2024	Walter Reed Army Institute of Research (WRAIR) (DoD)	
2011-0469	CTA - Clinical Trial Agreement	8/21/2012		Johns Hopkins Bloomberg School of Public Health (JHU), PATH (Program for Appropriate Technology in Health)	
2011-0469	CTA - Clinical Trial Agreement	8/21/2012		Johns Hopkins Bloomberg School of Public Health (JHU), PATH (Program for Appropriate Technology in Health)	
2011-0469	CTA - Clinical Trial Agreement	8/21/2012		Johns Hopkins Bloomberg School of Public Health (JHU), PATH (Program for Appropriate Technology in Health)	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2011-0555	CTA - Clinical Trial Agreement	4/30/2012		Merck Sharp & Dohme Corp	Shyamasundaran
2011-0571	Gift	2/10/2012		Bill & Melinda Gates Foundation (BMGF), Bouisson Bertrand Institute (Institut Bouisson Bertrand -IBB) [FR]	Thomas Nutman
2011-0571	Gift	2/10/2012		Bill & Melinda Gates Foundation (BMGF), Bouisson Bertrand Institute (Institut Bouisson Bertrand -IBB) [FR]	Thomas Nutman
2011-0571	Gift	2/10/2012		Bouisson Bertrand Institute (Institut Bouisson Bertrand -IBB) [FR]	Thomas Nutman
2011-0571	Gift	2/10/2012		Bouisson Bertrand Institute (Institut Bouisson Bertrand -IBB) [FR]	Thomas Nutman
2011-0629	Research Collaboration Agreement	8/8/2011	8/8/2016	National Center for Parasitology, Entomology and Malaria Control (CNM) [KH]	
2011-0629	Research Collaboration Agreement	8/8/2011	8/8/2016	National Center for Parasitology, Entomology and Malaria Control (CNM) [KH]	
2011-0629	Research Collaboration Agreement	8/8/2011	8/8/2016	National Center for Parasitology, Entomology and Malaria Control (CNM) [KH]	
2011-0705	CRADA	12/13/2012	12/13/2023	Sanofi US Services Inc.	Jeffrey Cohen
2011-0729	CRADA	9/17/2012	9/17/2023	Boehringer Ingelheim Pharmaceuticals, Inc.	Ethan Shevach
2011-0776	Gift	9/26/2011		Cancer Research Institute [US]	
2011-0776	Gift	9/26/2011		Cancer Research Institute [US]	
2011-0828	Research Collaboration Agreement	12/1/2011	12/1/2016	Merck Sharp & Dohme Corp	
2011-0828	Research Collaboration Agreement	12/1/2011	12/1/2016	Merck Sharp & Dohme Corp	
2011-0906	CRADA	6/14/2012	6/14/2017	VSL Pharmaceuticals [US]	Thomas Wynn
2011-1444	CRADA	10/5/2012	10/5/2017	GeoVax, Inc.	Bernard Moss
2011-19356	Research Collaboration Agreement	6/27/2012		Foundation for the National Institutes of Health, Inc. (FNIH), iThemba Pharmaceuticals (Pty) Ltd [ZA], Stellenbosch University (Universiteit Stellenbosch) [ZA], University of Cambridge (The Chancellor, Masters, and Scholars of the Universit, University of Cape Town (UCT) [ZA], University of Dundee [GB], University of the Witwatersrand (Wits University) [ZA]	Clifton Barry

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2011-19356	Research Collaboration Agreement	6/27/2012		Foundation for the National Institutes of Health, Inc. (FNIH), iThemba Pharmaceuticals (Pty) Ltd [ZA], Stellenbosch University (Universiteit Stellenbosch) [ZA], University of Cambridge (The Chancellor, Masters, and Scholars of the Universit, University of Cape Town (UCT) [ZA], University of Dundee [GB], University of the Witwatersrand (Wits University) [ZA]	Clifton Barry
2011-2272	Research Collaboration Agreement	7/6/2012	3/31/2017	RIKEN Research Center for Allergy and Immunology (RCAI) [JP]	Ronald Germain
2011-2853	CTA - Clinical Trial Agreement	4/16/2012		Quintiles, Inc., Tobira Therapeutics	Irini Sereti
2011-6009	Gift	12/5/2011		US Fish and Wildlife Service, Department of the Interior	Ronald Germain
2011-8242	Research Collaboration Agreement	4/17/2012	4/17/2023	Merck Sharp & Dohme Corp	Michael Lenardo
2012_32517	CRADA	4/15/2014	10/5/2017	GeoVax, Inc.	Bernard Moss
2012-0095	Gift	2/17/2012		Jane Coffin Childs Memorial Fund for Medical Research	Ronald Germain
2012-0112	Gift	7/19/2012	3/31/2017	RIKEN (The Institute of Physical and Chemical Research) [JP], RIKEN Research Center for Allergy and Immunology (RCAI) [JP]	Ronald Germain
2012-0222	Gift	3/5/2012		American Asthma Foundation [US]	Joshua Milner
2012-0245	Gift	7/19/2012	3/31/2024	RIKEN (The Institute of Physical and Chemical Research) [JP], RIKEN Research Center for Allergy and Immunology (RCAI) [JP]	Ronald Germain
2012-0245	Gift	7/19/2012	3/31/2024	RIKEN (The Institute of Physical and Chemical Research) [JP]	Ronald Germain
2012-0245	Gift	7/19/2012	3/31/2024	RIKEN (The Institute of Physical and Chemical Research) [JP], RIKEN Research Center for Allergy and Immunology (RCAI) [JP]	Ronald Germain
2012-0324	CRADA	1/8/2014	1/8/2017	Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2012-0447	CTA - Clinical Trial Agreement	6/21/2012		Gilead Sciences, Inc	
2012-0447	CTA - Clinical Trial Agreement	6/21/2012		Gilead Sciences, Inc	
2012-0448	CTA - Clinical Trial Agreement	8/23/2012		Gilead Sciences, Inc	Shyamasundaran

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2012-1951	CTA - Clinical Trial Agreement	2/12/2013		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2012-1951	CTA - Clinical Trial Agreement	2/12/2013		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2012-1951	CTA - Clinical Trial Agreement	2/12/2013		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2012-2154	CTA - Clinical Trial Agreement	6/21/2012	6/21/2017	Gilead Sciences, Inc	
2012-2154	CTA - Clinical Trial Agreement	6/21/2012	6/21/2017	Gilead Sciences, Inc	
2012-2176	CTA - Clinical Trial Agreement	6/21/2012	6/21/2017	Gilead Sciences, Inc	Colleen Hadigan
2012-2177	CTA - Clinical Trial Agreement	8/1/2012		Gilead Sciences, Inc	Colleen Hadigan
2012-2404	Research Collaboration Agreement	6/29/2012		Cancer Research Institute - Scott and White Healthcare	Stephen Leppla
2012-2460	Gift	9/7/2012	4/30/2018	University of Pittsburgh	Clifton Barry
2012-2460	Gift	9/7/2012	4/30/2018	University of Pittsburgh	Clifton Barry
2012-2460	Gift	9/7/2012	4/30/2018	University of Pittsburgh	Clifton Barry
2012-2460	Gift	9/7/2012	4/30/2018	University of Pittsburgh	Clifton Barry
2012-2470	CRADA	4/25/2014	4/25/2018	Janssen Research and Development, Inc. (formerly Johnson & Johnson Pharmaceutica, National Cancer Institute (NCI/NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK/NIH), National Institute on Aging (NIA/NIH)	Yasmine Belkaid
2012-2476	CRADA	1/18/2013	1/18/2018	Amgen Inc.	Ulrich Siebenlist
2012-2513	Gift	10/10/2012	12/31/2024	Foundation for the National Institutes of Health, Inc. (FNIH), National Institute of Allergy and Infectious Diseases (NIAID/NIH)	Thomas Nutman
2012-2513	Gift	10/10/2012	12/31/2024	Foundation for the National Institutes of Health, Inc. (FNIH)	Theodore Nash
2012-2636	Gift	3/26/2015	11/1/2018	Bill & Melinda Gates Foundation (BMGF)	David Sacks
2012-2636	Gift	3/26/2015	11/1/2018	Bill & Melinda Gates Foundation (BMGF)	David Sacks
2012-2639	CTA - Clinical Trial Agreement	8/6/2012		St. Jude Children's Research Hospital	Suk See De Ravin

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2012-2643	Gift	2/4/2013		Novartis Institute for Tropical Diseases [SG]	Clifton Barry
2012-2646	Research Collaboration Agreement	8/27/2012	10/17/2016	Tufts University [US]	Stephen Leppla
2012-2726	Research Collaboration Agreement	8/7/2013	10/2/2016	Bayer Pharma AG [DE]	Clifton Barry
2012-2731	Letter of Intent/MOU	8/16/2012		Children's National Medical Center (CNMC) [US]	Thomas Wynn
2012-2769	Letter of Intent/MOU	8/22/2012		Chiba University [JP]	Alan Sher
2012-2772	CTA - Clinical Trial Agreement	5/25/2013		Profectus Biosciences, Inc.	
2012-2772	CTA - Clinical Trial Agreement	5/25/2013		Profectus Biosciences, Inc.	
2012-2912	CTA - Clinical Trial Agreement	12/20/2012		Sarepta Therapeutics, Inc.	Richard Davey
2012-2968	Letter of Intent/MOU	7/19/2012	9/30/2018	US Army Medical Research and Materiel Command (USAMRMC) (DoD)	H Clifford Lane
2012-2980	CTA - Clinical Trial Agreement	3/13/2014		Bristol-Myers Squibb Company (BMS)	Shyamasundaran
2012-2988	Gift	2/22/2016	6/1/2017	Foundation for the National Institutes of Health, Inc. (FNIH), New York Blood Center, Thomas Jefferson University, University of Buea [CM]	Thomas Nutman
2012-2988	Gift	2/22/2016	6/1/2017	Foundation for the National Institutes of Health, Inc. (FNIH), New York Blood Center, Thomas Jefferson University, University of Buea [CM]	Thomas Nutman
2012-3096	CTA - Clinical Trial Agreement	4/24/2013		Synta Pharmaceuticals Corporation	Jeffrey Cohen
2013_32496	Research Collaboration Agreement	7/24/2012	7/24/2016	University of South Florida	Thomas Wellems
2013_32496	Research Collaboration Agreement	7/24/2012	7/24/2016	University of South Florida	Thomas Wellems
2013_32503	CRADA	4/29/2014	1/7/2017	Amgen Inc.	Ulrich Siebenlist
2013-0001	Gift	2/22/2013		American Asthma Foundation [US]	Joshua Milner
2013-0042	CRADA	4/18/2013	4/18/2019	GlaxoSmithKline (GSK)	Irini Sereti
2013-0097	Research Collaboration Agreement	11/7/2013		Piramal Enterprises Limited [IN]	Clifton Barry
2013-0097	Research Collaboration Agreement	11/7/2013		Piramal Enterprises Limited [IN]	Clifton Barry
2013-0158	CTA - Clinical Trial Agreement	8/28/2013		Genentech, Inc.	Sarah Browne
2013-0207	CRADA	9/3/2014	9/3/2016	Gilead Sciences, Inc	Shyamasundaran

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Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2013-0223	Letter of Intent/MOU	4/22/2013		Bill & Melinda Gates Foundation (BMGF), Center for Infectious Disease Research (CID) (Formerly Seattle Biomed) (Merged w, Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF;, Johns Hopkins Bloomberg School of Public Health (JHU), Naval Medical Research Center (NMRC) (DoD), PATH (Program for Appropriate Technology in Health), Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2013-0309	Gift	6/20/2013	6/20/2016	PATH (Program for Appropriate Technology in Health)	Patrick Duffy
2013-0378	CRADA	12/4/2014	12/4/2017	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Kanta Subbarao
2013-0378	CRADA	12/4/2014	12/4/2017	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Kanta Subbarao
2013-0449	Research Collaboration Agreement	9/30/2013	8/30/2016	WELLCOME TRUST SANGER INSTITUTE [GB]	Thomas Wellems
2013-0449	Research Collaboration Agreement	9/30/2013	8/30/2016	WELLCOME TRUST SANGER INSTITUTE [GB]	Thomas Wellems
2013-0510	CRADA	9/18/2013	9/18/2016	GlaxoSmithKline LLC (GSK)	Helene Rosenberg
2013-0524	Research Collaboration Agreement	2/24/2016	7/23/2016	INSTITUT PASTEUR OF SHANGHAI [CN]	Karin Peterson
2013-0566	Research Collaboration Agreement	6/26/2013	6/13/2020	Georgetown University School of Medicine [US]	Lisbeth Kim Green
2013-0567	CRADA	1/9/2014	7/9/2017	Vivaldi Biosciences, Inc.	Kanta Subbarao
2013-0594	CRADA	8/20/2013	8/20/2017	Novo Nordisk A/S [DK]	Michael Lenardo
2013-0596	Research Collaboration Agreement	2/9/2015	2/9/2020	Etna Biotech S.r.l.	Jesus Valenzuela
2013-0655	Letter of Intent/MOU	6/26/2013		Beth Israel Deaconess Medical Center (BIDMC)	
2013-0688	Research Collaboration Agreement	10/1/2013	10/7/2017	Merck Sharp & Dohme Corp	Michael Lenardo
2013-0695	CRADA	12/27/2013	12/26/2022	Knopp Biosciences LLC [US]	Amy Klion
2013-0697	CRADA	2/24/2014	2/24/2019	MedImmune, LLC. (acq by AstraZeneca in 6/2007)	Amy Klion
2013-0721	CTA - Clinical Trial Agreement	10/3/2013		Romark Laboratories, L.C.	Richard Davey
2013-0743	Research Collaboration Agreement	7/25/2013	7/25/2018	Walter Reed National Military Medical Center (WRNMMC) (DoD)	Daniel Douek
2013-0783	Gift	1/29/2016	8/31/2016	Banaras Hindu University [IN], Foundation for the National Institutes of Health, Inc. (FNIH)	David Sacks
2013-0810	CRADA	7/5/2016	7/5/2028	Sanofi US Services Inc.	Peter Collins
2013-0810	CRADA	7/5/2016	7/5/2028	Sanofi US Services Inc.	Peter Collins

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2013-0810	CRADA	7/5/2016	7/5/2028	Sanofi US Services Inc.	Ursula Buchholz
2013-0836	CTA - Clinical Trial Agreement	1/17/2014		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Sara Healy
2013-0836	CTA - Clinical Trial Agreement	1/17/2014		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Sara Healy
2013-0836	CTA - Clinical Trial Agreement	1/17/2014		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Sara Healy
2013-0871	Research Collaboration Agreement	6/26/2014	6/26/2016	Genocea Biosciences, Inc.	Peter Crompton
2013-0874	CRADA	1/4/2016	1/27/2017	EMD Serono Research & Development Institute	Roshanak Semnan
2013-0874	CRADA	1/4/2016	1/27/2017	EMD Serono Research & Development Institute	Roshanak Semnan
2013-0943	Research Collaboration Agreement	9/4/2013	9/5/2018	University of Sao Paulo (Universidade de São Paulo) (USP) [BR]	Jose Ribeiro
2013-1017	CTA - Clinical Trial Agreement	6/24/2014		GlaxoSmithKline PLC (formerly Glaxo Wellcome PLC) (GSK) [GB]	Amy Klion
2013-1017	CTA - Clinical Trial Agreement	6/24/2014		GlaxoSmithKline PLC (formerly Glaxo Wellcome PLC) (GSK) [GB]	Amy Klion
2013-1084	Research Collaboration Agreement	4/18/2014		DNA 2.0	Stephen Leppla
2013-1107	Research Collaboration Agreement	2/9/2015	2/10/2017	J. Craig Venter Institute	Bernard Moss
2013-1112	Gift	11/13/2015	8/31/2017	University of South Florida	
2013-1112	Gift	11/13/2015	8/31/2017	University of South Florida	
2013-1156	Research Collaboration Agreement	2/28/2014	2/28/2018	University of North Carolina at Chapel Hill	Edward Berger
2013-1175	Letter of Intent/MOU	3/13/2023	5/2/2026	Crucell Holland, B.V. (acq by Johnson & Johnson in 2011; J&J; Janssen Research a, Fred Hutchinson Cancer Research Center (FHCRC) [US]	Mary Marovich
2013-1217	CRADA	11/13/2013	7/23/2020	Crucell Vaccines Institute (part of Johnson & Johnson; J&J)	Jeffery Taubenber
2013-1217	CRADA	11/13/2013	7/23/2020	Crucell Vaccines Institute (part of Johnson & Johnson; J&J), Janssen Vaccines & Prevention B.V. (part of Johnson & Johnson; J&J) [NL]	Jeffery Taubenber
2013-1217	CRADA	11/13/2013	7/23/2020	Crucell Vaccines Institute (part of Johnson & Johnson; J&J)	Jeffery Taubenber

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2013-1217	CRADA	11/13/2013	7/23/2020	Crucell Vaccines Institute (part of Johnson & Johnson; J&J), Janssen Vaccines & Prevention B.V. (part of Johnson & Johnson; J&J) [NL]	Jeffery Taubenber
2013-1242	Research Collaboration Agreement	3/26/2014	8/26/2019	National Jewish Health [US]	Amy Klion
2013-1269	Gift	6/3/2014	6/3/2024	Animal Health Centre, British Columbia Ministry of Agriculture [CA]	Michael Grigg
2013-1269	Gift	6/3/2014	6/3/2024	Animal Health Centre, British Columbia Ministry of Agriculture [CA]	
2013-1269	Gift	6/3/2014	6/3/2024	Animal Health Centre, British Columbia Ministry of Agriculture [CA]	Michael Grigg
2013-1289	Gift	3/11/2014	7/31/2017	PATH (Program for Appropriate Technology in Health)	Patrick Duffy
2013-1299	Gift	4/22/2014	4/22/2021	Sanofi US Services Inc.	Carolina Barillas-M
2013-1307	Gift	7/21/2014	6/30/2019	Foundation for the National Institutes of Health, Inc. (FNIH)	Jeffrey Cohen
2013-1323	Research Collaboration Agreement	6/16/2016	6/16/2018	Cell Signaling Technology, Inc.	Michael Lenardo
2014-0038	CRADA	10/28/2014	10/18/2022	Sanofi US Services Inc.	
2014-0038	CRADA	10/28/2014	10/18/2022	Sanofi US Services Inc.	
2014-0150	Research Collaboration Agreement	8/25/2014	8/25/2017	Boston Children's Hospital	Jeffrey Cohen
2014-0181	Research Collaboration Agreement	12/10/2014	10/1/2017	London School of Hygiene & Tropical Medicine (LSHTM) (University of London) [GB]	David Sacks
2014-0200	Research Collaboration Agreement	10/29/2014		GE Healthcare	Peter Jahrling
2014-0201	Research Collaboration Agreement	6/26/2014	6/26/2016	Novartis Vaccines Institute for Global Health [IT]	Patrick Duffy
2014-0206	CTA - Clinical Trial Agreement	5/15/2014		Genethon [FR]	Harry Malech
2014-0227	Research Collaboration Agreement	9/15/2014	9/15/2017	University of Texas Southwestern Medical Center	Konrad Krzewski
2014-0244	Research Collaboration Agreement	8/29/2014	8/29/2017	Baylor College of Medicine	Jeffrey Cohen
2014-0304	Research Collaboration Agreement	6/20/2014	6/20/2016	Cornell University	DAVID NARUM
2014-0304	Research Collaboration Agreement	6/20/2014	6/20/2016	Cornell University	DAVID NARUM
2014-0304	Research Collaboration Agreement	6/20/2014	6/20/2016	Cornell University	DAVID NARUM
2014-0369	Research Collaboration Agreement	11/19/2014		University of Pittsburgh	Sarthak Gupta
2014-0369	Research Collaboration Agreement	11/19/2014		University of Pittsburgh	Sarthak Gupta
2014-0393	Research Collaboration Agreement	8/25/2014	8/25/2023	PATH (Program for Appropriate Technology in Health)	Thomas Nutman
2014-0455	Research Collaboration Agreement	10/20/2014	10/20/2016	Mymetics Corporation [CH]	Patrick Duffy

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2014-0457	Gift	12/18/2014	12/18/2016	PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2014-0462	Research Collaboration Agreement	9/23/2014		University of Hawaii [US]	Peter Jahrling
2014-0594	Gift	3/17/2015	7/30/2016	Alliance BioSecure Foundation [FR]	Byron Caughey
2014-0770	Research Collaboration Agreement	1/14/2015	12/1/2016	Genentech, Inc.	Thomas Wynn
2014-0805	Gift	11/5/2014	6/30/2016	Bill & Melinda Gates Foundation (BMGF), Johns Hopkins University (JHU)	Stephen Whitehea
2014-0924	CTA - Clinical Trial Agreement	10/6/2014		Sanofi US Services Inc.	Philip Murphy
2014-0924	CTA - Clinical Trial Agreement	10/6/2014		Sanofi US Services Inc.	Philip Murphy
2014-1039	Gift	9/16/2014	12/31/2018	Foundation for the National Institutes of Health, Inc. (FNIH), Pew Charitable Trusts [US]	Michael Grigg
2014-1039	Gift	9/16/2014	12/31/2018	Foundation for the National Institutes of Health, Inc. (FNIH), Pew Charitable Trusts [US]	Michael Grigg
2014-1121	Research Collaboration Agreement	7/31/2014		University of Wisconsin System (Board of Regents) [US]	Peter Jahrling
2014-1213	CRADA	5/12/2015	5/12/2017	Gilead Sciences, Inc	Kim Hasenkrug
2014-24474	CRADA	5/4/2015		Pfizer, Inc.	Thomas Wynn
2014-24499	Gift	8/20/2015		Foundation for the National Institutes of Health, Inc. (FNIH)	Steven Holland
2014-24501	CRADA	9/9/2014	9/9/2019	Biogen Idec, Inc.	Kathryn Zoon
2014-24515	Research Collaboration Agreement	10/16/2014	10/16/2019	La Jolla Institute for Allergy & Immunology	Thomas Nutman
2014-24537	Research Collaboration Agreement	12/5/2014	12/5/2019	National University of Singapore [SG]	Jose Ribeiro
2014-24562	Research Collaboration Agreement	1/23/2015	1/23/2020	Kansas State University	Peter Jahrling
2014-24572	Research Collaboration Agreement	1/30/2015	1/24/2024	Otsuka Pharmaceutical Co., Ltd. [JP]	
2014-24572	Research Collaboration Agreement	1/30/2015	1/24/2024	Otsuka Pharmaceutical Co., Ltd. [JP]	Clifton Barry
2014-24614	CTA - Clinical Trial Agreement	9/10/2014		Global Solutions for Infectious Diseases [US], PaxVax, Inc. (aquired by Emergent BioSolutions 10/04/2018)	Mark Connors
2014-24630	CRADA	2/15/2015	2/15/2019	Millennium Pharmaceuticals, Inc.	Alan Sher
2014-24674	CTA - Clinical Trial Agreement	10/6/2014		NewLink Genetics Corporation [US]	Richard Davey
2014-24680	CRADA	1/18/2016	1/18/2021	NOVARTIS PHARMA AG	Steven Holland
2014-24722	Research Collaboration Agreement	12/10/2014	12/10/2019	MacroGenics, Inc.	Tae Wook Chun
2014-24757	CRADA	5/22/2015	5/22/2018	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Michael Lenardo
2014-24759	CRADA	6/12/2015	6/12/2025	Novartis Pharmaceuticals Corporation [US]	Michael Lenardo

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2014-24759	CRADA	6/12/2015	6/12/2025	Pharming Technologies B.V.	Michael Lenardo
2014-24759	CRADA	6/12/2015	6/12/2025	Novartis Pharmaceuticals Corporation [US]	Michael Lenardo
2014-24778	Gift	11/2/2014		European Commission [EU]	Stephen Leppla
2014-24849	Letter of Intent/MOU	12/3/2014		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	
2014-24849	Letter of Intent/MOU	12/3/2014		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	
2014-24864	Gift	1/5/2015	1/1/2018	Cancer Research Institute [US]	Yasmine Belkaid
2014-24864	Gift	1/5/2015	1/1/2018	Cancer Research Institute [US]	Yasmine Belkaid
2014-24889	Research Collaboration Agreement	10/29/2014	10/28/2017	Pisces Therapeutics, LLC	Dean Metcalfe
2014-24902	Research Collaboration Agreement	10/23/2015	10/23/2017	Codagenix Inc.	Jeffrey Cohen
2014-24914	Research Collaboration Agreement	9/19/2015	9/19/2017	La Jolla Institute for Allergy & Immunology	Pamela Guerrerio
2014-24929	Research Collaboration Agreement	6/27/2015	6/27/2018	University of California-San Francisco (UCSF)	Steven Holland
2014-24940	Research Collaboration Agreement	1/11/2016	1/11/2019	Johns Hopkins Medicine (JHM)	Pamela Guerrerio
2014-24971	Research Collaboration Agreement	2/4/2016		WCCT Global	Mathew Memoli
2014-24971	Research Collaboration Agreement	2/4/2016		WCCT Global	Mathew Memoli
2014-25076	CTA - Clinical Trial Agreement	6/4/2015		Massachusetts General Hospital (MGH; General Hospital Corp.)	Colleen Hadigan
2014-25098	Research Collaboration Agreement	5/6/2016	5/6/2019	Naval Medical Research Center (NMRC) (DoD), Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2014-25111	Letter of Intent/MOU	12/16/2014		United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Heinrich Feldmann
2014-25138	Research Collaboration Agreement	4/13/2015	4/13/2020	GeoVax, Inc.	
2014-25138	Research Collaboration Agreement	4/13/2015	4/13/2020	GeoVax, Inc.	
2014-25148	Research Collaboration Agreement	1/29/2015		Google [US]	Martin Meier-Sche
2014-25148	Research Collaboration Agreement	1/29/2015		Google [US]	Martin Meier-Sche
2014-25153	Research Collaboration Agreement	12/21/2014	12/21/2017	BioAegis Therapeutics, Inc., NIH Clinical Center (CC/NIH)	Kol ZAREMBER
2014-25157	Letter of Intent/MOU	4/7/2015		Bill & Melinda Gates Foundation (BMGF)	David Sacks
2014-25168	Gift	3/23/2015	7/1/2016	American Academy of Allergy Asthma and Immunology	Jonathan Lyons
2014-25218	CTA - Clinical Trial Agreement	1/21/2015		GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]	H Clifford Lane
2014-25228	Research Collaboration Agreement	5/4/2015		Biocartis	Peter Jahrling

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2014-25231	CRADA	11/21/2016	11/21/2019	NovaDigm Therapeutics, Inc. [US]	Steven Holland
2014-25232	CTA - Clinical Trial Agreement	2/19/2015		MERCK SHARP AND DOHME RESEARCH LABS.	H Clifford Lane
2014-25261	Research Collaboration Agreement	1/12/2015	1/8/2025	Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2014-25261	Research Collaboration Agreement	1/12/2015	1/8/2025	Regeneron Pharmaceuticals, Inc.	
2014-25261	Research Collaboration Agreement	1/12/2015	1/8/2025	Regeneron Pharmaceuticals, Inc.	
2014-25261	Research Collaboration Agreement	1/12/2015	1/8/2025	Regeneron Pharmaceuticals, Inc.	
2014-25261	Research Collaboration Agreement	1/12/2015	1/8/2025	Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2014-25285	Gift	3/13/2015		Tradition Foundation	Byron Caughey
2014-25288	CTA - Clinical Trial Agreement	3/10/2015		MAPP BIOPHARMACEUTICAL, INC.	Richard Davey
2014-25299	Gift	5/7/2015	6/25/2016	American Academy of Allergy Asthma and Immunology	Pamela Guerrerio
2014-25305	CRADA	9/7/2015	9/7/2018	GlaxoSmithKline Investigacion y Desarrollo (GSK) [ES]	Clifton Barry
2014-25326	CRADA	9/28/2015	9/28/2021	Merck Sharp & Dohme Corp	
2014-25326	CRADA	9/28/2015	9/28/2021	Merck Sharp & Dohme Corp	Michael Lenardo
2014-25326	CRADA	9/28/2015	9/28/2021	Merck Sharp & Dohme Corp	Michael Lenardo
2014-25326	CRADA	9/28/2015	9/28/2021	Merck Sharp & Dohme Corp	
2014-25327	Research Collaboration Agreement	4/17/2015	4/17/2018	Third Medical University [CN]	
2014-25327	Research Collaboration Agreement	4/17/2015	4/17/2018	Third Medical University [CN]	
2015-25099	Research Collaboration Agreement	1/15/2016	1/15/2018	Selecta Biosciences	Patrick Duffy
2015-25129	CTA - Clinical Trial Agreement	4/30/2015		Aquarius Biotechnologies Inc. (purchased by Matinas Biopharma) [US]	
2015-25149	Gift	8/3/2015	4/1/2019	Cancer Research Institute [US]	
2015-25149	Gift	8/3/2015	4/1/2019	Cancer Research Institute [US]	
2015-25153	Letter of Intent/MOU	1/29/2015		University of Minho (Universidade do Minho) [PT]	Michael Otto
2015-25172	CRADA	10/29/2015	1/15/2023	Bristol-Myers Squibb Company (BMS)	Peter Sun
2015-25194	Research Collaboration Agreement	7/22/2015	7/22/2018	GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]	Patrick Duffy
2015-25197	CTA - Clinical Trial Agreement	2/13/2015		GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]	H Clifford Lane
2015-25249	Letter of Intent/MOU	2/18/2015		University of Michigan	Michael Otto
2015-25269	Gift	4/30/2015		Harvard University (The President and Fellows of Harvard College)	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-25269	Gift	4/30/2015		Harvard University (The President and Fellows of Harvard College)	
2015-25296	Research Collaboration Agreement	3/30/2015	3/30/2018	Intellectual Ventures, The Global Good Fund I, LLC	Thomas Nutman
2015-25297	CTA - Clinical Trial Agreement	3/13/2015		Astellas Pharma Global Development, Inc [US]	Alexandra Freema
2015-25307	Research Collaboration Agreement	7/2/2015	7/2/2018	GenVec, Inc.	Patrick Duffy
2015-25308	Research Collaboration Agreement	4/20/2015	4/20/2018	GenVec, Inc.	Patrick Duffy
2015-25348	Research Collaboration Agreement	7/7/2015	7/7/2016	Instituto de Medicina Molecular	Carolina Barillas-M
2015-25378	Gift	1/8/2016	1/8/2025	Regeneron Pharmaceuticals, Inc.	
2015-25378	Gift	1/8/2016	1/8/2025	Regeneron Pharmaceuticals, Inc.	
2015-25437	CTA - Clinical Trial Agreement	11/11/2015		Gilead Sciences, Inc	H Clifford Lane
2015-25438	Research Collaboration Agreement	12/2/2015	12/2/2020	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Jose Ribeiro
2015-25438	Research Collaboration Agreement	12/2/2015	12/2/2020	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Jose Ribeiro
2015-25439	Letter of Intent/MOU	4/3/2015	4/3/2020	Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA)	
2015-25456	CRADA	5/18/2017	5/18/2019	ViiV Healthcare Company [US]	Malcolm Martin
2015-25461	Research Collaboration Agreement	3/26/2015		University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Stephen Leppla
2015-25465	Research Collaboration Agreement	7/13/2015	7/13/2016	Loyola University Chicago	Fadila Bouamr
2015-25465	Research Collaboration Agreement	7/13/2015	7/13/2016	Albert Einstein College of Medicine, Inc. [US], Loyola University Chicago	Fadila Bouamr
2015-25465	Research Collaboration Agreement	7/13/2015	7/13/2016	Loyola University Chicago	Fadila Bouamr
2015-25465	Research Collaboration Agreement	7/13/2015	7/13/2016	Albert Einstein College of Medicine, Inc. [US], Loyola University Chicago	Fadila Bouamr
2015-25466	CTA - Clinical Trial Agreement	11/2/2015		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2015-25467	CTA - Clinical Trial Agreement	12/30/2015		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Sara Healy
2015-25467	CTA - Clinical Trial Agreement	12/30/2015		Malaria Research and Training Center at the Universite de Bamako (University of, Sanaria, Inc. (see also Protein Potential)	Sara Healy

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-25470	Letter of Intent/MOU	3/16/2015		Centers for Disease Control and Prevention (CDC), USDA Animal and Plant Health Inspection Service	Anthony Fauci
2015-25472	CRADA	10/19/2015	10/19/2023	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Mathew Memoli
2015-25472	CRADA	10/19/2015	10/19/2023	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Jeffery Taubenber
2015-25472	CRADA	10/19/2015	10/19/2023	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Jeffery Taubenber
2015-25472	CRADA	10/19/2015	10/19/2023	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Mathew Memoli
2015-25558	Letter of Intent/MOU	4/23/2015		Georgetown University	Michael Otto
2015-25592	Gift	2/17/2016	7/30/2018	Alliance BioSecure Foundation [FR]	Byron Caughey
2015-25597	Gift	8/13/2015		Lupus Foundation of America	Harry Malech
2015-25598	Research Collaboration Agreement	11/19/2015	11/19/2018	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	
2015-25598	Research Collaboration Agreement	11/19/2015	11/19/2018	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	
2015-25598	Research Collaboration Agreement	11/19/2015	11/19/2018	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	
2015-32595	CTA - Clinical Trial Agreement	10/7/2015	6/30/2021	French Institute of Health and Medical Research (INSERM, Institut National de la	H Clifford Lane
2015-32598	CTA - Clinical Trial Agreement	12/1/2015		Celgene Corporation [US]	Irini Sereti
2015-32599	Research Collaboration Agreement	9/10/2015	9/10/2020	Cadila Healthcare Ltd.	Jesus Valenzuela
2015-32600	Gift	9/10/2015	9/10/2019	Cadila Healthcare Ltd.	Jesus Valenzuela
2015-32656	CRADA	2/23/2016	12/31/2021	Matinas BioPharma Holding, Inc.	Steven Holland
2015-32656	CRADA	2/23/2016	12/31/2021	Matinas BioPharma Holding, Inc.	Steven Holland
2015-32694	Letter of Intent/MOU	6/15/2015		University of Washington	Heinrich Feldmann
2015-32701	Research Collaboration Agreement	10/20/2016	10/20/2019	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF;, Jordan University of Science and Technology [JO], Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Shaden Kamhawi
2015-32701	Research Collaboration Agreement	10/20/2016	10/20/2019	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF;, Jordan University of Science and Technology [JO], Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Shaden Kamhawi

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-32706	Research Collaboration Agreement	1/28/2016		Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-32734	Gift	1/15/2016	1/15/2018	Selecta Biosciences	Patrick Duffy
2015-32735	Gift	8/10/2015		Lupus Foundation of America	Helen Su
2015-32742	Gift	12/22/2016	12/31/2016	European Vaccine Initiative (EVI) [EU,DE]	Patrick Duffy
2015-32745	CRADA	10/27/2015	10/31/2020	Symmune Therapeutics LLC	Helene Rosenberg
2015-32751	Letter of Intent/MOU	6/29/2015		University of Wisconsin-Madison [US]	Heinrich Feldmann
2015-32752	Letter of Intent/MOU	6/29/2015		University of Wisconsin-Madison [US]	Heinrich Feldmann
2015-32796	Gift	11/19/2015	6/30/2018	Bill & Melinda Gates Foundation (BMGF)	Patrick Duffy
2015-32812	CRADA	10/29/2015	10/1/2023	Matinas BioPharma Holding, Inc.	Peter Williamson
2015-32824	Gift	11/9/2015	2/28/2020	Bill & Melinda Gates Foundation (BMGF), Rockefeller University	Malcolm Martin
2015-32827	CTA - Clinical Trial Agreement	7/7/2015		NewLink Genetics Corporation [US]	H Clifford Lane
2015-32829	Letter of Intent/MOU	7/27/2016		Frontiers	Alan Sher
2015-32829	Letter of Intent/MOU	7/27/2016		Frontiers	Alan Sher
2015-32830	Letter of Intent/MOU	7/30/2015		INBIOS INTERNATIONAL, INC.	Lisbeth Kim Green
2015-32831	Letter of Intent/MOU	7/13/2015		John A. Burns School of Medicine, University of Hawai'i at Manoa (JABSOM)	Heinrich Feldmann
2015-32836	Letter of Intent/MOU	7/13/2015		University of Washington	Heinrich Feldmann
2015-32837	Letter of Intent/MOU	7/13/2015		University of Washington	Heinrich Feldmann
2015-32849	Research Collaboration Agreement	7/27/2015	7/27/2016	Cepheid [US]	Peter Jahrling
2015-32858	Gift	8/20/2015	8/20/2016	International Biomedical Research Alliance	Iain Fraser
2015-32932	Research Collaboration Agreement	11/19/2015	11/19/2018	Carilion Roanoke Community Hospital	Michael Otto
2015-33028	CRADA	5/4/2016	5/4/2026	EMD Serono, Inc.	Michail Lionakis
2015-33034	Research Collaboration Agreement	12/2/2015	12/2/2018	Ionis Pharmaceuticals, Inc. (named Isis Pharmaceuticals, Inc. until 2015-12-18)	Byron Caughey
2015-33057	CRADA	8/16/2016	2/10/2019	Viamet Pharmaceuticals, Inc.	Michail Lionakis
2015-33063	Gift	2/1/2016	7/1/2019	Cancer Research Institute [US]	
2015-33063	Gift	2/1/2016	7/1/2019	Cancer Research Institute [US]	
2015-33077	CTA - Clinical Trial Agreement	8/31/2015		MAPP BIOPHARMACEUTICAL, INC.	H Clifford Lane

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-33141	Letter of Intent/MOU	10/6/2015		National Cancer Institute (NCI/NIH), National Center for Advancing Translational Sciences (NCATS/NIH), National Eye Institute (NEI/NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK/NIH)	Robert Hohman
2015-33141	Letter of Intent/MOU	10/6/2015		National Center for Advancing Translational Sciences (NCATS/NIH)	Robert Hohman
2015-33147	Research Collaboration Agreement	1/21/2016	1/21/2021	Baylor College of Medicine	Lisbeth Kim Green
2015-33150	CRADA	11/16/2015	11/16/2025	GlaxoSmithKline LLC (GSK)	
2015-33150	CRADA	11/16/2015	11/16/2025	GlaxoSmithKline LLC (GSK), VIIV HEALTHCARE UK (NO.5) LTD [GB]	
2015-33150	CRADA	11/16/2015	11/16/2025	VIIV HEALTHCARE UK (NO.5) LTD [GB]	
2015-33171	Gift	7/1/2016	6/30/2017	National Psoriasis Foundation	
2015-33171	Gift	7/1/2016	6/30/2017	National Psoriasis Foundation	
2015-33206	Research Collaboration Agreement	9/21/2015	9/21/2016	Gilead Sciences, Inc	Peter Jahrling
2015-33247	Letter of Intent/MOU	9/23/2015		Jagiellonian University [PL]	Frank DeLeo
2015-33268	CRADA	1/15/2016	1/15/2018	Amgen Inc.	
2015-33288	Research Collaboration Agreement	11/19/2015	11/19/2016	ARMS Pharmaceutical	Kanta Subbarao
2015-33292	Research Collaboration Agreement	11/25/2015	11/25/2019	National Institutes of Biomedical Innovation, Health and Nutrition [JP]	Jeffrey Cohen
2015-33302	Letter of Intent/MOU	2/29/2016		International Medical Corps (IMC)	H Clifford Lane
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Nicolas Riteau
2015-33378	Research Collaboration Agreement	11/19/2015	11/19/2020	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2015-33381	Gift	10/30/2015	4/30/2017	Bill & Melinda Gates Foundation (BMGF)	Brandyce St Laure
2015-33381	Gift	10/30/2015	4/30/2017	Bill & Melinda Gates Foundation (BMGF)	Brandyce St Laure
2015-33381	Gift	10/30/2015	4/30/2017	Bill & Melinda Gates Foundation (BMGF)	Brandyce St Laure
2015-33384	Gift	3/1/2016	3/1/2019	American Diabetes Association [US]	
2015-33384	Gift	3/1/2016	3/1/2019	American Diabetes Association [US]	
2015-33460	Gift	6/22/2017	6/22/2022	NovoBiotic Pharmaceuticals, Inc.	Laura Via
2015-33460	Gift	6/22/2017	6/22/2022	NovoBiotic Pharmaceuticals, Inc.	Laura Via
2015-33536	Gift	1/29/2016	12/31/2018	Food Allergy Research and Education Foundation	Pamela Guerrerio
2015-33542	Letter of Intent/MOU	12/1/2015		Foundation for the National Institutes of Health, Inc. (FNIH)	H Clifford Lane
2015-33573	CTA - Clinical Trial Agreement	10/3/2016		Merck Sharp & Dohme Corp	Richard Davey
2015-33592	Research Collaboration Agreement	2/1/2016	2/1/2018	ARNO Therapeutics	Suzette Priola
2015-33596	Research Collaboration Agreement	2/9/2016	2/9/2019	Mahidol University [TH]	Michael Otto
2015-33603	Research Collaboration Agreement	5/4/2016	5/4/2018	Gilead Sciences, Inc	Richard Koup
2015-33612	Gift	6/10/2016	10/31/2021	Massachusetts General Hospital (MGH; General Hospital Corp.)	Clifton Barry
2015-33617	Research Collaboration Agreement	3/11/2016	3/11/2018	Radboud University Nijmegen Medical Centre [NL], State Serum Institute (Statens Serum Institut, National Serum Institute; SSI) [D	Patrick Duffy
2015-33631	Letter of Intent/MOU	12/7/2015		Thomas Jefferson University	Michael Otto

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2015-33635	Research Collaboration Agreement	4/20/2016	4/20/2021	Kobe University Graduate School of Medicine [JP]	Jeffrey Cohen
2015-33646	Letter of Intent/MOU	12/14/2015		GeoVax, Inc.	Heinrich Feldmann
2015-33652	Gift	6/21/2016	6/21/2018	Ohio State University	Jesus Valenzuela
2015-33660	CTA - Clinical Trial Agreement	8/15/2016		Millennium Pharmaceuticals, Inc., TAKEDA PHARMACEUTICAL COMPANY, LTD.	
2015-33660	CTA - Clinical Trial Agreement	8/15/2016		Millennium Pharmaceuticals, Inc., TAKEDA PHARMACEUTICAL COMPANY, LTD.	
2015-33660	CTA - Clinical Trial Agreement	8/15/2016		Millennium Pharmaceuticals, Inc., TAKEDA PHARMACEUTICAL COMPANY, LTD.	
2015-33666	Research Collaboration Agreement	2/15/2016	2/15/2022	University of Minnesota	Edward Berger
2015-33678	Gift	1/20/2016	12/31/2016	Histiocytosis Association	Konrad Krzewski
2015-33678	Gift	1/20/2016	12/31/2016	Histiocytosis Association	Konrad Krzewski
2015-33685	Research Collaboration Agreement	6/9/2016	6/9/2021	Genocea Biosciences, Inc.	Jeffrey Cohen
2015-33699	CRADA	2/22/2016	2/22/2019	GlaxoSmithKline Investigacion y Desarrollo (GSK) [ES]	Clifton Barry
2015-33700	Research Collaboration Agreement	1/23/2016	1/23/2022	Food and Drug Administration (FDA)	Jesus Valenzuela
2015-33704	CTA - Clinical Trial Agreement	1/23/2017		French Institute of Health and Medical Research (INSERM, Institut National de la, London School of Hygiene & Tropical Medicine (LSHTM) (University of London) [GB]	H Clifford Lane
2015-33706	Research Collaboration Agreement	1/29/2016	1/29/2021	GlaxoSmithKline (GSK), PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2015-33710	Gift	7/15/2016	7/15/2017	Yale University	Jesus Valenzuela
2015-33722	CRADA	12/22/2016	9/22/2019	Pfizer, Inc.	
2015-33722	CRADA	12/22/2016	9/22/2019	Pfizer, Inc.	
2016-0025	Research Collaboration Agreement	2/5/2016		Albert Einstein College of Medicine, Inc. [US]	Peter Jahrling
2016-0032	CTA - Clinical Trial Agreement	12/9/2016		Bavarian Nordic A/S [DK], Janssen Vaccines & Prevention B.V. (part of Johnson & Johnson; J&J) [NL]	H Clifford Lane
2016-0033	Research Collaboration Agreement	7/18/2016	7/18/2021	University of Dundee [GB]	Mark Connors
2016-0036	Gift	3/25/2016		Creutzfeldt-Jakob Disease (CJD) Foundation, Inc.	Byron Caughey
2016-0069	CTA - Clinical Trial Agreement	1/5/2017		Merck Sharp & Dohme Corp	H Clifford Lane
2016-0070	CRADA	7/14/2017	7/14/2020	Sanofi US Services Inc.	Jeffrey Cohen

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-0073	CRADA	4/8/2016	4/8/2019	GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Helene Rosenberg
2016-0076	Letter of Intent/MOU	1/29/2016		Wayne State University [US]	Michael Otto
2016-0102	Letter of Intent/MOU	2/5/2016		Georgetown University	Michael Otto
2016-0103	Research Collaboration Agreement	9/6/2016	5/16/2019	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Jeffrey Cohen
2016-0107	Research Collaboration Agreement	8/23/2016	8/23/2019	University of California-San Francisco (UCSF)	Byron Caughey
2016-0115	Research Collaboration Agreement	5/13/2016	5/13/2019	Sigmovir Biosystems Inc [US]	Jeffrey Cohen
2016-0119	Research Collaboration Agreement	5/12/2016	5/12/2017	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Vincent Munster
2016-0123	Research Collaboration Agreement	8/26/2016	8/26/2027	HVIDOVRE HOSPITAL	Patrizia FARCI
2016-0129	Research Collaboration Agreement	6/16/2016	6/16/2019	Adaptive Therapeutics [US]	Patrick Duffy
2016-0152	CTA - Clinical Trial Agreement	8/16/2016		PepTcell Limited (renamed SEEK 12/1/10) [GB]	Mathew Memoli
2016-0152	CTA - Clinical Trial Agreement	8/16/2016		PepTcell Limited (renamed SEEK 12/1/10) [GB]	Mathew Memoli
2016-0152	CTA - Clinical Trial Agreement	8/16/2016		PepTcell Limited (renamed SEEK 12/1/10) [GB]	Mathew Memoli
2016-0170	Letter of Intent/MOU	3/4/2016		Thomas Jefferson University	Michael Otto
2016-0186	Research Collaboration Agreement	3/22/2016	3/22/2019	Yale University School of Medicine [US]	Kirk Druey
2016-0188	CRADA	1/5/2017	1/5/2020	GlaxoSmithKline (GSK)	Patrick Duffy
2016-0200	Research Collaboration Agreement	3/24/2016	3/24/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), Sanofi US Services Inc.	
2016-0200	Research Collaboration Agreement	3/24/2016	3/24/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), Sanofi US Services Inc.	
2016-0206	CRADA	7/6/2016	7/7/2020	GlaxoSmithKline LLC (GSK)	
2016-0212	Research Collaboration Agreement	3/2/2016		Sangamo Therapeutics (formerly Sangamo BioSciences, Inc) [US]	Harry Malech
2016-0216	CTA - Clinical Trial Agreement	6/9/2016	6/9/2019	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), Sanofi US Services Inc.	Kanta Subbarao
2016-0216	CTA - Clinical Trial Agreement	6/9/2016	6/9/2019	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), Sanofi US Services Inc.	Kanta Subbarao
2016-0218	Research Collaboration Agreement	7/10/2016	7/10/2019	RedHill Biopharma Ltd. [IL]	Peter Jahrling
2016-0222	CRADA	10/17/2016	10/16/2021	Amgen Inc.	David Sacks
2016-0224	Research Collaboration Agreement	3/12/2016	3/21/2018	Genentech, Inc.	Ronald Germain

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-0230	Letter of Intent/MOU	3/18/2016		Defense Threat Reduction Agency (DTRA) (DoD), Leidos Biomedical Research, Inc. (was SAIC-Frederick, Inc. (Science Applications	Heinrich Feldmann
2016-0233	Research Collaboration Agreement	5/25/2016	5/25/2019	University of North Carolina at Chapel Hill	Kanta Subbarao
2016-0238	Gift	5/25/2016	3/31/2018	Washington University in St. Louis	Herbert Morse
2016-0269	Letter of Intent/MOU	3/23/2016		University of Michigan	Michael Otto
2016-0271	Letter of Intent/MOU	3/22/2016		Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Harry Malech
2016-0313	CTA - Clinical Trial Agreement	5/27/2016		SAB BIOTHERAPEUTICS, INC.	Richard Davey
2016-0323	CRADA	5/11/2017	5/11/2018	Gilead Sciences, Inc	Malcolm Martin
2016-0354	CTA - Clinical Trial Agreement	6/27/2016		Gilead Sciences, Inc	H Clifford Lane
2016-0359	Gift	8/25/2016	12/31/2020	Foundation for the National Institutes of Health, Inc. (FNIH), Pew Charitable Trusts [US]	
2016-0367	Research Collaboration Agreement	1/16/2017	1/16/2023	Walter Reed Army Institute of Research (WRAIR) (DoD)	Jeffrey Cohen
2016-0373	CTA - Clinical Trial Agreement	5/3/2016		Sanofi US Services Inc.	Elizabeth Kang
2016-0379	Research Collaboration Agreement	5/20/2016	5/20/2017	The University of Tennessee Health Science Center [US]	Kathryn Zoon
2016-0379	Research Collaboration Agreement	5/20/2016	5/20/2017	The University of Tennessee Health Science Center [US]	Kathryn Zoon
2016-0401	Gift	3/8/2017	4/30/2018	Bill & Melinda Gates Foundation (BMGF), University of Georgia	Yasmine Belkaid
2016-0407	CTA - Clinical Trial Agreement	11/7/2016	11/7/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), GlaxoSmithKline LLC (GSK)	Jeffrey Cohen
2016-0407	CTA - Clinical Trial Agreement	11/7/2016	11/7/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), GlaxoSmithKline LLC (GSK)	Kanta Subbarao
2016-0407	CTA - Clinical Trial Agreement	11/7/2016	11/7/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), GlaxoSmithKline LLC (GSK)	Jeffrey Cohen
2016-0407	CTA - Clinical Trial Agreement	11/7/2016	11/7/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), GlaxoSmithKline LLC (GSK)	Jeffrey Cohen

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-0407	CTA - Clinical Trial Agreement	11/7/2016	11/7/2017	Biomedical Advanced Research and Development Authority (BARDA) (DHHS), GlaxoSmithKline LLC (GSK)	Kanta Subbarao
2016-0442	Research Collaboration Agreement	7/15/2016	7/15/2021	Sapienza University of Rome (Universita? degli Studi di Roma "La Sapienza") [IT]	Jose Ribeiro
2016-0443	CRADA	11/10/2016	11/10/2022	Matinas BioPharma Holding, Inc.	Michail Lionakis
2016-0467	Letter of Intent/MOU	6/17/2016		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Amy Klion
2016-0467	Letter of Intent/MOU	6/17/2016		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Amy Klion
2016-0469	Letter of Intent/MOU	5/18/2016		Triclinium Clinical Development Ltd	Clifton Barry
2016-0474	Gift	6/6/2016	6/6/2017	Infectious Disease Research Institute (IDRI)	Jesus Valenzuela
2016-0480	Letter of Intent/MOU	6/15/2016	6/15/2017	US Army Medical Material Development Activity (USAMMDA - DoD) [US], US Army Medical Research and Materiel Command (USAMRMC) (DoD)	
2016-0480	Letter of Intent/MOU	6/15/2016	6/15/2017	US Army Medical Material Development Activity (USAMMDA - DoD) [US], US Army Medical Research and Materiel Command (USAMRMC) (DoD)	
2016-0487	CRADA	2/6/2017	2/6/2024	Merck & Co., Inc. (currently Merck, Sharp, and Dohme), Merck Sharp & Dohme Corp	Warren Strober
2016-0487	CRADA	2/6/2017	2/6/2024	Merck & Co., Inc. (currently Merck, Sharp, and Dohme), Merck Sharp & Dohme Corp	Ivan Fuss
2016-0487	CRADA	2/6/2017	2/6/2024	Merck & Co., Inc. (currently Merck, Sharp, and Dohme), Merck Sharp & Dohme Corp	Warren Strober
2016-0503	Letter of Intent/MOU	5/26/2016		Charles University (Universitas Carolina) [CZ]	Jose Ribeiro
2016-0507	Research Collaboration Agreement	8/5/2016	8/5/2019	VDI Laboratory	Adriana Marques
2016-0533	Research Collaboration Agreement	11/7/2016	11/7/2024	University of Illinois	John Kash
2016-0533	Research Collaboration Agreement	11/7/2016	11/7/2024	University of Illinois	John Kash
2016-0533	Research Collaboration Agreement	11/7/2016	11/7/2024	University of Illinois	John Kash
2016-0535	Research Collaboration Agreement	8/23/2016	8/23/2019	University of Vermont and State Agricultural College	Kirk Druey

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-0537	Gift	11/10/2016	12/31/2017	Bill & Melinda Gates Foundation (BMGF), University of Maryland, Baltimore (UMB)	
2016-0543	CTA - Clinical Trial Agreement	7/5/2018		Rockefeller University	Tae Wook Chun
2016-0543	CTA - Clinical Trial Agreement	7/5/2018		Rockefeller University	Tae Wook Chun
2016-0567	Research Collaboration Agreement	7/1/2016	7/1/2018	University of Texas Medical Branch at Galveston (UTMB) [US]	
2016-0572	Research Collaboration Agreement	8/30/2016	8/30/2020	Food and Drug Administration (FDA)	Mathew Memoli
2016-0572	Research Collaboration Agreement	8/30/2016	8/30/2020	Food and Drug Administration (FDA)	Mathew Memoli
2016-0578	Research Collaboration Agreement	3/20/2017		Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Raphaela Goldbac
2016-0605	Letter of Intent/MOU	6/17/2016		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Paneez Khoury
2016-0605	Letter of Intent/MOU	6/17/2016		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Paneez Khoury
2016-0610	Research Collaboration Agreement	12/5/2016	12/5/2019	George Washington University (GWU)	Patrizia FARCI
2016-0612	Research Collaboration Agreement	8/9/2016	8/9/2019	Boston Children's Hospital	Steven Holland
2016-0619	Research Collaboration Agreement	8/4/2016	8/4/2019	Chinese Academy of Medical Sciences and Peking Union Medical College [CN]	Jeffery Taubenber
2016-0619	Research Collaboration Agreement	8/4/2016	8/4/2019	Chinese Academy of Medical Sciences and Peking Union Medical College [CN]	Jeffery Taubenber
2016-0643	Gift	8/24/2016		International Biomedical Research Alliance	Steven Holland
2016-0663	Letter of Intent/MOU	7/5/2016		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-0663	Letter of Intent/MOU	7/5/2016		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-0663	Letter of Intent/MOU	7/5/2016		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-0663	Letter of Intent/MOU	7/5/2016		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-0663	Letter of Intent/MOU	7/5/2016		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-0671	Research Collaboration Agreement	7/14/2016	7/14/2021	Gene By Gene, LTD	
2016-0671	Research Collaboration Agreement	7/14/2016	7/14/2021	Gene By Gene, LTD	
2016-0671	Research Collaboration Agreement	7/14/2016	7/14/2021	Gene By Gene, LTD	Joshua Milner
2016-0672	Research Collaboration Agreement	1/27/2017	1/27/2019	Abbott Laboratories, Inc. [US]	Thomas Quinn
2016-0680	CRADA	8/21/2017	8/21/2022	Swedish Orphan Biovitrum AB [SE]	Raphaela Goldbac
2016-0698	Research Collaboration Agreement	8/23/2016		Antigen Discovery Inc.	Patrick Duffy
2016-0731	Research Collaboration Agreement	11/2/2016	11/7/2017	Centers for Disease Control and Prevention (CDC)	Heinrich Feldmann
2016-0744	Research Collaboration Agreement	8/24/2016	8/24/2019	COMMENCE BIO, INC.	

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-0744	Research Collaboration Agreement	8/24/2016	8/24/2019	COMMENCE BIO, INC.	
2016-0757	CRADA	12/6/2016	12/6/2019	Amgen Inc.	Yasmine Belkaid
2016-0780	Gift	3/3/2017	3/3/2018	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Jesus Valenzuela
2016-0785	Gift	2/27/2017	7/15/2021	Bill & Melinda Gates Foundation (BMGF)	Jeffrey Cohen
2016-0785	Gift	2/27/2017	7/15/2021	Bill & Melinda Gates Foundation (BMGF)	Jeffrey Cohen
2016-0814	Research Collaboration Agreement	5/1/2017	5/5/2022	Broad Institute of Harvard and MIT [US]	Byron Caughey
2016-0834	Gift	1/13/2017		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2016-0848	Research Collaboration Agreement	11/15/2016	11/15/2019	GenVec, Inc., Precigen, Inc	Patrick Duffy
2016-0848	Research Collaboration Agreement	11/15/2016	11/15/2019	GenVec, Inc.	Patrick Duffy
2016-0853	CRADA	9/11/2017	9/11/2020	Innovate UK, University of Plymouth [GB]	Heinrich Feldmann
2016-0874	CRADA	1/30/2017	1/30/2022	ADMA Biologics	Jeffrey Cohen
2016-0898	Research Collaboration Agreement	12/20/2016	12/20/2019	Johns Hopkins University (JHU)	Jeffery Taubenber
2016-0911	Research Collaboration Agreement	10/25/2016		Miravista Diagnostics	Peter Williamson
2016-0957	CTA - Clinical Trial Agreement	9/13/2017		Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Andrea Lisco
2016-0957	CTA - Clinical Trial Agreement	9/13/2017		Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Andrea Lisco
2016-1005	CRADA	6/5/2017	6/5/2023	MaxCyte, Inc	Harry Malech
2016-1019	Research Collaboration Agreement	10/19/2016	10/19/2017	Patara Pharma	Dean Metcalfe
2016-1020	Gift	11/28/2016	11/28/2018	Patara Pharma	Dean Metcalfe
2016-1035	Research Collaboration Agreement	2/2/2017	2/2/2022	Boston Children's Hospital	Joshua Milner
2016-1036	Research Collaboration Agreement	11/3/2016		International Vaccine Institute	Patrick Duffy
2016-1037	CTA - Clinical Trial Agreement	6/15/2017	6/15/2018	Phadia US Inc. (part of Thermo Fisher Scientific)	Pamela Guerrerio
2016-1043	Research Collaboration Agreement	1/30/2017	1/30/2022	Universität Heidelberg (Heidelberg University) [DE]	Kirk Druey
2016-1061	Gift	12/22/2016	12/22/2020	Institut Pasteur [FR], Sanofi worldwide (was Sanofi-Aventis until 5/2011) [FR]	Yasmine Belkaid
2016-1074	Research Collaboration Agreement	5/12/2017	5/12/2021	Eisai, Inc., Merck Sharp & Dohme Corp	Clifton Barry
2016-1087	CTA - Clinical Trial Agreement	11/17/2016		Eli Lilly and Company	Raphaela Goldbac
2016-1212	Research Collaboration Agreement	1/27/2017	1/27/2022	Yale University School of Medicine [US]	Kirk Druey
2016-1227	Research Collaboration Agreement	11/22/2016	11/22/2020	OyaGen, Inc.	
2016-1246	CRADA	10/17/2017	10/17/2019	UCB Biopharma Sprl	Byron Caughey
2016-1289	Gift	1/20/2017		NOVARTIS PHARMA AG	Raphaela Goldbac

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2016-1311	Research Collaboration Agreement	12/6/2017	12/6/2021	BioNTech AG [DE], Translational Oncology at the University Medical Center of the Johannes Gutenber	Jeffrey Cohen
2016-1400	Research Collaboration Agreement	4/3/2017	4/3/2019	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Alexander Pletnev
2016-1400	Research Collaboration Agreement	4/3/2017	4/3/2019	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Alexander Pletnev
2016-1400	Research Collaboration Agreement	4/3/2017	4/3/2019	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Alexander Pletnev
2016-1417	Letter of Intent/MOU	1/18/2017		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-1417	Letter of Intent/MOU	1/18/2017		GlaxoSmithKline LLC (GSK)	Amy Klion
2016-1424	Research Collaboration Agreement	2/14/2017	2/14/2018	Moderna, Inc. (was Moderna Therapeutics, Inc., then ModernaTX, Inc.)	
2016-1426	Gift	3/31/2017		Parkinson's and Movement Disorder Foundation	Byron Caughey
2016-1426	Gift	3/31/2017		Parkinson's and Movement Disorder Foundation	Byron Caughey
2016-1430	Research Collaboration Agreement	6/1/2018	6/1/2022	New York Blood Center	Thomas Nutman
2016-1460	Research Collaboration Agreement	3/23/2017	3/23/2022	Rutgers University [US]	Kirk Druey
2016-1477	Research Collaboration Agreement	4/10/2017	4/10/2023	University of Michigan	Patrizia FARCI
2016-1499	Research Collaboration Agreement	2/27/2017		University of North Carolina at Chapel Hill	Lisbeth Kim Green
2016-1499	Research Collaboration Agreement	2/27/2017		University of North Carolina at Chapel Hill	Lisbeth Kim Green
2016-1504	Research Collaboration Agreement	2/28/2017		The Scripps Research Institute (TSRI)	Peter Collins
2016-1504	Research Collaboration Agreement	2/28/2017		The Scripps Research Institute (TSRI)	Peter Collins
2016-1504	Research Collaboration Agreement	2/28/2017		The Scripps Research Institute (TSRI)	Peter Collins
2016-1512	Research Collaboration Agreement	5/30/2017	5/30/2022	University of Brescia (Università degli Studi di Brescia) [IT]	
2016-1512	Research Collaboration Agreement	5/30/2017	5/30/2022	University of Brescia (Università degli Studi di Brescia) [IT]	
2016-1515	Research Collaboration Agreement	6/16/2017	6/16/2022	Health Partners Institute	Kirk Druey
2016-1662	Letter of Intent/MOU	12/23/2016	12/23/2024	Ministry of Health of Indonesia [ID], National Institutes of Health (NIH)	H Clifford Lane
2017-0014	Letter of Intent/MOU	1/6/2017		Catalyze	Patrick Duffy
2017-0019	Gift	3/16/2017	3/16/2019	The Philipps University of Marburg (Philipps-Universität Marburg) [DE]	Yasmine Belkaid

Released by Chairman Rand Paul

G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2017-0034	CRADA	2/8/2019	12/31/2023	GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]	Jeffrey Cohen
2017-0041	Gift	3/27/2017	5/31/2018	Boston Children's Hospital, March of Dimes	Luigi Notarangelo
2017-0057	Gift	4/26/2017	10/31/2022	Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry
2017-0057	Gift	4/26/2017	10/31/2022	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Peter Collins
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Ursula Buchholz
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Ursula Buchholz
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Peter Collins
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Peter Collins
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Ursula Buchholz
2017-0087	Research Collaboration Agreement	8/15/2017	9/19/2024	Codagenix Inc.	Ursula Buchholz
2017-0093	Research Collaboration Agreement	5/11/2017	5/11/2022	Veterans Administration San Diego Healthcare System (VA)	
2017-0093	Research Collaboration Agreement	5/11/2017	5/11/2022	Veterans Administration San Diego Healthcare System (VA)	
2017-0094	Gift	5/12/2017	12/31/2020	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry
2017-0094	Gift	5/12/2017	12/31/2020	Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry
2017-0102	Research Collaboration Agreement	12/3/2017	12/3/2020	Janus-I Science Inc.	Jeffery Taubenber
2017-0102	Research Collaboration Agreement	12/3/2017	12/3/2020	Janus-I Science Inc.	Jeffery Taubenber
2017-0102	Research Collaboration Agreement	12/3/2017	12/3/2020	Janus-I Science Inc.	Jeffery Taubenber
2017-0108	Research Collaboration Agreement	9/28/2017	9/28/2020	GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE], PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2017-0112	CTA - Clinical Trial Agreement	4/25/2017	4/25/2020	Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2017-0114	Research Collaboration Agreement	4/27/2017	4/27/2020	PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2017-0115	Research Collaboration Agreement	2/21/2018	2/21/2020	Mymetics Corporation [CH]	Patrick Duffy

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2017-0141	Letter of Intent/MOU	2/23/2017		Frontiers in Cellular and Infection Microbiology (published by Frontiers Media S	Amy Klion
2017-0147	Gift	4/27/2017	4/27/2018	University of Oslo (Universitetet i Oslo) [NO]	
2017-0147	Gift	4/27/2017	4/27/2018	University of Oslo (Universitetet i Oslo) [NO]	
2017-0153	Research Collaboration Agreement	4/21/2017		Baylor College of Medicine	Michael Lenardo
2017-0161	CRADA	9/6/2017		National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH, Regeneron Pharmaceuticals, Inc.	Raphaela Goldbac
2017-0173	Letter of Intent/MOU	2/5/2017		Massachusetts General Hospital (MGH; General Hospital Corp.)	Michail Lionakis
2017-0198	CRADA	5/15/2019	5/15/2024	Coalition for Epidemic Preparedness Innovations (CEPI), University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Vincent Munster
2017-0202	Research Collaboration Agreement	12/20/2019		QIMR Berghofer Medical Research Institute [AU]	Patrick Duffy
2017-0210	Research Collaboration Agreement	3/22/2017	3/22/2022	University of California-Davis, University of California-San Francisco (UCSF)	Alexander Pletnev
2017-0210	Research Collaboration Agreement	3/22/2017	3/22/2022	University of California-Davis, University of California-San Francisco (UCSF)	Alexander Pletnev
2017-0210	Research Collaboration Agreement	3/22/2017	3/22/2022	University of California-Davis, University of California-San Francisco (UCSF)	Alexander Pletnev
2017-0213	Research Collaboration Agreement	3/6/2017		Columbia University (incl Columbia Technology Ventures)	Adriana Marques
2017-0236	CRADA	5/25/2017	5/25/2020	Bristol-Myers Squibb Company (BMS)	John Coligan
2017-0298	Research Collaboration Agreement	6/5/2017	6/5/2021	MedImmune, LLC. (acq by AstraZeneca in 6/2007)	Barney Graham
2017-0319	Research Collaboration Agreement	5/1/2017		University of California-Berkeley, University of California-San Francisco (UCSF)	
2017-0319	Research Collaboration Agreement	5/1/2017		University of California-Berkeley, University of California-San Francisco (UCSF)	
2017-0374	Research Collaboration Agreement	2/21/2018	2/21/2021	RNAceuticals, Inc.	Mark Connors
2017-0380	Research Collaboration Agreement	4/5/2017	4/5/2024	Tulane University, University of Pittsburgh	Ulrich Siebenlist

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2017-0453	Research Collaboration Agreement	5/9/2017		Foundation for the National Institutes of Health, Inc. (FNIH), Helmholtz Center for Infection Research (Helmholtz-Zentrum für Infektionsforschu, University of Cambridge (The Chancellor, Masters, and Scholars of the Universit, University of Cape Town (UCT) [ZA], University of Dundee [GB]	Clifton Barry
2017-0484	Research Collaboration Agreement	12/11/2017	12/11/2019	Inimmune	Catharine Bosio
2017-0490	Gift	6/20/2017		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2017-0505	Research Collaboration Agreement	1/23/2019	1/23/2022	University of Texas Southwestern Medical Center	Patrizia FARCI
2017-0509	Research Collaboration Agreement	9/11/2017	9/11/2020	University of Pennsylvania School of Medicine	Jeffrey Cohen
2017-0510	Research Collaboration Agreement	7/7/2017		Brigham and Women's Hospital (BWH)	Katrin Mayer-Barb
2017-0525	Gift	12/15/2017	12/31/2021	Foundation for the National Institutes of Health, Inc. (FNIH), Pew Charitable Trusts [US]	
2017-0525	Gift	12/15/2017	12/31/2021	Foundation for the National Institutes of Health, Inc. (FNIH), Pew Charitable Trusts [US]	
2017-0527	Research Collaboration Agreement	9/27/2017	9/27/2020	National Center for Advancing Translational Sciences (NCATS/NIH), National Human Genome Research Institute (NHGRI/NIH)	Yasmine Belkaid
2017-0531	Research Collaboration Agreement	7/24/2017	7/24/2019	University of Washington	Joseph Marcotrigi
2017-0539	Research Collaboration Agreement	8/8/2017	8/8/2022	Institute for Glycomics, Griffith University [AU]	Patrick Duffy
2017-0568	Research Collaboration Agreement	3/20/2018	3/22/2021	Food and Drug Administration (FDA)	Lisbeth Kim Green
2017-0568	Research Collaboration Agreement	3/20/2018	3/22/2021	Food and Drug Administration (FDA)	Lisbeth Kim Green
2017-0568	Research Collaboration Agreement	3/20/2018	3/22/2021	Food and Drug Administration (FDA)	Lisbeth Kim Green
2017-0592	CTA - Clinical Trial Agreement	12/10/2017	12/10/2021	Biomedical Advanced Research and Development Authority (BARDA) (DHHS)	Jeffrey Cohen
2017-0592	CTA - Clinical Trial Agreement	12/10/2017	12/10/2021	Biomedical Advanced Research and Development Authority (BARDA) (DHHS)	Jeffrey Cohen
2017-0620	Research Collaboration Agreement	6/30/2017	6/30/2019	Roche Innovation Center	Ronald Germain
2017-0630	Gift	11/13/2017	2/28/2019	Yale University	Patricia Rosa
2017-0636	Research Collaboration Agreement	12/22/2017		Naval Medical Research Center (NMRC) (DoD)	Heinrich Feldmann
2017-0637	CRADA	11/30/2017	11/30/2019	Kineta, Inc. [US]	Heinrich Feldmann
2017-0644	Research Collaboration Agreement	11/13/2017	11/19/2020	Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Michael Otto

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2017-0682	Research Collaboration Agreement	8/23/2017	9/5/2019	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Heinrich Feldmann
2017-0714	Research Collaboration Agreement	10/19/2017	4/19/2019	CureVac AG [DE]	Patrick Duffy
2017-0751	Research Collaboration Agreement	7/11/2017		Children's Hospital of Philadelphia (CHOP)	Kol ZAREMBER
2017-0752	Research Collaboration Agreement	11/21/2017	11/21/2019	TAKEDA PHARMACEUTICAL COMPANY, LTD.	Patrick Duffy
2017-0769	Research Collaboration Agreement	3/2/2018	3/2/2021	Case Western Reserve University (CWRU)	Cathryn Haigh
2017-0775	Research Collaboration Agreement	8/2/2018	8/2/2026	Cincinnati Children's Hospital Medical Center	Amy Klion
2017-0827	Research Collaboration Agreement	9/19/2017	9/19/2019	Agios	Steven Holland
2017-0838	Research Collaboration Agreement	10/27/2017	10/27/2022	University of Dundee [GB]	Joshua Milner
2017-0839	Research Collaboration Agreement	8/4/2017	1/31/2021	Leica Microsystems, Inc. [US]	Ronald Germain
2017-0847	Research Collaboration Agreement	12/15/2017	12/15/2025	Emory University	Joseph Marcotrigi
2017-0848	Gift	11/6/2017	9/30/2019	Bill & Melinda Gates Foundation (BMGF)	Jeffery Taubenber
2017-0863	Research Collaboration Agreement	1/3/2018	1/3/2021	Washington University in St. Louis	
2017-0863	Research Collaboration Agreement	1/3/2018	1/3/2021	Washington University in St. Louis	
2017-0889	Gift	1/8/2018	9/30/2022	Damon Runyon Cancer Research Foundation	
2017-0889	Gift	1/8/2018	9/30/2022	Damon Runyon Cancer Research Foundation	
2017-0889	Gift	1/8/2018	9/30/2022	Damon Runyon Cancer Research Foundation	
2017-0889	Gift	1/8/2018	9/30/2022	Damon Runyon Cancer Research Foundation	
2017-0891	CTA - Clinical Trial Agreement	8/3/2017		Biogen, Inc. [US]	Peter Williamson
2017-0964	Research Collaboration Agreement	12/20/2017	12/20/2018	Quorum Therapeutics, Inc.	Michael Otto
2017-0979	CRADA	7/12/2018	12/31/2031	Incyte Corporation	Amy Klion
2017-0979	CRADA	7/12/2018	12/31/2031	Incyte Corporation, Incyte Corporation	Amy Klion
2017-1021	Research Collaboration Agreement	11/8/2017	3/31/2024	RIKEN (The Institute of Physical and Chemical Research) [JP]	Ronald Germain
2017-1038	Research Collaboration Agreement	4/2/2018	4/2/2023	Serimmune Inc. [US]	Jeffrey Cohen
2017-1047	Research Collaboration Agreement	9/13/2017	9/13/2019	University of Georgia, Walter Reed Army Institute of Research (WRAIR) (DoD)	Sanjay Desai
2017-1069	Research Collaboration Agreement	4/3/2018	4/3/2021	Stanford University (Leland Stanford Junior University)	Joseph Marcotrigi
2017-1084	Gift	6/11/2018	9/30/2018	Stanford University (Leland Stanford Junior University)	Ronald Germain
2017-1106	Gift	2/1/2018	1/31/2024	Bill & Melinda Gates Foundation (BMGF)	Clifton Barry
2017-1175	Research Collaboration Agreement	1/17/2018		Foundation for the National Institutes of Health, Inc. (FNIH)	Clifton Barry

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2017-1179	Research Collaboration Agreement	8/19/2022	5/14/2025	Moderna, Inc. (was Moderna Therapeutics, Inc., then ModernaTX, Inc.)	Nancy Sullivan
2017-1190	Gift	12/6/2017	12/6/2018	International Biomedical Research Alliance	Vincent Munster
2017-1206	Research Collaboration Agreement	3/21/2018	3/21/2019	Seattle Children's Hospital (Seattle Children's Research Institute) [US], University of Washington	Edward Berger
2017-1207	Research Collaboration Agreement	2/22/2018	2/22/2021	University of Glasgow [GB]	Thomas Wellems
2017-1226	Research Collaboration Agreement	2/5/2018	2/5/2021	University of California-San Francisco (UCSF)	Eli Boritz
2017-1236	Gift	6/1/2018	6/1/2020	American Partnership for Eosinophilic Disorders	
2017-1236	Gift	6/1/2018	6/1/2020	American Partnership for Eosinophilic Disorders	
2017-1237	CTA - Clinical Trial Agreement	7/19/2018		ALLAKOS INC.	Amy Klion
2017-1237	CTA - Clinical Trial Agreement	7/19/2018		ALLAKOS INC.	Amy Klion
2017-1240	Research Collaboration Agreement	2/7/2018	2/7/2021	Synthetic Genomics Vaccines	Peter Jahrling
2017-1249	Research Collaboration Agreement	2/14/2018		L2 Diagnostics, LLC [US]	Adriana Marques
2017-1257	Research Collaboration Agreement	5/2/2018		EcoHealth Alliance	Vincent Munster
2017-1258	Gift	12/21/2017		World Hellenic Biomedical Association	Michail Lionakis
2017-1363	Gift	2/6/2018		United States-Israel Binational Science Foundation (BSF) [IL]	Luigi Notarangelo
2017-1501	Gift	2/12/2018		Foundation for the National Institutes of Health, Inc. (FNIH)	Steven Holland
2017-1532	Letter of Intent/MOU	11/8/2017		Corixa Corporation (acq by GSK 3/16/17) [GB], GSK Vaccines	Theodore Pierson
2017-1594	Research Collaboration Agreement	1/22/2018	12/1/2019	University of Colorado School of Medicine (University of Colorado Denver, Anschu	Michail Lionakis
2017-1623	Research Collaboration Agreement	3/6/2018	3/6/2020	San Diego Biomedical Research Institute	Paolo Lusso
2017-1632	Research Collaboration Agreement	1/18/2018	1/18/2021	Kephera Diagnostics, LLC	Adriana Marques
2017-1648	Letter of Intent/MOU	8/8/2019	9/30/2021		Mathew Memoli
2017-1648	Letter of Intent/MOU	8/8/2019	9/30/2021		Mathew Memoli
2017-1648	Letter of Intent/MOU	8/8/2019	9/30/2021		Mathew Memoli
2017-1648	Letter of Intent/MOU	8/8/2019	9/30/2021		Mathew Memoli
2018-0003	Research Collaboration Agreement	3/19/2018	3/19/2021	University of Washington	
2018-0003	Research Collaboration Agreement	3/19/2018	3/19/2021	University of Washington	
2018-0009	Research Collaboration Agreement	1/29/2018	1/29/2021	Impact Biologicals Inc.	Byron Caughey
2018-0013	CRADA	1/11/2019	7/11/2020	Gilead Sciences, Inc	Vanessa Hirsch

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2018-0014	CRADA	1/29/2019	1/29/2020	VIIV HEALTHCARE UK (NO.5) LTD [GB]	Vanessa Hirsch
2018-0018	Research Collaboration Agreement	4/20/2018	4/20/2023	Children's National Medical Center (CNMC) [US]	
2018-0018	Research Collaboration Agreement	4/20/2018	4/20/2023	Children's National Medical Center (CNMC) [US]	
2018-0027	Gift	4/20/2018	4/20/2020	Creutzfeldt-Jakob Disease (CJD) Foundation, Inc.	Byron Caughey
2018-0033	Research Collaboration Agreement	5/21/2018	5/21/2020	New York University School of Medicine (NYU)	Pamela Guerrerio
2018-0038	Gift	9/11/2018	12/31/2019	National Psoriasis Foundation	Yasmine Belkaid
2018-0038	Gift	9/11/2018	12/31/2019	National Psoriasis Foundation	Yasmine Belkaid
2018-0097	Research Collaboration Agreement	10/11/2018		Inova Health Care Services [US]	Michael Lenardo
2018-0168	Letter of Intent/MOU	3/19/2018		Forte Biosciences Inc.	Ian Myles
2018-0175	Gift	6/8/2018	6/8/2024	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Mary Daucher
2018-0199	Research Collaboration Agreement	3/7/2018	3/7/2021	Duke University	
2018-0199	Research Collaboration Agreement	3/7/2018	3/7/2021	Duke University	
2018-0214	Research Collaboration Agreement	4/2/2018	4/2/2022	National Center for Advancing Translational Sciences (NCATS/NIH)	Hans Ackerman
2018-0224	Research Collaboration Agreement	5/30/2018		Radboud University Nijmegen Medical Centre [NL], State Serum Institute (Statens Serum Institut, National Serum Institute; SSI) [D	Patrick Duffy
2018-0261	Research Collaboration Agreement	3/26/2018	3/25/2024	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Peter Jahrling
2018-0262	Gift	11/9/2018	1/31/2021	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Thomas Nutman
2018-0262	Gift	11/9/2018	1/31/2021	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Thomas Nutman
2018-0291	CRADA	3/25/2019	3/25/2023	Coalition for Epidemic Preparedness Innovations (CEPI), Inovio Pharmaceuticals, Inc.	Heinrich Feldmann
2018-0354	Research Collaboration Agreement	9/12/2018	9/12/2023	Columbia University (incl Columbia Technology Ventures), National Institute of Neurological Disorders and Stroke (NINDS/NIH), University of British Columbia (UBC) [CA]	Michael Lenardo
2018-0357	CTA - Clinical Trial Agreement	5/14/2018		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2018-0378	Research Collaboration Agreement	6/4/2018	6/4/2023	Forsyth Institute [US]	Bernard Moss
2018-0379	CRADA	3/15/2019	3/15/2022	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Jesus Valenzuela
2018-0379	CRADA	3/15/2019	3/15/2022	PepTcell Limited (renamed SEEK 12/1/10) [GB]	Jesus Valenzuela
2018-0403	Research Collaboration Agreement	6/1/2018	6/1/2021	Institute of Microbiology and Virology [KZ]	Clifton Barry
2018-0407	Gift	5/1/2018	10/1/2021	International Human Frontier Science Program Organization (IHFSPO) [FR]	Yasmine Belkaid
2018-0407	Gift	5/1/2018	10/1/2021	International Human Frontier Science Program Organization (IHFSPO) [FR]	Yasmine Belkaid
2018-0448	Letter of Intent/MOU	5/11/2018		PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0448	Letter of Intent/MOU	5/11/2018		PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0503	Gift	6/14/2018	6/14/2019	PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0503	Gift	6/14/2018	6/14/2019	PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0524	Research Collaboration Agreement	8/10/2018	8/10/2020	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	
2018-0529	CRADA	12/20/2018	12/20/2024	Novartis Institutes for Biomedical Research, Inc. [US], SomaLogic	Bibi Bielekova
2018-0578	CTA - Clinical Trial Agreement	6/7/2019		Regeneron Pharmaceuticals, Inc.	Hirsh Komarow
2018-0578	CTA - Clinical Trial Agreement	6/7/2019		Regeneron Pharmaceuticals, Inc., Sanofi US Services Inc.	Hirsh Komarow
2018-0592	Letter of Intent/MOU	4/20/2018		Forte Biosciences Inc.	Ian Myles
2018-0593	Gift	8/18/2018	12/31/2019	PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0593	Gift	8/18/2018	12/31/2019	PATH Malaria Vaccine Initiative (MVI) [US]	
2018-0612	Research Collaboration Agreement	6/28/2018	6/28/2021	Harvard University (The President and Fellows of Harvard College)	
2018-0632	Gift	10/9/2018	6/30/2023	Kenneth Rainin Foundation	Yasmine Belkaid
2018-0632	Gift	10/9/2018	6/30/2023	Kenneth Rainin Foundation	Yasmine Belkaid
2018-0636	Research Collaboration Agreement	9/5/2018	9/5/2021	Virginia Tech [US]	Adriana Marques
2018-0655	Research Collaboration Agreement	12/18/2018	12/18/2021	Baylor College of Medicine	Jesus Valenzuela
2018-0699	Research Collaboration Agreement	6/14/2018	6/14/2023	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Peter Jahrling
2018-0720	Research Collaboration Agreement	12/12/2018	12/12/2023	Research Center Rene Rachou (Centro de Pesquisas Rene Rachou, CPqRR) (formerly I	Jesus Valenzuela
2018-0725	Gift	8/14/2018	8/31/2020	Loeys-Dietz Syndrome Foundation, Strong City Baltimore	Pamela Guerrerio

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2018-0741	CRADA	4/25/2019	4/25/2022	Bristol-Myers Squibb Company (BMS)	Steven Holland
2018-0744	Research Collaboration Agreement	11/16/2018	11/16/2023	Hospital for Sick Children [CA]	Jonathan Lyons
2018-0752	Research Collaboration Agreement	1/8/2019	12/4/2020	Illumina, Inc.	Michael Lenardo
2018-0762	Research Collaboration Agreement	8/22/2018	8/22/2021	AbCellera Biologics, Inc. [CA]	
2018-0765	Letter of Intent/MOU	6/21/2018			
2018-0765	Letter of Intent/MOU	6/21/2018			
2018-0787	Research Collaboration Agreement	7/9/2018	7/9/2021	Program for the Fight against Sexually Transmitted Diseases, including HIV / AID, University Institute Egas Moniz (Instituto Universitário Egas Moniz) [PT]	Klaus Strebel
2018-0795	Research Collaboration Agreement	5/8/2019	5/8/2022	Inovio Pharmaceuticals, Inc., Institute for Research in Biomedicine (IRB) [CH], Wistar Institute	
2018-0795	Research Collaboration Agreement	5/8/2019	5/8/2022	Inovio Pharmaceuticals, Inc., Institute for Research in Biomedicine (IRB) [CH], Wistar Institute	
2018-0828	Gift	10/31/2018	11/1/2021	National Psoriasis Foundation	Daniella Schwartz
2018-0855	Research Collaboration Agreement	10/5/2018	10/5/2021	Johns Hopkins University (JHU)	Jeffrey Cohen
2018-0860	Gift	2/4/2019	7/1/2022	Cancer Research Institute [US]	
2018-0860	Gift	2/4/2019	7/1/2022	Cancer Research Institute [US]	
2018-0870	Gift	9/6/2018		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2018-0884	Letter of Intent/MOU	8/31/2018	11/10/2019	Battelle Memorial Institute - Columbus Operations	Theodore Pierson
2018-0885	Letter of Intent/MOU	8/31/2018	9/12/2019	Battelle Memorial Institute - Columbus Operations	Theodore Pierson
2018-0900	Research Collaboration Agreement	2/5/2019		Inova Translational Medicine Institute, National Human Genome Research Institute (NHGRI/NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH	
2018-0900	Research Collaboration Agreement	2/5/2019		Inova Translational Medicine Institute, National Human Genome Research Institute (NHGRI/NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2018-0916	CTA - Clinical Trial Agreement	9/3/2020		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Amy Klion
2018-0919	Research Collaboration Agreement	9/19/2018	9/19/2021	QMENTA [ES]	Bibi Bielekova
2018-0932	Research Collaboration Agreement	10/1/2018	10/1/2023	University of Florida [US]	Maureen Goodenc
2018-0969	Research Collaboration Agreement	1/29/2019	1/29/2025	American Gene Technologies International, Inc.	Tae Wook Chun
2018-0972	Research Collaboration Agreement	2/28/2019	2/28/2023	Walter Reed Army Institute of Research (WRAIR) (DoD), Walter Reed National Military Medical Center (WRNMMC) (DoD)	Peter Crompton
2018-0975	Research Collaboration Agreement	10/1/2018	10/4/2021	Institute of Microbiology of the Federal Defense Forces (Institut fur Mikrobiolo	Alexander Pletnev
2018-0975	Research Collaboration Agreement	10/1/2018	10/4/2021	Institute of Microbiology of the Federal Defense Forces (Institut fur Mikrobiolo	Alexander Pletnev
2018-0975	Research Collaboration Agreement	10/1/2018	10/4/2021	Institute of Microbiology of the Federal Defense Forces (Institut fur Mikrobiolo	Alexander Pletnev
2018-0978	Gift	10/23/2018	3/31/2020	Bill & Melinda Gates Foundation (BMGF)	
2018-0978	Gift	10/23/2018	3/31/2020	Bill & Melinda Gates Foundation (BMGF)	
2018-1009	Research Collaboration Agreement	10/30/2018	10/30/2021	Xiamen University [CN]	XinZhuan Su
2018-1026	Research Collaboration Agreement	10/15/2018	10/15/2020	A2 Biotherapeutics	
2018-1071	Research Collaboration Agreement	10/30/2018	10/30/2021	Ohio State University	Yongli Xiao
2018-1071	Research Collaboration Agreement	10/30/2018	10/30/2021	Ohio State University	Yongli Xiao
2018-1075	Research Collaboration Agreement	10/17/2018	10/17/2021	University of Pennsylvania School of Medicine	Jeffrey Cohen
2018-1089	CRADA	8/26/2019	8/26/2025	Terraimmune, Inc. [US]	Ethan Shevach
2018-1125	CTA - Clinical Trial Agreement	10/2/2018		MAPP BIOPHARMACEUTICAL, INC.	Richard Davey
2018-1136	CTA - Clinical Trial Agreement	11/27/2018		Gilead Sciences, Inc	Richard Davey
2018-1146	CRADA	8/7/2019	2/15/2022	CureVac AG [DE]	
2018-1146	CRADA	8/7/2019	2/15/2022	CureVac AG [DE]	
2018-1147	Research Collaboration Agreement	3/5/2019	3/5/2021	Columbia University (incl Columbia Technology Ventures)	Ronald Germain
2018-1193	Letter of Intent/MOU	6/28/2019	6/28/2024	Ministry of Health (MOH) of Democratic Republic of Congo (DRC) [CD]	H Clifford Lane
2018-1199	CTA - Clinical Trial Agreement	11/22/2018		National Institute of Biomedical Research (INRB, Institut National de la Recherche Bio) [CD]	H Clifford Lane
2018-1220	Research Collaboration Agreement	10/10/2018	10/10/2021	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Peter Jahrling

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2018-1224	Research Collaboration Agreement	6/27/2019	6/27/2024	The Johns Hopkins University School of Medicine [US]	Pamela Guerrerio
2018-1263	Research Collaboration Agreement	10/10/2018	10/10/2021	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Peter Jahrling
2018-1303	CTA - Clinical Trial Agreement	10/18/2018		Novartis Pharmaceuticals Corporation [US]	Steven Holland
2018-1311	Research Collaboration Agreement	4/19/2019	4/19/2022	Amager and Hvidovre Hospital [DK]	Joseph Marcotrigi
2018-1327	Research Collaboration Agreement	1/14/2020	1/14/2023	Children's National Medical Center (CNMC) [US]	Hans Ackerman
2018-1429	CTA - Clinical Trial Agreement	12/20/2018		Regeneron Pharmaceuticals, Inc.	H Clifford Lane
2018-1430	CTA - Clinical Trial Agreement	4/11/2019		ALLAKOS INC.	Amy Klion
2018-1430	CTA - Clinical Trial Agreement	4/11/2019		ALLAKOS INC.	Amy Klion
2018-1459	Research Collaboration Agreement	5/22/2019	5/22/2024	Istanbul Technical University [TR], Istanbul University [TR], National Institute of Neurological Disorders and Stroke (NINDS/NIH)	Michael Lenardo
2018-1497	Letter of Intent/MOU	12/17/2018		Forte Biosciences Inc.	Ian Myles
2018-1503	Research Collaboration Agreement	2/7/2019	2/7/2022	Guangzhou University of Traditional Chinese Medicine	
2018-1503	Research Collaboration Agreement	2/7/2019	2/7/2022	Guangzhou University of Traditional Chinese Medicine	
2018-1519	Gift	5/1/2019		PATH Malaria Vaccine Initiative (MVI) [US]	
2018-1519	Gift	5/1/2019		PATH Malaria Vaccine Initiative (MVI) [US]	
2018-1523	Research Collaboration Agreement	2/27/2019	2/27/2022	Rutgers University [US], The Scripps Research Institute (TSRI)	Joseph Marcotrigi
2018-1525	CTA - Clinical Trial Agreement	1/2/2019		Eli Lilly and Company	Raphaela Goldbac
2018-1544	Research Collaboration Agreement	3/20/2020	4/28/2026	Baylor College of Medicine	Lisbeth Kim Green
2018-1564	Gift	3/15/2019		PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2019-0001	Gift	8/19/2019	12/31/2023	Bill & Melinda Gates Foundation (BMGF)	Thomas Nutman
2019-0001	Gift	8/19/2019	12/31/2023	Bill & Melinda Gates Foundation (BMGF)	Thomas Nutman
2019-0007	Gift	3/19/2020	12/10/2022	University of South Florida, Walter Reed Army Institute of Research (WRAIR) (DoD)	Joel Vega-rodrigue
2019-0014	Research Collaboration Agreement	1/18/2019	1/18/2021	Advanced Cell Diagnostics Inc	Ronald Germain
2019-0025	Research Collaboration Agreement	6/5/2019	6/5/2022	United BioPharma, Inc.	Jeffrey Cohen
2019-0041	Research Collaboration Agreement	3/7/2022	3/7/2027	Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2019-0046	Research Collaboration Agreement	4/1/2019	4/1/2022	Microgen Labs	Jeffrey Cohen
2019-0047	Research Collaboration Agreement	3/11/2019		University of Washington	Patrick Duffy

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2019-0064	Research Collaboration Agreement	4/30/2019	4/30/2022	BostonGene	Ronald Germain
2019-0069	Gift	4/18/2019	4/18/2020	Creutzfeldt-Jakob Disease (CJD) Foundation, Inc.	Cathryn Haigh
2019-0099	CRADA	8/20/2020	8/20/2024	Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2019-0103	Research Collaboration Agreement	8/16/2019	8/16/2024	Marmara University	Michael Lenardo
2019-0149	CRADA	9/13/2019	9/13/2022	Coalition for Epidemic Preparedness Innovations (CEPI), CureVac AG [DE]	Vincent Munster
2019-0151	CRADA	5/14/2019	5/14/2023	Coalition for Epidemic Preparedness Innovations (CEPI), Inovio Pharmaceuticals, Inc.	Heinrich Feldmann
2019-0159	Research Collaboration Agreement	5/7/2019		Pasteur Institute of Dakar (Institut Pasteur-Dakar) [SN]	Patrick Duffy
2019-0168	Research Collaboration Agreement	5/29/2019	4/29/2021	SutroVax, Inc.	Harlan Caldwell
2019-0171	Gift	5/23/2019	9/30/2020	PATH Malaria Vaccine Initiative (MVI) [US]	Patrick Duffy
2019-0186	Research Collaboration Agreement	5/13/2019	5/13/2020	Johnson C. Smith University	Thomas Wellems
2019-0220	Gift	5/10/2019	10/31/2020	Bill & Melinda Gates Foundation (BMGF)	
2019-0220	Gift	5/10/2019	10/31/2020	Bill & Melinda Gates Foundation (BMGF)	
2019-0226	Gift	9/18/2019	12/1/2021	University of Notre Dame [US]	Vincent Munster
2019-0227	CRADA	6/25/2020	6/25/2024	F2G Ltd. [GB]	Steven Holland
2019-0235	CTA - Clinical Trial Agreement	5/17/2019		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2019-0236	CTA - Clinical Trial Agreement	6/11/2019		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2019-0236	CTA - Clinical Trial Agreement	6/11/2019		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2019-0242	CTA - Clinical Trial Agreement	3/12/2019		Biogen, Inc. [US]	Peter Williamson
2019-0245	CRADA	4/2/2019	4/2/2024	Matinas BioPharma Holding, Inc.	Peter Williamson
2019-0260	Research Collaboration Agreement	10/17/2019	10/17/2021	Wistar Institute	Mark Connors
2019-0264	Research Collaboration Agreement	8/8/2019		Maferinyah National Center for Training and Research in Rural Health (Centre Nat, PATH Malaria Vaccine Initiative (MVI) [US], Radboud University Medical Center, State Serum Institute (Statens Serum Institut, National Serum Institute; SSI) [D, The National Public Health Institute of Liberia (NPHIL) [LR], University Sciences Techniques & Technologies of Bamako (USTTB) [ML]	Patrick Duffy
2019-0282	Gift	9/11/2019	12/31/2023	Bill & Melinda Gates Foundation (BMGF)	Mathew Memoli
2019-0294	Research Collaboration Agreement	5/15/2019	5/15/2021	ABCAM PLC [GB]	Thomas Leto

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2019-0318	Research Collaboration Agreement	4/17/2019		Duke University	Michail Lionakis
2019-0333	Research Collaboration Agreement	8/14/2020	8/14/2025	University of Pretoria (Universiteit van Pretoria) [ZA]	Hans Ackerman
2019-0350	Research Collaboration Agreement	12/6/2019	12/6/2022	Oswaldo Cruz Foundation (Fiocruz, Fundacao Oswaldo Cruz) [BR]	Jeffrey Cohen
2019-0350	Research Collaboration Agreement	12/6/2019	12/6/2022	Oswaldo Cruz Foundation (Fiocruz, Fundacao Oswaldo Cruz) [BR]	Jeffrey Cohen
2019-0407	Research Collaboration Agreement	10/15/2019	12/1/2021	University of Notre Dame [US]	Vincent Munster
2019-0430	Research Collaboration Agreement	11/14/2019	11/14/2022	BIOLEGEND, National Cancer Institute (NCI/NIH)	Ronald Germain
2019-0430	Research Collaboration Agreement	11/14/2019	11/14/2022	BIOLEGEND, National Cancer Institute (NCI/NIH)	Ronald Germain
2019-0430	Research Collaboration Agreement	11/14/2019	11/14/2022	BIOLEGEND, National Cancer Institute (NCI/NIH)	Ronald Germain
2019-0440	Gift	3/10/2020		Rutgers University [US]	Clifton Barry
2019-0449	Research Collaboration Agreement	3/20/2020	3/20/2023	Cepheid [US]	Vincent Munster
2019-0460	Research Collaboration Agreement	10/22/2019	10/22/2022	NOVAVAX, INC.	
2019-0460	Research Collaboration Agreement	10/22/2019	10/22/2022	NOVAVAX, INC.	
2019-0472	Research Collaboration Agreement	10/9/2019	10/9/2024	NOVARTIS PHARMA AG	
2019-0472	Research Collaboration Agreement	10/9/2019	10/9/2024	NOVARTIS PHARMA AG	
2019-0472	Research Collaboration Agreement	10/9/2019	10/9/2024	NOVARTIS PHARMA AG	Irini Sereti
2019-0486	Research Collaboration Agreement	8/20/2019	8/20/2022	Food and Drug Administration (FDA)	Hans Ackerman
2019-0492	Research Collaboration Agreement	6/14/2019		Cepheid [US]	Clifton Barry
2019-0501	Gift	4/17/2020	6/30/2022	University of California-Berkeley	Ronald Germain
2019-0501	Gift	4/17/2020	6/30/2022	University of California-Berkeley	Ronald Germain
2019-0503	Research Collaboration Agreement	6/3/2019	6/3/2022	Vanderbilt University [US]	John Kash
2019-0503	Research Collaboration Agreement	6/3/2019	6/3/2022	Vanderbilt University [US]	John Kash
2019-0504	Research Collaboration Agreement	10/4/2019	10/4/2022	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	
2019-0504	Research Collaboration Agreement	10/4/2019	10/4/2022	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	
2019-0521	Research Collaboration Agreement	6/12/2019	6/12/2022	United States Army Medical Research Institute of Infectious Diseases (USAMRIID)	Robert Heinzen
2019-0523	Research Collaboration Agreement	9/9/2019	9/9/2022	Broad Institute of Harvard and MIT [US], Dana-Farber Cancer Institute (DFCI), Massachusetts General Hospital (MGH; General Hospital Corp.)	Amy Klion
2019-0528	Research Collaboration Agreement	8/20/2019	8/20/2025	Food and Drug Administration (FDA)	Patrizia FARCI

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2019-0529	CRADA	2/4/2020	2/4/2024	Microbiotix, Inc.	Sanjay Desai
2019-0530	Research Collaboration Agreement	8/5/2019	8/5/2022	University of Washington	Jeffrey Cohen
2019-0544	CRADA	3/12/2020	4/30/2021	Gilead Sciences, Inc	Lisbeth Kim Green
2019-0544	CRADA	3/12/2020	4/30/2021	Gilead Sciences, Inc	Lisbeth Kim Green
2019-0560	CRADA	7/15/2019	7/14/2022	Amgen Inc.	Ethan Shevach
2019-0598	Research Collaboration Agreement	7/29/2019		Seattle Children's Hospital (Seattle Children's Research Institute) [US]	
2019-0598	Research Collaboration Agreement	7/29/2019		Seattle Children's Hospital (Seattle Children's Research Institute) [US]	
2019-0601	CRADA	1/21/2020	2/8/2025	GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]	Ronald Germain
2019-0603	Gift	6/28/2019	12/31/2020	Society for Immunotherapy of Cancer (SITC) [US]	Ronald Germain
2019-0606	Research Collaboration Agreement	1/22/2020	1/22/2024	MAPP BIOPHARMACEUTICAL, INC.	Andrea Marzi
2019-0615	Research Collaboration Agreement	7/18/2019	7/18/2020	University of Georgia	Joel Vega-rodrigue
2019-0645	Gift	8/21/2019	8/21/2020	Consortium of Multiple Sclerosis Centers	Bibi Bielekova
2019-0691	CTA - Clinical Trial Agreement	11/25/2019		United BioPharma, Inc.	Tae Wook Chun
2019-0698	CTA - Clinical Trial Agreement	6/25/2019		Shionogi, Inc	Harry Malech
2019-0729	Gift	3/10/2020	11/1/2024	Public Health Vaccines, LLC	Heinrich Feldmann
2019-0741	Research Collaboration Agreement	12/20/2019	11/24/2022	Magenta Therapeutics	Luigi Notarangelo
2019-0813	CRADA	1/24/2020	1/24/2022	NextCure, Inc.	Ethan Shevach
2019-0849	Gift	11/14/2019	12/31/2024	Bill & Melinda Gates Foundation (BMGF)	Clifton Barry
2019-0867	CRADA	10/20/2020	10/20/2025	AstraZeneca Pharmaceuticals LP	Amy Klion
2019-0897	Research Collaboration Agreement	9/19/2019	9/19/2022	InDevR, Inc. [US]	Jeffery Taubenber
2019-0901	Research Collaboration Agreement	11/26/2019	11/26/2022	Columbia University (incl Columbia Technology Ventures)	
2019-0901	Research Collaboration Agreement	11/26/2019	11/26/2022	Columbia University (incl Columbia Technology Ventures)	
2019-0905	Gift	9/20/2019		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2019-0918	Research Collaboration Agreement	10/1/2019	10/1/2024	Case Western Reserve University (CWRU)	Byron Caughey
2019-0943	CRADA	8/11/2020	8/11/2023	Janssen Research and Development, Inc. (formerly Johnson & Johnson Pharmaceutica	Ethan Shevach

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2019-0969	Research Collaboration Agreement	12/3/2019	12/3/2022	Instituto Nacional de Saúde Publica, Program for the Fight against Sexually Transmitted Diseases, including HIV / AID, University Institute Egas Moniz (Instituto Universitário Egas Moniz) [PT]	Klaus Strebel
2019-0970	Letter of Intent/MOU	8/23/2019			H Clifford Lane
2019-0991	Gift	10/17/2019	4/30/2022	Bill & Melinda Gates Foundation (BMGF)	
2019-0991	Gift	10/17/2019	4/30/2022	Bill & Melinda Gates Foundation (BMGF)	
2019-0994	Letter of Intent/MOU	11/22/2019		GlaxoSmithKline PLC (formerly Glaxo Wellcome PLC) (GSK) [GB]	
2019-1039	Gift	11/12/2019	12/31/2023	Bill & Melinda Gates Foundation (BMGF)	Mathew Memoli
2019-1050	Research Collaboration Agreement	1/16/2020	1/16/2023	Mayo Clinic	Patrizia FARCI
2019-1056	Research Collaboration Agreement	2/2/2020	2/2/2023	French Institute of Health and Medical Research (INSERM, Institut National de la, University of Strasbourg (Université de Strasbourg) [FR]	Joseph Marcotrigi
2019-1058	Research Collaboration Agreement	4/22/2020	4/22/2023	University of Washington	Mathew Memoli
2019-1059	CTA - Clinical Trial Agreement	8/17/2021		NOVAVAX, INC.	Jeffrey Cohen
2019-1066	Research Collaboration Agreement	12/26/2019	12/26/2022	Children's National Medical Center (CNMC) [US]	Jeffrey Cohen
2019-1072	Gift	11/15/2019	9/30/2024	Bill & Melinda Gates Foundation (BMGF)	Jeffery Taubenber
2019-1072	Gift	11/15/2019	9/30/2024	Bill & Melinda Gates Foundation (BMGF)	Jeffery Taubenber
2019-1072	Gift	11/15/2019	9/30/2024	Bill & Melinda Gates Foundation (BMGF)	Jeffery Taubenber
2019-1099	Research Collaboration Agreement	11/26/2019	11/26/2022	Fred Hutchinson Cancer Research Center (FHCRC) [US]	Jeffrey Cohen
2019-1113	Research Collaboration Agreement	11/5/2019	11/5/2021	Corvus Pharmaceuticals	Steven Holland
2019-1170	CTA - Clinical Trial Agreement	10/15/2019		SCYNEXIS [US]	Alexandra Freema
2019-1176	Research Collaboration Agreement	2/28/2020	2/28/2023	Leiden University Medical Center (Leids Universitair Medisch Centrum) [NL]	
2019-1176	Research Collaboration Agreement	2/28/2020	2/28/2023	Leiden University Medical Center (Leids Universitair Medisch Centrum) [NL]	
2019-1197	Gift	12/20/2019		American Society of Tropical Medicine & Hygiene	
2019-1197	Gift	12/20/2019		American Society of Tropical Medicine & Hygiene	
2019-1229	CRADA	9/17/2020	9/17/2025	IFM Therapeutics	Raphaela Goldbac
2019-1271	Research Collaboration Agreement	3/18/2021		Regeneron Pharmaceuticals, Inc.	Michael Lenardo
2019-1317	Letter of Intent/MOU	11/13/2019		Centers for Disease Control and Prevention (CDC)	Adriana Marques
2019-1323	Research Collaboration Agreement	7/13/2020	7/14/2023	Adaptive Biotechnologies Corp.	John Kash

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2019-1323	Research Collaboration Agreement	7/13/2020	7/14/2023	Adaptive Biotechnologies Corp.	John Kash
2019-1323	Research Collaboration Agreement	7/13/2020	7/14/2023	Adaptive Biotechnologies Corp.	John Kash
2019-1454	Gift	3/17/2020	4/30/2024	California Institute of Technology (Caltech)	Malcolm Martin
2019-1456	Gift	3/10/2020	3/10/2021	European Society for Paediatric Infectious Diseases (ESPID)	
2019-1456	Gift	3/10/2020	3/10/2021	European Society for Paediatric Infectious Diseases (ESPID)	
2019-1487	Letter of Intent/MOU	3/2/2020		GlaxoSmithKline (GSK)	Amy Klion
2019-1490	Letter of Intent/MOU	2/28/2020	8/31/2024	Battelle Memorial Institute - Columbus Operations	Theodore Pierson
2019-1494	Letter of Intent/MOU	6/28/2019		National Institute of Biomedical Research (INRB, Institut National de la Recherche Bio) [CD]	Anthony Fauci
2019-1495	Research Collaboration Agreement	3/4/2020	3/4/2023	National Center for Advancing Translational Sciences (NCATS/NIH), University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Carole Long
2020-0026	Research Collaboration Agreement	6/15/2020		CureVac AG [DE]	Vincent Munster
2020-0045	Research Collaboration Agreement	1/31/2020	1/31/2024	National Cancer Institute (NCI/NIH), National Center for Advancing Translational Sciences (NCATS/NIH), National Heart, Lung and Blood Institute (NHLBI/NIH), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS/NIH	Iain Fraser
2020-0052	Gift	3/5/2020		Creutzfeldt-Jakob Disease (CJD) Foundation, Inc.	Byron Caughey
2020-0053	Gift	1/17/2020		Arthritis National Research Foundation (ANRF)	Daniella Schwartz
2020-0187	CTA - Clinical Trial Agreement	3/2/2021		Gilead Sciences, Inc	
2020-0213	CTA - Clinical Trial Agreement	2/24/2020		Pfizer, Inc.	Raphaela Goldbac
2020-0240	Letter of Intent/MOU	8/17/2020	8/12/2021	Genentech, Inc.	Amy Klion
2020-0274	CRADA	6/25/2020	12/25/2023	PharmAbcine	Kirk Druey
2020-0277	CRADA	7/13/2020	11/2/2023	National Cancer Institute (NCI/NIH), NIH Clinical Center (CC/NIH), Nvidia Corporation	Steven Holland

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2020-0296	Research Collaboration Agreement	4/1/2020	4/1/2023	National Center for Advancing Translational Sciences (NCATS/NIH), Uniformed Services University of the Health Sciences (USUHS; USU) (DoD), University of Cape Town (UCT) [ZA], University of Sao Paulo (Universidade de São Paulo) (USP) [BR]	Carole Long
2020-0312	Research Collaboration Agreement	4/30/2020	4/30/2023	University of Washington	Heinrich Feldmann
2020-0333	Research Collaboration Agreement	6/3/2020	6/3/2023	BIOLEGEND	Ronald Germain
2020-0367	CTA - Clinical Trial Agreement	4/13/2020		Emergent BioSolutions Inc.	H Clifford Lane
2020-0378	Research Collaboration Agreement	5/20/2021	5/20/2024	Cepheid [US]	Vincent Munster
2020-0426	CTA - Clinical Trial Agreement	5/1/2020		Baxalta US, Inc a wholly owned subsidiary of Takeda Pharmaceuticals Company Limi	H Clifford Lane
2020-0438	CRADA	6/11/2020	6/11/2023	ChromaDex	Sonja Best
2020-0450	CTA - Clinical Trial Agreement	3/18/2021		Grifols Therapeutics, LLC	H Clifford Lane
2020-0467	Gift	6/21/2021	6/21/2024	University of Glasgow [GB]	
2020-0467	Gift	6/21/2021	6/21/2024	University of Glasgow [GB]	
2020-0468	Research Collaboration Agreement	4/22/2021	7/17/2023	Walter Reed Army Institute of Research (WRAIR) (DoD)	Joel Vega-rodrigue
2020-0487	CTA - Clinical Trial Agreement	4/10/2020		Eli Lilly and Company	John Beigel
2020-0530	Research Collaboration Agreement	9/3/2020	9/25/2023	Naval Medical Research Center (NMRC) (DoD)	Alexander Pletnev
2020-0530	Research Collaboration Agreement	9/3/2020	9/25/2023	Naval Medical Research Center (NMRC) (DoD)	Alexander Pletnev
2020-0532	Research Collaboration Agreement	6/10/2020	6/19/2026	Research Institute at Nationwide Children's Hospital [US]	Ursula Buchholz
2020-0534	CTA - Clinical Trial Agreement	12/28/2020		Children's National Medical Center (CNMC) [US]	Lisbeth Kim Green
2020-0534	CTA - Clinical Trial Agreement	12/28/2020		Children's National Medical Center (CNMC) [US]	Lisbeth Kim Green
2020-0541	Research Collaboration Agreement	4/21/2020	4/21/2023	Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Helen Su
2020-0553	CTA - Clinical Trial Agreement	7/3/2020		NeoImmunetech, Inc. [US]	Irini Sereti
2020-0554	Research Collaboration Agreement	5/13/2020	5/13/2023	Children's National Hospital	Jeffrey Cohen
2020-0557	Research Collaboration Agreement	4/23/2020	4/23/2021	Seer, Inc.	
2020-0601	Gift	12/3/2020	12/31/2024	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Paolo Lusso

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2020-0601	Gift	12/3/2020	12/31/2024	Bill & Melinda Gates Foundation (BMGF), Foundation for the National Institutes of Health, Inc. (FNIH)	Paolo Lusso
2020-0607	CTA - Clinical Trial Agreement	5/1/2020		Emergent BioSolutions Inc.	H Clifford Lane
2020-0663	CTA - Clinical Trial Agreement	5/21/2020		Grifols Shared Services North America, Inc.	H Clifford Lane
2020-0664	CTA - Clinical Trial Agreement	5/1/2020		CSL Behring	H Clifford Lane
2020-0666	CTA - Clinical Trial Agreement	5/5/2020		CSL Behring	H Clifford Lane
2020-0685	Research Collaboration Agreement	7/2/2020	7/18/2022	National Institute of Biomedical Imaging and Bioengineering (NIBIB/NIH), US Department of Defense (DoD) [US]	Mathew Memoli
2020-0687	Letter of Intent/MOU	6/6/2020	12/6/2021	Center for Advancing Innovation, Inc. [US], National Cancer Institute (NCI/NIH)	Shirin Munir
2020-0687	Letter of Intent/MOU	6/6/2020	12/6/2021	Center for Advancing Innovation, Inc. [US], National Cancer Institute (NCI/NIH)	Shirin Munir
2020-0687	Letter of Intent/MOU	6/6/2020	12/6/2021	Center for Advancing Innovation, Inc. [US], National Cancer Institute (NCI/NIH)	Shirin Munir
2020-0692	Research Collaboration Agreement	5/14/2020	5/14/2023	National Institute on Aging (NIA/NIH)	Helen Su
2020-0692	Research Collaboration Agreement	5/14/2020	5/14/2023	National Institute on Aging (NIA/NIH)	Helen Su
2020-0713	Research Collaboration Agreement	6/4/2020	6/4/2022	Calithera Biosciences, Inc.	Ronald Germain
2020-0744	Gift	6/10/2021	5/21/2024	Insmed Inc. [US]	Steven Holland
2020-0837	Letter of Intent/MOU	7/20/2020		Excerpta Medica (funded by Sanofi), Genzyme (acq by Sanofi 2/16/2011) [US], Regeneron Pharmaceuticals, Inc.	Amy Klion
2020-0879	Gift	9/8/2020	8/31/2022	Chan Zuckerberg Initiative, Silicon Valley Community Foundation	John Tsang
2020-0884	Research Collaboration Agreement	6/19/2020	7/6/2025	Food and Drug Administration (FDA)	Jeffery Taubenber
2020-0884	Research Collaboration Agreement	6/19/2020	7/6/2025	Food and Drug Administration (FDA)	Jeffery Taubenber
2020-0886	CTA - Clinical Trial Agreement	6/16/2020		AstraZeneca Pharmaceuticals LP, National Cancer Institute (NCI/NIH)	Michail Lionakis
2020-0906	Research Collaboration Agreement	8/27/2020	8/27/2022	Yale University, Yale University School of Medicine [US]	
2020-0906	Research Collaboration Agreement	8/27/2020	8/27/2022	Yale University, Yale University School of Medicine [US]	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2020-0906	Research Collaboration Agreement	8/27/2020	8/27/2022	Yale University, Yale University School of Medicine [US]	
2020-0906	Research Collaboration Agreement	8/27/2020	8/27/2022	Yale University, Yale University School of Medicine [US]	
2020-0908	Gift	9/20/2021	6/30/2023	Bill & Melinda Gates Foundation (BMGF)	Jessica Manning
2020-0915	CTA - Clinical Trial Agreement	9/25/2020		Mustang Bio, Inc.	Harry Malech
2020-0919	CTA - Clinical Trial Agreement	10/14/2020		Eli Lilly and Company	H Clifford Lane
2020-0924	CTA - Clinical Trial Agreement	6/28/2020		Jasper Therapeutics	Harry Malech
2020-0960	Letter of Intent/MOU	2/24/2021	6/30/2022	Children's National Hospital	Amy Klion
2020-0961	Gift	7/23/2020	7/1/2023	Cancer Research Institute [US]	Yasmine Belkaid
2020-0961	Gift	7/23/2020	7/1/2023	Cancer Research Institute [US]	Yasmine Belkaid
2020-0970	Research Collaboration Agreement	2/25/2021	2/25/2024	New York Blood Center	Elodie Ghedin
2020-0982	CTA - Clinical Trial Agreement	7/16/2020		Gilead Sciences, Inc	H Clifford Lane
2020-0983	Research Collaboration Agreement	7/30/2020	6/1/2021	Verndari, Inc.	Mark Connors
2020-0997	CTA - Clinical Trial Agreement	8/24/2020		EFFECTOR Therapeutics, Inc.	Harry Malech
2020-1003	Gift	3/2/2021	3/31/2024	National Multiple Sclerosis Society	Bibi Bielekova
2020-1015	CTA - Clinical Trial Agreement	7/27/2020		EMD Serono Research & Development Institute	
2020-1030	CTA - Clinical Trial Agreement	8/27/2020		GlaxoSmithKline LLC (GSK), Vir Biotechnology, Inc. (Vir)	H Clifford Lane
2020-1061	CTA - Clinical Trial Agreement	10/23/2020		Brii Biosciences (Beijing) Co Ltd [CN]	H Clifford Lane
2020-1064	Gift	8/21/2020		Consortium of Multiple Sclerosis Centers, University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Michael Lenardo
2020-1094	CTA - Clinical Trial Agreement	8/18/2020		Gilead Sciences, Inc	
2020-1101	Research Collaboration Agreement	3/17/2021	3/17/2024	Ifakara Health Institute [TZ], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Carole Long
2020-1103	CTA - Clinical Trial Agreement	12/8/2020		AstraZeneca Pharmaceuticals LP	H Clifford Lane
2020-1148	Research Collaboration Agreement	10/6/2020	10/9/2023	University of California-Berkeley	Jeffrey Cohen
2020-1166	Gift	10/2/2020		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2020-1167	Gift	9/16/2020	5/31/2023	Bill & Melinda Gates Foundation (BMGF)	Joshua Tan
2020-1177	Research Collaboration Agreement	3/11/2022	3/11/2023	Aarhus University [DK]	Byron Caughey
2020-1193	Research Collaboration Agreement	12/3/2020	12/3/2021	MAXIM BIOMEDICAL INC.	Oliver Laeyendeck

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2020-1292	Research Collaboration Agreement	12/18/2020	12/18/2021	BC Cancer Research Centre (BCCRC) (BC Cancer Agency) [CA]	Peter Sun
2020-1320	CRADA	7/1/2022	7/1/2025	Pharming Healthcare	Vemulkonda (Kon
2020-1320	CRADA	7/1/2022	7/1/2025	Pharming Healthcare	Vemulkonda (Kon
2020-1353	Research Collaboration Agreement	11/19/2020	11/19/2025	NIH Clinical Center (CC/NIH)	Irini Sereti
2020-1378	Research Collaboration Agreement	11/5/2020		Sloan Biologics, LLC	Ian Myles
2020-1385	CRADA	10/30/2020	10/29/2023	Amgen Inc.	Yasmine Belkaid
2020-1522	Research Collaboration Agreement	6/4/2021	6/4/2024	Washington University in St. Louis	Jonathan Lyons
2020-1526	Research Collaboration Agreement	11/17/2020	12/2/2022	Virginia Tech [US]	Alexander Pletnev
2020-1527	Research Collaboration Agreement	6/23/2021	7/21/2025	University of Toronto [CA], University of Washington	Mathew Memoli
2020-1532	Research Collaboration Agreement	6/1/2021	6/1/2022	Editas Medicine, Inc.	Eric Long
2020-1549	Research Collaboration Agreement	4/30/2021	4/30/2022	Peak Proteins [GB]	Byron Caughey
2020-1569	Research Collaboration Agreement	6/29/2022	12/16/2024	German Center for Neurodegenerative Diseases (DZNE), ND Biosciences [CH]	Byron Caughey
2020-1580	Gift	10/20/2021	12/13/2023	Paul G. Allen Family Foundation, Van Andel Institute, Vulcan	Yasmine Belkaid
2020-1586	Gift	7/2/2021	7/2/2025	Cincinnati Children's Hospital Medical Center	Paneez Khoury
2020-1586	Gift	7/2/2021	7/2/2025	Cincinnati Children's Hospital Medical Center	Paneez Khoury
2020-1593	Research Collaboration Agreement	1/30/2021	1/30/2023	JoMoCo, Inc.	
2020-1604	Research Collaboration Agreement	4/5/2021	4/5/2023	The Scripps Research Institute (TSRI)	Joshua Tan
2020-1607	Gift	1/6/2021	12/31/2021	National Eczema Association	
2020-1607	Gift	1/6/2021	12/31/2021	National Eczema Association	
2020-1646	Research Collaboration Agreement	5/12/2021	5/12/2024	University of British Columbia (UBC) [CA]	Jonathan Lyons
2020-1664	CRADA	11/24/2021	11/25/2025	JANSSEN PHARMACEUTICA PRODUCTS, L.P. [BE]	Stephen Whitehea
2020-1666	Research Collaboration Agreement	1/26/2021	1/29/2024	University of North Carolina at Chapel Hill	Leah Katzelnick
2020-1690	Research Collaboration Agreement	4/8/2021	4/8/2026	Naval Medical Research Center (NMRC) (DoD)	John Tsang
2020-1691	Gift	4/20/2021	9/30/2024	National Science Foundation (NSF) [US], Pennsylvania State University (Penn State; PSU) [US]	Elodie Ghedin
2020-1691	Gift	4/20/2021	9/30/2024	National Science Foundation (NSF) [US], Pennsylvania State University (Penn State; PSU) [US]	Elodie Ghedin
2021-0022	CTA - Clinical Trial Agreement	3/22/2021		Gilead Sciences, Inc	H Clifford Lane

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-0023	CTA - Clinical Trial Agreement	1/27/2021		NeuroRx	H Clifford Lane
2021-0040	CTA - Clinical Trial Agreement	4/16/2021		Molecular Partners AG [CH]	H Clifford Lane
2021-0040	CTA - Clinical Trial Agreement	4/16/2021		NOVARTIS PHARMA AG	H Clifford Lane
2021-0072	Research Collaboration Agreement	5/20/2021	5/20/2024	Icahn School of Medicine at Mount Sinai	Joseph Marcotrigi
2021-0077	Letter of Intent/MOU	2/26/2021	12/31/2024	Genentech, Inc.	Yasmine Belkaid
2021-0079	Research Collaboration Agreement	5/17/2021	5/17/2022	Signify Health	Vincent Munster
2021-0091	Letter of Intent/MOU	3/11/2021		Tokyo Medical and Dental University [JP]	John Beigel
2021-0187	Research Collaboration Agreement	3/15/2022	3/31/2025	The University of Adelaide [AU]	Sonja Best
2021-0194	CTA - Clinical Trial Agreement	4/26/2021		Pfizer, Inc.	H Clifford Lane
2021-0272	CRADA	9/30/2022	9/30/2025	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Jessica Manning
2021-0273	CRADA	1/4/2023	1/4/2026	Merck & Co., Inc. (currently Merck, Sharp, and Dohme)	Jessica Manning
2021-0287	Research Collaboration Agreement	3/23/2022	3/23/2027	Cincinnati Children's Hospital Medical Center, Northwestern University, University of Utah	Amy Klion
2021-0287	Research Collaboration Agreement	3/23/2022	3/23/2027	Cincinnati Children's Hospital Medical Center, Northwestern University, University of Utah	Amy Klion
2021-0288	Research Collaboration Agreement	7/8/2021	7/8/2026	University of Malaya	Png Loke
2021-0288	Research Collaboration Agreement	7/8/2021	7/8/2026	University of Malaya	Png Loke
2021-0311	Research Collaboration Agreement	8/25/2021	8/27/2024	Rutgers New Jersey Medical School [US]	Ursula Buchholz
2021-0312	Research Collaboration Agreement	7/23/2021	8/5/2024	Kansas State University	Ursula Buchholz
2021-0319	Gift	8/20/2021	7/24/2022	Foundation for the National Institutes of Health, Inc. (FNIH), NYU Langone Medical Center	Elodie Ghedin
2021-0379	Research Collaboration Agreement	5/26/2021	5/26/2024	Food and Drug Administration (FDA)	Mathew Memoli
2021-0394	CTA - Clinical Trial Agreement	2/8/2022		Cincinnati Children's Hospital Medical Center	Amy Klion
2021-0394	CTA - Clinical Trial Agreement	2/8/2022		Cincinnati Children's Hospital Medical Center	Amy Klion
2021-0432	CTA - Clinical Trial Agreement	5/7/2021		Jasper Therapeutics	Harry Malech
2021-0432	CTA - Clinical Trial Agreement	5/7/2021		Jasper Therapeutics	Harry Malech
2021-0502	Research Collaboration Agreement	12/7/2021	12/7/2026	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Png Loke
2021-0502	Research Collaboration Agreement	12/7/2021	12/7/2026	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Png Loke
2021-0502	Research Collaboration Agreement	12/7/2021	12/7/2026	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	Png Loke

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-0555	Research Collaboration Agreement	11/24/2021	11/24/2024	University of York	Joshua Tan
2021-0574	Letter of Intent/MOU	5/20/2021	5/20/2024	Vir Biotechnology, Inc. (Vir)	Yasmine Belkaid
2021-0613	Research Collaboration Agreement	6/30/2021	6/30/2024	Kansas State University	Mark Connors
2021-0646	Research Collaboration Agreement	8/16/2021	9/10/2024	University of the Philippines – Manila	Leah Katzelnick
2021-0658	Research Collaboration Agreement	6/4/2021	6/4/2024	University of Wisconsin-Madison [US]	Kirk Druey
2021-0701	Letter of Intent/MOU	12/1/2021		Lawrence Berkeley National Laboratory [US]	Peter Sun
2021-0721	Research Collaboration Agreement	2/17/2022	2/17/2025	Children's National Medical Center (CNMC) [US], Fred Hutchinson Cancer Research Center (FHCRC) [US], George Washington University (GWU), Infectious Disease Research Center (CIENI, Centro de Investigacion en Enfermedad, Joan & Sanford I. Weill Medical College of Cornell University (current name: Wei, Makerere University [UG], Maple Leaf Medical Clinic, Rakai Health Sciences Program [US], Rockefeller University, Simon Fraser University [CA], University of Louisville [US], University of Massachusetts Medical School [US], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars, University of Pittsburgh, University of Toronto [CA], University of Western Ontario [CA], Yale University	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-0721	Research Collaboration Agreement	2/17/2022	2/17/2025	Children's National Medical Center (CNMC) [US], Fred Hutchinson Cancer Research Center (FHCRC) [US], George Washington University (GWU), Infectious Disease Research Center (CIENI, Centro de Investigacion en Enfermedad, Joan & Sanford I. Weill Medical College of Cornell University (current name: Wei, Makerere University [UG], Maple Leaf Medical Clinic, Rakai Health Sciences Program [US], Rockefeller University, Simon Fraser University [CA], University of Louisville [US], University of Massachusetts Medical School [US], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars, University of Pittsburgh, University of Toronto [CA], University of Western Ontario [CA], Yale University	
2021-0721	Research Collaboration Agreement	2/17/2022	2/17/2025	Children's National Medical Center (CNMC) [US], Fred Hutchinson Cancer Research Center (FHCRC) [US], George Washington University (GWU), Infectious Disease Research Center (CIENI, Centro de Investigacion en Enfermedad, Joan & Sanford I. Weill Medical College of Cornell University (current name: Wei, Makerere University [UG], Maple Leaf Medical Clinic, Rakai Health Sciences Program [US], Rockefeller University, Simon Fraser University [CA], University of Louisville [US], University of Massachusetts Medical School [US], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars, University of Pittsburgh, University of Toronto [CA], University of Western Ontario [CA], Yale University	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-0721	Research Collaboration Agreement	2/17/2022	2/17/2025	Children's National Medical Center (CNMC) [US], Fred Hutchinson Cancer Research Center (FHCRC) [US], George Washington University (GWU), Infectious Disease Research Center (CIENI, Centro de Investigacion en Enfermedad, Joan & Sanford I. Weill Medical College of Cornell University (current name: Wei, Makerere University [UG], Maple Leaf Medical Clinic, Rakai Health Sciences Program [US], Rockefeller University, Simon Fraser University [CA], University of Louisville [US], University of Massachusetts Medical School [US], University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars, University of Pittsburgh, University of Toronto [CA], University of Western Ontario [CA], Yale University	
2021-0725	Gift	7/12/2021	7/12/2023	Cathy Wall	Kirk Druey
2021-0734	CRADA	7/26/2021	7/26/2023	Amgen Inc.	Yasmine Belkaid
2021-0734	CRADA	7/26/2021	7/26/2023	Amgen Inc.	Yasmine Belkaid
2021-0755	CTA - Clinical Trial Agreement	6/15/2021		Sanaria, Inc. (see also Protein Potential)	Patrick Duffy
2021-0764	Research Collaboration Agreement	6/11/2021	6/11/2024	National Center for Advancing Translational Sciences (NCATS/NIH)	XinZhuan Su
2021-0765	CRADA	6/30/2021	6/30/2025	Amgen Inc.	Michail Lionakis
2021-0816	Gift	12/15/2021	12/31/2023	Jeffrey Modell Foundation (JMF)	Jonathan Lyons
2021-0817	Gift	8/16/2021	10/31/2023	Jim Miller	Jonathan Lyons
2021-0817	Gift	8/16/2021	10/31/2023	Jim Miller	Jonathan Lyons
2021-0821	Research Collaboration Agreement	5/6/2022	5/6/2025	University of Oxford (incl Isis Innovation, The Chancellor, Masters and Scholars	
2021-0825	Research Collaboration Agreement	9/9/2021	9/10/2024	Children's Research Institute	Jeffrey Cohen
2021-0854	Research Collaboration Agreement	5/11/2022	5/11/2027	Universidade Federal do Rio Grande do Sul (UFRGS)	
2021-0854	Research Collaboration Agreement	5/11/2022	5/11/2027	Universidade Federal do Rio Grande do Sul (UFRGS)	
2021-0861	Letter of Intent/MOU	6/28/2021		Veterans Health Administration (VA)	

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-0861	Letter of Intent/MOU	6/28/2021		Veterans Health Administration (VA)	
2021-0885	Research Collaboration Agreement	2/3/2022	2/8/2027	Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. (HJF;, Uniformed Services University of the Health Sciences (USUHS; USU) (DoD)	Leah Katzelnick
2021-0941	CTA - Clinical Trial Agreement	6/13/2022		SIGA Technologies, Inc	H Clifford Lane
2021-0966	Research Collaboration Agreement	9/20/2021	9/20/2022	Avalia Immunotherapies Limited, Malaghan Institute of Medical Research [NZ], University of Melbourne [AU], Victoria University of Wellington, Wellington UniVentures (Victoria Link)	
2021-0966	Research Collaboration Agreement	9/20/2021	9/20/2022	Avalia Immunotherapies Limited, Malaghan Institute of Medical Research [NZ], University of Melbourne [AU], Victoria University of Wellington, Wellington UniVentures (Victoria Link)	
2021-0972	CRADA	11/10/2021	5/9/2024	Axovant Sciences, Inc., National Human Genome Research Institute (NHGRI/NIH)	Elizabeth Kang
2021-1004	CTA - Clinical Trial Agreement	8/26/2022		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	
2021-1004	CTA - Clinical Trial Agreement	8/26/2022		GLAXO WELLCOME, INC. (now GlaxoSmithKline; GSK)	Irini Sereti
2021-1059	Gift	1/3/2022	1/3/2023	Jeffrey Leventhal	Jonathan Lyons
2021-1070	Gift	12/21/2021	12/31/2025	Cancer Research Institute [US]	Yasmine Belkaid
2021-1070	Gift	12/21/2021	12/31/2025	Cancer Research Institute [US]	Yasmine Belkaid
2021-1121	Research Collaboration Agreement	10/29/2021	10/29/2024	University of Pennsylvania	Jonathan (Jon) Ye
2021-1129	Gift	9/20/2021		Foundation for the National Institutes of Health, Inc. (FNIH)	Steven Holland
2021-1139	Gift	11/17/2021		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2021-1154	Research Collaboration Agreement	9/30/2021	9/30/2024	National Center for Advancing Translational Sciences (NCATS/NIH)	Peter Sun
2021-1163	Letter of Intent/MOU	12/22/2021	12/31/2026	Children's National Hospital	Suchitra Hourigan
2021-1199	CRADA	3/3/2022	3/3/2025	F2G Ltd. [GB]	Steven Holland

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2021-1205	Research Collaboration Agreement	1/26/2022	7/31/2025	University of Georgia, US Department of Agriculture (USDA)	Michael Grigg
2021-1244	Research Collaboration Agreement	1/23/2023	1/23/2025	Excision Biotherapeutics	Tae Wook Chun
2021-1256	CTA - Clinical Trial Agreement	12/7/2021		CellScript, Inc.	Suk See De Ravin
2021-1283	CTA - Clinical Trial Agreement	12/15/2021		NOVAVAX, INC.	John Beigel
2021-1288	Letter of Intent/MOU	12/2/2021		Ministry of Health (MOH) of Liberia [LR]	H Clifford Lane
2021-1292	Gift	9/30/2021		Canadian Institutes of Health Research (CIHR) [CA]	Michail Lionakis
2021-1322	Gift	1/10/2022	1/31/2024	European Molecular Biology Organization (EMBO) [EU]	Yasmine Belkaid
2021-1327	Research Collaboration Agreement	10/18/2021	10/18/2023	Canopy Biosciences, LLC	Ronald Germain
2021-1430	Research Collaboration Agreement	2/1/2022	2/11/2027	Walter Reed Army Institute of Research (WRAIR) (DoD)	Leah Katzelnick
2021-1431	Research Collaboration Agreement	3/30/2023	4/19/2028	University of California-Berkeley	Leah Katzelnick
2021-1432	Research Collaboration Agreement	7/15/2022	8/10/2027	University of California-Berkeley	Leah Katzelnick
2021-1459	Research Collaboration Agreement	11/19/2021		National Cancer Institute (NCI/NIH)	Clifton Barry
2021-1633	Letter of Intent/MOU	2/9/2022		George Mason University	Katrin Mayer-Barb
2021-1654	Research Collaboration Agreement	3/17/2022	3/17/2025	NIH Clinical Center (CC/NIH)	Peter Sun
2021-1663	Letter of Intent/MOU	1/4/2022		Forte Biosciences Inc.	Ian Myles
2021-1675	Research Collaboration Agreement	2/10/2022	2/10/2023	University of Pennsylvania	Patrick Duffy
2021-1676	Research Collaboration Agreement	1/26/2022		Ehime University [JP]	Patrick Duffy
2021-1681	Research Collaboration Agreement	2/28/2022	2/28/2027	Georgetown University School of Medicine [US]	Lisbeth Kim Green
2022-0034	Gift	3/31/2022	3/31/2024	JOB RESEARCH FOUNDATION	Suk See De Ravin
2022-0036	Gift	4/19/2022	10/19/2023	Creutzfeldt-Jakob Disease (CJD) Foundation, Inc.	Cathryn Haigh
2022-0054	Research Collaboration Agreement	6/8/2022	6/8/2025	University of South Bohemia in Ceské Budejovice	Lucas Tirloni
2022-0083	CRADA	4/25/2022	4/25/2025	Prime Medicine	Harry Malech
2022-0105	Research Collaboration Agreement	11/11/2023	11/11/2026	MLL Munchner Leukamielabor GmbH	Jonathan Lyons
2022-0113	CTA - Clinical Trial Agreement	9/8/2022		Rockefeller University	Tae Wook Chun
2022-0113	CTA - Clinical Trial Agreement	9/8/2022		Rockefeller University	Tae Wook Chun
2022-0178	Research Collaboration Agreement	3/10/2022		Merck Sharp & Dohme Corp	Clifton Barry
2022-0218	Research Collaboration Agreement	6/2/2022	6/2/2025	Moderna, Inc. (was Moderna Therapeutics, Inc., then ModernaTX, Inc.)	Paolo Lusso
2022-0226	CTA - Clinical Trial Agreement	3/13/2022		Novartis Pharmaceuticals Corporation [US]	Alexandra Freema

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2022-0229	Research Collaboration Agreement	7/11/2022	7/11/2025	Houston Methodist Hospital Research Institute [US]	
2022-0229	Research Collaboration Agreement	7/11/2022	7/11/2025	Houston Methodist Hospital Research Institute [US]	Jeffery Taubenber
2022-0229	Research Collaboration Agreement	7/11/2022	7/11/2025	Houston Methodist Hospital Research Institute [US]	
2022-0230	Letter of Intent/MOU	3/9/2022		10X Genomics, Inc.	Felipe Lopes de As
2022-0248	Research Collaboration Agreement	3/18/2022	3/18/2024	Walter Reed Army Institute of Research (WRAIR) (DoD)	Patrick Duffy
2022-0262	Research Collaboration Agreement	5/3/2022	4/30/2023	King's College London (KCL) (University of London) [GB]	Yasmine Belkaid
2022-0262	Research Collaboration Agreement	5/3/2022	4/30/2023	King's College London (KCL) (University of London) [GB]	Yasmine Belkaid
2022-0271	Research Collaboration Agreement	7/11/2022	7/8/2025	Purdue University	Ashley Groshong
2022-0272	Research Collaboration Agreement	5/10/2022	6/2/2026	University of Minnesota, University of Wisconsin System (Board of Regents) [US]	Mattia Bonsignori
2022-0321	Research Collaboration Agreement	7/18/2022	7/18/2024	AltPep Corp, University of Washington	Byron Caughey
2022-0333	CRADA	12/6/2022	12/6/2024	University of Texas Medical Branch at Galveston (UTMB) [US], US Department of Defense (DoD) [US]	Heinrich Feldmann
2022-0333	CRADA	12/6/2022	12/6/2024	University of Texas Medical Branch at Galveston (UTMB) [US], US Department of Defense (DoD) [US]	Heinrich Feldmann
2022-0354	CTA - Clinical Trial Agreement	8/5/2022		Siriraj Hospital, Mahidol University [TH]	Stephen Whitehea
2022-0383	CTA - Clinical Trial Agreement	8/12/2022		Shionogi, Inc	H Clifford Lane
2022-0385	Research Collaboration Agreement	5/3/2022	5/3/2025	Wuhan University	Michael Lenardo
2022-0432	CTA - Clinical Trial Agreement	5/6/2022		Sanofi Pasteur Inc. [US]	John Beigel
2022-0433	CTA - Clinical Trial Agreement	5/11/2022		Pfizer, Inc.	Paul Roberts
2022-0444	Research Collaboration Agreement	1/12/2023	1/12/2026	Helmholtz Center Munich, German Research Center for Environmental Health, GmbH (	Cathryn Haigh
2022-0453	CTA - Clinical Trial Agreement	4/29/2022		Amplyx Pharmaceuticals, Inc. [US]	Harry Malech
2022-0468	CRADA	6/3/2022	6/3/2024	CSL Behring	Harry Malech
2022-0468	CRADA	6/3/2022	6/3/2024	CSL Behring	Harry Malech
2022-0475	Gift	2/1/2023	2/28/2026	Novo Nordisk A/S [DK]	Emmie de Wit

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2022-0516	Research Collaboration Agreement	11/14/2022	11/14/2025	University of Texas Southwestern Medical Center	Patrizia FARCI
2022-0532	Gift	12/5/2022	12/5/2027	Jeffrey Ferrill	Amy Klion
2022-0584	CTA - Clinical Trial Agreement	9/12/2022		Centers for Disease Control and Prevention (CDC), Kenya Medical Research Institute (KEMRI) [KE], Liverpool School of Tropical Medicine [GB]	
2022-0597	CTA - Clinical Trial Agreement	1/31/2023		Indonesia Research Partnership of Infectious Disease (INA-RESPOND)	H Clifford Lane
2022-0608	CRADA	4/20/2023	4/20/2026	SymBio Pharmaceuticals Limited	Jeffrey Cohen
2022-0613	Letter of Intent/MOU	6/1/2022		American Type Culture Collection (ATCC)	Ian Myles
2022-0614	Letter of Intent/MOU	10/31/2022	10/31/2027	Naval Medical Research Center (NMRC) (DoD)	
2022-0614	Letter of Intent/MOU	10/31/2022	10/31/2027	Naval Medical Research Center (NMRC) (DoD)	
2022-0619	CRADA	7/22/2022	7/22/2027	ViiV Healthcare Company [US]	Malcolm Martin
2022-0621	Research Collaboration Agreement	6/15/2022	6/15/2027	University of Pittsburgh	
2022-0621	Research Collaboration Agreement	6/15/2022	6/15/2027	University of Pittsburgh	
2022-0631	CRADA	8/21/2023	9/4/2026	Taiho Pharmaceutical Co., Ltd.	Jeffrey Cohen
2022-0721	Gift	8/26/2022		Jeffrey and Mary Smith Family Foundation	Byron Caughey
2022-0722	Research Collaboration Agreement	11/22/2022	11/22/2023	University of Georgia	Ivan Fuss
2022-0800	Gift	12/5/2022	12/31/2026	Damon Runyon Cancer Research Foundation	Yasmine Belkaid
2022-0800	Gift	12/5/2022	12/31/2026	Damon Runyon Cancer Research Foundation	Yasmine Belkaid
2022-0908	Gift	10/10/2022		Bill & Melinda Gates Foundation (BMGF)	Clifton Barry
2022-0942	Gift	3/7/2023	3/7/2025	Banner Sun Health Research Institute [US]	Byron Caughey
2022-0977	Gift	8/4/2023	9/30/2026	The G. Harold & Leila Y. Mathers Foundation	Tijana Ivanovic
2022-0982	Research Collaboration Agreement	11/7/2022		Sidra Medical and Research Center [Qatar]	Luigi Notarangelo
2022-1018	Research Collaboration Agreement	3/8/2023		Calico Life Sciences, LLC.	Raphaela Goldbac
2022-1042	CRADA	11/18/2022	11/18/2024	Amgen Inc.	Yasmine Belkaid
2022-1042	CRADA	11/18/2022	11/18/2024	Amgen Inc.	Yasmine Belkaid
2022-1067	CRADA	4/5/2023	4/5/2033	Pfizer, Inc.	Christa Zerbe
2022-1069	Research Collaboration Agreement	5/23/2023	5/23/2024	University of Bologna [IT]	Cathryn Haigh
2022-1085	Gift	12/19/2022		University of Oxford	Vincent Munster
2022-1097	CTA - Clinical Trial Agreement	2/28/2023		Bristol-Myers Squibb Company (BMS)	H Clifford Lane
2022-1125	Research Collaboration Agreement	3/13/2023	3/13/2025	Icahn School of Medicine at Mount Sinai	Ronald Germain
2022-1153	CTA - Clinical Trial Agreement	12/7/2022		CellScript, Inc.	Suk See De Ravin
2022-1155	Research Collaboration Agreement	11/20/2022	11/20/2023	Icahn School of Medicine at Mount Sinai	Ronald Germain
2022-1158	Research Collaboration Agreement	6/23/2023	6/23/2025	Vaccine Company, Inc.	Bernard Moss

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
2022-1187	Gift	6/22/2020	6/30/2024	National Multiple Sclerosis Society	Faraniz Safavi
2022-1233	Letter of Intent/MOU	11/30/2022		Vaccigen, SAS, VaxThera, SAS	Bernard Moss
2022-1287	CTA - Clinical Trial Agreement	6/20/2023		Sanofi Pasteur S.A.	H Clifford Lane
2022-1289	Gift	3/23/2023	11/29/2024	American Society of Tropical Medicine & Hygiene	
2022-1289	Gift	3/23/2023	11/29/2024	American Society of Tropical Medicine & Hygiene	Christina Yek
2022-1289	Gift	3/23/2023	11/29/2024	American Society of Tropical Medicine & Hygiene	
C-008-2014	CRADA	1/20/2015		Knopp Biosciences, LLC	Amy Klion
C-020-2024	CRADA	10/11/2023	10/11/2027	NeoImmunetech, Inc. [US]	Andrea Lisco
C-020-2024	CRADA	10/11/2023	10/11/2027	NeoImmunetech, Inc. [US]	Andrea Lisco
C-032-2014	CRADA	3/29/2017		Janssen Research and Development	
C-035-2023	CRADA	1/12/2023	6/25/2023	PharmAbcine	Kirk Druey
C-053-2021	CRADA	11/10/2021		Amgen, Inc.	
C-084-2023	CRADA	8/23/2023	8/23/2026	Imunon, Inc.	Heinrich Feldmann
C-084-2023	CRADA	8/23/2023	8/23/2026	Imunon, Inc.	Heinrich Feldmann
C-100-2020	CRADA	9/24/2021		AstraZeneca Pharmaceuticals LP	Amy Klion
C-129-2023	CRADA	12/1/2023	12/1/2028	Viracta Therapeutics, Inc.	Jeffrey Cohen
C-137-2023	CRADA	9/25/2023	9/25/2025	MacroGenics, Inc.	Ethan Shevach
C-137-2023	CRADA	9/25/2023	9/25/2025	MacroGenics, Inc.	Ethan Shevach
C-156-2023	CRADA	11/2/2023	11/2/2028	GlaxoSmithKline	Clifton Barry
C-162-2023	CRADA	9/27/2023	9/27/2025	Leyden Laboratories B.V.	Joshua Tan
C-163-2023	CRADA	10/11/2023	10/11/2026	PARI Pharma GmBH	Peter Sun
C-164-2023	CRADA	7/14/2023	7/14/2025	Dartmouth College, Exothera [BE]	Mark Connors
C-2019-0227	CRADA	7/11/2023	6/25/2024	F2G Ltd. [GB]	Steven Holland
T-00057-2023	Research Collaboration Agreement	8/10/2023	8/11/2025	ModernaTX, Inc.	Jeffrey Cohen
T-00143-2024	CTA - Clinical Trial Agreement	10/18/2023		TFF Pharmaceuticals Inc.	Alexandra Freema
T-00202-2023	Research Collaboration Agreement	4/14/2023	4/14/2033	Yale University	Rachel Sparks
T-00203-2023	CTA - Clinical Trial Agreement	5/6/2023		CellScript, LLC	Suk See DeRavin
T-00303-2024	Research Collaboration Agreement	12/13/2023	12/13/2025	Stellenbosch University (Universiteit Stellenbosch) [ZA]	Michal Fried
T-00467-2023	Research Collaboration Agreement	2/25/2023	2/25/2024	New Mexico State University	Joel Vega-rodrigue
T-00471-2023	Research Collaboration Agreement	3/3/2023	3/3/2024	Eugenia Lo, The University of North Carolina at Charlotte	Louis Miller
T-00509-2023	Letter of Intent/MOU	11/19/2022		Post Graduate Institute of Medical Education and Research	Michail Lionakis

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G1 - NIAID DIR collaborative agreements active between June 1 2016 and Dec 13 2023

Reference #	Agreement Type	Effective Date	Expiration Da	External Parties	*Lead PI
T-00627-2024	Letter of Intent/MOU	11/15/2023	11/15/2025	Rocketvax AG (c/o Swiss Rockets AG)	John Beigel
T-00655-2023	Research Collaboration Agreement	3/14/2023	3/19/2024	University of Wisconsin	Mattia Bonsignori
T-00659-2023	Research Collaboration Agreement	3/2/2023		Children's National Medical Center (CNMC) [US]	Jeffrey Cohen
T-01216-2023	Research Collaboration Agreement	6/1/2023	10/1/2023	Leica Microsystems, Inc. [US]	Ronald Germain
T-01340-2023	CTA - Clinical Trial Agreement	3/16/2023		Amplyx Pharmaceuticals, Inc. [US]	Christa Zerbe
T-01420-2023	Gift	8/16/2021		Jim Miller	Jonathan Lyons
T-01815-2023	Gift	6/7/2023		University of Cagliari	Byron Caughey
T-01865-2023	Research Collaboration Agreement	5/12/2023		Walter Reed Army Institute of Reseach (WRAIR)	Patrick Duffy
T-01966-2023	Research Collaboration Agreement	7/6/2023	7/6/2028	Yale University	Rachel Sparks
T-02191-2023	Research Collaboration Agreement	5/8/2023	5/9/2025	Integral Molecular [US]	Leah Katzelnick
T-02327-2023	Research Collaboration Agreement	11/1/2023	11/1/2026	Vitarka Therapeutics Ltd	Stephen Leppla
T-02339-2023	Gift	10/5/2023	10/5/2026	Foundation for the National Institutes of Health, Inc. (FNIH), Jane Coffin Childs Memorial Fund for Medical Research	Michael Grigg
T-02353-2023	Gift	5/24/2023	9/30/2025	Bill & Melinda Gates Foundation (BMGF)	Joshua Tan
T-02608-2023	Gift	7/11/2023		Infectious Diseases Society of America	Patrick Duffy
T-02916-2023	Research Collaboration Agreement	6/20/2023	6/20/2026	Yale University	Byron Caughey
T-03182-2023	Research Collaboration Agreement	6/29/2023	6/29/2026	Akagera Medicines, Inc	Theodore Pierson
T-03225-2023	Research Collaboration Agreement	7/5/2023	4/5/2024	The Scripps Research Institute (TSRI)	Joshua Tan
T-03609-2023	Gift	8/16/2023		Jeffrey and Mary Smith Family Foundation	Byron Caughey
T-04145-2023	Research Collaboration Agreement	9/22/2023	6/2/2026	Moderna, Inc. (was Moderna Therapeutics, Inc., then ModernaTX, Inc.)	Paolo Lusso
T-04588-2023	Research Collaboration Agreement	11/7/2023	11/7/2024	AstraZeneca	Clifton Barry

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Dean, National School of Tropical Medicine, Baylor College of Medicine;
Director, Center for Vaccine Development, Texas Children's Hospital

Kathrin Jansen, Ph.D. (Co-Chair)
Senior Vice President and Head of Vaccine Research and Development
Pfizer

Antonio Lanzavecchia, M.D.
Senior Vice President and Senior Research Fellow, Vir Biotechnology, Inc.;
Director, Institute for Research in Biomedicine

Douglas Lowy, M.D. (Co-Chair)
Principal Deputy Director
National Cancer Institute, NIH

Peter Marks, M.D., Ph.D.
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

John Mascola, M.D.
Director, Dale and Betty Bumpers Vaccine Research Center
National Institute of Allergy and Infectious Diseases, NIH

Nancy Messonnier, M.D.
Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

Nelson Michael, M.D., Ph.D.
Director, Center for Infectious Diseases Research
Walter Reed Army Institute of Research, U.S. Army Medical Research and Development Command

Paul Offit, M.D.
Director, Vaccine Education Center
Maurice R. Hilleman Professor of Vaccinology, Perelman School of Medicine, University of Pennsylvania;
Professor, Children's Hospital of Philadelphia

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Members of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Partnership

Hanneke Schuitemaker, Ph.D.
Global Head of Viral Vaccine Discovery and Translational Medicine, Johnson & Johnson;
Professor, Virology, Amsterdam University Medical Center, University of Amsterdam

Jonathan Seals, Ph.D.
Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

Jim Tartaglia, Ph.D.
Vice President for Research and Development
Sanofi Pasteur

Tonya Villafana, M.P.H., Ph.D.
Vice President, Global Franchise Head, Infection
AstraZeneca

Tal Zaks, M.D., Ph.D.
Chief Medical Officer
Moderna, Inc.

FNIH Project Management

Maria Freire, Ph.D.
President and Executive Director
FNIH

Steve Paul, M.D.
Chairman, FNIH; Chief Executive Officer and Chairman, Karuna Therapeutics

David Wholley, M.Phil.
Senior Vice President of Research Partnerships
FNIH

Joseph Menetski, Ph.D.
Associate Vice President of Research Partnerships
FNIH

Stacey Adam, Ph.D.
Director, Cancer, Research Partnerships
FNIH

Karen Tountas, Ph.D.
Scientific Program Manager
FNIH

Michael Santos, Ph.D.
Associate Vice President, Science
FNIH

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Stephanie James, Ph.D.
Senior Vice President, Science
FNIH

NIH Staff

Michelle Culp, B.S.N., M.P.H.
Senior Policy Advisor, Office of Science Policy
Office of the Director, NIH

Ellen Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy, Office of Science Policy
Office of the Director, NIH

Ashley Parker, Ph.D.
Special Assistant to the Acting Chief of Staff and NIH Director for ACTIV
Health Science Policy Analyst, Office of Science Policy
Office of the Director, NIH

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NIH-Funded ACTIV/ACTIV-Associated Clinical Trials | National Institutes of Health (NIH)

nih.gov/activ/nih-funded-activ/activ-associated-clinical-trials

February 11, 2021

National Institutes of Health
Turning Discovery Into Health

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Company	Therapeutic	Class	Administration	New/ Repurposed	Estimated End Date
ACTIV-1 Inpatient					
BMS	Orencia (abatacept)	Immune Modulator	Intravenous	Repurposed	Q4 2021
Janssen	Remicade (Infliximab)	Immune Modulator	Intravenous	Repurposed	Q4 2021
AbbVie	Cenicriviroc	Immune Modulator	Oral	New	Q4 2021
ACTIV-2 Outpatient					
AstraZeneca	AZD7442	Monoclonal Antibody Cocktail	Intramuscular	New	Q4 2021
AstraZeneca	AZD7442	Monoclonal Antibody Cocktail	Intravenous	New	Q4 2021
Brii Biosciences	Brii-196 & Brii-198	Monoclonal Antibody Cocktail	Intravenous	New	Q4 2021
Eli Lilly	LY-CoV-555	Monoclonal Antibody Single	Intravenous	New	Q1 2021
Sagent	Camostat Mesylate	Antiviral	Oral	Repurposed	Q4 2021
Synairgen	SNG001 IFN-beta	Immune Modulator	Inhaled	Repurposed	Q4 2021
ACTIV-3 Inpatient					

AstraZeneca	AZD7442	Monoclonal Antibody Cocktail	Intravenous	New	Q3 2021
Brii Biosciences	Brii-196 & Brii-198	Monoclonal Antibody Cocktail	Intravenous	New	Q2 2021
Eli Lilly	LY-CoV-555	Monoclonal Antibody Single	Intravenous	New	Q4 2020
GSK-Vir	VIR-7831	Monoclonal Antibody Single	Intravenous	New	Q2 2021
ACTIV-4					
Outpatients					
BMS/Pfizer	Apixaban	Anticoagulant	Oral	Repurposed	Q4 2021
BMS/Pfizer	Aspirin	Antiplatelet	Oral	Repurposed	Q4 2021
Inpatients					
Other	Un-fractionated (UF) Heparin	Anticoagulant	Intravenous	Repurposed	Q2 2021
Other	Low Molecular Weight (LMW) Heparin	Anticoagulant	Injection	Repurposed	Q2 2021
ACTIV-5 Inpatient					
AbbVie/Boehringer Ingelheim	Risankizumab	Immune Modulator	Intravenous	Repurposed	Q4 2021
Humanigen	Lenzilumab	Immune Modulator	Intravenous	New	Q4 2021
ACTIV-Associated					
Adaptive COVID-19 Treatment Trial (ACTT) Inpatient					
Gilead	Remdesivir	Antiviral	Intravenous	Repurposed	Q4 2020
Eli Lilly	Remdesivir and Baricitinib	Antiviral/Anti-Inflammatory	Intravenous/Oral	Repurposed	Q4 2020
Eli Lilly	Remdesivir and Baricitinib or Dexamethasone	Antiviral/Anti-Inflammatory/ Immune Modulator	Intravenous/Oral	Repurposed	Q2 2021

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Merck	Remdesivir and IFN-beta (Rebif)	Antiviral/Immune Modulator	Injection	Repurposed	Q1 2021
Inpatient Treatment with Anti-Coronavirus Immunoglobulin (ITAC)					
Gilead & Other	Remdesivir and Hyperimmune Intravenous Immunoglobulin (hIVIG)	Antiviral	Intravenous	N/A	Q3 2021
Convalescent Plasma in Outpatients with COVID-19 (C3PO)					
Other	Convalescent Plasma	Convalescent Plasma	Intravenous	N/A	Q4 2022
Convalescent Plasma to Limit COVID-19 Complications in Hospitalized Patients (CONTAIN COVID-19)					
Other	Convalescent Plasma	Convalescent Plasma	Intravenous	N/A	Q2 2021
Passive Immunity Trial of Our Nation (PassItOn) Inpatient					
Other	Convalescent Plasma	Convalescent Plasma	Intravenous	N/A	Q2 2021

This page last reviewed on February 12, 2021

Released by Chairman Rand Paul

National Institutes of Health (NIH)

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This page last reviewed on December 23, 2020

Released by Chairman Rand Paul

From: "Rick Klausner"[redacted]gatesfoundation.org>
To: "Anthony Fauci (E-mail)" [redacted]@NIH.GOV>
Subject: PAVE - please clarify
Date: Fri, 24 Oct 2003 15:49:04 -0400
Importance: Normal

I just came back from speaking at the HVTN and there, as anywhere I go and HIV vaccines are discussed, I am asked about PAVE. Particularly now that PAVE seems to be setting up the same committees the Enterprise agreed to set up and asking some of the same people. I don't know what to tell people, especially since, in marked contrast to the Enterprise, the Gates Foundation has never been talked to about this (none of us). So I talk about how well we are working together, etc etc but everyone I speak to (I never bring it up) seems confused. I am sure that PAVE pre-dated our meetings in the Spring of 2002 about an enterprise approach but we really need to know how to respond about this.
You can hear my frustration in this email. Am I mis-reading this? I have not run into anyone who is not "confused".

Released by Chairman Rand Paul

From: "Tramont, Ed (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=ETRAMONT>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Subject: RE: PAVE - please clarify
Date: Sat, 25 Oct 2003 21:18:28 -0400
Importance: Normal

Tony,
We have already started a dialogue with Jose – he is going to be "stationed" in Washington. This "American takeover" stuff is a smoke screen, there is precious little money being put towards vaccines except for ours; Hence, – my suspicion is that they are angling to play Gates off against us.
Ed

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID)
Sent: Saturday, October 25, 2003 3:51 PM
To: 'Rick Klausner'
Subject: RE: PAVE - please clarify

Rick:
As I had mentioned in my e-mail and illustrated in the slides that I sent to you, you are correct that PAVE is for USG coordination, but also, if others want to participate, they are most welcome. Importantly, PAVE only relates to clinical trials and Enterprise is the whole picture including clinical trials. Thus, PAVE fits into the concept of Enterprise. That is the message that needs to get out It is true that the distrust of the USG is enormous, but I do not think that I can cure that; I can only try to not make it worse and hopefully dispell it a bit. In any event, your idea about having Jose visit NIAID to raise the level of communication is an excellent one. I will communicate this to Ed and Peggy.
Take care of your self.
Warm regards,
Tony

-----Original Message-----
From: Rick Klausner [redacted]@gatesfoundation.org]
Sent: Saturday, October 25, 2003 10:37 AM
To: Fauci, Anthony (NIH/NIAID)
Subject: RE: PAVE - please clarify

Tony,
I keep looking at my email to you to see whether it sounded angry, which I was not, or just confused and truly looking for clarification. Maybe this is what happens through the terseness of a quick email. I am confused about PAVE and fully recognize that much of this confusion is because of information/perceptions that come via the filter of others. This was particularly intense at the HVTN meeting and especially with Europeans and Africans who seem (they are explicit) to be worried, threatened, wary of "an American Takeover" (I am not sure what is beneath it except that the distrust of the USG is so enormous around the world). When I say that PAVE is for USG coordination, that you and we are working closely together and well, and that the enterprise is truly about a global compact - not a US hegemony for HIV vaccines, they counter that that is not what they are being told when they (Non US people) are asked to be part of new planning committees. I do not push to understand because I do not want to communicate that we have no communication with NIAID about PAVE. My line - you need to know- to everyone is that we are in agreement and I also say that PAVE is a really important step that is perfectly compatible with the Enterprise. My frustration is that I do not know what is going on and when I turn to Helene (who I hope is in contact with Ed and Peggy as I am always reinforcing to her how important that is) she also doesn't know and also feels confused.
I think that it would be helpful to ask Jose to visit NIAID (he starts with us Nov 1) and work to raise the level of communication.
I am also sure that we can straighten this out and we can be as helpful to all of this as possible.
Rick

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [mailto:AFAUCI@niaid.nih.gov]
Sent: Friday, October 24, 2003 5:20 PM

Released by Chairman Rand Paul

To: Rick Klausner
Subject: RE: PAVE - please clarify

Rick:

Two things: 1) I really do not have any idea what you are talking about, and 2) I am very, very sorry that you are upset and obviously angry. I cannot figure out what the issue is. I have been saying and doing nothing more or less than what we have discussed many times. The PAVE is a partnership of government agencies facilitated by NIAID. We have been planning this for a long time and it relates only to clinical trials, particularly phase 3 trials. It was further instigated by DHHS wanting to have consistency in what we do among agencies (NIH and CDC). Since the NIAID has developed a strong relationship with the DoD, they have been brought into this partnership now consisting of 3 agencies (NIAID/NIH, CDC, and DoD). The purpose was to create consistency and harmonization in clinical trials (protocols, laboratory measures, etc.) run by the government so that the agencies can synergize. Since we (mainly the NIAID) also collaborate with many other entities, we would offer our partnered network to any group that wishes to collaborate provided that they agree to share the common goal of transparency, consistency, and harmonization. This would have happened whether or not there was an Enterprise. The "Enterprise" is much bigger in scope than the PAVE, but the PAVE can certainly be an important part of the Enterprise. You and I have discussed this several times. When I speak about vaccines I almost always (with minor variations) talk about: 1) what the Federal government, particularly NIAID is doing; 2) the need for a new look and an accelerated effort, i.e. the Enterprise; and 3) the role that the PAVE may play in the Enterprise. I am attaching one of my typical talks that goes through this sequence of thoughts. I do not think that I can be any more clear. I always end with a slide showing the PAVE being a part of the Global Vaccine Enterprise. If people are confused, they either are not listening or they do not want to hear. Please take a look at these slides and see if they do not indicate what I have said to you several times and above in this e-mail.

Again, I am very sorry that this has upset you. I hope that we can straighten this out. I would be happy to speak with you at your convenience. I will be at a meeting in Wye River on Saturday AM and early afternoon, but I will be either in the office or home for the rest of the weekend.

Best regards,
Tony

<< File: AIDS Vaccine Enterprise-PAVE.ppt >>

-----Original Message-----
From: Rick Klausner [redacted]@gatesfoundation.org]
Sent: Friday, October 24, 2003 3:49 PM
To: Anthony Fauci (E-mail)
Subject: PAVE - please clarify

I just came back from speaking at the HVTN and there, as anywhere I go and HIV vaccines are discussed, I am asked about PAVE. Particularly now that PAVE seems to be setting up the same committees the Enterprise agreed to set up and asking some of the same people. I don't know what to tell people, especially since, in marked contrast to the Enterprise, the Gates Foundation has never been talked to about this (none of us). So I talk about how well we are working together, etc etc but everyone I speak to (I never bring it up) seems confused. I am sure that PAVE pre-dated our meetings in the Spring of 2002 about an enterprise approach but we really need to know how to respond about this.
You can hear my frustration in this email. Am I mis-reading this? I have not run into anyone who is not "confused".

Released by Chairman Rand Paul

From: "Tramont, Ed (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=ETRAMONT>

To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>, "Johnston, Margaret (Peggy) (NIH/NIAID)" [redacted]@niaid.nih.gov>

Cc: "La Montagne, John (NIH/NIAID)" [redacted]@niaid.nih.gov>, "Moore, Marg (NIH/NIAID)" [redacted]@niaid.nih.gov>

Subject: RE: PAVE - please clarify

Date: Sat, 25 Oct 2003 10:51:03 -0400

Importance: Normal

Tony,
thanks for sharing with us - I think that your response is right on the money. But I can speculate: (1) those asking have little idea of what a vaccine strategic plan is - because if they did, they would not be focusing on PAVE in the context of vaccine R&D as it addresses only one part; by that I mean that a vaccine or any product R&D progresses from **discovery** to **product development/QA/QC manufacturing** to **clinical trials** and PAVE addresses only the conduct of clinical trials; (2) there is growing recognition that NIAID has these steps covered, albeit with funding restrictions, and people are using PAVE as a sedge way for them to ask how the Enterprise will be of **value added** to our strategic plan; (3) Rick's motives are not as benevolent as he portrays or he has a very thin skin, (4) Judy Wiesherheit, Chuck Vietek (CDC), Peggy, Jorge, Barney and Sandi accompanied Debbie on a 10 day visit of the USMHRP sites in Uganda and Kenya which has resulted in a better understanding of how the partnership (PAVE) will work, and all have told me that they are excited about our expanding ability to conduct vaccine trials in Africa - I believe that this optimism was portrayed by them at the recent HVTN meeting but all recognize that there are significant issues with infrastructure building, training and procurement of ART's and obviously, Gates could be very helpful here.
Ed

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID)
Sent: Friday, October 24, 2003 8:23 PM
To: Tramont, Ed (NIH/NIAID); Johnston, Margaret (Peggy) (NIH/NIAID)
Cc: La Montagne, John (NIH/NIAID); Moore, Marg (NIH/NIAID)
Subject: FW: PAVE - please clarify

Ed:
This is the e-mail that Rick sent to me and my response to him. What is going on here? Please touch bases with Peggy and then get back to me as to what you think is happening here? Who has been instigating Rick?
Tony

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID)
Sent: Friday, October 24, 2003 8:20 PM
To: 'Rick Klausner'
Subject: RE: PAVE - please clarify

Rick:
Two things: 1) I really do not have any idea what you are talking about, and 2) I am very, very sorry that you are upset and obviously angry. I cannot figure out what the issue is. I have been saying and doing nothing more or less than what we have discussed many times. The PAVE is a partnership of government agencies facilitated by NIAID. We have been planning this for a long time and it relates only to clinical trials, particularly phase 3 trials. It was further instigated by DHHS wanting to have consistency in what we do among agencies (NIH and CDC). Since the NIAID has developed a strong relationship with the DoD, they have been brought into this partnership now consisting of 3 agencies (NIAID/NIH, CDC, and DoD). The purpose was to create consistency and harmonization in clinical trials (protocols, laboratory measures, etc.) run by the government so that the agencies can synergize. Since we (mainly the NIAID) also collaborate with many other entities, we would offer our partnered network to any group that wishes to collaborate provided that they agree to share the common goal of transparency, consistency, and harmonization. This would have happened whether or not there was an Enterprise. The "Enterprise" is much bigger in scope than the PAVE, but the PAVE can certainly be an important part of the Enterprise. You and I have discussed this several times. When I speak about vaccines I almost always (with minor variations) talk about: 1) what the Federal government, particularly NIAID is doing; 2) the need for a new look and an accelerated effort, i.e. the Enterprise; and 3) the role that the PAVE may play in the Enterprise. I am attaching one of my typical talks that goes through this sequence of thoughts. I do not think that I can be any more clear. I

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Best regards,
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From: Rick Klausner [redacted]@gatesfoundation.org]
Sent: Friday, October 24, 2003 3:49 PM
To: Anthony Fauci (E-mail)
Subject: PAVE - please clarify

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You can hear my frustration in this email. Am I mis-reading this? I have not run into anyone who is not "confused".

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From: "Rick Klausner" [redacted]@gatesfoundation.org>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Subject: RE: PAVE - please clarify
Date: Sat, 25 Oct 2003 10:36:45 -0400
Importance: Normal

Tony,
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Best regards,
Tony

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From: "Johnston, Margaret (Peggy) (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=PJOHNSTON>

To: "Tramont, Ed (NIH/NIAID)" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>

Cc: "La Montagne, John (NIH/NIAID)" [redacted]@niaid.nih.gov>, "Moore, Marg (NIH/NIAID)" [redacted]@niaid.nih.gov>

Subject: RE: PAVE - please clarify

Date: Sun, 26 Oct 2003 00:24:19 -0400

Importance: Normal

TOny,

I concur. To my knowledge, we in NIAID have all been saying the same thing about PAVE and it's relationship to Enterprise, as you outlined in NYC.

My take from Aerlie is that the next step would be writing "white papers" covering a range of topics. Shortly thereafter I received a draft list of papers and possible contributors and gave feedback to Helene. I have heard nothing and when I asked Helene for an update pre-HVTN meeting she admitted they were stretched thin and were waiting for Jose Esparza to join to really get things moving. So if Gates has moved foward to "set up committees" and has approached individuals for certain tasks/committees, that is news to me.

There will be overlap between PAVE and ENTERPRISE if Rick sets up new working groups to discuss what PAVE has already taken on - labs, infrastructure development, protocol/endpoint harmonization. We can not stop and wait for Enterprise to catch up.

Until Enterprise is better defined, there will likely continue to be confusion.

From China,

Peggy

-----Original Message-----
From: Tramont, Ed (NIH/NIAID)
To: Fauci, Anthony (NIH/NIAID); Johnston, Margaret (Peggy) (NIH/NIAID)
Cc: La Montagne, John (NIH/NIAID); Moore, Marg (NIH/NIAID)
Sent: 10/25/2003 10:51 AM
Subject: RE: PAVE - please clarify

Tony,
thanks for sharing with us - I think that your response is right on the money. But I can speculate: (1) those asking have little idea of what a vaccine strategic plan is - because if they did, they would not be focusing on PAVE in the context of vaccine R&D as it addresses only one part; by that I mean that a vaccine or any product R&D progresses from discovery to product development/QA/QC manufacturing to clinical trials and PAVE addresses only the conduct of clinical trials; (2) there is growing recognition that NIAID has these steps covered, albeit with funding restrictions, and people are using PAVE as a sedge way for them to ask how the Enterprise will be of value added to our strategic plan; (3) Rick's motives are not as benevolent as he portrays or he has a very thin skin, (4) Judy Wiesherheit, Chuck Vietek (CDC), Peggy, Jorge, Barney and Sandi accompanied Debbie on a 10 day visit of the USMHRP sites in Uganda and Kenya which has resulted in a better understanding of how the partnership (PAVE) will work, and all have told me that they are excited about our expanding ability to conduct vaccine trials in Africa - I believe that this optimism was portrayed by them at the recent HVTN meeting but all recognize that there are significant issues

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with infrastructure building, training and procurement of ART's and
obviously, Gates could be very helpful here.
Ed

> -----Original Message-----
>From: Fauci, Anthony (NIH/NIAID)
>Sent: Friday, October 24, 2003 8:23 PM
>To: Tramont, Ed (NIH/NIAID); Johnston, Margaret (Peggy) (NIH/NIAID)
>Cc: La Montagne, John (NIH/NIAID); Moore, Marg (NIH/NIAID)
>Subject: FW: PAVE - please clarify
>
>Ed:
> This is the e-mail that Rick sent to me and my response to him.
>What is going on here? Please touch bases with Peggy and then get back
>to me as to what you think is happening here? Who has been instigating
>Rick?
>Tony
>
> -----Original Message-----
>From: Fauci, Anthony (NIH/NIAID)
>Sent: Friday, October 24, 2003 8:20 PM
>To: 'Rick Klausner'
>Subject: RE: PAVE - please clarify
>
>Rick:
> Two things: 1) I really do not have any idea what you are
>talking about, and 2) I am very, very sorry that you are upset and
>obviously angry. I cannot figure out what the issue is. I have been
>saying and doing nothing more or less than what we have discussed many
>times. The PAVE is a partnership of government agencies facilitated by
>NIAID. We have been planning this for a long time and it relates only
>to clinical trials, particularly phase 3 trials. It was further
>instigated by DHHS wanting to have consistency in what we do among
>agencies (NIH and CDC). Since the NIAID has developed a strong
>relationship with the DoD, they have been brought into this partnership
>now consisting of 3 agencies (NIAID/NIH, CDC, and DoD). The purpose
>was to create consistency and harmonization in clinical trials
>(protocols, laboratory measures, etc.) run by the government so that
>the agencies can synergize. Since we (mainly the NIAID) also
>collaborate with many other entities, we would offer our partnered
>network to any group that wishes to collaborate provided that they
>agree to share the common goal of transparency, consistency, and
>harmonization. This would have happened whether or not there was an
>Enterprise. The "Enterprise" is much bigger in scope than the PAVE,
>but the PAVE can certainly be an important part of the Enterprise. You
>and I have discussed this several times. When I speak about vaccines I
>almost always (with minor variations) talk about: 1) what the Federal
>government, particularly NIAID is doing; 2) the need for a new look and
>an accelerated effort, i.e. the Enterprise; and 3) the role that the
>PAVE may play in the Enterprise. I am attaching one of my typical
>talks that goes through this sequence of thoughts. I do not think that
>I can be any more clear. I always end with a slide showing the PAVE
>being a part of the Global Vaccine Enterprise. If people are confused,
>they either are not listening or they do not want to hear. Please take
>a look at these slides and see if they do not indicate what I have said
>to you several times and above in this e-mail.
> Again, I am very sorry that this has upset you. I hope that we
>can straighten this out. I would be happy to speak with you at your
>convenience. I will be at a meeting in Wye River on Saturday AM and
>early afternoon, but I will be either in the office or home for the
>rest of the weekend.
>Best regards,
>Tony
>

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> << File: AIDS Vaccine Enterprise-PAVE.ppt >>
>
> -----Original Message-----
>From: Rick Klausner [redacted]@gatesfoundation.org]
>Sent: Friday, October 24, 2003 3:49 PM
>To: Anthony Fauci (E-mail)
>Subject: PAVE - please clarify
>
>I just came back from speaking at the HVTN and there, as anywhere I go
>and HIV vaccines are discussed, I am asked about PAVE. Particularly now
>that PAVE seems to be setting up the same committees the Enterprise
>agreed to set up and asking some of the same people. I don't know what
>to tell people, especially since, in marked contrast to the Enterprise,
>the Gates Foundation has never been talked to about this (none of us).
>So I talk about how well we are working together, etc etc but everyone
>I speak to (I never bring it up) seems confused. I am sure that PAVE
>pre-dated our meetings in the Spring of 2002 about an enterprise
>approach but we really need to know how to respond about this.
>You can hear my frustration in this email. Am I mis-reading this? I
>have not run into anyone who is not "confused".

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From: "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
Cc: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:35:02 -0400
Importance: Normal

Larry,

Not sure if this is relevant, but I believe FNIH still has some collaborations with BMGF, which are somewhat independent of NIH, although some may also overlap with Grand Challenges. If it would be helpful to have info about that, I can reach out to Stephanie James. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health
[redacted]

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:29:41 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov> wrote:

For reasons I can't currently explain, I need answers to the following:

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1) are we giving any grants to BMGF (I assume no)

2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?

Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.

Questions? Call [redacted] Getting on a plane in 10 minutes

FC

Sent from my iPhone

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:02:49 -0400
Importance: Normal

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>
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>
> FC
>
> Sent from my iPhone

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>
Subject: POTUS meeting
Date: Sun, 27 May 2018 08:52:29 -0400
Importance: Normal

Hi Tony,

Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.

Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)

Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.

What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

Francis

P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Just spoke with Larry, he has the full scoop

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>
> For reasons I can't currently explain, I need answers to the following:
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is it from BMGF?
>
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>
> Questions? Call [redacted] Getting on a plane in 10 minutes
>
> FC
>
> Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:01:45 -0400
Importance: Normal

Tara:
I have no idea how to answer this question from Francis. I will call you about it and perhaps we can figure this out. He needs an answer by tomorrow.....YIKES!
Thanks,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 4:55 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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Questions? Call [redacted] Getting on a plane in 10 minutes

FC

Sent from my iPhone

Released by Chairman Rand Paul

From: "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:32:24 -0400
Importance: Normal

Tara,

BMGF will not accept money from NIH. We operate more by getting monies directly from them as gift funds, in the past through the NIH foundation (I don't recall any right now coming through the foundation) and by collaboratively working together where they partially fund a trial by giving funds to an institution and where we have awarded a grant.

I have copied Wayne and Martin so they can get you the financial gift fund information. Carl (not sure about DMID with Emily) can provide project information.

JJ

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 4:55 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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FC

Sent from my iPhone

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting
Date: Mon, 28 May 2018 19:44:41 -0400
Importance: Normal

Sorry not sure I understand. I think this is for Francis Colin's to take to the WH meeting. I think we can get someone to pick it up. Is that what you mean?

Sent from my iPhone

> On May 28, 2018, at 6:43 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Thanks, Barney.
>
> -----Original Message-----
> From: Graham, Barney (NIH/VRC) [E]
> Sent: Monday, May 28, 2018 6:29 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Haskins, Melinda (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: Re: POTUS meeting
>
> I'll be in my office by 7 am tomorrow and have them packed.
>
> Barney
>
>
>
> Sent from my iPhone
>
>> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>>
>> Melinda/Sara:
>> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
>> Thanks,
>> Tony
>>
>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Monday, May 28, 2018 5:40 PM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Hi Tony,
>>
>> Still no more information about the agenda for tomorrow's WH meeting.
>>

Released by Chairman Rand Paul

>> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>>
>> Francis
>>
>> -----Original Message-----
>> From: Fauci, Anthony (NIH/NIAID) [E]
>> Sent: Sunday, May 27, 2018 9:31 AM
>> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Francis:
>> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
>> Best regards,
>> Tony
>>
>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Sunday, May 27, 2018 8:52 AM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
>> Subject: POTUS meeting
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>> Hi Tony,
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>>
>> What's the answer to that?
>>
>> Glad to speak by phone if that would make this easier. [redacted]
>>
>> Francis
>>
>> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
>>
>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Friday, May 25, 2018 5:02 PM
>> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Released by Chairman Rand Paul

>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
>> Subject: Re: Need info on BMGF — Urgent
>>
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>> Sent from my iPhone
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>>> Sent from my iPhone

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 19:46:09 -0400
Importance: Normal

Yes. We need someone (? Sara) to go over to VRC in the AM to pick up the prop and then we deliver it to Dr. Collins in Room 126 in Building 1.

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E]
Sent: Monday, May 28, 2018 7:45 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting

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> Sent: Monday, May 28, 2018 6:29 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Haskins, Melinda (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: Re: POTUS meeting
>
> I'll be in my office by 7 am tomorrow and have them packed.
>
> Barney
>
>
>
> Sent from my iPhone
>
>> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>>
>> Melinda/Sara:
>> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
>> Thanks,
>> Tony
>>
>> -----Original Message-----

Released by Chairman Rand Paul

>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Monday, May 28, 2018 5:40 PM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Hi Tony,
>>
>> Still no more information about the agenda for tomorrow's WH meeting.
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>> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
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>> Francis
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>> -----Original Message-----
>> From: Fauci, Anthony (NIH/NIAID) [E]
>> Sent: Sunday, May 27, 2018 9:31 AM
>> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
>> Subject: RE: POTUS meeting
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>> Francis:
>> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
>> Best regards,
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>> Sent: Sunday, May 27, 2018 8:52 AM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
>> Subject: POTUS meeting
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>> Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.
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>> What's the answer to that?
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>> Glad to speak by phone if that would make this easier. [redacted]
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Released by Chairman Rand Paul

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>> Subject: Re: Need info on BMGF — Urgent
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>>>
>>> Questions? Call [redacted] Getting on a plane in 10 minutes
>>>
>>> FC
>>>
>>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "McGowan, John J. (NIH/NIAID) [redacted]@niaid.nih.gov)" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [C] [redacted]@niaid.nih.gov)" [redacted]@niaid.nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:01:45 -0400
Importance: Normal

Tara:
I have no idea how to answer this question from Francis. I will call you about it and perhaps we can figure this out. He needs an answer by tomorrow.....YIKES!
Thanks,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 4:55 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Released by Chairman Rand Paul

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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:08:17 -0400
Importance: Normal

Larry:
I assume that you are going to get this information for Francis. I am the only one here and I really have no way of getting what he wants. I can try to mobilize Tara to start digging, but we may not get what he needs.
Tony

-----Original Message-----
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:03 PM
To: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:07:57 -0400
Importance: Normal

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov> wrote:

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

Released by Chairman Rand Paul

larry

--

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FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:03:20 -0400
Importance: Normal

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From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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To: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
Cc: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov)" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: POTUS meeting
Date: Mon, 28 May 2018 17:55:58 -0400
Importance: Normal

Melinda/Sara:
See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
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Subject: RE: POTUS meeting

Hi Tony,

Still no more information about the agenda for tomorrow's WH meeting.

Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.

Francis

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To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
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Francis:
We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
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What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

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To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: POTUS meeting
Date: Sun, 27 May 2018 09:31:21 -0400
Importance: Normal

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Released by Chairman Rand Paul

Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:28:05 -0400
Importance: Normal

OK. If you need me, call my cell at [redacted]

-----Original Message-----
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:21 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

I'm on it- I may ask you to take a look at what I find for reality check. Should be back in office shortly

Sent from my iPhone

> On May 25, 2018, at 5:08 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
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> Subject: Re: Need info on BMGF — Urgent
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Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 18:43:15 -0400
Importance: Normal

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Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:26:31 -0400
Importance: Normal

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Branch Chief, SPEB/NIAID
A: Building 31, Room 7A46D
P: [redacted] | M: [redacted]

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Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, May 27, 2018 8:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
Subject: POTUS meeting

Hi Tony,

Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.

Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)

Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.

What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

Francis

P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Released by Chairman Rand Paul

Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Just spoke with Larry, he has the full scoop

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
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> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.
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>
> FC
>
> Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:07:57 -0400
Importance: Normal

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov> wrote:

Dropping FC off.
Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.
With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518
FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994
NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279
NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091
larry
--
On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov> wrote:
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Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:08:17 -0400
Importance: Normal

Larry:
I assume that you are going to get this information for Francis. I am the only one here and I really have no way of getting what he wants. I can try to mobilize Tara to start digging, but we may not get what he needs.
Tony

-----Original Message-----
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:03 PM
To: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
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> FC
>
> Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 19:46:09 -0400
Importance: Normal

Yes. We need someone (? Sara) to go over to VRC in the AM to pick up the prop and then we deliver it to Dr. Collins in Room 126 in Building 1.

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E]
Sent: Monday, May 28, 2018 7:45 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting

Sorry not sure I understand. I think this is for Francis Colin's to take to the WH meeting. I think we can get someone to pick it up. Is that what you mean?

Sent from my iPhone

> On May 28, 2018, at 6:43 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Thanks, Barney.
>
> -----Original Message-----
> From: Graham, Barney (NIH/VRC) [E]
> Sent: Monday, May 28, 2018 6:29 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Haskins, Melinda (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: Re: POTUS meeting
>
> I'll be in my office by 7 am tomorrow and have them packed.
>
> Barney
>
>
>
> Sent from my iPhone
>
>> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>>
>> Melinda/Sara:
>> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
>> Thanks,
>> Tony
>>
>> -----Original Message-----

Released by Chairman Rand Paul

>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Monday, May 28, 2018 5:40 PM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Hi Tony,
>>
>> Still no more information about the agenda for tomorrow's WH meeting.
>>
>> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>>
>> Francis
>>
>> -----Original Message-----
>> From: Fauci, Anthony (NIH/NIAID) [E]
>> Sent: Sunday, May 27, 2018 9:31 AM
>> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
>> Subject: RE: POTUS meeting
>>
>> Francis:
>> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
>> Best regards,
>> Tony
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>> -----Original Message-----
>> From: Collins, Francis (NIH/OD) [E]
>> Sent: Sunday, May 27, 2018 8:52 AM
>> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
>> Subject: POTUS meeting
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>> What's the answer to that?
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>> Glad to speak by phone if that would make this easier. [redacted]
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Released by Chairman Rand Paul

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>> Sent: Friday, May 25, 2018 5:02 PM
>> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
>> Subject: Re: Need info on BMGF — Urgent
>>
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>> Sent from my iPhone
>>
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>>> FC
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>>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "McGowan, John J. (NIH/NIAID) [redacted]@niaid.nih.gov)" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [C] [redacted]@niaid.nih.gov)" [redacted]@niaid.nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:01:45 -0400
Importance: Normal

Tara:
I have no idea how to answer this question from Francis. I will call you about it and perhaps we can figure this out. He needs an answer by tomorrow.....YIKES!
Thanks,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 4:55 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Need info on BMGF — Urgent

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Sent from my iPhone

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:03:20 -0400
Importance: Normal

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:28:05 -0400
Importance: Normal

OK. If you need me, call my cell at [redacted]

-----Original Message-----
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:21 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

I'm on it- I may ask you to take a look at what I find for reality check. Should be back in office shortly

Sent from my iPhone

> On May 25, 2018, at 5:08 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Larry:
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> Tony
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> -----Original Message-----
> From: Tabak, Lawrence (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:03 PM
> To: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>
> Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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Released by Chairman Rand Paul

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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:05:32 -0400
Importance: Normal
Attachments: Select_Recent_Highlights.docx

Hi Larry,

In reviewing the spreadsheet and links, here are two additions:

- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

- NIH and the Gates Foundation also are co-supporting an African Post-Doctoral Training Initiative (APTI) within the intramural program. The Gates Foundation commitment over six years is $2 million. The NIH commitment over that timeframe is $2.2 million

I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] [redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

From: Anthony Fauci [redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole

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(NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>

Subject: Re: Need info on BMGF — Urgent

Larry:

BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.

Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov> wrote:

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:

https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:

https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:

https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:

https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov> wrote:

For reasons I can't currently explain, I need answers to the following:
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2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?

Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.

Questions? Call [redacted] Getting on a plane in 10 minutes

FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Select Recent Highlights
NIH-Bill & Melinda Gates Foundation Cooperation

- **Efficacy studies of two HIV vaccines moving forward**
  - The P5 vaccine efficacy study (HVTN 702), which launched in November 2016 in South Africa, is the first HIV vaccine efficacy study in 7 years
  - The Imbokodo (HVTN 705) study, which launched in November 2017, is a Phase 2b proof-of-concept study evaluating the safety and efficacy of a Ad26 mosaic vaccine and Clade C gp140. The vaccine regimen is based on "mosaic" immunogens — vaccine components designed to induce immune responses against a wide variety of global HIV strains.

- **Evaluation of a novel, long acting injectable antiviral for HIV Prevention**
  - In November 2017, launched Phase III efficacy study (HPTN 084) to compare long-acting cabotegravir to daily Truvada for pre-exposure prophylaxis in HIV-uninfected women.

- **TB Drug development and clinical endpoints**
  - NIAID intramural collaborations with BMGF have contributed to novel clinical markers for treatment response (PET/CT, NexGenNCT02371681) that are now further evaluated in the "PREDICT TB" trial (NCT02821832) to identify patients who may benefit from shortened therapy.
  - NIAID intramural, in collaboration with pharmaceutical partners (GSK, Merck) through the BMGF funded "TB Drug Accelerator" are co-developing novel anti-TB agents that are now entering clinical evaluation.
  - NIAID extramural programs are continuing to contribute to the establishment of best practices and preclinical/clinical evaluation of new drug candidates that are advanced through BMGF funded PDPs.

- **Single-dose HPV vaccine**
  - In early November, NCI participated in high-level meetings at the Gates Foundation to discuss ongoing efforts to evaluate single-dose protection of the HPV vaccines**.**
  - If the hypothesis that one dose can confer strong protection is verified by the results of the trial, these results should enable this approach to be the standard of care and greatly increase HPV vaccination uptake – which currently stands at around 3% of eligible girls in LMICs - throughout the world.
  - In late November, the new Costa Rica Vaccine Trial ("ESCUDDO") started-- the first girls have now been immunized.
  - Additional studies planned to complement Costa Rica Trial; one immunogenicity study built to harmonize with the Costa Rica trial has already been initiated.

- **Contraception**
  - A comprehensive analysis of publicly available gene expression and protein expression data has been performed to identify reproductive-tract specific transcripts/proteins to serve as potential non-hormonal targets for male and/or female contraceptive development.
  - A web-based contraceptive target database containing all pertinent information is in development for public access with a beta version released early to mid-2018.

  - Results from early collaborations in two Grand Challenges Explorations topics related to contraceptive research and development for either men or women anticipated in 2018 and 2019.
    - Successful projects may be integrated into a small, focused program
    - Research resulting from these awards is expected to have a large positive impact on the quality of applications to the NIH in the near-term future

- **Indoor air pollution**

  - Jointly launched RCT of liquefied petroleum gas (LPG) cookstoves and fuel in four LMICs (India, Rwanda, Guatemala and Peru).
  - First large-scale trial to investigate whether home use of cookstoves that run on LPG improve air quality sufficiently to offer measurable health benefits.
  - Enrollment began February 1, 2018.
  - Increased BMGF interest in endpoint of severe pneumonia confirmed by the study team with consolidations in the lungs and/or hypoxemia is leading to potential new designs, including proceeding with the trial as initially proposed, and in parallel, developing local pneumonia surveillance systems in the same localities.

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:59:57 -0400
Importance: Normal

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

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Subject: Re: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 13:36:50 -0400
Importance: Normal

Hi Francis,

I did review and the only additions I offered were the HPV post licensure vaccine trial and the new African postdoctoral fellowship program, to bring more African trainees to our intramural labs.

The group relied on the Gates Foundation awards data base to identify the Foundation's publicly accessible funding commitments for joint projects with NIH. Also, I'm digging out info on the Gates contribution to the WorldReport database maintenance (although this would be modest expenditure compared to the collaborative projects Larry has outlined)

The Gates Foundation and ICs have made parallel investments surrounding some of the NIH/BMGF working group initiatives, but the funding is not easily sourced (e.g., the contraceptive targets database). We would need to confer with ICs to assemble reliable estimates

Based on the intent of the request, I would be happy to provide any additional info that might be of use in your response. As one example, NIH and the Gates Foundation have cooperated in the development of such transformative global health interventions as MenAfriVac and the rapid TB diagnostic- Xpert MTB/RIF. NIH cooperation with the Foundation extends to eleven ICs, etc

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: sábado, 26 de mayo de 2018 12:06 p.m.
To: Eiss, Robert (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Glass, Roger (NIH/FIC) [E]
Subject: RE: Need info on BMGF — Urgent

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:46:37 -0400
Importance: Normal

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:49:55 -0400
Importance: Normal

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:01:54 -0400
Importance: Normal

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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 17:40:24 -0400
Importance: Normal

Hi Tony,

Still no more information about the agenda for tomorrow's WH meeting.

Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.

Francis

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, May 27, 2018 9:31 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: POTUS meeting

Francis:
We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
Best regards,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, May 27, 2018 8:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
Subject: POTUS meeting

Hi Tony,

Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.

Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)

Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be

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considered the highest priority for the nation.

What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

Francis

P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Subject: RE: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 12:06:44 -0400
Importance: Normal

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>>> Questions? Call [redacted] Getting on a plane in 10 minutes
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>>> FC
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>>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Cc: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Subject: Re: POTUS meeting

Date: Mon, 28 May 2018 18:23:24 -0400

Importance: Normal

Dr. Fauci,

Will do.

Have a great evening,
Sara

> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Melinda/Sara:
> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
> Thanks,
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> Sent: Monday, May 28, 2018 5:40 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: RE: POTUS meeting
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> Hi Tony,
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> Still no more information about the agenda for tomorrow's WH meeting.
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> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
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> From: Fauci, Anthony (NIH/NIAID) [E]
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> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
> Subject: RE: POTUS meeting
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> Francis:

Released by Chairman Rand Paul

> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
> Best regards,
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> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
> Subject: POTUS meeting
>
> Hi Tony,
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> Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)
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> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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> Subject: Re: Need info on BMGF — Urgent
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Released by Chairman Rand Paul

From: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:22:48 -0400
Importance: Normal

I am leaving for WV now, and will be available by phone/email on my iphone for the next two hours. I can be back online by 7:30 pm or so, if needed - just let me know.

Have a nice weekend and hope you get to actually enjoy some of it!

Best,

Tara A. Schwetz, PhD
Branch Chief, SPEB/NIAID
A: Building 31, Room 7A46D
P: [redacted] | M: [redacted]

On 5/25/18, 5:08 PM, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov> wrote:

Larry:
I assume that you are going to get this information for Francis. I am the only one here and I really have no way of getting what he wants. I can try to mobilize Tara to start digging, but we may not get what he needs.
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Sent: Friday, May 25, 2018 5:03 PM
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Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

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Released by Chairman Rand Paul

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Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:20:47 -0400
Importance: Normal

I'm on it- I may ask you to take a look at what I find for reality check. Should be back in office shortly

Sent from my iPhone

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>
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Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:21:12 -0400
Importance: Normal

Many thanks

Sent from my iPhone

On May 25, 2018, at 9:05 PM, Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov> wrote:

Hi Larry,

In reviewing the spreadsheet and links, here are two additions:

- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

- NIH and the Gates Foundation also are co-supporting an African Post-Doctoral Training Initiative (APTI) within the intramural program. The Gates Foundation commitment over six years is $2 million. The NIH commitment over that timeframe is $2.2 million

I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] [redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

Released by Chairman Rand Paul

From: Anthony Fauci [redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov> wrote:

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

Released by Chairman Rand Paul

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Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

<Select Recent Highlights.docx>

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Subject: Re: POTUS meeting
Date: Mon, 28 May 2018 18:28:52 -0400
Importance: Normal

I'll be in my office by 7 am tomorrow and have them packed.

Barney

Sent from my iPhone

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>
> Melinda/Sara:
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Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:28:50 -0400
Importance: Normal

Many thanks Rob

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- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

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I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] [redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Schwetz, Tara

Released by Chairman Rand Paul

(NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

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Released by Chairman Rand Paul

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larry

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FC

Sent from my iPhone

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:09:06 -0400
Importance: Normal

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larry

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Sent from my iPhone

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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
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Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 16:55:10 -0400
Importance: Normal

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From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Fwd: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 19:01:44 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx; ATT00001.htm

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Still checking

Sent from my iPhone

Begin forwarded message:

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Date: May 25, 2018 at 6:29:41 PM EDT
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
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larry

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:09:04 -0400
Importance: Normal

Many thanks

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Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
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Bcc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:29:40 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:28:49 -0400
Importance: Normal

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Date: Friday, May 25, 2018 at 9:05 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, Anthony Fauci [redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
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From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] [redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Schwetz, Tara

Released by Chairman Rand Paul

(NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

From: Anthony Fauci [redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

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https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

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NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

Released by Chairman Rand Paul

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

On 5/25/18, 4:55 PM, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov> wrote:

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Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.

Questions? Call [redacted] Getting on a plane in 10 minutes

FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

From: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Automatic reply: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:08:18 -0400
Importance: Normal

Thank you for your message. I'm currently on business travel with limited access to email until June 11. For immediate assistance please contact my office at [redacted]

Released by Chairman Rand Paul

From: "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Automatic reply: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:07:58 -0400
Importance: Normal

Thanks for your message. I am out of the office until June 4 and will have limited access to email until then. In case of urgency, please call [redacted]

Released by Chairman Rand Paul

From: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Automatic reply: POTUS meeting
Date: Mon, 28 May 2018 17:56:00 -0400
Importance: Normal

I am out of the office with only limited access to email. If you require assistance, please contact Sara Selgrade, Ph.D., NIAID OCGR LACMB.

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
Cc: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: POTUS meeting
Date: Mon, 28 May 2018 17:55:58 -0400
Importance: Normal

Melinda/Sara:
See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
Thanks,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Monday, May 28, 2018 5:40 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting

Hi Tony,

Still no more information about the agenda for tomorrow's WH meeting.

Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.

Francis

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, May 27, 2018 9:31 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: POTUS meeting

Francis:
We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
Best regards,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, May 27, 2018 8:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Released by Chairman Rand Paul

Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
Subject: POTUS meeting

Hi Tony,

Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.

Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)

Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.

What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

Francis

P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Just spoke with Larry, he has the full scoop

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>
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> 1) are we giving any grants to BMGF (I assume no)
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>
> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.
>
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>
> FC
>

Released by Chairman Rand Paul

> Sent from my iPhone

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: Roger Glass [redacted]@mail.nih.gov>, [redacted]@mail.nih.gov, Anthony Fauci [redacted]@niaid.nih.gov>
Cc: [redacted]@nih.gov, [redacted]@nih.gov, [redacted]@nih.gov
Subject: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 16:55:09 -0400
Importance: Normal

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Sent from my iPhone

Released by Chairman Rand Paul

From: "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
To: "Collins, Dexter (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Ancarrow, Belinda (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Spiro, David (NIH/FIC) [E]" [redacted]@nih.gov>
Subject: FW: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:47:17 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx

Hi Dexter and Belinda,
Can you let us know:

1. How much we have remaining for MAL-ED funds?
2. How much will be spent in all of FY '18?
3. Will there be any funds left/carried over into FY '19?
4. Confirm that no NIH funds spent on MAL-ED in FY '18? (Can ignore FTE staff salary and travel.)

Thanks,
PK

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 6:30 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>
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larry

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Sent from my iPhone

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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, [redacted]@niaid.nih.gov, "John McGowan (NIH/NIAID)" [redacted]@niaid.nih.gov>, [redacted]@nih.gov
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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:20:47 -0400
Importance: Normal

I'm on it- I may ask you to take a look at what I find for reality check. Should be back in office shortly

Sent from my iPhone

> On May 25, 2018, at 5:08 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Larry:
> I assume that you are going to get this information for Francis. I am the only one here and I really have no way of getting what he wants. I can try to mobilize Tara to start digging, but we may not get what he needs.
> Tony
>
> -----Original Message-----
> From: Tabak, Lawrence (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:03 PM
> To: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>
> Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
> Subject: Re: Need info on BMGF — Urgent
>
> Dropping FC off- I spoke with him and have a better idea of the ask.
>
> Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.
>
> Larry
>
> Sent from my iPhone
>
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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:01:54 -0400
Importance: Normal

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Sent from my iPhone

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> Sent from my iPhone

Released by Chairman Rand Paul

From: "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:32:24 -0400
Importance: Normal

Tara,

BMGF will not accept money from NIH. We operate more by getting monies directly from them as gift funds, in the past through the NIH foundation (I don't recall any right now coming through the foundation) and by collaboratively working together where they partially fund a trial by giving funds to an institution and where we have awarded a grant.

I have copied Wayne and Martin so they can get you the financial gift fund information. Carl (not sure about DMID with Emily) can provide project information.

JJ

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Friday, May 25, 2018 5:02 PM
To: Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
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Subject: FW: Need info on BMGF — Urgent

Tara:
I have no idea how to answer this question from Francis. I will call you about it and perhaps we can figure this out. He needs an answer by tomorrow.....YIKES!
Thanks,
Tony

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Sent: Friday, May 25, 2018 4:55 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Need info on BMGF — Urgent

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FC

Sent from my iPhone

Released by Chairman Rand Paul

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To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:28:50 -0400
Importance: Normal

Many thanks Rob

--

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Date: Friday, May 25, 2018 at 9:05 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, Anthony Fauci [redacted]@niaid.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
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Released by Chairman Rand Paul

(NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

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Released by Chairman Rand Paul

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larry

--

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Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

From: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:46:37 -0400
Importance: Normal

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In past , they fully supported FNIH for malnutrition enteric disease project led by FIC.

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Subject: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 16:55:10 -0400
Importance: Normal

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:21:12 -0400
Importance: Normal

Many thanks

Sent from my iPhone

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<Select Recent Highlights.docx>

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:49:55 -0400
Importance: Normal

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Sent from my iPhone

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Subject: Re: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 13:36:50 -0400
Importance: Normal

Hi Francis,

I did review and the only additions I offered were the HPV post licensure vaccine trial and the new African postdoctoral fellowship program, to bring more African trainees to our intramural labs.

The group relied on the Gates Foundation awards data base to identify the Foundation's publicly accessible funding commitments for joint projects with NIH. Also, I'm digging out info on the Gates contribution to the WorldReport database maintenance (although this would be modest expenditure compared to the collaborative projects Larry has outlined)

The Gates Foundation and ICs have made parallel investments surrounding some of the NIH/BMGF working group initiatives, but the funding is not easily sourced (e.g., the contraceptive targets database). We would need to confer with ICs to assemble reliable estimates

Based on the intent of the request, I would be happy to provide any additional info that might be of use in your response. As one example, NIH and the Gates Foundation have cooperated in the development of such transformative global health interventions as MenAfriVac and the rapid TB diagnostic- Xpert MTB/RIF. NIH cooperation with the Foundation extends to eleven ICs, etc

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: sábado, 26 de mayo de 2018 12:06 p.m.
To: Eiss, Robert (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Glass, Roger (NIH/FIC) [E]
Subject: RE: Need info on BMGF — Urgent

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Released by Chairman Rand Paul

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
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From: "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting
Date: Mon, 28 May 2018 18:28:52 -0400
Importance: Normal

I'll be in my office by 7 am tomorrow and have them packed.

Barney

Sent from my iPhone

> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Melinda/Sara:
> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
> Thanks,
> Tony
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> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Monday, May 28, 2018 5:40 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: RE: POTUS meeting
>
> Hi Tony,
>
> Still no more information about the agenda for tomorrow's WH meeting.
>
> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
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> Francis
>
> -----Original Message-----
> From: Fauci, Anthony (NIH/NIAID) [E]
> Sent: Sunday, May 27, 2018 9:31 AM
> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
> Subject: RE: POTUS meeting
>
> Francis:

Released by Chairman Rand Paul

> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
> Best regards,
> Tony
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> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Sunday, May 27, 2018 8:52 AM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
> Subject: POTUS meeting
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> Hi Tony,
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> What's the answer to that?
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> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
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> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:02 PM
> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
> Subject: Re: Need info on BMGF — Urgent
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> Just spoke with Larry, he has the full scoop
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>> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.
>>
>> Questions? Call [redacted] Getting on a plane in 10 minutes
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>>
>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting
Date: Mon, 28 May 2018 19:44:41 -0400
Importance: Normal

Sorry not sure I understand. I think this is for Francis Colin's to take to the WH meeting. I think we can get someone to pick it up. Is that what you mean?

Sent from my iPhone

> On May 28, 2018, at 6:43 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Thanks, Barney.
>
> -----Original Message-----
> From: Graham, Barney (NIH/VRC) [E]
> Sent: Monday, May 28, 2018 6:29 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Haskins, Melinda (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: Re: POTUS meeting
>
> I'll be in my office by 7 am tomorrow and have them packed.
>
> Barney
>
>
>
> Sent from my iPhone
>
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Released by Chairman Rand Paul

>> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:02:49 -0400
Importance: Normal

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
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Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 12:06:44 -0400
Importance: Normal

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

Sent from my iPhone

> On May 25, 2018, at 6:46 PM, Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov> wrote:
>
> Looking into this. They provide support for world report along with Wellcome, UK MRC, Canada, European Union. We don't give to Gates.
>
> In past , they fully supported FNIH for malnutrition enteric disease project led by FIC.
>
>
>
> Sent from my iPhone
>
>> On May 25, 2018, at 5:01 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
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>> Just spoke with Larry, he has the full scoop
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Released by Chairman Rand Paul

>> Sent from my iPhone
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To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:29:41 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx

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With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
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NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
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NICHD:
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larry

--

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Subject: RE: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 21:05:32 -0400
Importance: Normal
Attachments: Select_Recent_Highlights.docx

Hi Larry,

In reviewing the spreadsheet and links, here are two additions:

- As Francis notes, NCI and the Gates Foundation are cost-sharing an HPV vaccine post licensure trial to find out if giving only one dose of either the Cervarix or Gardasil 9 vaccines work the same as giving two doses of these vaccines to young women - The ESCUDDO Study. The Gates Foundation commitment is $20 million.

- NIH and the Gates Foundation also are co-supporting an African Post-Doctoral Training Initiative (APTI) within the intramural program. The Gates Foundation commitment over six years is $2 million. The NIH commitment over that timeframe is $2.2 million

I'm unsure if the attached document would be useful to you, given the nature of the request, but if so, attached is a sampling of recent highlights/developments in the NIH-Gates cooperation, including the HIV vaccine cooperation

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 8:09 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Kilmarx, Peter (NIH/FIC) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>; Garbarini, Nicole (NIH/OD) [E] [redacted]@nih.gov>; Johnson, Martin S. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; McGowan, John J. (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Schwetz, Tara (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Many thanks

--

From: Anthony Fauci [redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole

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(NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>

Subject: Re: Need info on BMGF — Urgent

Larry:

BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.

Tony

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larry

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:59:57 -0400
Importance: Normal

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

Sent from my iPhone

> On May 25, 2018, at 6:46 PM, Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov> wrote:
>
> Looking into this. They provide support for world report along with Wellcome, UK MRC, Canada, European Union. We don't give to Gates.
>
> In past , they fully supported FNIH for malnutrition enteric disease project led by FIC.
>
>
>
> Sent from my iPhone
>
>> On May 25, 2018, at 5:01 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>>
>> Just spoke with Larry, he has the full scoop
>>
>> Sent from my iPhone
>>
>>> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>>>
>>> For reasons I can't currently explain, I need answers to the following:
>>> 1) are we giving any grants to BMGF (I assume no)
>>> 2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?
>>>
>>> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4

Released by Chairman Rand Paul

pm.
>>>
>>> Questions? Call [redacted] Getting on a plane in 10 minutes
>>>
>>> FC
>>>
>>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 17:22:48 -0400
Importance: Normal

I am leaving for WV now, and will be available by phone/email on my iphone for the next two hours. I can be back online by 7:30 pm or so, if needed - just let me know.

Have a nice weekend and hope you get to actually enjoy some of it!

Best,

Tara A. Schwetz, PhD
Branch Chief, SPEB/NIAID
A: Building 31, Room 7A46D
P: [redacted] | M: [redacted]

On 5/25/18, 5:08 PM, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov> wrote:

Larry:
I assume that you are going to get this information for Francis. I am the only one here and I really have no way of getting what he wants. I can try to mobilize Tara to start digging, but we may not get what he needs.
Tony

-----Original Message-----
From: Tabak, Lawrence (NIH/OD) [E]
Sent: Friday, May 25, 2018 5:03 PM
To: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>
Cc: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Dropping FC off- I spoke with him and have a better idea of the ask.

Mike- are you able to do initial look? I am traveling back from meeting with SG and will be back in about 30 min.

Larry

Sent from my iPhone

> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>
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Released by Chairman Rand Paul

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To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>
Subject: POTUS meeting
Date: Sun, 27 May 2018 08:52:29 -0400
Importance: Normal

Hi Tony,

Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.

Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)

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What's the answer to that?

Glad to speak by phone if that would make this easier. [redacted]

Francis

P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

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Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Just spoke with Larry, he has the full scoop

Sent from my iPhone

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>
> Sent from my iPhone

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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
Cc: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:35:02 -0400
Importance: Normal

Larry,

Not sure if this is relevant, but I believe FNIH still has some collaborations with BMGF, which are somewhat independent of NIH, although some may also overlap with Grand Challenges. If it would be helpful to have info about that, I can reach out to Stephanie James. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health
[redacted]

Select Recent Highlights
NIH-Bill & Melinda Gates Foundation Cooperation

- **Efficacy studies of two HIV vaccines moving forward**
  - The P5 vaccine efficacy study (HVTN 702), which launched in November 2016 in South Africa, is the first HIV vaccine efficacy study in 7 years
  - The Imbokodo (HVTN 705) study, which launched in November 2017, is a Phase 2b proof-of-concept study evaluating the safety and efficacy of a Ad26 mosaic vaccine and Clade C gp140. The vaccine regimen is based on "mosaic" immunogens — vaccine components designed to induce immune responses against a wide variety of global HIV strains.

- **Evaluation of a novel, long acting injectable antiviral for HIV Prevention**
  - In November 2017, launched Phase III efficacy study (HPTN 084) to compare long-acting cabotegravir to daily Truvada for pre-exposure prophylaxis in HIV-uninfected women.

- **TB Drug development and clinical endpoints**
  - NIAID intramural collaborations with BMGF have contributed to novel clinical markers for treatment response (PET/CT, NexGenNCT02371681) that are now further evaluated in the "PREDICT TB" trial (NCT02821832) to identify patients who may benefit from shortened therapy.
  - NIAID intramural, in collaboration with pharmaceutical partners (GSK, Merck) through the BMGF funded "TB Drug Accelerator" are co-developing novel anti-TB agents that are now entering clinical evaluation.
  - NIAID extramural programs are continuing to contribute to the establishment of best practices and preclinical/clinical evaluation of new drug candidates that are advanced through BMGF funded PDPs.

- **Single-dose HPV vaccine**
  - In early November, NCI participated in high-level meetings at the Gates Foundation to discuss ongoing efforts to evaluate single-dose protection of the HPV vaccines**.**
  - If the hypothesis that one dose can confer strong protection is verified by the results of the trial, these results should enable this approach to be the standard of care and greatly increase HPV vaccination uptake – which currently stands at around 3% of eligible girls in LMICs - throughout the world.
  - In late November, the new Costa Rica Vaccine Trial ("ESCUDDO") started-- the first girls have now been immunized.
  - Additional studies planned to complement Costa Rica Trial; one immunogenicity study built to harmonize with the Costa Rica trial has already been initiated.

- **Contraception**
  - A comprehensive analysis of publicly available gene expression and protein expression data has been performed to identify reproductive-tract specific transcripts/proteins to serve as potential non-hormonal targets for male and/or female contraceptive development.
  - A web-based contraceptive target database containing all pertinent information is in development for public access with a beta version released early to mid-2018.

  - Results from early collaborations in two Grand Challenges Explorations topics related to contraceptive research and development for either men or women anticipated in 2018 and 2019.
    - Successful projects may be integrated into a small, focused program
    - Research resulting from these awards is expected to have a large positive impact on the quality of applications to the NIH in the near-term future

- **Indoor air pollution**

  - Jointly launched RCT of liquefied petroleum gas (LPG) cookstoves and fuel in four LMICs (India, Rwanda, Guatemala and Peru).
  - First large-scale trial to investigate whether home use of cookstoves that run on LPG improve air quality sufficiently to offer measurable health benefits.
  - Enrollment began February 1, 2018.
  - Increased BMGF interest in endpoint of severe pneumonia confirmed by the study team with consolidations in the lungs and/or hypoxemia is leading to potential new designs, including proceeding with the trial as initially proposed, and in parallel, developing local pneumonia surveillance systems in the same localities.

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From: "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Cc: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Subject: Re: POTUS meeting

Date: Mon, 28 May 2018 18:23:24 -0400

Importance: Normal

Dr. Fauci,

Will do.

Have a great evening,
Sara

> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
>
> Melinda/Sara:
> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
> Thanks,
> Tony
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Monday, May 28, 2018 5:40 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: RE: POTUS meeting
>
> Hi Tony,
>
> Still no more information about the agenda for tomorrow's WH meeting.
>
> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>
> Francis
>
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> From: Fauci, Anthony (NIH/NIAID) [E]
> Sent: Sunday, May 27, 2018 9:31 AM
> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
> Subject: RE: POTUS meeting
>
> Francis:

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> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
> Best regards,
> Tony
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> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Sunday, May 27, 2018 8:52 AM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
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>
> What's the answer to that?
>
> Glad to speak by phone if that would make this easier. [redacted]
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> Francis
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> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:02 PM
> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:09:06 -0400
Importance: Normal

Many thanks

--

From: Anthony Fauci [redacted]@niaid.nih.gov>
Date: Friday, May 25, 2018 at 8:07 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>, "Johnson, Martin S. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "McGowan, John J. (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Schwetz, Tara (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Larry:
BMGF is co-funding with NIAID the Cabotegravir PrEP study. I do not know how much they are in for. Also, Bob Seder of the VRC heavily advises and consults for the BMGF; however, no $ is involved . Everything else that you have listed is correct.
Tony

On May 25, 2018, at 6:29 PM, Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov> wrote:

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

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NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

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FC

Sent from my iPhone

<SR_25May2018_053723_24581657[3].xlsx>

Released by Chairman Rand Paul

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Released by Chairman Rand Paul

From: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Automatic reply: POTUS meeting
Date: Mon, 28 May 2018 17:56:00 -0400
Importance: Normal

I am out of the office with only limited access to email. If you require assistance, please contact Sara Selgrade, Ph.D., NIAID OCGR LACMB.

Released by Chairman Rand Paul

From: "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Automatic reply: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 20:07:58 -0400
Importance: Normal

Thanks for your message. I am out of the office until June 4 and will have limited access to email until then. In case of urgency, please call [redacted]

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 17:40:24 -0400
Importance: Normal

Hi Tony,

Still no more information about the agenda for tomorrow's WH meeting.

Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.

Francis

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Sent: Sunday, May 27, 2018 9:31 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: POTUS meeting

Francis:
We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
Best regards,
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What's the answer to that?

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P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?

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Sent: Friday, May 25, 2018 5:02 PM
To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Subject: RE: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 12:06:44 -0400
Importance: Normal

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

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Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:49:55 -0400
Importance: Normal

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Subject: POTUS meeting
Date: Sun, 27 May 2018 08:52:29 -0400
Importance: Normal

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To: Roger Glass [redacted]@mail.nih.gov>, [redacted]@mail.nih.gov, Anthony Fauci [redacted]@niaid.nih.gov>
Cc: [redacted]@nih.gov, [redacted]@nih.gov, [redacted]@nih.gov
Subject: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 16:55:09 -0400
Importance: Normal

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Subject: Re: POTUS meeting
Date: Mon, 28 May 2018 18:28:52 -0400
Importance: Normal

I'll be in my office by 7 am tomorrow and have them packed.

Barney

Sent from my iPhone

> On May 28, 2018, at 5:55 PM, Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov> wrote:
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Date: Fri, 25 May 2018 16:55:11 -0400
Importance: Normal

Thank you for your message. I'm currently on business travel with limited access to email until June 11. For immediate assistance please contact my office at [redacted]

Released by Chairman Rand Paul

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Subject: Re: POTUS meeting

Date: Mon, 28 May 2018 18:23:24 -0400

Importance: Normal

Dr. Fauci,

Will do.

Have a great evening,
Sara

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> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:02 PM
> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
> Subject: Re: Need info on BMGF — Urgent
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Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:59:57 -0400
Importance: Normal

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

Sent from my iPhone

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
Cc: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: POTUS meeting
Date: Mon, 28 May 2018 17:55:58 -0400
Importance: Normal

Melinda/Sara:
See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
Thanks,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Monday, May 28, 2018 5:40 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting

Hi Tony,

Still no more information about the agenda for tomorrow's WH meeting.

Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.

Francis

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, May 27, 2018 9:31 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: POTUS meeting

Francis:
We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
Best regards,
Tony

-----Original Message-----
From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, May 27, 2018 8:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Released by Chairman Rand Paul

Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
Subject: POTUS meeting

Hi Tony,

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What's the answer to that?

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To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: POTUS meeting
Date: Sun, 27 May 2018 09:31:21 -0400
Importance: Normal

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Released by Chairman Rand Paul

Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

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To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 13:36:50 -0400
Importance: Normal

Hi Francis,

I did review and the only additions I offered were the HPV post licensure vaccine trial and the new African postdoctoral fellowship program, to bring more African trainees to our intramural labs.

The group relied on the Gates Foundation awards data base to identify the Foundation's publicly accessible funding commitments for joint projects with NIH. Also, I'm digging out info on the Gates contribution to the WorldReport database maintenance (although this would be modest expenditure compared to the collaborative projects Larry has outlined)

The Gates Foundation and ICs have made parallel investments surrounding some of the NIH/BMGF working group initiatives, but the funding is not easily sourced (e.g., the contraceptive targets database). We would need to confer with ICs to assemble reliable estimates

Based on the intent of the request, I would be happy to provide any additional info that might be of use in your response. As one example, NIH and the Gates Foundation have cooperated in the development of such transformative global health interventions as MenAfriVac and the rapid TB diagnostic- Xpert MTB/RIF. NIH cooperation with the Foundation extends to eleven ICs, etc

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: sábado, 26 de mayo de 2018 12:06 p.m.
To: Eiss, Robert (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Glass, Roger (NIH/FIC) [E]
Subject: RE: Need info on BMGF — Urgent

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
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To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
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Cc: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:46:37 -0400
Importance: Normal

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From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Fwd: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 19:01:44 -0400
Importance: Normal
Attachments: SR_25May2018_053723_24581657[3].xlsx; ATT00001.htm

---

Still checking

Sent from my iPhone

Begin forwarded message:

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Date: May 25, 2018 at 6:29:41 PM EDT
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Kilmarx, Peter (NIH/FIC) [E]" [redacted]@nih.gov>
Cc: "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Garbarini, Nicole (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Dropping FC off.

Could you all please do a quick check to make sure I haven't included anything that is wrong. I would like to get this to FC either late tonight or first thing in the AM before I get on a plane.

With thanks to Mike and Nicole, here is what we have found thus far:

1. We found nothing in which the BMGF is the primary recipient of NIH funds – they are not in our organization list meaning they have never been an applicant for grant money from NIH. I don't know anything about contracts.
2. The first attachment displays projects with co-funding- NIH $ are displayed – that is NOT going to BMGF, it is going to the listed investigator
3. BMGF has funded various components of NIH (through the Grand Challenges Program, although that may not be the only program) - I have only listed funding from 2018-2015; there are earlier grants

NIAID:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2018/02/OPP1162695
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/11/OPP1178956
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/02/OPP1159915
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/11/OPP1139518

FIC:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2017/07/OPP1169078
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/09/OPP1129994

NHLBI:
https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/08/OPP1131279

NICHD:

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https://www.gatesfoundation.org/How-We-Work/Quick-Links/Grants-Database/Grants/2015/05/OPP1129091

larry

--

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Cc: "Haskins, Melinda (NIH/NIAID) [E]" [redacted]@mail.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Selgrade, Sara (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: POTUS meeting
Date: Mon, 28 May 2018 18:43:15 -0400
Importance: Normal

Thanks, Barney.

-----Original Message-----
From: Graham, Barney (NIH/VRC) [E]
Sent: Monday, May 28, 2018 6:29 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Haskins, Melinda (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>; Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: Re: POTUS meeting

I'll be in my office by 7 am tomorrow and have them packed.

Barney

Sent from my iPhone

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>
> Melinda/Sara:
> See note below from Dr. Collins. Please go over or have someone go over to the VRC to get the 3D model of the entire hemagglutinin molecule as well as the model of the nanoparticle with the attached HA stem (the one that I showed at the recent Congressional Hearing). We need it as early as possible in the AM tomorrow since the White House meeting is in the very early afternoon.
> Thanks,
> Tony
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Monday, May 28, 2018 5:40 PM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Subject: RE: POTUS meeting
>
> Hi Tony,
>
> Still no more information about the agenda for tomorrow's WH meeting.
>

Released by Chairman Rand Paul

> Just in case he brings up the flu vaccine, can I borrow your model of hemagglutinin? Could someone bring it over to 1/126 in the AM? I promise to take good care of it.
>
> Francis
>
> -----Original Message-----
> From: Fauci, Anthony (NIH/NIAID) [E]
> Sent: Sunday, May 27, 2018 9:31 AM
> To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
> Subject: RE: POTUS meeting
>
> Francis:
> We now have $104 million in our budget devoted to the development of a universal influenza vaccine. We have a plan that can accommodate between $150 million and $200 million per year for the next 5 years and so $1 billion over 5 years is a good number. I will call to confirm.
> Best regards,
> Tony
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Sunday, May 27, 2018 8:52 AM
> To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>
> Subject: POTUS meeting
>
> Hi Tony,
>
> Another strange chapter. Sec. Azar and I are supposed to meet with the POTUS in the Oval on Tuesday at 1:30 PM, but there is no information about the agenda. Apparently POTUS asked for this meeting to be set up, but no one in the WH seems to know why.
>
> Alex is trying to guess what this might be about; one possibility might be the universal flu vaccine, since Bill Gates recently spoke to the POTUS about that. See https://www.statnews.com/2018/04/30/bill-gates-vaccine-trump-meeting/ for the report on this conversation. (By the way, I'm surprised that Bill seems to be promoting this idea of the universal flu vaccine as if the US government hasn't been properly focused on it -- surely he knows about all the work that NIH has been doing, and about the current strategic plan? And how could his promised $12M add much to the much larger investment NIAID is making? Is this coordinated in some way, or is Bill going rogue?)
>
> Alex indicated that Gates had apparently told the POTUS that $5-6 billion was really needed to prepare for a worldwide flu pandemic. I'm not sure where that number comes from. The specific question that Alex thought might come up on Tuesday is what the funding trajectory is that's really needed if the preparation of the universal flu vaccine was to be considered the highest priority for the nation.
>
> What's the answer to that?
>
> Glad to speak by phone if that would make this easier. [redacted]
>
> Francis
>
> P.S. Can I borrow your 3D printed model of the hemagglutinin protein, in case that turns out to be relevant?
>
> -----Original Message-----
> From: Collins, Francis (NIH/OD) [E]
> Sent: Friday, May 25, 2018 5:02 PM
> To: Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Released by Chairman Rand Paul

> Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
> Subject: Re: Need info on BMGF — Urgent
>
> Just spoke with Larry, he has the full scoop
>
> Sent from my iPhone
>
>> On May 25, 2018, at 4:55 PM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:
>>
>> For reasons I can't currently explain, I need answers to the following:
>> 1) are we giving any grants to BMGF (I assume no)
>> 2) what are our current collaborative projects with BMGF? For each one , what is the rough NIH annual spend, and what is it from BMGF?
>>
>> Hoping this won't be too hard to dig out. Ideally I need a response (at least a rough version) by Saturday 4 pm.
>>
>> Questions? Call [redacted] Getting on a plane in 10 minutes
>>
>> FC
>>
>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
CC: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 13:36:50 -0400

Hi Francis,

I did review and the only additions I offered were the HPV post licensure vaccine trial and the new African postdoctoral fellowship program, to bring more African trainees to our intramural labs.

The group relied on the Gates Foundation awards data base to identify the Foundation's publicly accessible funding commitments for joint projects with NIH. Also, I'm digging out info on the Gates contribution to the WorldReport database maintenance (although this would be modest expenditure compared to the collaborative projects Larry has outlined)

The Gates Foundation and ICs have made parallel investments surrounding some of the NIH/BMGF working group initiatives, but the funding is not easily sourced (e.g., the contraceptive targets database). We would need to confer with ICs to assemble reliable estimates

Based on the intent of the request, I would be happy to provide any additional info that might be of use in your response. As one example, NIH and the Gates Foundation have cooperated in the development of such transformative global health interventions as MenAfriVac and the rapid TB diagnostic- Xpert MTB/RIF. NIH cooperation with the Foundation extends to eleven ICs, etc

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: sábado, 26 de mayo de 2018 12:06 p.m.
To: Eiss, Robert (NIH/FIC) [E]
Cc: Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]; Glass, Roger (NIH/FIC) [E]
Subject: RE: Need info on BMGF — Urgent

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

Released by Chairman Rand Paul

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
Subject: Re: Need info on BMGF — Urgent

And aren't we cosponsoring the Costa Rica HPV single dose trial?

Sent from my iPhone

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>
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>
>
>
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>
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Released by Chairman Rand Paul

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
CC: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: Need info on BMGF — Urgent
Date: Sat, 26 May 2018 12:06:44 -0400

Rob, have you had a chance to review? Any additions?

Tx, FC

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, May 25, 2018 7:00 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent

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Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
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To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
CC: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Need info on BMGF — Urgent
Date: Fri, 25 May 2018 18:59:57 -0400

I'm reviewing the list against the projects supported by the NIH-BMGF working groups (incl IAP, HPV trials) and can respond shortly

Sent from my BlackBerry 10 smartphone.

From: Collins, Francis (NIH/OD) [E]
Sent: viernes, 25 de mayo de 2018 06:49 p.m.
To: Glass, Roger (NIH/FIC) [E]
Cc: Eiss, Robert (NIH/FIC) [E]; Fauci, Anthony (NIH/NIAID) [E]; Tabak, Lawrence (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lauer, Michael (NIH/OD) [E]
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Released by Chairman Rand Paul

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>>>
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>>> Sent from my iPhone

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "'Melinda French'" [redacted]@mfgates.com>
Bcc: "Diane Baker" [redacted]@gmail.com>
Subject: RE: With admiration
Date: Fri, 08 Oct 2021 04:25:51 -0400
Importance: Normal

Dear Melinda,

Thanks for your message and your kind words. It has been a privilege to work with the Bill and Melinda Gates Foundation over these 12 years, and I am glad to have had the chance to bring our global health efforts even closer together than ever. I will continue to seek ways to help with this mission, even after stepping down as Director.

With warm personal regards, Francis

From: Melinda French [redacted]@mfgates.com>
Sent: Thursday, October 7, 2021 4:56 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: NIH Executive Secretariat [redacted]@nih.gov>
Subject: With admiration

Francis,

I saw the news of your stepping down from the helm of the NIH and wanted to send a note of gratitude for all you've done as Director.

I know you've been a tremendous colleague and valued partner to the foundation. I've admired and appreciated your leadership both over the course of our collaboration and during the extraordinarily challenging moments the pandemic has brought.

Your ability to take on vastly varied challenges and to lead across division has done so much for the world and for the inclusivity of your field. What a bar you've set for whoever comes next, and what a distance you've carried the baton they'll pick up.

Thank you, for your partnership and your leadership,

- Melinda French Gates

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>

To: "Albert, Paul (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Blithe, Diana (NIH/NICHD) [E]" [redacted]@exchange.nih.gov>, "Brewinski Isaacs, Maggie (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Freund, Lisa (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Hazra, Rohan (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Ilekis, John (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Krotoski, Danuta (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Lee, Sonia (NIH/NICHD) [E]" [redacted]@nih.gov>, "Moss, Stuart (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Newcomer, Susan (NIH/NICHD) [E]" [redacted]@exchange.nih.gov>, "Raiten, Daniel (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Reddy, Uma (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Signore, Caroline (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Barry, Clifton (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Boyce, Jim (NIH/NIAID) [E]" [redacted]@nih.gov>, "Cassels, Fred (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Datta, Sandip (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Green, Kim (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Hall, Lee (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Koso-Thomas, Marion (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Lacourciere, Karen (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Lambert, Linda (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Ledgerwood, Julie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Marovich, Mary (NIH/NIAID) [E]" [redacted]@nih.gov>, "Marston, Hilary (NIH/NIAID) [E]" [redacted]@nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Zwerski, Sheryl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Kreimer, Aimee (NIH/NCI) [E]" [redacted]@mail.nih.gov>, "Schiffman, Mark (NIH/NCI) [E]" [redacted]@exchange.nih.gov>, "Pringle, Beverly (NIH/NIMH) [E]" [redacted]@mail.nih.gov>, "Buckley, Shu (NIH/NIMH) [E]" [redacted]@nih.gov>, "Rosenthal, Josh P. (NIH/FIC) [E]" [redacted]@ficod.fic.nih.gov>, "Gottlieb, Michael (FNIH) [T]" [redacted]@fnih.org>, "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Rao, Malla (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Costero-Saint Denis, Adriana (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Deye, Greg (NIH/NIAID) [E]" [redacted]@nih.gov>, "Mcgugan, Glen (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Cc: "Kline, Lydia (NIH/FIC) [C]" [redacted]@nih.gov>, "Weymouth, Kristen (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Wan, Melissa (NIH/FIC) [C]" [redacted]@nih.gov>, "Officer, Jackie (NIH/FIC) [E]" [redacted]@nih.gov>

Subject: NIH-Gates Foundation Workshop, July 8: Agenda and list of participants

Date: Wed, 01 Jul 2015 17:08:29 -0400

Importance: Normal

Attachments: BMGF-NIH_Second_Annual_Meeting_(7.1).docx; NIH-Bill_&_Melinda_Gates_Foundation_Participant_List_July_Workshop_7.1.docx

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Dear Colleagues,

We look forward to your participation the NIH-Bill & Melinda Gates Foundation Workshop next week I attach the current agenda and list of Gates Foundation and NIH participants. There may be a few late confirmations and/or needed corrections. A final list of participants will be available at the meeting I also will send on any pre-reads suggested by any of the working group co-chairs.

Please don't hesitate to contact me with and questions If needed, my cell is [redacted] (office [redacted]

Released by Chairman Rand Paul

Best regards

Released by Chairman Rand Paul

Bill & Melinda Gates Foundation-NIH Second Annual Consultative Workshop

July 8, 2015
John Edward Porter Neuroscience Research Center (Building 35A)
NIH Campus, Bethesda, Maryland

8:30 AM – 8:40 AM

Welcome -- Francis Collins, Trevor Mundel

8:40 AM – 9:30 AM

Drug Repurposing and Global Health: Accelerating the Pace.
Co-Moderators: Dr. Chris Austin, NCATS; Dr. Trevor Mundel, BMGF

The session will focus on innovations in early and late stage drug repurposing, and relevance to priority therapeutics for global health. Priority topics include:

- accessing data & compounds from innovator firms
- corporate incentives and models of collaboration
- creative IP management
- crowdsourcing and clearinghouses
- support for Phase IIb and III

9:30 AM – 10:30 AM

Research Preparedness and Lessons Learned from the Ebola Outbreak
Co-moderators: Dr Cliff Lane, NIAID; Alan Magill, BMGF

The session will take stock of the challenges encountered in responding to microbial outbreaks, based on the recent experience with Ebola epidemic. The aim is to understand generalizable lessons from this response, and explore ways to most effectively address future outbreaks. Priority topics include:

- clinical trial design
- implementing clinical trials
- developing protocols and guidance for research studies in advance
- sharing of specimens and data, and access to specialized reagents
- community engagement
- coordination and real-time, open sharing of information across diverse disciplines
- challenges of implementing rapid funding

10:30 AM – 10:45 AM

Coffee break

Released by Chairman Rand Paul

10:45 AM – 02:45 PM

Working Group Breakout Sessions
Discussion of current activities and plans over the next 6-12 months

Working groups:

MNCH

- Maternal and newborn health (co-chairs: Dr. Jeff Murray and Dr. Alan Guttmacher)
- Child health and development (co-chairs: Dr. Dan Marks *via phone* and Dr. Vesna Kutlesic)
- Pediatric pneumonia and indoor air pollution (Dr. Gail Rodgers and Drs. Josh Rosenthal and Linda Lambert)
- Contraceptive research (co-chairs: Dr. Dan Hartman and Dr. Cathy Spong)

Infectious Disease Priorities

- HIV (co-chairs: Dr. Emilio Emini or Nina Russell and Dr. Carl Dieffenbach)
- Malaria (co-chairs: Dr. Alan Magill and Dr. Lee Hall)
- TB (co-chairs: Dr. Gilla Kaplan and Dr. Carole Heilman)
- HPV/cervical cancers (*to include brief updates on dengue and VL vaccine cooperation*) (co-chairs: Dr. Peter Dull and Dr. Doug Lowy)

(12:00 PM – 12:45 PM Working Group lunches)

2:45 PM – 3:45 PM

Open Session

- Reports of the Working Groups
- Proposed new areas of cooperation

Discussion

3:45 PM – 4:00 PM

Wrap up and Review of Next Steps
Dr. Francis Collins and Dr. Trevor Mundel

4:00 PM Adjourn

Released by Chairman Rand Paul

Event: NIH-BMGF Senior Leadership Meeting

Start Date: 2016-04-18 08:30:00 -0400

End Date: 2016-04-18 16:00:00 -0400

Organizer: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>

Location: Building 35 A, Room G20/30 (Porter Neuroscience Research Center)

Categories: ,Important Appt/Must Attend

Class: X-PERSONAL

Date Created: 2018-07-14 18:25:46 -0400

Date Modified: 2024-04-04 18:08:14 -0400

Priority: 5

DTSTAMP: 2016-04-15 15:58:08 -0400

Attendee: Event Information Calendar (NIH/OD) [redacted]@od.nih.gov>

Attach: 401.eml; 402.eml; 403.eml; 404.eml; Agenda for NIH_BMGF Workshop.docx; NIH-BMGF_Participant_list.docx; 4-18-16 Gates Foundation visit room set-up.pptx; Item 1 Minute by Minute Agenda.doc; Item 2 Workshop Agenda.docx; Item 3 workshop opening remarks.docx; Item 4a panelist bios.doc; Item 4b panel questions.docx; Item 4c panelist publications.doc; Item 5 Santangelo slides.pptx; Item 6 participant list.docx

ES—IMOD has printed these out

POC – Rob Eiss

><

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: FW: 2016 NIH-BMGF Annual Meeting- Bill's Participation
Date: Fri, 20 Nov 2015 13:37:32 -0500
Importance: Normal
Inline-Images: image007.png; image008.png; image009.jpg

Hi Francis,

See the note below from the Gates Foundation. In my view, scheduling an April date for the NIH-BMGF workshop that accommodates Bill's travel to DC is a preferred option to organizing a July date, when he would not be available I look forward to your thoughts

If we respond positively, I'll do a quick survey to determine the availability of the NIH co-chairs

---

From: Josie Ekberg [mailto [redacted]@gatesfoundation.org]
Sent: Friday, November 20, 2015 1:15 PM
To: Eiss, Robert (NIH/FIC) [E]
Cc: Josie Ekberg; Traci Terry
Subject: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Robert,

As you know, we've been batting around possible dates for the 2016 NIH-BMGF Annual Meeting. Bill is keen to attend (like he was last year) but aligning dates is pretty tough. We just heard from his office that his participation may be possible on either April 18 or 19 because he will already be on the East Coast at that time. I know we were looking at the July time frame but would this earlier time frame work with leadership and co-chairs on your side? I did a quick calendar scan for our side and the majority would be available.

Any guidance you can provide would be much appreciated!

Josie

Josie Ekberg
Program Manager, Office of the Director
Global Health Discovery & Translational Sciences
V [redacted]
C [redacted]
E [redacted] gatesfoundation.org

Bill & Melinda Gates Foundation
www.gatesfoundation.org
Facebook
Twitter
Impatient Optimists

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Re: 2016 NIH-BMGF Annual Meeting- Bill's Participation
Date: Sat, 21 Nov 2015 10:44:52 -0500
Importance: Normal
Inline-Images: image007.png; image008.png; image009.jpg; image008(1).png; image009(1).jpg

---

Having Bill present would be terrific. I can do April 18-19, please check with others.
FC

Sent from my iPhone

On Nov 20, 2015, at 1:37 PM, Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov> wrote:

Hi Francis,

See the note below from the Gates Foundation. In my view, scheduling an April date for the NIH-BMGF workshop that accommodates Bill's travel to DC is a preferred option to organizing a July date, when he would not be available I look forward to your thoughts

If we respond positively, I'll do a quick survey to determine the availability of the NIH co-chairs

---

From: Josie Ekberg [mailto [redacted]@gatesfoundation.org]
Sent: Friday, November 20, 2015 1:15 PM
To: Eiss, Robert (NIH/FIC) [E]
Cc: Josie Ekberg; Traci Terry
Subject: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Robert,

As you know, we've been batting around possible dates for the 2016 NIH-BMGF Annual Meeting. Bill is keen to attend (like he was last year) but aligning dates is pretty tough. We just heard from his office that his participation may be possible on either April 18 or 19 because he will already be on the East Coast at that time. I know we were looking at the July time frame but would this earlier time frame work with leadership and co-chairs on your side? I did a quick calendar scan for our side and the majority would be available.

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Released by Chairman Rand Paul

Bill & Melinda Gates Foundation

www.gatesfoundation.org

<image007.png> Facebook

Twitter

Impatient Optimists

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" [redacted]@od.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: 2016 NIH-BMGF Annual Meeting- Bill's Participation
Date: Tue, 08 Dec 2015 00:34:57 -0500
Importance: Normal
Inline-Images: image001.png; image002.png; image003.jpg

Excellent!

From: Eiss, Robert (NIH/FIC) [E]
Sent: Monday, December 07, 2015 7:14 PM
To: Collins, Francis (NIH/OD) [E]
Cc: Glass, Roger (NIH/FIC) [E]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: Fw: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Francis,

Good news. Bill Gates is able to join the NIH-BMGF workshop on April 18, to coincide with a planned trip to DC.

This certainly raises the bar on assembling a stimulating and forward thinking agenda - and influencing and informing his perspectives

Among the NIH working group co chairs, only Doug Lowy has a current conflict on that date.

From: Josie Ekberg [mailto [redacted]@gatesfoundation.org]
Sent: Monday, December 07, 2015 05:52 PM
To: Eiss, Robert (NIH/FIC) [E]
Cc: Traci Terry [redacted]@gatesfoundation.org>; Christopher Wilson
Subject: RE: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Robert,

Please pencil in April 18th for the Annual NIH-BMGF meeting. We just received confirmation from Bill's office that he will be able to attend the meeting on this date.

Thanks and I'm sure we'll be in touch soon.

Josie

From: Eiss, Robert (NIH/FIC) [E] [mailto [redacted]@mail.nih.gov]
Sent: Tuesday, November 24, 2015 10:18 AM
To: Josie Ekberg [redacted]@gatesfoundation.org>
Cc: Traci Terry [redacted]@gatesfoundation.org>
Subject: RE: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Josie

Released by Chairman Rand Paul

These dates work for Dr Collins, as well as each of the co-chairs, with the exception of Doug Lowy, who would be at a cancer association meeting in New Orleans So they do look feasible for us

---

From: Josie Ekberg [mailto [redacted]@gatesfoundation.org]
Sent: Friday, November 20, 2015 1:15 PM
To: Eiss, Robert (NIH/FIC) [E]
Cc: Josie Ekberg; Traci Terry
Subject: 2016 NIH-BMGF Annual Meeting- Bill's Participation

Hi Robert,

As you know, we've been batting around possible dates for the 2016 NIH-BMGF Annual Meeting. Bill is keen to attend (like he was last year) but aligning dates is pretty tough. We just heard from his office that his participation may be possible on either April 18 or 19 because he will already be on the East Coast at that time. I know we were looking at the July time frame but would this earlier time frame work with leadership and co-chairs on your side? I did a quick calendar scan for our side and the majority would be available.

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Josie

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Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "McManus, Ayanna (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Gates Foundation dinner and workshop
Date: Wed, 13 Apr 2016 17:07:53 -0400
Importance: Normal

Hi Ayanna

Just to note that I am assembling the brief for the Bill & Melinda Gates Foundation dinner event and workshop, including remarks, preparation for the panel Dr Collins will moderate, final participant list etc. I will pass these to you as soon as feasible The Gates advance team will be here on Friday at 10:00 AM, so a few of the logistic details of the visit will clarify then

I'll be sending Dr. Collins some interim information on the proposed configuration of the conference room and seating arrangements and a few other details

Released by Chairman Rand Paul

Visit agenda

Bill Gates

8:20 am	Bill Gates arrives at the Center Drive and Old Georgetown entry gate with a 3 car convoy.
	NIH Police are waiting at Center Drive and Old Georgetown to escort the 3 vehicles to Building 35. Mr. Gates' vehicle will pull in to the driveway.
8:25 am	Bill Gates arrives at Building 35, enters the building, and is welcomed by Dr. Collins.
	Dr. Collins will meet Bill Gates after he exits the car and steps inside of the building.
	NIH Photographer is asked to take photos of the welcome.
	TO NOTE – If Mr. Gates arrives early, he will use the designated green room.
	Dr. Collins is asked to follow Daozhong Jin who will lead him to the conference room (or green room, if Mr. Gates is early).
8:27 am	Bill Gates is escorted by Dr. Collins into the main auditorium (620/630) of Building 35.
	Bill Gates and Dr. Collins have reserved seats at a front left table, angled Chevron style.
8:30 am	Dr. Collins makes opening remarks.
8:35 am	Bill Gates speaks for 10 minutes.
8:45 am	Panel discussions begin, with Bill Gates and Dr. Collins seated at front left table.
10:25 am	Coffee break
10:50 am	Panel discussions resume, with Bill Gates and Dr. Collins seated at front left table.
12:30 pm	Bill Gates is escorted, by Dr. Collins, out of the building through the same hallway he entered.
12:33 pm	NIH Police escort Mr. Gates and staff to the exit gate.

Released by Chairman Rand Paul

Bill & Melinda Gates Foundation- National Institutes of Health
Third Annual Consultative Workshop
April 18, 2016

John Edward Porter Neuroscience Research Center
Building 35A, Room 620/630
NIH Campus, Bethesda, Maryland

8:30 A.M. – 8:35 A.M.

Welcome
Francis S. Collins, MD, PhD, Director, National Institutes of Health (NIH)

Trevor Mundel, MD, PhD, President, Global Health Division, Bill & Melinda Gates Foundation (BMGF)

8:35 A.M. – 8:45 A.M.

Opening Remarks
Bill Gates, Co-Chair and Trustee, Bill & Melinda Gates Foundation

8:45 A.M. – 9:35 A.M.

Panel 1: The Research Response to Zika Virus and Research Preparedness for Future Microbial Outbreaks
Moderator: Anthony S. Fauci, MD, Director, National Institute of Allergy and Infectious Diseases (NIAID), NIH

Discussants
Cristina Cassetti, PhD, Translational Science Program Director, Virology Branch, NIAID, NIH

Stephen S. Whitehead, PhD, Senior Associate Scientist in the Laboratory of Infectious Diseases, NIAID, NIH

Catherine Y. Spong, MD, Acting Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH

Chris Wilson, MD, Senior Advisor, Global Health Discovery & Translational Sciences, BMGF

Steve Kern, PhD, Deputy Director, Quantitative Sciences, BMGF

Discussion to include:

- Status of basic research on ZIKV pathogenesis and transmission
- Status of research on ZIKV as a cause of birth defects
- Development of diagnostic tools, treatments and vaccines
- Research preparedness for future microbial outbreaks; e.g., real-time genomic sequencing and other capacities
- Industrial incentives to develop pandemic preventive vaccines and requirements for effective collaboration

Released by Chairman Rand Paul

9:35 A.M. – 10: 25 A.M.

Panel 2: Emerging concepts in neonatal health and pediatric neurodevelopment

Moderator: Catherine Y. Spong, MD, Acting Director, NICHD, NIH

Discussants:

Jeff Murray, MD, Deputy Director, Family Health, BMGF
Janna Patterson, MD, MPH, Senior Program Officer, Maternal and Child Health, BMGF

Paul Albert, PhD, Senior Investigator and Branch Chief, Biostatistics and Bioinformatics Branch, NICHD, NIH

Vesna Kutlesic, PhD, Director, Office of Global Health, NICHD, NIH

Shasha Jumbe, Senior Program Officer, Quantitative Science, BMGF

Discussion to include:

- Follow-up studies on antenatal steroids in low-resource settings
- Determinants of fetal growth and growth velocity
- Child neurodevelopment, nutrition, and inflammation

10:25 A.M. – 10:50 A.M.

Coffee Break

10:50 A.M. – 11:40 A.M.

Panel 3: Research on Engineered Gene Drives and Vector Borne-Disease Control: Status and Next Direction

Moderator: Francis S. Collins, MD, PhD, Director, NIH

Discussants

Anthony James, PhD, Distinguished Professor, Microbiology and Molecular Genetics, University of California at Irvine

Fil Randazzo, PhD, Deputy Director, Discovery, BMGF

Scott Miller, MD, Deputy Director, Malaria, BMGF

Stephanie James, PhD, Scientific Director, Foundation for the National Institutes of Health (FNIH), NIH

Fred Gould, PhD, William Neal Reynolds Professor of Agriculture, Department of Entomology, North Carolina State University

Lee Hall, MD, PhD, Chief, Parasitology and International Programs Branch Division of Microbiology and Infectious Diseases, NIAID, NIH

Discussion to include:

- Capabilities and limitations of gene drive techniques
- Determining off-target effects
- Understanding ecological and evolutionary conditions for gene flow

Released by Chairman Rand Paul

11:40 A.M. – 12:30 P.M.

Panel 4: Progress in HIV Prevention Science and Potential Scale-up

Moderator: Trevor Mundel, MD, PhD, President, Global Health Division, BMGF

Discussants

Emilio A. Emini, PhD, Director, HIV, BMGF

Carl W. Dieffenbach, PhD, Director, Division of AIDS (DAIDS), NIAID, NIH

Nina Russell, MD, Deputy Director, HIV, BMGF

Mary Marovich, MD, Director Vaccine Research Program, DAIDS, NIH

Discussion to include:

- Follow-up to RV144
- Next generation PrEP and microbicides
- Breaking through the challenges of vaccine manufacture

12:30 P.M. – 12:45 P.M.

Break

12:45 P.M. – 2:20 P.M.

Working Group Lunches and Breakout Sessions

HIV/AIDS

Co-chairs: Dr. Emilio Emini, Dr. Nina Russell and Dr. Carl Dieffenbach

Room 1G600 (1st Floor Skybox)

Malaria

Co-chairs: Dr. Lee Hall and Dr. Scott Miller

Room 2G600 (2nd Floor Skybox)

TB

Co-chairs: Dr. Gilla Kaplan and Dr. Christine Sizemore

Room 640

Maternal and newborn health

Co-chairs: Dr. Tonse N.K. Raju and Dr. Jeff Murray

Room 620/630

Child health and development

Co-chairs: Dr. Dan Marks and Dr. Vesna Kutlesic

Room 610

Pneumonia, enteric diseases, and indoor air pollution

Co-chairs: Dr. Gail Rodgers, Dr. Josh Rosenthal and Dr. Linda Lambert

Room 607

Contraceptive research

Co-chairs: Dr. Dan Hartman and Dr. Dan Johnston

Room 3G600 (3rd Floor Skybox)

Released by Chairman Rand Paul

	HPV/cervical cancers *Co-chairs*: Dr. Peter Dull and Dr. Aimee Kreimer (for Doug Lowy) **Room 606**
2:00 P.M. – 2:20 P.M.	**Point of care diagnostics** *Co-chairs*: Dr. Cristina Giachetti and Dr. Roderic Pettigrew **Room GD913**
2:20 P.M. – 3:40 P.M.	**Open Session** *Moderators*: Francis S. Collins, MD, PhD, Director, NIH Trevor Mundel, MD, PhD, President, Global Health Division, BMGF • Reports of the Working Groups • Proposed new areas of cooperation with discussion
3:40 P.M.	**Wrap-up and Review of Next Steps** Francis S. Collins, MD, PhD, Director, NIH Chris Wilson, MD, Senior Advisor, Global Health Discovery & Translational Sciences, BMGF
4:00 P.M.	**Adjourn**

Released by Chairman Rand Paul

Gates Event – Welcoming Remarks

- Welcome group to the third annual workshop
- Acknowledge HHS colleagues: Rob Califf, Lu Borio, Richard Hatchett
- NIH and BMGF have enjoyed a working partnership since the creation of Grand Challenges in Global Health over a decade ago
- I'm delighted that Bill is able to join us over the morning
    - Bill, I think you would find broad consensus that the Foundation has been the single most transformative influence on global health over the past decade
    - You have bridged the gap where there is no promise of a significant market to motivate private investment in drugs, vaccines, and diagnostics
- Since Bill's last visit – in December 2013, to present our annual Barmes lecture – NIH and the Gates Foundation have taken our partnership to a new level
- Nine NIH institutes are now engaged with Foundation colleagues, extending to such critical areas as
    - An HPV post licensure vaccine trial, to determine if a single dose can confer long term protection – simplifying administration and reducing cost
    - Joint research, on causes of preterm birth, and on biomarkers of gestational age
- In short, NIH's partnership with the Gates Foundation is one of our most critical
- And it couldn't be more timely. We have experienced an inflection point in global health since this group first convened.
    - Emergencies of Ebola, Zika, underscore the importance of real time, innovative responses at all levels of research – from genomic surveillance to advanced product development
- The purpose of meeting is to discuss progress of joint projects – as well as opportunities for cooperation, arising from emerging scientific and public health developments
- The morning will be given over to discussion panels on several highly topical priorities, to prompt new ideas and collaborative thinking. After lunch, the nine working groups will convene to discuss joint work. We will conclude the day with an open session to report our discussions.
- I hope over the course of the day we can address some pivotal questions:
    - Are there opportunities so compelling we should design a collaborative crash program to catalyze progress?
    - How do we better coordinate, collaborate, and communicate our efforts?
    - How can we mobilize new partners, to use existing platforms and investments more effectively?
    - How can we better involve LMIC governments in supporting institutional and scientific capacity building?
- I look forward to what promises to be a vibrant and productive set of discussions!

Released by Chairman Rand Paul

Event: NIH - BMGF meeting (ASF Panel 9:30 A.M. – 10:15 A.M)

Start Date: 2017-06-02 08:30:00 -0400

End Date: 2017-06-02 10:15:00 -0400

Organizer: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Location: John Edward Porter Neuroscience Research Center - 35 Convent Drive Bethesda MD

Categories: ♀,▲,ImportantTravel Required

Class: X-PERSONAL

Date Created: 2019-08-29 12:19:12 -0400

Date Modified: 2024-08-17 01:39:38 -0400

Priority: 5

Attach: 400.eml; 401.eml; 402.eml; 403.eml

Released by Chairman Rand Paul

From: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: NIH-BMGF consultative meeting
Date: Tue, 28 Feb 2017 15:26:44 -0500
Importance: Normal

From: Kline, Lydia (NIH/FIC) [C]
Sent: Tuesday, February 28, 2017 2:57 PM
To: Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>
Cc: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Subject: NIH-BMGF consultative meeting

Dear Meaghan,

Rob Eiss and I wanted to alert you to the scheduled date for the next annual NIH-BMGF consultative workshop, which will be June 2 from 8:30am-4pm, at NCATS (9800 Medical Center Drive, Rockville, Maryland 20850). We anticipate participation from senior NIH and BMGF staff, including Francis (who will lead the meeting) and Bill Gates, as well as IC Directors and Dr. Trevor Mundel of BMGF.

Dr. Fauci has participated in this annual workshop in the past, and we do hope he will be able to do so again. As we obtain more information on the times of specific sessions that will be of particular interest to Dr. Fauci (there will, for example, be a session on Zika), I will be sure to let you know. Please do not hesitate to reach out with any questions.

Best regards,
Lydia

Lydia Mann Kline, MPH, M.S. [Contractor]
Global Health Research and Policy Analyst
Office of the Director
Fogarty International Center
National Institutes of Health
[redacted]

Released by Chairman Rand Paul

From: "Kline, Lydia (NIH/FIC) [C]" [redacted]@nih.gov>
To: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>
Cc: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: NIH-BMGF consultative meeting
Date: Tue, 21 Mar 2017 12:36:36 -0400
Importance: Normal

Dear Meaghan,

We do not have more details on times for any of the specific sessions at the June 2 meeting that will be of particular interest to Dr. Fauci. (We are certainly keeping in mind that he is not available before 10am).

However, I wanted to let you know that we have moved the location of the meeting. It will now be at NCI Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850.

Best,
Lydia

Lydia Mann Kline, MPH, M.S. [Contractor]
Global Health Research and Policy Analyst
Office of the Director
Fogarty International Center
National Institutes of Health
[redacted]

From: Vance, Meaghan (NIH/NIAID) [C]
Sent: Wednesday, March 01, 2017 10:43 AM
To: Kline, Lydia (NIH/FIC) [C] [redacted]@nih.gov>
Cc: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: RE: NIH-BMGF consultative meeting

Lydia:

Thank you very much for the heads-up. Dr. Fauci has a meeting on campus that morning, but will be available to participate in the NIH-BMGF meeting any time after 10am. We look forward to receiving more information about the sessions.

Thanks!
Meaghan

From: Kline, Lydia (NIH/FIC) [C]
Sent: Tuesday, February 28, 2017 2:57 PM
To: Vance, Meaghan (NIH/NIAID) [C] [redacted]@nih.gov>
Cc: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Subject: NIH-BMGF consultative meeting

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Best regards,
Lydia

Lydia Mann Kline, MPH, M.S. [Contractor]
Global Health Research and Policy Analyst
Office of the Director
Fogarty International Center
National Institutes of Health
[redacted]

Released by Chairman Rand Paul

From: "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>
Cc: "Daucher, Marybeth (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Chan, Alan (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Stover, Kathy (NIH/NIAID) [E]" [redacted]@nih.gov>, "Koup, Richard (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Graham, Barney (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Kelley, Ken (NIH/NIAID) [C]" [redacted]@nih.gov>, "Mittelman, Abraham (NIH/VRC) [C]" [redacted]@mail.nih.gov>, "Kwong, Peter (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>
Subject: RE: JOHN: June NIH/BMGF meeting
Date: Fri, 12 May 2017 10:36:21 -0400
Importance: Normal

Just came from morning meeting. ASF agrees with your approach and would indeed like to do the usual format used for VIP visits, where he presents some slides and then turns it to you. Greg will take the lead on ASF's slides.

I'll ask Rob Eiss to keep me in the loop on the Gates cameraperson's needs. If there's anything that requires any sort of set-up, my office will coordinate that with Marybeth, the way we would with a media film crew.

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Thursday, May 11, 2017 9:47 PM
To: Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>
Cc: Daucher, Marybeth (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Chan, Alan (NIH/VRC) [E] [redacted]@mail.nih.gov>; Stover, Kathy (NIH/NIAID) [E] [redacted]@nih.gov>; Koup, Richard (NIH/VRC) [E] [redacted]@mail.nih.gov>; Graham, Barney (NIH/VRC) [E] [redacted]@mail.nih.gov>; Kelley, Ken (NIH/NIAID) [C] [redacted]@nih.gov>; Mittelman, Abraham (NIH/VRC) [C] [redacted]@mail.nih.gov>; Kwong, Peter (NIH/VRC) [E] [redacted]@mail.nih.gov>
Subject: Re: JOHN: June NIH/BMGF meeting

Sounds good to me. I'll mention to Tony and see if he wants to preface the overview. Pretty sure he will want to - you two have done that drill before. I'll be back in touch. Thanks!

On May 11, 2017, at 8:37 PM, Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov> wrote:

Hi Courtney,

Thanks for the update. We will hold the 1-2pm timeframe on June 2nd, and Marybeth can be POC for coordinating logistics.

I don't think Bill knows much about VRC; i.e. our portfolio of diseases, technologies, capabilities, pilot plan etc, so I think it would be useful for me to give a 15 min overview. Tony can decide if he wants to preface that. While tours are great – at the end of the day, a lab is a lab, so I favor

Given that a hour often ends up being 50 min, I'd propose 15 min overview and 5 min questions and 30 min tour.
For tour – given BMGF request to focus on structure-based vaccine design, that should be one key element

Tour

Released by Chairman Rand Paul

- Structure based vaccine design – Suggest we highlight how concepts and lessons from structure-based vaccine design from HIV and RSV are informing vaccine design of additional diseases such as Flu, PIV, MERS and related CoV. Would suggest that Barney and Peter could tag team this.
- Above may be all we can fit for an hour tour. If we want another topic, we can discuss if Malaria or other, but that may be too ambitious.

Lest us know what you think,

Best,
John

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Thursday, May 11, 2017 4:58 PM
To: Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>
Cc: Daucher, Marybeth (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Chan, Alan (NIH/VRC) [E] [redacted]@mail.nih.gov>; Stover, Kathy (NIH/NIAID) [E] [redacted]@nih.gov>; Koup, Richard (NIH/VRC) [E] [redacted]@mail.nih.gov>; Graham, Barney (NIH/VRC) [E] [redacted]@mail.nih.gov>; Kelley, Ken (NIH/NIAID) [C] [redacted]@nih.gov>
Subject: RE: JOHN: June NIH/BMGF meeting

Hi John – just wanted to follow up on this. Rob Eiss from Fogarty called me this afternoon and said that Gates would like to do the VRC tour from 1-2 pm on June 2. Can you confirm that that time would work for you all? They are suggesting that in addition to ASF, key participants would be you, Barney, and Peter.

The hour is ours to design. Would you be able to sketch out a brief proposed itinerary? And, in the meantime, I'll bring it up with Tony in our daily meeting tomorrow too. Although these tours often start with a brief presentation in the conference room to orient the visitor to the history, mission, and science, I wonder if that might be shorter (or even dropped?) in this case, since you'll have been involved in discussions/presentations in the morning. I would think the main thing would be identifying things to see in the afternoon that would connect with what you discussed in the morning.

Re: the filming request, Rob didn't have any more significant details about what they're looking to film. Right now it still sounds like a Gates cameraman will simply be trailing him, documentary-style.

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Wednesday, April 19, 2017 4:08 PM
To: Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>
Cc: Daucher, Marybeth (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Chan, Alan (NIH/VRC) [E] [redacted]@mail.nih.gov>; Stover, Kathy (NIH/NIAID) [E] [redacted]@nih.gov>; Koup, Richard (NIH/VRC) [E] [redacted]@mail.nih.gov>; Graham, Barney (NIH/VRC) [E] [redacted]@mail.nih.gov>; Kelley, Ken (NIH/NIAID) [C] [redacted]@nih.gov>
Subject: RE: JOHN: June NIH/BMGF meeting

Not sure – I've asked for more details and apparently Bldg 1 is waiting to hear more from Gates. I'll let you know as soon as I hear anything else, and I'll also raise it with Tony in our morning meeting tomorrow, to see if he has more info. But if I had to guess, I suspect what they have in mind is essentially a VIP tour (like the one for President Obama) with cameraman tagging along.

From: Mascola, John (NIH/VRC) [E]
Sent: Wednesday, April 19, 2017 4:04 PM
To: Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Daucher, Marybeth (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Chan, Alan (NIH/VRC) [E] [redacted]@mail.nih.gov>;

Released by Chairman Rand Paul

Stover, Kathy (NIH/NIAID) [E] [redacted]@nih.gov>; Koup, Richard (NIH/VRC) [E] [redacted]@mail.nih.gov>; Graham, Barney (NIH/VRC) [E] [redacted]@mail.nih.gov>; Kelley, Ken (NIH/NIAID) [C] [redacted]@nih.gov>
Subject: RE: JOHN: June NIH/BMGF meeting

Hi Courtney,

I have the date for the BMGF annual meeting on calendar – but was not aware of Bill's visit to VRC. So thanks and let us know plans.
Is this just filming, or does he want tour etc?

John

From: Billet, Courtney (NIH/NIAID) [E]
Sent: Wednesday, April 19, 2017 2:56 PM
To: Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>
Cc: Daucher, Marybeth (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Chan, Alan (NIH/VRC) [E] [redacted]@mail.nih.gov>; Stover, Kathy (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: JOHN: June NIH/BMGF meeting

Hi – a heads-up about this desire by the Gates Foundation to film Bill Gates visiting the VRC on June 2. Are you in the loop on this visit? We're working to get more information on what they have in mind. We'll work with them the same way we would with other visiting film crews, to determine scope and try to minimize disruption on the day of. We will provide more information as we get it – just wanted to put this on your radar screen for now.

From: Folkers, Greg (NIH/NIAID) [E]
Sent: Wednesday, April 19, 2017 2:42 PM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Burklow, John (NIH/OD) [E] [redacted]@OD.NIH.GOV>
Cc: Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: RE: June NIH/BMGF meeting

Rob,

Our communications director Courtney Billet and her team will be in charge at our end

thanks

From: Eiss, Robert (NIH/FIC) [E]
Sent: Wednesday, April 19, 2017 10:35 AM
To: Folkers, Greg (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Burklow, John (NIH/OD) [E] [redacted]@OD.NIH.GOV>
Subject: FW: June NIH/BMGF meeting

Dear John and Greg,

The Gates Foundation would like to arrange a filming of Bill at the VRC, during his visit on June 2 to participate in the annual NIH-BMGF workshop (see Chris Karp's note below). Dr. Collins noted this could be useful for many purposes. I'm awaiting further details but wanted both to give a heads-up and ask how I should coordinate with your teams as plans move forward?

The workshop itself will now be on campus, and we'll seek space in the Porter Neuroscience Research Center

Released by Chairman Rand Paul

Best regards,

From: Chris Karp [mailto [redacted]@gatesfoundation.org]
Sent: Tuesday, April 18, 2017 1:16 PM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>
Subject: June NIH/BMGF meeting

Greetings, Rob,

I trust all is well with you and yours.

A couple of things as we move towards firming up the June 2nd meeting:

1) There is interesting in doing some (lab) filming during Bill's visit, as part of bolstering the narrative around US R&D funding commitments and its role in global health and beyond. We'd specifically like to explore doing this at the VRC--which would dovetail with panel discussion planned on structure-guided immunogen design. Herewith an electronic handshake with Bose, who is a Science Advisor to Bill, and can follow up on details and permissions.

2) That said, we're now wondering whether the better part of valor is to have the meeting, as before, on the main campus. If there is time, Bill could potentially visit NCAT later in the day.

best,

Chris K

Released by Chairman Rand Paul

From: "Eisinger, Robert (NIH/NIAID) [E]" [redacted]@nih.gov>
To: "Vance, Meaghan (NIH/NIAID) [C]" [redacted]@nih.gov>
Subject: FW: BMGF Annual Workshop, June 2 - Draft Agenda
Date: Thu, 18 May 2017 14:47:50 -0400
Importance: Normal

Meaghan

This is the latest agenda for the June 2 BMGF meeting. Hilary would like to discuss it with Dr. Fauci when they both return to the office.

Thanks
Bob

From: Eiss, Robert (NIH/FIC) [E]
Sent: Thursday, May 18, 2017 2:44 PM
To: Lowy, Douglas (NCI) [redacted]@nih.gov>; Peter Dull [redacted]@gatesfoundation.org>
Cc: Cohen, Jeffrey (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; [redacted]@gatesfoundation.org; Josie Ekberg [redacted]@gatesfoundation.org>; Marston, Hilary (NIH/NIAID) [E] [redacted]@nih.gov>; Eisinger, Robert (NIH/NIAID) [E] [redacted]@nih.gov>; Johnson, Maureen (NIH/NCI) [E] [redacted]@dea.nci.nih.gov>; Kreimer, Aimee (NIH/NCI) [E] [redacted]@mail.nih.gov>
Subject: BMGF Annual Workshop, June 2 - Draft Agenda

Dear Doug and Peter,

We're delighted you are helping to lead what no doubt will be a dynamic set of panel discussions on June 2. As you know, this will be the fourth annual BMGF-NIH workshop to discuss progress of joint projects and opportunities for cooperation, based on emerging scientific opportunities and public health developments. It will be the second that Bill Gates has joined.

Attached is the current draft agenda. I have the immediate challenge of assembling the moving parts into a fixed, final agenda, and would welcome your guidance. We plan to present Bill and Francis with a final agenda early next week.

May I ask the following, in developing a final draft:

- Who should be listed as moderator, to open discussion and guide the conversation?
- Does the agenda reflect the correct composition and order of panelists, as well as scientific topics?

I'm happy to incorporate your additions and corrections, including any descriptive bullets that help characterize the session

As last year, we're hoping to ensure a conversational format for each panel, to allow for new ideas and collaborative thinking to emerge, and to enable Bill to participate in the discussion. We therefore request that each panelist limit their introductory remarks to 3 minutes, to enable at least half of the 45 minute session to constitute open discussion, led by the moderator, with participation from the panelists, as well as relevant experts in the audience. We ask that you use PowerPoint only when absolutely necessary, such as to present a point that cannot be made verbally. Should you wish for certain graph, charts, or tables to be available as background for your panel, please send these along to me. I'll make sure they are available to all attendees.

Released by Chairman Rand Paul

Finally, we would like to request that the moderators be sure to include a few minutes at the end of the panel to allow Bill to make any final comments or ask any final questions, should he choose.

Please advise if I can answer any questions Thank you for your preparations and guidance. I will be sending along a full list of attendees and additional background when available.

Best,

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Fw: October 7 visit of Bill Gates
Date: Thu, 26 Sep 2013 22:37:09 -0400
Importance: Normal
Attachments: NIH_Visit_of_Bill_Gates_..docx; Wilson_Young_bios.docx

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From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric [redacted]@state.gov) [redacted]@state.gov>
Cc: Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: October 7 visit of Bill Gates

Dear colleagues,

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Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD), and Kathy Young, Senior Project Manager for Strategic Planning and Engagement in Bill's office. Their bios area attached.

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We will include a working lunch as part of the roundtable discussion Details on the lunch are forthcoming.

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Rob Eiss of the FIC has assisted with the planning and organization of this visit. Please feel free to contact Rob with any questions you or your staff may have surrounding the visit.

Best regards, Francis

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 08:47:36 -0400
Importance: Normal
Attachments: NIH_Visit_of_Bill_Gates_..docx; Wilson_Young_bios.docx

---

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Rob Eiss of the FIC has assisted with the planning and organization of this visit. Please feel free to contact Rob with any questions you or your staff may have surrounding the visit.

Best regards, Francis

Released by Chairman Rand Paul

From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 12:08:12 -0400
Importance: Normal

I would have assumed that Eric's own staff would provide these materials since the activities are funded by OGAC. Melanie would be the person to ask about this as she keeps track of these initiatives….but very informally because multiple ICs are actually in charge of their bits and pieces.

On the revised visit schedule, wouldn't it make more sense for Francis to have his one-on-one before the press event rather than after?

G

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 8:48 AM
To: Handley, Gray (NIH/NIAID) [E]
Subject: FW: October 7 visit of Bill Gates

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To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Bacon, Melanie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:35:45 -0400
Importance: Normal

A-OK. I would check with Melanie and will copy her here just to save time.

Melanie can you pull something off the shelf to help Rob out or would you like some help from OGR?

Thanks. Gray

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 12:12 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: RE: October 7 visit of Bill Gates

He does have time with Bill prior to the media roundtable, and then again prior to the leadership roundtable I will be updating the agenda to reflect

There have been a few instances where the background OGAC staff have provided is outdated, so I'm just trouble shooting in case we have information we could provide

---

From: Handley, Gray (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 12:08 PM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: October 7 visit of Bill Gates

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To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric [redacted]@state.gov) [redacted]@state.gov>
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From: "Bacon, Melanie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:40:01 -0400
Importance: Normal
Attachments: PEPFAR_update_2013.xlsx

Hi Gray,

I wasn't really sure what he needed, but I just sent this…. Let me know if you think there is something else I should provide.

Melanie

From: Bacon, Melanie (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 1:21 PM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: October 7 visit of Bill Gates

Wow – there has been a lot going on, so I'll give you some general info and will attach a list of the current R01/U01s which we are working on in collaboration. Let me know if you need something else.

- NIH began doing limited evaluations for PEPFAR in 2005.
- In 2010 we did a collaborative admin supp program where NIH grantees were funded (by OGAC, $10m, and OAR, $3m) to address implantation science topics of particular importance to PEPFAR programming. Six ICs participated: NIAID, NICHD, NIDA, NIMH, NIAAA, NCI, and FIC and 35 – 1yr supplements were awarded (out of 141 applications – our investigators really see the importance of this). 18 countries were represented in the research.
- Based on the success of this, in FY11 we issued a FOA for 3 year grants addressing PEPFAR related Implementation Science, again funded by OGAC and OAR. 15 grants were awarded in the first half of FY12, through 4 different ICs. They are named in the attached list.

- At nearly the same time, NICHD issued a PA for an NIH/PEPFAR collaboration on PMTCT projects. They have begun to set up a research network for those working on these projects, and others in the field. I am double checking on the number awarded.

- In addition to these, the large collaborative project which is funded by NIH, OGAC, BMGF and WB, is called PopART, HPTN071, which is a combination prevention intervention study involving 21 communities (12 in Zambia, 9 in Western Cape, South Africa). The intervention, taking place in PEPFAR-funded clinics in the intervention communities, is scheduled to begin by September 30. Enrollment in the population cohort (which will be used to measure the HIV incidence outcome)will begin next month. DAVID BURNS in NIAID PSP is the Program Officer for this and can give you more details. BMGF works with this as well.

Please let me know what other info you would like.

Thanks,
Melanie

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 12:18 PM
To: Bacon, Melanie (NIH/NIAID) [E]

Released by Chairman Rand Paul

Subject: FW: October 7 visit of Bill Gates
Importance: High

Hi Melanie,

I hope things are well Dr Collins will ask Eric Goosby to say a few words about the implementation science partnership, during the roundtable discussion with Bill Gates on Oct 7

I'm staffing Dr Collins for this May I ask, is there any information on progress, from our end, that we might pass to Eric that may help him prepare? Thanks for any assistance you might be

Best

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Subject: October 7 visit of Bill Gates

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I am delighted you are able to join the roundtable discussion with Bill Gates on Monday, October 7, from 11:15 AM-12:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with staff from the Global Health Program at the BMGF.

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We will include a working lunch as part of the roundtable discussion Details on the lunch are forthcoming.

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Released by Chairman Rand Paul

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Best regards, Francis

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HPTN 071: PopART								
NIAID	Hayes		LSHTM	PopART	South Africa/ Zambia	$10,000,000 PEPFAR	PEPFAR, NIAID, NIMH, BMGF	Randomized study of combination prevention interventions involving 21 communities in Zambia and South Africa. The intervention, taking place in PEPFAR-funded clinics in the intervention communities, is scheduled to begin by September 30. Enrollment in the population cohort (which will be used to measure the HIV incidence outcome)will begin next month.
Project SEARCH								
NIAID	Havlir	CTU suppl	UCSF	SEARCH	Uganda/Kenya	$2,000,000 PEPFAR	PEPFAR, WB, NIAID	POC CD4 testing with streamlined initiation of care in Uganda.
RFA AI-11-003: NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation (R01)								
IC	**PI**	**Grant #**	**Institution**	**Title**	**Country**	**1st year amount (=request -3.5%)**	**$ Source**	**AIM**
NIAID	Farquhar	99974	UW	Assisted partner notification to augment HIV treatment an prevention in Kenya	Kenya	$650,587.56	OAR	introduce assisted partner notification services (aPS) into 18 facilities in Kenya and estimate its capacity to promote HIV testing, identify partners with HIV infection, and link these partners to care
NIAID	Gray	100031	JHU/Rakai	Male Circumcision for HIV Prevention	Uganda	$964,670.94	PEPFAR	To increase MC uptake in a rural setting, particularly in higher risk men, using enhanced messaging, targeted outreach, task shifting, task sharing and mobile camps, and to compare MC uptake, coverage, and client sociodemographic/behavioral characteristics and cost-effectiveness in static clinics versus mobile camps; and conduct a randomized study of the acceptability and safety of EIMC provided by clinical officers (COs) who currently perform adult MC, compared with nurse-midwives (NMWs) who are not currently licensed to perform the procedure
NIAID	Stringer	100053	UAB/CIDRZ	Point-of-care virologic testing to improve outcomes of HIV-infected children	Zambia	$964,980.70	PEPFAR	a cluster-randomized trial of the SAMBA POC virologic test to improve outcomes of HIV-infected children in Zambia
NIAID	Braithwaite	99970	NYU/Ampath	Implementation science to optimize HIV prevention in East Africa PEPFAR programs.	Uganda/Kenya/ Tanzania	$889,221.45	PEPFAR	create a model that will simulate the HIV epidemic in east Africa, taking into account person-to-person HIV transmission, in order to evaluate the benefit and value of retention-in-care interventions in east Africa
NIAID	Havlir	99959	UCSF	Initiate ART: Sreamlined ART Start Strategy (START)	Uganda	$963,331.52	PEPFAR	evaluate the effectiveness of a multi-component Streamlined ART Start Strategy (START) based on an empirically validated model of change that deploys 1) portable point of care (POC) CD4 testing and adapted counseling to enable ART start, 2) dissemination of information through education that predisposes provider behavior and 3) feedback reporting on FTIs that reinforces uptake of ART
NIAID	Frenkel	100037	Seattle Child	Drug resistance testing in Kenya to improve ART suppression of HIV replication	Kenya	$934,684.53	PEPFAR	An inexpensive simple assay (oligonucleotide ligation assay (OLA)) to detect HIV drug-resistance will be implemented in Kenya. We will study the benefits conferred by this assay to improving infected individuals health, and compare the overall cost of using to not using this test.
NIAID	El Sadr	100059	Columbia	Link4Health: a combination strategy for linkage and retention: Swaziland	Swaziland	$962,976.40	OAR	two-arm cluster site-randomized trial to compare the effectiveness of a novel combination package of evidence-based interventions, the combination intervention strategy (CIS), compared to standard of care (SOC) on linkage and retention of HIV-positive patients from point of testing to retention in care
NIAID	Bailey	99953	U-IL/UNIM	integration of infant male circumcision with community health services in Kenya	Kenya	$964,748.14	PEPFAR	To provide the evidence-base necessary to guide implementation of IMC services, we propose a simultaneous, prospective comparison of two sustainable, scalable models of IMC service delivery
NIAID	Rosen	100015	Boston U	Rapid initiation of ART to promote early HIV/AIDS treatment in	South Africa	$331,692.70	OAR	The study is designed as an unblinded randomized strategy trial comparing the current standard of care to a rapid ART initiation strategy for outpatient adults and pregnant women who come to a South African clinic for an HIV test and are eligible for ART
NIAID	Howard	100044	Columbia	A combination intervention package for Isoniazid preventive therapy in Ethiopia	Ethiopia	$632,048.95	PEPFAR	ENhance Initiation and Retention in IPT Care for HIV Study (ENRICH Study), which aims to evaluate the effectiveness of a combination intervention package (CIP) versus standard of care (SOC), to improve IPT initiation, adherence, and completion among HIV-infected individuals enrolled in HIV care at health centers in Ethiopia
NCI	Campbell	100026	U CO	Strategies to improve KS Outcomes in Zimbabwe	Zimbabwe	$965,000.00	PEPFAR	develop evidence-based, cost-efficient approaches to improve detection and management of AIDS-KS and its related symptoms in low resource environments, and to evaluate the implementation of these approaches in primary care settings in urban and rural communities in Zimbabwe
NICHD	Abrams	99951	Columbia	ART in pregnant women in SA	South Africa	$768,676.54	PEPFAR	"fast tracking" ART initiation in pregnancy, combines strategies to address the key health systems, clinical, and patient education and adherence issues that currently act as barriers to rapid ART initiation in pregnancy - HIV viral suppression at the time of delivery as the primary outcome. Secondary aims include the transmission of HIV from mother-to-child and retention in care through 6 months postpartum, as well as the acceptability and cost-effectiveness of this intervention
NICHD	Pfeiffer	99987	UW	Among HIV-positive pregnant women in central MZ	Mozambique	$593,311.92	PEPFAR	develop and test a pilot intervention in central Mozambique to implement the new WHO guidelines and increase the proportion of HIV-positive pregnant women in target ANC clinics who start ART prior to delivery, without reducing ART adherence. The intervention will emphasize a "test and treat" approach.
NIMH	Blattner	100101	UMD	TRUST	Nigeria	$964,909.29	PEPFAR	TRUST is that Network-based recruitment to expand engagement of Nigerian MSM that links clients to combination prevention and comprehensive HIV and medical services delivered at community-trusted venues achieves measurable behavioral change, and durable high quality clinical outcomes
NIMH	Wagner	99884	RAND	Task shifting model of depression treatment to unleash HIV Public Health Benefits		$392,755.00	PEPFAR	We will test an algorithm-based, nurse-driven model for managing antidepressant treatment.
TOTAL per YEAR						**$11,943,595.64**		
OAR Funds						$1,945,256.66		
PEPFAR Funds						$9,998,338.98		
RFA HD-12-210: NIH/PEPFAR Collaboration for Advancing Implementaton Science in Prevention of Maternal-Child HIV Transmission (PMTCT) R01								
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IC	**PI**	**Grant #**	**Institution**	**Title**	**Country**			

Released by Chairman Rand Paul

NICHD	Sherr	75057		Systems analysis and improvement to optimize pMTCT: A cluster randomized Trial	Cote d'Ivoire/ Kenya/ Mozambique			
	Aliyu	75075		Optimizing integrated PMTCT services in rural North Central Nigeria	Nigeria			
	Yotebeing	75171		Conditional cash transfers to increase uptake and retention of PMTCT services	Democratic Republic of Congo			
	Israel-Ballard	75090		Effect of feeding buddies on adherence to WHO PMTCT guidelines in South Africa	South Africa			
	Abrams	75163		Mother and infant retention for health (MIR4Health)	Kenya			
	Chi	75131		Validation of a community survey methodology formeasuring PMTCT impact	Zambia			
	Ezeanolue	75050		Comparative effectiveness of congregation and clinic based approaches to PMTCT	Nigeria			
	Davies	75156		Closing the gaps in PMTCT program coverage, early infant diagnosis and treatment	South Africa			
	Farquhar	75108		HIV testing and educating male partners to improve maternal and infant outcomes	Kenya			
TOTAL per YEAR						**$3million**		
PEPFAR Funds						$2.5million		
NICHD Funds						$500,000		
RFA DA-12-002: HIV/AIDS Implemenation Science Targeting Drug Using Populations: A Collaboration with PEPFAR (R01)								
NIDA	Altice	33679		Expanding Medication Assisted Therapies in Ukraine				
NIDA	Owczarzak	33644		A Novel, Bottom Up Approach to Promote Evidence Based HIV Prevention for IDUs				
NIDA	Goldsamt	33673		Implementation of a Sexual Health Intervention for YMSM in Two Vietnamese Cities				
NIDA	Page	33672		Cambodia Integrated HIV and Drug Prevention Implementation Program				
NIDA	Li	33609		Enhancing the Role of Commune Health Workers in HIV and Drug Control in Vietnam				
NIDA	O'Brien	33671		A Pilot Implementation Project of Methadone and Suboxone for Injecting Drug Users				
NIDA	Woody	33670		Opioid Relaps & HIV Risk: 48 vs. 24 Weeks of ER Injectable Naltrexone Opioid Relaps & HIV Risk: 48 vs. 24 Weeks of ER Injectable Naltrexone				
No PEPFAR funding was supplied - all of these grants funded through NIDA								
FOGARTY INTERNATIONAL CENTER								
Medical Education Partnership Initiative (MEPI)								
FIC	multiple			Medical School Training/Education	multi	~$10m/yr	OGAC	
					multi	$6 - 7m/yr	FIC	

Released by Chairman Rand Paul

From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Bacon, Melanie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 13:45:43 -0400
Importance: Normal

Seems just right to me. Rob will let you know if he has any other questions. He is a good guy and we want to help him. Sorry for the duplication. I did not know he had written you already. Many thanks. g

---

From: Bacon, Melanie (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 1:40 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: FW: October 7 visit of Bill Gates

Hi Gray,

I wasn't really sure what he needed, but I just sent this…. Let me know if you think there is something else I should provide.

Melanie

From: Bacon, Melanie (NIH/NIAID) [E]
Sent: Friday, September 27, 2013 1:21 PM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: October 7 visit of Bill Gates

Wow – there has been a lot going on, so I'll give you some general info and will attach a list of the current R01/U01s which we are working on in collaboration. Let me know if you need something else.

- NIH began doing limited evaluations for PEPFAR in 2005.
- In 2010 we did a collaborative admin supp program where NIH grantees were funded (by OGAC, $10m, and OAR, $3m) to address implantation science topics of particular importance to PEPFAR programming. Six ICs participated: NIAID, NICHD, NIDA, NIMH, NIAAA, NCI, and FIC and 35 – 1yr supplements were awarded (out of 141 applications – our investigators really see the importance of this). 18 countries were represented in the research.
- Based on the success of this, in FY11 we issued a FOA for 3 year grants addressing PEPFAR related Implementation Science, again funded by OGAC and OAR. 15 grants were awarded in the first half of FY12, through 4 different ICs. They are named in the attached list.

- At nearly the same time, NICHD issued a PA for an NIH/PEPFAR collaboration on PMTCT projects. They have begun to set up a research network for those working on these projects, and others in the field. I am double checking on the number awarded.

- In addition to these, the large collaborative project which is funded by NIH, OGAC, BMGF and WB, is called PopART, HPTN071, which is a combination prevention intervention study involving 21 communities (12 in Zambia, 9 in Western Cape, South Africa). The intervention, taking place in PEPFAR-funded clinics in the intervention communities, is scheduled to begin by September 30. Enrollment in the population cohort (which will be used to measure the HIV incidence outcome)will begin next month. DAVID BURNS in NIAID PSP is the Program Officer for this and can give you more details. BMGF works with this as well.

Released by Chairman Rand Paul

Please let me know what other info you would like.

Thanks,
Melanie

From: Eiss, Robert (NIH/FIC) [E]
Sent: Friday, September 27, 2013 12:18 PM
To: Bacon, Melanie (NIH/NIAID) [E]
Subject: FW: October 7 visit of Bill Gates
Importance: High

Hi Melanie,

I hope things are well Dr Collins will ask Eric Goosby to say a few words about the implementation science partnership, during the roundtable discussion with Bill Gates on Oct 7

I'm staffing Dr Collins for this May I ask, is there any information on progress, from our end, that we might pass to Eric that may help him prepare? Thanks for any assistance you might be

Best

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric [redacted]@state.gov) [redacted]@state.gov>
Cc: Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: October 7 visit of Bill Gates

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From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 14:09:17 -0400
Importance: Normal

As always…>Thanks.

Can I call you?

From: Eiss, Robert (NIH/FIC) [E]
Sent: Thursday, September 26, 2013 10:37 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: Fw: October 7 visit of Bill Gates

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Harvey, Hillery (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Cantrel, Katherine (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>, "Burklow, John (NIH/OD) [E]" [redacted]@OD.NIH.GOV>, "Doepel, Laurie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013
Date: Tue, 05 Nov 2013 11:13:36 -0500
Importance: Normal
Inline-Images: image001.png

Hi Hillery,

Absolutely, that was our intention since both of the lab visits involve NIAID. The one positive in having to cancel the event due to the shutdown, is the availability of Dr. Fauci to participate on the rescheduled date.

With regards to the format of the roundtable discussion, below is the note that Dr. Collins sent to the IC Directors and Deputies participating in the roundtable, prior to the cancellation I hope this is instructive and would be happy to provide any additional background and clarifications.

The costs of the catered lunch will be supported out of the representational fund – covering both the guests and IC Directors.

Best,

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Cc: Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
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Best regards, Francis

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Tuesday, November 05, 2013 10:08 AM
To: Wood, Gretchen (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Burklow, John (NIH/OD) [E]; Doepel, Laurie (NIH/NIAID) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Thank you Gretchen. Very helpful.

ROB: Dr. Fauci would like to be included in the tour of Bldg. 33 with Clif Barry and Kathy Zoon. As the schedule evolves, can you incorporate this modification?

Many thanks again to you both.
Hillery

From: Wood, Gretchen (NIH/OD) [E]
Sent: Tuesday, November 05, 2013 9:57 AM
To: Harvey, Hillery (NIH/NIAID) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hi Hillery,

Sorry to be late in responding. We will actually be re-working the agenda to have the media briefing at the end of the day's agenda so Mr. Gates will have the opportunity to hear from Senior Leadership and be better prepared for questions from the media. I do not believe that we were intending for ICD to use slides, but rather have an open dialogue with Mr. Gates. Given the time allotted, it would appear that each topic would have between 12 and 15 minutes, and I imagine that the opening comments for

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each would be up to the lead discussant. I have cc'd Rob Eiss here on this e-mail as he has been working on the format and can relay any ideas that he has received from Dr. Collins.

Please do not hesitate to contact me should you need anything further. Rob and I are hoping to hear from remaining ICD before the end of the week to pin down a more accurate agenda.

Best wishes,

Gretchen

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 04, 2013 1:01 PM
To: Wood, Gretchen (NIH/OD) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hello Gretchen—

In discussing Dr. Fauci's preparation for his role in Mr. Gates' visit December 2nd, several questions arose regarding the agenda discussion on HIV, malaria, and TB:

- What is the general discussion format? e.g., opening slides or comments followed by organic discussion?
- For the 11:45am-1pm agenda items, how much time is allotted for each? For the lead discussant's opening comments?
- Should Dr. Fauci plan to use slides?

And any other information on how Dr. Collins envisions this roundtable/working lunch would be helpful.
Many thanks for your help!
Best wishes,
Hillery

Hillery A. Harvey, Ph.D.
Special Assistant to the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bldg. 31 Rm. 7A-03
Bethesda, MD 20892
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Sent: Friday, November 01, 2013 2:26 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Green, Eric (NIH/NHGRI) [E]; Mascola, John (NIH/VRC) [E]; Barry, Clifton (NIH/NIAID) [E]
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F: [redacted]
E: [redacted]@od.nih.gov

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To: NIAID OD AM [redacted]@niaid.nih.gov>
Subject: FW: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013
Date: Tue, 05 Nov 2013 11:19:57 -0500
Importance: Normal
Inline-Images: image001.png

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To: NIAID OD AM [redacted]@niaid.nih.gov>
Subject: FW: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013
Date: Tue, 05 Nov 2013 22:18:19 -0500
Importance: Normal
Inline-Images: image001.png

Let us discuss tomorrow and I will also separately discuss with Hillery Harvey.

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Tuesday, November 05, 2013 11:20 AM
To: NIAID OD AM
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Released by Chairman Rand Paul

From: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>

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Subject: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December

Date: Fri, 29 Nov 2013 09:56:46 -0500

Importance: High

Attachments: Revised_NIH_Visit_of_Bill_Gates_December_2_fsc.docx; NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding_NIAID_final_c_.docx; 2013_BMGF_AL_English.pdf

Inline-Images: image001.png

Good morning,

Attached please find the final agenda for Mr. Gates' visit this Monday, 2 December. For your review we have also included a briefer on the NIH/BMGF partnerships in Global Health and the BMGF Annual Letter. If you have any questions or concerns, please do not hesitate to contact me and Rob Eiss. Many thanks and enjoy your weekend.

Best wishes,

Gretchen

Gretchen S. Wood

Released by Chairman Rand Paul

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PROGRAM OF ACTIVITY
NIH VISIT OF BILL GATES
DECEMBER 2, 2013

8:45 AM Dr. Francis Collins and colleagues arrive at VRC

9:00 AM Mr. Gates and colleagues arrive (The Dale and Betty Bumpers Vaccine Research Center (VRC)

9:05 AM – 9:10 AM Dr. Francis Collins one-on-one with Bill Gates (room 1107, building 40)

9:10 AM – 9:50 AM Scientific Tour of the VRC

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. John Mascola, Director, VRC

9:50 AM – 10:00 AM Dr. Collins, Mr. Gates, and colleagues travel to Clinical Center, South entrance (building 10)

10:00 AM – 10:45 AM Media Roundtable (Library Conference Room, Clinical Center)

- Associated Press
- New York Times
- Wall Street Journal
- Washington Post

10:45 AM – 11:00 AM Dr. Collins and Mr. Gates go to Masur Auditorium's Green room

11:00 AM – 12:00 PM David E. Barmes Global Health Lecture (Masur Auditorium, Clinical Center)

- 11:00 AM – 11:05 AM Introduction by Dr. Francis Collins
- 11:05 AM – 11:40 AM "Why the Future Needs Biomedical Innovation"
- 11:40 AM – 12:00 PM Q's and A's

12:00 PM – 12:15 PM Dr. Collins, Mr. Gates, and colleagues travel from Masur Auditorium to Medical Board Room

12:15 PM – 1:20 PM Roundtable Discussion with NIH Senior Leadership and Working Lunch
Select priorities in global health: state of the science, questions to resolve
(Medical Board Room, Clinical Center)

- **Opening remarks***: Dr. Francis Collins and Mr. Bill Gates*

- **HIV, malaria, TB and other infectious disease priorities**
  Lead discussant: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
  Dr. Roger Glass, Director, Fogarty International Center

- **Understanding the molecular basis of growth and nutrition**
  Lead discussant: Dr. Alan Guttmacher, Director, Eunice Kennedy Shriver, National Institute of Child Health and Human Development
  Dr. Gregory Germino, Deputy Director, National Institute of Diabetes and Digestive and Kidney Diseases

- **Point-of-care diagnostics and therapeutics for neglected diseases**
  Lead discussant: Dr. Roderic Pettigrew, Director, National Institute of Biomedical Imaging and Bioengineering
  Dr. Martha Somerman. Director, National Institute of Dental and Craniofacial Research
  Dr. Christopher Austin, Director, National Center for Advancing Translational Sciences

- **Integrating NCD research into global health**
  Lead Discussant: Dr. Harold Varmus, Director, National Cancer Institute
  Dr. Gary Gibbons, Director, National Heart Lung and Blood Institute
  Dr. Thomas Insel, Director, National Institute of Mental Health

- **New partnerships in discovery science and capacity building: H3Africa and the Medical Education Partnership Initiative**
  Lead Discussant: Dr. Eric Green, Director, National Human Genome Research Institute
  Dr. Francis Collins, Dr. Roger Glass

1:20 PM – 1:30 PM Dr. Collins, Mr. Gates, and colleagues travel to Building 33

1:30 PM – 2:20 PM Innovations in TB Drug Development (The C.W. "Bill" Young Center)

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. Clif Barry, Chief, Tuberculosis Research Section, National Institute of Allergy and Infectious Diseases
Dr. Kathryn Zoon, Director, Division of Intramural Research, National Institute of Allergy and Infectious Diseases

2:20 PM – 2:30 PM Wrap up discussion (The C.W. "Bill" Young Center)

Dr. Collins and Mr. Gates

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NATIONAL INSTITUTES OF HEALTH (NIH) – BILL & MELINDA GATES FOUNDATION (BMGF) ACTIVE FUNDED PARTNERSHIPS IN GLOBAL HEALTH

1. The Foundation for the National Institutes of Health (FNIH), which leverages the resources of the NIH with the public and private sectors, has the following initiatives.

- Global Health
    - *Grand Challenges in Global Health (GCGH)* aims to create "deliverable technologies" – health tools that are not only effective, but also inexpensive to produce, easy to distribute, and simple to use in developing countries ($201M; 2003-2015).
    - *Vector-Based Control of Transmission: Discovery Research (VCTR)* aims to extend GCGH research and establish a pipeline of innovative new tools that will be safe, easily deployed, effective, and sustainable for use in the control of mosquito-borne diseases such as malaria and dengue ($52M; 2009-2016).
    - *Etiology, Risk Factors & Interactions of Enteric Infections and Malnutrition and the Consequences for Child Health & Development (MAL-ED)* aims to understand the interactions between enteric infections and malnutrition in association with poor health outcomes, including physical growth, cognitive development deficits, and poor immunological responses to childhood vaccines, in order to design better intervention strategies ($40M; 2008-2014) (Partner: Fogarty International Center (FIC).
    - *Identification of High-Quality HITs for Tuberculosis (HIT-TB)* aims to produce high-quality chemical hit series with defined, tractable targets as drug leads for tuberculosis ($2.9M; 2010-2013) (Partner: National Institute of Allergy and Infectious Diseases (NIAID).
    - *Rapid Identification of Individuals with Viable Adult Worms of Onchocerca volvulus: A Means to an End (pending)* aims to identify host and parasite specific biomarkers in human subjects of adult female *O. volvulus* and develop rapid point of care methods to detect these biomarkers ($1.5M; 2013-2015) (Partner: NIAID).
- Collaboration for AIDS Vaccine Discovery (CAVD)
    - *T-Cell Vaccine Immune Monitoring Consortium (CTC-VIMC)* provides standardized T cell assays for both non-human primate and clinical vaccine trials and facilitates comparison of efficacy data from different vaccine development efforts across the CAVD ($50M; 2006-2016) (Partner: NIH).
    - *Centralized Envelope Comparative Immunogenicity Phase I Study (CECI)* aims to understand how best to design T-cell immunogens in order to develop a vaccine that addresses the broad genetic diversity of HIV-1 ($4.5M; 2009-2014) (Partner: NIAID).
    - *Development of a Second Generation Broadly Neutralizing Antibody Product to Prevent HIV-1 Infection* aims to develop a second generation broadly neutralizing antibody product to prevent HIV-1 infection, with improved potency and longer half-life ($1.2; 2011-2016) (Partner: NIAID).

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2. NIAID, in addition to the work it is doing in partnership with FNIH, is involved in the following activities with the support of the BMGF:

- Testing whether "unnatural immunity" (antibodies that are not generated in natural infection) against structures that form a capsule uniquely on the surface of infecting Leishmania promastigotes can prevent infection in the mammalian host, as well as block the development of infectious promastigotes in the sandfly vector (~$310K)

- Working to produce additional amounts of HIV clade C gp145 envelope protein, for use as a research reagent and potential HIV vaccine immunogen. Additional protein would be produced at a reduced cost and shortened development time due to the decrease in the number of production runs and associated release and stability testing ($2.9M)

- NIAID is also involved as a sub-grantee on the following BMGF-funded projects:

    - Application of clinical imaging modalities to tuberculosis treatment and transmissions: whole body imaging technology as a means of facilitating development of new drugs that may shorten chemotherapy duration. ($5M, University of Pittsburg)

    - Coordinating and administering collaborative research in chemistry and microbiology for advancement of new TB medicines ($690K, Infectious Disease Research Institute)

    - Ascertaining the adjuvant effects, when combined with HIV/SIV immunogens, on innate/adaptive immunity in tissue sites and on protection from SIV challenge using the *in vivo* macaque model (~614K, Fred Hutchinson Cancer Research Center)

    - Supporting development of biomarkers for TB that can be used in treatment evaluation and disease diagnosis (~893K, Catalysis Foundation)

    - Assessing neutralizing antibody responses against HIV-1 in human clinical trials in a Good Clinical Laboratory Practices (GCLP) compliant manner and working on developing a second generation broadly neutralizing antibody product to prevent HIV-1 infection in humans through participation in the CAVD/Comprehensive Antibody Vaccine Immune Monitoring Consortium (CAVIMC) ($1.42M, Duke University)

    - Working in Cameroon to develop and test a strategy to extend mass drug treatment for lymphatic filariasis and hyperendemic onchocerciasis to areas endemic for loiasis ($324K, Institut Bouisson Bertrand)

    - Screening 80,000 diversity-oriented synthesis (DDS) molecules against *Mycobacterium tuberculosis* (TB) and developing a whole body imaging technology as a means of facilitating development of new drugs that may shorten the duration of chemotherapy in patients with TB ($110K, Broad Institute)

    - Working to develop a global HIV-1 incidence assay through determination of cell-associated viral load in CD4 T cells ($130K, Duke University)

3. NICHD has done extensive global work with the support of the BMGF.

- The establishment of NICHD's Global Network for Women's and Children's Health Research was the first public-private partnerships between NIH and the BMGF. The BMGF provided $15M over the first 3 years and was instrumental in laying the foundation for the Global Network's numerous achievements over the past 12 years. Achievements include, but are not limited to:
    - Initial large-scale individual site studies conducted during the first cycle, which found that training birth attendants in neonatal resuscitation and essential newborn care reduced neonatal mortality and morbidity from birth asphyxia and neonatal infections and that oral misoprostol reduced postpartum hemorrhage
    - The development of "common" trials, conducted by at least 3 sites, which led to increased collaboration and scientific capacity building, and to numerous findings, including that local instructor-training in newborn resuscitation and essential newborn care significantly reduced perinatal deaths and was cost-effective
    - A current Global Network comprised of 7 multidisciplinary research units existing in India, Pakistan, Zambia, the Democratic Republic of the Congo, Kenya and Guatemala with the aim of addressing the three major causes of perinatal morbidity and mortality: asphyxia, prematurity, and infection
    - The maintenance of a detailed birth registry, which enrolls mothers early in pregnancy and has provided outcome data on 340,000 mother-infant pairs
    - Publishing of 170 manuscripts in 10 years, almost half with a scientist from the developing world as first author
    - Tremendous independent research capacity evidenced by funding of global collaborators by the World Health Organization, the World Bank, the government of France, the Thrasher Foundation, and the Church of the Latter Day Saints, among others
- NICHD, with the support of the BMGF, is currently working on an integrated approach to infection, noncommunicable diseases, food insecurity, and the dual burden of over- and under-nutrition through the following projects:
    - The *Biomarkers of Nutrition for Development* (*BOND)* program, which aims to develop a unified, scientific approach to select biomarkers for assessing the function and effect of diet and nutrition on health and diseases in individuals and populations (~$450K)
    - The *Iron and Malaria* project, which aims to identify safe and effective interventions (such as iron supplementation) to prevent iron deficiency and related health problems in areas where malaria and other infections are common ($9.4M)

4. Fogarty International Center (FIC) is supported by the BMGF as well.

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- In a collaborative effort with NICHD, FIC is working to obtain clinical outcome results of an experimental Vi-conjugate vaccine and to produce a human sera reference standard to be used to accelerate the development of commercialized Vi-conjugate vaccines ($586K).

- FIC's director, Roger Glass, who has worked extensively in India on a rotavirus vaccine as part of the Indo-U.S. Vaccine Action program, which began at the Centers for Disease Control and Prevention (CDC) and with the support of NIAID in preparing the first pilot lots, credits project funding from the BMGF in 2000 to its ultimate success and the recent licensing of the vaccine in India. The rotavirus vaccine was developed in India, with an Indian seed strain of virus, an Indian company, Bharat, clinical trials in India, and support from the government of India and the Gates foundation, with long term input from CDC and NIH.

5. The National Cancer Institute (NCI) is working on human papilloma virus (HPV) vaccination and screening through the Programme for Appropriate Technology in Health (PATH) and the GAVI Alliance.

6. *The Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (PopART),* which is funded primarily by PEPFAR and administered by OGAC, ($~103M), is also co-funded by the BMGF (~15M), NIAID ($~12M), NIMH ($~2.3M) and NIDA ($~2.1M). The study, which will involve 21 communities in South Africa and Zambia, builds on the results of the NIAID-funded HIV Prevention Trials Network (HPTN) 052, which found that HIV-infected individuals who start treatment early dramatically reduce the risk of transmitting the virus to their partners. *PopART* aims to assess whether house-to-house voluntary HIV testing and prompt treatment of HIV infection, along with other proven HIV prevention measures, can substantially reduce population-level HIV incidence.

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NATIONAL INSTITUTES OF HEALTH (NIH) – BILL & MELINDA GATES FOUNDATION (BMGF) ACTIVE PARTNERSHIPS IN GLOBAL HEALTH (no current exchange of funds)

***P5 (the Pox-Protein Public-Private Partnership*) –** P5 is an AIDS vaccine development initiative involving NIAID, BMGF, the HIV Vaccine Trials Network (HVTN), the U.S. Military HIV Research Program (MHRP), Sanofi-Pasteur and Novartis. It seeks to advance clinical development of pox vector, Env protein boost vaccine concepts in order to extend and confirm the RV 144 efficacy results in high risk populations, advance the candidates toward licensure, and evaluate next generation pox-protein vaccine candidates for safety, immunogenicity and efficacy. NIAID and the BMGF are the primary funders of this enterprise and have so far co-funded efforts for HIV Env down-selection, processes and analytics development, tech transfer, and manufacture of the protein components for southern Africa. Novartis will oversee manufacturing at a CMO beginning in September 2013. BMGF, with NIAID, will begin soon to fund clinical trial sites in Southern Africa for training in preparation for vaccine efficacy studies.

***Malaria Vaccine Development and Evaluation* -** NIAID and BMGF have supported and coordinated efforts to develop malaria vaccines for many years. Both are engaged in the Malaria Vaccine Funders Group, along with USAID, the European Commission, the Wellcome Trust, the European Vaccine Initiative, the European-Developing Country Clinical Trials Partnership (EDCTP), and the PATH Malaria Vaccine Initiative (MVI). The Malaria Vaccine Funders Group, with active NIAID and BMGF scientific engagement, will release the Update of the Malaria Vaccine Technology Roadmap in November, 2014. Both NIAID and BMGF are represented on the PfSPZ Multilateral Integration Team for development of a whole sporozoite vaccine against falciparum malaria by Sanaria. NIAID scientists serve as advisors for several BMGF-supported vaccine discovery projects implemented by the PATH Malaria Vaccine Initiative. tVI. Recently the organizations collaborated in a joint Phase 1/2 Prime-Boost study of an Adenovirus Serotype 35-based malaria vaccine (Ad35.CS) followed by RTS,S. NIAID supported the preclinical and clinical development of Ad35.CS, provided clinical trial material for the study, and participated on the protocol team that designed and oversaw the study.

"Decade of Vaccines" Collaboration (DoVC) – This initiative, launched in 2010, engaged multiple public and private sector vaccine-focused organizations under WHO, BMGF and NIAID leadership. It produced the Global Vaccine Action Plan (GVAP), which was endorsed by the World Health Assembly in 2012. To continue the work launched by the DoVC, representatives of BMGF, NIAID, and WHO signed a Memorandum of Understanding (MOU) in March, 2013 to extend collaborative vaccine R&D efforts and establish the ***Global Vaccine and Immunization Research Forum (GVIRF)***. This forum will track R&D progress as compared to the goals and strategic objectives of the Global Vaccine Action Plan. It will also help identify and respond to R&D opportunities. The first GVIRF will take place 4-6 March 2014 in Bethesda MD, and approximately every 18 months thereafter.

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BILL & MELINDA GATES *foundation*

Annual Letter *from* Bill Gates

2013

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Getting a closer look at charts documenting rural health progress at the Germana Gale Health Post in Ethiopia. Over the past year I've been impressed with progress in using data and measurement to improve the human condition *(Dalocha, Ethiopia, 2012).*

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Measuring Progress

We can learn a lot about improving the world in the 21st century from an icon of the industrial era: the steam engine.

Over the holidays I read *The Most Powerful Idea in the World*, a brilliant chronicle by William Rosen of the many innovations it took to harness steam power. Among the most important were a new way to measure the energy output of engines and a micrometer dubbed the "Lord Chancellor," able to gauge tiny distances.

Such measuring tools, Rosen writes, allowed inventors to see if their incremental design changes led to the improvements—higher-quality parts, better performance, and less coal consumption—needed to build better engines. Innovations in steam power demonstrate a larger lesson: Without feedback from precise measurement, Rosen writes, invention is "doomed to be rare and erratic." With it, invention becomes "commonplace."

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Starting around 1805, the "Lord Chancellor" micrometer, according to author William Rosen, was "an Excalibur of measurement, slaying the dragon of imprecision" for inventors in the Industrial Revolution.

Of course, the work of our foundation is a world away from the making of steam engines. But in the past year I have been struck again and again by how important measurement is to improving the human condition. You can achieve amazing progress if you set a clear goal and find a measure that will drive progress toward that goal—in a feedback loop similar to the one Rosen describes.

Meeting with a group of Ethiopia's community health workers. The country has made great gains in health, thanks to a program using 34,000 trained workers to deliver health services throughout the country *(Dalocha, Ethiopia, 2012)*.

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Melinda and I having lunch with teachers at South High School *(Denver, CO, 2012).*

This may seem pretty basic, but it is amazing to me how often it is not done and how hard it is to get right.

In previous annual letters, I've focused a lot on the power of innovation to reduce hunger, poverty, and disease. But any innovation—whether it's a new vaccine or an improved seed—can't have an impact unless it reaches the people who will benefit from it. That's why in this year's letter I discuss how innovations in measurement are critical to finding new, effective ways to deliver these tools and services to the clinics, family farms, and classrooms that need them.

Our foundation is supporting these efforts, but we and others need to do more. Given how tight budgets are around the world, governments are rightfully demanding effectiveness in the programs they pay for. To address these demands, we need better measurement tools to determine which approaches work and which do not.

In this letter I'll highlight strong examples I've seen in the past year of how measurement is making a difference. In Colorado, Melinda and I learned how a school district is pioneering a new system to measure and promote teacher effectiveness. In Ethiopia, I witnessed how a poor country, pursuing goals set by the United Nations, delivered better health services to its people. In Nigeria, I've seen how the digital revolution allows us to improve the use of measurement in the campaign to eradicate polio. Thanks to cell phones, satellites, and cheap sensors, we can gather and organize data with increasing speed and accuracy. These modern-day Lord Chancellors will also help speed progress in education and agriculture, as well as other health efforts.

Reviewing a polio team's vaccination plan in Mashakeri Village *(Kebbi State, Nigeria, 2011).*

The World's Report Card

A business has increasing profit as its primary goal. Management decides the actions—such as improving customer satisfaction or adding new product capabilities—that will drive profit and then develops a system to measure those on a regular basis. If the managers pick the wrong measures or don't do better than their competition, profit goes down. Business magazines and business schools analyze which measures companies use and which companies have done particularly well or poorly. Other companies benefit from these analyses, learning from the performance of their competitors which tactics and strategies work and which don't. The understanding of how to use measurement to drive excellence in business has improved dramatically in the last 50 years.

Unlike business, where profit is the "bottom line," foundations and government programs pick their own goals. In the United States our foundation focuses mostly on improving education, so our goals include reducing the number of kids who drop out of high school. In poor countries we focus on health, agriculture, and family planning. Given a goal, you decide on what key variable you need to change to achieve it—the same way a business picks objectives for inside the company like customer satisfaction—and develop a plan for change and a way of measuring the change.

Released by Chairman Rand Paul

You use the measurement as feedback to make adjustments. I think a lot of efforts fail because they don't focus on the right measure or they don't invest enough in doing it accurately.

I think the best example of picking an important goal and using measurement to achieve it is the vaccination work UNICEF did under Jim Grant's leadership in the 1980s. Few people may have heard of Grant, but his impact on the world was as significant as any profit-driven leader like a Henry Ford or Thomas Watson.

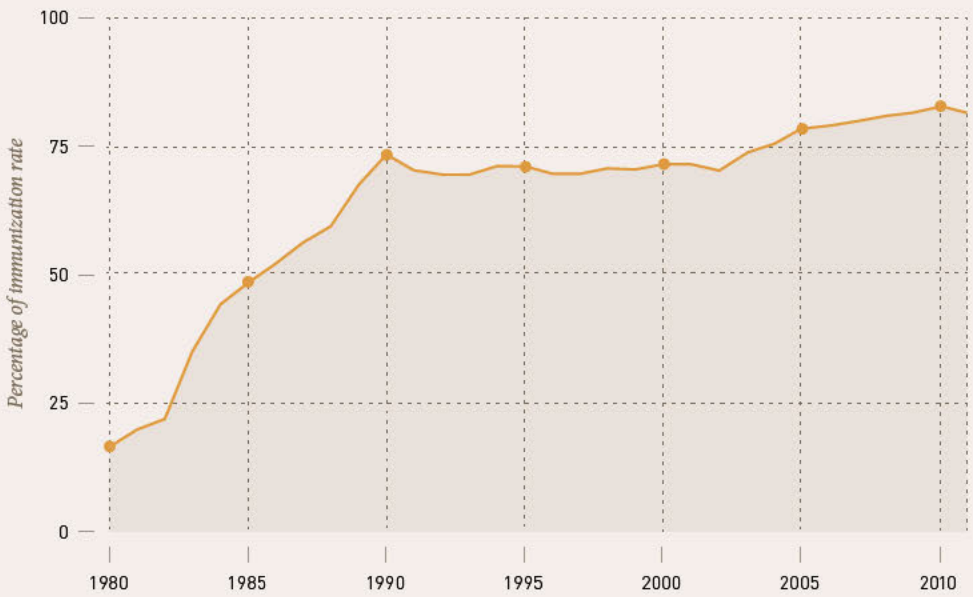
©UNICEF

As head of UNICEF in the 1980s, Jim Grant sparked a global effort to increase the number of children vaccinated against deadly diseases. Here, he is holding a boy separated from his parents during the 1994 genocide *(Nyamata, Rwanda, 1994).*

Grant set an ambitious goal of getting lifesaving vaccines out to 80 percent of children worldwide. This wasn't easy in poor countries at a time when the fax machine was the most advanced communication tool. But once Grant put a robust data-gathering system in place, he was able to drive change. He could see which countries were successful in increasing their vaccination coverage rates and used that data to help other countries to do the same. The countries that were falling behind were embarrassed, and they focused more resources and attention on the problem than they would have without the data. Thanks to Grant's efforts and thousands of vaccinators, the percentage of infants worldwide receiving necessary vaccines rose from 17 percent in 1980 to 75 percent in 1990, saving millions of lives every year.

Immunization Coverage Rising

Over the past three decades, growing numbers of children have received the diphtheria-tetanus-pertussis vaccine, which guards against three deadly diseases and is a strong indicator of overall vaccine coverage.



SOURCE: Global Health Observatory & World Health Organization

Released by Chairman Rand Paul

Sadly, some of the gains didn't last. Once the vaccination goal was reached, donor attention shifted elsewhere and coverage rates drifted down in many countries.

But the spirit of Grant was behind an agreement in 2000 by the United Nations to focus on eight goals aimed at improving the lives of the world's poorest people. These Millennium Development Goals (MDGs) were supported by 189 nations, and the UN set 2015 as the deadline for achieving them. This was the first time goals that called for specific percentage improvement were picked across a set of crucial areas—such as health, education, and basic income. Many people assumed the pact would be filed away and forgotten like so many UN and government pronouncements. However, since the goals were clear and concrete, they brought focus to the highest priorities. The UN agencies, donor countries, and developing countries looked at which programs would achieve the goals at the lowest cost. They saw that many programs were not delivering interventions in an effective way. They started demanding more rigorous evaluation to measure effectiveness. In some cases, the goals were used to persuade countries to pursue pro-poor policies.

As 2015 approaches, the world is taking a hard look at how it is doing on the goals. Although we won't achieve them all, we've made amazing progress, and the goals have become a report card for how the world is performing against major problems affecting the poor. The MDG target of reducing extreme poverty by half has been reached ahead of the deadline, as has the goal of halving the proportion of people who lack access to safe drinking water. Living conditions for more than 200 million slum dwellers have also improved—double the target. Some goals, however, were set at such an ambitious level that they will be missed. For instance, while we have reduced the number of mothers who die during childbirth by almost 50 percent—which is incredible—we will, however, fall short of the goal of a 75 percent reduction.

Millennium Development Goals

The Millennium Development Goals, agreed to by all countries and leading development institutions in 2000, have helped the world make substantial progress to improve the lives of its poorest people.

SOURCE: United Nations

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Margarida Matsinhe with medical staff and patients at a health center *(Maputo, Mozambique, 2013).*

Improving Lives by Delivering Vaccines to Children in Mozambique

2013 Gates Vaccine Innovation Award Recipient

Vaccines inspire me. They make it possible to do something amazing: protect a young child from a host of diseases for life with a relatively cheap and simple solution. The trick is making sure that all children get fully immunized. That is why I created the Gates Vaccine Innovation Award, to recognize those who are pioneering new strategies to increase vaccine coverage.

This year's recipient is Margarida Matsinhe, a field officer for VillageReach, a nonprofit working to improve health care in Mozambique. In the region where Margarida works, half the people live at least two hours from the nearest health post. She has been instrumental in overhauling the vaccine logistics system by removing numerous obstacles that prevent children from getting immunized.

As a result of VillageReach's work:

1. The monthly incidence of stockouts in rural health centers: down from 80 percent to 1 percent.
2. The amount of time the cold chain is working: up from 40 percent to 96 percent.
3. The percentage of children receiving basic vaccines: up from 69 percent to 95 percent.

The lessons from Margarida's work are being applied to improve health systems in Mozambique, throughout Africa, and even in parts of India. I hope others continue to draw on the work of Margarida Matsinhe to provide access to vaccines for all children.

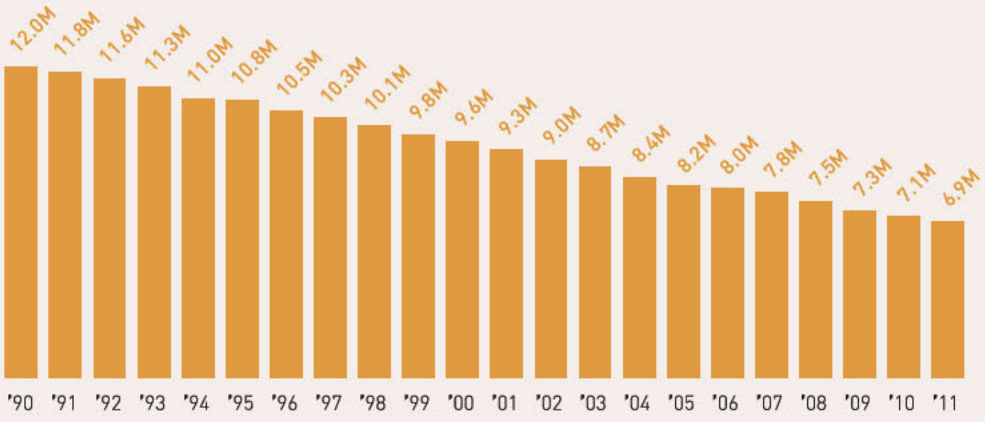
We're also not on track to meet one of the most critical goals—reducing the number of children who die under the age of five by two-thirds. We've made substantial progress. The number of children who die has declined from nearly 12 million in 1990 to 6.9 million in 2011. While that means 14,000 fewer children around the world are dying every day than in 1990, we won't reach the two-thirds target by 2015.

Released by Chairman Rand Paul

Still, many individual countries are on track to achieve this target. One of them is Ethiopia, which used the MDGs to drive an overhaul of its primary health care system that has led to a dramatic decline in childhood deaths.

Childhood Deaths Declining

A combination of vaccines, malaria prevention, and improved newborn health care has helped reduce child mortality globally since 1990—progress that brings the world closer to achieving one of the eight Millennium Development Goals.



SOURCE: The World Bank

Global Goals, Local Change

I remember the disturbing images from Ethiopia of the 1980s when more than one million people died in a famine that swept through the Horn of Africa. It was a tragedy brought to the world's attention by the 1985 Live Aid concert and part of a long period of war, political unrest, and instability for Ethiopians. Their country ranked near the bottom on nearly every key health indicator, including child mortality.

About a decade ago that picture started to change—thanks in large part to a government goal to bring primary health care to all Ethiopian citizens. When Ethiopia signed on to the MDGs in 2000, the country put hard numbers on its health ambitions. The concrete MDG goal of reducing child mortality by two-thirds created a clear target for success or failure. Ethiopia's commitment to the MDGs attracted unprecedented amounts of donor money to help improve its primary health care services.

Ethiopia found a successful model for achieving this goal in the Indian state of Kerala, which had lowered its child mortality rate and improved a host of other health indicators, in part through a vast network of community health care posts. This is one of the benefits of measurement—the ability it gives government leaders to make comparisons across countries, find who's doing well, and then learn from the best. With help from Kerala representatives, Ethiopia launched its own community health program in 2004.

©Corbis, Chris Rainier

Famine, war, and political unrest in Ethiopia displaced hundreds of thousands of people in the 1980s, sparking an outpouring of money and aid from around the world *(Ethiopia, 1984-1985)*.

Released by Chairman Rand Paul

Today, Ethiopia has more than 15,000 health posts delivering primary health care to the farthest reaches of this rural country of 85 million. They are staffed by 34,000 health workers, most of them young women from the communities they serve with one year of basic health training.

In 2009, Melinda traveled to Ethiopia and saw how these health reforms were transforming the country. Where health services were once nonexistent, rural areas had health clinics stocked with vaccines and medicine. Where once there was little local health expertise, Melinda learned how health workers delivered babies, administered vaccines, and supported family planning.

Over the past decade, Ethiopia's government has focused on the challenge of extending health services to more people in a rural country with high malnutrition and chronic food shortages. Here, a worker cross-breeds bean plants at an agricultural research station *(Melkassa, Ethiopia, 2012)*.

I got the chance to see that progress on my first trip to Ethiopia last March. Driving through the countryside, I felt the challenge Ethiopia faces in connecting its people to health care. Rural Ethiopia is composed of vast tracts of farm land—85 percent of the population survives on farm plots of less than two acres—connected by sometimes very rough roads. On the way to the Germana Gale Health Post, I saw piles of teff, a grain used to make Ethiopia's spongy flatbread, and I saw people walking everywhere. There were few other vehicles, even few bicycles.

Examining a bed net display at the Germana Gale Health Post *(Dalocha, Ethiopia, 2012)*.

The post, a faded green cement building, was bigger than I thought it would be, and you could tell workers took great care of the place. Inside, two health workers showed me a well-stocked cabinet of the tools for their job, including folic acid, Vitamin A supplements, and malaria drugs.

The workers provide most services at the post, though they also visit the homes of pregnant women and sick people. They ensure that each home has access to a bed net to protect the family from malaria, a pit toilet, first aid training, and other basic health and safety practices. One health worker told me she had done 41 deliveries so far that year, most of which were performed at people's homes.

Released by Chairman Rand Paul

All these interventions are quite basic, yet they've dramatically improved the lives of people in this country. Childhood death has decreased. So has the number of women dying in childbirth. More women have access to contraceptives to plan if and when they want to have children. Melinda has been leading the foundation to strengthen our commitment to family planning (see her feature below).

Sadi Seyni, a mother of five, learned about contraceptives after her second child was born, and then began spacing the births of her children *(Talle, Niger, 2012).*

Measurement, Contraceptives, and Investing in Every Family's Future

By Melinda Gates

In country after country over centuries, parents' ability to plan their families—to decide whether and when to have children—has been correlated to massive improvements in health, prosperity, and quality of life. But in much of sub-Saharan Africa and South Asia, hundreds of millions of women still don't have access to contraceptives.

Last year, I spent most of my time learning and telling others why access (to contraceptives, information about family planning, and health services) matters, why it's a challenge in many countries, and what we can do together to fix it. For me, the most important way I learn is traveling to developing countries and listening to the women who are struggling against great odds to give their children the chance at a better life. A few months ago, I was in Niger where I met a young mother named Sadi Seyni. She has five children now and didn't learn about contraceptives until after her second child. She still wants more children, but she walks 10 miles every three months to get a contraceptive injection because she knows it's healthier for her and her children to space her pregnancies.

Every time I come back from a trip, I am overflowing with stories about why women like Sadi are so inspiring to me. By meeting people on the ground, I also get to see first-hand how the theme of Bill's annual letter, the role of measurement in improving delivery, can help poor countries serve people's needs.

My big project in 2012 was the London Summit on Family Planning, which I led with Prime Minister David Cameron and the U.K.'s Department for International Development. The goal of the Summit was to help generate a global conversation about how to close the gap between the number of

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The leadership of British Prime Minister David Cameron at the London Summit on Family Planning last year was crucial in raising awareness of the need to provide access to contraceptives and family planning *(London, England, 2012)*.

women who want to use contraceptives and the number of women who are currently using them.

Dozens of partners from many different sectors—leaders of donor and developing countries, people working for nonprofits on the ground in poor countries, and pharmaceutical companies and other businesses—signed on to a concrete, measurable goal that is ambitious yet achievable: making contraceptives available to an additional 120 million women and girls in the world's poorest countries by 2020.

When we started the project, though, I have to admit I was frustrated by how loose the numbers were. Population-based surveys happen infrequently, and since contraceptives have to do with sensitive topics like sex and gender roles, solid service statistics can be hard to come by. I didn't feel I had an accurate picture of how many women currently have or lack access to contraceptives, or what could realistically be done to drive improvement.

It was hard enough to develop a baseline of how many women were using contraceptives in 2012. Figuring out how many women wanted to use them but didn't have access was even more difficult. I learned, for example, that some health clinics reported having contraceptives "in stock" as long as condoms were on the shelves. However, many women prefer contraceptive injections and implants, in part because they have trouble negotiating the use of condoms with their sex partners. As a result, nobody was counting the many women who had access only to contraceptives they didn't want and couldn't use.

For months, the Summit's sponsors studied numbers from many sources to model a rigorous baseline. They also combed through historical data from countries that have invested in family planning services to estimate what could be achieved in the future with adequate investment. That's how we landed on the goal of 120 million women.

Now individual countries are in the process of creating plans based on an analysis of the unique challenges they face. As a result, they zero in on the dominant constraints in their particular situation—whether that's funding, supply chain, procurement policies, demand, health education, or any other factor. These plans include clear milestones to help countries stay on track. This is the exciting part, where we can see how measurement leads to sweeping changes in the way health systems serve people.

Senegal is one impressive example. An important part of their plan is to improve their contraceptive supply chain, and they're basing changes on a model that was pilot tested last year. The results were astounding: Not only were stockouts eliminated in the pilot clinics, but the amount of contraceptives provided to women shot up (IUDs by 52 percent, contraceptive injections by 61 percent, oral contraceptive pills by 73 percent, and implants by 940 percent).

At the Dominique Health Center in Dakar, Senegal, family planning pilot programs have vastly improved access to contraceptives in the past year *(Dakar, Senegal, 2012)*.

The energy created at the London Summit is spreading to the countries where the work is happening. I am certain that we have the tools and the broad-based, long-term commitment to turn that energy into results for millions of women.

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Nuria Ali, a community health worker, teaching Sebsebila Nassir about caring for her newborn daughter, Amira *(Dalocha, Ethiopia, 2012).*

Just consider the story of one young mother from Dalocha. Sebsebila Nassir was born in 1990 on the dirt floor of her family's hut. With little access to lifesaving vaccines or basic health care, about 20 percent of all children in Ethiopia at that time did not survive to their fifth birthdays. Two of Sebsebila's six siblings died as infants.

But a few years ago, when a health post opened its doors in Dalocha, life started to change. For the first time, she had access to contraceptives, so she could have children when she and her husband were ready. When the time came last year and Sebsebila became pregnant, she received regular check-ups from her health worker. The worker also encouraged her to have the baby at a local health center, instead of at home where she gave birth to her first child.

On November 28, the day Sebsebila went into labor, she traveled by donkey cart to the health center. There, a midwife was at her bedside during her seven-hour labor. Shortly after her daughter was born, the baby received vaccines against polio and tuberculosis. The health worker also handed Sebsebila an immunization card with a schedule for her daughter to receive vaccinations to protect her from diphtheria, tetanus, whooping cough, hepatitis B, meningitis, pneumonia, and measles.

At the top of the immunization card was a blank for the name of her baby daughter. According to a long-held Ethiopian custom, parents wait to name their children because disease is rampant, health care is sparse, and children often die in the first weeks of life. Sebsebila didn't receive her own name until several weeks after her birth. And when her first daughter was born three years ago, she followed tradition and waited a month to bestow a name, afraid her child would not survive.

But a lot has changed in Ethiopia since the birth of Sebsebila's first child. This time, with more confidence in her new baby's chances of survival, Sebsebila didn't hesitate to name her. In the blank at the top of the vaccination card, she put "Amira"—"princess" in Arabic. Sebsebila's newfound optimism is not an isolated case. Ethiopia's effort on health has lowered child mortality over 60 percent since 1990, putting the country on track to achieve this important MDG target by 2015 and giving many parents the confidence to name children the day they are born.

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Stories of progress like this underscore the importance of setting goals and measuring progress toward them. A decade ago, there was no official record of a child's birth or death in rural Ethiopia. At the Germana Gale Health Post, I saw charts of immunizations, malaria cases, and other health data plastered to walls. Each indicator had an annual target and a quarterly target. All this information goes into a government information system to generate regular reports. Government officials meet every two months to go over the reports to see where things are working and to take action in places where they aren't.

At health posts in Ethiopia, meticulous record-keeping, including folders tracking the health of newborns, has helped the country reduce child mortality and increase vaccination coverage *(Dalocha, Ethiopia, 2012)*.

Yet while measurement is critical to making progress in global health, it's very hard to do well. You have to measure accurately, as well as create an environment where problems can be discussed openly so you can effectively evaluate what's working and what's not. Setting targets for immunization and other interventions can motivate government health workers, but it can also encourage over-reporting to avoid problems with supervisors.

Ethiopia's recent effort to monitor the progress of its immunization program is a good example of learning from data and—the hardest part—using data to improve delivery of the right solutions. A recent national survey of Ethiopia's vaccination coverage reported vastly different results from the government's own estimates. Ethiopia could have ignored this conflict and reported the most favorable data. Instead, it brought in independent experts to understand why the measurements were so different. They commissioned a detailed independent survey that pinpointed geographic pockets of very high coverage—and very low coverage. The government is now working to develop better plans for the poorer performing regions.

The progress Ethiopia is making on the MDGs is now capturing the attention of its neighbors. Much like Ethiopia, which learned from the Indian state of Kerala, other countries including Malawi, Rwanda, and Nigeria are now rolling out health extension programs after visiting Ethiopia to learn from its experience.

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Mapping the End of Polio

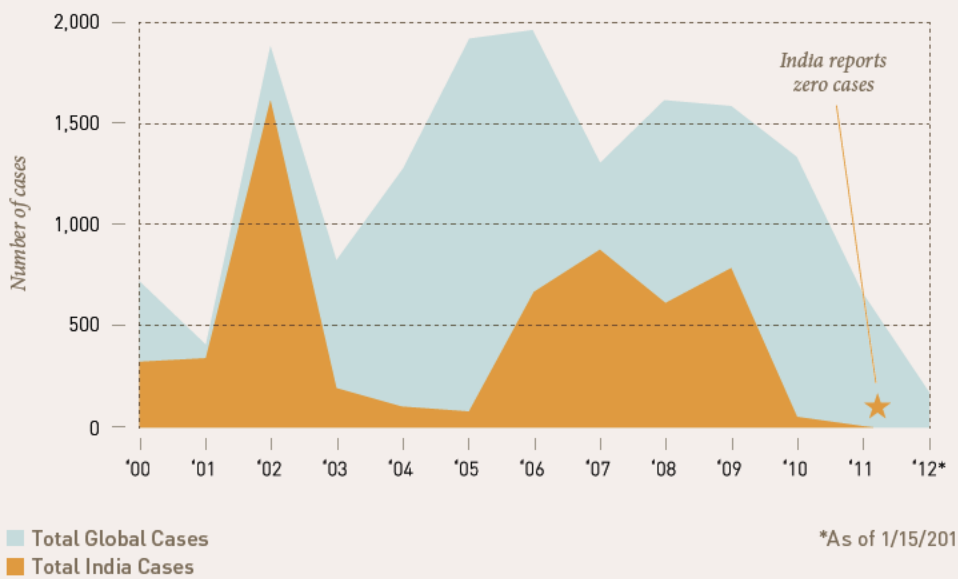
Polio eradication is a top priority for the foundation, a primary focus for me, and a powerful example of the importance of accurate measurement. Starting in 1988, organizations including the U.S. Centers for Disease Control and Prevention, Rotary International, UNICEF, and the World Health Organization, along with many countries of the world, agreed to the goal of eradicating polio. Targeting an explicit goal focused political will and opened purse strings to pay for large-scale immunization campaigns that led to very rapid progress. By 2000, the virus had been wiped out of the Americas, Europe, and most of Asia.

The number of global polio cases has been under 1,000 cases for the last two years, but getting rid of the very last few cases is the hardest part. For some diseases like smallpox—which was visible on the skin—you can track where the cases show up and focus on vaccinating children in those areas. However, polio takes weeks to confirm, and over 95 percent of people infected with the polio virus never develop symptoms—so they can spread the virus without anyone realizing it. That's why it's called "silent transmission." In order to stop the spread of infections, health workers have to vaccinate nearly all children under the age of five multiple times a year to achieve the necessary immunity thresholds in polio-affected countries. It's estimated that this threshold is 80 to 95 percent in the parts of Africa and Asia that still have polio. Achieving consistent coverage levels to reach these thresholds requires timely, accurate, local measurement so you can see where you are falling below the threshold, figure out what is wrong, and fix it.

Last January, after years of battling the disease, India celebrated a full year without a single case of polio. Most people expected India to be the most difficult place to eliminate polio because of its densely crowded urban areas, huge rural areas in the North, poor sanitation, large mobile

The Last Percent

The number of polio cases dropped by 99 percent from 1988 to 2000, from 350,000 cases to less than 1,000, yet it's challenging to eradicate the virus. India is a good sign: Once home to the majority of polio cases in the world, the country has been polio-free since 2011, thanks to innovative approaches to eradication.



SOURCE: World Health Organization & Global Polio Eradication Initiative

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populations, and over 27 million children born every year—more than in all of sub-Saharan Africa—who need to be vaccinated. Stopping the circulation of the virus everywhere in the country was the eradication initiative's biggest accomplishment in the past decade.

Vaccine team preparing to vaccinate children against polio at Patna Railway Station *(Bihar, India, 2011).*

There are now just three countries that have never eliminated polio: Nigeria, Pakistan, and Afghanistan. I visited Northern Nigeria four years ago to try to understand why eradication is so difficult there. I saw that routine public health services were failing: Fewer than half the kids were getting vaccines regularly, and there were no reliable figures for how many children lived in each area. Also, the normal process of quality monitoring done as part of each polio campaign was not working. Statistics about the quality of coverage varied greatly. We decided we needed to invest heavily in another layer of quality monitoring to understand what was going wrong. This involved picking random locations on the map and randomly checking children in those places to see if they had been vaccinated. The work required specially trained staff working independently of the people implementing the vaccination campaigns. That impartiality was crucial.

One huge problem the polio program found was that many small settlements in the region were missing from vaccinators' hand-drawn maps and lists documenting the location of villages and numbers of children. As a result, children weren't getting vaccinated. Often villages on the border between two maps weren't assigned to any team. To make matters worse, the estimated distance between villages was sometimes off by miles, making it impossible for some vaccinators to do the job they were assigned.

To fix this, the polio workers walked through all high-risk areas in the northern part of the country. Step by step, they explored these areas and spoke with people, adding 3,000 communities to the immunization campaigns. The program

Shabida Bibi holding her daughter, Rushkar Khatoon, who had the last known case of polio in India *(West Bengal, India, 2011).*

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is also using high-resolution satellite images to create even more detailed maps. And since the new maps show the true distances between settlements, managers can now allocate vaccinators efficiently by giving them a full day's work but no more.

Another problem was that some teams were simply not going to the places they were assigned to go. To help address this, the program is piloting the use of phones equipped with a Global Positioning System (GPS) application for the vaccinators to carry. Tracks are downloaded from the phone to a laptop at the end of the day so managers can see the route the vaccinators followed and compare it to the route they were assigned. This helps ensure that areas that were missed can be revisited so children are not left unprotected from polio.

The Nigerian government and its partners will need to keep working closely to adjust tools and approaches like these to measure coverage in Northern Nigeria more accurately. But progress is definitely being made, and more children are being reached.

In Nigeria, satellite imagery is being used to improve upon hand-drawn maps, helping health workers reach previously overlooked villages with vaccines. The yellow dots indicate areas visited by vaccinators.

The insecurity in Pakistan and Afghanistan represents another challenge for the campaign. In December nine polio vaccinators in Pakistan were murdered. It is unimaginable to me why health workers, whose only goal was to improve children's health and end polio, were targeted. In my eyes the victims are heroes, and the best way to respect their memory is to finish the job they gave their lives for. The polio program will continue, with additional efforts to improve the safety of workers and to increase the support of community leaders. The global polio community is now finalizing a detailed plan that I believe should allow us to finish the job of polio eradication within the next six years.

The measurement systems put in place by the eradication initiative will be invaluable for other health care activities, including routine vaccination of infants, which means the legacy of polio eradication will live beyond stopping a disease that once paralyzed over 400,000 children every year.

©Corbis, Rajput Yasir

A health worker gives polio drops to a child in Pakistan *(Hyderabad, Pakistan, 2012).*

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Feedback for Teacher Growth

In October, Melinda and I found ourselves near Vail, Colorado, sitting among two dozen twelfth graders learning how to write narrative nonfiction pieces. Looking around, I saw about a third of the class was Hispanic. Approximately half of Eagle County School District's 6,300 students are Hispanic, and the district has among the highest rates of English language learners in Colorado.

We were there to watch the person at the front of the room, Mary Ann Stavney, a veteran of Colorado's education system who taught high school, served on the county school board, and instructed at a local college before taking on her current role as a language arts and speech teacher at Eagle Valley High School.

In class that day, Mary Ann taught a 40-minute lesson on how students could use evidence to bolster claims in their essays, including a lively mini-lesson on how to use starters like "because," "as a result," and "although." She engaged her students, walking among them, asking good questions, and eliciting great participation.

As a Master Teacher in Eagle Valley High School, Mary Ann Stavney splits her time between teaching students and evaluating teachers *(Gypsum, CO, 2012)*.

Both Melinda and I could see why Mary Ann is a Master Teacher, a distinction given to the school's best teachers and an important component of the teacher-evaluation system in Eagle County. In that role, she is trained to evaluate and provide feedback to other teachers. Her work is part of a broader approach to measuring teacher performance that includes test data showing student learning, evaluations from Master Teachers and the school principal, and students' surveys about their teachers. The district is an early innovator in using a mix of measures to help teachers improve.

I was amazed to learn a few years ago that over 90 percent of teachers get zero feedback on how to improve. A lot of the debate in education today really amounts to a circular discussion of how to implement tools to measure teacher effectiveness and whether such measurement is even possible. We know that if all teachers were anywhere near as good as the best, our education system would be fantastic.

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Starting in 2009, the foundation funded a project called Measures of Effective Teaching, or MET, that worked with 3,000 classroom teachers to better understand how to build an evaluation and feedback system to help teachers improve. In January 2013, we announced the final results of the MET project. The report concluded that there were observable, repeatable, and verifiable ways of measuring teacher effectiveness. MET highlighted several measures that schools should use to assess teacher performance, including student surveys and reports from trained evaluators who observe teachers at work.

Discussing class work with students at South High School *(Denver, CO, 2012).*

Colorado is a pioneer in introducing these principles, and Eagle County is helping lead the way. About 10 years ago the district threw out its traditional seniority-based evaluation system and moved to a performance-based one. It didn't go over well. Teachers spoke out against what they thought was a flawed plan with too much emphasis on student tests and too little support from the district—among other concerns. By 2008 the majority of the district's central office had changed, and the school board had hired a new superintendent, Dr. Sandra Smyser, whom we met on our trip.

Fourth-grade teacher Courtney Artis, whose class is part of the MET project, talking with a student at Cornelius Elementary School *(Cornelius, NC, 2012).*

Now teachers feel the system helps them improve. Over the course of a school year, each of Eagle County's 470 teachers is evaluated three times and is observed in class at least nine times. The process starts with Mentor Teachers, who spend 30 percent of their time observing their colleagues in their classrooms and coaching them in areas that need improvement. Then a Master Teacher and the principal observe classes, some with advance notice, others unannounced. Master Teachers, who dedicate 70 percent of their time to this work, hold conferences with the teacher before each planned evaluation and give feedback afterwards.

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The Eagle County system is impressive because it focuses on helping each teacher grow. The evaluations are used to give a teacher not only a score but also specific feedback on areas to improve and ways to build on their strengths. In addition to one-on-one coaching, Mentors and Masters lead weekly group meetings in which teachers discuss student work and collaborate to spread their skills. Teachers are eligible for annual salary increases and bonuses based on the classroom observations and student achievement. Sandra, the superintendent, said the system has helped retain teachers.

Melinda and I meeting Sandra Smyser, superintendent of Eagle County Schools, and Greg Doan, principal at Eagle Valley High School *(Gypsum, CO, 2012)*.

Colorado state law mandates that by the 2013–2014 school year, ratings for all teachers should be based half on the change in students' test results and half on other measures. Sandra and her colleagues said they've struggled with how to incorporate student test scores into the evaluation process. One reason: It's harder to test student improvement in some areas—music and art—than in others—such as math and science.

The program also faces challenges from tightening budgets. Mentor and Master Teachers are paid extra, and since a chunk of their time is dedicated to coaching and evaluating, the district needed to bring on other teachers to fill in for them. I found it amazing, though, that even with budget cuts in each of the last two years, Eagle County was able to keep its evaluation and support system intact. The system is likely one reason why student test scores have improved in Eagle County over the past five years.

I think the most critical change we can make in U.S. K–12 education is to create teacher feedback systems like the one in Eagle County that are properly funded, high quality, and trusted by teachers. These measurement systems need to provide teachers with the tools to help support their professional development. The lessons from these efforts will help us improve teacher education programs. The countries that have better education systems than the United States provide more teacher feedback than we do today, but I think it is possible to do even better than any country has done so far.

The Way Forward

The lives of the poorest have improved more rapidly in the last 15 years than ever before, yet I am optimistic that we will do even better in the next 15 years. After all, human knowledge is increasing. We can see this concretely in the invention of new medicines like HIV drugs and the way their prices have come down, and in the creation of new seeds that allow poor farmers to be more productive. Once these tools are invented, they are never un-invented—they just improve.

Skeptics point out that we have a hard time delivering new tools to the people who need them. This is where the innovation of using measurement is making a big difference. The process I have described—setting clear goals, picking the right approach, and then measuring results to get feedback and refine the approach continually—helps us to deliver tools and services to everybody who will benefit. This innovation to reduce the delivery bottleneck is critical. Following the path of the steam engine long ago, progress isn't "doomed to be rare and erratic." We can, in fact, make it commonplace.

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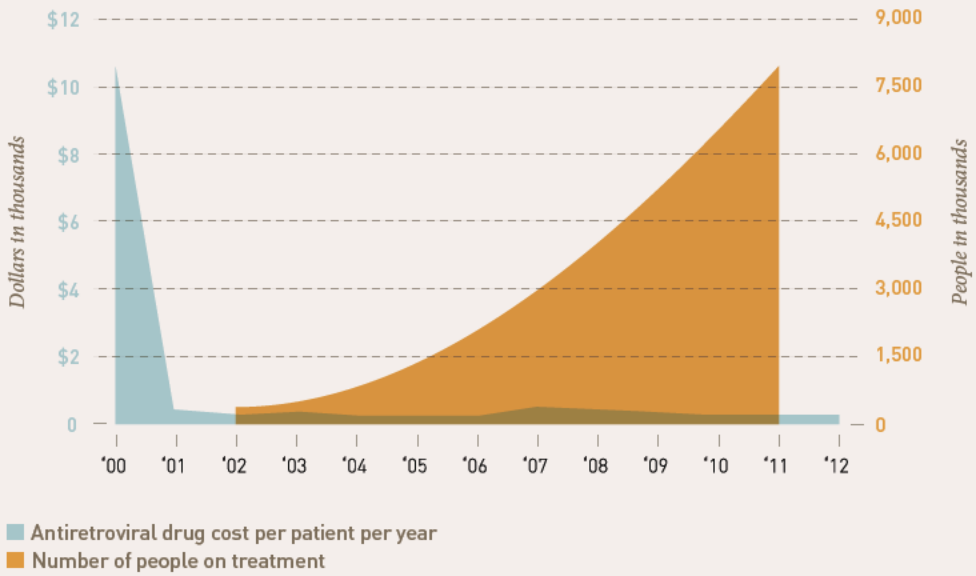
HIV Drug Prices Down, Treatment Up

Since 2000, HIV drug prices have fallen by more than 99 percent, while the number of people on treatment has risen dramatically to approximately eight million.

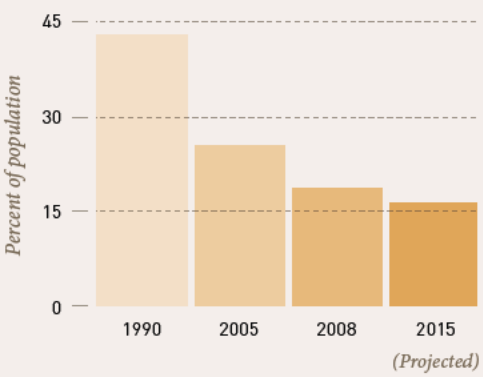


SOURCE: UNAIDS, World Health Organization & Medicins Sans Frontières

Though I am an optimist, I am not blind to the problems we face. There are challenges we must overcome to speed up progress in the next 15 years. Two that worry me the most are the possibility that we won't be able to raise the funds needed to pay for health and development projects, and that we won't align around clear goals to help the poorest.

Halving Extreme Poverty

The World Bank estimates that the percentage of people living on less than $1.25 per day has fallen by half since 1990, marking the achievement of the Millennium Development Goal target to reduce poverty before the 2015 deadline.



SOURCE: The World Bank

The good news on resources is that many developing countries have growing economies that allow them to devote more resources to helping their poorest people. India, for example, is less dependent on aid and will eventually not need it.

Some countries, like the United Kingdom, Norway, Sweden, Korea, and Australia, are increasing their aid; others, even traditionally generous givers like Japan and the Netherlands, have reduced it. The direction in many countries, including the United States, France, Germany, and Canada, is unclear.

Still, aid is critical. It helps meet the basic needs of people in the poorest countries. It funds innovation—in the creation of new tools and services and in their delivery. Unfortunately, aid generosity is threatened by big deficits in almost all of

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the rich countries. Unless voters hear about the positive impact their generosity is having, they'll inevitably focus on issues closer to home. A single story, true or not, about a small amount of aid being misused can often cloud the entire field. Imagine how you would feel about investing if every article you read was only about stocks that did poorly and not about the big successes.

Meeting Florence Daka, a woman living with HIV, and her son, Stephen, during a visit to the Coptic Mission Hospital *(Lusaka, Zambia, 2012).*

Historically, aid was discussed largely in terms of the total amount of money invested. But now that we're more precisely measuring indicators like child mortality, people are able to see the impact aid has in stark terms—that it's the difference between putting people on HIV treatment or letting them die. When framed this way, aid has a better chance of becoming a priority for people.

My second concern about the next 15 years is whether the world will align around a clear set of goals. The United Nations is starting to map out new goals for the years following the 2015 expiration of the current MDGs. As with the first round, the next set of goals could help align groups doing the work, remind voters what their generosity supports, and allow us to see where we are making progress in delivering solutions to the poor.

The success of the MDGs means that there is a lot of interest in expanding them to include a broader set of issues. But many of the potential new goals don't have unanimous support, and adding many new goals, or goals that are not easily measurable, may sap momentum.

The MDGs were coherent because they focused on helping the poorest people in the world. The groups that needed to work together on the MDGs were easy to identify, and they could be held accountable for cooperation and progress. When the UN reaches agreement on other important goals like mitigating climate change, it should consider whether a different set of actors and a separate process might be best for those efforts.

I hope everyone who reads this is excited to see how much progress the world has made in helping the poorest in the last 15 years. It is the kind of good-news story that happens one life at a time and so it often doesn't get the same visibility as a big setback like the outbreak of a new epidemic. From time to time we should step back and celebrate the achievements that come with having the right goals—combined with political will, generous aid, and innovation in tools and their delivery. It has certainly deepened my commitment to this work.

Bill Gates

Bill Gates
Co-chair, Bill & Melinda Gates Foundation
January 2013

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From: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Somerman, Martha (NIH/NIDCR) [E]" [redacted]@nih.gov>, "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Guttmacher, Alan (NIH/NICHD) [E]" [redacted]@mail.nih.gov>, "Germino, Gregory (NIH/NIDDK) [E]" [redacted]@niddk.nih.gov>, "Pettigrew, Roderic (NIH/NIBIB) [E]" [redacted]@mail.nih.gov>, "Austin, Christopher (NIH/NCATS) [E]" [redacted]@mail.nih.gov>, "Varmus, Harold (NIH/NCI) [E]" [redacted]@nih.gov>, "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Insel, Thomas (NIH/NIMH) [E]" [redacted]@mail.nih.gov>, "Green, Eric (NIH/NHGRI) [E]" [redacted]@nhgri.nih.gov>, "Barry, Clifton (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Zoon, Kathryn (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

Cc: "Cantrel, Katherine (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Stover, Kathleen (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Qiao, Mo (NIH/NIDCR) [C]" [redacted]@nih.gov>, "Brown, Crystal (NIH/NICHD) [C]" [redacted]@nih.gov>, "Wilkerson, Anita D. (NIH/NIDDK) [E]" [redacted]@niddk.nih.gov>, "Poole, Charlene (NIH/NIDDK) [E]" [redacted]@EXTRA.NIDDK.NIH.GOV>, "Brawley, David (NIH/NIDDK) [E]" [redacted]@nih.gov>, "Izzard, Tom (NIH/NIBIB) [C]" [redacted]@mail.nih.gov>, "Finnegan, Sean (NIH/NCATS) [C]" [redacted]@nih.gov>, "Wiszneauckas, Joy (NIH/NCI) [E]" [redacted]@od.nci.nih.gov>, "Togashi, Mieko (NIH/NCI) [E]" [redacted]@exchange.nih.gov>, "Wells, Connie (NIH/NHLBI) [E]" [redacted]@nhlbi.nih.gov>, "Earle, Melody (NIH/NHLBI) [E]" [redacted]@nhlbi.nih.gov>, "Sante, Annette (NIH/NHGRI) [C]" [redacted]@mail.nih.gov>, "Holt, Tracy (NIH/NIMH) [E]" [redacted]@mail.nih.gov>, "Guzman, Marlene (NIH/NIMH) [E]" [redacted]@mail.nih.gov>, "Rodela, Gloria (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Suhana, Tina (NIH/VRC) [E]" [redacted]@mail.nih.gov>, "Lebron, Janette (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>, "McManus, Ayanna (NIH/OD) [E]" [redacted]@od.nih.gov>, "Burklow, John (NIH/OD) [E]" [redacted]@OD.NIH.GOV>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>

Subject: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December

Date: Fri, 29 Nov 2013 18:19:11 -0500

Importance: Normal

Inline-Images: image001.png

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Best wishes,

Gretchen

Released by Chairman Rand Paul

From: Wood, Gretchen (NIH/OD) [E]
Sent: Friday, November 29, 2013 9:57 AM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Mascola, John (NIH/VRC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]; Barry, Clifton (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]
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Importance: High

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F: [redacted]
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Celebration of Science at NIH: *watch how medical research saves lives and improves health*

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To: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Cantrel, Katherine (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Fri, 29 Nov 2013 19:37:45 -0500
Importance: Normal
Inline-Images: image001.png

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(NIH/VRC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]; Barry, Clifton (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]
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Subject: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Importance: High

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Subject: Re: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Sat, 30 Nov 2013 07:27:24 -0500
Importance: Normal
Inline-Images: image001.png

Hi Dr. Fauci,

Francis directed the agenda back to Chris to see what Bill prefers. Based upon his response we will rework the agenda for the BSL3 tour and ICD round table. It is a shame we had to cut out the VRC. Rob and I will send around a revised agenda once the ICD respond. Thanks again for your flexibility.

Gretchen

Sent from my iPhone

On Nov 29, 2013, at 19:37, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov> wrote:

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Celebration of Science at NIH: *watch how medical research saves lives and improves health*

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Jin, Daozhong (NIH/OD) [C]" [redacted]@nih.gov>
Subject: Fw: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Sat, 30 Nov 2013 11:00:32 -0500
Importance: Normal
Inline-Images: image001.png

Dear Dr Tabak

You already may have seen this, but just in case, I am forwarding on. Gretchen is awaiting responses

In readjusting the morning agenda, the Gates Foundation asks that we keep the media event in place and would prefer the planned visit to Bldg 33 over VRC

From: Wood, Gretchen (NIH/OD) [E]
Sent: Friday, November 29, 2013 06:19 PM Eastern Standard Time
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Mascola, John (NIH/VRC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]; Barry, Clifton (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]
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Released by Chairman Rand Paul

(NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]; Barry, Clifton (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]
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Subject: FW: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Sat, 30 Nov 2013 11:22:23 -0500
Importance: Normal
Inline-Images: image001.png

Hi Larry,

Sorry to now just be looping you in. Gates is going to the WH event beginning at 1:00 PM on Monday with ASF (and now FC) so the agenda has been truncated. I will be sending shortly a marked up agenda for decision regarding the ICD roundtable discussion. Leo has responded as of this morning and knows that there will be some changes on Monday and he is waiting to hear from us. Thanks.

From: Wood, Gretchen (NIH/OD) [E]
Sent: Friday, November 29, 2013 6:19 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Mascola, John (NIH/VRC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]; Barry, Clifton (NIH/NIAID) [E]; Zoon, Kathryn (NIH/NIAID) [E]
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Subject: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December

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[E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Holt, Tracy (NIH/NIMH) [E]; Guzman, Marlene (NIH/NIMH) [E]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Importance: High

Good morning,

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Best wishes,

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Gretchen S. Wood
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Follow @NIHDirector on Twitter
Celebration of Science at NIH: *watch how medical research saves lives and improves health*

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Sat, 30 Nov 2013 12:02:48 -0500
Importance: Normal
Inline-Images: image001.png

John:
See e-mails below. Looks like the Gates visit to the VRC for Monday AM is off the table. Sorry.
Best regards,
Tony

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Sent: Saturday, November 30, 2013 7:27 AM
To: Fauci, Anthony (NIH/NIAID) [E]
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Subject: Re: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December

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Sent from my iPhone

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Annette (NIH/NHGRI) [C]; Holt, Tracy (NIH/NIMH) [E]; Guzman, Marlene (NIH/NIMH) [E]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]
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Importance: High

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Celebration of Science at NIH: *watch how medical research saves lives and improves health*

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From: "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: TIME SENSITIVE/YOUR RESPONSE REQUESTED: Updated agenda and supplemental materials for visit of Bill Gates this Monday, 2 December
Date: Sat, 30 Nov 2013 12:28:37 -0500
Importance: Normal

Hi Tony,

Got it, thanks. We'll be around in case anything changes. Rick and I are going to BMBF annual CAVD meeting later on Monday.

John

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Saturday, November 30, 2013 12:03 PM
To: Mascola, John (NIH/VRC) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]
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Released by Chairman Rand Paul

Annual Letter. If you have any questions or concerns, please do not hesitate to contact me and Rob Eiss. Many thanks and enjoy your weekend.

Best wishes,

Gretchen

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Subject: Agenda for Bill Gates visit to NIH on December 2

Date: Sun, 24 Nov 2013 12:38:32 -0500

Importance: Normal

Attachments: Mundel_&_Nikolic_BIOs.doc; NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc; Program_for_Visit_of_Bill_Gates_December_2_(3).docx; Wilson_Young_bios.docx

---

Dear Colleagues,

I am delighted you are able to join the roundtable discussion and working lunch with Bill Gates on Monday, December 2, from 12:15 AM-1:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with Bill and other staff from the Global Health Program at the BMGF.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than a series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format

Released by Chairman Rand Paul

should work well and allow us to discuss the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD); Trevor Mundel, President of the Global Health Program at the BMGF; Boris Nikolic, Scientific Advisor; and Kathy Young**,** Senior Project Manager for Strategic Planning and Engagement. Their bios are attached.

Please feel free to contact Rob Eiss at FIC [redacted] with any questions you or your staff may have surrounding the visit.

I'm delighted that Bill was able to reschedule so soon after the shutdown, and will remain on campus a good portion of the day to visit labs and hold discussions with senior leadership, in addition to the presenting the annual David Barmes Global Health lecture.

Best regards, Francis

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: NIAID OD AM [redacted]@niaid.nih.gov>
Subject: FW: Agenda for Bill Gates visit to NIH on December 2
Date: Sun, 24 Nov 2013 12:54:22 -0500
Importance: Normal
Attachments: Mundel_&_Nikolic_BIOs.doc;
NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc;
Program_for_Visit_of_Bill_Gates_December_2_(3).docx; Wilson_Young_bios.docx

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Let us discuss the second attachment listing the collaborations and/or interactions between the BMGF and NIAID.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:39 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
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Best regards, Francis

Dr. Trevor Mundel
BIO

Dr. Trevor Mundel, president of the Global Health Program, leads the foundation's efforts in research and development of health solutions including vaccines, drugs, and diagnostics, focusing on health problems that have a major impact in developing countries but get too little attention and funding. He oversees the Global Health Program's work which harnesses innovations in science and technology, to fight diseases such as HIV/AIDS, tuberculosis, and malaria. Mundel joined the foundation in 2011.

Prior to joining the Gates Foundation, Dr. Mundel served as Head of Global Development Functions for Novartis Pharmaceuticals, where he was is responsible for the development of drug candidates provided by the Novartis Institutes for Biomedical Research (NIBR) or licensing partners. Prior to joining Novartis, Dr. Mundel worked for Warner Lambert and Pfizer in senior clinical development roles including Director in Central Nervous System Clinical Development and Head of Experimental Medicine, respectively.

In both instances, Dr. Mundel was recruited to restructure their research and development programs and streamline the process of translating basic research into new drugs. Dr. Mundel is a proponent of modeling and simulation, using mathematical models to optimize and expedite everything from biochemical drug mechanisms to decision-making and profits. Dr. Mundel's appointment may reflect the Gates Foundation's desire to apply that approach to their health and drug development projects.

Dr. Mundel holds an M.D. from the University of the Witwatersrand, Johannesburg, South Africa. He also studied Mathematics, Logic and Philosophy at Balliol College of the University Oxford as a Rhodes Scholar and then completed graduate studies in Mathematics at the University of Chicago, where he focused on Dynamical Systems and Neural Networks. Dr. Mundel completed training in Neurology at the University of Chicago Hospitals.

Dr. Boris Nikolic
BIO

Dr. Boris Nikolic is a Scientific Advisor to Bill Gates at Bill Gates Catalyst 3 (bgC3) and at the Bill and Melinda Gates Foundation (BMGF). He received his MD from Zagreb Medical School and his clinical training from the University's Medical Center, University of Zagreb, Croatia. In 1994, Dr. Nikolic joined the Harvard Graduate Program in Immunology (postdoctoral fellowship in transplantation immunology).

Subsequently, Dr. Nikolic continued to serve in roles of increasing authority including postdoctoral fellowship, Instructor in Surgery and Medicine to Assistant Professor in Medicine at Harvard Medical School. Between 2002 and 2007, Founder and Director, Advanced Immunology Laboratory for Tolerance Induction Stem Cell Transplantation, Renal Unit, Massachusetts General Hospital-Harvard Medical School. In 2007, Dr. Nikolic joined the BMGF and in 2010 he joined bgC3.

Dr. Nikolic is the author of over 70 articles and patent applications and co-founder of three biotechnology companies. Research interests: immunogenetics, immunological tolerance induction for transplant, auto immunity and stem cell research.

Released by Chairman Rand Paul

PROGRAM OF ACTIVITY
NIH VISIT OF BILL GATES
DECEMBER 2, 2013

9:00 AM Arrival and Greetings (The Dale and Betty Bumpers Vaccine Research Center (VRC)

9:05 AM – 9:45 AM Scientific Tour of the VRC

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. John Mascola, Director, VRC

10:00 AM – 10:45 AM Media Roundtable (Library Conference Room, Clinical Center)

- Associated Press
- New York Times
- Wall Street Journal
- Washington Post

11:00 AM – 12:00 PM David E. Barmes Global Health Lecture (Masur Auditorium, Clinical Center)

- 11:00 AM – 11:05 AM Introduction by Dr. Francis Collins
- 11:05 AM – 11:40 AM "Why the Future Needs Biomedical Innovation"
- 11:40 AM – 12:00 PM Q's and A's

12:15 PM – 1:30 PM Roundtable Discussion with NIH Senior Leadership and Working Lunch
Select priorities in global health: state of the science, questions to resolve
(Medical Board Room, Clinical Center)

- **Opening remarks***: Dr. Francis Collins and Mr. Bill Gates*

- **HIV, malaria, TB and other infectious disease priorities**
  Lead discussant: Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
  Dr. Roger Glass, Director, Fogarty International Center

- **Understanding the molecular basis of growth and nutrition**
  Lead discussant: Dr. Alan Guttmacher, Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development
  Dr. Gregory Germino, Deputy Director, National Institute of Diabetes and Digestive and Kidney Diseases

- **Point-of-care diagnostics and therapeutics for neglected diseases**
  Lead discussant: Dr. Roderic Pettigrew, Director, National Institute of Biomedical Imaging and Bioengineering
  Dr. Martha Somerman. Director, National Institute of Dental and Craniofacial Research
  Dr. Christopher Austin, Director, National Center for Advancing Translational Sciences

- **Integrating NCD research into global health**
  Lead Discussant: Dr. Harold Varmus, Director, National Cancer Institute
  Dr. Gary Gibbons, Director, National Heart Lung and Blood Institute
  Dr. Thomas Insel, Director, National Institute of Mental Health

- **New partnerships in discovery science and capacity building: H3Africa and the Medical Education Partnership Initiative**
  Lead Discussant: Dr. Eric Green, Director, National Human Genome Research Institute
  Dr. Francis Collins, Dr. Roger Glass

1:45 PM – 2:20 PM Innovations in TB Drug Development (The C.W. "Bill" Young Center)

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases
Dr. Clif Barry, Chief, Tuberculosis Research Section, National Institute of Allergy and Infectious Diseases

2:20 PM – 2:30 PM Wrap up discussion (The C.W. "Bill" Young Center)

Dr. Collins and Mr. Gates

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Released by Chairman Rand Paul

Chris Wilson

Bill and Melinda Gates Foundation

Dr. Chris Wilson, director of the Global Health Discovery & Translational Sciences program, leads a team that targets fundamental scientific and technological advances in global health that could lead to new ways to prevent, treat, and diagnose disease. Wilson joined the foundation in 2009 as Deputy Director, Vaccine Discovery and Human Biology, Global Health Discovery.

Wilson is a pediatrician and immunologist. He joined the faculty at the University of Washington in 1979 in the Infectious Diseases Division of the Department of Pediatrics and later served as head of the Division of Infectious Diseases, Immunology and Rheumatology. In 1989, he became one of the founding faculty members in the new Department of Immunology, and served as Chairman of the Department of Immunology and head of the graduate program in immunology from 1999-2009.

He has also served on a number of national advisory panels, including the Institute of Medicine Vaccine Safety Review Committee (2001-2004) and the National Advisory Council on Child Health and Human Development, the NIH Advisory Committee to the Director, and he co-chaired the NIAID US Immunodeficiency Network Pilot Grant Review Committee. He is an elected fellow of the American Association for the Advancement of Science.

Wilson received a bachelor's degree from the University of California, Irvine and a medical degree from UCLA. He trained in pediatrics at Boston Children's Hospital /Harvard Medical School, served in the US Public Health Service, and then was a post-doctoral fellow in infectious diseases while performing immunology research at Stanford University.

Kathleen Young

Bill and Melinda Gates Foundation

Prior to joining the Gates Foundation in 1997, Kathy worked for the Paul Allen Group (the personal investment vehicle for Paul G. Allen, co-founder of Microsoft) for three years. Before relocating to Seattle in 1994, Kathy spent 10 years in the Washington D.C. area working for the Fairfax County Chamber of Commerce and a residential building firm based in Bethesda, Maryland. Kathy, a graduate of Illinois's Parkland College, now resides in Kirkland, Washington.

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Fw: Agenda for Bill Gates visit to NIH on December 2
Date: Sun, 24 Nov 2013 13:22:56 -0500
Importance: Normal
Attachments: Mundel_&_Nikolic_BIOs.doc;
NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc;
Program_for_Visit_of_Bill_Gates_December_2_(3).docx; Wilson_Young_bios.docx

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Sent: Sunday, November 24, 2013 12:38 PM Eastern Standard Time
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
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From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 09:57:33 -0500
Importance: Normal

Thanks much, Rob. G

From: Eiss, Robert (NIH/FIC) [E]
Sent: Sunday, November 24, 2013 1:23 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: Fw: Agenda for Bill Gates visit to NIH on December 2

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From: "Harvey, Hillery (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Hudgings, Carole (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Marston, Hilary (NIH/NIAID) [C]" [redacted]@nih.gov>, "Stover, Kathy (NIH/NIAID) [E]" [redacted]@nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Touchette, Nancy (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Doepel, Laurie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 14:51:26 -0500
Importance: Normal
Attachments: NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc; NIAID-BMGF_Partnerships_2013.NAT_edt.docx

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Hi Gray,

During our staff meeting this morning it was noted that several major NIAID-Gates partnerships were not included in the document Dr. Collins sent around yesterday (attachment #1). Notably, P5, malaria activities, and the Decade of Vaccines.

Could you work with your contacts at FIC or Bldg. 1 to ensure that these are incorporated? In case helpful, I attach an internal NIAID document with these three activities highlighted on pages 3, 4, and 7 (attachment #2).

Also, it might make sense to include the word "Selected" in the title of Dr. Collins' document since the list is not comprehensive, at least from the NIAID perspective.

Many many thanks and Happy Thanksgiving to you and yours.
Hillery

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, November 24, 2013 12:54 PM
To: NIAID OD AM
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

Let us discuss the second attachment listing the collaborations and/or interactions between the BMGF and NIAID.

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NIAID – BILL & MELINDA GATES FOUNDATION PARTNERSHIPS
GLOBAL HEALTH
2013

HIGHLIGHTS OF CURRENT ACTIVITIES

- **Tuberculosis**

  - The TB Biomarker Development Consortium is a collaboration between the NIAID AIDS Clinical Trials Group (ACTG), CDC TB Trials Consortium (CDC/TBTC) and the Global Alliance for Tuberculosis Drug Development (GATB) to facilitate the discovery and qualification of biomarkers for TB treatment outcome using a common sample collection and processing protocol to biobank biologic samples linked to clinical and microbiological data from TB patients during treatment and follow-up. As of mid-2013, biological samples have been collected from 1/3 of the 1000 targeted TB treated patients. Biosamples are anticipated to be available to qualified researchers by 2014/2015.

  - ACTG is collaborating with the GATB to conduct three clinical studies:
    - **A5306:** a Phase I study to evaluate the safety and pharmacokinetic interaction of PA-824, an investigational Nitroimidazole for the treatment of tuberculosis, together with efavirenz, ritonavir-boosted lopinavir, or rifampin. This study is closed to follow up.
    - **A5304/REMox:** a randomized placebo–controlled double blind trial comparing two treatment shortening regimens with the standard regimen (two months ethambutol, isoniazid, rifampicin and pyrazinamide) followed by four months isoniazid and rifampicin. This study is closed to follow up.
    - **A5289:** a randomized controlled Phase II study in intensive phase treatment of drug-sensitive TB in HIV infected and uninfected individuals with pulmonary TB. This study is in development.

  - DMID is collaborating with GATB to conduct a phase 1 study to assess the effects ofsupratherapeutic doses of clofazimine on the QTc interval in healthy subjects. DMID has also collaborated with GATB to conduct a phase 1 study to assess the effects of PA-824 and PA-824 plus moxifloxacin on QTc interval in healthy subjects and to conduct a phase 1 study to assess the interaction of rifabutin or rifampin and bedaquiline in healthy subjects

  - NIAID is involved in the Critical Paths to TB Drug Regimens (CPTR) initiative (http://cptrinitiative.org/), which is funded by the BMGF. This partnership brings together the world's leading pharmaceutical and other drug developers, global regulatory agencies, and civil society organizations to support advances in regulatory science, the development of infrastructure, and other progress needed to facilitate the development and availability of new TB drug treatments. NIAID staff serve as co-chairs on CPTR working groups to assure coordination with NIAID activities and are represented on the CPTR Advisory Panel (Dr. Fauci or delegate).

  - The Regional Prospective Observational Research for Tuberculosis (RePORT) project,established under the Indo-U.S. Vaccine Action Program (VAP) Initiative on Tuberculosis Research,was awarded in 2013. The aim of this initiative involving joint teams of Indian and U.S. scientists is to build and enhance biomedical and clinical research capacity in India by establishing long-term

longitudinal cohorts of TB patients and their contacts (or other high TB risk patients) for studies using state-of-the art research tools. RePORT is funded jointly by the Government of India's (GOI) Department of Biotechnology (DBT), the Indian Council of Medical Research (ICMR), the Bill and Melinda Gates Foundation (BMGF), and CRDF Global [utilizing funds provided NIAID and NIH's Office of AIDS Research (OAR)]. After peer review by a panel of TB and HIV experts from the United Statesand India, five teams out of 22 applications were selected for funding. These are: (1) National Institute of Research in Tuberculosis / B.J. Medical College - Johns Hopkins University; (2) Jawaharlal Institute of Postgraduate Medical Education and Research - Boston University / Boston Medical Center; (3) Prof. M. Viswanathan Diabetes Research Centre - University of Massachusetts Medical School; (4) Christian Medical College - University of Washington; and (5) LEPRA - Blue Peter Public Health & Research Centre - CPIDC, Biomedical Research, The University of Texas Health Center Health Science Center at Tyler. In addition, the BMGF has recently awarded funds to CRDF Global to facilitate support for the RePORT India sites that plan to follow house-hold contacts of incidence TB cases, so that the number and quality of specimens collected are adequate to address critical biomarker questions of importance to the TB field, particularly in India.

- Through the NIH-funded Clinical Diagnostics Research Consortium, NIAID is collaborating with the Foundation for Innovative New Diagnostics (FIND) to evaluate early stage TB diagnostics in TB endemic countries. Recent studies include the evaluation of the Inverness Urine LAM assay in HIV-positive subjects, evaluation of the TREK MYCOTB MIC plate for susceptibility testing of *Mycobacterium tuberculosis* and the identification of serological markers for pediatric TB.

- DMID staff serve as technical advisors on GATB and AERAS technical working groups to assure NIAID resources are optimally leveraged and coordinated for product development in TB.

- NIAID has conducted several workshops in collaboration with AERAS to discuss contemporary issues in TB vaccine discovery and development.

- NIAID staff serve as reviewers for applications in response to BMGF Initiatives to assure applications addressing gaps in TB research not already filled by NIAID are considered.

- **HIV/AIDS**

  - The DAIDS-funded International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT) and HIV Vaccine Trials Network (HVTN) are collaborating with AERAS to conduct Phase I/II TB vaccine trials in the HIV uninfected infant population in South Africa.

  - Through the NIH-funded Microbicide Trials Network and the International Partnership for Microbicides, NIAID is collaborating with the BMGF to conduct a Phase III safety and effectiveness study of a vaginal matrix ring containing the NNRTI dapivirine for the prevention of HIV-1 infection in women. Designated ASPIRE, for A Study to Prevent Infection with a Ring for Extended Use, this trial is currently enrolling at several sites in Africa. The study will take about two years to conduct with results anticipated in late 2014 or early 2015.

  - NIAID/OGAC/BMGF are co-funding a trial entitled, "Population Effects of Antiretroviral Therapy to Reduce HIV Transmission (POPART)" study to determine the impact of two community-level

combination prevention packages, both of which include universal HIV testing and intensified provision of HIV antiretroviral therapy and care, on population-level HIV incidence. This study is being conducted in 24 communities in Zambia and South Africa.

- NIAID works closely with BMGF to lead the Pox-Protein Public-Private Partnership which includes our two organizations, the HIV Vaccine Trials Network (HVTN), the U.S. Military HIV Research Program (MHRP), Sanofi-Pasteur and Novartis. The goals of the partnership are to advance clinical development of pox vector, Env protein boost vaccine concepts in order to extend and confirm the RV 144 efficacy results in high risk populations, advance the candidates toward licensure, and to evaluate next generation pox-protein vaccine candidates for safety, immunogenicity and efficacy. NIAID and the BMGF are the primary funders of this enterprise and thus far have co-funded the efforts for HIV Env down-selection, Processes and Analytics development, Tech Transfer, and manufacture the protein components for southern Africa. Novartis will oversee the manufacturing at a CMO which has begun in September 2013. In addition, the BMGF will be working with NIAID to begin funding some of the clinical trial sites in Southern Africa for training in preparation for vaccine efficacy studies

- A whole genome sequencing of 200 HIV-exposed seronegative Hemophilia subjects (David Goldstein/Duke University/CHAVI), co-funded by the BMGF and NIAID, will search for rare genetic variants that could explain reduced susceptibility to HIV infection through whole genome resequencing of 200 Hemophilia patients who were exposed to HIV in the early 80s but did not become infected. Whole genome sequencing is being performed as a follow-up to an initial GWAS analysis of about 600 such subjects that failed to reveal any common genetic variants as an explanation for reduced susceptibility to infection.

- **Other Diseases**

  - **Highly Pathogenic Avian Influenza (HPAI) H5N1 -** Highly significant research findings published in Nature in 2012 by Dr. Yoshihiro Kawaoka were funded with grants from both NIAID and the Gates Foundation. This paper demonstrated that highly pathogenic avian influenza (HPAI) H5N1 viruses can be transmitted between mammals via respiratory droplets. This important work validated the pandemic threat that HPAI H5N1 viruses pose in nature and has informed surveillance of circulating avian influenza viruses for pandemic potential. This work has also provided basic knowledge on how animal influenza viruses gain the ability to transmit in mammalian species and will aid in the development and evaluation of countermeasures against these viruses.

  - **Childhood Pneumonia -** NIAID is supporting a clinical study on childhood pneumonia that will be tested within an existing BMGF-funded birth cohort study. The birth cohort study supported by BMGF is designed to enroll approximately 500 children who will have nasopharyngeal (NP) sampling at birth, 6 weeks of life and every 6 months thereafter for the first 2 years. The NIAID-supported activity includes a more detailed analysis in a subset of approximately 300 children, using sequence-, culture- and specific PCR-based approaches to define the composition and dynamics of the infant NP microbiome from birth to two years of age and to determine the association between the NP microbiome and pneumonia or wheezing in African infants.

  - **Global Polio Eradication -** Both DMID and BMGF participate and interact as members of the WHO Polio Research Committee (PRS) and the Polio Antiviral Initiative (PAI), which focus on

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facilitating global polio eradication and maintaining a polio-free world after eradication. The PRS emphasizes new vaccination strategies and the development of new vaccines including monovalent ones to tailor control of transmission in specific outbreaks. The PAI concentrates on the development of effective antivirals to facilitate quick control of outbreaks and to treat persistent shedders who are often immune-compromised and unable to respond to a vaccine.

- **Malaria –** NIAID and the BMGF have both supported development of malaria vaccines for many years. Interactions between program staff at both institutions are frequent, and include:

  - Representation of both organizations in the Malaria Vaccine Funders Group, along with USAID, the European Commission, the Wellcome Trust, the European Vaccine Initiative, the European-Developing Country Clinical Trials Partnership (EDCTP), and the PATH Malaria Vaccine Initiative (MVI). Along with other members of the Malaria Vaccine Funders Group, NIAID and BMGF Staff recently contributed to the Update of the Malaria Vaccine Technology Roadmap, to be released in November, 2014.
  - Representation of both organizations on the PfSPZ Multilateral Integration Team for development of a whole sporozoite vaccine against falciparum malaria by Sanaria.
  - Frequent interactions between NIAID Program Staff and Staff at the PATH MVI, a principal implementer of BMGF-supported malaria vaccine R&D.
  - NIAID and the BMGF coordinate research activities on systems biology of malaria that are funded jointly by the two organizations.
  - NIAID supports genomic and immunologic analysis of clinical samples from the RTS,S Phase 3 trial that has been supported by BMGF through PATH MVI.
  - Collaboration in a joint Phase 1/2 Prime-Boost study of an Adenovirus Serotype 35-based malaria vaccine (Ad35.CS) followed by RTS,S. NIAID supported the preclinical and clinical development of Ad35.CS, provided clinical trial material for the study, and participated on the protocol team that designed and oversaw the study.

- **Neglected Tropical Diseases**
  - NIAID and the BMGF jointly convened a meeting on "Schistosomiasis Elimination Strategies and the Potential Role of a Vaccine in Achieving Global Health Goals." A meeting report is currently under review at the *American Journal of Tropical Medicine & Hygiene*. A follow up meeting will be held in November, 2013 in Washington DC.
  - BMGF supported a U.S. Phase I trial of a promising *Leishmania* vaccine candidate originally developed by the Infectious Diseases Research Institute (IDRI) with NIAID research funding. DMID/NIAID subsequently supported a second U.S.Phase I trial of the same candidate to address dosage and formulation issues. Future development plans are under discussion.
  - NIAID supports Tropical Medicine Research Centers in endemic countries. One of these Centers, located in Muzaffarpur, India, is conducting research on transmission of visceral leishmaniasis. The BMGF is working collaboratively with NIAID Program Staff and co-funding a study to determine the role of asymptomatic infections and whether sandflies are able to transmit the disease from this reservoir.

- NIAID Program Staff currently serve on the Technical Advisory Group for the "Eradication Investment Cases Project for Onchocerciasis, Lymphatic Filariasis and Human African Trypanosomiasis," an initiative funded by BMGF.

- **Dengue Vaccine Initiative -** DMID has a significant presence in the Dengue Vaccine Initiative (DVI), a large project supported by BMGF to advance the development of a dengue vaccine. Activities include an annual research meeting with DMID participation. In June 2013, NIAID and DVI co-sponsored a Consultation on Dengue Vaccines, which was attended by two BMGFdirectors: Lance Gordon, the director for Neglected Tropical Diseases and Chris Karp, the director of the Discovery & Translational Sciences team. Aside from the research conferences, we remain in contact throughout the year to co-ordinate DMID and BMGF activities in dengue.

- **Cryptosporidiosis -** BGMF has supported large multicenter, multi-national studies to determine the burden of disease due to diarrheal pathogens. These studies have identified cryptosporidia as a major contributor to diarrheal morbidity. BMGF and NIAID Program Staff have jointly organized a meeting to identify knowledge gaps and research needs for cryptosporidiosis. A meeting of experts, including BMGF and NIAID Program Staff, is planned for Nov 21-22, 2013 to define the gold standard for cryptosporidium diagnostics.

- **Rotavirus -** Through cooperation with BMGF, India's first indigenously developed oral rotaviral diarrhea vaccine (Human Rotavirus strain 116E, *ROTAVAC*) has been created, with successful completion of phase II trials and large phase III community clinical trials for safety and efficacy currently underway in Delhi, Pune and Vellore. Indian licensing for *ROTAVAC®* is expected during 2014 and WHO prequalification in 2015 for supply to UN agencies at a price of US$1. The rotavirus vaccine development project is a public-private partnership project between Bharat Biotech, the Dept. of Biotechnology, Gates Foundation, Program for Appropriate Technologies in Health, CDC, NIAID and other partners Bharat Biotech has an installed capacity of 300 million doses and is well positioned to manufacture and supply *ROTAVAC®* to UNICEF, PAHO, and for national immunization programs

- **ENTERICS AND HEPATIC DISEASES COLLABORATIONS**
  - On October 26, 2011, Drs. Heilman and Cassels met with a BMGF high level group, invited and led by Dr. Gina Rabinowitz, and gave presentations on DMID and EHDB programs and priorities. Dr. Robin Robinson, BARDA, also attended and presented.
  - DMID is collaborating with the BMGF on their cholera program: The BMGF has developed a translational research program to introduce cholera vaccine to both epidemic and endemic situations. DMID has a robust product development program which can contribute to public health efforts in cholera surveillance, diagnostics, vaccination, and treatment. These programs are coordinated through periodic conversations and telecons when we exchange information and ideas about our programs.
  - DMID collaborates with the BMGF on the U.S.-Japan Cholera and Other Bacterial Enteric Infections Panel meetings. The U.S. secretariat organizes the biannual U.S. conference to include areas of mutual interest and importance, such as recently focusing on typhoid diagnostics; BMGF has provided travel support for developing country scientists to attend the meetings. These conferences receive substantial support in the research community, and provide the key forum for exchanging ideas and approaches for controlling bacterial enteric infections.

- On April 18019, 2012, Drs. Fred Cassels and Melody Mills invited to attend and participate in the conference on "***H. pylori in Children in Developing Countries."*** The meeting was supported by BMGF.

OVERVIEW OF COOPERATIVE PROGRAMS

- **Centralized Envelope Comparative Immunogenicity Phase I Study (CECI)**

  Goal: Understand how best to design T-cell immunogens in order to develop a vaccine that addresses the broad genetic diversity of HIV-1

  Funding: $4.4M (2009-2014)

  CECI is a partnership with BMGF, NIAID, IPPOX Foundation, and several academic institutions. The project will test, in a phase 1 clinical trial, a vaccine regimen composed of a DNA prime-NYVac Boost containing a new set of artificial computer-designed HIV genes that should provoke the immune system to respond to a wide variety of HIV strains. The BMGF grant will cost-share vaccine production with NIAID's Division of AIDS and IPPOX Foundation, while NIAID will support the clinical trial. Scientific leadership of CECI is provided though Duke University's Human Vaccine Institute. Manufacturing of the vaccine products has been completed, an IND filed, and the FDA has allowed the clinical trial to initiate (HVTN098). The trial is set to begin enrollment in 3Q2013.

- **cGMP Production of a Trimeric HIV gp145 Clade C Env Protein**

  Goal: To manufacture a clade C HIV Env protein as a clinical research reagent for clinical research studies

  Funding: 2.9M (2012-2016)

  This grant is to provide additional support to the ongoing NIAID manufacturing efforts to provide an HIV Env protein (collaboration with the MHRP) to the HIV vaccine community for testing in clinical research studies such as adjuvant comparison studies, boosting vaccines, etc.

- **Identification of high-quality HITs for Tuberculosis (HIT-TB)**

  Goal: Produce high-quality chemical hit series with defined, tractable targets as drug leads for tuberculosis

  Funding: $7.3M (2010-2013)

  Scientific leadership of the project is based at the Tuberculosis Research Section of NIAID

- **Comprehensive T-Cell Vaccine Immune Monitoring (CTC-VIMC)**

  Goal: Establish standardized T-cell assays and capacity to support HIV vaccine testing

  Funding: $50M (2006-2016)

  (CTC-VIMC) is an integral part of the BMGF-sponsored Collaboration for AIDS Vaccine Discovery, which is a component of the larger Global HIV/AIDS Vaccine Enterprise. CTC-VIMC aims to ensure broad access to assays and technologies that will enable valid comparisons of the cellular immune responses induced by new candidate HIV/AIDS vaccines as they undergo preclinical research and

clinical trials. The consortium supports an international network of 20 investigators in the United States., Europe and Africa, incorporating four core laboratories and three nonhuman primate laboratories. Scientific leadership of the consortium resides at the VRC.

- **"Decade of Vaccines" Collaboration and Related Activities**

The "Decade of Vaccines" Collaboration (DoVC), launched in 2010, brought together multiple constituencies and stakeholders to produce a Global Vaccine Action Plan (GVAP). BMGF, NIAID and WHO played key leadership roles in the DoVC. The GVAP was endorsed by the World Health Assembly in 2012. The DoVC formally "sunset" in December 2012.

  - In March, 2013, representatives of BMGF, NIAID, and WHO signed a Memorandum of Understanding (MOU) to formally recognize their continuing collaborative efforts in vaccine R&D. A major activity under this MOU is the ***Global Vaccine and Immunization Research Forum (GVIRF)***. The purpose of the GVIRF is to track progress in the R&D arena against the goals and strategic objectives of the Global Vaccine Action Plan, and to provide an opportunity to identify and capitalize on R&D opportunities. BMGF, NIAID, and WHO are all represented on the Secretariat of the GVAP and the GVIRF. The first GVIRF will take place 4-6 March 2014 in Bethesda MD, and approximately every 18 months thereafter.

- **Development of a Second-Generation Broadly Neutralizing Antibody Product to Prevent HIV-1 Infection (2GVRC01)**

  Goal: Develop a second generation broadly neutralizing antibody product to prevent HIV-1 infection, with improved potency and longer half-life

  Funding: $1.9M (2011-2016)

- **Multinational Study of Enteric Infections and their Relation to Malnutrition, Growth, Development and Vaccine Response (MAL-ED)**

  Goal: Understand the complex interaction between enteric infections, malnutrition, and impaired growth and cognitive development in order to design better intervention strategies

  Funding: $30M (2008-2013)

  NIH Partner: FIC

  Researchers at sites in Bangladesh, Brazil, India, Nepal, Pakistan, Peru, South Africa, and Tanzania are conducting longitudinal studies using harmonized protocols to describe the global pattern of nutritional and enteric disease factors influencing early childhood development, among populations in highly endemic countries. Central questions to be addressed by this work include: 1) Whether specific enteric pathogens or combinations of pathogens have stronger associations with malnutrition than others; 2) Whether there is a particularly vulnerable period in infancy/early childhood during which specific enteric infections cause greater morbidity; and, 3) Whether results from one locale can be extrapolated to other populations based on common environmental and biological determinants.

- **Use of Iron Interventions to reduce malaria morbidity and mortality:**

Goal: To understand effects of iron supplementation during early childhood on risks of severe morbidity and mortality from malaria, especially when supplements are given to individuals who are not iron deficient.

Partner: NICHD

Funding: $9M ((2007-2012)

Ten projects have been funded to date, including studies on absorption, iron status, stages of the malaria life-cycle, different modes of iron intervention, non-transferinn bound iron, mircobiota, co-infections.

- **Biomarkers for Nutrition and Development (BOND)**
  Goal: To develop a unified, scientific approach to select biomarkers for assessing the function and effect of diet and nutrition on health and disease in individuals and populations
  Funding: $0.5m

  NIH Partner: NICHD

  Funding: $.0.5M (2011-2013)

  This project is intended to develop a process for harmonization of decisions surrounding optimal biomarkers for specific uses under specific conditions, and a research agenda that will advance the discovery, development and implementation of new biomarkers and technologies for both point of care and population based assessments of micronutrient exposure, status, and health impact. A website has been developed for the BOND project and six expert panels are developing materials on iodine, Vitamin A, zinc, iron, folic acid, and Vitamin B-12.

- **FNIH-Managed Initiatives with BMGF**

  Grand Challenges in Global Health (GCGH)

  Goal: Overcome persistent bottlenecks in creating new tools that can radically improve health in the developing world.

  Funding: $201M (2003-2015)

  Vector-based Control of Transmission: Discovery Research (VCTR)

  Goal: Collaboration between NIH grantee David Williams and the NIH Chemical Genomics Center identified a promising new class of drugs for the treatment of schistosomiasis. Extend GCGH research on chemical or genetic strategies to deplete or incapacitate disease-transmitting insects

  Funding: $48M (2009-2016)

  The VCTR grant portfolio consists of five major projects extended beyond the original GCGH funding. Three of these support research on novel strategies for making mosquito populations incompetent to transmit disease agents, or for substantially reducing numbers of malaria and dengue vector mosquitoes, by the introduction of heritable microbial agents or of genetic constructs. Another two projects are working to develop repellents to prevent malaria-carrying mosquitoes from locating hosts

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- **PATH**

  - May 24, 2012: NIAID/DMID/EHDB (Bill Alexander, Fred Cassels, Melody Mills, Ryan Ranallo, and Shahida Baqar) met with Tom Brewer and other BMGF program staff to discuss specific branch portfolios and potential for collaborative interactions. The same day the same EHDB group met with PATH diagnostics and formulations staff in their Seattle office, also to discuss specific branch portfolios and potential for collaborative interactions.
  - With EHDB- Enteric Vaccine Initiative (EVI) PATH collaboration on an oral dose escalation clinical trial of double mutant LT (dmLT, LT(R192G/L211A) of Enterotoxigenic *E. coli* (ETEC) in adults was initiated in 2010 and completed in 2012. dmLT is a component of ETEC vaccines and a viable mucosal adjuvant platform for delivery of enteric and non-enteric vaccines. Primary outcome of the clinical trial is this that dmLT is safe and devoid of any toxicity given orally up to 100µg, whereas, 50 µg is the optimal immunogenic dose (Clin, Vacc. Immunol., In press, 2013).
    - DMID provided clinical trial and laboratory support.
    - PATH cGMP manufactured the product, supported all pre-clinical studies, conducted GLP toxicity studies and funds stability studies since the production. PATH maintains/updates CMC and IB as needed.
    - **Based on the results of this trial, PATH is testing this product as an ETEC vaccine component or oral adjuvant for Shigella vaccine in Bangladesh.**

  - Sublingual route of immunization of dmLT clinical trial protocol has been approved by PRA/OCRA, site IRB and all FDA requirements are met. Study was to initiate in the fall of 2013, but due to H7N9 flu studies has been delayed until Jan 2014.
    - DMID will be providing the support to conduct the clinical study.
    - EVI-PATH will be providing the product, current stability data and all support to conduct trial related immunological studies.
  - Intradermal route of immunization clinical trial – concept has been reviewed and approved by DMID;currently protocol is under development.
  - ETEC antigen to be used in pre-clinical or clinical research. EHDB and EVI has agreed to collaboratively produce (on contract with WRAIR) sufficient amounts of six surface antigens (each organization will fund production cost of three antigens) to be provided to the scientific community to allow direct comparison of various clinical trials and epidemiological studies conducted around the globe.
  - "Enteric Vaccine Portfolio Holders Workshop" a DMID-EVI PATH jointly funded international meeting was held (Feb 2013) to discuss progress in vaccine development against ETEC and Shigella.Multiple major gaps were identified andways to bridge them are being determined..
  - Shahida Baqar, EHDB PO, is a voting member of EVI PATH Scientific Advisory Board.
  - Future plans
    - Evaluation/comparison of dmLT for safety and immunogenicity vial oral, sublingual and intradermal routes in adults residing in endemic areas. A safe dose via each route will likely also be tested in children.
    - Candidate Vaccine-Adjuvant-Route trial in U.S. adults, and adults and children living in endemic areas.

NIAID PRECLINICAL RESOURCES FOR PRODUCT DEVELOPMENT

One of the biggest challenges to product development for infectious diseases is the cost of moving promising candidates through the pipeline. Recognizing this challenge, NIAID helps to provide the critical information necessary to advance products and lessen the financial risks associated with investing in product development.

DMID offers a suite of preclinical services to conduct:

- In vitro assessment for antimicrobial activity— high-throughput and specific and broad spectrum screens to stimulate research towards discovery of improved antimicrobial therapies;
- In vivo services (screening, efficacy, development of animal models)— the provision of a broad range of in vivo models, development of novel models, and refinement of existing models. Product screening and efficacy testing for FDA submissions are also include;
- Therapeutic development services— preclinical services to support the development of products intended for use in the cure, mitigation, diagnosis, or treatment of disease caused by a pathogen or certain toxins;
- Vaccine development services—resources to support the development of vaccines; vaccine components including adjuvants; vaccine delivery systems; other biologics; and biosafety lab (BSL)-2, BSL-3, and BSL-4 challenge material. Services include vaccine testing and vaccine manufacturing resources.

DMID also provides resources to support:

- Basic research to identify and develop targets. Services include repositories and 'omics resources;
- Clinical evaluation resources to conduct and support clinical trials. DMID programs encompass a wide range of pathogens for nearly every human infectious agent spanning bacteria, viruses, parasites, fungi, toxins and vectors (DMID resources do not include those for HIV/AIDS). Services are provided by DMID-funded contractors and are offered free of charge.

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From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Harvey, Hillery (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 15:19:14 -0500
Importance: Normal

I don't want to get anyone in trouble but I have been waiting to hear from Wayne Crum's group for some time to verify the listing. I think it will be no problem to have the list revised. Rob had asked for our final input by Thanksgiving so I have no idea why Building 1 already sent this around. Seems premature.

I had assumed that Wayne would send back to me a corrected version of this listing that included whatever was missing or inaccurate. Shall I just forward your note to him? I was under the impression that he would have the final information about all our Gates program linkages that involved money.

Or better yet, do you feel comfortable editing the document to make it accurate and returning it to me?

Gray

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 25, 2013 2:51 PM
To: Handley, Gray (NIH/NIAID) [E]
Cc: Hudgings, Carole (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]; Stover, Kathy (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Touchette, Nancy (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Doepel, Laurie (NIH/NIAID) [E]
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

Hi Gray,

During our staff meeting this morning it was noted that several major NIAID-Gates partnerships were not included in the document Dr. Collins sent around yesterday (attachment #1). Notably, P5, malaria activities, and the Decade of Vaccines.

Could you work with your contacts at FIC or Bldg. 1 to ensure that these are incorporated? In case helpful, I attach an internal NIAID document with these three activities highlighted on pages 3, 4, and 7 (attachment #2).

Also, it might make sense to include the word "Selected" in the title of Dr. Collins' document since the list is not comprehensive, at least from the NIAID perspective.

Many many thanks and Happy Thanksgiving to you and yours.
Hillery

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, November 24, 2013 12:54 PM
To: NIAID OD AM
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

Let us discuss the second attachment listing the collaborations and/or interactions between the BMGF and NIAID.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:39 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher

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(NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Agenda for Bill Gates visit to NIH on December 2

Dear Colleagues,

I am delighted you are able to join the roundtable discussion and working lunch with Bill Gates on Monday, December 2, from 12:15 AM-1:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with Bill and other staff from the Global Health Program at the BMGF.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than a series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to discuss the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD); Trevor Mundel, President of the Global Health Program at the BMGF; Boris Nikolic, Scientific Advisor; and Kathy Young**,** Senior Project Manager for Strategic Planning and Engagement. Their bios are attached.

Please feel free to contact Rob Eiss at FIC [redacted] with any questions you or your staff may have surrounding the visit.

I'm delighted that Bill was able to reschedule so soon after the shutdown, and will remain on campus a good portion of the day to visit labs and hold discussions with senior leadership, in addition to the presenting the annual David Barmes Global Health lecture.

Best regards, Francis

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From: "Touchette, Nancy (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 15:37:49 -0500
Importance: Normal
Attachments: NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc; NIAID-BMGF_Partnerships_2013.NAT_edt.docx

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You want me to do anything, or do you know who to contact ?

Nancy

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 25, 2013 2:51 PM
To: Handley, Gray (NIH/NIAID) [E]
Cc: Hudgings, Carole (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]; Stover, Kathy (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Touchette, Nancy (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Doepel, Laurie (NIH/NIAID) [E]
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

Hi Gray,

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Many many thanks and Happy Thanksgiving to you and yours.
Hillery

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Sunday, November 24, 2013 12:54 PM
To: NIAID OD AM
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

Let us discuss the second attachment listing the collaborations and/or interactions between the BMGF and NIAID.

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:39 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C];

Released by Chairman Rand Paul

McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
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Best regards, Francis

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From: "Touchette, Nancy (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 15:43:56 -0500
Importance: Normal
Attachments: NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc; NIAID-BMGF_Partnerships_2013.NAT_edt.docx

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And btw, these are broken down into BMGF-funded projects and those that are funded by BMGF in which NIAID is a sub-grantee. In the case of the GVIRF (Decade of Vaccines), NIAID is not a grantee; both NIAID and BMGF are contributing funds to WHO. I think it is a similar situation for the 2 other examples cited: projects that are co-funded by both NIAID and BMGF

Nancy

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 25, 2013 2:51 PM
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Cc: Hudgings, Carole (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]; Stover, Kathy (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Touchette, Nancy (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Doepel, Laurie (NIH/NIAID) [E]
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[E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
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From: "Handley, Gray (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=HANDLEYGR>
To: "Touchette, Nancy (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 18:36:27 -0500
Importance: Normal

Thanks. I sorted it out I think. G

From: Touchette, Nancy (NIH/NIAID) [E]
Sent: Monday, November 25, 2013 3:38 PM
To: Handley, Gray (NIH/NIAID) [E]
Subject: FW: Agenda for Bill Gates visit to NIH on December 2

You want me to do anything, or do you know who to contact ?

Nancy

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 25, 2013 2:51 PM
To: Handley, Gray (NIH/NIAID) [E]
Cc: Hudgings, Carole (NIH/NIAID) [E]; Harper, Jill (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [C]; Stover, Kathy (NIH/NIAID) [E]; Billet, Courtney (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Touchette, Nancy (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Doepel, Laurie (NIH/NIAID) [E]
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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "micheleb@watermark-llc.com" [redacted]@watermark-llc.com>
Bcc: "Marston, Hilary (NIH/NIAID) [C]" [redacted]@nih.gov>
Subject: Note for Melinda Gates
Date: Tue, 24 Sep 2013 20:18:23 -0400
Importance: Normal

John and Michele:
I was given your e-mail addresses by Hilary Marston who is now a Policy Fellow in my office. I would greatly appreciate if you could see that my e-mail gets to Melinda Gates.
Thanks,
Tony

Dear Melinda:
I am so sorry that I did not get a chance to personally congratulate you on receiving the Lasker-Bloomberg Public Service Award at the Lasker Lunch. I was able to get to Bill and congratulate him and chat a bit; however, the crowd around the dias was so dense, I could not negotiate my way to you before the ceremony. Since I had to catch a 3:00 PM Amtrak back to Washington, D.C., I left immediately after the end of the ceremony. And so now I want to take the opportunity to sincerely congratulate you on a much, much deserved honor. I remember when I received the Lasker Public Service Award in 2007 (before they named it after Mayor Bloomberg), I thought at the time that this award must someday soon go to Bill and Melinda. They made a terrific choice. Keep up your magnificent work.
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Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

Released by Chairman Rand Paul

From: Melinda French [redacted]@mfgates.com>
To: [redacted]@niaid.nih.gov'" [redacted]@niaid.nih.gov>
Subject: RE: Note for Melinda Gates
Date: Fri, 11 Oct 2013 13:25:39 -0400
Importance: Normal

Tony,

Thanks for sending this. Was really kind of you to follow-up. Sorry to have missed you at the lunch.

Best,
Melinda

From: Fauci, Anthony (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Tuesday, September 24, 2013 5:18 PM
To: John Sage; Michele Boyer
Subject: Note for Melinda Gates

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To: "Marston, Hilary (NIH/NIAID) [C]" [redacted]@nih.gov>
Subject: FW: Note for Melinda Gates
Date: Fri, 11 Oct 2013 13:28:20 -0400
Importance: Normal

FYI

From: Melinda French [mailto [redacted]@mfgates.com]
Sent: Friday, October 11, 2013 1:26 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: Note for Melinda Gates

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From: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Harvey, Hillery (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Cantrel, Katherine (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>, "Burklow, John (NIH/OD) [E]" [redacted]@OD.NIH.GOV>, "Doepel, Laurie (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Handley, Gray (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013
Date: Tue, 05 Nov 2013 12:20:21 -0500
Importance: Normal
Inline-Images: image001.png

Hi all,

I just wanted to note that for the Building 33 visit we have Dr. Collins not only visiting Dr. Barry's lab but also he will be touring the BSL3 facility with Mr. Gates. I just wanted to note (and apologize if you already know) that there are certain clearance steps and training that needs to be done before the BSL3 clearance is given. I did not want to assume that Drs. Fauci and Zoon are already cleared to visit the BSL3. If they have not been cleared, Janette LeBron in Dr. Barry's lab was very helpful in guiding me through the process. Many thanks and apologize if I am stating the obvious.

Best wishes,

Gretchen

From: Eiss, Robert (NIH/FIC) [E]
Sent: Tuesday, November 05, 2013 11:14 AM
To: Harvey, Hillery (NIH/NIAID) [E]; Wood, Gretchen (NIH/OD) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Burklow, John (NIH/OD) [E]; Doepel, Laurie (NIH/NIAID) [E]; Handley, Gray (NIH/NIAID) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hi Hillery,

Absolutely, that was our intention since both of the lab visits involve NIAID. The one positive in having to cancel the event due to the shutdown, is the availability of Dr. Fauci to participate on the rescheduled date.

With regards to the format of the roundtable discussion, below is the note that Dr. Collins sent to the IC Directors and Deputies participating in the roundtable, prior to the cancellation I hope this is instructive and would be happy to provide any additional background and clarifications.

The costs of the catered lunch will be supported out of the representational fund – covering both the guests and IC Directors.

Best,

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:18 PM
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha

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(NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric [redacted]@state.gov)
Cc: Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: October 7 visit of Bill Gates

Dear colleagues,

I am delighted you are able to join the roundtable discussion with Bill Gates on Monday, October 7, from 11:15 AM-12:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with staff from the Global Health Program at the BMGF.

I had an opportunity to review the agenda briefly with Bill at the Lasker Awards ceremony (where he and Melinda received the Lakser~Bloomberg award) last week. He is very much looking forward to the discussion.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I also ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to relate the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD), and Kathy Young, Senior Project Manager for Strategic Planning and Engagement in Bill's office. Their bios area attached.

We are delighted and honored that Eric Goosby (a former Barmes Lecturer) will join the roundtable. I am asking Eric to comment on the NIH/PEPFAR partnership in implementation science.

We will include a working lunch as part of the roundtable discussion Details on the lunch are forthcoming.

Prior to the discussion, we also will send a background summary of current IC (and FNIH) activities with the Gates Foundation.

Rob Eiss of the FIC has assisted with the planning and organization of this visit. Please feel free to contact Rob with any questions you or your staff may have surrounding the visit.

Best regards, Francis

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Tuesday, November 05, 2013 10:08 AM
To: Wood, Gretchen (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Burklow, John (NIH/OD) [E]; Doepel, Laurie (NIH/NIAID) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Thank you Gretchen. Very helpful.

Released by Chairman Rand Paul

ROB: Dr. Fauci would like to be included in the tour of Bldg. 33 with Clif Barry and Kathy Zoon. As the schedule evolves, can you incorporate this modification?

Many thanks again to you both.
Hillery

From: Wood, Gretchen (NIH/OD) [E]
Sent: Tuesday, November 05, 2013 9:57 AM
To: Harvey, Hillery (NIH/NIAID) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hi Hillery,

Sorry to be late in responding. We will actually be re-working the agenda to have the media briefing at the end of the day's agenda so Mr. Gates will have the opportunity to hear from Senior Leadership and be better prepared for questions from the media. I do not believe that we were intending for ICD to use slides, but rather have an open dialogue with Mr. Gates. Given the time allotted, it would appear that each topic would have between 12 and 15 minutes, and I imagine that the opening comments for each would be up to the lead discussant. I have cc'd Rob Eiss here on this e-mail as he has been working on the format and can relay any ideas that he has received from Dr. Collins.

Please do not hesitate to contact me should you need anything further. Rob and I are hoping to hear from remaining ICD before the end of the week to pin down a more accurate agenda.

Best wishes,

Gretchen

From: Harvey, Hillery (NIH/NIAID) [E]
Sent: Monday, November 04, 2013 1:01 PM
To: Wood, Gretchen (NIH/OD) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Cantrel, Katherine (NIH/NIAID) [C]
Subject: RE: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Hello Gretchen—

In discussing Dr. Fauci's preparation for his role in Mr. Gates' visit December 2nd, several questions arose regarding the agenda discussion on HIV, malaria, and TB:

- What is the general discussion format? e.g., opening slides or comments followed by organic discussion?
- For the 11:45am-1pm agenda items, how much time is allotted for each? For the lead discussant's opening comments?
- Should Dr. Fauci plan to use slides?

And any other information on how Dr. Collins envisions this roundtable/working lunch would be helpful.
Many thanks for your help!
Best wishes,
Hillery

Hillery A. Harvey, Ph.D.
Special Assistant to the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bldg. 31 Rm. 7A-03
Bethesda, MD 20892

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ph [redacted]
fx [redacted]
[redacted] niaid.nih.gov

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From: Wood, Gretchen (NIH/OD) [E]
Sent: Friday, November 01, 2013 2:26 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Somerman, Martha (NIH/NIDCR) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Green, Eric (NIH/NHGRI) [E]; Mascola, John (NIH/VRC) [E]; Barry, Clifton (NIH/NIAID) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Mr. Bill Gates visit and lecture rescheduled for Monday, December 2, 2013

Good afternoon,

We have received confirmation from the Gates Foundation that Mr. Gates is available to deliver the Barmes Global Health Lecture and meet with NIH Senior Leadership on Monday, December 2, 2013. Attached please find a preliminary draft of the day's agenda which mirrors the one from October and now includes a scientific tour of the VRC. It has not been approved by the Foundation. Please review and indicate whether you have any conflict that would prevent or delay your participation on the agenda as it is currently presented.

Please do not hesitate to contact me should you have any questions or concerns.

Best wishes,

Gretchen

Gretchen S. Wood
Staff Assistant
National Institutes of Health
Immediate Office of the Director
One Center Drive
Building 1, Room 126
Bethesda, Maryland 20892
V: [redacted]
F: [redacted]
E: [redacted]@od.nih.gov

Follow @NIHDirector on Twitter
Celebration of Science at NIH: *watch how medical research saves lives and improves health*

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From: "Conrad, Patricia (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=RECIPIENTS/CN=CONRADPA>
To: "Cantrel, Katherine (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>
Subject: FW: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 08:44:13 -0500
Importance: Normal
Attachments: Mundel_&_Nikolic_BIOs.doc; NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc; Program_for_Visit_of_Bill_Gates_December_2_(3).docx; Wilson_Young_bios.docx

---

Pls add hardcopies ot bill gates Dec 2 folder. thx

Patricia L. Conrad
Special Assistant to the DIrector

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:39 PM
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Agenda for Bill Gates visit to NIH on December 2

Dear Colleagues,

I am delighted you are able to join the roundtable discussion and working lunch with Bill Gates on Monday, December 2, from 12:15 AM-1:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with Bill and other staff from the Global Health Program at the BMGF.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than a series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to discuss the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD); Trevor Mundel, President of the Global Health Program at the BMGF; Boris Nikolic,

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Scientific Advisor; and Kathy Young, Senior Project Manager for Strategic Planning and Engagement. Their bios are attached.

Please feel free to contact Rob Eiss at FIC [redacted] with any questions you or your staff may have surrounding the visit.

I'm delighted that Bill was able to reschedule so soon after the shutdown, and will remain on campus a good portion of the day to visit labs and hold discussions with senior leadership, in addition to the presenting the annual David Barmes Global Health lecture.

Best regards, Francis

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From: [redacted]@nsf.gov" [redacted]@nsf.gov>
To: [redacted]@bgc3.com" [redacted]@bgc3.com>, [redacted]@gene.com" [redacted]@gene.com>, [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Subject: Request for Letter of Support for Leroy Hood for the 2013 National Medal of Science
Date: Fri, 27 Jan 2012 19:03:12 -0500
Importance: Normal

Dear Sir/Madam,

Alan Aderem has nominated Leroy Hood for the 2013 National Medal of Science. As part of the nomination process, you have been listed as one of several references for Leroy Hood.

Your reference supporting the nomination of Leroy Hood must be submitted by 11:59 PM Eastern Time on March 31, 2012 through FastLane at the following Web site: https://www.fastlane.nsf.gov/honawards/.

If you are a new user to the Honorary Awards FastLane System, you will have to create a User Name and password before logging in.

Thank you.

(This is an automatically generated e-mail.)

This e-mail was sent from an address that cannot accept incoming e-mail therefore please DO NOT REPLY TO THIS MESSAGE.

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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Request for Letter of Support for Leroy Hood for the 2013 National Medal of Science
Date: Sun, 29 Jan 2012 15:38:16 -0500
Importance: Normal

Let us discuss.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]**@niaid.nih.gov**
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: [redacted]@nsf.gov [mailto [redacted]@nsf.gov]
Sent: Friday, January 27, 2012 7:03 PM
To: [redacted]@bgc3.com; [redacted]@gene.com; Fauci, Anthony (NIH/NIAID) [E]
Subject: Request for Letter of Support for Leroy Hood for the 2013 National Medal of Science

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From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Jin, Daozhong (NIH/OD) [C]" [redacted]@nih.gov>
Subject: RE: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 09:02:58 -0500
Importance: Normal

Thanks very much Dr Tabak would join Dr Collins and Kathy to welcome Mr Gates and colleagues and I will provide details Thanks for your patience as we complete a minute-by-minute itinerary (The Gates advance team is here today for a walk thru and review of events flow)

From: Jin, Daozhong (NIH/OD) [C]
Sent: Monday, November 25, 2013 8:58 AM
To: Eiss, Robert (NIH/FIC) [E]
Subject: RE: Agenda for Bill Gates visit to NIH on December 2

Hello Robert,

Thanks so much for forwarding me the materials below. I've noted the Barmes lecture at 11:00 AM – 12:00 PM and the roundtable discussions at 12:15 PM – 1:30 PM on Dr. Tabak's calendar. Could you let me know whether Dr. Tabak should also plan to join the arrival and greetings or scientific tours or are the lecture and discussion the full extent of what I needed to include?

Thanks,
Daozhong

From: Eiss, Robert (NIH/FIC) [E]
Sent: Sunday, November 24, 2013 1:52 PM
To: Jin, Daozhong (NIH/OD) [C]
Subject: Fw: Agenda for Bill Gates visit to NIH on December 2

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:38 PM Eastern Standard Time
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
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From: "Jin, Daozhong (NIH/OD) [C]" </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=JINDAO>
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: Agenda for Bill Gates visit to NIH on December 2
Date: Mon, 25 Nov 2013 09:06:55 -0500
Importance: Normal

Thanks again for the information, Robert! I'm making sure to keep plenty of flexibility on Dr. Tabak's calendar for the visit, so there's no hurry, I'll keep an eye out of the itinerary whenever it is ready.

From: Eiss, Robert (NIH/FIC) [E]
Sent: Monday, November 25, 2013 9:03 AM
To: Jin, Daozhong (NIH/OD) [C]
Subject: RE: Agenda for Bill Gates visit to NIH on December 2

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Sent: Sunday, November 24, 2013 1:52 PM
To: Jin, Daozhong (NIH/OD) [C]
Subject: Fw: Agenda for Bill Gates visit to NIH on December 2

From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:38 PM Eastern Standard Time
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C];

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McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Agenda for Bill Gates visit to NIH on December 2

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To: "Jin, Daozhong (NIH/OD) [C]" [redacted]@nih.gov>
Subject: Fw: Agenda for Bill Gates visit to NIH on December 2
Date: Sun, 24 Nov 2013 13:51:54 -0500
Importance: Normal
Attachments: Mundel_&_Nikolic_BIOs.doc;
NIH_Briefing_on_Bill_and_Melinda_Gates_Foundation_Funding.doc;
Program_for_Visit_of_Bill_Gates_December_2_(3).docx; Wilson_Young_bios.docx

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From: Collins, Francis (NIH/OD) [E]
Sent: Sunday, November 24, 2013 12:38 PM Eastern Standard Time
To: Fauci, Anthony (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Insel, Thomas (NIH/NIMH) [E]; Green, Eric (NIH/NHGRI) [E]
Cc: Cantrel, Katherine (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Stover, Kathleen (NIH/FIC) [E]; Qiao, Mo (NIH/NIDCR) [C]; Brown, Crystal (NIH/NICHD) [C]; Wilkerson, Anita D. (NIH/NIDDK) [E]; Poole, Charlene (NIH/NIDDK) [E]; Brawley, David (NIH/NIDDK) [E]; Izzard, Tom (NIH/NIBIB) [C]; Finnegan, Sean (NIH/NCATS) [C]; Wiszneauckas, Joy (NIH/NCI) [E]; Togashi, Mieko (NIH/NCI) [E]; Wells, Connie (NIH/NHLBI) [E]; Earle, Melody (NIH/NHLBI) [E]; Sante, Annette (NIH/NHGRI) [C]; Rodela, Gloria (NIH/VRC) [E]; Suhana, Tina (NIH/VRC) [E]; Lebron, Janette (NIH/NIAID) [C]; McManus, Ayanna (NIH/OD) [E]; Eiss, Robert (NIH/FIC) [E]; Burklow, John (NIH/OD) [E]
Subject: Agenda for Bill Gates visit to NIH on December 2

Dear Colleagues,

I am delighted you are able to join the roundtable discussion and working lunch with Bill Gates on Monday, December 2, from 12:15 AM-1:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with Bill and other staff from the Global Health Program at the BMGF.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than a series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to discuss the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD); Trevor Mundel, President of the Global Health Program at the BMGF; Boris Nikolic, Scientific Advisor; and Kathy Young, Senior Project Manager for Strategic Planning and Engagement. Their bios are attached.

Please feel free to contact Rob Eiss at FIC [redacted] with any questions you or your staff may have surrounding the visit.

Released by Chairman Rand Paul

I'm delighted that Bill was able to reschedule so soon after the shutdown, and will remain on campus a good portion of the day to visit labs and hold discussions with senior leadership, in addition to the presenting the annual David Barmes Global Health lecture.

Best regards, Francis

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Jin, Daozhong (NIH/OD) [C]" [redacted]@nih.gov>
Subject: Fw: October 7 visit of Bill Gates
Date: Fri, 27 Sep 2013 06:34:26 -0400
Importance: Normal
Attachments: NIH_Visit_of_Bill_Gates_..docx; Wilson_Young_bios.docx

---

Dear Daozhong,

Attached is Dr Collins' note on the discussion roundtable with Bill Gates that Dr Tabak and Dr Hudson will join

---

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, September 26, 2013 10:17 PM Eastern Standard Time
To: Auchincloss, Hugh (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Glass, Roger (NIH/FIC) [E]; Guttmacher, Alan (NIH/NICHD) [E]; Germino, Gregory (NIH/NIDDK) [E]; Pettigrew, Roderic (NIH/NIBIB) [E]; Somerman, Martha (NIH/NIDCR) [E]; Austin, Christopher (NIH/NCATS) [E]; Varmus, Harold (NIH/NCI) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Goosby, Eric [redacted]@state.gov) [redacted]@state.gov>
Cc: Eiss, Robert (NIH/FIC) [E]; Wood, Gretchen (NIH/OD) [E]
Subject: October 7 visit of Bill Gates

Dear colleagues,

I am delighted you are able to join the roundtable discussion with Bill Gates on Monday, October 7, from 11:15 AM-12:30 PM, to take place in the Medical Board Room of the NIH Clinical Center. Attached is the program for the visit, outlining the agenda for the roundtable discussion. The topics are based on conversations with staff from the Global Health Program at the BMGF.

I had an opportunity to review the agenda briefly with Bill at the Lasker Awards ceremony (where he and Melinda received the Lakser~Bloomberg award) last week. He is very much looking forward to the discussion.

Based on Bill's preferences, we are organizing the roundtable as a conversation, rather than series of presentations. In order to make best use of available time, I have identified lead discussants for each agenda topic. I ask that you comment *briefly*, not to exceed 3 minutes, on one or several select scientific challenges of relevance to the BMGF: 1) the state of current knowledge and 2) the important questions to resolve. The comments would be intended to seed discussion. Unless you have compelling reasons to include powerpoints, I would suggest avoiding those for this informal conversation. I will try to ensure we cover as much of the agenda as feasible in the time available, while keeping flexible and responsive to Bill's interests and the flow of discussion.

Could I also ask lead discussants to confer with colleagues identified under their area, to discuss how to share the time allocated to introduce topics? Given Bill's extensive knowledge in global health R&D and scientific savvy, this format should work well and allow us to relate the diverse scope of exciting science surrounding global health.

Bill will be joined at the roundtable by Chris Wilson, Director of the Global Health Discovery & Translational Sciences program (and a member of the ACD), and Kathy Young, Senior Project Manager for Strategic Planning and Engagement in Bill's office. Their bios area attached.

We are delighted and honored that Eric Goosby (a former Barmes Lecturer) will join the roundtable. I am asking Eric to comment on the NIH/PEPFAR partnership in implementation science.

We will include a working lunch as part of the roundtable discussion Details on the lunch are forthcoming.

Released by Chairman Rand Paul

Prior to the discussion, we also will send a background summary of current IC (and FNIH) activities with the Gates Foundation.

Rob Eiss of the FIC has assisted with the planning and organization of this visit. Please feel free to contact Rob with any questions you or your staff may have surrounding the visit.

Best regards, Francis

Released by Chairman Rand Paul

Event: Breakfast Mtg. w/ Bill Gates

Start Date: 2011-09-13 07:00:00 -0400

End Date: 2011-09-13 08:00:00 -0400

Organizer: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Location: Four Seasons Hotel - Georgetown

Categories: ,Travel Required

Class: X-PERSONAL

Date Created: 2019-04-25 16:33:48 -0400

Date Modified: 2024-08-16 05:32:15 -0400

Priority: 5

Attach: 400.eml; 401.eml

Released by Chairman Rand Paul

From: Christine Turner [redacted]@bgc3.com>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Cc: Christine Turner [redacted]@bgc3.com>, Floramie Phillips [redacted]@gatesfoundation.org>, Beth McManus [redacted]@gatesfoundation.org>, Robert Rosen [redacted]@gatesfoundation.org>
Subject: RE: Bill Gates Meeting with Dr. Fauci
Date: Fri, 09 Sep 2011 16:31:16 -0400
Importance: Normal

7:00-8:00am would be fantastic. Would he be available to meet Bill at the Four Seasons?

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Friday, September 09, 2011 11:00 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

Sorry for the delay. Sept. 13 is pretty packed for us. Dr. Fauci would not be able to do late afternoon but he can be available between 10 am - 12 noon or for an early breakfast at 7 or 7:30 am perhaps?

Fingers crossed one of these times may work but I understand if it can't....

Thanks
-patty

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Thursday, September 08, 2011 2:03 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patricia.

Understand completely.

One last attempt for the 13th. Would anytime between 3:00-5:00pm work? If not, I will get back to you about time on October 18 that does not interfere with the Malaria Summit. Many thanks.

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Thursday, September 08, 2011 9:26 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

Unfortunately Dr. Fauci has a dinner that evening with former President Bush which has been on his calendar for quite some time. I am sorry we could not make this work. Dr. Fauci is scheduled to be in Seattle at the Malaria Forum on October 18th. Perhaps they can have the meeting then.

Released by Chairman Rand Paul

Again, sorry and hopefully we can schedule this sometime soon.

Best,
-patty

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Wednesday, September 07, 2011 5:49 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patty,

Sorry for the delay on this. Bill will be at the Capitol all day Tuesday. Would a dinner with Dr. Fauci be an option - somewhere in the vicinity of the Capitol?

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Friday, September 02, 2011 11:30 AM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Christine Turner; Floramie Phillips; Beth McManus
Subject: Re: Bill Gates Meeting with Dr. Fauci

Christine:
Just touching base to see if you had anything further on a possible meeting on September 13th. Let me know when you can. Thanks.
-patty.

Sent from my iPhone

On Aug 18, 2011, at 12:11 PM, "Conrad, Patricia (NIH/NIAID) [E]"
[redacted]@niaid.nih.gov<mailto [redacted]@niaid.nih.gov>> wrote:

Hi Christine:

Dr. Fauci is in an all-day meeting that day as well. He may be able to step out of his meeting to meet with Mr. Gates but it would depend on where you would want them to meet. Can you tell me what address/location would be and then I can see if a late afternoon meeting would be possible. Sorry that this is such a challenge – I will do my best to see if we can make this happen. I am thinking around 4 pm but again, it will depend on the location.

Let me know and thanks for your patience and flexibility.

Best,
Patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Wednesday, August 17, 2011 2:49 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patricia – many thanks for your response.

Released by Chairman Rand Paul

Bill will now be in DC on September 13. Would Dr. Fauci happen to have some time available late that afternoon for a meeting? If not, I will get back to you regarding the October possibility.

Many thanks -Christine

From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Monday, August 15, 2011 9:59 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

So sorry for the delay in getting back to you – I was out of the office for most of last week. Unfortunately September is quite busy for Dr. Fauci and he will not be able to make a trip out west. If that changes I will let you know but it is very unlikely. Having said that – Dr. Fauci will be at the Gates Fdn Malaria Forum in Seattle on October 18th – I believe he is speaking at that meeting. I am not sure exactly when he will be able to fly into Seattle but perhaps we can have something work out then. Let me know if you think that October date may work.

Thanks and I look forward to hearing from you.

-patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Wednesday, August 10, 2011 5:50 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: Bill Gates Meeting with Dr. Fauci

Hello Patricia,

I have been given your name as best contact to see about scheduling a date that Dr. Fauci might be able to make a trip to Seattle to meet with Bill Gates.

Mr. Gates does have an upcoming trip to DC on September 13, but is in an all-day meeting then. His next trip after that to DC is not until the end of October and I know Mr. Gates would love to have the meeting sooner than that, in Seattle, if at all possible.

Please let me know if any of the following might work:

Thursday, September 1
Tuesday, September 6
Wednesday, September 7
Thursday, September 8
Friday, September 9
Wednesday, September 14
Friday, September 16

Many thanks for the consideration.

Christine Turner
Executive Assistant to Bill Gates
[redacted]

Released by Chairman Rand Paul

From: Christine Turner [redacted]@bgc3.com>
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Floramie Phillips [redacted]@gatesfoundation.org>, Beth McManus [redacted]@gatesfoundation.org>, Robert Rosen [redacted]@gatesfoundation.org>, Chris Presley [redacted]@bgc3.com>, Christine Turner [redacted]@bgc3.com>
Subject: RE: Bill Gates Meeting with Dr. Fauci
Date: Fri, 09 Sep 2011 16:49:57 -0400
Importance: Normal

Patricia,

Thank YOU for your patience in getting this scheduled.

Bill is so looking forward to this meeting. Chris Presley will be on the ground with Bill so providing his cell phone for best contact that morning.

[redacted] Chris Presley, Cell

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Friday, September 09, 2011 1:48 PM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Success! Dr. Fauci will be in the Lobby of the Four Seasons in Georgetown at 7:00 am. Can you please send me a cell number - for emergent purposes only. Dr. Fauci's cell number is [redacted] and mine is [redacted] in case you need a back up.

So glad we could work this out.

Best regards,

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Friday, September 09, 2011 4:31 PM
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Fingers crossed one of these times may work but I understand if it can't....

Thanks
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Special Assistant to the Director

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Hi Patricia.

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Released by Chairman Rand Paul

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Subject: RE: Bill Gates Meeting with Dr. Fauci

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Special Assistant to the Director

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Sent: Wednesday, August 10, 2011 5:50 PM
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Released by Chairman Rand Paul

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Friday, September 9
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Friday, September 16

Many thanks for the consideration.

Christine Turner
Executive Assistant to Bill Gates
[redacted]>

Released by Chairman Rand Paul

From: "Inglesby, Thomas" [redacted]@upmc-biosecurity.org>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Subject: Invitation to Oct 4 Biosecurity Event in DC
Date: Thu, 23 Jun 2011 17:30:40 -0400
Importance: Normal

Dear Tony,

Hope you are well. Belated congratulations for your superb performance on Colbert. I saw it just recently, and you really held your own and were good.

I wanted to invite you to speak at a meeting we are holding called: ***Ten Years After Anthrax: The Greatest Challenges Ahead for Biosecurity.*** Its being held on the **afternoon of October 4 in Washington DC.** In small part it will be to reflect on the state of US biosecurity at the 10 yr anniversary of the anthrax attacks. But for the most part it will be to look forward at the biosecurity policy agenda in the years ahead. We will ask leaders to think ambitiously about the future of biosecurity, and give their views regarding what needs to be done to make progress in the years ahead.

Speakers who are now confirmed**: Senator Daschle, Senator Talent, Tara O'Toole, Richard Danzig**, **Andy Weber, George Poste, Heidi Avery, Tom Frieden, and Jeanne Meserve from CNN.** We've also invited **Peggy Hamburg, Craig Venter, Bill Gates** and a few others. It will be a distinguished group, and we expect about 125 attendees.

Its being held at the **W Hotel** in downtown Washington.

Let me know if you can join us.

All the best
Tom

Released by Chairman Rand Paul

From: [redacted]@niaid.nih.gov
To: Greg Folkers [redacted]@niaid.nih.gov>, Patty Conrad [redacted]@niaid.nih.gov>
Subject: Fwd: Invitation to Oct 4 Biosecurity Event in DC
Date: Thu, 23 Jun 2011 22:56:10 -0400
Importance: Normal

Let us discuss. In dc; good cast. What do you think?

Sent from my iPad

Begin forwarded message:

From: "Inglesby, Thomas" [redacted]@upmc-biosecurity.org>
Date: 23 Jun 2011 05:30:40 PM EDT
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Invitation to Oct 4 Biosecurity Event in DC

Dear Tony,

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Its being held at the **W Hotel** in downtown Washington.

Let me know if you can join us.

All the best

Tom

Released by Chairman Rand Paul

From: Rick Klausner [redacted]@thecolumngroup.net>
To: Harold Varmus [redacted]@nih.gov>, Bruce Alberts [redacted]@ucsf.edu>, Tony Fauci [redacted]@NIH.GOV>, Marc Kirschner [redacted]@hms.harvard.edu>, Kai Simons [redacted]@mpi-cbg.de>, Elias Zerhouni [redacted]@sanofi-aventis.com>, Mike Brown [redacted]@UTSouthwestern.edu>, David Baltimore [redacted]@caltech.edu>, "Eric Lander" [redacted]@broadinstitute.org>, President [redacted]@royalsociety.org>, Mark Walport [redacted]@wellcome.ac.uk>, Bill Gates [redacted]@bgc3.com>, "Raj Shah" [redacted]@usaid.gov>, Robert Tjian [redacted]@berkeley.edu>
Subject: amazing daily show clip: CAUGHT - The Truth About Science
Date: Sat, 29 Oct 2011 10:12:31 -0400
Importance: Normal

---

an in depth investigation of science in America. Enjoy!

http://www.thedailyshow.com/watch/wed-october-26-2011/weathering-fights---science---what-s-it-up-to-

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Grady, Christine (NIH/CC/BEP) [E]" [redacted]@cc.nih.gov>
Subject: RE: amazing daily show clip: CAUGHT - The Truth About Science
Date: Sat, 29 Oct 2011 14:49:12 -0400
Importance: Normal

Depends on what you mean by "for real". She is a Republican strategist and consultant who has worked ad hoc for various Republican candidates.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Grady, Christine (NIH/CC/BEP) [E]
Sent: Saturday, October 29, 2011 2:46 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: amazing daily show clip: CAUGHT - The Truth About Science

Is Noelle Nikpour for real??

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Saturday, October 29, 2011 1:29 PM
To: 'Megan Fauci'; Grady, Christine (NIH/CC/BEP) [E]; 'Jenny Fauci'; 'Ali Fauci'
Subject: FW: amazing daily show clip: CAUGHT - The Truth About Science

This is hysterical!

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

an in depth investigation of science in America. Enjoy!

http://www.thedailyshow.com/watch/wed-october-26-2011/weathering-fights---science---what-s-it-up-to-

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Fwd: Bill Gates Meeting with Dr. Fauci
Date: Wed, 10 Aug 2011 18:13:19 -0400
Importance: Normal

Let us discuss.

Sent from my iPhone

Begin forwarded message:

From: Christine Turner [redacted]@bgc3.com>
Date: August 10, 2011 5:50:13 PM EDT
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Floramie Phillips [redacted]@gatesfoundation.org>, Beth McManus [redacted]@gatesfoundation.org>, Christine Turner [redacted]@bgc3.com>
Subject: Bill Gates Meeting with Dr. Fauci

Hello Patricia,

I have been given your name as best contact to see about scheduling a date that Dr. Fauci might be able to make a trip to Seattle to meet with Bill Gates.

Mr. Gates does have an upcoming trip to DC on September 13, but is in an all-day meeting then. His next trip after that to DC is not until the end of October and I know Mr. Gates would love to have the meeting sooner than that, in Seattle, if at all possible.

Please let me know if any of the following might work:

Thursday, September 1

Tuesday, September 6

Wednesday, September 7

Thursday, September 8

Friday, September 9

Wednesday, September 14

Friday, September 16

Released by Chairman Rand Paul

From: [redacted]@niaid.nih.gov
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: Bill Gates Meeting with Dr. Fauci
Date: Wed, 10 Aug 2011 23:35:29 -0400
Importance: Normal

Ok. Let us Discuss next week. I will be in Seattle twice inthe next 2 months,but i willnot make a special trip to Seattle just to see him.

Sent from my iPad

On 10 Aug 2011, at 04:13 PM, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov> wrote:

Let us discuss.

Sent from my iPhone

Begin forwarded message:

From: Christine Turner [redacted]@bgc3.com>
Date: August 10, 2011 5:50:13 PM EDT
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Floramie Phillips [redacted]@gatesfoundation.org>, Beth McManus [redacted]@gatesfoundation.org>, Christine Turner [redacted]@bgc3.com>
Subject: Bill Gates Meeting with Dr. Fauci

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Mr. Gates does have an upcoming trip to DC on September 13, but is in an all-day meeting then. His next trip after that to DC is not until the end of October and I know Mr. Gates would love to have the meeting sooner than that, in Seattle, if at all possible.

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Thursday, September 1

Tuesday, September 6

Released by Chairman Rand Paul

Wednesday, September 7

Thursday, September 8

Friday, September 9

Wednesday, September 14

Friday, September 16

Many thanks for the consideration.

Christine Turner

Executive Assistant to Bill Gates

[redacted]

[redacted]

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Fwd: Bill Gates Meeting with Dr. Fauci
Date: Wed, 07 Sep 2011 18:52:39 -0400
Importance: Normal

Oy... You have the bush dinner.

Sent from my iPhone

Begin forwarded message:

From: Christine Turner [redacted]@bgc3.com>
Date: September 7, 2011 5:49:27 PM EDT
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Floramie Phillips [redacted]@gatesfoundation.org>, Beth McManus [redacted]@gatesfoundation.org>, Christine Turner [redacted]@bgc3.com>
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patty,

Sorry for the delay on this. Bill will be at the Capitol all day Tuesday. Would a dinner with Dr. Fauci be an option - somewhere in the vicinity of the Capitol?

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Friday, September 02, 2011 11:30 AM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Christine Turner; Floramie Phillips; Beth McManus
Subject: Re: Bill Gates Meeting with Dr. Fauci

Christine:
Just touching base to see if you had anything further on a possible meeting on September 13th. Let me know when you can. Thanks.
-patty.

Sent from my iPhone

On Aug 18, 2011, at 12:11 PM, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov<mailto [redacted]@niaid.nih.gov>> wrote:

Hi Christine:

Dr. Fauci is in an all-day meeting that day as well. He may be able to step out of his meeting to meet with Mr. Gates but it would depend on where you would want them to meet. Can you tell me what address/location would be and then I can see if a late afternoon meeting would be possible. Sorry that this is such a challenge – I will do my best to see if we can make this happen. I am thinking around 4 pm but again, it will depend on the location.

Released by Chairman Rand Paul

Let me know and thanks for your patience and flexibility.

Best,
Patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Wednesday, August 17, 2011 2:49 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patricia – many thanks for your response.

Bill will now be in DC on September 13. Would Dr. Fauci happen to have some time available late that afternoon for a meeting? If not, I will get back to you regarding the October possibility.

Many thanks -Christine

From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Monday, August 15, 2011 9:59 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

So sorry for the delay in getting back to you – I was out of the office for most of last week. Unfortunately September is quite busy for Dr. Fauci and he will not be able to make a trip out west. If that changes I will let you know but it is very unlikely. Having said that – Dr. Fauci will be at the Gates Fdn Malaria Forum in Seattle on October 18th – I believe he is speaking at that meeting. I am not sure exactly when he will be able to fly into Seattle but perhaps we can have something work out then. Let me know if you think that October date may work.

Thanks and I look forward to hearing from you.

-patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Wednesday, August 10, 2011 5:50 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: Bill Gates Meeting with Dr. Fauci

Hello Patricia,

I have been given your name as best contact to see about scheduling a date that Dr. Fauci might be able to make a trip to Seattle to meet with Bill Gates.

Released by Chairman Rand Paul

Mr. Gates does have an upcoming trip to DC on September 13, but is in an all-day meeting then. His next trip after that to DC is not until the end of October and I know Mr. Gates would love to have the meeting sooner than that, in Seattle, if at all possible.

Please let me know if any of the following might work:

Thursday, September 1
Tuesday, September 6
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Thursday, September 8
Friday, September 9
Wednesday, September 14
Friday, September 16

Many thanks for the consideration.

Christine Turner
Executive Assistant to Bill Gates
[redacted]

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Aviles, Ricardo (NIH/NIAID) [C]" [redacted]@niaid.nih.gov>
Cc: "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Bill Gates Meeting with Dr. Fauci
Date: Fri, 09 Sep 2011 16:49:07 -0400
Importance: Normal

FYI - I added this to the calendar. Sept 13.

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E]
Sent: Friday, September 09, 2011 4:48 PM
To: 'Christine Turner'
Cc: Floramie Phillips; Beth McManus; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Success! Dr. Fauci will be in the Lobby of the Four Seasons in Georgetown at 7:00 am. Can you please send me a cell number - for emergent purposes only. Dr. Fauci's cell number is [redacted] and mine is [redacted] in case you need a back up.

So glad we could work this out.

Best regards,

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto [redacted]@bgc3.com]
Sent: Friday, September 09, 2011 4:31 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Christine Turner; Floramie Phillips; Beth McManus; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

7:00-8:00am would be fantastic. Would he be available to meet Bill at the Four Seasons?

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto [redacted]@niaid.nih.gov]
Sent: Friday, September 09, 2011 11:00 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

Sorry for the delay. Sept. 13 is pretty packed for us. Dr. Fauci would not be able to do late afternoon but he can be available between 10 am - 12 noon or for an early breakfast at 7 or 7:30 am perhaps?

Fingers crossed one of these times may work but I understand if it can't....

Thanks

Released by Chairman Rand Paul

-patty

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto[redacted]@bgc3.com]
Sent: Thursday, September 08, 2011 2:03 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner; Robert Rosen
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patricia.

Understand completely.

One last attempt for the 13th. Would anytime between 3:00-5:00pm work? If not, I will get back to you about time on October 18 that does not interfere with the Malaria Summit. Many thanks.

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto[redacted]@niaid.nih.gov]
Sent: Thursday, September 08, 2011 9:26 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

Unfortunately Dr. Fauci has a dinner that evening with former President Bush which has been on his calendar for quite some time. I am sorry we could not make this work. Dr. Fauci is scheduled to be in Seattle at the Malaria Forum on October 18th. Perhaps they can have the meeting then.

Again, sorry and hopefully we can schedule this sometime soon.

Best,
-patty

Patricia L. Conrad
Special Assistant to the Director

-----Original Message-----
From: Christine Turner [mailto[redacted]@bgc3.com]
Sent: Wednesday, September 07, 2011 5:49 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patty,

Sorry for the delay on this. Bill will be at the Capitol all day Tuesday. Would a dinner with Dr. Fauci be an option - somewhere in the vicinity of the Capitol?

-----Original Message-----
From: Conrad, Patricia (NIH/NIAID) [E] [mailto[redacted]@niaid.nih.gov]
Sent: Friday, September 02, 2011 11:30 AM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Christine Turner; Floramie Phillips; Beth McManus
Subject: Re: Bill Gates Meeting with Dr. Fauci

Christine:

Released by Chairman Rand Paul

Just touching base to see if you had anything further on a possible meeting on September 13th. Let me know when you can. Thanks.
-patty.

Sent from my iPhone

On Aug 18, 2011, at 12:11 PM, "Conrad, Patricia (NIH/NIAID) [E]"
[redacted]@niaid.nih.gov<mailto[redacted]@niaid.nih.gov>> wrote:

Hi Christine:

Dr. Fauci is in an all-day meeting that day as well. He may be able to step out of his meeting to meet with Mr. Gates but it would depend on where you would want them to meet. Can you tell me what address/location would be and then I can see if a late afternoon meeting would be possible. Sorry that this is such a challenge – I will do my best to see if we can make this happen. I am thinking around 4 pm but again, it will depend on the location.

Let me know and thanks for your patience and flexibility.

Best,
Patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto[redacted]@bgc3.com]
Sent: Wednesday, August 17, 2011 2:49 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Patricia – many thanks for your response.

Bill will now be in DC on September 13. Would Dr. Fauci happen to have some time available late that afternoon for a meeting? If not, I will get back to you regarding the October possibility.

Many thanks -Christine

From: Conrad, Patricia (NIH/NIAID) [E] [mailto[redacted]@niaid.nih.gov]
Sent: Monday, August 15, 2011 9:59 AM
To: Christine Turner
Cc: Floramie Phillips; Beth McManus
Subject: RE: Bill Gates Meeting with Dr. Fauci

Hi Christine:

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Thanks and I look forward to hearing from you.

-patty

Patricia L. Conrad
Special Assistant to the Director

From: Christine Turner [mailto[redacted]@bgc3.com]
Sent: Wednesday, August 10, 2011 5:50 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Cc: Floramie Phillips; Beth McManus; Christine Turner
Subject: Bill Gates Meeting with Dr. Fauci

Hello Patricia,

Released by Chairman Rand Paul

I have been given your name as best contact to see about scheduling a date that Dr. Fauci might be able to make a trip to Seattle to meet with Bill Gates.

Mr. Gates does have an upcoming trip to DC on September 13, but is in an all-day meeting then. His next trip after that to DC is not until the end of October and I know Mr. Gates would love to have the meeting sooner than that, in Seattle, if at all possible.

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Thursday, September 1
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Thursday, September 8
Friday, September 9
Wednesday, September 14
Friday, September 16

Many thanks for the consideration.

Christine Turner
Executive Assistant to Bill Gates
[redacted]

Released by Chairman Rand Paul

From: "Clifton, Dawn (NIH/NIAID) [E]" [redacted]@nih.gov>
To: NIAID LIR Senior Staff [redacted]@niaid.nih.gov>
Cc: "Clifton, Dawn (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Please respond by 1/5 Request for Outside Organization Affiliations for NIAID Director
Date: Mon, 03 Jan 2022 11:32:52 -0500
Importance: High
Attachments: NIAID_Director_Council_Recusal_List_without_MTAs_2022_Oct_signed.pdf; NIAID_Director_Council_Recusal_List_without_MTAs_2022_Oct.doc; LIR_Pending_Agreements_2021_12_23.xlsx; LIR_Active_Agreements_2021_12_23.xlsx

---

Dear PIs, it is time to provide updates of any collaborations or activities with outside organizations that could result in a real or apparent conflict of interest for Dr. Fauci, but that hasn't yet been brought to TTIPO's attention.

Please review the attached documents, which include a list from TTIPO. **If you have an activity or collaboration that is not yet included, please reply to me with the name of the institution, the nature of the relationship, and the duration of the activity.**

NIH 2400-04 Managing Conflicts of Interests and the Introduction of Bias gives additional guidance on real and apparent conflicts of interest.

Thank you,
Dawn

Released by Chairman Rand Paul

CHAIRPERSON'S RECUSAL LIST

Date of Council Meeting: September 13, 2021
Name of Chairperson: Anthony S. Fauci, M.D.

By law, you are prohibited from participating in Council/Committee discussions or actions on or relating to any specific party matter involving or affecting any of the following entities:

Name of Entity	**Nature of Interest or Relationship**	**Expiration Date**
FINANCIAL INTERESTS		n/a
None		
COVERED RELATIONSHIPS		
Ongoing Collaborations and Co-Publications		
American Association of Blood Banks		n/a
Northwestern University		ongoing
Northwestern University-Chicago		ongoing
University of Minnesota-Rochester		ongoing
University of Minnesota-Duluth		ongoing
University of Minnesota-Morris		ongoing
University of Minnesota-Twin Cities		ongoing
Duke University		ongoing
University of Washington/FHCRC		ongoing
University of Louisville		ongoing
Cornell Medical School		ongoing
Temple University		ongoing
Thomas Jefferson University		ongoing
Georgia State University		ongoing
Pfizer		2024
University of Washington		2024
Novartis		2024
Evryes Bio		2024
Gilead Sciences		2024
Vanderbilt University		2024

Released by Chairman Rand Paul

Scripps	2024
University of Alberta [Canada]	2024
University of Virginia	2024
Merck & Co	2024
Walter Reed Army Institute of Research	2024
Purdue University	2024
University of Alabama	2024
1910 Genetics Inc	2024
Evotec [France]	2024
Takeda California	2024
University of Texas Medical School	2024
University of Texas	2024
Arbutus Biopharma	2024
PTC Therapeutics	2024
University of Connecticut	2024
Institute for Bioscience and Biotechnology	2024
University of North Carolina Chapel Hill	2024
University of Massachusetts Medical School	2024
Emory University	2024
University of Pennsylvania	2024
University of Nebraska Medical Center	2024
Rockefeller University	2024
Centre for the AIDS Programme of Research in South Africa (CAPRISA)	2023
Icahn School of Medicine at Mount Sinai	2023
Nat'l Inst. for Communicable Diseases of the Nat'l Health Lab. Service (SA)	2023
Instituto Nacional de Câncer	2023
Universidade Federal do Rio de Janeiro (Brazil)	2023
Fred Hutchinson Cancer Research Center	2023
Washington University	2023
Frederick National Laboratory for Cancer Research	2023
Georgetown University	2023
Emory School of Medicine	2023
Duke University	2023
Yale University School of Medicine	2022
AIDS Vaccine Advocacy Coalition	2022
Bridge HIV	2022
Swiss Vaccine Research Institute [Switzerland]	2022
University of Lausanne [Switzerland]	2022
Vaccine Research Institute [France]	2022
Chinese Center for Disease Control and Prevention [China]	2022
European and Developing Countries Clinical Trials Partnership [Netherlands]	2022
International Vaccine Institute [South Korea]	2022
South African Medical Research Council	2022
Africa Health Research Institute	2022

Released by Chairman Rand Paul

University of KwaZulu-Natal [South Africa]	2022
Uganda Virus Research Institute [Uganda]	2022
Treatment Action Group	2022
France Recherche Nord and Sud Sida-HIV Hépatites [France]	2022
International Aids Society	2022
International Aids Vaccine Initiative, Inc.	2022
University of Witwatersrand [South Africa]	2022
London School of Hygiene and Tropical Medicine [UK]	2022
University of Cape Town [South Africa]	2022
World Health Organization	2022
Bill & Melinda Gates Foundation	2022
Imperial College London [UK]	2022
Aaron Diamond AIDS Research Center (ADARC)	2022
Tulane University	2022
University of Louisiana Lafayette	2022
Center of Biomedical Research, Population Council	2022
University of Maryland (Baltimore)	2022
Stop TB Partnership	2022
The Wellcome Trust	2022
Volunteer Health Services [Ethiopia]	2022
International Union Against Tuberculosis and Lung Disease [France]	2022
Treatment Action Group	2022
Houses of Parliament [UK]	2022
Ministry of Health, Labor and Welfare [Japan]	2022
Interactive Research & Development [Pakistan]	2022
Resource Group for Education and Advocacy for Community Health [India]	2022
South African National Department of Health [South Africa]	2022
University of Milan [Italy]	2022
University of Geneva [Switzerland]	2022
Academy of Preventive Medicine of Kazakhstan [Kazakhstan]	2022
Stony Brook University	2022
Mayo Clinic	2022
University of Amsterdam [Netherlands]	2022
The Economic Times [India]	2022
KNCV Tuberculosis Foundation [Netherlands]	2022
Institutul de Ftiziopneumologie Chiril Draganiuc [Moldova]	2022
The Center for Health Policies and Studies [Moldova]	2022
University of Hawaii	2022
Case Western Reserve University	2022
University of Melbourne [Australia]	2022
Burnet Institute [Australia]	2022
Kenyan Ministry of Health [Kenya]	2022
General TB control [India]	2022
United Nations [Switzerland]	2022

Released by Chairman Rand Paul

Erasmus University Rotterdam [Netherlands]	2022
The Graduate Institute Geneva [Switzerland]	2022
Linksbridge	2022
McGill University [Canada]	2022
Ministry of Health and Family Welfare [India]	2022
United Nations University [Malaysia]	2022
Revised National TB Control Program [India]	2022
United States Agency for International Development	2022
Harvard University	2022
Foundation for Innovative New Diagnostics [Switzerland]	2022
Johns Hopkins University (School of Medicine)	2022
The Aurum Institute [South Africa]	2022
Stanford University	2022
Maple Leaf HIV Medical Research Collaborative, Inc [Canada]	2022
University of California (San Francisco)	2022
Mahidol University [Thailand]	2021
University of Witwatersrand [South Africa]	2021
New York University School of Medicine	2021
Harvard Medical School	2021
Pedro Kourí Tropical Medicine Institute (IPK) [Cuba]	2021
National Cancer Institute / Instituto Nacional de Câncer [Brazil]	2021
Universidade Federal do Rio de Janeiro / Federal Univ. of Rio de Janeiro [Brazil]	2021

Agreements

Aelix Therapeutics	Pending
Boston College	Pending
American Gene Technologies International, Inc.	Pending
Celltrion, Inc.	Pending
Centro de Investigación en Enfermedades Infecciosas	Pending
Children's National Medical Center (CNMC) [US]	Pending
China National Biotec Group Company Limited [China]	Pending
Dartmouth College	Pending
Emory University	Pending
Fred Hutchinson Cancer Research Center	Pending
George Washington University (GWU)	Pending
Immunitybio, Inc.	Pending
Instituto D'Or de Pesquisa e Ensino (IDOR)	Pending
Joan & Sanford I. Weill Medical College of Cornell University	Pending
Makerere University [UG]	Pending
Maple Leaf Medical Clinic	Pending
Ministry of Health of Indonesia [Indonesia]	Pending
NeoImmunetech, Inc.	Pending
Pfizer, Inc.	Pending

Rakai Health Sciences Program [US]	Pending
Rockefeller University	Pending
RNAceuticals, Inc.	Pending
Sanofi U.S. Services Inc.	Pending
SIGA Technologies, Inc	Pending
Simon Fraser University [CA]	Pending
Springer Nature Switzerland AG [Switzerand]	Pending
ViiV Healthcare UK (No.6) Ltd [GB]	Pending
Viro-Gen LTD.	Pending
Western University	Pending
Yale University	Pending

A.C. Camargo Cancer Center	5/10/2022
AbbVie Inc.	10/9/2024
Adamas Pharmaceuticals, Inc	Active
American Gene Technologies International, Inc	1/29/2023
Arbutus Biopharma Corporation [Canada]	Active
AstraZeneca Pharmaceuticals LP	Active
Bavarian Nordic A/S [Denmark]	Active
Baxalta US, Inc	Active
Beneficia Portuguesa de Sao Paulo [Brazil]	5/10/2022
Beth Israel Deaconess Medical Center (BIDMC)	Active
Bill & Melinda Gates Foundation (BMGF)	12/31/2023
BIOLEGEND	11/14/2022
Bioverativ (f.k.a. True North Therapeutics)	2/17/2022
Brii Biosciences (Beijing) Co Ltd [China]	Active
Bristol-Myers Squibb Company (BMS)	Active
California Institute for Regenerative Medicine (CIRM)	Active
Celgene Corporation	Active
Cerus Corporation	Active
Charles River Laboratories, Inc.	9/29/2023
Columbia University	Active
Columbia University Irving Medical Center	11/9/2021
Crucell Vaccines Institute	Active
CSL Behring	Active
Dartmouth College	2/11/2026
District of Columbia Department of Health (DC DOH)	Active
Eli Lilly and Company	Active
Elsevier	Active
EMD Serono Research & Development Institute	Active
Emergent BioSolutions Canada Inc. [Canada]	3/18/2022
Emergent BioSolutions Inc.	Active
Emory University	5/9/2024
Excision Biotherapeutics	2/22/2026

Released by Chairman Rand Paul

Fred Hutchinson Cancer Research Center (FHCRC)	11/8/2024
French Institute of Health and Medical Research (INSERM) [France]	Active
Gilead Sciences, Inc.	Active
GlaxoSmithKline Biologicals SA (GSK Biologicals) [Belgium]	Active
Glaxosmithkline Intellectual Property Limited	Active
GlaxoSmithKline PLC (GSK) [GB]	Active
Global Solutions for Infectious Diseases	Active
GlobImmune, Inc	Active
Grifols Shared Services North America, Inc.	Active
Grifols Therapeutics LLC	Active
HCor Research Institute	4/7/2022
Hospital Baía Sul	5/10/2022
Hospital de Base de São José do Rio Preto	5/10/2022
Hospital e Maternidade Sepaco	5/10/2022
Hospital Moinhos de Vento	5/10/2022
Hospital Naval Marcílio Dias	5/10/2022
Hospital Nereu Ramos	5/10/2022
Hospital São José	5/10/2022
Hospital São Paulo	5/10/2022
Hospital Unimed Vitória	5/10/2022
Incyte Corporation	4/27/2022
Institut Pasteur Korea [South Korea]	11/3/2025
Institute for Advanced Study	Active
International AIDS Vaccine Initiative, Inc. (IAVI)	Active
International Medical Corps (IMC)	Active
Janssen Vaccines & Prevention B.V.	Active
JoMoCo. Inc	1/30/2023
Just Biotherapeutics	4/10/2024
Kansas State University	6/30/2024
Laboratory Corporation of America Holdings (LabCorp)	Active
Leidos Biomedical Research, Inc.	9/12/2021
London School of Hygiene & Tropical Medicine (LSHTM) [GB]	Active
MAPP Biopharmaceutical, Inc.	Active
Massachusetts General Hospital (MGH)	Active
MedImmune, LLC.	Active
Merck Research Laboratories	Active
Merck Sharp & Dohme Corp	Active
Merck Sharp and Dohme Research Labs.	Active
Millennium Pharmaceuticals, Inc.	Active
Millipore Sigma	5/29/2025
Ministry of Health (MOH), Democratic Republic of Congo [DRC]	6/28/2024
ModernaTX, Inc.	4/9/2022
Molecular Partners AG	Active
National Institute of Biomedical Research (INRB) [DRC]	Active

NeoImmunetech, Inc.	Active
NeuroRx	Active
NewLink Genetics Corporation	Active
NexBio, Inc	Active
Novartis Pharma AG	10/9/2022
PATH (Program for Appropriate Technology in Health)	11/8/2024
PaxVax, Inc.	Active
Pfizer	Active
PGEN Therapeutics, Inc.	4/20/2025
Precigen, Inc	4/20/2025
Profectus Biosciences, Inc.	Active
Quintiles	Active
Regeneron Pharmaceuticals, Inc.	9/26/2022
Retrogenix	9/21/2021
Ridgeback Biotherapeutics	5/9/2024
Rockefeller University	Active
Romark Laboratories, L.C.	Active
SAB Botherapeutics, Inc.	Active
SAGE Pulications LTD	Active
Sanofi US Services Inc.	10/18/2022
Santa Cruz Biotechnology, Inc.	11/9/2026
Science Magazine	9/12/2021
Senhwa Biosciences	4/23/2022
Springer Nature Limited	Active
TaiMed Biologics USA	Active
TAKEDA Pharmaceutical Company, LTD [Japan]	Active
Tandem Labs	Active
Teva Pharmaceuticals	3/16/2026
The Scripps Research Institute (TSRI)	4/24/2042
Theravance, Inc.	3/25/2022
Tobira Therapeutics	Active
United BioPharma, Inc.	Active
Univercells	4/15/2024
Universidade de Marília	5/10/2022
University of Florida	Active
University of Kansas	9/12/2021
University of Maryland	Active
University of Maryland, Baltimore	Active
University of Washington	Active
Vigene Biosciences, Inc.	7/6/2023
ViiV Healthcare UK Ltd [GB]	Active
Vir Biotechnology, Inc. (VirBio)	Active
Weird Science, LLC	Active
Wistar Institute	11/8/2024

Released by Chairman Rand Paul

Yale University 12/10/2021

OUTSIDE ACTIVITIES

McGraw-Hill Publishing	ongoing
Doris Duke Charitable Foundation	ongoing

AWARDS/HONORARY DEGREES

National Academy of Public Administration	2024
Dan David Foundation	2024
College of William & Mary	2024
McGill University	2024
University of North Carolina	2024
Mayo Clinic	2024
City College of NY	2024
University of Pennsylvania	2024
Tel Aviv University	2024
Partnership for Public Service	2024
Rensselaer Polytechnic University	2024
Bowdoin College	2024
Rockefeller University	2024
Charles R. Drew University of Medicine and Science	2024
University of North Carolina	2024
Smithsonian Institution	2024
American Association for the Advancement of Science (AAAS)	2024
National Academies of Medicine	2024
Emory University	2024
Tufts University	2024
Vanderbilt University	2024
American University	2021
Boston University	2021

You are permitted to participate in general matters discussed in either open or closed sessions involving or affecting any of the above parties.

We have reviewed all other disclosures you have made, and have determined that such interests, holdings and relationships do not pose a conflict of interest or an appearance of a conflict of interest.

Released by Chairman Rand Paul

Prepared by: Andrea L. Wurster -S Digitally signed by Andrea L. Wurster -S Date: 2021.08.26 07:29:47 -04'00' Date: _____
Director, OERPO, DEA, NIAID

Approved by: Matthew J. Fenton -S Digitally signed by Matthew J. Fenton -S Date: 2021.08.26 10:56:41 -04'00' Date: _____
Director, DEA, NIAID

Released by Chairman Rand Paul

CHAIRPERSON'S RECUSAL LIST

Date of Council Meeting: September 13, 2021
Name of Chairperson: Anthony S. Fauci, M.D.

By law, you are prohibited from participating in Council/Committee discussions or actions on or relating to any specific party matter involving or affecting any of the following entities:

Name of Entity	**Nature of Interest or Relationship**	**Expiration Date**
FINANCIAL INTERESTS		n/a
None		
COVERED RELATIONSHIPS		
Ongoing Collaborations and Co-Publications		
American Association of Blood Banks		n/a
Northwestern University		ongoing
Northwestern University-Chicago		ongoing
University of Minnesota-Rochester		ongoing
University of Minnesota-Duluth		ongoing
University of Minnesota-Morris		ongoing
University of Minnesota-Twin Cities		ongoing
Duke University		ongoing
University of Washington/FHCRC		ongoing
University of Louisville		ongoing
Cornell Medical School		ongoing
Temple University		ongoing
Thomas Jefferson University		ongoing
Georgia State University		ongoing
Pfizer		2024
University of Washington		2024
Novartis		2024
Evryes Bio		2024
Gilead Sciences		2024
Vanderbilt University		2024

Scripps	2024
University of Alberta [Canada]	2024
University of Virginia	2024
Merck & Co	2024
Walter Reed Army Institute of Research	2024
Purdue University	2024
University of Alabama	2024
1910 Genetics Inc	2024
Evotec [France]	2024
Takeda California	2024
University of Texas Medical School	2024
University of Texas	2024
Arbutus Biopharma	2024
PTC Therapeutics	2024
University of Connecticut	2024
Institute for Bioscience and Biotechnology	2024
University of North Carolina Chapel Hill	2024
University of Massachusetts Medical School	2024
Emory University	2024
University of Pennsylvania	2024
University of Nebraska Medical Center	2024
Rockefeller University	2024
Centre for the AIDS Programme of Research in South Africa (CAPRISA)	2023
Icahn School of Medicine at Mount Sinai	2023
Nat'l Inst. for Communicable Diseases of the Nat'l Health Lab. Service (SA)	2023
Instituto Nacional de Câncer	2023
Universidade Federal do Rio de Janeiro (Brazil)	2023
Fred Hutchinson Cancer Research Center	2023
Washington University	2023
Frederick National Laboratory for Cancer Research	2023
Georgetown University	2023
Emory School of Medicine	2023
Duke University	2023
Yale University School of Medicine	2022
AIDS Vaccine Advocacy Coalition	2022
Bridge HIV	2022
Swiss Vaccine Research Institute [Switzerland]	2022
University of Lausanne [Switzerland]	2022
Vaccine Research Institute [France]	2022
Chinese Center for Disease Control and Prevention [China]	2022
European and Developing Countries Clinical Trials Partnership [Netherlands]	2022
International Vaccine Institute [South Korea]	2022
South African Medical Research Council	2022
Africa Health Research Institute	2022

Released by Chairman Rand Paul

University of KwaZulu-Natal [South Africa]	2022
Uganda Virus Research Institute [Uganda]	2022
Treatment Action Group	2022
France Recherche Nord and Sud Sida-HIV Hépatites [France]	2022
International Aids Society	2022
International Aids Vaccine Initiative, Inc.	2022
University of Witwatersrand [South Africa]	2022
London School of Hygiene and Tropical Medicine [UK]	2022
University of Cape Town [South Africa]	2022
World Health Organization	2022
Bill & Melinda Gates Foundation	2022
Imperial College London [UK]	2022
Aaron Diamond AIDS Research Center (ADARC)	2022
Tulane University	2022
University of Louisiana Lafayette	2022
Center of Biomedical Research, Population Council	2022
University of Maryland (Baltimore)	2022
Stop TB Partnership	2022
The Wellcome Trust	2022
Volunteer Health Services [Ethiopia]	2022
International Union Against Tuberculosis and Lung Disease [France]	2022
Treatment Action Group	2022
Houses of Parliament [UK]	2022
Ministry of Health, Labor and Welfare [Japan]	2022
Interactive Research & Development [Pakistan]	2022
Resource Group for Education and Advocacy for Community Health [India]	2022
South African National Department of Health [South Africa]	2022
University of Milan [Italy]	2022
University of Geneva [Switzerland]	2022
Academy of Preventive Medicine of Kazakhstan [Kazakhstan]	2022
Stony Brook University	2022
Mayo Clinic	2022
University of Amsterdam [Netherlands]	2022
The Economic Times [India]	2022
KNCV Tuberculosis Foundation [Netherlands]	2022
Institutul de Ftiziopneumologie Chiril Draganiuc [Moldova]	2022
The Center for Health Policies and Studies [Moldova]	2022
University of Hawaii	2022
Case Western Reserve University	2022
University of Melbourne [Australia]	2022
Burnet Institute [Australia]	2022
Kenyan Ministry of Health [Kenya]	2022
General TB control [India]	2022
United Nations [Switzerland]	2022

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Erasmus University Rotterdam [Netherlands]	2022
The Graduate Institute Geneva [Switzerland]	2022
Linksbridge	2022
McGill University [Canada]	2022
Ministry of Health and Family Welfare [India]	2022
United Nations University [Malaysia]	2022
Revised National TB Control Program [India]	2022
United States Agency for International Development	2022
Harvard University	2022
Foundation for Innovative New Diagnostics [Switzerland]	2022
Johns Hopkins University (School of Medicine)	2022
The Aurum Institute [South Africa]	2022
Stanford University	2022
Maple Leaf HIV Medical Research Collaborative, Inc [Canada]	2022
University of California (San Francisco)	2022
Mahidol University [Thailand]	2021
University of Witwatersrand [South Africa]	2021
New York University School of Medicine	2021
Harvard Medical School	2021
Pedro Kourí Tropical Medicine Institute (IPK) [Cuba]	2021
National Cancer Institute / Instituto Nacional de Câncer [Brazil]	2021
Universidade Federal do Rio de Janeiro / Federal Univ. of Rio de Janeiro [Brazil]	2021

Agreements

Aelix Therapeutics	Pending
Boston College	Pending
American Gene Technologies International, Inc.	Pending
Celltrion, Inc.	Pending
Centro de Investigación en Enfermedades Infecciosas	Pending
Children's National Medical Center (CNMC) [US]	Pending
China National Biotec Group Company Limited [China]	Pending
Dartmouth College	Pending
Emory University	Pending
Fred Hutchinson Cancer Research Center	Pending
George Washington University (GWU)	Pending
Immunitybio, Inc.	Pending
Instituto D'Or de Pesquisa e Ensino (IDOR)	Pending
Joan & Sanford I. Weill Medical College of Cornell University	Pending
Makerere University [UG]	Pending
Maple Leaf Medical Clinic	Pending
Ministry of Health of Indonesia [Indonesia]	Pending
NeoImmunetech, Inc.	Pending
Pfizer, Inc.	Pending

Rakai Health Sciences Program [US]	Pending
Rockefeller University	Pending
RNAceuticals, Inc.	Pending
Sanofi U.S. Services Inc.	Pending
SIGA Technologies, Inc	Pending
Simon Fraser University [CA]	Pending
Springer Nature Switzerland AG [Switzerand]	Pending
ViiV Healthcare UK (No.6) Ltd [GB]	Pending
Viro-Gen LTD.	Pending
Western University	Pending
Yale University	Pending

A.C. Camargo Cancer Center	5/10/2022
AbbVie Inc.	10/9/2024
Adamas Pharmaceuticals, Inc	Active
American Gene Technologies International, Inc	1/29/2023
Arbutus Biopharma Corporation [Canada]	Active
AstraZeneca Pharmaceuticals LP	Active
Bavarian Nordic A/S [Denmark]	Active
Baxalta US, Inc	Active
Beneficia Portuguesa de Sao Paulo [Brazil]	5/10/2022
Beth Israel Deaconess Medical Center (BIDMC)	Active
Bill & Melinda Gates Foundation (BMGF)	12/31/2023
BIOLEGEND	11/14/2022
Bioverativ (f.k.a. True North Therapeutics)	2/17/2022
Brii Biosciences (Beijing) Co Ltd [China]	Active
Bristol-Myers Squibb Company (BMS)	Active
California Institute for Regenerative Medicine (CIRM)	Active
Celgene Corporation	Active
Cerus Corporation	Active
Charles River Laboratories, Inc.	9/29/2023
Columbia University	Active
Columbia University Irving Medical Center	11/9/2021
Crucell Vaccines Institute	Active
CSL Behring	Active
Dartmouth College	2/11/2026
District of Columbia Department of Health (DC DOH)	Active
Eli Lilly and Company	Active
Elsevier	Active
EMD Serono Research & Development Institute	Active
Emergent BioSolutions Canada Inc. [Canada]	3/18/2022
Emergent BioSolutions Inc.	Active
Emory University	5/9/2024
Excision Biotherapeutics	2/22/2026

Fred Hutchinson Cancer Research Center (FHCRC)	11/8/2024
French Institute of Health and Medical Research (INSERM) [France]	Active
Gilead Sciences, Inc.	Active
GlaxoSmithKline Biologicals SA (GSK Biologicals) [Belgium]	Active
Glaxosmithkline Intellectual Property Limited	Active
GlaxoSmithKline PLC (GSK) [GB]	Active
Global Solutions for Infectious Diseases	Active
GlobImmune, Inc	Active
Grifols Shared Services North America, Inc.	Active
Grifols Therapeutics LLC	Active
HCor Research Institute	4/7/2022
Hospital Baía Sul	5/10/2022
Hospital de Base de São José do Rio Preto	5/10/2022
Hospital e Maternidade Sepaco	5/10/2022
Hospital Moinhos de Vento	5/10/2022
Hospital Naval Marcílio Dias	5/10/2022
Hospital Nereu Ramos	5/10/2022
Hospital São José	5/10/2022
Hospital São Paulo	5/10/2022
Hospital Unimed Vitória	5/10/2022
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Univercells	4/15/2024
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University of Florida	Active
University of Kansas	9/12/2021
University of Maryland	Active
University of Maryland, Baltimore	Active
University of Washington	Active
Vigene Biosciences, Inc.	7/6/2023
ViiV Healthcare UK Ltd [GB]	Active
Vir Biotechnology, Inc. (VirBio)	Active
Weird Science, LLC	Active
Wistar Institute	11/8/2024

Released by Chairman Rand Paul

Yale University 12/10/2021

OUTSIDE ACTIVITIES

McGraw-Hill Publishing	ongoing
Doris Duke Charitable Foundation	ongoing

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National Academy of Public Administration	2024
Dan David Foundation	2024
College of William & Mary	2024
McGill University	2024
University of North Carolina	2024
Mayo Clinic	2024
City College of NY	2024
University of Pennsylvania	2024
Tel Aviv University	2024
Partnership for Public Service	2024
Rensselaer Polytechnic University	2024
Bowdoin College	2024
Rockefeller University	2024
Charles R. Drew University of Medicine and Science	2024
University of North Carolina	2024
Smithsonian Institution	2024
American Association for the Advancement of Science (AAAS)	2024
National Academies of Medicine	2024
Emory University	2024
Tufts University	2024
Vanderbilt University	2024
American University	2021
Boston University	2021

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Prepared by: _____ Date: _____
Director, OERPO, DEA, NIAID

Approved by: _____ Date: _____
Director, DEA, NIAID

Organization
Aelix Therapeutics
Boston College
Centro de Investigación en Enfermedades Infecciosas
Children's National Medical Center (CNMC)
China National Biotec Group Company Limited [CN]
Columbia University Irving Medical Center
Creative Biolabs, Inc.
Dartmouth College
Dartmouth College
Dartmouth College
Excision Biotherapeutics
Exothera [BE]
Fred Hutchinson Cancer Research Center (FHCRC)
Fred Hutchinson Cancer Research Center (FHCRC)
George Washington University (GWU)
Gilead Sciences, Inc
GlaxoSmithKline LLC (GSK)
Greys Hospital
Howard Hughes Medical Institute (HHMI)
Immunitybio, Inc.
Imperial College London (ICL) [GB]
Joan & Sanford I. Weill Medical College of Cornell University (current name: Weill Cornell Medicine)
LumiraDx
Makerere University [UG]
Maple Leaf Medical Clinic
Ministry of Health of Indonesia [ID]
National Center for Global Health and Medicine (was International Medical Center of Japan) [JP]
NeoImmunetech, Inc.
Rakai Health Sciences Program
Rockefeller University
Sanofi U.S. Services Inc.
Sanofi U.S. Services Inc.
SIGA Technologies, Inc
Simon Fraser University [CA]
Springer Nature Switzerland AG [CH]
The Scripps Research Institute (TSRI)
University of Kentucky
University of Massachusetts Medical School
University of Oxford (incl Isis Innovation) [GB]
University of Pittsburgh
University of Toronto [CA]

Released by Chairman Rand Paul

ViiV Healthcare Company
ViiV Healthcare UK (No.6) Ltd [GB]
Viro-Gen Ltd.
Western University
Yale University

Released by Chairman Rand Paul

Agreement Type	Status
License	Pending
RCA	Pending
RCA	Pending
RCA	Pending
License	Pending
MTA	Pending
License	Pending
CDA	Pending
CRADA	Pending
MTA	Pending
RCA	Pending
CRADA	Pending
MTA	Pending
RCA	Pending
RCA	Pending
CTA	Pending
CTA	Pending
MTA	Pending
MTA	Pending
License	Pending
CDA	Pending
RCA	Pending
CTA	Pending
RCA	Pending
RCA	Pending
MOU	Pending
MTA	Pending
CRADA	Pending
RCA	Pending
RCA	Pending
License	Pending
License	Pending
CTA	Pending
RCA	Pending
PUB	Pending
CDA	Pending
RCA	Pending
RCA	Pending
RCA	Pending
RCA	Pending
RCA	Pending

Released by Chairman Rand Paul

MTA	Pending
License	Pending
CDA	Pending
RCA	Pending
RCA	Pending

Organization
9th of July Hospital [BR]
A.C.Camargo Cancer Center
Aaron Diamond AIDS Research Center (ADARC)
Abbott Laboratories, Inc.
AbbVie Inc.
Academic Medical Center, University of Amsterdam [NL]
Accelevir, LLC (Accelevir Diagnostics)
ACROBiosystems, Inc.
Adagio Therapeutics, Inc.
Addgene, Inc.
Aevum Bio Labs
Altor BioScience Corp.
American Gene Technologies International, Inc.
Arbutus Biopharma Corporation [CA]
Ashvattha Therapeutics, Inc.
AstraZeneca Pharmaceuticals LP
Base Hospital Sao Jose Do Rio Preto [BR] (Hospital de Base de São José do Rio Preto)
Battelle Memorial Institute - Columbus Operations
Bavarian Nordic A/S [DK]
Baxalta US, Inc.
Baxalta US, Inc.
Baylor College of Medicine
Beth Israel Deaconess Medical Center (BIDMC)
Bill & Melinda Gates Foundation (BMGF)
BioLegend
BioProtection Systems
Bioverativ (f.k.a. True North Therapeutics)
Blood Center Wisconsin
Boston Children's Hospital
Boston University
Brigham and Women's Hospital (BWH)
Brii Biosciences (Beijing) Co Ltd [CN]
Bristol-Myers Squibb Company (BMS)
Broad Institute of Harvard and MIT
Broad Institute, Inc
California Institute for Regenerative Medicine (CIRM)
California Institute of Technology (Caltech)
Celgene Corporation
Cerus Corporation
Charles River Laboratories, Inc.
CHU Sainte-Justine Research Centre [FR]
ClearB Therapeutics
Cold Spring Harbor Laboratory

Colorado State University
Columbia University
Columbia University
Cornell University
Crucell Vaccines Institute
CSL Behring
CSL Behring
Dana-Farber Cancer Institute (DFCI)
Dartmouth College
Dartmouth College
District of Columbia Department of Health (DC DOH)
Doctors Without Borders
D'Or Institute for Research and Education (IDOR) [BR]
Drexel University
Drexel University College of Medicine
Duke University
Duke University Medical School
Duke-NUS Medical School [SG]
Eli Lilly and Company
Eli Lilly and Company
Eli Lilly and Company
Elsevier
EMD Serono Research & Development Institute
Emergent BioSolutions Canada Inc. [CA]
Emergent BioSolutions Canada Inc. [CA]
Emergent BioSolutions Inc.
Emergent BioSolutions Inc.
Emergent BioSolutions Inc.
Emory University
Emory University
EPFL (Ecole Polytechnique Federale de Lausanne) [CH]
Essen University Hospital [DE]
Excision Biotherapeutics
Exothera [BE]
Florida State University
Fox Chase Cancer Center
Fred Hutchinson Cancer Research Center (FHCRC)
Fred Hutchinson Cancer Research Center (FHCRC)
French Institute of Health and Medical Research (INSERM) [FR]
French Institute of Health and Medical Research (INSERM) [FR]
Geisinger Center for Health Research
Genentech, Inc.
George Washington University (GWU)
Georgetown University

Georgetown University School of Medicine
German Cancer Research Center (DKFZ) [DE]
German Primate Center (DPZ) [DE]
Gilead Sciences, Inc
Gilead Sciences, Inc
Gilead Sciences, Inc
Gilead Sciences, Inc.
Ginkgo Bioworks
GlaxoSmithKline Biologicals SA (GSK Biologicals, GSK) [BE]
Glaxosmithkline Intellectual Property Limited
GlaxoSmithKline LLC (GSK)
GlaxoSmithKline PLC (GSK) [GB]
Global Solutions for Infectious Diseases
Grifols Shared Services North America, Inc.
Grifols Shared Services North America, Inc.
Grifols Shared Services North America, Inc.
Grifols Therapeutics, LLC
GSK Vaccines
H. Lee Moffitt Cancer Center and Research Institute, Inc.
Harvard University
HCor Research Institute
Hennepin Healthcare
Hennepin Healthcare Research Institute (HHRI)
Hospital for Sick Children [CA]
Hospital S. Anna and S. Sebastiano, Caserta [IT]
Hospital Sao Jose [BR]
Hospital Sao Paulo [BR]
Hospital Unimed Vitoria [BR]
Houston Methodist Hospital Research Institute
Howard Hughes Medical Institute (HHMI)
Howard Hughes Medical Institute (HHMI), Janelia Farm Research Campus
Icahn School of Medicine at Mount Sinai
Imperial College London (ICL) [GB]
Incyte Corporation
Indiana University
Institut Pasteur [FR]
Institut Pasteur Korea [KR]
Institute of Bioengineering and Nanotechnology [SG]
Institute of Human Virology, University of Maryland School of Medicine
International AIDS Vaccine Initiative, Inc.
International Centre for Genetic Engineering and Biotechnology [IT]
International Medical Corps (IMC)
J. David Gladstone Institutes
Janssen Vaccines & Prevention B.V. [NL]

Janssen Vaccines & Prevention B.V. [NL]
Janssen Vaccines & Prevention B.V. [NL]
Joan & Sanford I. Weill Medical College of Cornell University (current name: Weill Cornell Medicine)
Johns Hopkins Medicine (JHM)
Johns Hopkins University (JHU)
JoMoCo, Inc.
Just Biotherapeutics
Kansas State University
Karolinska Institute [SE]
Kyoto University [JP]
La Jolla Institute for Immunology
Laboratory Corporation of America Holdings (LabCorp)
London School of Hygiene & Tropical Medicine (LSHTM) (University of London) [GB]
Ludwig Institute for Cancer Research
MAPP Biopharmaceutical, Inc.
MAPP Biopharmaceutical, Inc.
MAPP Biopharmaceutical, Inc.
Marcilio Dias Naval Hospital [BR] (Hospital Naval Marcílio Dias)
Massachusetts General Hospital (MGH; General Hospital Corp.)
Massachusetts General Hospital (MGH; General Hospital Corp.)
Mayo Clinic
Medical University of South Carolina (MUSC)
Medical University of Vienna [AT]
MedImmune, LLC.
MedImmune, LLC.
Medstar Washington Hospital Center
Memorial Sloan-Kettering Cancer Center
Merck Research Laboratories
Merck Sharp & Dohme Corp
Merck Sharp & Dohme Corp
Merck Sharp & Dohme Corp
Merck Sharp and Dohme Research Labs.
Michael J. Fox Foundation for Parkinson's Disease
Millennium Pharmaceuticals, Inc.
Millipore Sigma
Ministry of Health (MOH) of Democratic Republic of Congo (DRC) [CD]
Ministry of Health (MOH) of Liberia [LR]
Ministry of Health of Indonesia [ID]
Moderna, Inc. (was Moderna Therapeutics, Inc., then ModernaTX, Inc.)
Molecular Partners AG [CH]
National Health Security Agency [GN]
National Institute for Biological Standards and Control (NIBSC) [GB]
National Institute of Biomedical Research (INRB) [CD]

National Institute of Biomedical Research (INRB) [CD]
National Institute of Biomedical Research (INRB) [CD]
National Institute of Medical Sciences and Nutrition [MX]
National University of Singapore [SG]
Nelson Hardiman
NeoImmunetech, Inc.
NeoImmunetech, Inc.
NeoImmunetech, Inc.
Nereu Ramos Hospital [BR] (Hospital Nereu Ramos)
NeuroRx
New York University School of Medicine (NYU)
NewLink Genetics Corporation
NewLink Genetics Corporation
Northeast Ohio Medical University
Northwestern University
Novartis Pharma AG
Novavax, Inc.
Novavax, Inc.
Ohio Northern University
OncoImmune
Osaka University [JP]
Oswaldo Cruz German Hospital [BR]
Partners HealthCare
PATH (Program for Appropriate Technology in Health)
PaxVax, Inc.
PaxVax, Inc.
Pepper Hamilton LLP
PepTcell Limited (renamed SEEK) [GB]
Pfizer, Inc.
Pfizer, Inc.
PGEN Therapeutics, Inc.
PGEN Therapeutics, Inc.
Population Council
Precigen, Inc
Precigen, Inc
Public Health England [Health Protection Agency] [GB]
Q Squared Solutions LLC
Q2 Solutions
Quality Biological, Inc.
Queensland Institute of Medical Research [AU]
Ragon Institute of MGH, MIT and Harvard
Rega Institute for Medical Research, University of Leuven (KU Leuven) [BE]
Regeneron Pharmaceuticals, Inc.
Regeneron Pharmaceuticals, Inc.

Relief Therapeutics Holding AG
Ridgeback Biotherapeutics
Rockefeller University
Rockefeller University
Rockefeller University
Roivant Sciences, Inc.
Rutgers University
SAB Biotherapeutics, Inc.
SAB Biotherapeutics, Inc.
SAGE Pulications LTD
Salk Institute for Biological Studies
San Diego Biomedical Research Institute
Sanford-Burnham Preybs Medical Discovery Institute
Sanofi US Services Inc.
Santa Cruz Biotechnology, Inc.
Schering Plough Research Institute (SPRI)
Senhwa Biosciences
Sepaco Hospital and Maternity [BR] (Hospital e Maternidade Sepaco)
Seraph Research Institute
SIGA Technologies, Inc
South Bay Hospital [BR] (Hospital Baía Sul)
Springer Nature Limited
St George's Hospital Medical School (St. George's, University of London) [GB]
St. Jude Children's Research Hospital
Stanford University (Leland Stanford Junior University)
Sun Yat-Sen University, Zhong-Shan Medical School [CN]
TaiMed Biologics USA Corp.
TaiMed Biologics USA, Inc
TAKEDA Pharmaceutical Company, Ltd.
Tandem Labs
TEVA PPharmaceuticals USA
Thai Red Cross AIDS Research Centre (TRCARC) [TH]
The Liver Center
The National Public Health Institute of Liberia (NPHIL) [LR]
The Portuguese Charity of Sao Paulo (BP) [BR] (Beneficencia Portuguesa de São Paulo)
The Research Foundation for The State University Of New York
The Scripps Research Institute (TSRI)
The Scripps Research Institute (TSRI)
The University Clinical Research Center (UCRC)
Theravance, Inc.
Tohoku Medical and Pharmaceutical University [JP]
Tokyo Medical and Dental University [JP]
Tokyo Medical and Dental University [JP]
Tokyo University of Science [JP]

Released by Chairman Rand Paul

Toscana Life Sciences
United Biomedical, Inc. (UBI)
United BioPharma, Inc.
United BioPharma, Inc.
United Kingdom Research - Polaris House [GB]
Univercells
University College London (UCL) (University of London) [GB]
University of Amsterdam [NL]
University of Arizona
University of Bari [IT]
University of Calgary [CA]
University of California - Regents SF Campus
University of California-Berkeley
University of California-Irvine
University of California-Los Angeles (UCLA)
University of California-San Diego (UCSD)
University of California-San Francisco (UCSF)
University of Cambridge [GB]
University of Cape Town Lung Institute (UCT) [ZA]
University of Chicago
University of Colorado
University of Connecticut Health Center
University of Dundee [GB]
University of Florida
University of Florida
University of Foggia
University of Geneva [CH]
University of Georgia
University of Glasgow [GB]
University of Hong Kong (HKU) [HK] [CN]
University of Illinois
University of Kentucky
University of Lausanne [CH]
University of Leuven (KU Leuven) [BE]
University of Manitoba [CA]
University of Marilia [BR] (Universidade de Marília)
University of Maryland
University of Maryland
University of Maryland School of Medicine
University of Maryland, Baltimore (UMB)
University of Maryland, Baltimore (UMB)
University of Massachusetts
University of Massachusetts Medical School
University of Michigan

Released by Chairman Rand Paul

University of Minnesota
University of Nebraska Medical Center
University of North Carolina at Chapel Hill School of Medicine
University of Oslo [NO]
University of Oxford (incl Isis Innovation) [GB]
University of Padua [IT]
University of Pavia [IT]
University of Pennsylvania
University of Pittsburgh
University of Pittsburgh School of Medicine
University of Rhode Island
University of Rome Tor Vergata [IT]
University of South Florida
University of Texas at Austin
University of Texas Health Science Center at San Antonio
University of Texas MD Anderson Cancer Center
University of Texas Southwestern Medical Center
University of Toronto [CA]
University of Washington
University of Washington
University of Western Ontario [CA]
University of Zurich [CH]
Vanderbilt University
Vigene Biosciences, Inc.
ViiV Healthcare Company
ViiV Healthcare UK (No.5) Ltd [GB]
ViiV Healthcare UK (No.6) Ltd [GB]
Vir Biotechnology, Inc. (Vir)
Vir Biotechnology, Inc. (Vir)
Virginia Commonwealth University
Washington University in St. Louis
Wayne State University
Weird Science, LLC
Whitehead Institute for Biomedical Research (MIT)
Windmills Hospital [BR] (Hospital Moinhos de Vento)
Wistar Institute
Wistar Institute
Yale University
Yale University School of Medicine

Released by Chairman Rand Paul

Agreement Type	Status
CDA	12/14/2022
CDA	5/10/2022
MTA	Active
MTA	Active
CDA	10/9/2024
MTA	Active
MTA	Active
MTA	4/5/2024
MTA	Active
MTA	Active
MTA	Active
MTA	Active
RCA	1/29/2023
CDA	Active
CDA	8/16/2022
CTA	Active
CDA	5/10/2022
MTA	Active
CTA	Active
CDA	3/18/2022
CTA	Active
MTA	Active
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GIFT	12/31/2023
RCA	11/14/2022
MTA	Active
CDA	2/17/2022
MTA	Active
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MTA	Active
MTA	Active
CTA	Active
CTA	Active
MTA	Active
MTA	Active
CDA	Active
MTA	Active
CTA	Active
CDA	Active
CDA	9/29/2023
MTA	Active
MTA	Active
MTA	Active

Released by Chairman Rand Paul

MTA	Active
License	Active
MTA	4/19/2024
MTA	Active
CDA	Active
CDA	3/18/2022
CTA	Active
MTA	Active
CDA	2/11/2026
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CDA	8/8/2022
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MTA	Active
MTA	Active
MTA	Active
CDA	3/30/2025
CTA	Active
MTA	Active
PUB	Active
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CDA	11/8/2024
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CTA	Active
MTA	2/25/2022
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Released by Chairman Rand Paul

MTA	Active
MTA	Active
MTA	Active
CDA	10/26/2025
CTA	Active
MTA	Active
License	9/24/2022
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CTA	Active
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CTA	Active
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License	Active
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Released by Chairman Rand Paul

CTA	Active
MTA	7/1/2022
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RCA	1/30/2023
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CDA	11/28/2022
CTA	Active
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License	5/29/2025
MOU	6/28/2024
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CDA	4/9/2022
CTA	Active
MTA	Active
MTA	Active
CTA	Active

Released by Chairman Rand Paul

MOU	Active
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MTA	Active
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CDA	9/26/2022
CTA	Active

Released by Chairman Rand Paul

CDA	6/12/2022
CDA	6/24/2025
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MTA	7/26/2024
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Released by Chairman Rand Paul

MTA	3/5/2024
MTA	Active
CTA	Active
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CDA	4/15/2024
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CDA	5/10/2022
License	Active
MTA	Active
MTA	Active
License	Active
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Released by Chairman Rand Paul

MTA	12/20/2022
MTA	Active
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MTA	4/3/2023
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MTA	Active
MTA	Active
MTA	Active
License	Active
MTA	7/11/2024
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CDA	7/6/2023
CDA	10/5/2026
CRADA	11/16/2025
License	Active
CTA	Active
License	2/14/2023
MTA	Active
MTA	4/16/2022
MTA	Active
CDA	Active
MTA	Active
CDA	5/10/2022
CDA	11/8/2024
MTA	Active
MTA	Active
MTA	Active

Released by Chairman Rand Paul

From: "Barber, Susanna (NIH/NIAID) [E]" [redacted]@nih.gov>
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Pau, Alice (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Carver, Trea (NIH) [C]" [redacted]@nih.gov>, NIAID DCR FOIA [redacted]@mail.nih.gov>, "Tierney, John (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Herpin, Betsey (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FOIA Search Request: Redshaw #57999
Date: Mon, 14 Mar 2022 14:13:25 -0400
Importance: Normal
Attachments: CHD_FOIA_NIAID_1.pdf

Cliff and Alice,

This new FOIA request has been forwarded to us by Robin. Please see her notes / questions in GREEN (below) which are directed to both of you – I've highlighted them in yellow. Does CIT have permission to search records, per the parameters described by Robin, using the algorithm in her email, for just Alice's records, or for both of you?

I'm wondering if searching "Treatment Guidelines Exec. Sec." and "Ivermectin" might be an alternate / optimal route.

Let me know your preference(s) / permissions.

Susanna

From: Schofield, Robin (NIH/NHLBI) [E] [redacted]@nih.gov>
Sent: Monday, March 14, 2022 12:24 PM
To: Awwad, David (NIH/NIAID) [C] [redacted]@niaid.nih.gov>; Folkers, Greg (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Barber, Susanna (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; NIAID DCR FOIA [redacted]@mail.nih.gov>
Subject: FOIA Search Request: Redshaw #57999

Good morning,

Megan Redshaw of Children's Health Defense submitted a 5-part FOIA request for (IOD – please see red; DCR – please see green):

1. Please provide CHD with a list of all studies, reports, scientific papers or records relied on by NIAID and any of its employees, including Dr. Anthony Fauci, that prove or suggest ivermectin is not effective in controlling, reducing the symptoms of, curing or avoiding the death of persons positively confirmed to have COVID-19 through appropriate testing, as well as persons having COVID-19 who were not tested for SARS-CoV-2, and persons having coronavirus disease and/or COVID-19.

IOD AND DCR: Is there an already assembled list? If not, I will ask NIH FOIA to respond that the support for the official recommendations on Ivermectin is already in the public domain in the Covid-19 Treatment Guidelines and provide the links:

Ivermectin | COVID-19 Treatment Guidelines (nih.gov)
Table: Ivermectin Clinical Data | COVID-19 Treatment Guidelines (nih.gov)

2. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present between any NIAID employee, including Dr. Anthony Fauci, and the WHO and/or any of its officials, including, but not limited to, Tedros Adhanom Ghebreyesus, Michael Ryan, Soumya Swaminathan, Dr. Gro Harlem Brundtland and Ana Maria Restrepo that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and the domain @who.int containing the term ivermectin for the time period 1/1/19 to present.

DCR: We are required to search where we are reasonably likely to find documents. Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

3. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and any National Institutes of Health (NIH) employee including, but not limited to, Francis Collins, Roy M. Gulick, H. Clifford Lane and Dr. Henry Masur that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and Dr. Collins OR [redacted]@med.cornell.edu OR Dr. Lane OR Dr. Masur containing the term ivermectin for the time period 1/1/19 to present.

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD except swap the places of Dr. Lane (or Pau or whoever) and Dr. Fauci.

4. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Jeremy Farrar, Lawrence Tabak, William Pao, Dr. Deborah Birx and Dr. Robert Redfield that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and [redacted]@wellcome.ac.uk OR Dr. Tabak OR [redacted]@vanderbilt.edu OR [redacted]@roche.com OR [redacted]@mskcc.org OR [redacted]@gmail.com OR [redacted]@nsc.eop.gov OR [redacted]@cdc.gov OR [redacted]@pennmedicine.upenn.edu containing the term ivermectin for the time period 1/1/19 to present.

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

5. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Elhadj As Sy, Dr. Victor Dzau, Dr. Chris Elias, Henrietta Fore, Dr. George F. Gao, and Bill Gates that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and [redacted]@kofiannanfoundation.org OR [redacted]@duke.edu OR [redacted]@gatesfoundation.org OR [redacted]@unicef.org OR [redacted]@im.ac.cn OR [redacted]@gatesventures.com containing the term ivermectin for the time period January 1, 2019 to present

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

Please reply with permission to search and let me know if you have any questions.

Thank you.

Robin

Robin L. Schofield

Released by Chairman Rand Paul

NHLBI FOIA Service Center

Released by Chairman Rand Paul

Children's Health Defense

March 11, 2022

VIA ONLINE PORTAL

National Institute of Allergy and Infectious Diseases (NIAID)
Room 6G51
5601 Fishers Lane
Rockville, MD 20892
[redacted] (phone)
(fax)

Re: Freedom of Information Act Request

Dear Sir or Madam:

In an interview with CNN on August 29, 2021, Dr. Anthony Fauci warned against using the anti-parasitic drug ivermectin to treat or prevent a COVID-19 infection.[1] Fauci stated: "Don't do it. There's no evidence whatsoever that it works and it could potentially have toxicity… with people who have gone to poison control centers because they've taken the drug at a ridiculous dose and wind up getting sick. There's no clinical evidence that indicates that this works."

On January 11, 2022, Fauci testified to lawmakers that there have been mixed guidelines about the use of ivermectin against COVID-19 from different health agencies around the world, and guidance issued by the National Institutes of Health (NIH) previously concluded there was not enough evidence to say whether it is effective against COVID-19. [2]

"Ivermectin has had noncontrolled trials suggesting that it might be effective — mostly

[1] *'Don't do it': Dr. Fauci warns against taking Ivermectin to fight Covid-19,"* CNN, https://www.cnn.com/videos/health/2021/08/29/dr-anthony-fauci-ivermectin-covid-19-sotu-vpx.cnn, (last accessed March 7, 2022).
[2] *Senate Hearing on Federal Response to COVID-19 Variants,* C-SPAN, (Jan. 11, 2022), https://www.c-span.org/video/?517046-1/senate-hearing-federal-response-covid-19-variants (last accessed March 7, 2022).

anecdotal," Fauci said. "The NIH active studies are doing a whole bunch of studies with ivermectin, as well as others, to try and settle it once and for all."

Fauci said the World Health Organization has also advised against using ivermectin for treating COVID-19. The agency put out a statement in March 2021 saying the drug should only be used in clinical studies until more data are available.[3,4]

In August, 2020, the NIH committee that issues COVID-19 treatment guidelines recommended against the use of ivermectin outside of clinical trials.[5] But after a presentation by Dr. Pierre Kory and his colleagues in January 2021, the panel adopted a neutral stance, saying there were "insufficient data to recommend either for or against the use of ivermectin for the treatment of covid-19." [6,7]

In April 2020, the Infectious Diseases Society of America (IDSA), made up of more than 12,000 medical doctors, research scientists and public health experts, including Anthony Fauci, issued a statement in support of Fauci encouraging members to "stand with science." [8,9]

In April 2020, ISDA published Guidelines on the Treatment and Management of Patients with COVID-19, which speak against the use of ivermectin in hospitalized patients and ambulatory persons with COVID-19, outside of a clinical trial.[10] The ISDA also stated

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[3] Laura McGinley, *Supporters tout anti-parasite drug as covid-19 treatment, but skeptics call it the 'new hydroxychloroquine,'* The Washington Post, https://www.washingtonpost.com/health/2021/04/08/ivermectin-covid-drug/, (last accessed March 7, 2022).

[4] *See* https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials, (last accessed March 7, 2022).

[5] Laura McGinley, *Supporters tout anti-parasite drug as covid-19 treatment, but skeptics call it the 'new hydroxychloroquine,'* The Washington Post, https://www.washingtonpost.com/health/2021/04/08/ivermectin-covid-drug/, (last accessed March 7, 2022).

[6] *NIH Revises Treatment Guidelines for Ivermectin for the Treatment of COVID-19,* Coronavirus News Source, https://www.newswise.com/coronavirus/nih-revises-treatment-guidelines-for-ivermectin-for-the-treatment-of-covid-19, (last accessed March 7, 2022).

[7] *See Ivermectin*, National Institutes of Health, https://www.covid19treatmentguidelines.nih.gov/antiviral-therapy/ivermectin/, (last accessed March 7, 2022).

[8] *See IDSA Statement in Support of Anthony Fauci, M.D.*, FIDSA, Infectious Diseases Society of America https://www.idsociety.org/news--publications-new/articles/2020/isda-statement-in-support-of-anthony-fauci-m.d.-fidsa/, (last accessed March 7, 2022).

[9] *See Dr. Anthony Fauci Shares ID Insights on COVID-19,* Infectious Diseases Society of America, https://www.idsociety.org/multimedia/podcasts/dr.-anthony-fauci-shares-id-insights-on-covid-19/ (last accessed March 7, 2022).

[10] https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/

Released by Chairman Rand Paul

there was no evidence to suggest ivermectin could be used to successfully prevent COVID-19 infection.

In August, 2021, the IDSA issued a joint statement with the HIV Medicine Association and the Society for Healthcare and Epidemiology of America recommending against the use of ivermectin for the treatment of COVID-19 and determined the certainty of evidence is very low for both hospitalized patients and outpatients. For this reason, the panel made a conditional recommendation against the use of ivermectin outside the context of a clinical trial."[11,12]

The Centers for Disease Control and Prevention (CDC) in August 2021 issued a health advisory warning physicians and the public about the rise in prescriptions for the anti-parasitic drug ivermectin for use in the treatment or prevention of COVID-19.[13]

The U.S. Food and Drug Administration echoed the CDC's warning against the use of ivermectin for prevention or treatment of COVID-19 and refused to authorize or approve the drug for such purposes.[14, 15]

On December 8, 2020, the Senate Homeland Security and Governmental Affairs Committee held a hearing titled, "Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, Part II," to discuss early outpatient treatments for COVID-19 using widely available, safe and low cost drugs, including ivermectin. Physicians testified that early outpatient treatments like ivermectin could possibly save hundreds of thousands of lives.[16]

Pursuant to the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and the implementing regulations of your agency, 45 C.F.R Part 5, Children's Health Defense (CHD), a non-governmental organization, makes the following request for our records.

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[11] *See* https://www.idsociety.org/globalassets/idsa/public-health/covid-19/final-ivermectin-joint-statement-dsw-aw-fc_bda_tf-laj.pdf, (last accessed March 7, 2022).
[12] *See* https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/, (last accessed March 7, 2022).
[13] *See* https://emergency.cdc.gov/han/2021/pdf/CDC_HAN_449.pdf, (last accessed March 7, 2022).
[14] *See* https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19, (last accessed March 7, 2022).
[15] Sara Berg, MS, *Why ivermectin should not be used to prevent or treat COVID-19* https://www.ama-assn.org/delivering-care/public-health/why-ivermectin-should-not-be-used-prevent-or-treat-covid-19, (last accessed March 7, 2022).
[16] *See* https://www.hsgac.senate.gov/imo/media/doc/40-317_Comm.%20Homeland%20Security%20%20Gov.%20Affairs%2012-10-2020.pdf, (last accessed March 7, 2022).

Requested Records

1. Please provide CHD with a list of all studies, reports, scientific papers or records relied on by NIAID and any of its employees, including Dr. Anthony Fauci, that prove or suggest ivermectin is not effective in controlling, reducing the symptoms of, curing or avoiding the death of persons positively confirmed to have COVID-19 through appropriate testing, as well as persons having COVID-19 who were not tested for SARS-CoV-2, and persons having coronavirus disease and/or COVID-19.

2. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present between any NIAID employee, including Dr. Anthony Fauci, and the WHO and/or any of its officials, including, but not limited to, Tedros Adhanom Ghebreyesus, Michael Ryan, Soumya Swaminathan, Dr. Gro Harlem Brundtland and Ana Maria Restrepo that includes the keyword “ivermectin.”

3. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and any National Institutes of Health (NIH) employee including, but not limited to, Francis Collins, Roy M. Gulick, H. Clifford Lane and Dr. Henry Masur that includes the keyword “ivermectin.”

4. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Jeremy Farrar, Lawrence Tabak, William Pao, Dr. Deborah Birx and Dr. Robert Redfield that includes the keyword “ivermectin.”

5. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Elhadj As Sy, Dr. Victor Dzau, Dr. Chris Elias, Henrietta Fore, Dr. George F. Gao, and Bill Gates that includes the keyword “ivermectin.”

Released by Chairman Rand Paul

Please note that Children's Health Defense does not seek initial mailing of news clips or other mass-distribution emails. However, subsequent communications forwarding such emails are responsive to this request. For example, if an official received a mass-distribution news clip email, that initial email would not be responsive to this request. However, if the official forwarded that email to another individual with commentary, that subsequent message would be responsive to this request and should be produced.

Guidance Regarding the Search and Processing of Requested Records

In connection with its request for records, CHD provides the following guidance regarding the scope of the records sought and the search and processing of records:

- Please search all locations and systems likely to have responsive records, regardless of format, medium, or physical characteristics. For instance, if the request seeks "communications" please search all locations likely to contain communications, including relevant hard-copy files, correspondence files, appropriate locations on hard drives and shared drives, emails, text messages or other direct messaging systems (such as iMessage, WhatsApp, Signal, or Twitter direct messages), voicemail messages, instant messaging systems such as Lync or ICQ, and shared messages systems such as Slack. The same applies to "correspondence."

- In conducting your search, please understand the terms "record," "correspondence," and "communications" in their broadest sense, to include any written, typed, recorded, graphic, printed, or audio material of any kind. We seek records of any kind, including electronic records, audiotapes, and photographs, as well as letters, emails, instant messages, facsimiles, transcripts, notes, or minutes of any meetings, telephone conversations or discussions.

- Our request for records includes any attachments to those records or other materials enclosed with those records when they were previously transmitted. To the extent that an email is responsive to our request, our request includes all prior messages sent or received in that email chain, as well as any attachments to the email.

- Please search all relevant records or systems containing records regarding agency business. Do not exclude records regarding agency business contained in files, email accounts, or devices in the personal custody of your officials, such as personal email accounts or text messages. Records of official business conducted using unofficial systems or stored outside of official files are subject to the Federal Records Act and FOIA.[17] It is not adequate to rely on policies and procedures that require officials to move such information to official systems

[17] See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, 827 F.3d 145, 149–50 (D.C. Cir. 2016); cf. Judicial Watch, Inc. v. Kerry, 844 F.3d 952, 955–56 (D.C. Cir. 2016).

Released by Chairman Rand Paul

within a certain period of time; CHD has a right to records contained in those files even if material has not yet been moved to official systems or if officials have, by intent or through negligence, failed to meet their obligations. [18]

- Please use all tools available to your agency to conduct a complete and efficient search for potentially responsive records. Agencies are subject to government-wide requirements to manage agency information electronically,[19] and many agencies have adopted the National Archives and Records Administration (NARA) Capstone program, or similar policies. These systems provide options for searching emails and other electronic records in a manner that is reasonably likely to be more complete than just searching individual custodian files. For example, a custodian may have deleted a responsive email from his or her email program, but your agency's archiving tools may capture that email under Capstone. At the same time, custodian searches are still necessary; agencies may not have direct access to files stored in PST files, outside of network drives, in paper format, or in personal email accounts.

- In the event some portions of the requested records are properly exempt from disclosure, please disclose any reasonably segregable non-exempt portions of the requested records. If a request is denied in whole, please state specifically why it is not reasonable to segregate portions of the record for release.

- Please take appropriate steps to ensure that records responsive to this request are not deleted by the agency before the completion of processing for this request. If records potentially responsive to this request are likely to be located on systems where they are subject to potential deletion, including on a scheduled basis, please take steps to prevent that deletion, including, as appropriate, by instituting a litigation hold on those records.

Fee Waiver Request

In accordance with 5 U.S.C. § 552(a)(4)(A)(iii) and your agency's regulations, CHD requests a waiver of fees associated with processing this request for records. The subject of this request concerns the operations of the federal government, and the disclosures will likely contribute to a better understanding of relevant government procedures by the general public in a significant way.

Moreover, the request is primarily and fundamentally for non-commercial purposes. CHD requests a waiver of fees because disclosure of the requested information is "in the public interest because it is likely to contribute significantly to public understanding

[18] See Competitive Enter. Inst. v. Office of Sci. & Tech. Policy, No. 14-cv-765, slip op. at 8 (D.D.C. Dec. 12, 2016).
[19] Presidential Memorandum—Managing Government Records, 76 Fed. Reg. 75,423 (Nov. 28, 2011), https://obamawhitehouse.archives.gov/the-pressoffice/2011/11/28/presidential-memorandum-managing-government-records; Office of Mgmt. & Budget, Exec. Office of the President, Memorandum for the Heads of Executive Departments & Independent Agencies, "Managing Government Records Directive," M-12-18 (Aug. 24, 2012), https://www.archives.gov/files/records-mgmt/m-12-18.pdf

Released by Chairman Rand Paul

of operations or activities of the government."[20] The public has a significant interest in the federal government's response to the SARS-CoV-2 virus and COVID-19.

CHD is committed to transparency and makes the responses agencies provide to FOIA requests publicly available, and the public's understanding of the government's activities would be enhanced through CHD's analysis and publication of these records.

This request is primarily and fundamentally for non-commercial purposes.[21] As a 501(c)(3) nonprofit, CHD does not have a commercial purpose and the release of the information requested is not in the organization's financial interest.

The mission of CHD is to work tirelessly to end the childhood health epidemics by working to expose causes, eliminate harmful exposures, hold those responsible accountable, seek justice for those injured, and establish safeguards to prevent future harm.

CHD uses the information gathered, and its analysis of it, to educate the public through reports, press releases, or other media. The organization also makes materials it gathers available on its public website[22] and newsletter and promotes their availability on social media platforms, such as Facebook[23] and Twitter.[24]

CHD has also demonstrated its commitment to the public disclosure of documents and creation of editorial content through numerous articles and analyses posted to its news website.[25]

Accordingly, CHD qualifies for a fee waiver.

Expedited Processing

CHD requests expedited processing of this request. FOIA provides for "expedited processing of requests for records" upon a showing of a "compelling need." 5 U.S.C. § 552(a)(6)(E)(i)(II). When the person requesting the information is "primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity" constitutes a "compelling public need" for expedited processing. § 552(a)(6)(E)(v)(II).

CHD is an organization made up of public health professionals, medical professionals, lawyers, scientists and journalists. CHD exists for the purpose of disseminating public

[20] *See* 5 U.S.C. § 552(a)(4)(A)(iii).
[21] *Id*.
[22] *See* Children's Health Defense https://childrenshealthdefense.org/.
[23] *See* https://www.facebook.com/ChildrensHealthDefense
[24] *See* https://twitter.com/ChildrensHD
[25] *See* The Defender https://childrenshealthdefense.org/defender/.

Released by Chairman Rand Paul

health information and data and does so through its publication,[26] website,[27] newsletter, press briefings, media channel,[28] and social media platforms.[29,30,31]

CHD intends to make any records produced in response to this FOIA request immediately available to the public through both its website and its individual members' platforms. Many of CHD's individual members, including all its members who are journalists, are primarily engaged with disseminating information to the public and do so across various platforms including through interviews,[32,33] blogs,[34] articles,[35] essays,[36] podcasts[37] and videos.[38]

Therefore, CHD and many of its members are "engaged in disseminating information to the general public, and as explained below, there is a clear "urgency to inform the public concerning actual or alleged Federal Government activity, here, the data and information underlying Dr. Anthony Fauci, the NIAID, and NIH's position on ivermectin as a treatment for COVID. Accordingly, expedited processing of this request is warranted.

Recognizing the importance of transparency and accountability, the National Institutes of Health website states the agency — which is made up of 27 institutes including the NIAID[39] — has a "long-standing commitment to promote the principles of transparency, participation, and collaboration by publishing NIH data that generates significant benefit for citizens and which helps the public hold the government accountable.[40]

A lack of transparency erodes the confidence the medical and scientific community, and the public have in the conclusions reached by Dr. Anthony Fauci and NIH, NIAID, and other U.S. health agencies. There is an urgent public need for such transparency in regards to ivermectin.

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[26] *Id.*
[27] *See* https://childrenshealthdefense.org/
[28] *See* CHD.TV https://live.childrenshealthdefense.org/
[29] *See* https://www.facebook.com/ChildrensHealthDefense
[30] *See* https://twitter.com/ChildrensHD
[31] *See* https://rumble.com/user/childrenshealthdefense
[32] *See e.g.,* https://childrenshealthdefense.org/defender/chd-tv-rfk-jr-defender-vanden-bossche-vaccinating-omicron-pandemic/, (last accessed March 7, 2022).
[33] *See e.g.,* https://childrenshealthdefense.org/defender/meryl-nass-tessa-lena-under-attack/, (last accessed March 7, 2022).
[34] *See* https://childrenshealthdefense.org/defender/
[35] *See e.g.,* https://childrenshealthdefense.org/defender/ivermectin-beats-meds-treating-omicron/
[36] *See e.g.,* https://childrenshealthdefense.org/defender/cory-zue-coming-clean-stand-against-covid-vaccines/
[37] *See* The Defender Podcast, Robert F. Kennedy, Jr., https://podcasts.apple.com/us/podcast/rfk-jr-the-defender-podcast/id1552000243
[38] *See* https://live.childrenshealthdefense.org/
[39] See https://www.nih.gov/institutes-nih#:~:text=NIH%20is%20made%20up%20of,particular%20diseases%20or%20body%20systems (last accessed March 8, 2022).
[40] *See* https://grants.nih.gov/grants/public_accountability/ (last accessed March 7, 2022).

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First, there is ongoing national debate about the adequacy of the data and information relied upon by Dr. Fauci, the NIH, NIAID, CDC, FDA and WHO in adopting their positions on ivermectin. On the one hand, there are numerous public health officials, media outlets, journalists, scientists, public figures, and others with large social media platforms that have declared there's no data showing ivermectin is safe or effective at preventing or treating COVID.

The FDA went so far as to discourage individuals from using ivermectin on Twitter because they are not a "horse" or a "cow," despite the fact ivermectin has been safely used as an antiparasitic for humans for decades.[41] Others have gone to great lengths to censor scientific data on ivermectin and/or manipulate study results.[42]

On the other hand, there are highly educated and well-trained scientists, physicians, and public health experts touting the benefits of ivermectin,[43] filing lawsuits to obtain access to the drug, physicians who have faced disciplinary action for prescribing ivermectin,[44, 45] and critical care doctors who claim ivermectin has reduced mortality rates in the ICU by 50%.[46]

Given this widespread and ongoing public debate, the medical and scientific community and the public have an immediate need to review the information and data underlying public health recommendations.

The NIAID should produce the data and information necessary to address this widespread public debate by immediately producing the information requested in this FOIA request.

There is also an urgent need for the public to have immediate access to the data underlying the positions of U.S. health agencies, including the NIAID, and public health officials like Dr. Anthony Fauci, as people are being denied potentially safe, effective and lifesaving COVID treatments.

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[41] *See* https://twitter.com/us_fda/status/1429050070243192839

[42] Megan Redshaw, *Groundbreaking: Nebraska AG Says Doctors Can Legally Prescribe Ivermectin, HCQ for COVID, Calls Out FDA, CDC, Fauci, Media for 'Fueling Confusion and Misinformation,'* The Defender, https://childrenshealthdefense.org/defender/nebraska-ag-doug-peterson-legal-opinion-ivermectin-hcq-covid/, (last accessed March 7, 2022).

[43] *Ivermectin in COVID-19*, FLCCC Alilance, https://covid19criticalcare.com/ivermectin-in-covid-19/, (last accessed March 8, 2022).

[44] Marlene Lenthang, *Suspended Texas Doctor Who Promoted Ivermectin As Covid Treatment Resigns From Hospital,* NBC News https://www.nbcnews.com/news/us-news/suspended-texas-doctor-promoted-ivermectin-covid-treatment-resigns-hos-rcna5833, (last accessed March 8, 2022).

[45] Tessa Lena, *Under Attack: An Interview With Dr. Meryl Nass,* The Defender, https://childrenshealthdefense.org/defender/meryl-nass-tessa-lena-under-attack/, (last accessed March 8, 2022).

[46] Megan Redshaw, *Top ICU Doctor Suspended After Suing Hospital for Banning Life-Saving COVID Treatments,* The Defender, https://childrenshealthdefense.org/defender/paul-marik-lawsuit-hospital-remdesivir-ban-life-saving-drugs/, (last accessed March 7, 2022).

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CHD certifies that the foregoing statements regarding the basis for expedited processing are true and correct to the best of our knowledge and belief. 5 U.S.C. § 552(a)(6)(E)(vi).

Note that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable or can be deidentified. We further request that you describe any redacted, deleted, or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies.

Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. CHD reserves all rights to appeal the withholding or deletion of any information.

As indicated above, we are applying for expedited processing of this Request. A determination regarding expedited processing should be made within ten (10) days. Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter as required under 5 U.S.C. § 552(a)(6)(A)(i). Failure to respond in a timely manner shall be viewed as a denial of this request and CHD may immediately file an administrative appeal or an action.

Conclusion

If you have any questions regarding how to construe this request for records or believe that further discussions regarding search and processing would facilitate a more efficient production of records of interest to CHD, please do not hesitate to contact CHD to discuss this request. Children's Health Defense welcomes an opportunity to discuss its request with you before you undertake your search or incur search or duplication costs.

By working together at the outset, CHD and your agency can decrease the likelihood of costly and time-consuming litigation in the future. Where possible, please provide responsive material in an electronic format by email.

Alternatively, please provide responsive material in native format or in PDF format on a USB drive. Please send any responsive material being sent by mail to Children's Health Defense at 852 Franklin Ave., Suite 511, Franklin Lakes, New Jersey, 07417.

If it will accelerate release of responsive records to CHD, please provide responsive material on a rolling basis. We share a common mission to promote public health and transparency in government. Children's Health Defense looks forward to working with your agency on this request. If you do not understand any part of this request, please contact me at [redacted]@childrenshealthdefense.org or [redacted] during normal business hours.

Released by Chairman Rand Paul

Also, if CHD's request for a fee waiver is not granted in full, please contact us immediately upon making such a determination.

Thank you for your time and attention to this matter.

Sincerely yours,

Megan Redshaw, JD
Children's Health Defense

Released by Chairman Rand Paul

From: "Pau, Alice (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Barber, Susanna (NIH/NIAID) [E]" [redacted]@nih.gov>, "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Carver, Trea (NIH) [C]" [redacted]@nih.gov>, NIAID DCR FOIA [redacted]@mail.nih.gov>, "Tierney, John (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Herpin, Betsey (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: FOIA Search Request: Redshaw #57999
Date: Mon, 14 Mar 2022 14:22:19 -0400
Importance: Normal

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1. The list of references reviewed by the Panel are in the Ivermectin Clinical Data table listed below.
2. I have not had any communication with the WHO.
3. You can search my email.
4. I have not had any communications with any of the individuals listed.
5. Same response as #4

From: "Barber, Susanna (NIH/NIAID) [E]" [redacted]@nih.gov>
Date: Monday, March 14, 2022 at 2:13 PM
To: Cliff Lane [redacted]@niaid.nih.gov>, Alice Pau [redacted]@niaid.nih.gov>
Cc: "Carver, Trea (NIH) [C]" [redacted]@nih.gov>, NIAID DCR FOIA [redacted]@mail.nih.gov>, "Tierney, John (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Herpin, Betsey (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FOIA Search Request: Redshaw #57999

Cliff and Alice,

This new FOIA request has been forwarded to us by Robin. Please see her notes / questions in GREEN (below) which are directed to both of you – I've highlighted them in yellow. Does CIT have permission to search records, per the parameters described by Robin, using the algorithm in her email, for just Alice's records, or for both of you?

I'm wondering if searching "Treatment Guidelines Exec. Sec." and "Ivermectin" might be an alternate / optimal route.

Let me know your preference(s) / permissions.

Susanna

From: Schofield, Robin (NIH/NHLBI) [E] [redacted]@nih.gov>
Sent: Monday, March 14, 2022 12:24 PM
To: Awwad, David (NIH/NIAID) [C] [redacted]@niaid.nih.gov>; Folkers, Greg (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Barber, Susanna (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; NIAID DCR FOIA [redacted]@mail.nih.gov>
Subject: FOIA Search Request: Redshaw #57999

Good morning,

Megan Redshaw of Children's Health Defense submitted a 5-part FOIA request for (IOD – please see red; DCR – please see green):

Released by Chairman Rand Paul

1. Please provide CHD with a list of all studies, reports, scientific papers or records relied on by NIAID and any of its employees, including Dr. Anthony Fauci, that prove or suggest ivermectin is not effective in controlling, reducing the symptoms of, curing or avoiding the death of persons positively confirmed to have COVID-19 through appropriate testing, as well as persons having COVID-19 who were not tested for SARS-CoV-2, and persons having coronavirus disease and/or COVID-19.

IOD AND DCR: Is there an already assembled list? If not, I will ask NIH FOIA to respond that the support for the official recommendations on Ivermectin is already in the public domain in the Covid-19 Treatment Guidelines and provide the links:

Ivermectin | COVID-19 Treatment Guidelines (nih.gov)
Table: Ivermectin Clinical Data | COVID-19 Treatment Guidelines (nih.gov)

2. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present between any NIAID employee, including Dr. Anthony Fauci, and the WHO and/or any of its officials, including, but not limited to, Tedros Adhanom Ghebreyesus, Michael Ryan, Soumya Swaminathan, Dr. Gro Harlem Brundtland and Ana Maria Restrepo that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and the domain @who.int containing the term ivermectin for the time period 1/1/19 to present.

DCR: We are required to search where we are reasonably likely to find documents. Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

3. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and any National Institutes of Health (NIH) employee including, but not limited to, Francis Collins, Roy M. Gulick, H. Clifford Lane and Dr. Henry Masur that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and Dr. Collins OR [redacted]@med.cornell.edu OR Dr. Lane OR Dr. Masur containing the term ivermectin for the time period 1/1/19 to present.

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD except swap the places of Dr. Lane (or Pau or whoever) and Dr. Fauci.

4. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Jeremy Farrar, Lawrence Tabak, William Pao, Dr. Deborah Birx and Dr. Robert Redfield that includes the keyword "ivermectin."

IOD: We will request a CIT search for emails between Dr. Fauci and [redacted]@wellcome.ac.uk OR Dr. Tabak OR [redacted]@vanderbilt.edu OR [redacted]@roche.com OR [redacted]@mskcc.org OR [redacted]@gmail.com OR [redacted]@nsc.eop.gov OR [redacted]@cdc.gov OR [redacted]@pennmedicine.upenn.edu containing the term ivermectin for the time period 1/1/19 to present.

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

5. Please provide any and all email communications (including emails, complete email chains, email attachments, calendar invitations, and calendar invitation attachments) or correspondence of any type between January 1, 2019, to present, to, and from, and between any NIAID employee, including Dr. Anthony Fauci, and Elhadj As Sy, Dr. Victor Dzau, Dr. Chris Elias, Henrietta Fore, Dr. George F. Gao, and Bill Gates that includes the keyword "ivermectin."

Released by Chairman Rand Paul

IOD: We will request a CIT search for emails between Dr. Fauci and [redacted]@kofiannanfoundation.org OR [redacted]@duke.edu OR [redacted]@gatesfoundation.org OR [redacted]@unicef.org OR [redacted]@im.ac.cn OR [redacted]@gatesventures.com containing the term ivermectin for the time period January 1, 2019 to present

DCR: Please advise whether that would be Dr. Lane, Dr. Pau, both or other. We will conduct the same search as IOD.

Please reply with permission to search and let me know if you have any questions.

Thank you.

Robin

Robin L. Schofield
NHLBI FOIA Service Center

Released by Chairman Rand Paul

Kind regards,

Ian

From: Niranjan Bose [redacted]@bgc3.com>
Date: Thursday, May 18, 2017 at 2:58 PM
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Routh, Jennifer (NIH/NIAID) [E]" [redacted]@nih.gov>, Ian Saunders [redacted]@bgc3.com>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Dear Robert,

Adding my colleague, Ian Saunders to the email thread, who will be able to work with Jennifer on the filming needs, etc.

Your proposed split of 15 min and 45 min. sounds good to me. The elements of the tour outlined below are also good. As you outline your minute by minute, we would like to see the technical aspects that will be covered in the 45 min walking tour.

I have heard a lot about the wonderful work at the VRC, so I am sure it will be tough to squeeze everything in within 45 min. we are excited about hearing more about the structure guided immunogen design work in the HIV, RSV, Flu and related areas. The RNA vaccine platforms work is also something that Bill is very keen to learn more about.

Best,
Bose

From: Eiss, Robert (NIH/FIC) [E] [mailto [redacted]@mail.nih.gov]
Sent: Wednesday, May 17, 2017 9:24 AM
To: Niranjan Bose [redacted]@bgc3.com>
Cc: Routh, Jennifer (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Hi Bose,

Following outlines how we were planning to allocate time. Dr. Fauci and Dr. Mascola (the VRC's director) would offer a 15 min scientific overview or the VRC's research and capabilities, and then proceed with a 45 minute walking tour of the facility. Does this align with your office's expectations? As discussed, the tour will focus on structure-guided immunogen design applied to vaccine development for HIV, RSV, Flu, PIV, MERS and related CoV

The contact for the film crew is Jennifer Routh, cc'd on this message She can offer detail on what the different spaces will look like at the VRC and where the crew can leave and/or set up any equipment during the visit.

Best,

From: Niranjan Bose [mailto [redacted]@bgc3.com]
Sent: Monday, May 15, 2017 3:51 PM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Dear Robert,

Released by Chairman Rand Paul

Thank you for the update. I don't think we need a sit down interview. It would be good to have this as a walking tour… with time for Q&A/discussion along the tour.

We would like to make sure that Bill has a good portion of the tour/discussion dedicated to the scientific discussions that you point out below (highlighted). Are you able to propose an outline of how the 60 minutes might get split out in the tour?

Finally, should I connect our communications/filming team with someone at your end? To sort through logistics, etc.

Best,
Bose

Released by Chairman Rand Paul

From: Jen Krajicek [redacted]@bgc3.com>
To: "Routh, Jennifer (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "Fine, Amanda (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop
Date: Tue, 23 May 2017 12:12:01 -0400
Importance: Normal

Tomorrow would work best for us. Would 1pm ET on Wednesday work for both of you?

From: Routh, Jennifer (NIH/NIAID) [E] [mailto [redacted]@nih.gov]
Sent: Tuesday, May 23, 2017 9:10 AM
To: Jen Krajicek [redacted]@bgc3.com>
Cc: Fine, Amanda (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Hi Jen,

Sorry for the delay. I've cc'd my colleague Amanda Fine, who will also be joining the call. I will be your contact at the VRC since I'm familiar with taking camera crews through this building, but Amanda will help assist with the rest of the day since she has done more campus-wide tours with Dr. Collins. We are available between 2 and 4 ET today, but we're pretty open tomorrow or Thursday if you had a time in mind.

Thanks,
Jen

Jennifer Routh [E]
Scientific Communications Editor
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
NIH/HHS
31 Center Drive Room 7A17B
Bethesda, MD 20892
Direct: [redacted]
[redacted]@nih.gov
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Date: Tue, 23 May 2017 12:19:31 -0400
Importance: Normal

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To: "Routh, Jennifer (NIH/NIAID) [E]" [redacted]@nih.gov>, "Jen Krajicek" [redacted]@bgc3.com>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop
Date: Tue, 23 May 2017 12:20:37 -0400
Importance: Normal

Works for me as well! Do we have a conference line or shall I look into booking one of ours?

Thanks!
Amanda

Amanda Fine
Deputy, News Media Branch
National Institutes of Health
Tel: [redacted]
Email: [redacted]@nih.gov
Web: http://www.nih.gov

NIH . . . *Turning Discovery Into Health*

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NIH/HHS
31 Center Drive Room 7A17B
Bethesda, MD 20892
Direct: [redacted]
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Cc: Niranjan Bose [redacted]@bgc3.com>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Josh Daniel [redacted]@bgc3.com>
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Jen can set up a call next week. Perhaps the three of chat together and report back to Bose and Robert what we end up deciding to do.

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Date: Tue, 23 May 2017 16:56:03 -0400
Importance: Normal

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Sent: Friday, May 19, 2017 9:03 AM
To: Routh, Jennifer (NIH/NIAID) [E] [redacted]@nih.gov>; Jen Krajicek [redacted]@bgc3.com>
Cc: Niranjan Bose [redacted]@bgc3.com>; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Josh Daniel [redacted]@bgc3.com>
Subject: Re: Draft agenda for June 2 NIH-BMGF workshop

Hi Jennifer –

Very nice to meet you

I would love to set a time to chat with you and our producer here in Bill's office (Jen Krajicek, cc'd here) so we can chat about how we might be able to figure out a way forward to lightly capture some footage of Bill's visit to NIH next month.

Typically we have followed Bill on the "non-conference room" and "non-confidential" parts of his visits, capturing the learning he's doing.

We also typically take 5-10 minutes at the end of the visit and have Bill stand outside or inside for a "stand up" interview where he runs over what he just saw.

We'd love to chat with you about the best way to be unobtrusive followers on this upcoming trip.

Jen can set up a call next week. Perhaps the three of chat together and report back to Bose and Robert what we end up deciding to do.

Kind regards,

Ian

From: Niranjan Bose [redacted]@bgc3.com>
Date: Thursday, May 18, 2017 at 2:58 PM
To: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Cc: "Routh, Jennifer (NIH/NIAID) [E]" [redacted]@nih.gov>, Ian Saunders [redacted]@bgc3.com>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Dear Robert,

Adding my colleague, Ian Saunders to the email thread, who will be able to work with Jennifer on the filming needs, etc.

Your proposed split of 15 min and 45 min. sounds good to me. The elements of the tour outlined below are also good. As you outline your minute by minute, we would like to see the technical aspects that will be covered in the 45 min walking tour.

I have heard a lot about the wonderful work at the VRC, so I am sure it will be tough to squeeze everything in within 45 min. we are excited about hearing more about the structure guided immunogen design work in the HIV, RSV, Flu and related areas. The RNA vaccine platforms work is also something that Bill is very keen to learn more about.

Released by Chairman Rand Paul

Best,
Bose

From: Eiss, Robert (NIH/FIC) [E] [mailto [redacted]@mail.nih.gov]
Sent: Wednesday, May 17, 2017 9:24 AM
To: Niranjan Bose [redacted]@bgc3.com>
Cc: Routh, Jennifer (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Hi Bose,

Following outlines how we were planning to allocate time. Dr. Fauci and Dr. Mascola (the VRC's director) would offer a 15 min scientific overview or the VRC's research and capabilities, and then proceed with a 45 minute walking tour of the facility. Does this align with your office's expectations? As discussed, the tour will focus on structure-guided immunogen design applied to vaccine development for HIV, RSV, Flu, PIV, MERS and related CoV

The contact for the film crew is Jennifer Routh, cc'd on this message She can offer detail on what the different spaces will look like at the VRC and where the crew can leave and/or set up any equipment during the visit.

Best,

From: Niranjan Bose [mailto [redacted]@bgc3.com]
Sent: Monday, May 15, 2017 3:51 PM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Subject: RE: Draft agenda for June 2 NIH-BMGF workshop

Dear Robert,

Thank you for the update. I don't think we need a sit down interview. It would be good to have this as a walking tour… with time for Q&A/discussion along the tour.

We would like to make sure that Bill has a good portion of the tour/discussion dedicated to the scientific discussions that you point out below (highlighted). Are you able to propose an outline of how the 60 minutes might get split out in the tour?

Finally, should I connect our communications/filming team with someone at your end? To sort through logistics, etc.

Best,
Bose

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" </O=NIH/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=COLLINSFR>
To: [redacted]@its.jnj.com" [redacted]@its.jnj.com>
Cc: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: NIH, BMGF, and you
Date: Sun, 14 May 2017 08:48:14 -0400
Importance: Normal
Attachments: DRAFT_agenda_BMGF-NIH_meeting_2017_5_12.docx

Dear Paul,

Over the past several years, the scientific leadership of the NIH and Bill & Melinda Gates Foundation have met annually to review progress of joint activities and plan future projects. Bill Gates will join our next meeting in person, to take place Friday, June 2, on the NIH campus in Bethesda, Maryland.

Discussions will include innovations in vaccine R&D, led by Tony Fauci. Emphasis will be placed on therapeutic vaccines as well as developments in structure-based immunogen design. In addition, we will discuss new concepts in point-of-care diagnostics, and measures to create a durable network of African sites capable of licensure standard trials, among other capacity needs. This latter topic will include requirements to enable clinical testing of CEPI priority vaccines, as well as the activities of the Coalition for African Research and Innovation (CARI) to incentivize African governments to support and sustain biomedical R&D infrastructure.

We would be delighted if you would be available to participate, and join Bill and conference participants in these important discussions. If so, we would hope you could join us in a panel discussion surrounding infrastructural and training requirements in Africa, and future directions of CARI.
These discussions are truly timely. As discussed at WEF and other venues, to accelerate progress and new potentials in translational science, new African partnerships and platforms are needed to plan efficiently and implement high-quality multi-site research, harmonized standards and best practices, training and robust use of informatics, among other capabilities - yielding greater impact than any sum of unique, individual effort. I know this has been a topic of continuing interest during your time at J&J. Your thoughtful perspectives would be of great value as we consider joint strategies and engage industry partners.
We are sure you are prodigiously busy, but very much hope your schedule might allow you to join us. Attached is the current draft agenda. We look forward to providing additional details.

Best regards,

Francis and Trevor

Released by Chairman Rand Paul

From: "Stoffels, Paul [JJCUS]" [redacted]@its.jnj.com>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: Re: NIH, BMGF, and you
Date: Fri, 19 May 2017 11:48:38 -0400
Importance: Normal

Francis,

I very much appreciate you including me in the reviews. For the moment I'm planned to be in Israel and Europe that week and it would be very challenging for me to adapt my agenda to make it on time to the US.

Happy to follow up afterwards on the topics where I can support.

It was nice to see you at the FNIH event. Looking forward to connecting soon,

Best regards,

Paul

Sent from my iPad

On May 14, 2017, at 8:48 AM, Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov> wrote:

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To: "Stoffels, Paul [JJCUS]" [redacted]@its.jnj.com>
Cc: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>, "Glass, Roger (NIH/FIC) [E]" [redacted]@mail.nih.gov>
Subject: RE: NIH, BMGF, and you
Date: Sat, 20 May 2017 17:44:19 -0400
Importance: Normal

Totally understand, Paul. We will follow up later.

All the best, Francis

From: Stoffels, Paul [JJCUS] [mailto[redacted]@its.jnj.com]
Sent: Friday, May 19, 2017 11:49 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: [redacted]@gatesfoundation.org; [redacted]@gatesfoundation.org; Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>; Glass, Roger (NIH/FIC) [E] [redacted]@mail.nih.gov>
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<DRAFT agenda BMGF-NIH meeting 2017_5_12.docx>

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From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: Trevor Mundel [redacted]@gatesfoundation.org>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>
Subject: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 12:34:23 -0400
Importance: Normal

Per the call today with Mr. Gates – am adding Dr. Lane here so that you can connect and follow up.

Please let me know if you need anything else from me – always happy to help.

Best regards,

Patricia L. Conrad
Public Health Analyst and
Special Assistant to the Director
National Institute of Allergy and Infectious Diseases
The National Institutes of Health
31 Center Drive, MSC 2520 - Room 7A03
Bethesda, Maryland 20892
[redacted]
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Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 14:43:01 -0400
Importance: Normal

Thanks Pat, hi Cliff we were just on a call with Tony and Bill and they agreed that we should look at how we might coordinate our activities in the plasma trial space as we are working with the same consortium to see if recruitment of donors and the actual trial might be accelerated. As we're more focused on post-exposure prophylaxis and treatment of mild high risk cases to prevent progression there might be some synergies with your focus. I'm copying in my colleague Mike Poole who is leading our efforts and though we might get together on a call soon. Trevor

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Executive Assistant
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M [redacted]
E [redacted]@gatesfoundation.org
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www.gatesfoundation.org

From: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 9:34:23 AM
To: Trevor Mundel [redacted]@gatesfoundation.org>
Cc: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Christa Bowles [redacted]@gatesfoundation.org>
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From: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@nih.gov>
To: Trevor Mundel [redacted]@gatesfoundation.org>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 14:46:59 -0400
Importance: Normal

Any time 6 PM EDT or later would work for me. Easiest way is by cell: [redacted]

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 2:43 PM
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci

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From: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 9:34:23 AM
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Cc: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Christa Bowles [redacted]@gatesfoundation.org>
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Best regards,

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From: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@nih.gov>
To: Linda Lane [redacted]@aol.com>
Subject: FW: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 14:47:18 -0400
Importance: Normal

Another one for the files.

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 2:43 PM
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci

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Cc: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Christa Bowles [redacted]@gatesfoundation.org>
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Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
Subject: Re: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 15:07:47 -0400
Importance: Normal

Cliff, that would be great let's target 6:30pm EDT - we'll send a dial in as Mike and Penny will join. Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
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From: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 11:46 AM
To: Trevor Mundel; Conrad, Patricia (NIH/NIAID) [E]
Cc: Christa Bowles; Mike Poole
Subject: Re: on behalf of Dr. Fauci

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Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
Subject: Re: on behalf of Dr. Fauci
Date: Wed, 15 Apr 2020 15:11:58 -0400
Importance: Normal

Thanks – talk to you then.

Cliff

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 3:08 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
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V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

From: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 11:46 AM
To: Trevor Mundel; Conrad, Patricia (NIH/NIAID) [E]
Cc: Christa Bowles; Mike Poole
Subject: Re: on behalf of Dr. Fauci

Any time 6 PM EDT or later would work for me. Easiest way is by cell: [redacted]

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 2:43 PM
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>

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Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci

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E[redacted]@gatesfoundation.org

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V[redacted]
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From: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 9:34:23 AM
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Best regards,

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31 Center Drive, MSC 2520 - Room 7A03
Bethesda, Maryland 20892
[redacted]
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To: Trevor Mundel [redacted]@gatesfoundation.org>
Cc: Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
Subject: Staging site for the guidelines
Date: Wed, 15 Apr 2020 18:54:37 -0400
Importance: Normal

---

https://staging-coronavirus.rocbis.com/
username: [redacted]
password: [redacted]

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 3:08 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
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Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>, Jim Neaton [redacted]@umn.edu>
Subject: IVIg Protocol Team
Date: Wed, 15 Apr 2020 19:00:40 -0400
Importance: Normal

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Thank-you again for the discussion earlier today.

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Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Jim Neaton [redacted]@umn.edu>
Subject: RE: IVIg Protocol Team
Date: Wed, 15 Apr 2020 19:28:04 -0400
Importance: Normal

Nice to meet you, Jim, albeit virtually. I will get back to you with a name shortly.

And Cliff – thanks again for the call.

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Sent: Wednesday, April 15, 2020 7:01 PM
To: Trevor Mundel [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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F [redacted]
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To: Penny Heaton [redacted]@gatesmri.org>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Trevor Mundel [redacted]@gatesfoundation.org>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: IVIg Protocol Team
Date: Wed, 15 Apr 2020 20:55:54 -0400
Importance: Normal

Thanks Penny - nice to meet you too.

On Wed, Apr 15, 2020 at 6:28 PM Penny Heaton [redacted]@gatesmri.org> wrote:

> Nice to meet you, Jim, albeit virtually. I will get back to you with a name shortly.
>
> And Cliff – thanks again for the call.
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To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Jim Neaton [redacted]@umn.edu>
Cc: Jintanat Ananworanich [redacted]@gatesmri.org>
Subject: RE: IVIg Protocol Team
Date: Sat, 18 Apr 2020 17:43:27 -0400
Importance: Normal

Dear Cliff and Jim,

Greetings! I hope this weekend finds you with at least a moment to relax.

By way of this email, I would like to introduce you to Jintanat Ananworanich. She is a pediatrician and immunologist, currently co-leading our RSV monoclonal antibody program among others. She has much clinical trial experience, particularly in LMICs. She declares she has a some additional bandwidth and would love to join you on the weekly team calls and help in any way she can.

I will leave it to the three of you to coordinate from here.

Best,

Penny

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Sent: Wednesday, April 15, 2020 7:28 PM
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Sent: Wednesday, April 15, 2020 7:01 PM
To: Trevor Mundel [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>; Mike Poole [redacted]@gatesfoundation.org>; Penny Heaton [redacted]@gatesmri.org>; Jim Neaton [redacted]@umn.edu>
Subject: IVIg Protocol Team

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F [redacted]
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From: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Penny Heaton" [redacted]@gatesmri.org>
Cc: "Jim Neaton" [redacted]@umn.edu>, "Jintanat Ananworanich" [redacted]@gatesmri.org>
Subject: Re: IVIg Protocol Team
Date: Sat, 18 Apr 2020 18:27:44 -0400
Importance: Normal

Penny - We are very happy to have Jintanat join the calls.

Jintanat - nice to have a chance to work with you again. Sorry it is under these circumstances.

Jim will send the meeting invites.

Cliff

On Apr 18, 2020, at 5:43 PM, Penny Heaton [redacted]@gatesmri.org> wrote:

Dear Cliff and Jim,

Greetings! I hope this weekend finds you with at least a moment to relax.

By way of this email, I would like to introduce you to Jintanat Ananworanich. She is a pediatrician and immunologist, currently co-leading our RSV monoclonal antibody program among others. She has much clinical trial experience, particularly in LMICs. She declares she has a some additional bandwidth and would love to join you on the weekly team calls and help in any way she can.

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To: Penny Heaton [redacted]@gatesmri.org>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Jintanat Ananworanich [redacted]@gatesmri.org>
Subject: Re: IVIg Protocol Team
Date: Sat, 18 Apr 2020 19:09:53 -0400
Importance: Normal

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On Sat, Apr 18, 2020 at 4:43 PM Penny Heaton [redacted]@gatesmri.org> wrote:

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To: "Jim Neaton" [redacted]@umn.edu>
Subject: Re: IVIg Protocol Team
Date: Sat, 18 Apr 2020 19:12:45 -0400
Importance: Normal

I think Mark knows her well. She used to work with Praphan and Kiat.

On Apr 18, 2020, at 7:10 PM, Jim Neaton [redacted]@umn.edu> wrote:

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From: Jim Neaton [redacted]@umn.edu>
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: IVIg Protocol Team
Date: Sat, 18 Apr 2020 19:14:06 -0400
Importance: Normal

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Trevor Mundel, MD, PhD

President, Global Health Program

V [redacted]

F [redacted]

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Office of the President, Global Health

V [redacted]

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M [redacted]

E [redacted]@gatesfoundation.org

Bill & Melinda Gates Foundation

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To: Jim Neaton [redacted]@umn.edu>, Penny Heaton [redacted]@gatesmri.org>
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Date: Sat, 18 Apr 2020 19:20:01 -0400
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Cliff, I agree it is under an unfortunate circumstance. Nevertheless it is a pleasure to work with you again.

Jim, our paths crossed many years ago. I was at HIV-NAT and was a study physician on Esprit and other INSIGHT protocols in Thailand. David Cooper was a codirector at HIVNAT and we all miss him.

I look forward to the call on Wednesday.

Best regards,
Jintanat

Jintanat Ananworanich, M.D., Ph.D.
Clinical Development Leader
W [redacted]
M [redacted]
E [redacted]@GatesMRI.org

Bill & Melinda Gates Medical Research Institute
245 Main Street, Cambridge, MA 02142

BILL & MELINDA GATES
MEDICAL RESEARCH
INSTITUTE

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Subject: Re: IVIg Protocol Team
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>
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>
> **M** [redacted]
>
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From: Penny Heaton
Sent: Wednesday, April 15, 2020 7:28 PM
To: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Trevor Mundel [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>; Mike Poole [redacted]@gatesfoundation.org>; Jim Neaton [redacted]@umn.edu>
Subject: RE: IVIg Protocol Team

Nice to meet you, Jim, albeit virtually. I will get back to you with a name shortly.

And Cliff – thanks again for the call.

From: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 7:01 PM
To: Trevor Mundel [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>; Mike Poole [redacted]@gatesfoundation.org>; Penny Heaton [redacted]@gatesmri.org>; Jim Neaton [redacted]@umn.edu>
Subject: IVIg Protocol Team

Attention: This message was sent from an external domain.

Colleagues,

Thank-you again for the discussion earlier today.

Jim Neaton (copied) is the Head of the INSIGHT Network and has been coordinating the Wednesday 9 AM EDT call with the investigators and the companies. As we discussed it would be great to have a representative from the Gates Foundation as part of that team.

Please let us know who you would like to have join and Jim will make sure they are in the loop.

Thanks again,

Released by Chairman Rand Paul

Cliff

From: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Date: Wednesday, April 15, 2020 at 3:11 PM
To: Trevor Mundel [redacted]@gatesfoundation.org>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
Subject: Re: on behalf of Dr. Fauci

Thanks – talk to you then.

Cliff

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 3:08 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>, Penny Heaton [redacted]@gatesmri.org>
Subject: Re: on behalf of Dr. Fauci

Cliff, that would be great let's target 6:30pm EDT - we'll send a dial in as Mike and Penny will join. Trevor

Trevor Mundel, MD, PhD

President, Global Health Program

V [redacted]

F [redacted]

E [redacted]@gatesfoundation.org

Christa Bowles

Executive Assistant

Released by Chairman Rand Paul

Office of the President, Global Health

V [redacted]

M [redacted]

E [redacted]@gatesfoundation.org

Bill & Melinda Gates Foundation

www.gatesfoundation.org

From: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 11:46 AM
To: Trevor Mundel; Conrad, Patricia (NIH/NIAID) [E]
Cc: Christa Bowles; Mike Poole
Subject: Re: on behalf of Dr. Fauci

Any time 6 PM EDT or later would work for me. Easiest way is by cell: [redacted]

From: Trevor Mundel [redacted]@gatesfoundation.org>
Date: Wednesday, April 15, 2020 at 2:43 PM
To: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Christa Bowles [redacted]@gatesfoundation.org>, Mike Poole [redacted]@gatesfoundation.org>
Subject: Re: on behalf of Dr. Fauci

Thanks Pat, hi Cliff we were just on a call with Tony and Bill and they agreed that we should look at how we might coordinate our activities in the plasma trial space as we are working with the same consortium to see if recruitment of donors and the actual trial might be accelerated. As we're more focused on post-exposure prophylaxis and treatment of mild high risk cases to prevent progression there might be some synergies with your focus. I'm copying in my colleague Mike Poole who is leading our efforts and though we might get together on a call soon. Trevor

Trevor Mundel, MD, PhD

President, Global Health Program

V [redacted]

F [redacted]

E [redacted]@gatesfoundation.org

Christa Bowles

Released by Chairman Rand Paul

Executive Assistant

Office of the President, Global Health

V [redacted]

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From: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Sent: Wednesday, April 15, 2020 9:34:23 AM
To: Trevor Mundel [redacted]@gatesfoundation.org>
Cc: Lane, Cliff (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Christa Bowles [redacted]@gatesfoundation.org>
Subject: on behalf of Dr. Fauci

Per the call today with Mr. Gates – am adding Dr. Lane here so that you can connect and follow up.

Please let me know if you need anything else from me – always happy to help.

Best regards,

Patricia L. Conrad

Public Health Analyst and

Special Assistant to the Director

National Institute of Allergy and Infectious Diseases

The National Institutes of Health

31 Center Drive, MSC 2520 - Room 7A03

Bethesda, Maryland 20892

[redacted]

[redacted] fax

Released by Chairman Rand Paul

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Released by Chairman Rand Paul

From: "Jones, David M" [redacted]@state.gov>

To: "Ruscio, Bruce A" [redacted]@state.gov>, [redacted]@cdc.gov'" [redacted]@cdc.gov>, [redacted]@cdc.gov'" [redacted]@cdc.gov>, "'Ferriter, Karin'" [redacted]@USPTO.GOV>, "Lewis, Oliver M" [redacted]@state.gov>, [redacted]@nsf.gov'" [redacted]@nsf.gov>, "'Katz, Jackie M. (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, "Park, Christopher J" [redacted]@state.gov>, "Frisk, Megan L" [redacted]@state.gov>, "'Stevens, James (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, [redacted]@nsf.gov'" [redacted]@nsf.gov>, [redacted]@nsf.gov'" [redacted]@nsf.gov>, "'Bohon, Ellen'" [redacted]@trade.gov>, "'Urban, JoEllen'" [redacted]@USPTO.GOV>, "'Epstein, Gerald L. EOP/OSTP'" [redacted]@ostp.eop.gov>, "'Jones, Franca R CDR USN DHA HEALTH SURV (US)'" [redacted]@mail.mil>, "'Weinberger, Collin (OS/OGA) (CTR)'" [redacted]@hhs.gov>, "'Barna, Lauren (OS/ASPR/OPP)'" [redacted]@hhs.gov>, "'Marinissen, Maria (OS/ASPR/OPP)'" [redacted]@hhs.gov>, "'Bright, Rick (OS/ASPR/BARDA)'" [redacted]@hhs.gov>, "'Wong, Holly (HHS/OS/OGA)'" [redacted]@hhs.gov>, "Schlegelmilch, Kristine (Geneva)" [redacted]@state.gov>, "'deborah_e_lashley-[redacted]@ustr.eop.gov'" [redacted]@ustr.eop.gov>, "'Touchette, Nancy (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "Blackwood, Ann S" [redacted]@state.gov>, [redacted]@ustr.eop.gov'" [redacted]@ustr.eop.gov>, "'York, George E.'" [redacted]@ustr.eop.gov>, "'Moezie, Minna F.'" [redacted]@USPTO.GOV>, "'Ranjan, Mukul (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "'Wegrzyn, Renee'" [redacted]@darpa.mil>, "'Parr, Lianne (contr-bto)'" [redacted]@darpa.mil>, "'Post, Diane (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "'Spiro, David (NIH/NIAID) [E]'" [redacted]@nih.gov>, "'Mowatt, Michael (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "'Miers, Sarah (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "'Shaw, Michael (CDC/OID/OD)'" [redacted]@cdc.gov>, "'Snyder, Anne (HHS/OS/OGA)'" [redacted]@hhs.gov>, "Scholl, Katlyn M" [redacted]@state.gov>, "'Chandrasekera, Ruvani (HHS/ASPR/OPP)'" [redacted]@hhs.gov>, 'Stevan Mitchell' [redacted]@trade.gov>, "'Sherman, Susan (HHS/OGC)'" [redacted]@HHS.GOV>, "'Foster, Joseph (CDC/OCOO/OGC)'" [redacted]@cdc.gov>, "Music, Francesca" [redacted]@mail.mil>, "'DuLaney, Megan M CTR OSD OSD (US)'" [redacted]@mail.mil>, "Aktipis, Stephanie" [redacted]@state.gov>, "'Jernigan, Daniel B. (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, "'Marano, Nina (CDC/OID/NCEZID)'" [redacted]@cdc.gov>, "'Berkley, Dale (NIH/OD) [E]'" [redacted]@OD.NIH.GOV>, "Lugo, Neha S" [redacted]@state.gov>, [redacted]@ARS.USDA.GOV'" [redacted]@ARS.USDA.GOV>, "'Jiang, Chengyong G CTR (US)'" [redacted]@mail.mil>, [redacted]@nifa.usda.gov'" [redacted]@nifa.usda.gov>, [redacted]@nifa.usda.gov'" [redacted]@nifa.usda.gov>, [redacted]@USPTO.GOV'" [redacted]@USPTO.GOV>, "Kim, Elizabeth AB (OES)" [redacted]@state.gov>, "Reed, Allison D" [redacted]@state.gov>, "Margolis, Jonathan A" [redacted]@state.gov>, "'Eisenberg, Emily (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, "Steiger, William R. (AID/A)" [redacted]@usaid.gov>, "'Raychaudhuri, Gopa (FDA/CBER)'" [redacted]@fda.hhs.gov>, "'Bell, Tammie Jo (CDER) (FDA/CDER)'" [redacted]@fda.hhs.gov>, "'Donis, Ruben (OS/ASPR/BARDA)'" [redacted]@hhs.gov>, "'Yu, Anne (HHS/OS/OGA)'" [redacted]@hhs.gov>, "Lobel, Hannah J" [redacted]@state.gov>, "'Urban, JoEllen'" [redacted]@omb.eop.gov>, "'Moudy, Robin (OS/ASPR/OPP)'" [redacted]@hhs.gov>, "Lim, Matthew L (Geneva)" [redacted]@state.gov>, "'Pearson, Kate L. (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, "'Cho, David S (CBER) (FDA/CBER)'" [redacted]@fda.hhs.gov>, "'Arcuri, Guy (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "Colby, Michelle - NIFA" [redacted]@nifa.usda.gov>, "'Epting, Mallory (OS/OGA)'"

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[redacted]@hhs.gov>, "'Galloway, Summer (CDC/OID/NCIRD) (CTR)'" [redacted]@cdc.gov>, "'Kerr, Lawrence (HHS/OS/OGA)'" [redacted]@hhs.gov>, "'Handley, Gray (NIH/NIAID) [E]'" [redacted]@niaid.nih.gov>, "Mallory, Jerrold L" [redacted]@state.gov>, "'Chretien, JP EOP/OSTP'" [redacted]@ostp.eop.gov>, "'Olsen, Sonja (CDC/OID/NCIRD)'" [redacted]@cdc.gov>, "Kopolow McCall, Melissa J" [redacted]@state.gov>, "'Karem, Kevin (CDC/CGH/OD)'" [redacted]@cdc.gov>, "'Azar, Ramzy G CTR DHA HEALTH OPS DIR (US)'" [redacted]@mail.mil>, "'West, William Lionel (Lionel) II CIV DHA READINESS (US)'" [redacted]@mail.mil>, "'Kishimori, Jennifer M COL USARMY OSD HA (US)'" [redacted]@mail.mil>, "'Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US)'" [redacted]@mail.mil>, "'Petersen, Juliette R CTR OSD OUSD P-R (US)'" [redacted]@mail.mil>, "West, Matthew B" [redacted]@state.gov>, "Borio, Luciana L. EOP/NSC" [redacted]@nsc.eop.gov>, "Carter, Hillary H. EOP/NSC" [redacted]@nsc.eop.gov>, "Carroll, Dennis (GH/ID)" [redacted]@usaid.gov>, "Cleary, Susan M" [redacted]@state.gov>

Cc: "MacCannell, Duncan (CDC/OID/NCEZID)" [redacted]@cdc.gov>, "Giovanni, Maria (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Armstrong, Gregory (CDC/OID/NCEZID)" [redacted]@cdc.gov>, "Cheever, Anne (contr-bto)" [redacted]@darpa.mil>, "Patterson, Jenica (contr-i2o)" [redacted]@darpa.mil>

Subject: RE: Confirmation and Concept Note for Global Bioinformatics Capacity Mapping Consultation with representatives from the Bill and Melinda Gates foundation

Date: Tue, 13 Mar 2018 09:32:19 -0400

Importance: Normal

Inline-Images: Picture_(Device_Independent_Bitmap)_1.jpg; Picture_(Device_Independent_Bitmap)_2.jpg

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Thank you to everyone who attended the March 8 meeting at the DOS on Bioinformatics Mapping. Special thanks to the Bill and Melinda Gates Foundation for sending such star presenters who provided the Foundation's valuable perspective about the subject. For anyone interested, below are the links to our OES Facebook and Twitter posts regarding the meeting. We look forward to our next gathering.

Facebook: https://www.facebook.com/StateDepartment.OES/posts/1614952051886759

Twitter: https://twitter.com/StateDeptOES

Regards,

David Maurice Jones

Foreign Service Officer

Office of International Health and Biodefense (IHB)

Bureau of Oceans and International Environmental and Scientific Affairs (OES)

United States Department of State

Tel: [redacted]

[redacted]@state.gov

Released by Chairman Rand Paul

-----Original Appointment-----
From: Ruscio, Bruce A
Sent: Tuesday, September 26, 2017 10:08 AM
To: Ruscio, Bruce A; Jones, David M; [redacted]@cdc.gov'; [redacted]@cdc.gov'; 'Ferriter, Karin'; Lewis, Oliver M; [redacted]@nsf.gov'; 'Katz, Jackie M. (CDC/OID/NCIRD)'; Park, Christopher J [redacted]@state.gov); Frisk, Megan L; 'Stevens, James (CDC/OID/NCIRD)'; [redacted]@nsf.gov'; [redacted]@nsf.gov'; 'Bohon, Ellen'; 'Urban, JoEllen'; 'Epstein, Gerald L. EOP/OSTP'; 'Jones, Franca R CDR USN DHA HEALTH SURV (US)'; 'Weinberger, Collin (OS/OGA) (CTR)'; 'Barna, Lauren (OS/ASPR/OPP)'; 'Marinissen, Maria (OS/ASPR/OPP)'; 'Bright, Rick (OS/ASPR/BARDA)'; 'Wong, Holly (HHS/OS/OGA)'; Schlegelmilch, Kristine (Geneva); [redacted]@ustr.eop.gov'; 'Touchette, Nancy (NIH/NIAID) [E]'; Blackwood, Ann S; [redacted]@ustr.eop.gov'; 'York, George E.'; 'Moezie, Minna F.'; 'Ranjan, Mukul (NIH/NIAID) [E]'; 'Wegrzyn, Renee'; 'Parr, Lianne (contr-bto)'; 'Post, Diane (NIH/NIAID) [E]'; 'Spiro, David (NIH/NIAID) [E]'; 'Mowatt, Michael (NIH/NIAID) [E]'; 'Miers, Sarah (NIH/NIAID) [E]'; 'Shaw, Michael (CDC/OID/OD)'; 'Snyder, Anne (HHS/OS/OGA)'; Scholl, Katlyn M; 'Chandrasekera, Ruvani (HHS/ASPR/OPP)'; 'Stevan Mitchell'; 'Sherman, Susan (HHS/OGC)'; 'Foster, Joseph (CDC/OCOO/OGC)'; Music, Francesca; 'DuLaney, Megan M CTR OSD OSD (US)'; Aktipis, Stephanie; 'Jernigan, Daniel B. (CDC/OID/NCIRD)'; 'Marano, Nina (CDC/OID/NCEZID)'; 'Berkley, Dale (NIH/OD) [E]'; Lugo, Neha S; [redacted]@ARS.USDA.GOV'; 'Jiang, Chengyong G CTR (US)'; [redacted]@nifa.usda.gov'; [redacted]@nifa.usda.gov'; [redacted]@USPTO.GOV'; Kim, Elizabeth AB (OES); Reed, Allison D; Margolis, Jonathan A; 'Eisenberg, Emily (CDC/OID/NCIRD)'; Steiger, William R. (AID/A); 'Raychaudhuri, Gopa (FDA/CBER)'; 'Bell, Tammie Jo (CDER) (FDA/CDER)'; 'Donis, Ruben (OS/ASPR/BARDA)'; 'Yu, Anne (HHS/OS/OGA)'; Lobel, Hannah J; 'Urban, JoEllen'; 'Moudy, Robin (OS/ASPR/OPP)'; Lim, Matthew L (Geneva); 'Pearson, Kate L. (CDC/OID/NCIRD)'; 'Cho, David S (CBER) (FDA/CBER)'; 'Arcuri, Guy (NIH/NIAID) [E]'; Colby, Michelle - NIFA; 'Epting, Mallory (OS/OGA)'; 'Galloway, Summer (CDC/OID/NCIRD) (CTR)'; 'Kerr, Lawrence (HHS/OS/OGA)'; 'Handley, Gray (NIH/NIAID) [E]'; Mallory, Jerrold L; 'Chretien, JP EOP/OSTP'; 'Olsen, Sonja (CDC/OID/NCIRD)'; Kopolow McCall, Melissa J; 'Karem, Kevin (CDC/CGH/OD)'; 'Azar, Ramzy G CTR DHA HEALTH OPS DIR (US)'; 'West, William Lionel (Lionel) II CIV DHA READINESS (US)'; 'Kishimori, Jennifer M COL USARMY OSD HA (US)'; 'Pawlicki, Nathan J CTR DHA MED COUNTERMEASURES (US)'; 'Petersen, Juliette R CTR OSD OUSD P-R (US)'; West, Matthew B; Borio, Luciana L. EOP/NSC; Carter, Hillary H. EOP/NSC; Carroll, Dennis (GH/ID); Cleary, Susan M
Cc: MacCannell, Duncan (CDC/OID/NCEZID); Giovanni, Maria (NIH/NIAID) [E]; Armstrong, Gregory (CDC/OID/NCEZID); Cheever, Anne (contr-bto); Patterson, Jenica (contr-i2o)
Subject: Confirmation and Concept Note for Global Bioinformatics Capacity Mapping Consultation with representatives from the Bill and Melinda Gates foundation
When: Thursday, March 08, 2018 1:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: U.S. Department of State, 2201 C ST NW, Washington, DC 20520, Room 6833

Dear All,

- This email is to confirm the *Global Bioinformatics Capacity Mapping Consultation* with representatives from the Bill and Melinda Gates foundation for Thursday, March 8, 2018; 1:00– 4:00 pm at U.S. Department of State, 2201 C ST NW, Washington, DC 20520, Room 6833.

- Dr. Jonathan Margolis (State) and Dr. Maria Giovanni (NIH) will be co-chairing the consultation.

- Representatives from the BMGF will be sharing their perspectives and initiatives on Global Bioinformatics Capacity.

- A detailed meeting agenda will be forward shortly that includes a USG information sharing session with the BMGS followed by a USG only discussion session.

- Attached is the Concept Note for the meeting.

○ We ask that you read the concept note and take time to complete the questions at the end so that we can have a valuable information exchange with the BMGF and a separate USG only international policy discussion.

Released by Chairman Rand Paul

- We would like to have your responses in writing in order to accurately capture all of the input for the meeting summary.

- Please responds to the meeting invite, if you have not already.

- This will allow us to pre-clear you with State Security and to make your name tent for the table.

- As background for this meeting, recall that at the 5 Dec 2017 Consultation on Pathogen Genetic Sequence Data, participants identified a follow-up U.S. government discussion with the BMGF on global bioinformatics capacity as a next step. (See attached)

- Finally, I have updated the meeting invite list to best reflect the current information I have on interested participant in this policy discussion. Please forward to anyone I may have inadvertently missed.

- We are looking forward to seeing you on the 8th and please let me know if you have any questions.

<< File: Executive Summary of 5 Dec 2017 PGSD meeting.pdf >>

<< File: Concept note for Global Bioinformatics Capacity Mapping Consultation on 8 March 2018.docx >>

v/r

Bruce

Official
UNCLASSIFIED

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From: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>
To: "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 06:47:31 -0400
Importance: Normal

Hi all,

Bill Gates is at the White House tomorrow and asked to see me at 9 AM. Among the topics we will likely discuss is the HIV-SCD joint NIH-BMGF effort to develop cures that will be applicable in low income settings. Are there any new developments since the Sunnylands meeting back in May? Bill will likely ask about the future of this partnership.

Thanks, Francis

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From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>
Subject: Automatic reply: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 06:47:36 -0400
Importance: Normal

Thank you for your email. I am currently away and will return online Tuesday late afternoon, September 27. I will respond to your message upon my return, but there will be a delay owing to the inevitable backlog.

If you need immediate assistance during my absence, please contact Dr. Tara Schwetz, who will be acting NIH Director during my absence. You may reach Dr. Schwetz at [redacted]@nih.gov or [redacted]

Thanks for your patience,
Larry

Lawrence A. Tabak, DDS, PhD
Performing the Duties of the NIH Director

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>
To: "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 06:58:10 -0400
Importance: Normal
Attachments: Sickle_mouse_gene_editing.pdf

P.S. I did see the recent JCI Insight paper that shows impressive results for in vivo gene editing of the fetal globin promoter in the mouse model of sickle cell disease. Cites support from NHLBI, NHGRI, and NIGMS. Also support from BMGF. Cool stuff. See attached.

From: Collins, Francis (NIH/NHGRI) [E]
Sent: Tuesday, September 27, 2022 6:48 AM
To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
Subject: Seeing Bill Gates tomorrow

Hi all,

Bill Gates is at the White House tomorrow and asked to see me at 9 AM. Among the topics we will likely discuss is the HIV-SCD joint NIH-BMGF effort to develop cures that will be applicable in low income settings. Are there any new developments since the Sunnylands meeting back in May? Bill will likely ask about the future of this partnership.

Thanks, Francis

Released by Chairman Rand Paul

JCI insight

In vivo base editing by a single intravenous vector injection for treatment of hemoglobinopathies

Chang Li, … , Evangelia Yannaki, André Lieber

JCI Insight. 2022. https://doi.org/10.1172/jci.insight.162939.

Research In-Press Preview Hematology Stem cells

Individuals with beta-thalassemia or Sickle Cell Disease and hereditary persistence of fetal hemoglobin (HPFH) possessing 30% HbF appear to be symptom-free. Here, we used a non-integrating HDAd5/35++ vector expressing a highly efficient and accurate version of an adenine base editor (ABE8e) to install, in vivo, a -113A>G HPFH mutation in the gamma-globin promoters in “healthy” CD46/β-YAC mice carrying the human β-globin locus. Our in vivo hematopoietic stem cell (HSC) editing/selection strategy involves only subcutaneous and intravenous injections and does not require myeloablation and HSC transplantation. In vivo HSC base editing in CD46/β-YAC mice resulted in >60% -113A>G conversion with 30% γ-globin of human beta globin expressed in 70% of erythrocytes. Importantly, no off-target editing at sites predicted by CIRCLE-Seq or in silico was detected. Furthermore, no critical alterations in the transcriptome of in vivo edited mice were found by RNA-seq. In vitro, in HSCs from beta-thalassemia and Sickle Cell Disease patients, transduction with the base editor vector mediated efficient -113 A>G conversion and reactivation of γ-globin expression with subsequent phenotypic correction of erythroid cells. Because our in vivo base editing strategy is safe and technically simple, it has the potential for clinical application in developing countries where hemoglobinopathies are prevalent.

Find the latest version:

https://jci.me/162939/pdf

Released by Chairman Rand Paul

In vivo base editing by a single intravenous vector injection for treatment of hemoglobinopathies

Chang Li[1], Aphrodite Georgakopoulou[2], Gregory A. Newby[3, 4, 5], Kelcee A. Everette[3, 4, 5], Evangelos Nizamis[6], Kiriaki Paschoudi [2,7], Efthymia Vlachaki[8], Sucheol Gil[1], Anna K. Anderson[1], Theodore Koob[1], Lishan Huang[1], Hongjie Wang[1], Hans-Peter Kiem[9], David R. Liu[3, 4, 5], Evangelia Yannaki[2], André Lieber[1,10]

[1]University of Washington, Department of Medicine, Division of Medical Genetics, Seattle, WA 98195

[2]Gene and Cell Therapy Center, Hematology Department, George Papanicolaou Hospital, Thessaloniki, Greece

[3]Merkin Institute of Transformative Technologies in Healthcare, Broad Institute of MIT and Harvard, Cambridge, MA, USA

[4]Department of Chemistry and Chemical Biology, Harvard University, Cambridge, MA, USA

[5]Howard Hughes Medical Institute, Harvard University, Cambridge, MA, USA

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Abstract

Individuals with β-thalassemia or Sickle Cell Disease and hereditary persistence of fetal hemoglobin (HPFH) possessing 30% HbF appear to be symptom-free. Here, we used a non-integrating HDAd5/35++ vector expressing a highly efficient and accurate version of an adenine base editor (ABE8e) to install, in vivo, a -113A>G HPFH mutation in the γ-globin promoters in "healthy" CD46/β-YAC mice carrying the human β-globin locus. Our in vivo hematopoietic stem cell (HSC) editing/selection strategy involves only subcutaneous and intravenous injections and does not require myeloablation and HSC transplantation. In vivo HSC base editing in CD46/β-YAC mice resulted in >60% -113A>G conversion with 30% γ-globin of β-globin expressed in 70% of erythrocytes. Importantly, no off-target editing at sites predicted by CIRCLE-Seq or *in silico* was detected. Furthermore, no critical alterations in the transcriptome of in vivo edited mice were found by RNA-seq. In vitro, in HSCs from β-thalassemia and Sickle Cell Disease patients, transduction with the base editor vector mediated efficient -113 A>G conversion and reactivation of γ–globin expression with subsequent phenotypic correction of erythroid cells. Because our in vivo base editing strategy is safe and technically simple, it has the potential for clinical application in developing countries where hemoglobinopathies are prevalent.

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Key points

- In vivo HSC transduction of β-YAC mice with an ABE8e expressing HDAd5/35++ vector is safe and results in efficient and stable γ-globin reactivation in ~70% of erythrocytes at levels of 30% of human β-globin.

- Therapeutic editing is achieved in thalassemia and Sickle Cell Disease patient $CD34^+$ cells with HDAd-EF1α.ABE8e, leading to phenotypic correction in in vitro differentiated erythroid cells.

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Introduction

Autologous HSC gene therapy for hemoglobinopathies has shown promising clinical efficacy [1-4]. However, current protocols involving isolation of patient HSCs, their in vitro genetic modification with integrating vectors, and reinfusion of the modified HSCs following myelotoxic bone marrow conditioning, are technically complex and expensive. We are attempting to develop an in vivo HSC gene therapy approach that does not require myeloablation and integrating vectors, and that is technically easier. In this approach, we are using capsid-modified, helper-dependent HDAd5/35++ vectors (1, 2). These vectors target CD46, a receptor that is expressed on primitive HSCs (2, 3). HDAd5/35++ vectors are injected intravenously after mobilization of HSCs from the bone marrow by agents routinely used for HSC mobilization/harvesting. Mobilized HSCs are transduced while they are in the periphery. A large fraction of HSCs returns to the bone marrow. Mobilization of HSCs is critical for in vivo transduction because in the bone marrow they are surrounded by extracellular stroma proteins (4), and are not accessible to gene transfer vectors (2). To expand in vivo transduced HSCs, we currently use an in vivo selection mechanism based on a mutant O^6-methylguanine-DNA methyltransferase (*mgmt*^{P140K}) gene that confers resistance to O^6-BG/BCNU (O^6-Benzylguanine/Carmustine) given at doses that are 20-30-fold lower than used for cancer chemotherapy (5-7). We have demonstrated the safety (including the absence of clonal dominance (8-10)) and efficacy of the in vivo approach in mice (9-15) and rhesus macaques (3, 8, 16). One of our goals is to broadly apply this approach for the treatment of hemoglobinopathies, i.e. β-thalassemia and Sickle Cell Disease (SCD). Because of its simplicity and lower costs, this method could be applicable in developing countries where the burden from these diseases is high (17).

β-thalassemia and Sickle Cell Disease (SCD) are the most common inherited diseases in humans worldwide. β-thalassemia is caused by mutations in the *β-globin* gene which result in absent (β^0/β^0) or deficient (β^+/β^+, β^+/β^0) β-globin chain synthesis. β-thalassemia patients have a multitude of pathological symptoms and die prematurely. Most SCD patients are homozygous for a Glu6Val substitution resulting in the production of β^S-globin. Clinically, SCD is characterized by recurrent episodes of severe bone pain, multi-organ failure, and early mortality. Individuals with Hereditary Persistence of Fetal Hemoglobin (HPFH) and thalassemic β-globin mutations exhibit few or no pathological effects because HbF inhibits hemoglobin precipitation by reversing the globin chain imbalance and improving erythropoiesis (18).

This led to a number of hematopoietic stem cell (HSC) gene therapy approaches aimed toward the reactivation of fetal/γ-globin, e.g. by targeting two transcriptional repressors, ZBTB7A and BCL11A, that participate in the developmental silencing of the two *γ-globin* genes (*HBG1/Gγ and HBG2/Aγ*) through

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binding to their respective promoter cis-regulatory elements (19). An approach based on RNA interference to silence *bcl11a* expression (19) or reactivation of γ-globin expression by CRISPR-Cas9 editing of the erythroid *bcl11a* enhancer (20) have delivered promising clinical data. Furthermore, preclinical studies to reactivate γ-globin by CRISPR/Cas9 editing of the BCL11A and ZBTB7A binding motifs within the *HBG1/2* promoters have shown efficient HbF reactivation (21). Along this line, we used an in vivo HSC transduction approach to express a CRISPR/Cas9 specific to the BCL11A binding site within the *HBG1/2* promoters and showed efficient γ–globin reactivation in transgenic mice carrying the wild-type 248-kb b-globin locus yeast artificial chromosome (β-YAC mice) (22). However, we also detected an undesired deletion of the *HBG1* gene due to CRISPR/Cas9 mediated double strand DNA breaks (DSBs) in both the *HBG1* and the *HBG2* promoter. There is also accumulating evidence that DSBs catalyzed by CRISPR/Cas9 can result in large genomic deletions, chromosomal rearrangements, as well as p53-induced cell cycle arrest and apoptosis (23-25). To address these problems, we focused our work on base editors, enzymes that are capable of introducing precise cytidine or adenine substitutions with minimal occurrence of DSBs and indels at the target site (26-29). Here we employed an advanced adenine base editor version (ABE8e). ABE8e contains additional mutations that increase on-target activity and greatly decrease off-target activity (30).

We targeted ABE8e to the BCL11A binding site in the *HBG1/2* promoters (Fig.1A) to mediate a A>G conversion at the -113 position. The corresponding sgRNA was selected in an earlier study from a series of sgRNAs targeting the BCL11A binding motif as the most efficient in γ-globin reactivation (12). It is thought that the -113 A>G mutation does not disrupt BCL11A binding, but rather creates a *de novo* binding site for the transcriptional activator GATA1 ((T/A)GATA(A/G)) that outcompetes binding of the BCL11A (31). However, as a result of the relatively wide editing window of ABE8e, in addition to the -113A>G conversion, bystander editing at neighboring adenines is expected. (Fig.1A, right panel). Specifically, the -116A>G conversion would destroy the BCL11A binding motif.

Here, we evaluated a new HDAd-EF1α.ABE8e vector in vitro in $CD34^+$ cells from β-thalassemia and SCD patients as well as in ex vivo and in vivo HSC gene therapy setting in the β-YAC mouse model. In this context, we tested a new regimen of base editing that does not require the integration of the $mgmt^{P140K}$ cassette for in vivo selection.

Results

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HBG1/2 promoter editing in healthy CD34⁺ cells. We used HDAd5/35++ vectors to express ABE8e either under the control of the phosphoglycerate kinase (PGK) promoter (HDAd-PGK.ABE8e), or the strong EF1α promoter (HDAd-EF1α.ABE8e) (Fig.1B). The HDAd vectors also contained a human $mgmt^{P140K}$ expression cassette that allows for enrichment of edited cells after treatment with O^6BG/BCNU. To produce HDAd-EF1α.ABE8e, suppression of ABE8e expression on HDAd producer cells was required. This was achieved by placing the *ABE8e* gene under the regulation of miR-183-5p, miR-218-5p (32) and mi-vaRNAI (33). The first strategy makes use of two microRNAs (miRNAs), hsa-miR183-5p and hsa-miR218-5p, expressed exclusively by the HDAd producer cells. The second strategy makes use of a miRNA expressed by the helper virus called mivaRNAI. Because these miRNAs are only present during vector production, transgene expression from the HDAd is unimpeded in the transduced target, In addition, we further modified the helper vector by inserting expression cassettes for anti-CRISPR peptides capable of blocking ABE8e activity (Fig.S1) (34). The editing rate of HDAd-ABE8e vectors was tested in human $CD34^+$ cells from two healthy donors at day 3 after transduction (Fig.1C). HDAd-EF1α.ABE8e catalyzed on average ~26% of target site -113 A>G conversions, while HDAd-PGK.ABE8e and HDAd-ABEmax (used in an earlier study (12)), conferred 6.6% and 1.3% editing, respectively. Subsequent studies therefore focused on HDAd-EF1α.ABE8e. Due to the wide editing window of ABE8e, in addition to the -113 adenine (shown as A8 at the bottom of Fig.1D), neighboring adenines (A5, A9, A11) can also be converted to guanines. To analyze the effect of editing on reactivation of γ-globin/HbF expression, HDAd-EF1α.ABE8e-transduced $CD34^+$ were subjected to 18 days of erythroid differentiation (ED) with and without O^6BG/BCNU in vitro selection (Fig1E). Target site conversion rates were measured at days 7, 13, and 18 of ED (Fig.1F). Starting at about 20% of editing, one time treatment with of O^6BG plus 25 or 35μM BCNU increased the editing rate to ~60% by day 18 of ED.

HDAd-ABE8e HBG1/2 promoter editing, γ-globin reactivation, and phenotypic improvement in CD34⁺ cells from β-thalassemia and SCD patients. $CD34^+$ cells were from three β-thalassemia patients and three SCD patients previously enrolled in mobilization trials. After transduction with HDAd-EF1α.ABE8e, cells were subjected to ED with and without in vitro selection (Fig.2A). Rates of -113 A>G conversion reached ~60% by Next Generation Sequencing (NGS) (Fig.2B) or by Sanger sequencing (Fig.S2) in HDAd-EF1α.ABE8e-transduced cells that were subjected to O^6BG/BCNU selection.

In ED cultures, the percentages of HbF^+ cells in total erythroid cells and enucleated erythroid ($NucRed^-$) cells were significantly higher in the HDAd-EF1α.ABE8e-transduced over the untransduced cells (Figs.2C, S3A). Notably, background γ-globin expression in the control vector-transduced samples is triggered by cytokines present in the culture medium (35). In vitro selection at day 3, further increased the percentage

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of γ-globin expressing red blood cells (RBCs). Reactivation of γ-globin protein expression was also shown by HPLC where γ-globin chains reached levels of 30% relative to β- and α-globin chains (Fig.2D).

Efficient γ-globin reactivation resulted in a significant reduction of reactive oxygen species levels (ROS), a hall-mark of oxidative stress seen in β-thalassemia and SCD (36) (Figs.3A, S3B). γ-globin re-activation by HDAd-EF1α.ABE8e also improved erythroid differentiation/expansion of Thal and SCD $CD34^+$ cells. To total number of erythroid cells increased 2- and 7-fold, for Thal and SCD samples between days 7 and 18 in settings with in vitro selection (Fig.3B). Improved erythropoiesis is also supported by microscopic analyses of cells at the end of ED which shows more differentiated cells (maturing orthochromatic erythroblasts, reticulocytes/pyrenocytes in the Thal (Fig.4A and SCD (Fig.4B) samples.

HDAd-EF1α.ABE8e transduction and base editing did not cause cytotoxicity as demonstrated by *i)* no reduction in the percentage of primitive HSCs ($CD34^+/CD38^-/CD90^+$) (Fig.S4A) and *ii)* no significant effect on progenitor colony formation (Fig.S4B).

In summary, transduction of $CD34^+$ cells from β-thalassemia and SCD patients with HDAd-EF1α.ABE8e mediated efficient editing of the *HBG1/2* target site and reactivation of γ-globin expression resulting in phenotypic amelioration of erythroid cells after in vitro ED of HSCs.

Ex vivo HSC genome editing without O^6BG/BCNU selection. We used transgenic mice carrying the wild-type 248-kb β-globin locus (β-YAC) including the LCR, *γ- and β-globin* genes (22). They were crossed with human CD46-transgenic mice to allow for HDAd5/35++ transduction via CD46. First, we tested an *ex vivo* HDAd-EF1α.ABE8e editing approach. Bone marrow lineage-negative (Lin^-) cells (a fraction enriched for HSCs) from β-YAC/CD46 mice were transduced with HDAd-EF1α.ABE8e and transplanted into lethally irradiated C57BL/6 mice (Fig.5A). Engraftment, measured based on human CD46 expression on PBMCs, was >95% after week 8, indicating that ex vivo HSC transduction and editing did not affect HSC functions (Fig.5B). After transplantation, A>G conversion rates measured in PBMCs by Sanger sequencing were >90% at the first time point analyzed (4 weeks post-transplantation) and remained stable over the 16 week ("week 16-P", see Fig.5A) observation period (Fig.5C). As seen in in vitro studies with human $CD34^+$ cells (e.g. Fig.1D), substantial bystander A>G editing was observed, specifically at position A5. A>G conversion rates in splenocytes, bone marrow mononuclear cells (MNCs), and Lin^- cells as well as colony-forming units were in agreement with the PBMC data (Fig.5D). The comparison of editing rates in the transplanted cells (~38% -113 A>G) and in week-16P mice (>95% -113 A>G) likely indicates preferential transduction of repopulating HSCs and expansion of edited cells after transplantation (Fig.5E). The vast majority of edits were A>G conversions (Fig.5E). The rate of A>T and A>C conversions was ~3 and ~4 orders

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of magnitude lower, respectively. NGS of the target area confirmed the A>G conversion rates detected by Sanger sequencing and determined that indels (mostly deletions) were <1.5% of all reads (Fig.5F, S5). HSCs contain two *HBG* promoters (*HBG1* and *HBG2*) on each allele. To assess editing of the four target sites on a single cell level, we isolated individual progenitor colonies and sequenced their DNA (n=20 colonies). The data showed 100% bi-allelic editing of both promoters (Fig.5G).

γ-globin protein was detected by flow cytometry in 80-90% of peripheral RBCs starting after week 8 (Fig.6A), which is in accordance with the HSC engraftment/expansion kinetics (Fig.5B) and previous studies with CRISPR/Cas9 (36). Relative γ-globin expression levels were measured on the mRNA and protein levels. *HBG* mRNA levels were ~35% of human *HBB* mRNA levels and ~22% of mouse *HBA* and *HBB* mRNA (Fig.6B). In mice transplanted with ex vivo edited Lin^- cells, human γ-globin levels were about 30% of human β-globin chains and ~20% of mouse α- or β-globin chains (Fig.6C). Editing rates and γ-globin reactivation were stable in secondary recipients demonstrating that editing occurred in long-term repopulating HSCs (Fig.S6).

In summary, HDAd-EF1α.ABE8e confers efficient ex vivo HSC editing without toxicity associated with the transduction and editing processes. After editing, γ-globin levels were 35% of human β-globin levels without any O^6BG/BCNU in vivo selection.

In vivo HSC genome editing. One of our hypotheses was that after in vivo HSC transduction, HDAd genomes and, consequently, ABE8e and $mgmt^{P140K}$ expression would be gradually lost due to cell division and vector genome degradation (Fig.S7). We therefore designed a new in vivo HSC transduction/selection regimen shown in Fig.7A. After mobilization of CD46/β-YAC transgenic mice and intravenous injection of a single HDAd-EF1α.ABE8e vector, O^6BG/BCNU treatment was started at day 2 and repeated at days 12 and 26 to capitalize on $mgmt^{P140K}$ expression from episomal HDAd-EF1α.ABE8e genomes and to dilute out the vector by stimulating cell division. The latter was demonstrated by qPCR that measured vector copy numbers (VCN) in bone marrow MNCs. In in vivo transduced "primary" mice, during the 16-week experiment, the VCN declined by 2-4 orders of magnitude (Fig.7B), resulting in undetectable *ABE8e* and $mgmt^{P140K}$ mRNA levels at week 16 after transduction (data not shown). Base editing was measured by Sanger sequencing in PBMCs (Fig.7C). A>G conversion rates increased after selection to 50-90% (average 67%) for the -113 target site with a similar pattern of bystander adenine editing seen in the ex vivo study. Furthermore, conversion rates were similar in PBMCs, splenocytes, and bone marrow MNCs (Fig.7D). Editing rates were comparable for $CD3^+$ (T-cell), $CD19^+$ (B-cell), $Gr\text{-}1^+$ (myeloid), and $Ter\text{-}119^+$ (erythroid) lineages in the bone marrow, indicating that editing occurred in multi-potential HSCs and that *HBG1/2*

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editing (and γ-globin reactivation) did not provide a proliferative advantage or disadvantage for any specific lineage in β-YAC mice (Fig.7E). NGS demonstrated again a high specificity for A>G conversions with less than 1.5% of indels (Fig.7F-H, S8). Editing of the four *HBG* target sites on a single cell level was less efficient than in the ex vivo setting (Fig.7I). 66.7% and 71.4% of colonies had biallelic conversion in the *HBG1* and *HBG2* promoters, respectively. 21% (*HBG1*) and 23.6% (*HBG2*) of colonies had mono-allelic -113A>G conversions. The percentages without *HBG1* and *HBG2* editing were 21 and 23.8%, respectively. Flow cytometry measuring γ-globin in peripheral RBCs showed a gradual increase from 30% (average at week 4) to 70% γ-globin$^+$ RBCs (average at week 16-P) (Fig.8A). A similar kinetic has been observed in our previous studies (12, 37). Levels of human γ-globin (*hHBG*) mRNA relative to human *HBB* mRNA were 30% on average at week 16 after in vivo transduction (Fig.8B). Relative to mouse *HBA* and *HBB* mRNA, the level of *hHBG* mRNA was 12% and 15%, respectively. Human γ-globin protein levels, measured by HPLC of erythrocyte lysates, were about 25% of human β-globin chains and ~15%/20% of mouse α- or β-globin chains, respectively (Fig.8C). The presence of HbF in peripheral RBCs of in vivo treated CD46/β-YAC mice was also shown by staining of cytospins with a human HbF specific antibody (Figs.8D and E). The signals show a spectrum of intensity, most likely related to how many of the four target sites were edited. HbF staining on human peripheral blood and cord blood RBCs were used as negative and positive controls, respectively.

Editing rates and percentages of γ-globin$^+$ RBCs were maintained in secondary recipients (Fig.S9).

In summary, in vivo HSC transduction by a single intravenous HDAd injection into mobilized β-YAC/CD46 mice followed by early in vivo selection resulted in >60% editing at the -113A site. 25% γ-globin of human β-globin is expressed in >60% of erythrocytes in healthy mice.

Off-target editing. Using non-integrating vectors eliminates the risk of insertional mutagenesis. However, the application of genome editing enzymes bears the possibility of genotoxicity due to off-target editing. To assess this, we screened potential off-target editing sites using "Circularization for In vitro Reporting of Cleavage Effects by sequencing" (CIRCLE-seq), a highly sensitive in vitro method capable of interrogating genome-wide off-target activity (38) (Fig.9). CD46/β-YAC genomic DNA was cleaved with SpCas9 coupled with sgHBG#2 guide RNA for CIRCLE-Seq. The sgHBG#2 RNA was identical to that used in the HDAd-EF1α.ABE8e vector. CIRCLE-Seq identified a total of 272 candidate off-target sites (Supplementary Excel file S1). To investigate off-target editing in in vivo transduced mice, we performed targeted deep sequencing for the top 20 out of the 272 sites based on the CIRCLE-seq read count. Genomic DNA from the mouse with the highest on-target editing (65%) (week 16-S, secondary) and a naïve mouse

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was used. Results showed that no significant off-target base editing in the editable window (position 3 to 14) occurred at these 20 sites (Fig.9, middle panels). Notably, ~4% of alleles with single nucleotide variants in off-target site (OTS) #11 were found in both naïve and treated animals. Indel frequencies around the predicted nicking sites (70-bp at each side) of the 20 candidates showed no significant difference between naïve and treated animals (Fig.9, bottom panel). We conducted further off-target analyses using Cas-OFFinder, an *in silico* algorithm to predict potential off-target sites. A total of 76 and 89 sites with four or fewer mismatches to sgHBG#2 guide RNA were nominated in mouse and human genome, respectively (Figs.10A and B, Supplementary Excel file S2 and S3). Twenty four of the 76 Cas-OFFinder sites in the mouse genome overlapped with the CIRCLE-Seq OTS list (31.6%). The top 5 ranked sites from each list were amplified from the in vivo transduced mouse (analyzed above) or in vitro transduced thalassemia $CD34^+$ cells for amplicon NGS. Results showed no significant editing at these sites.

Effect on transcriptome. We compared RNA-Seq data of total RNA from bone marrow MNCs of CD46/β-YAC mice before treatment and mice at week 16 after in vivo HSC transduction with HDAd-EF1α.ABE8e (N=3 animals) (Fig.11, Suppl. Tables S5 and 6). Of the 2742 genes annotated to the human genome, only 13 were considered differentially expressed (adjusted p-value <0.01) (Suppl. Table S5). Six of them were upregulated and were clustered based on their biological pathways, into 3 groups: *i)* Hemoglobin genes, specifically *HBG2, HBG1*, and *HBD*. Their upregulation is most likely the result of in vivo editing of the β-globin locus present in CD46/β-YAC mice. *ii) mgmt,* as a result of residual expression of human $mgmt^{P140K}$ mRNA from the HDAd vector. Based on the mouse annotation process, we mapped 9037 genes in total, from which 7 were considered differentially expressed (adjusted p-value <0.01) (Suppl. Table S6). However, the level of upregulation was barely above the threshold set at 2.0-fold log. Of the seven genes, one gene is listed in the Catalogue of Somatic Mutations in Cancer (COSMIC). This gene, *Creg1* (cellular repressor of E1A-stimulated genes), is upregulated in treated animals. Creg is considered to be a tumor suppressor and its upregulation should not be associated with cancer (39). Additional studies are required whether the modest upregulation of these genes is due to O^6BG/BCNU treatment.

Hematological analyses. There were no clinical side effects of the in vivo HSC transduction and selection approach. Histological analyses of major organs did not show abnormalities. To further assess the safety of in vivo base editing with HDAd-EF1α.ABE8e, we performed hematological analyses of blood and bone marrow samples of week 16 in vivo transduced CD46/β-YAC mice. No significant differences between

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treated and untreated mice in blood cells counts (Fig.S10A), erythroid parameters (Fig.S10B), platelet counts (Fig.S10C), and reticulocyte counts (Fig.S10D) were found.
Furthermore, there were no significant differences in the lineage composition of bone marrow cells (Fig.S10E). Moreover, in agreement with the disappearance of vector DNA over time, ABE8e was expressed only transiently, which triggered IgM but not a stable IgG anti-Cas antibody response (Fig.S10F).

In summary, in vivo HSC editing with HDAd-EF1α.ABE8e was found to be safe and yielded γ-globin reactivation at levels that are therapeutically relevant.

Discussion

The approach described here is aimed toward the reactivation of γ-globin/HbF for the treatment of β-thalassemia and SCD. HbF has powerful anti-polymerization properties because its γ-globin subunits form mixed hybrid tetramers of two α-globin chains with one γ-globin and one mutated β-globin chain that are largely excluded from the polymer (40). We used a non-integrating HDAd5/35++ vector that would trigger permanent genetic edits in HSCs through the transient expression of ABE8e and a sgRNA that targets the distal BCL11A binding motif in the HBG1/2 promoters. Studies were performed in ex vivo and in vivo settings in CD46/β-YAC transgenic mice. The ex vivo approach yielded > 80% HbF^+ RBCs with γ-globin levels that were 30% of human β-globin levels. Notably, this study was done without any in vivo O^6BG/BCNU selection. More importantly, we demonstrated that in vivo HSC transduction of CD46/β-YAC transgenic mice with a single HDAd-EF1α.ABE8e vector and early treatment with O^6BG/BCNU resulted in >60% HbF^+ RBCs with human γ-globin levels that were 30% of those of human β-globin, in the absence of a competitive background (healthy mice). This outcome is potentially curative in β-thalassemia and SCD patients. In individuals with HPFH, HbF makes up approximately 30% of total hemoglobin and is homogeneously distributed in the red-cell population (41, 42). Furthermore, murine ex vivo gene therapy studies with γ-globin lentivirus vectors demonstrated that long-term amelioration of disease of murine β-thalassemia and SCD occurred when approximately 20% gene-modified HSCs repopulated the marrow, HbF levels were ~20% and HbF^+ cells constituted two-thirds of the circulating RBCs (43-46).

In the absence of β-YAC mice with a thalassemia or SCD geno-/phenotype, we tested disease correction using $CD34^+$ cells from β-thalassemia and SCD patients. We demonstrated that HDAd-EF1α.ABE8e transduction mediated efficient target site editing and reactivation of γ-globin after erythroid

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differentiation. This resulted in the reduction of ROS to background level and improved erythroid differentiation/expansion of thalassemia and SCD $CD34^+$ cells and suggests that the in vivo base editing could be curative in β-thalassemia and SCD patients.

Several factors could have contributed to the high efficacy of in vivo editing:

i) the greatly enhanced catalytic activity of ABE8e (30). ***ii)*** the high level of ABE8e expression in HSC mediated by the EF1α promoter. This is supported by comparative studies with HDAd-PGK.ABE8e where ABE8e expression was driven by the relatively weak PGK promoter and rates of editing (both ex vivo and in vivo) and γ-globin reactivation were significantly lower (Fig.S11, specifically S11I). ***iii)*** the prolonged expression of the base editing machinery from episomal HDAd vector in some transduced HSCs. The VCN declined only by one order of magnitude within 6 weeks, which would imply that the editing machinery is active during that time. This is in part supported by the ex vivo study (performed without O^6BG/BCNU selection), where an increase of editing rates from the transplant (~38%) to >95% in week 16 mice was observed. We speculate that the extended presence of the HBG1/2 sgRNA and ABE8e in HSCs could increase the probability for editing of poorly accessible target sites (i.e. sites blocked by heterochromatin at a certain stage of HSC differentiation). In this context, stimulation of cell division by O^6BG/BCNU selection could have further increased target site accessibility. As the data in secondary recipients indicate, editing must have occurred in primitive long-term repopulating HSCs (before cell division and differentiation). ***iv)*** Bystander editing of adenines near the -113 target site, specifically -116 A>G, which would destroy the BCL11A binding motif and, most likely, further inhibit the binding of the repressor. The -116 A>G bystander conversion was found in >99% of -113 A>G edited alleles (Fig.S12). Also, in the absence of the -110 A>G substitution, a GATA binding motif would be created similar to the -113A>G HPFH (31) . This would enable binding of the transcriptional activator GATA1 to the destroyed BCL11A motif and could further increase γ-globin re-activation. ***v)*** Expansion of edited HSPCs with episomal HDAd-EF1α.ABE8e genomes by early treatment with O^6BG/BCNU capitalizing on the prolonged presence of episomal vector genomes. While we did not perform in vivo studies without O^6BG/BCNU treatment, the in vitro data with $CD34^+$ cells from healthy donors (Fig.1F) and β-thalassemia patients (Fig.2), illustrate the effect of selection.

Notably, in β-thalassemia and SCD patients, γ-globin-expressing erythroid cells would have a survival advantage created by the disease background. In this context, we expect that rates of γ-globin reactivation achieved with our approach could be even higher in patients with hemoglobinopathies and the in vivo selection with O^6BG/BCNU on demand.

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Safety concerns with our approach are related to the intravenous injection of HDAd5/35++ vectors and genotoxicity due to off-target base editing. HDAd vectors are sensed by the RES and can trigger the release/production of pro-inflammatory cytokines. We have developed pharmacological approaches to avoid these responses in mice (2) and NHPs (8). Furthermore, intravenously injected HDAd5/35++ vectors preferentially transduce mobilized HSCs (8, 47), minimizing base editing in non-hematopoietic tissues.
Recently, virus-like particles (VLPs) have been used for in vivo editing of murine liver or retina(48). Furthermore, non-viral vehicles based on lipid nanoparticles (LNPs) for mRNA delivery (49, 50) hold great promise for in vivo HSC genome editing. However, these new approaches also face the hurdles accounted with intravascular administration of viral vectors, namely the unproductive sequestration, which require high vector doses, and associated acute toxicity. Furthermore, while viruses have evolved highly efficient mechanisms for cellular uptake and intracellular trafficking, it is not straightforward to incorporate these functions into nonviral delivery vehicles.

Clearly, prolonged expression of the editing machinery could increase the frequency of off-target editing and the genotoxicity risk. Our data indicate that off-target DNA or RNA editing is minimal while on-target activity is high. *i)* No hematological or histological abnormalities were found in primary and secondary mice over a total period of 32 weeks. *ii)* More than 98% of edits at the target site were the desired A>G conversions; less than 1.5% of reads had small deletions or insertions in the observation window. Interestingly, the indel frequency in secondary mice (at week 16) was significantly lower than in primary mice, indicating a selection against cells with indels over time. *iii)* NGS of off-target sites predicted by CIRCLE-Seq or CasOFFinder did not show editing in the quantification window. *iv*) Off-target base editing can manifest as guide-independent, spurious editing of RNA (51, 52) or genomic DNA (30). This, as well as clonal expansion of malignant cells could result in alterations in the transcriptome. While RNA-seq showed the expected activation of human *γ-globin* genes (10- to 100-fold log10)) and residual human $mgmt^{P140K}$ mRNA, changes in the mouse transcriptome were minimal (2.0- to 2.15-fold log10) and it is debatable whether these small alterations have biological consequences.
Extensive off-target analyses are crucial for a potential clinical translation of the approach. Therefore, in upcoming NHP studies with an improved HDAd-EF1α.ABE8e vector, great attention will be given to genomic analyses and potential long-term effects of in vivo base editing.

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Our current attempts are focused to further improve the safety and efficacy of the approach, including new HDAd vector platforms (53), alternative mobilization regimens (54), and in vivo selection strategies. The latter includes an in vivo selection strategy that would not involve low-dose BCNU (55).

We believe that our study is an additional step towards the vision to treat hemoglobinopathies by a simple intravenous injection of a non-integrating vector.

Methods

The following information can be found under Supplementary Methods: Reagents for in vivo transduction and selection, generation of HDAd vectors, in vitro erythroid differentiation of $CD34^+$ cells with O^6BG/BCNU selection, blood analyses, colony-forming unit (CFU) assay, measurement of base conversion by Sanger sequencing and Next-Generation Sequencing (NGS), flow cytometry, globin HPLC, analysis of Reactive Oxygen Species (ROS) levels, cytospin slide preparation, HbF immunofluorescence, real-time reverse transcription PCR, measurement of vector copy number, off-target analyses, RNA-seq analysis.

$CD34^+$ cell culture: $CD34^+$ cells from G-CSF-mobilized healthy adult donors were provided by the Fred Hutch Cell Processing Facility. $CD34^+$ cells from thalassemic and SCD patients were previously collected during mobilization clinical trials conducted at G. Papanikolaou Hospital, Thessaloniki, Greece (56). $CD34^+$ cells were recovered from frozen stocks and incubated overnight in StemSpan H3000 medium (STEMCELL Technologies, Vancouver, Canada) supplemented with penicillin/streptomycin, Flt3 ligand (Flt3L, 25 ng/ml), interleukin 3 (10 ng/ml), thrombopoietin (TPO) (2 ng/ml), and stem cell factor (SCF) (25 ng/ml). Cytokines and growth factors were from Peprotech (Rocky Hill, NJ). $CD34^+$ cells were transduced with HDAd5/35++ vectors in low- attachment 12-well plates.

Animal studies: C57BL/6-based transgenic mice that contained the human CD46 genomic locus and provide CD46 expression at a level and in a pattern similar to humans (human CD46tg mice) were described earlier (57). Transgenic mice carrying the wild-type 248-kb β-globin locus yeast artificial chromosome (β-YAC) were used (22). β-YAC mice were crossed with human CD46tg mice to obtain CD46/β-YAC mice for ex vivo and in vivo studies. The following primers were used for genotyping of mice: *CD46* forward, 5'-GCCAGTTCATCTTTTGACTCTATTAA-3', and reverse, 5'-AATCACAGCAATGACCCAAA-3'; β-

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YAC (γ-globin promoter) forward, 5'-AAACGGTCCCTGGCTAAACT-3', and reverse, 5'-GCTGAAGGGTGCTTCCTTTTT-3'.

Bone marrow Lin$^-$ cell transplantation. Recipients were 6-8- week-old female C57BL/6 mice (The Jackson laboratory). On the day of transplantation, recipient mice were irradiated (1000 rad). Four hours after irradiation, 1x10^6 Lin$^-$ cells were injected intravenously through the tail vein. This procedure was used for ex vivo HSC transduction studies and for secondary transplantations. The secondary recipients were kept for 16 weeks after transplantation for terminal point analyses.

HSC mobilization and in vivo transduction: HSCs were mobilized in mice by subcutaneous (SC) injections of human recombinant G-CSF (250μg/kg/mouse/day, 4 days) followed by an SC injection of AMD3100 (5mg/kg) on day 5. In addition, animals received Dexamethasone (10 mg/kg, IP) 16 h and 2 h before virus injection to blunt innate toxicity associated with intravenous HDAd injection. Fourty five minutes after AMD3100, animals were intravenously injected with virus vectors through the retro-orbital plexus (4x10^{10} viral particles per mouse).

In vivo selection: Selection was started at day 2 after transduction. Mice were injected with O^{6}BG (15mg/kg, IP) two times, 30 minutes apart. One hour after the second injection of O^{6}BG, mice were injected (IP) with 5mg/kg BCNU. At days 12 and 26, two more rounds were performed with BCNU doses at 9 and 10mg/kg, respectively.

Statistical analyses*:* Data are presented as means ± standard error of the mean (SEM). For comparisons of multiple groups, one-way and two-way analysis of variance (ANOVA) with Bonferroni post-testing for multiple comparisons was employed. Statistical analysis was performed using GraphPad Prism version 6.01 (GraphPad Software Inc., La Jolla, CA). *p≤0.05, ***p≤0.0001. A P value less than 0.05 was considered significant.

Next-generation sequencing data have been deposited to the NCBI Sequence Read Archive (SRA) with accession code PRJNA867400.

Animal study approval: All experiments involving animals were conducted in accordance with the institutional guidelines set forth by the University of Washington. The University of Washington is an Association for the Assessment and Accreditation of Laboratory Animal Care International (AALAC)–accredited research institution and all live animal work conducted at this university is in accordance with the Office of Laboratory Animal Welfare (OLAW) Public Health Assurance (PHS) policy, USDA Animal

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Welfare Act and Regulations, the Guide for the Care and Use of Laboratory Animals and the University of Washington's Institutional Animal Care and Use Committee (IACUC) policies. The studies were approved by the IACUC of the University of Washington (Protocol No. 3108-01).

Authors contributions:

A.L. and C.L. provided the conceptual framework for the study. A.L., C.L., A.G. and E.N. designed the experiments. C.L., A.G., G.A.N., K.E., E.N., P.K., S.G., H.W., A.K.A., L.H., T.K. and H.W. performed the experiments. D.R.L provided critical comments on the manuscript. A.L. wrote the manuscript.

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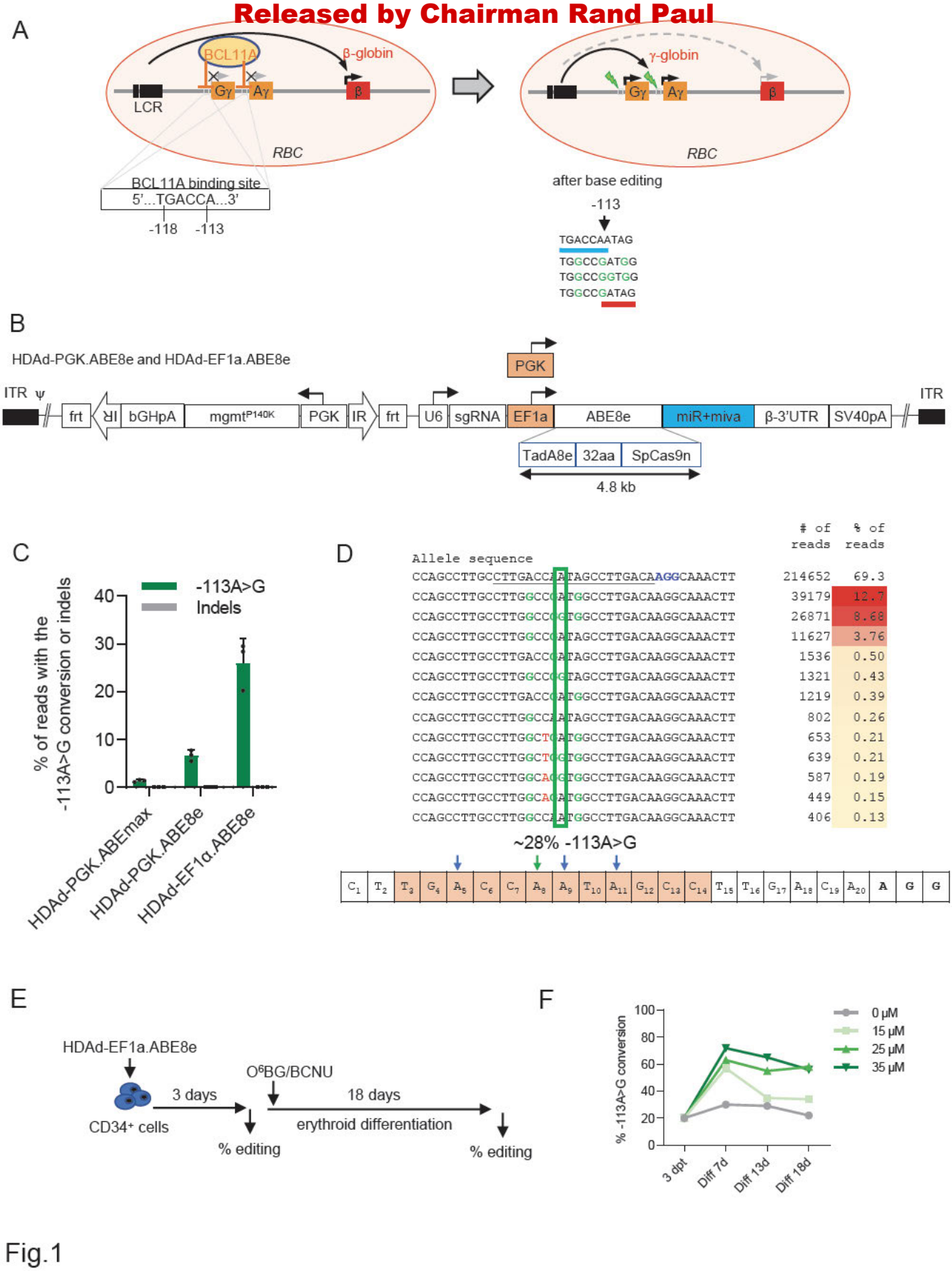

Fig.1

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Fig.1. *In vitro* studies with HDAd-ABE8e vectors in CD34$^+$ cells from healthy donors. A) Reactivation of γ-globin by *HBG1/2* base editor. In adult erythroid cells, expression of γ-globin is inhibited by a number of repressor proteins including BCL11A that binds within the promoter of the two copies of the *HBG* gene (*HBG1*/Gγ and *HBG2*/Aγ). This directs the action of the strong β-globin locus control region (LCR) toward expression of β-globin. LCR activity can be switched back to the γ-globin by targeting the BCL11A binding motif using an adenine base editor. Expected outcomes of editing the -118 to -113 TGACCA BCL11A binding motif by ABE8e are shown on the bottom. In addition to the target -113 A>G conversion, bystander editing of neighboring adenines. The -116 A>G conversion would further destroy the BCL11A binding motif (underlined blue). In the absence of the -110 A>G bystander conversion, a GATA motif would be created (underlined red). **B)** The vectors contain an *HBG1/2* sgRNA and the *ABE8e* gene linked to miRNA regulatory elements. The *ABE8e* gene is either under the control of the PGK promoter (HDAd-PGK.ABE8e) or the EF1α promoter (HDAd-EF1α.ABE8e). The vectors also contain a PGK-mgmt^{P140K} cassette for O^{6}BG/BCNU selection. The *IR* and *frt* sequences are remnants from previous vectors that were integrated by SB100x transposase. They are irrelevant for this study that does not employ the SB100x integrating system. **C)** Editing rate in CD34$^+$ cells from three healthy, G-CSF-mobilized donors. Cells were transduced at an MOI of 2000 vp/cell and three days later, genomic DNA was analyzed by Sanger sequencing for the -113A>G conversion. ABEmax is an early adenine base editor version. **D)** Sequences of the top 12 edited alleles in CD34$^+$ cells from donor #1 after transduction with HDAd-EF1α.ABE8e. The target site -113 A (A8 in the sequence shown in the lower panel) is marked by a green box. Editable window in the spacer by ABE8e is highlighted in orange. **E, F)** In vitro transduction studies with donor #1 CD34$^+$ cells that were subjected to erythroid differentiation (ED) and one cycle of O^{6}BG/BCNU selection. **E)** Schematic of the experiment. **F)** Percentage of -113A>G conversion at different time points without or with O^{6}BG + 15, 25, 35μM BCNU added at day 3. The standard deviation was less than 10% for all time points. n=3 technical replicates.

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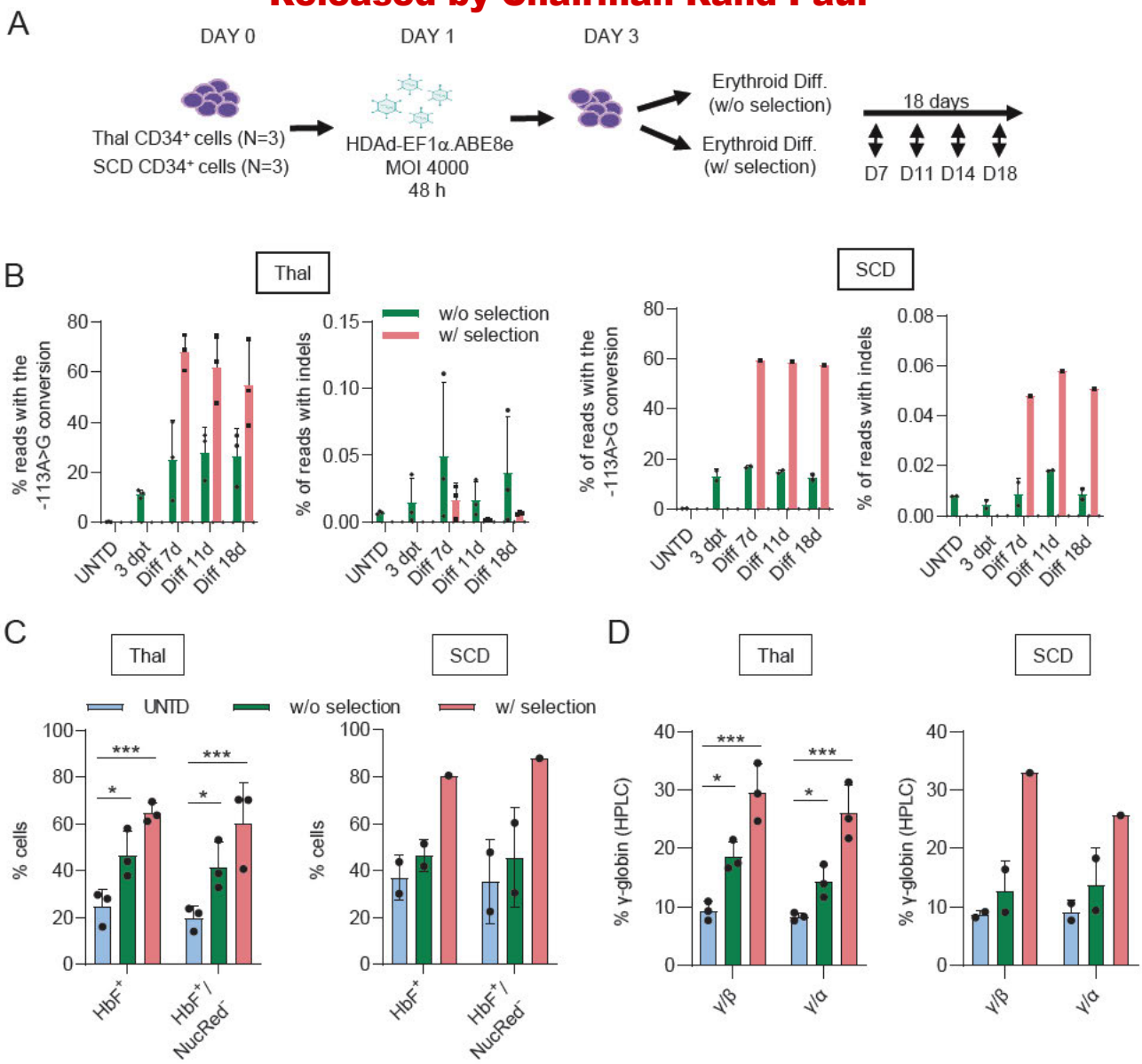

Fig.2

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Fig.2. *In vitro* editing studies with CD34$^+$ cells from β-thalassemia and SCD patients. **A)** Schematic of the experiment. G-CSF/Plerixafor mobilized CD34$^+$ cells from three β-thalassemia (Thal) patients were used. SCD CD34$^+$ cells from fresh peripheral blood were isolated post blood transfusion of three patients (one β^0/β^S, two β^S/β^S patients). CD34$^+$ cells were transduced with HDAd-EF1α.ABE8e or left untransduced (UNTD). Cells were then subjected to erythroid differentiation for 18 days. Aliquots were collected at the indicated time points. On Day 3, one set of ED cells was treated once with O^{6}BG/BCNU for in vitro selection. (Only from second β^S/β^S patient, we obtained sufficient numbers of CD34$^+$ cell to perform in vitro selection). **B)** Editing rate of the -113 A target site and percentage of reads with indels analyzed by NGS for the thalassemia samples (left panel) and SCD samples (right panel). Note the different scale on the y-axes for on-target editing and indels. **C)** Flow cytometry analysis for γ-globin/HbF at the end of ED in total cells and in differentiated enucleated erythroid (NucRed$^-$) cells in Thal and SCD samples. **D)** Measurement of globin protein chains by HPLC. Shown is the percentage of human γ-globin relative to human β- and α-globin chains in Thal samples (N=3), two SCD (β^S/β^S) samples without selection, and one SCD (β^S/β^S) sample with selection. Statistical analyses of the data from the Thal samples were performed using two-way ANOVA.

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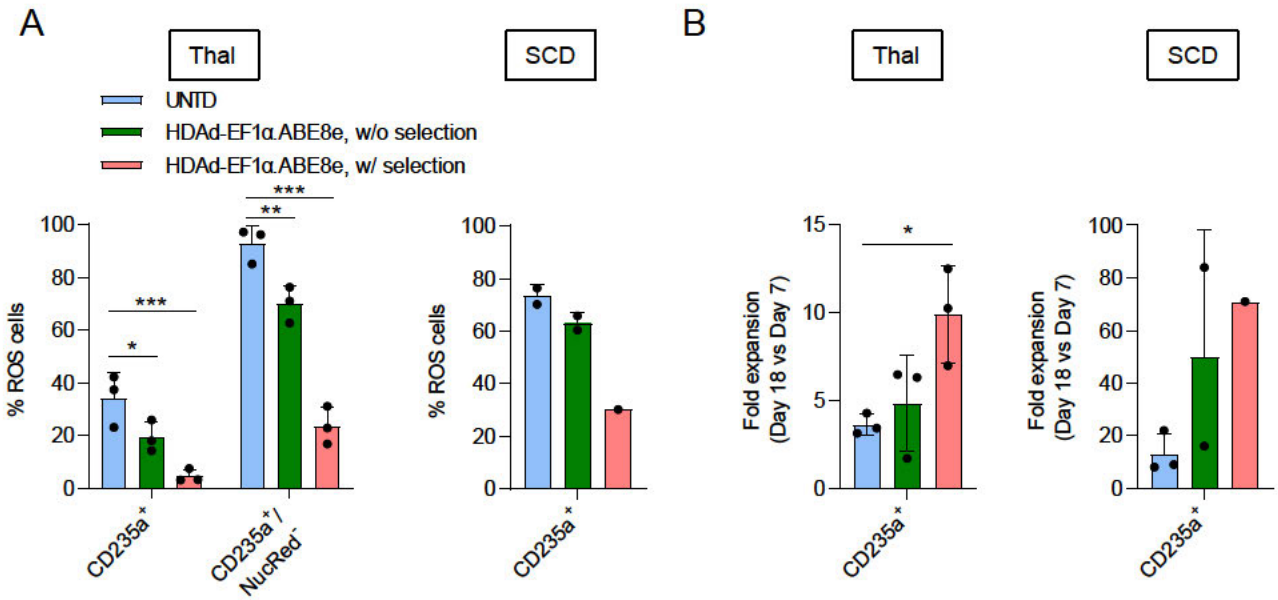

Fig.3

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Fig.3. Phenotypic improvement in *in vitro* editing studies with CD34$^+$ cells from β-thalassemia and SCD patients. Analyses were done with the samples described in Fig.2. **A)** Percentage of Reactive Oxygen Species (ROS)-positive cells within total erythroid cells (CD235a$^+$) and denucleated erythroid cells (CD235a$^+$/NucRed$^-$ cells) for Thal samples and in total erythroid cells for SCD samples. **B)** Fold increase in erythroid cell numbers between days 7 and 18 of ED. Statistical analyses of the data from the Thal samples were performed using two-way ANOVA.

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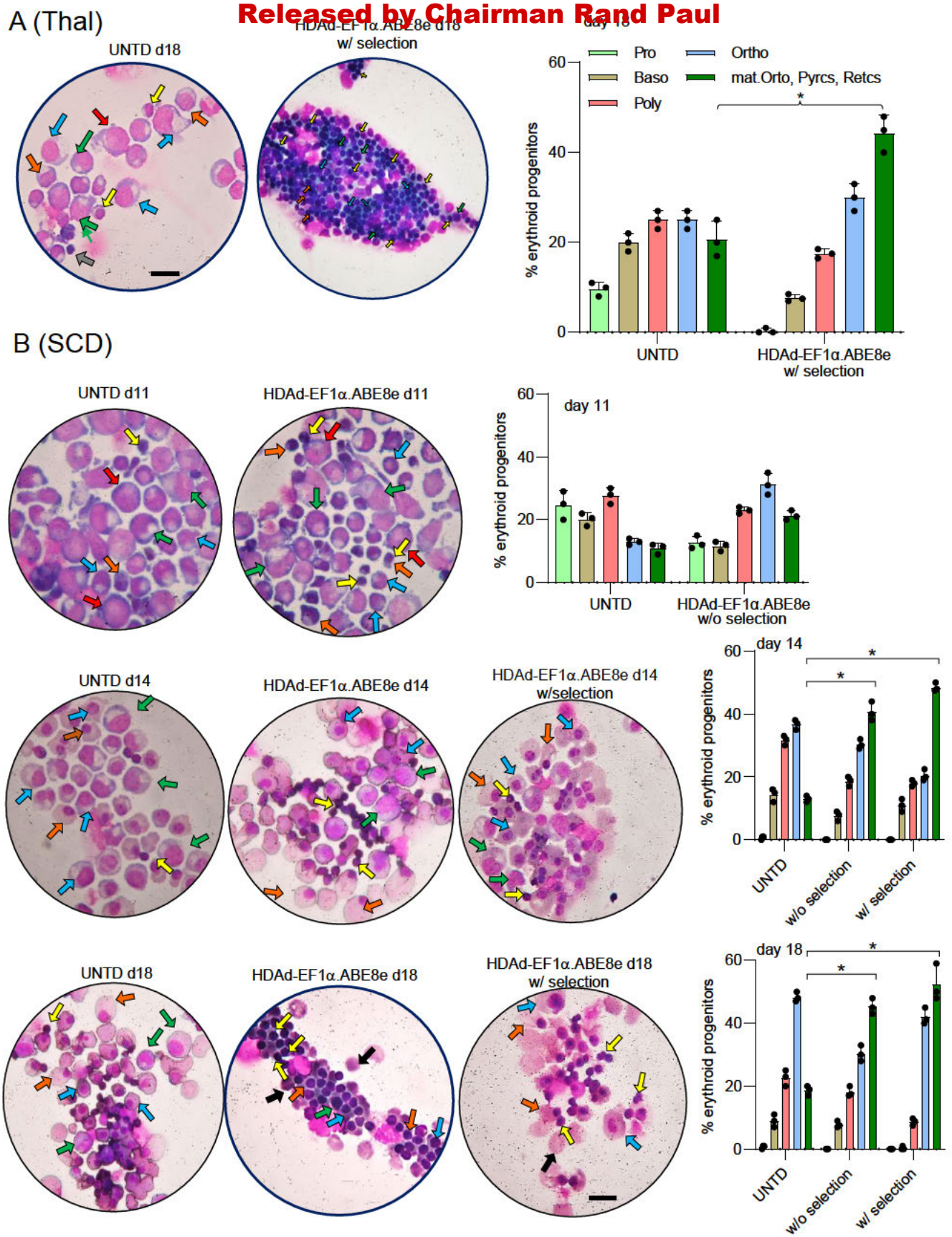

Fig.4

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Fig.4. Cytospins from cultures at different time points of ED. A) Representative samples from Thal $CD34^+$ cells, either untransduced or transduced with HDAd-EF1α.ABE8e and O^6BG/BCNU selected. Left panel: cytospins stained with Giemsa/May-Grünwald. The arrows indicate cells at different stages of erythroid differentiation: proerythroblasts (red) → basophilic erythroblasts (green) →polychromatic erythroblasts (blue) → orthochromatic erythroblasts (orange) → maturing orthochromatic erythroblasts (yellow)→ reticulocytes (black)/pyrenocytes (grey). The scale bar is 25μm. Right panel: Quantification of erythroid progenitors. Five random fields were counted by two scientists. *$p<0.05$. Pro: proerythroblasts, Baso: basophilic erythroblasts, Poly: polychromatic erythroblasts, Ortho: orthochromatic erythroblasts, mat. Ortho: maturing orthochromatic erythroblasts, Retics: reticulocytes, Pyrcs: pyrenocytes. **B)** Cytospins from differentiated SCD $CD34^+$ cells at days 11, 14 and 18 of ED, untransduced and HDAd-EF1α.ABE8e-transduced without and with selection. Statistical analyses were performed using two-way ANOVA.

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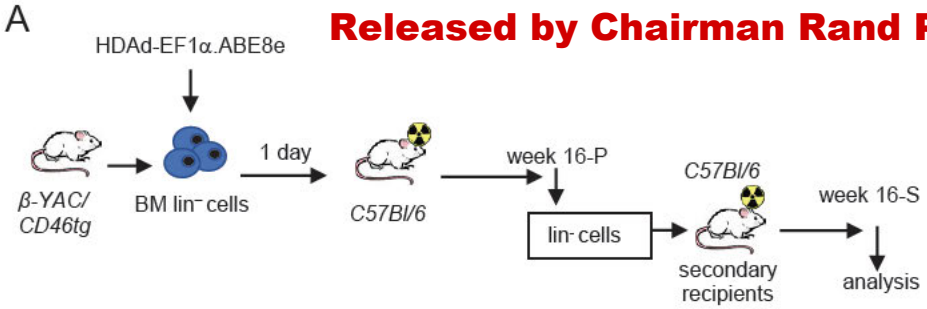

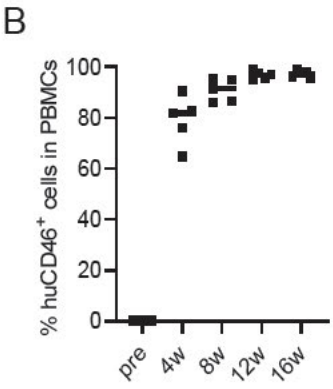

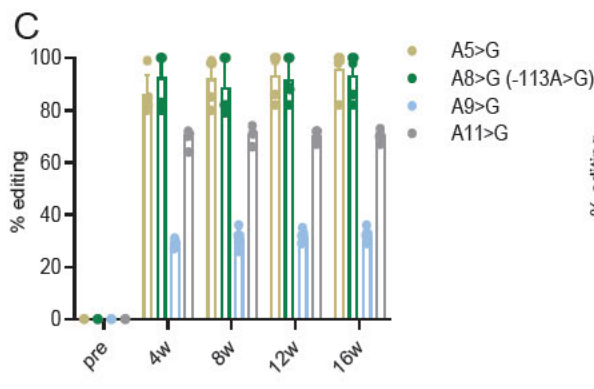

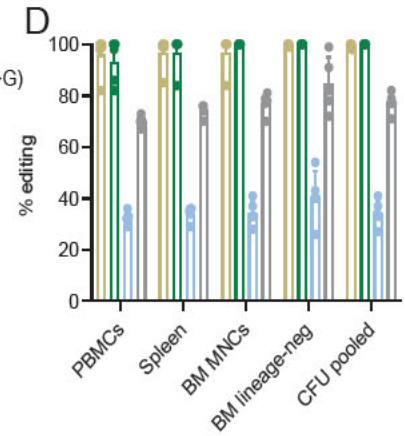

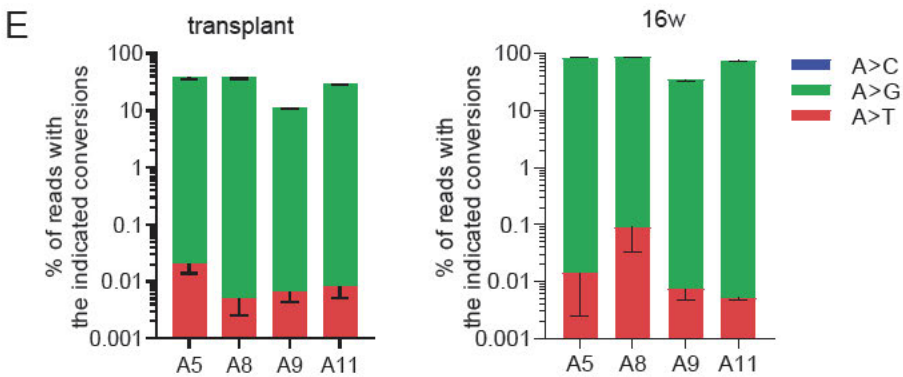

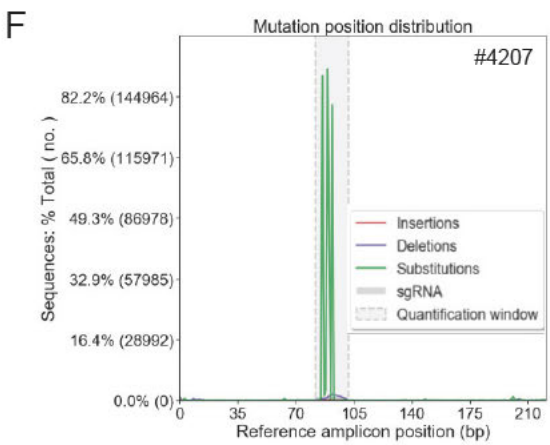

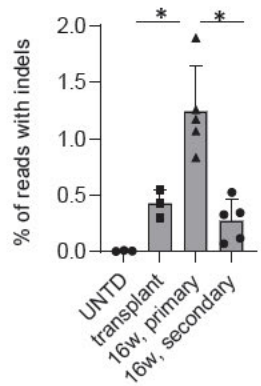

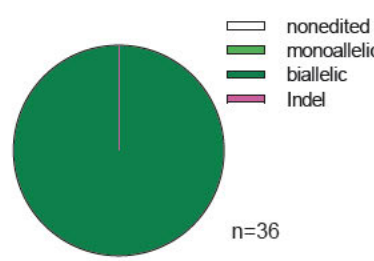

Fig.5

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Fig.5. *Ex vivo* HSC base editing for γ-globin reactivation by HDAd-EF1α.ABE8e. A) Schematic of the experiment. Bone marrow Lin$^-$ cells were isolated from β-YAC/CD46-transgenic mice and transduced ex vivo with HDAd-EF1α.ABE8e at an MOI of 500 vp/cell. After one day in culture, one million cells per mouse were transplanted into lethally irradiated C57Bl/6 mice, which were followed for 16 weeks ("week 16-P - primary"). Data from these mice are shown in this figure. Bone marrow Lin$^-$ cells from these mice were then used for secondary transplantation and these mice were monitored for another 16 weeks ("week 16-S-secondary", see Fig.S6). **B)** Engraftment of transplanted HDAd-EF1α.ABE8e-transduced HSCs measured by flow cytometry of human CD46 in PBMCs. Each symbol is an individual mouse. N=5 animals. **C)** Analysis of target site editing in PBMCs by Sanger sequencing. Shown are percentages of conversion for the -113A>G site and neighboring adenines. N=5 animals. **D)** Analysis of target site editing in PBMCs, spleen, bone marrow MNCs, bone marrow lineage-negative cells and colony-forming units (CFU) at week 16 after transplantation by Sanger sequencing. N=5 animals. **E)** Comparison of editing rates (by next-generation sequencing - NGS) at the 4 adenines in the transplant (ex vivo transduced Lin$^-$ cells cultured for 3 days) and bone marrow MNCs at week 16 after transplantation. Shown are percentages of reads. Note the $\log_{10}$ scale of the Y-axis. N=3 animals. **F)** Next-generation sequencing of the target area (222 bp amplicon; ~100 nucleotides up- and downstream of the spacer). Left panel: Shown are base substitutions (green), deletions (blue), and insertions (red) in the target area for one representative mouse. Right panel: Summary of all indel reads in the transplant, week 16 primary mice and week 16 secondary mice. * $p<0.05$. Statistical analyses were performed using two-way ANOVA. **G)** Editing on a single cell basis. Week 16 bone marrow Lin$^-$ cells were plated for progenitor assay and individual colonies were subjected to NGS. Shown is a representative mouse with 100% bi-allelic editing of the *HBG1/2* sites. n=36 (3 mice, 12 colonies per mouse analyzed).

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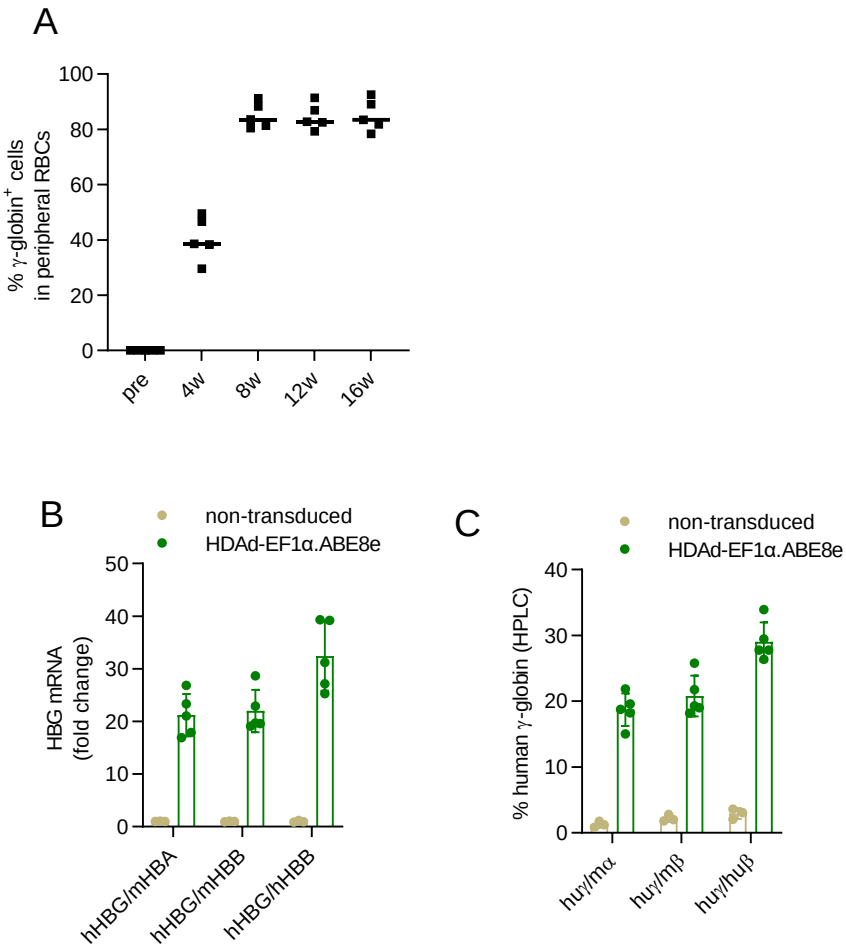

Fig.6

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Fig.6. γ-globin analysis after *ex vivo* base editing with by HDAd-EF1α.ABE8e. A) Percentage of γ-globin positive peripheral RBCs measured by flow cytometry at different time points after transplantation. N=5 animals. **B)** qRT-PCR for globin mRNA (human HBG/γ-globin vs mouse HBA/α-globin; human HBG/γ-globin vs mouse HBB/β-globin; human HBG/γ-globin vs human HBB/β-globin). Shown are the fold changes between untreated and treated animals. N=5 animals. **C)** Percentage of human γ–globin chains relative to mouse α–globin chains, mouse β–globin, and human β-globin chain measured by HPLC.

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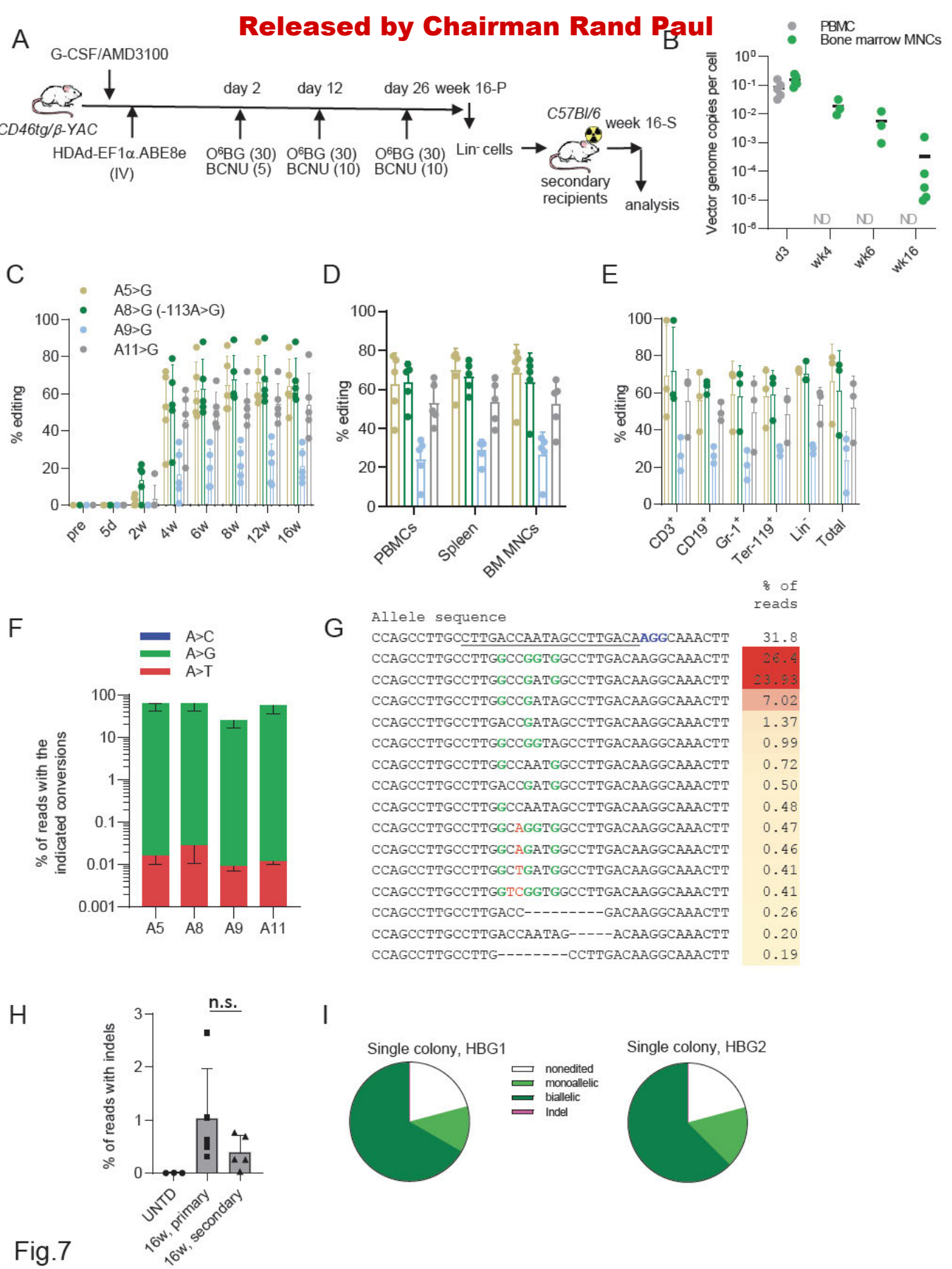

Fig.7

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Fig.7. In vivo HSC transduction of β-YAC/CD46 mice to achieve γ-globin reactivation by HDAd-EF1α.ABE8e. A) Experimental procedure. β-YAC/CD46 mice (N=5 animals) were mobilized by G-CSF/AMD3100 and in vivo transduced by intravenous (IV) injection of HDAd-EF1α.ABE8e. In vivo selection with O^6BG/BCNU was started at day 2 after HDAd injection and repeated at days 12 and 26 at the indicated doses (30mg/kg O^6BG and 5, 10, 10mg/kg BCNU). The mice were euthanized at week 16 ("week 16-P"). The data from "primary" in vivo transduced mice are sown in this figure. Lineage-negative cells were isolated from bone marrow and IV injected into lethally irradiated C57BL/6J mice. The secondary transplanted mice were followed for another 16 weeks ("week 16-S", see Fig.S10). **B)** Loss of vector genomes in PBMCs and bone marrow MNCs. Vector copy number (VCN) was measured by qPCR with human $mgmt^{P140K}$ primers. ND: not detectable. N=5 animals for d3 and wk16; N=3 animals for wk4 and wk6. **C-E)** Target base conversion measured by Sanger sequencing. Each dot represents one animal. N=5 animals. **C)** Percent conversion in DNA from PBMCs. **D)** Percent conversion at week 16 in PBMCs and MNCs in the spleen and bone marrow. **E)** Percent conversion at week 16 in lineage ($CD3^+$, $CD19^+$, $Gr\text{-}1^+$, $Ter119^+$) cells and in Lin^- cells in the bone marrow. **F**) Comparison of editing rates at the 4 adenines in Bone marrow MNCs at week 16 after in vivo transduction. Shown are percentages of reads. N=5 animals. **G)** Representative NSG results showing target base conversion and indels at week 16 (mouse #446). **H)** Summary of all indel reads in week 16 primary mice and week 16 secondary mice. N=5 animals. **I)** Editing on a single cell basis. Week 16 bone marrow Lin^- cells were plated for progenitor assays and individual colonies were subjected to NGS. Shown are sequencing data of the *HBG1* and *HBG2* sites of a representative colony with mono- and bi-allelic conversions as well as indels (<1%, not visible).

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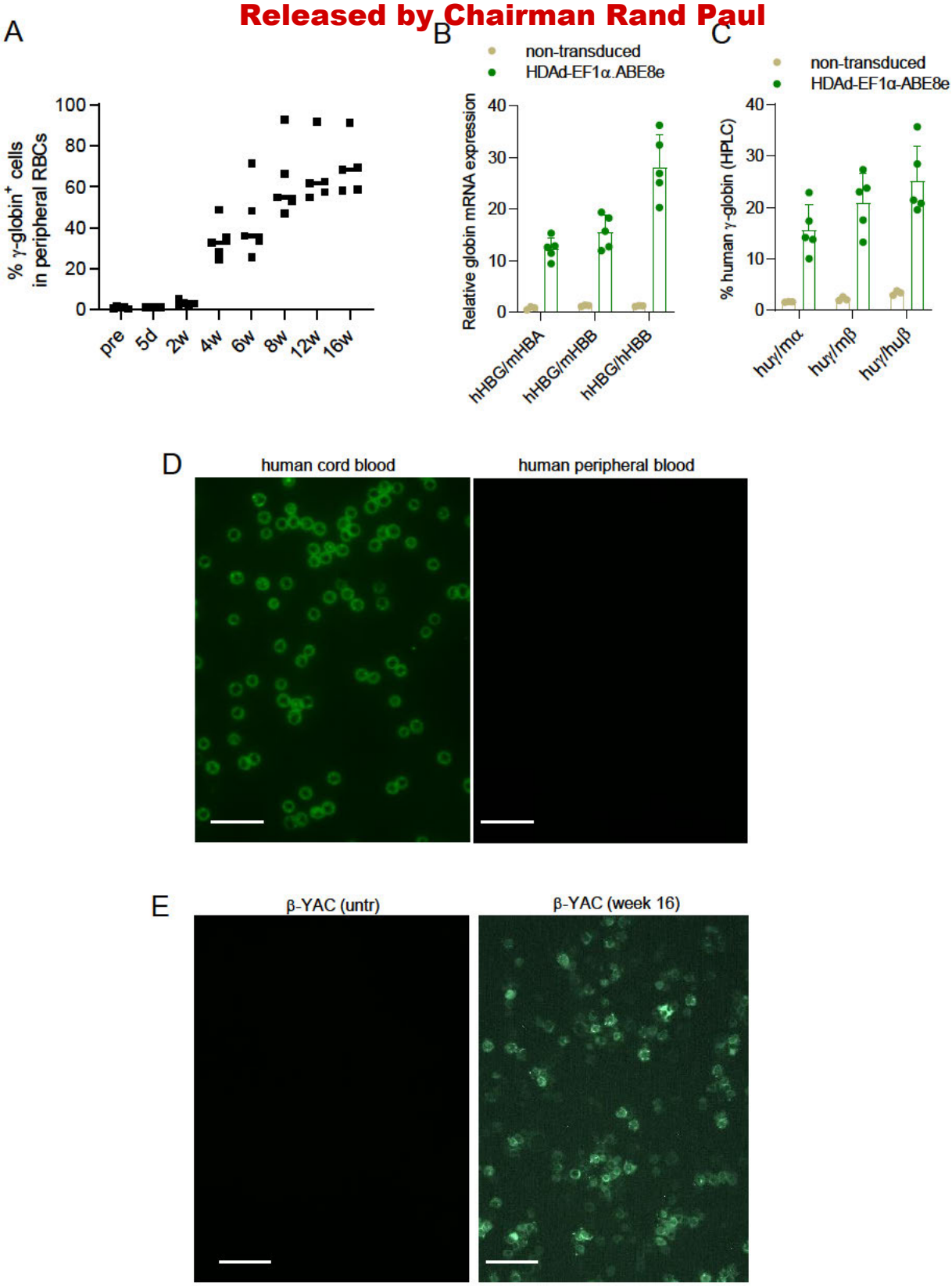

Fig.8

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Fig.8. γ-globin analysis after in vivo base editing with by HDAd-EF1α.ABE8e. A) γ-globin expression in peripheral RBCs measured by flow cytometry. N=5 animals. **B**) γ-globin expression at mRNA level measured by qRT-PCR. Data shown are fold of change over mouse HBA, mouse HBB, or human HBB mRNA. N=5 animals. **C**) Human γ-globin chain levels in RBC lysates measured by HPLC. Data shown are percentages over mouse α- or β-globin or human β-globin. N=5 animals. **D, E)** Immunofluorescence analysis of HbF in erythrocytes. **D)** Human samples. Cytospins of total blood cells from umbilical cord blood (fetus-derived) and from an adult donor. **E)** Samples from untreated and treaded β-YAC mice (total blood). Cytospins were stained with a GFP-specific antibody. Shown are representative samples out of 5 cytospins per group. The scale bar is 20μm.

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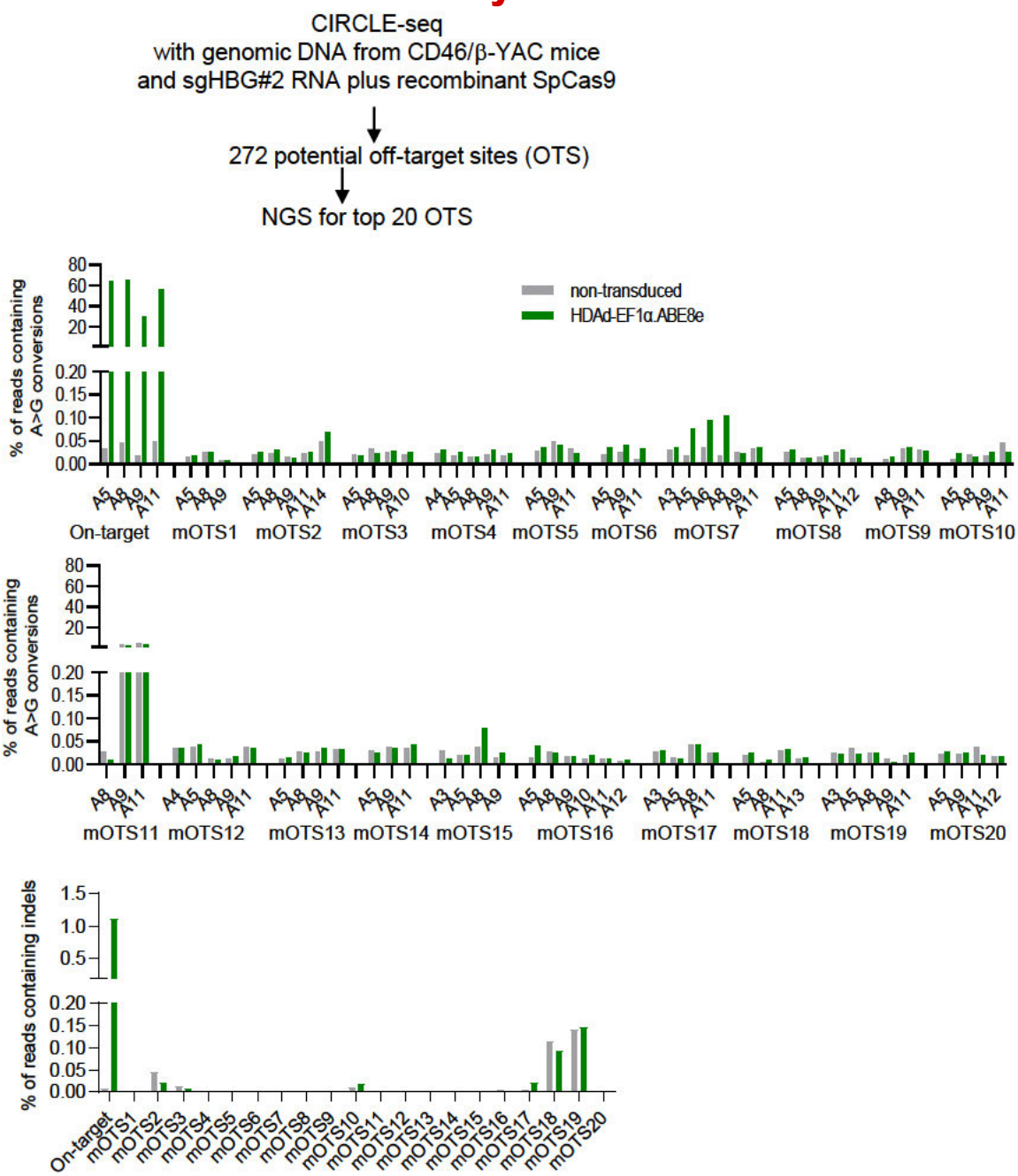

Fig.9

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Fig.9. Off-target analysis after *in vitro* and in vivo base editing with HDAd-EF1α.ABE8e (based on CIRCLE-seq prediction). Genomic DNA from naïve CD46/β-YAC mice was cleaved with recombinant SpCas9 plus sgHBG#2 RNA. CIRCLE-seq identified 272 OTS from which the top 20 were subjected to NGS. Amplicons were prepared using genomic DNA template from a naïve mouse and an in vivo transduced mouse with the highest on-targeting editing rate. The middle two panels show A>G conversion frequencies in the targetable window (position 3 to 14) of the top 20 candidate OTSs. Note that for site mOTS11, the percentage of target site conversion was similar for untreated and HDAd-EF1α.ABE8e treated mice, making it unlikely that the conversions were triggered by ABE8e. The bottom panel shows the indel frequency in a quantification window of 140 bp.

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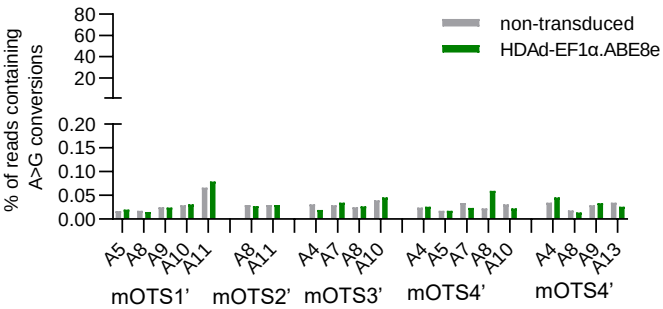
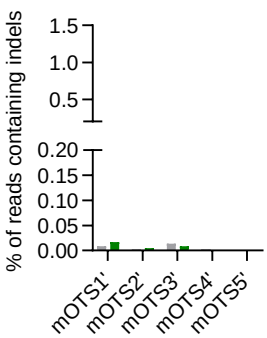
A

Cas-OFFinder

76 OTSs in mouse genome

NGS for top 5 OTS
(gDNA, week 16)



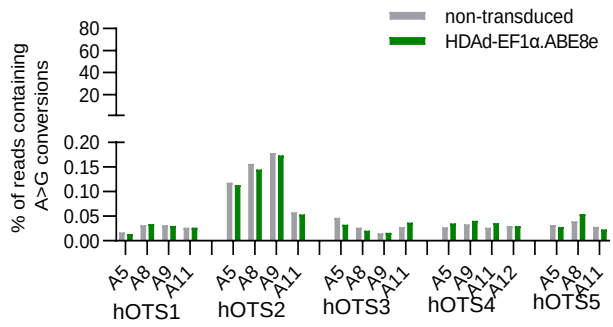


B

Cas-OFFinder

89 OTSs in human genome

NGS for top 5 OTS
(gDNA from Thal cells, day 18 ED)



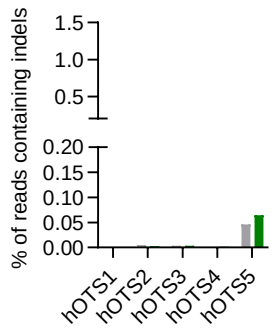


Fig.10

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Fig.10. Off-target analysis after *in vitro* and in vivo base editing with HDAd-EF1α.ABE8e (based on *in silico* prediction). A) Analysis based on in silico OTS prediction using Cas-OFFinder software for the mouse genome. 74 sites were nominated, from which the top 5 were subjected to NGS. Amplicons were prepared using genomic DNA template from a naïve mouse and an in vivo transduced mouse with the highest on-targeting editing rate. The middle and lower panels show the frequency of A>G conversions and indels, respectively. **B)** Analysis based on in silico OTS prediction using Cas-OFFinder software for the human genome. 89 sites were nominated, from which the top 5 were subjected to NGS. Amplicons were prepared using genomic DNA from erythroid cells derived from $CD34^+$ cells of a thalassemia patient that were in vitro transduced with HDAd-EF1α.ABE8e.

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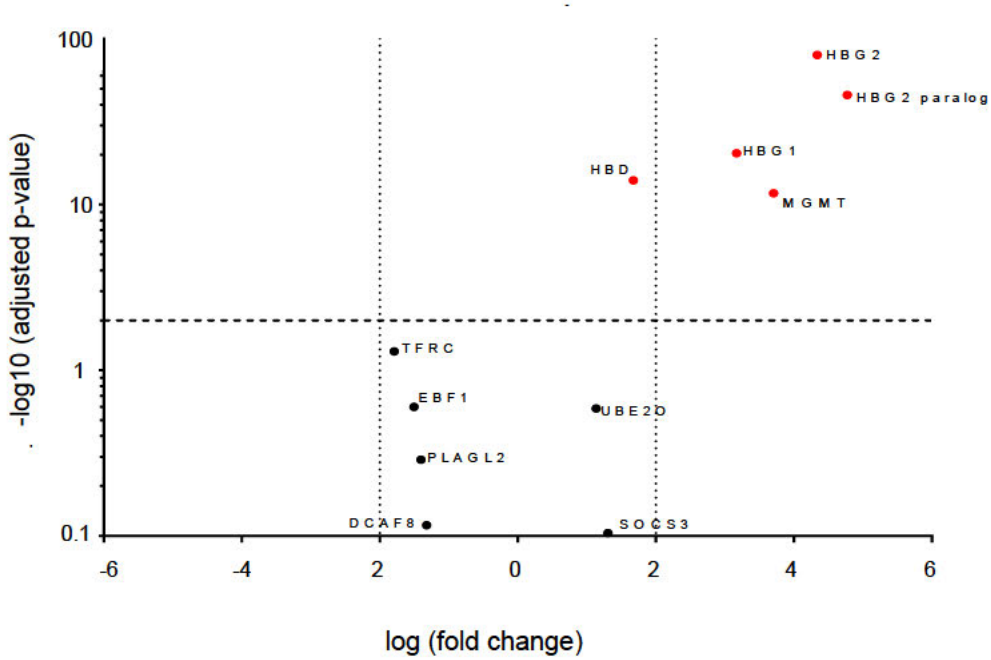
A



B

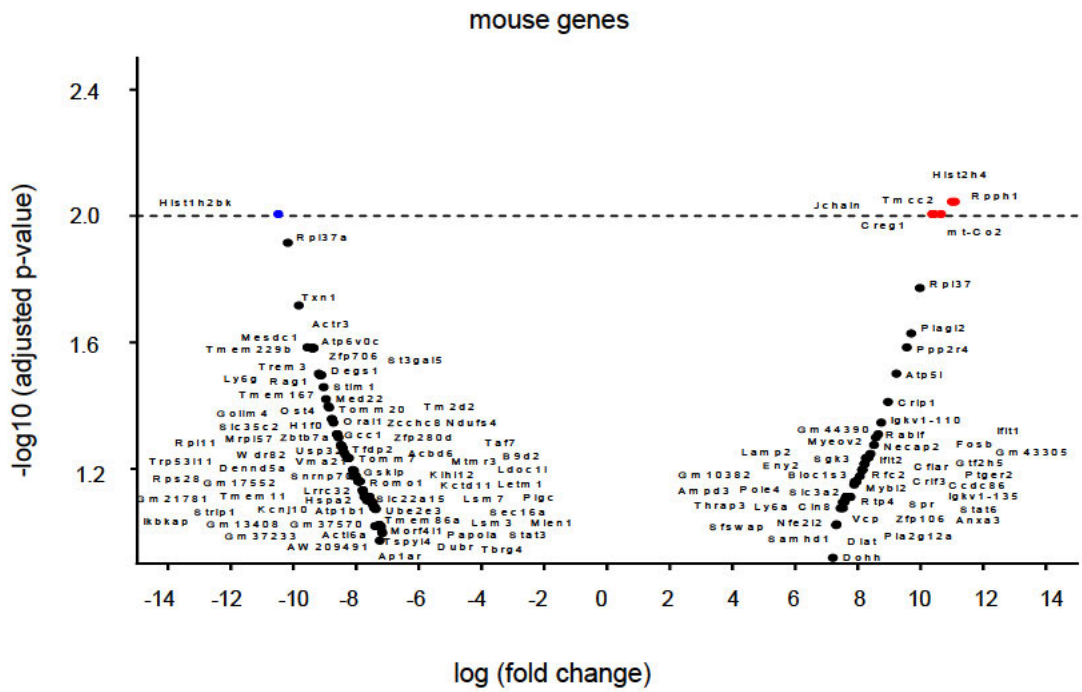


Fig.11

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Fig.11. Differentially expressed genes post in vivo base editing HDAd-EF1α.ABE8e. RNA-seq analysis was performed with bone marrow MNCs collected before treatment and at week 16 after in vivo HSC transduction/selection with HDAd-EF1α-ABE8e (N=3 females, age 8-12 weeks). The genome of CD46/βYAC mice contains the wild-type 248-kb β-globin locus (β-YAC) including the LCR, γ-, δ-, and β-globin genes. Shown are genes with altered mRNA expression based on their adjusted p-value after annotation with the human genome. **A)** Altered mRNA expression after annotation with a reference human genome Statistically significant changes ($p<0.01$) are highlighted in red (upregulated). **B)** Volcano plot of mRNA data after annotation with the mouse reference genome are shown. Statistically significant changes ($p<0.01$) are highlighted in red (upregulated) or blue (downregulated).

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From: "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>
To: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>, "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 07:51:11 -0400
Importance: Normal

Hi Francis,

On the DBDR side, we recently hosted Dr. Andre Lieber (the last author of the JCI manuscript) to present his work in this area as part of our CureSci initiative at NHLBI-agree very exciting.
I continue to meet with Mike McCune and his team on SCD and am also participating in the SCD TPP activity that is progressing slowly.

Thanks, Julie

Julie A. Panepinto, MD, MSPH
Acting Director, Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute, NIH
6705 Rockledge Drive
Bethesda, MD 20817
[redacted]

From: Collins, Francis (NIH/NHGRI) [E] [redacted]@nih.gov>
Sent: Tuesday, September 27, 2022 5:58 AM
To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Seeing Bill Gates tomorrow

P.S. I did see the recent JCI Insight paper that shows impressive results for in vivo gene editing of the fetal globin promoter in the mouse model of sickle cell disease. Cites support from NHLBI, NHGRI, and NIGMS. Also support from BMGF. Cool stuff. See attached.

From: Collins, Francis (NIH/NHGRI) [E]
Sent: Tuesday, September 27, 2022 6:48 AM
To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
Subject: Seeing Bill Gates tomorrow

Hi all,

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Bill Gates is at the White House tomorrow and asked to see me at 9 AM. Among the topics we will likely discuss is the HIV-SCD joint NIH-BMGF effort to develop cures that will be applicable in low income settings. Are there any new developments since the Sunnylands meeting back in May? Bill will likely ask about the future of this partnership.

Thanks, Francis

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From: "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>
To: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>, "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 07:57:33 -0400
Importance: Normal

Hi Francis,

Yes, the Cure SCD team is tracking this landscape. We are intrigued by progress being made toward the vision of "single shot" in vivo gene editing with homing to HSCs.

Indeed Lieber was invited to present to our Cure SCD Executive Meeting last week to give us an update of his work. In addition to what is in the JCI paper you found; they have also used their approach to editing with a SCD mouse model. They are in the process of spinning up a company. Given the Jim Wilson experience with Ad5 many years ago; they've made lots of modifications of the vector to manage the immune response and cytokine storm to mitigate acute toxicity — a likely issue they will undoubtedly need to still navigate with the FDA.

We are also still interested in non-viral strategies ; but Lieber's work is clearly at the CSC vanguard.

Overall, the SCD component is very much on track toward the vision we outlined 4 years ago.

Best

Gary

From: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>
Date: Tuesday, September 27, 2022 at 6:58:15 AM
To: "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
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To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
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Thanks, Francis

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From: "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>, "Gibbons, Gary (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Panepinto, Julie (NIH/NHLBI) [E]" [redacted]@nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 09:57:32 -0400
Importance: Normal

Francis,

We have continued to meet with Mike and his team. One of his team members is coming for a visit in October so we can have a face to face deep dive.

Since Sunnylands the Temple group initiated the phase one of a anti-HIV CRISPR trial in Philadelphia, part of the NIAID Collaboratory. We have reviewed a set of grants looking new and improved delivery systems for gene therapies. We plan to fund 3-4 and the details will be announced in the new fiscal year. We are expanding in 2023 the process for sites in LMICs to apply for assistance to support cure trials including but not limited to gene-based technologies. The first iteration of this strategy has been completed, now on to version 2.0. Last, the plans for an bNAb treatment and cure trial in Africa with BMGF is moving forward. Waiting for BMGF to finish production of the bNAbs.

This continues to be parallel and complementary activities with BMGF.

Best regards,

Carl

From: Collins, Francis (NIH/NHGRI) [E] [redacted]@nih.gov>
Sent: Tuesday, September 27, 2022 6:48 AM
To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Thanks, Francis

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Collins, Francis (NIH/NHGRI) [E]" [redacted]@nih.gov>
Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 10:27:15 -0400
Importance: Normal

See note from Carl Dieffenbach regarding NIAID activities with BMGF.
Thanks,
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
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From: Collins, Francis (NIH/NHGRI) [E] [redacted]@nih.gov>
Sent: Tuesday, September 27, 2022 6:58 AM
To: Gibbons, Gary (NIH/NHLBI) [E] [redacted]@nih.gov>; Panepinto, Julie (NIH/NHLBI) [E] [redacted]@nih.gov>; Dieffenbach, Carl (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Seeing Bill Gates tomorrow

P.S. I did see the recent JCI Insight paper that shows impressive results for in vivo gene editing of the fetal globin promoter in the mouse model of sickle cell disease. Cites support from NHLBI, NHGRI, and NIGMS. Also support from BMGF. Cool stuff. See attached.

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Released by Chairman Rand Paul

Thanks, Francis

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Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 17:42:36 -0400
Importance: Normal

Thanks, Carl. Is the anti-HIV CRISPR trial targeting CCR5 or integrated proviruses?

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Subject: Re: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 18:08:27 -0400
Importance: Normal

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https://medicine.temple.edu/news/first-clinical-trial-crispr-based-hiv-therapy-founded-breakthrough-research-lewis-katz-school#:~:text=The%20first%20clinical%20trial%20of,investigators%20at%20Excision%20BioTherapeutics%2C%20Inc.

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To: "Dieffenbach, Carl (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Seeing Bill Gates tomorrow
Date: Tue, 27 Sep 2022 18:52:58 -0400
Importance: Normal

Cool! That's the kind of protocol I was hoping might work. Let me know what you hear about results.

Francis

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From: Bill Gates [redacted]@gatesventures.com>
To: Tony Fauci [redacted]@niaid.nih.gov>
Cc: Larry Cohen [redacted]@gatesventures.com>, Ian Saunders [redacted]@gatesventures.com>, Josh Daniel [redacted]@gatesventures.com>
Subject: [EXTERNAL] My new book "How to Prevent the Next Pandemic"
Date: Mon, 03 Jan 2022 23:57:09 -0500
Importance: Normal
Attachments: HTPTNP_Jan_3.docx

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Tony,

Happy New Year! I hope this note finds you well.

I have been working on a book entitled "How to Prevent the Next Pandemic" - and I am getting ready to submit it to the publisher.

It would mean a lot to me if you would be able to find time to look it over before I submit.

I will be curious to hear your ideas for improving it, especially chapter 9, which is the plan I am proposing for the world.

It may be too much to ask, but if you had time to look over the book before this Sunday the 9th, it would allow me to incorporate your thoughts into the manuscript I submit. Even if you don't have time this week, I would appreciate any thoughts you have at any time.

The book is scheduled to be released on May 3, 2022.

Bill

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "'Bill Gates'" [redacted]@gatesventures.com>
Cc: "Larry Cohen" [redacted]@gatesventures.com>, "Ian Saunders" [redacted]@gatesventures.com>, "Josh Daniel" [redacted]@gatesventures.com>
Subject: RE: My new book "How to Prevent the Next Pandemic"
Date: Wed, 05 Jan 2022 13:52:59 -0500
Importance: Normal

Bill:
Thank you for your note. I am rather overwhelmed but I will try to get to the book this weekend , at least to give you my take on Chapter 9 and then the rest of the book later on . I will try my best
Warm regards,
Tony

Anthony S. Fauci, MD
Director
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From: Bill Gates [redacted]@gatesventures.com>
Sent: Monday, January 3, 2022 11:57 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Larry Cohen [redacted]@gatesventures.com>; Ian Saunders [redacted]@gatesventures.com>; Josh Daniel [redacted]@gatesventures.com>
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To: "Bill Gates" [redacted]@gatesventures.com>
Cc: "Larry Cohen" [redacted]@gatesventures.com>, "Ian Saunders" [redacted]@gatesventures.com>, "Josh Daniel" [redacted]@gatesventures.com>
Subject: RE: My new book "How to Prevent the Next Pandemic"
Date: Sat, 08 Jan 2022 13:21:47 -0500
Importance: Normal
Attachments: Gates_document_with_Fauci_comments_and_edits_on_Chapter_9.docx; BG_book_comments_from_David_Morens_01_06_2022.docx

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Bill:

Thanks for sending this. I have done 3 thing: 1) I skimmed the book in its entirety; 2) I very carefully read Chapter 9 very carefully and provided tracked edits and several comments; and 3) I gave the manuscript in close confidence to a trusted colleague who destroyed it after reading it. His name is Dr. David Morens and he has read the entire book and have provided comments on every chapter. His comments are a bit granular and you might not be able to address them in the limited time frame; however, I am providing them in the attached document for your interest and use if you wish. Regarding the book (especially chapter 9), I agree completely with Dr. Morens. This is really well-done and easily understandable with crisp and clear messages for the general public. Chapter 9 is very well done and my comments are in the attached document. I am sorry that I did not have time to read the entire book carefully (except for Chapter 9), but I have another Senate HELP hearing on Tuesday and I need to prepare over the weekend. I hope our comments are helpful. Thank you for giving me the opportunity to read the manuscript. Again, well done!

Warm regards,

Tony

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National Institutes of Health
Bethesda, MD 20892-2520
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<~?~Recto page a is blank.>

Released by Chairman Rand Paul

Also by Bill Gates

The Road Ahead (with Nathan Myhrvold and Peter Rinearson)

Business @ the Speed of Thought (with Collins Hemingway)

How to Avoid a Climate Disaster

Released by Chairman Rand Paul

How to Prevent the Next Pandemic

Released by Chairman Rand Paul

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How to Prevent the Next Pandemic

Bill Gates

<~?~Insert colophon.>

Alfred A. Knopf, New York

2022

Released by Chairman Rand Paul

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Contents

Introduction 3

Chapter 1: Learn from COVID 000

Chapter 2: Create a pandemic prevention team 000

Chapter 3: Get better at detecting outbreaks early 000

Chapter 4: Help people protect themselves right away 000

Chapter 5: Find new treatments fast 000

Chapter 6: Get ready to make vaccines 000

Chapter 7: Practice, practice, practice 000

Chapter 8: Go after malaria, HIV, and TB too 000

Chapter 9: Make a plan for preventing pandemics 000

Afterword: How COVID changed the course of our digital future 000

Acknowledgments 000

Notes 000

Index 000

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How to Prevent the Next Pandemic

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<~?~Commence Introduction>

Introduction

I was having dinner on Valentine's Day 2020 when I realized that COVID-19 would become a global disaster.

For several weeks, I had been talking with experts at the Gates Foundation about a new respiratory disease that was circulating in China. We're lucky to have a team of world-class people with decades of experience in tracking, treating, and preventing infectious diseases, and they were following COVID-19 closely. We had already committed several million dollars in grants to help keep the virus out of Africa, where it could devastate countries that were already struggling. Our working assumption was: We hope this virus won't go global, but we have to assume it will until we know otherwise.

At that point, there was still reason to believe that the virus could be contained within China. The government had taken unprecedented safety measures to lock down Wuhan—schools and public places were closed and citizens were issued permission cards that allowed them to leave their home every other day for thirty minutes at a time.[1] And the virus was still limited enough that countries were letting people travel freely. I had flown to South Africa in early February for a charity tennis match.

When I got back from South Africa, it had been a few weeks since we'd had an in-depth conversation about COVID at the foundation. There was one central question I could not stop thinking about and wanted to explore at length: Was I right to hope that COVID-19 could be contained, or would it go global?

Released by Chairman Rand Paul

I turned to a favorite tactic that I've been relying on for years: the working dinner. You don't bother with an agenda; you simply bring together a dozen or so smart people, provide the food and drinks, tee up a few questions, and let them start thinking out loud. I've had some of the best conversations of my working life with a fork in my hand and a napkin in my lap.

On February 9, I sent an email about scheduling something for that Friday night: "We could try and do a dinner with the people involved with coronavirus work to touch base." Conscious of the date, I added: "It is Valentine's Day, so I wouldn't want to mess up anyone's plans for that at short notice."

That Friday, a dozen experts from the foundation and other organizations came to my office outside Seattle for dinner. Over short ribs and salads, we turned to that key question: Would COVID-19 turn into a pandemic?

My optimism, I learned that night, was unwarranted. The numbers were simply not in humanity's favor. Especially because COVID-19 spread through the air—making it more transmissible than, say, a virus that is spread through contact, like HIV or Ebola—there was little to no chance of containing it to one country or even one continent. Within a few months, millions of people all over the world would have contracted this disease, and inevitably millions would die from it.

I was struck that governments weren't more concerned about this looming disaster. I asked, "Why aren't governments taking urgent action?"

One scientist on the team, a South African researcher who came to our foundation after a distinguished career at Emory University, simply said: "They should be."

***

Released by Chairman Rand Paul

Infectious diseases—both the kind that turn into pandemics and the kind that don't—are something of an obsession for me. Unlike software or climate change, the subjects of my previous books, deadly infectious diseases are not generally something that people want to spend time on. (COVID-19 is the exception that proves the rule.) I've had to learn to temper my enthusiasm for talking about AIDS treatments and a malaria vaccine at parties. I could also be accused of seeking out the kind of parties where I won't have to temper my enthusiasm.

My passion for the subject goes back almost twenty-five years, to January 1997, when Melinda and I read an article in *The New York Times* by Nicholas Kristof. Nick reported that diarrhea was killing 3.1 million people every year, almost all of them children.[2] We were shocked. Three million kids a year! How could that many children be dying from something that was, as far as we knew, little more than an uncomfortable inconvenience?

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This was when I was still reading the print edition and could cut out articles I wanted to share with others.

We learned that the simple lifesaving treatment for diarrhea—an inexpensive liquid that replaces the nutrients lost during an episode—wasn't reaching millions of children. That seemed like a problem we could help with, and we started making grants to get the treatment out more broadly and to support work on a vaccine that would stop diarrheal diseases in the first place.*

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* Today about 500,000 children die of diarrheal diseases every year—still a horrific number, but a reduction of nearly 84 percent is real progress. A lot of this improvement is due to the development of cheap vaccines that prevent rotavirus, the main cause of childhood diarrhea.

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I wanted to know more. I reached out to Dr. Bill Foege, one of the epidemiologists responsible for the eradication of smallpox and a former head of the Centers for Disease Control and Prevention. Bill gave me a stack of eighty-one textbooks and journal articles on smallpox, malaria, and public health in poor countries; I read them as fast as I could and asked for more. One of the most influential for me had a mundane title: *World Development Report 1993: Investing in Health, Volume 1*.[3] My obsession with infectious diseases—and particularly infectious diseases in the developing world—had begun.

When you start reading up on infectious diseases, it isn't long before you come to the subject of outbreaks, epidemics, and pandemics. There aren't strict definitions for these terms; a good rule of thumb is that an outbreak is when a disease spreads locally, through a community or small region, an epidemic is when an outbreak goes national, and a pandemic is when an epidemic goes global, affecting more than one continent. And some diseases don't come and go, but stay consistently in a specific location—those are known as *endemic* diseases. Malaria is endemic to many equatorial regions. If COVID-19 never goes away completely, it'll be classified as an endemic disease.

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<~?~NO CAPTION FOR ABOVE ILLUSTRATION (Illustration comparing the classifications of outbreaks, epidemics, and pandemics.)>

In 1969, the surgeon general of the United States announced that it was "time to close the book on the problem of infectious diseases." Yet since then, according to the World Health

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The Gates Foundation helped fund this work and the vaccine's distribution to children in low- and middle-income countries.

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Organization (WHO), scientists have identified more than 1,500 new pathogens, most of which began in animals and then spread to humans.

Some never caused much harm; others, such as HIV and COVID, were catastrophes. HIV/AIDS has killed more 36 million people, and more than 37 million people are living with HIV today. There are 1.5 million new cases every year[4], though the number of new cases is going down each year because people who are being properly treated with antiviral drugs don't spread the disease.

And with the exception of smallpox—the only human disease ever eradicated—old infectious diseases are still hanging around. Even plague, a disease most of us associate with ancient times, is still with us. It struck Madagascar in 2017, infecting more than 2,400 people and killing more than 200.[5] The WHO receives reports of at least 40 cholera outbreaks every year. Between 1976 and 2018, there were 24 localized outbreaks and one epidemic of Ebola. If you include small outbreaks, there are probably 200 or more every year.

In other words, the book on infectious diseases is not closed. We're not even near the last page.

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Endemic killers. HIV/AIDS, malaria, and tuberculosis have killed more than 100 million people worldwide since the year 1990. Failure to contain and stop COVID transmission will make it an unwelcome addition to this dangerous group. (Institute for Health Metrics and Evaluation)

AIDS and other "silent epidemics," as they came to be known—tuberculosis, malaria, diarrheal diseases, maternal and neonatal conditions, and others—are the focus of the foundation's global health work. In 2000, they killed more than 15 million people, many of them

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children, and yet shockingly little money was being spent on these diseases.[6] Melinda and I saw this as the area where our resources and our understanding of how to build teams to create new innovations could make the biggest difference.

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A billboard promoting AIDS awareness and prevention in Lusaka, Zambia.

This is a source of a common misconception about our foundation's health work. It's not concentrated on protecting people in rich countries from diseases. It concentrated on the gap in health between high-income countries and low-income ones. Now, in the course of that work, we learn a lot about diseases that can affect the rich world, and some of our funding will help with these diseases, but they are not a focus of our grantmaking. The market system, rich-country governments, and other philanthropists put a lot of resources into that work.

Pandemics of course affect all countries, and I have worried a lot about them since I first studied infectious diseases. Respiratory viruses, including the influenza family and the coronavirus family, are particularly dangerous because they can spread so fast. The possibility of a flu pandemic was, relatively speaking, well known; many people had at least heard of the 1918 flu, which killed something like 50 million people, and they might have remembered the swine flu pandemic of 2009–10. But a century is a long time, so almost no one alive lived through the flu pandemic, and the swine flu pandemic didn't turn out to be a huge problem because it wasn't much more fatal than the normal flu. At the time I was learning all this, in the early 2000s, coronaviruses—which are one of three virus types that cause most common colds—weren't discussed nearly as often as the flu.

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A notice from the U.S. Treasury Department encouraging proper hygiene and social distancing during the 1918 influenza pandemic.

The more I learned, the more I realized just how unprepared the world was for a serious respiratory virus epidemic. I read a report on the World Health Organization's response to the 2009 swine flu epidemic that concluded, prophetically: "The world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained and threatening public-health emergency." The report laid out a step-by-step plan for getting prepared. Few of the steps were taken.

The next year, my friend Nathan Myhrvold started telling me about some research he was doing into the greatest threats faced by humanity. Although his biggest worry was an engineered bioweapon—a disease made in the lab—naturally occurring viruses were high on the list.

I've known Nathan for decades: He created Microsoft's cutting-edge research division and is a polymath who has done research on cooking (!), dinosaurs, and astrophysics, among other things. He's not prone to exaggerating risks. So when he argued that governments around the world were doing essentially nothing to prepare for pandemics of any kind, either natural or intentionally created, we talked about how to change that.*

Nathan uses an analogy that I like. Right now, the building you are sitting in (assuming you're not reading this book at the beach) is probably fitted with smoke detectors. Now, the odds that the building you're in will burn down today are very low—in fact, it might go 100 years

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* Nathan eventually wrote a paper about these ideas called "Strategic Terrorism: A Call to Action" for the journal *Lawfare.* You can find it at **https://papers.ssrn.com**. I wouldn't advise reading it before bed—it is sobering.

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without burning down. But that building isn't the only one around, of course, and somewhere in the world, at this very moment, a building is burning down. That's why we install smoke detectors: to protect against something that's rare but potentially very destructive.

When it comes to pandemics, the world is one big building fitted with smoke detectors that aren't especially sensitive and have trouble communicating with each other. If there's a fire in the kitchen, it might spread to the dining room before enough people hear about it to go put it out.

In the spring of 2014, I started getting emails from the health team at the foundation about an outbreak that sounded ominous: A few cases of Ebola virus had been identified in southeastern Guinea. By that July, there had been Ebola cases in Conakry, the capital of Guinea, and in the capital cities of Guinea's neighbors, Liberia and Sierra Leone. Eventually the virus would spread to seven other countries, including the United States, and more than 11,000 people would die.7

Ebola is a scary disease—it causes patients to bleed to death from their orifices—but it can't infect tens of millions of people, because it only spreads through physical contact with the bodily fluids of an infected person. And by the time you're really infectious, you're too sick to move around. The biggest risks were to people who were taking care of Ebola patients, either at home or in the hospital, and during funeral rites, when someone would wash the body of a person who had died of the disease.

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In this photo we see a funeral taking place near the village of Macenta in Guinea in 2014. Many people contracted Ebola during funeral gatherings because they would come into close contact with a recent victim of the disease.

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Even though Ebola wasn't going to kill many Americans, it did remind them that an infectious disease can travel long distances.. A frightening disease had come to the United States as well as the United Kingdom and Italy—places that American tourists liked to visit. The fact that there had been a total of six cases and one death in those three countries, versus more than 11,000 in West Africa, didn't matter. Americans were paying attention to epidemics, at least for the moment.

I thought it might be an opportunity to highlight the fact that the world wasn't ready to handle an infectious disease that really could cause a pandemic. *If you think Ebola is bad, let me tell you what the flu could do.* Over the Christmas holidays of 2014, I started writing a memo about the gaps in the world's readiness that had been highlighted by Ebola.

The gaps were enormous. There was no systematic way to monitor the progress of disease through communities. Diagnostic tests, when they were available, took days to return results—an eternity when you need to quarantine people if they're infected. There was a volunteer network of brave infectious disease experts who went to help authorities in the affected countries, but no large full-time team of paid experts. And even if there had been such a team, there was no plan in place to move them to where they needed to be.

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<~?~NO CAPTION FOR THIS ILLUSTRATION (Illustration showing a checklist for responding to the 2014 Ebola outbreak.)>

In other words, the problem was not that there was some system in place that didn't work well enough. The problem was that there was no system at all.

I still didn't think it made sense for the Gates Foundation to make this one of its top priorities. I also thought that rich world governments would get in gear after the Ebola scare, if they understood what was at stake. I published a paper in *The New England Journal of Medicine,*

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pointing out how unprepared the world was and laying out what we needed to do to get ready. I adapted the warning for a TED talk called "The Next Epidemic? We're Not Ready," complete with an animation showing 30 million people dying from a flu as infectious as the 1918 one. Pointing out that there would be trillions of dollars of economic losses and massive disruption, I wanted to be alarming to make sure the world got ready. The talk was viewed xx times after the pandemic started but only yy times before.

jThe Gates Foundation, in partnership with the governments of Germany, Japan, Norway, and Wellcome, , created an organization called CEPI—the Coalition for Epidemic Preparedness Innovations—to accelerate work on vaccines against new infectious diseases and help those vaccines reach people in the poorest countries. I also funded a local study in Seattle to learn more about how the flu and other respiratory diseases move through a community.

Although CEPI and the Seattle Flu Study were good investments that helped when COVID came, not much else was done. Six years after I gave my TED talk and published that NEJM paper, as COVID-19 was spreading around the world, reporters and friends would ask me if I wished I had done more back in 2015. I am not sure how I could have gotten more attention on the need for better tools and practice scaling them up rapidly. Maybe I should have written this book in 2015, but I am not sure how many people would have read it. CEPI is now raising money to scale up the great work it did, and I hope it gets a strong response.

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In early January 2020, the team we had set up to monitor outbreaks after the Ebola scare was tracking the spread of SARS-CoV-2, the one we now know as the virus that causes COVID-19.*

On January 23, Trevor Mundel, who leads our global health work, sent Melinda and me an email outlining his team's thinking and requesting the first round of funding for COVID work. "Unfortunately," he wrote, "the coronavirus outbreak continues to spread with the potential to become a serious pandemic (too early to be sure but essential to act now)."†

Melinda and I have a system for making decisions when a request comes to both of us, as this one did. Whoever sees it first sends it to the other and says, basically, "This looks good, do you want to go ahead and approve it?" Then the other one sends an e-mail approving the spending. We still use this system today for making big decisions related to the foundation, even though we're no longer married.

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* A word about terminology. SARS-CoV-2 is the name of the virus that causes the disease COVID-19. Technically, COVID refers to all diseases caused by coronaviruses, of which COVID-19 is one. (The 19 comes from the fact that it was discovered in 2019.) But to keep things readable, from here on out, I'm going to use "COVID" to refer to COVID-19 and "the COVID virus" to refer to SARS-CoV-2.

† I've already mentioned the Gates Foundation several times in this Introduction, and I'll be mentioning it more throughout this book. This is not because I want to toot our horn, but because the foundation's health team played an important part in much of the effort to develop vaccines, treatments, and diagnostics for COVID-19. It would be hard to tell that story completely without mentioning their work.

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Ten minutes after Trevor's mail came through, I told Melinda I thought we should approve it; she agreed and replied to Trevor: "We are approving $5M [i.e., $5 million] today and realize there may be an additional amount needed in the future. Glad the team has jumped on top of this so quickly. It is very concerning."

As we both suspected, there were definitely additional amounts needed, as became clear at the Valentine's Day dinner and many other meetings. The foundation has committed $1.8 billion to different aspects of fighting COVID, including slowing its spread, developing vaccines and treatments, and helping make sure that these lifesaving tools reach people in poor countries.

Since the pandemic began, I've had the chance to work with and learn from countless health experts at the foundation and outside it. One deserves special mention.

In March 2020, I had my first call with Anthony Fauci, the head of the infectious diseases division of the National Institutes of Health. I'm lucky to have known Tony for years (long before he was on the cover of pop-culture magazines), and I wanted to hear what he was thinking about all this—especially the potential for various vaccines and treatments that were being developed. Our foundation was backing many of them, and I wanted to make sure our agenda for developing and deploying innovations was aligned with his. Also, I wanted to understand what he was saying publicly so I could help by giving consistent advice about things like social distancing and wearing masks.

We had a productive first call, and Tony and I would check in monthly for the rest of the year, discussing the progress on different treatments and vaccines and strategizing about how work done in the United States could benefit the rest of the world. We even did a few interviews together. It was an honor to sit next to him (virtually, of course).

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One side effect of speaking out, though, is that it has brought out more of the criticisms of the Gates Foundation's work that I've been hearing for years. The most thoughtful version goes like this: Bill Gates is an unelected billionaire—who is he to set the agenda on health or anything else? Two corollaries of that criticism are that the Gates Foundation has too much influence, and that I'm a technophile who thinks new inventions will solve all our problems.

It's certainly true that I've never been elected to any public position, and I don't plan to seek one. And I agree that it's not good for society when rich people have undue influence out of the spotlight.

But there's nothing secret about the Gates Foundation. We're open about what we fund and what the results have been. And we know that some of our critics don't speak up because they don't want to risk losing grants from us, which is one of the reasons we make extra effort to consult outside experts and seek out different viewpoints. (We expanded our board of trustees in 2022 for similar reasons.) We aim to improve the quality of the ideas that go into public policies and to steer funding toward those ideas that are likely to have the most impact. It would be even better if there were more funders in the areas we work in, but that isn't a reason for us to stay away from this work. I know this answer won't satisfy every critic, but it's the best one I can give.

And yes, I am a technophile. Innovation is my hammer, and I try to use it on every nail I see. But innovation doesn't just have to be a new machine or vaccine, as important as those are. It can be a different way of doing things, a new policy, or a clever scheme for financing a public good. You'll read about some of these innovations in this book as well as the technological ones. And I'll also make the case for the unsexy work of strengthening public health systems, which—when functioning well—can serve as the first line of defense against emerging diseases.

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Unfortunately, not every criticism of me is as thoughtful. Throughout COVID, I've marveled at how I became the target of crazy conspiracy theories. It's not an entirely new sensation—nutty ideas about Microsoft have been around for decades—but the attacks are more intense now. I have never known whether to engage with them or not. If I ignore them, they keep spreading. But does it actually persuade anyone who buys into these ideas if I go out and say, "I am not interested in tracking your movements—I honestly don't care where you're going—and there is no movement tracker in any vaccine"? I've decided that the best way forward is to just keep doing the work and believe that the truth will outlive the lies.

Years ago, the eminent epidemiologist Dr. Larry Brilliant coined a memorable phrase: "Outbreaks are inevitable, but pandemics are optional." Diseases have always spread among humans, but they don't have to become global disasters. This book is about how we can build a system that will contain the inevitable outbreaks so they don't become large-scale pandemics.

There is, for obvious reasons, more momentum than ever to do this now. Nobody who has been through COVID will ever forget it. Just as World War II changed the way my parents' generation looked at the world, COVID has changed the way we see the world.

But we do not have to live in fear of another pandemic. We can have a global health system that provides basic health care to everyone, and that is ready to respond to and contain any emerging diseases.

What would it look like in practice? Imagine:

> Research in the next five years allows us to understand all respiratory pathogens and prepares us to create tools like diagnostics, antiviral drugs, and vaccines at scale far faster than today.

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A potentially threatening disease is rapidly detected by local public health agencies, which function effectively in even the world's poorest countries.

Anything out of the ordinary is shared with capable labs for study, including genetic sequencing, and the information uploaded to a global database that is being monitored by a dedicated team.

When a threat is detected, governments sound the alarm and initiate public recommendations for travel, social distancing, and emergency planning.

We start using the blunt tools that we already have on hand, such as mandatory quarantines, antivirals that protect against almost any strain, and tests that can be performed in any health clinic, workplace, or home.

If that isn't sufficient, then the world's innovators immediately get to work developing tests, treatments, and vaccines for the pathogen. Diagnostics in particular ramp up extremely fast so that large numbers of people can be tested in a short time.

New drugs and vaccines are approved quickly, because we've agreed ahead of time on how to run trials quickly and share the results. Once they're ready to go into production, manufacturing gears up right away because factories are already set up and approved.

No one gets left behind, because we've already worked out how the new tools will be allocated and how to rapidly make enough for everyone.

Everything gets where it's supposed to, when it's supposed to, because we've set up systems to get products delivered all the way to the patient.

Communications about the situation are clear and avoid pani.c.

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> And this all happens quickly. We go from raising the first red flag to making enough safe, effective vaccines to protect the population of the earth in six months.

To some people reading this book, the scenario I've just described will sound overly ambitious. It's certainly a big goal, but we're already headed in that direction. In 2021, the White House announced a plan for developing a vaccine in the next epidemic within 100 days, if resources are allocated.[8] And lead times are already shrinking: It took just twelve months from the time the COVID virus was analyzed genetically until the moment the first vaccines were tested and ready for use, a process that usually takes at least half a decade. And technological advances made during this pandemic will speed things up even more in the future. If we make the right choices and investments, we can do this. Each chapter in this book explains one step we need to take. Together, they add up to a plan for eliminating the pandemic as a threat to humanity and reducing the chance that anyone ever has to live through another COVID.

One final thought before we dive in: COVID is a fast-moving disease. In the time since I started writing this book, several variants of the virus have appeared, most notably Omicron, and some have vanished. Some treatments that appeared very promising in early studies turned out to be less effective than we had hoped. There are questions about vaccines, including how long they provide protection, that can only be answered over time.

In this book I have done my best to write what is true at the time of publication, with the understanding that some facts will inevitably change in the coming months and years. In any case, the key points of the pandemic prevention plan that I propose will be relevant just the same.

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The world still has a lot of work to do before it can hope to keep outbreaks from turning into global disasters, no matter what COVID does in the short term.

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Chapter 1

Learn from COVID

It's easy to say that people never learn from the past. But there are times when we do. Why hasn't there been a World War III? Partly because in 1945, world leaders looked at history and decided there were better ways to settle their differences.

That's the spirit in which I look at the lessons from COVID, the worst global calamity since World War II. We can learn from it and decide to do a better job of protecting ourselves from deadly diseases—in fact, it's imperative to put a plan in place and fund it now, before the sense of urgency fades and the world's attention moves on to something else.

Many reports have documented the good and the bad of the world's response to COVID, and I've benefited from reading them. I have also puloled together a number of key lessons through my work in global health—including projects such as eradicating polio and following the pandemic day to day working with experts at the foundation and in governments, academia, and the private sector. A key element is to look at the countries that did better than others.

1. Doing the right things early pays huge dividends later.

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I know this sounds odd, but my favorite website is a treasure trove of data that tracks diseases and health problems all over the world. It's called the Global Burden of Disease,* and the level of detail it contains is astonishing. (The 2019 version tracked 286 causes of death and 369 types of diseases and injuries in 204 countries and territories.) If you're interested in how long people live, what makes them sick, and how these things change over time, this site is the best source. I can spend hours at a time looking at the data.

The site is published by the Institute for Health Metrics and Evaluation, which is located at the University of Washington in my hometown of Seattle (and a Gates Foundation grantee). As you can probably guess from its name, IHME specializes in measuring health around the world. It also does sophisticated computer modeling that attempts to establish cause-and-effect relationships: What factors might explain why cases are going up or down in some country, and what does the forecast look like a few months out?†

Since early 2020, I've been peppering the team at IHME with questions about COVID. What I've hoped to find out is what the countries that are dealing most successfully with COVID have in common. What did they all do right? Once we answer that question with some certainty, we'll understand the best practices and be able encourage other countries to adopt them.

The first thing you have to do is define success, but that's not as easy as you might think. For example, you can't just look at how often people with COVID in a given country went on to

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* **https://vizhub.healthdata.org/gbd-compare/**

† You may have heard about "the Chris Murray Model." That's actually the IHME model. Chris runs IHME and was chagrined to hear the organization's work ascribed only to him.

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die from it. That statistic will be skewed by the fact that older people are more likely to die from COVID than younger people, so countries with especially old populations will almost inevitably look worse. (One country that did particularly well—even though it has the oldest population—is Japan. It had the best compliance with mask mandates of any country, which helps explain some of its success, but other factors were probably also at play.)

What you really want in a measure of success is a number that captures the overall impact of the disease. People who die of heart attacks because the hospital is too overwhelmed by COVID patients to treat them ought to be counted just as much as people who die of the disease itself.

There's a measure that does exactly that—it's called the rate of excess deaths, and it includes people who die directly of COVID and people who die because the disease had a ripple effect. (It's a rate because it's the number of excess deaths per capita, in order to account for the size of a country's population.) The lower your rate is, the better you're doing. In fact, some countries' rates are actually negative. That's because they had relatively few fatalities from COVID, and there were also fewer traffic accidents and other fatal incidents because people were staying home so much more.

Toward the end of 2021, America's rate of excess deaths was more than 2,000 per million people, roughly on par with Iran's. Canada's, by contrast, was in the low 100s, while Russia's was well over 6,000.1

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Worse than it looks. Here we see the total number of COVID-19 deaths compared to the estimated number of excess deaths associated with the pandemic worldwide, through

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December 2021. Excess deaths help us account for all causes of mortality greater than what would've been expected without the pandemic. *(Economist)*

Many of the countries with the lowest rates (near zero or negative)—Australia, Vietnam, New Zealand, Taiwan, and South Korea—did three things well early in the pandemic. They tested a large share of the population quickly, isolated people who tested positive or had been exposed, and made a plan for detecting and dealing with cases that may have come across their borders.

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Containing COVID in Vietnam. With a population of 96 million people, Vietnamese officials implemented measures for detecting, isolating, and preventing new cases from emerging throughout the country during the first year of the pandemic. (Exemplars in Global Health)

Unfortunately, early success can be hard to maintain. Relatively few people in Vietnam were vaccinated for COVID—partly because of the limited supply of vaccines, and partly because vaccines didn't seem as urgent when the country had done such a good job controlling the virus. So when the much more transmissible variant Delta came along, there were relatively few people in Vietnam who had any immunity, and the country was hit especially hard. Its rate of excess deaths went from just over 500 per million people in July 2021 to nearly 1,500 per million people in December—though even at the higher rate, Vietnam was still doing better than the United States.[2]

The second thing the data makes clear is that, once the infection got to a large portion of the population, there was essentially no pattern to explain which countries kept down their excess death rates and which did not. The experts at IHME have looked at everything: income

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level, geography, public policies regarding lockdowns and other steps, and many more factors. None of them reliably predicts how a country will do. A few high-income countries with significant infections managed to keep the deaths from spiraling out of control, for example, while others did not.

IHME's data also suggests that a country's success against COVID correlates roughly with how much people there trust the government. This makes intuitive sense, since if you have confidence in your government, you're more likely to follow its guidelines for preventing COVID. On the other hand, trust in government is measured by polls, and if you live under an especially repressive regime, you're probably not going to tell a random pollster what you really think about the government. And in any case, this finding doesn't easily translate into practical advice that can be implemented quickly. Building trust between a people and their government takes years of painstaking, purposeful work.

Another good approach to identifying what works is to look at the problem from the other end: Find exemplars that did individual things especially well and study how they did it. A group I fund that's called, appropriately enough, Exemplars in Global Health is doing just that, and they have made some fascinating connections.

For example, all other things being equal, countries whose health systems function well in general were more likely to respond well to COVID. If you have a strong network of health clinics that are well staffed with trained personnel, are trusted by people in their community, have supplies when they're needed, and so on, you are in a better position to fight off a new disease. This suggests that any pandemic prevention plan needs to include, among other things, helping low- and middle-income countries improve their health systems. We'll return to this subject in Chapter 8.

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Another example: The data suggests that cross-border traffic between countries was responsible for a fair amount of transmission. So we can look for places that managed it well. For example, early in the pandemic, Uganda required COVID tests for all truckers coming into the country, and a regional agreement in East Africa followed suit soon after. But because the testing process was slow and kits were in short supply, the policy caused major backups at the border—of up to four days—and transmission went up while truckers waited around in cramped quarters.

Uganda and its neighbors did several things to fix the logjam—including dispatching mobile testing labs to border crossings, creating an electronic system to track and share results, and requiring truckers to get tested in the country where they started their route, rather than at the border.[3] Soon, traffic was flowing again, and cases were kept under control.

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Naliku Musa, a truck driver at the border between Uganda and South Sudan, waits for the results of his COVID test.

Bottom line: In the early days, if you're able to test a large share of your population, isolate the positive cases and their contacts, and handle possible cases coming from abroad, you'll be well positioned to keep the caseload manageable. If you don't do those things quickly, then only extreme measures can prevent a large number of infections and deaths.

2. Some countries show us what not to do.

I don't like to dwell on failures, but some are too egregious to ignore. Although there are positive exemplars, most countries handled at least some aspects of their COVID response

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poorly. I'm calling out the United States here because I know its situation well, and because it should have done so much better than it did, but by no means is it the only country that made a lot of mistakes.

The White House's response in 2020 was disastrous. The president and his senior aides downplayed the pandemic and gave the public terrible advice. Incredibly, federal agencies refused to share data with each other.

It certainly didn't help that the director of the Centers for Disease Control and Prevention is a political appointee subject to political pressure, and some of the CDC's public guidance was clearly influenced by politics. Even worse, the person running the CDC in 2020 wasn't trained as an epidemiologist. The former CDC directors who are still remembered today for their amazing work—people like Bill Foege and Tom Frieden—were experts who had spent their careers in the organization. Imagine a general who has never even been through a battle simulation suddenly having to run a war.

The worst failure, though, is that the United States never got testing right: Not nearly enough people were tested, and results took far too long to come back. If you're carrying the virus but don't know it for another seven days, you've just spent a week potentially infecting other people. To me, the most mind-boggling problem—because it would have been so easy to avoid—is that the U.S. government never fully scaled up the capacity for testing people or created a website to identify those who should be first in line for get quick results and record the outcomes of all tests.

In the early months of 2020, anyone in America who was worried they might have COVID should have been able to go to a government website, answer a few questions about their symptoms and risk factors (such as age and location), and find out where they could get tested.

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Or, if test supplies were limited, the site might determine that their case wasn't a high enough priority and notify them when they could be tested.

Not only would the site have made sure that testing kits were used most efficiently—for the people most likely to actually test positive—it also would have given the government additional information about parts of the country where too few people were showing an interest in getting tested. With this data, the government could have directed more resources toward getting the word out and expanding testing in those areas. The site would also have provided people with instant eligibility to participate in a clinical trial, if they tested positive or were at high risk, and it could later have been used to help make sure that vaccines went to the people at the highest risk of getting severely sick or dying. And it would be useful in non-pandemic times too for fighting other infectious diseases.

Any software company worth its salt could have built this site in no time,* but instead states and cities were left to their own devices, and the whole process was chaotic. It was like the Wild West. I remember one especially heated call with people from the White House and CDC in which I was quite rude about their refusal to take this basic step. To this day I don't understand why they wouldn't let the most innovative country in the world use modern communications technology to fight a deadly disease.

3. In the face of something the world should have been

* Microsoft would've done it for free, and I'm sure many other companies would have too.

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better prepared for, people did heroic work.

Whenever there's a disaster, the children's TV host Fred Rogers used to say, "Look for the helpers. You will always find people who are helping." During COVID, it takes very little looking to find the helpers. They are everywhere, and I've had the pleasure of meeting some of them and learning about many more.

Every day for five months of 2020, as a COVID-19 tester in Bangalore, India, Shilpashree A.S. would put on a protective gown, goggles, latex gloves, and a mask. (Like many people in India, she uses initials referring to her hometown and her father's name as her last name.) Then she'd step into a tiny booth with two holes for her arms and spend hours performing nasal swab tests on long lines of patients. To protect her family, she had no physical contact with themfor five months they saw each other only on video calls.4

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A COVID-19 tester takes samples from a patient in Bangalore, India, while stationed inside of a booth and wearing protective gear.

Thabang Seleke was one of 2,000 volunteers in Soweto, South Africa, to participate in a study on the effectiveness of the COVID vaccine developed at Oxford University. The stakes for his country were high: In just six months in 2020, more than 600,000 people were diagnosed with COVID and more than 13,000 people have died from it. Thabang heard about the trial from a friend and stepped forward to join to help bring an end to the coronavirus in Africa and beyond.

Sikander Bizenjo left his job at a business school in Karachi and went to his home province of Balochistan, a dry, mountainous region in southwestern Pakistan where 70 percent of

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the population lives in poverty. He founded a group called Balochistan Youth Against Corona, raising money to buy food for 10,000 households each month as well as personal protective equipment for health workers.

Ethel Branch, a member of the Navajo Nation in the U.S., quit her job at a law firm to create Navajo Hopi Solidarity, an organization that delivers water, food, and other necessities to people in need throughout the Navajo and Hopi Reservations. She has raised millions of dollars (including through a GoFundMe campaign) and organized teams of young volunteers who have helped thousands of families on both reservations.

The stories of other people who are making sacrifices to help others during this crisis could fill an entire book. Around the world, health care workers put themselves at risk to treat sick people—according to the WHO, more than 115,000 had lost their lives taking care of COVID patients by May 2021.[5] First responders and frontline workers kept showing up and doing their jobs. People checked in on neighbors and bought groceries for them when they couldn't leave home. Countless people followed the mask mandates and stayed home as much as possible. Scientists worked overtime, using all their brainpower to stop the virus and save lives. Politicians made decisions based on data and evidence, even though these decisions weren't always the popular choice.

Not everyone did the right thing, of course. Some people have refused to wear masks or get vaccinated. Some politicians have denied the severity of the disease, shut down attempts to limit its spread, and even implied that there's something sinister in the vaccines. It's impossible to ignore the impact their choices are having on millions of people, and there's no better proof of those old political clichés: Elections have consequences, and leadership matters.

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4. Variants and breakthrough cases weren't a surprise, but some subsequent waves were.

Unless you work on infectious diseases, you had probably never heard of variants until COVID. The idea may have seemed new and scary, but there's nothing particularly unusual about variants. Influenza can quickly mutate into new variants, which is why we get a new flu shot every year—the vaccine needs to be updated annually to keep up with constantly shifting flu virus strains.

Early in the pandemic, there was a broad assumption in the scientific community that mutations of COVID wouldn't cause a big problem. By early 2021, scientists knew that variants were emerging, but they appeared to be evolving in similar ways, leading some scientists to wonder whether the world had already seen the worst mutations that the virus was capable of. But the Delta variant proved otherwise—its genome had evolved to make it far more transmissible. The arrival of Delta was a negative surprise, but it finally convinced everyone that even more variants could show up.

In future outbreaks, variants will always be a possibility. Scientists will monitor them closely to make sure that whatever new vaccines come out will still protect people from the variants. But, because every time a virus moves from one person to another is an opportunity for it to mutate, the most important thing will be to keep doing the things that we know reduce transmission: Follow the experts' recommendations on masks, social distancing, and vaccines,

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and make sure low-income countries get vaccines and the other tools they need to fight the pathogen.

Just as variants weren't a surprise, neither were so-called breakthrough cases, in which people who have been vaccinated end up getting infected anyway. Until we have the 100 percent effective vaccines or drugs I mentioned in the previous section,* some vaccinated people will still become infected. As more people get vaccinated in a given population, the total number of cases will go down, and a growing percentage of the cases that do occur will be breakthroughs.

Here's one way to think about it. Imagine that COVID starts spreading through a town with a fairly low vaccination rate. A thousand people get so sick that they end up in the hospital. Out of those 1,000 severe cases, 10 are breakthroughs.

Then the virus spreads to the next town over, which has a high vaccination rate. That town sees only 100 severe cases, of which 8 are breakthroughs.

In the first town, breakthroughs represented 10 out of 1,000 severe cases, or 1 percent. In the second, they made up 8 out of 100, or 8 percent of the total. Eight percent sounds like bad news for town #2, right?

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<~?~NO CAPTION FOR THIS ILLUSTRATION (Illustration comparing a town with low vaccination rate to a town with high vaccination rate.)>

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* In the medical field, "effectiveness" and "efficacy" mean different things. Efficacy is a measure of how well a vaccine works in a clinical trial. Effectiveness is a measure of how well it works in the real world. For the sake of simplicity, and because "efficacious" is an eyesore of a word, I'll use "effectiveness" to mean both.

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But remember, the important number is not the breakthrough rate. It's the total number of severe cases, and that number went from 1,000 in the first town to just 100 in the next. That is progress by any definition. You're safer by far in town #2, where lots of people are vaccinated, and if you're one of them.

Along with variants and breakthrough cases, waves—big spikes in the number of cases—were not a surprise in and of themselves. We know from the history of previous pandemics that waves occur, yet countries in every region of the world were caught off guard by them. (I admit to having been surprised, as many people were, by the size of the delta wave in India in mid-2021.) It was partly the result of wishful thinking—the mistaken idea that because they had contained the virus in the early days of 2020, that they could relax because it wasn't coming back. Another explanation is sadly ironic: Countries that do the best job of suppressing the virus early on will often be susceptible to later surges, because their suppression measures kept people from getting sick and developing natural immunity. Introduce an especially transmissible variant like Delta into an environment like that, and a big wave is almost inevitable.

5. Good science is messy, uncertain, and prone to change.

Here's a partial list of the U.S. government's various positions on wearing masks during COVID:

- Feb. 29, 2020: The surgeon general tweets that people should "STOP BUYING MASKS" because they are "not preventing" COVID (which turned out not to be true) and buying them will make it harder for health workers to access them (which was true at the time, although it was fairly easy to make

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more masks).

- March 20, 2020: The CDC reiterates that healthy people who do not work in health care or are not taking care of a sick person do not need masks.
- April 3, 2020: Two weeks later, the CDC recommends masks for all people over age two who were in a public setting, traveling, or around others in the same household who might be infected.
- Sept. 15, 2020: The CDC recommends that all teachers and students who attend school in person wear masks whenever feasible.
- Jan. 20, 2021: President Biden signs an executive order requiring masking and physical distancing in federal buildings, on federal lands, and by government contractors. The next day he signs an order requiring masks when traveling, and nine days later the CDC issues an order that makes refusing to wear a mask in federally mandated spaces a violation of federal law.
- March 8, 2021: The CDC releases new guidance that fully vaccinated people do not need to wear a mask when visiting other vaccinated people inside.
- April 27, 2021: The CDC announces that people do not need to wear masks outdoors when they walk, bike, or run alone or with members of their household regardless of vaccination status. Fully vaccinated people do not need to wear masks outdoors at all unless they're at a large gathering like a concert.
- May 13, 2021: The CDC announces that fully vaccinated people no longer need to wear a mask or physically distance inside. Some states, like Washington and California, continue mask mandates through some or all of

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June.

- July 27, 2021: The CDC recommends that fully vaccinated people resume wearing masks indoors in parts of the country where case counts are surging. It also recommends that masks be worn indoors by all teachers, staff, students, and visitors to schools regardless of their vaccination status

You could get whiplash from trying to follow along.

Does this mean the staff of the CDC were incompetent? No. I won't defend every decision the CDC made—many experts thought at the time that the May 13, 2021, advice on masks was a mistake, for example, and I agreed—but during a public health emergency, decisions are made by imperfect people using imperfect data in an environment that's constantly changing. We should have studied respiratory virus transmission a lot more beforehand, instead of learning during the pandemic. And, expecting perfection during an outbreak actually sets up a perverse dynamic, as the story of David Sencer illustrates.6*

Born in Michigan in 1924, Sencer joined the U.S. Navy after graduating from college. After a yearlong bout with tuberculosis, he ended up joining the U.S. Public Health Service, intent on saving people from diseases like the one that had sidelined him for so long.

Sencer made his mark early on with vaccines. After moving to the Centers for Disease Control, he helped draft legislation that created the first broad vaccination program in the U.S. and dramatically expanded the number of children who received the polio vaccine. He became director of the CDC in 1966 and led its expansion into work on malaria, family planning, smoking prevention, and even the quarantine of astronauts after returning from space. Sencer

* Michael Lewis tells Sencer's story well in his book *The Premonition.*

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was a master of logistics, a skill that made him indispensable in the successful effort to eradicate smallpox.

In January 1976, a solider serving at Fort Dix in New Jersey died from swine flu after doing a five-mile march while sick. Thirteen others were hospitalized with the disease. Doctors discovered that the men all had a strain of influenza similar to the one that had caused the 1918 pandemic.

The outbreak never expanded beyond Fort Dix. But in February 1976, worried that there could be a replay of the 1918 disaster when flu season came around that fall—which would mean tens of millions of deaths around the world—Sencer called for mass immunization against this particular strain of swine flu. A presidential panel that included the legendary researchers Jonas Salk and Albert Sabin, both of whom had developed groundbreaking polio vaccines, backed the idea. President Gerald Ford went on television to announce his support for a mass immunization drive, and the campaign quickly kicked into gear.

By mid-December, signs of trouble were emerging. Ten states reported cases of vaccinated people contracting Guillain-Barré syndrome, or GBS, an autoimmune disease that causes nerve damage and muscle weakness. The vaccination program was suspended later that month and never reinstated. Shortly thereafter, Sencer was informed that he would be replaced as head of the CDC. He was never told why.

In total, GBS cases occurred in 362 patients out of the 45 million people vaccinated[7]—a rate around four times higher than you would expect with the general population. Today, some experts doubt whether there is a connection between the vaccine and GBS, a belief that Sencer stood by until his death. One study concluded that, even if the vaccine did cause GBS in rare

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cases, its benefits vastly outweighed the risk. But someone needed to take the blame, and Sencer was the fall guy.[8]

Sencer, who died in 2011, remains highly regarded in the world of public health. The consensus is that pushing for mass immunizations was worth the risk; if he had been right about a pandemic, the cost of inaction would have been enormous. But critics focused more on the risk of a rare autoimmune disease—which was real—than on the possibility that tens of millions could die.

In public health, you have to be careful about sending a message that says, "act early and you'll be fired if you get it wrong." Of course, if someone makes a truly wretched decision, firing may be in order. But officials need the leeway to make tough calls, because there will always be false alarms, and distinguishing them from the real thing is not an easy task.

What if Sencer had done nothing, and his fears had turned out to be valid? Tens of millions of people would have died of a virus that had started in the United States, which had a chance to stop it but chose not to. When people like Sencer act in good faith and with the best data they have available to them, they should not be attacked for possibly having made the wrong call purely because we have the benefit of hindsight. It creates a perverse incentive to be overly cautious—to protect their careers by holding back. And when it comes to public health, holding back can lead to disaster.

6. It pays to invest in innovation.

It's tempting to assume that invention occurs practically overnight. If in January you wouldn't know what messenger RNA was if it walked up to you on the street, and by July you've read all about it and are getting a vaccine that uses it, you might think it went from idea to reality in just

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six months. But innovation does not happen in an instant. It takes years of patient, persistent effort by scientists—who will fail more often than they succeed—as well as funding, smart policies, and an entrepreneur's mindset to get an idea out of the lab and into the market.

It's frightening to imagine how much worse COVID would've been if the U.S. government and others hadn't invested years ago in research on vaccines that use mRNA or another approach called a viral vector. In 2021 alone, they accounted for more than half a billion people doses worldwide.9 (I'll explain how both work in Chapter 6.) Without them, we would've been far worse off.

The pandemic has offered up dozens of other concrete examples of innovative ideas, new diagnostic tools, treatments, policies, and even ways to fund the delivery of all these things around the world. Scientists have gained crucial insights into how viruses move from person to person. And since transmission of the flu virus essentially shut down during the first year of COVID, researchers now know that it's possible to stop influenza, which bodes well for future outbreaks of flu and other diseases.

COVID also highlights an inescapable fact about innovation: Most of the world's greatest talent for translating research into products is in the private sector. Not everyone likes that arrangement, but the profit motive is often the most powerful force in the world for getting new products created quickly. It's the government's role to invest in the basic research that leads to major innovations, and to create policies that let new ideas flourish. And when there are market failures—when the people who need lifesaving tools the most can't afford them—then governments, nonprofits, and foundations should step in to fill the gap, often by finding the right way to work with the private sector.

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7. We can do better next time—if we start taking pandemic preparation seriously.

The world responded to COVID faster and more effectively than to any other disease in history. But as the late educator and physician Hans Rosling put it, "Things can be better and bad."[10] In the Better column, for example, I'd put the fact that the world developed safe, effective vaccines in record time. In the Bad column, I'd put the fact that too few people in poor countries are getting them. I'll return to this problem in Chapter 8.

Another entry in the Bad column: the world's failure to get serious about preparing for and trying to prevent pandemics.

Governments are responsible for the safety of their people. For common events that cause damage and deaths—fires, natural disasters, wars—governments have a structure for their response: They have experts who understand the risks, get the resources and tools they need, and practice how they'll respond in an emergency. Militaries run large-scale drills to make sure they're prepared for action. Airports run exercises to see if they're ready for an emergency. City, state, and federal governments practice responding to natural disasters. Even schoolchildren go through fire drills.

When it comes to pandemics, though, virtually none of this happens. Although people had been raising the alarm for decades about novel diseases that could kill millions of people—a long succession of warnings came before and after mine in 2015—the world didn't respond. For all the effort that humans put into preparing for attacks from fires, storms, and other humans, we had not prepared seriously for an attack by the smallest possible enemy: a pathogen.

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In Chapter 2, I'll argue that what we need is a corps of people globally whose job is to wake up every day thinking about diseases that could kill huge numbers of people—how to spot them early, how to respond, and how to measure whether we're ready to respond.

To sum up: The world has never invested in the tools it needs or properly prepared for a pandemic. It's time we did. The rest of this book will describe how we can do it.

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Chapter 2

Create a pandemic prevention team

In the year 6 CE, a fire devastated the city of Rome. In its aftermath, the emperor, Augustus, did something that had never been done in the history of the empire: He created a permanent team of firefighters. [1]

The fire brigade, which would grow to include 7,000 men, was equipped with buckets, brooms, and axes and divided into seven groups that stood watch at barracks placed strategically throughout the city. (One of these barracks was discovered in the mid-nineteenth century and is sometimes open to visitors.) Officially, the squad was known as the *Cohortes Vigilum*—which can be loosely translated as "Brothers of the Watch"—but locals came to use the term of endearment *Sparteoli,* or "Little Bucket Fellows."

Elsewhere around the world, China's first professional brigade was established in the eleventh century by Emperor Renzong. Europe followed roughly 200 years later.[2] In America, there were volunteer groups before the American Revolution, formed at the urging of a young Benjamin Franklin (who else?), as well as private ones that were paid by insurance companies to save burning buildings.[3] But the United States didn't have a single government-run, full-time firefighting corps until 1853, when one was established by Cincinnati, Ohio.

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There are now about 370,000 full-time firefighters in the United States, stationed at nearly 30,000 departments.[4]* Local governments in the U.S. spend more than $50 billion a year staying ready to deal with fires. (I was surprised by how large these numbers are when I looked them up!)

And that's not to mention all the steps we take to prevent fires from starting in the first place. For nearly 1,000 years, governments have passed laws to reduce the risk of conflagration, including banning thatched roofs (London in the tenth century) and requiring the safe storage of fuels for bread ovens (Manchester, England, in the sixteenth).[5] Today, one large fire-prevention nonprofit publishes a list of more than 300 building codes and standards designed to minimize the risk and extent of fires.[6]

In other words, for some 2,000 years, humans have recognized that individual families and businesses aren't solely responsible for protecting themselves—they need help from the community. If your neighbor's house is on fire, your home is at risk, and firefighters will take steps to prevent the flames from spreading. And when they're not actively battling a blaze, the fire department will run drills to keep their skills sharp and help out with other activities related to public safety and service.

Fires don't spread across the entire world, of course, but diseases do. A pandemic is the equivalent of a fire that starts in one building and within weeks is burning in every country in the world. So to prevent pandemics, we need the equivalent of a global fire department.

At the global level, we need a group of experts whose full-time job is to help the world prevent pandemics. It should be responsible for watching out for potential outbreaks, raising the

* There are also about 740,000 volunteer firefighters in the United States.

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alarm when they emerge, helping contain them, creating data systems to share case numbers and other information, standardizing policy recommendations and training, tracking the capacity to scale up tools (particularly diagnostics),, organizing drills to look for weak spots in the system, and so on. It should also coordinate the many professionals and systems around the globe who do this work at the country level.

Creating this organization requires a serious commitment from rich-country governments, including making sure it is staffed properly. It will be hard to get the right consensus at the global level, as well as the right level of funding—but even knowing the obstacles, I feel it is a critical priority for the world to put this team in place. In this chapter I want to make clear how it should work.

***

You might think a group like the one I'm proposing already exists. How many movies and TV shows have you seen where there's an outbreak of a scary disease and the world seems perfectly prepared? Someone starts showing symptoms. The president of the United States gets briefed on the situation with a dramatic animated computer model that shows the disease spreading worldwide. A team of experts get the phone call they've been waiting for (always during breakfast with their families, for some reason) and spring into action. Wearing hazmat suits and carrying expensive equipment, they are flown in on helicopters to assess the situation. They take a few samples, speed off to the lab, and go on to save humanity.

Reality is a lot more complicated than that. For one thing, the Hollywood version underplays one of the most important (but admittedly undramatic) tasks in pandemic prevention: making sure that countries have strong health systems. In a well-run system, clinics are well

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staffed and equipped, pregnant women get pre- and post-natal care, and children get their routine vaccines; health care workers are well trained in public health and pandemic prevention; and reporting systems make it easy to identify suspicious clusters of cases and raise the red flag. When that kind of infrastructure is in place—as it is in most wealthy nations and some low- and middle-income ones—you're much more likely to notice the early stage of a new disease emerging. Without that infrastructure, you don't notice the new disease until it has spread to tens of thousands of people and probably gotten into multiple countries.

But what's most unrealistic about what you see in the movies is that it suggests there's some agency that pulls together all these different capabilities, acting swiftly and decisively to prevent a pandemic. My favorite example is an episode of the TV show *24*—a show I really liked—where a terrorist intentionally releases a pathogen in Los Angeles. Word gets to practically every government entity in no time. The hotel where the release took place is immediately sealed off. A computer modeling genius figures out not only how the disease will spread, but how quickly news of the disease will get around, and (the best part) how bad traffic will get as people flee the city. I remember watching that episode and thinking, "Wow, that government sure knew how to prepare."

It made for great TV, and of course we could all sleep better at night if things really worked that way. But they don't. Although there are many organizations that work hard to respond to a major outbreak, their efforts largely depend on volunteers. (The best known is the Global Outbreak Alert and Response Network.) Regional and national response teams are understaffed and underfunded, and none of them has a mandate from the international community to work globally. The only organization that sort of has that mandate, the WHO, has very little funding and almost no personnel. There is no organization with the size, scope,

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resources, and responsibility for detecting and responding to outbreaks and preventing them from becoming pandemics.

Let's consider the sequence of events that are involved in an effective pandemic prevention response. Sick people have to go to a clinic, and the health workers there have to diagnose them properly. Those cases must get reported up the chain, and an analyst has to notice an unusual cluster of cases with similar suspicious symptoms or test results. A microbiologist must get samples of the pathogen and determine whether it's something we've seen before. A geneticist may need to map its genome. Epidemiologists have to understand how transmissible and severe the disease is.

Community leaders need to get, and share, accurate information. Quarantines might need to be put in place and enforced. Scientists need to get cracking on diagnostic tests, treatments, and vaccines. And, just as firefighters run drills when they're not putting out a blaze, all of these groups need to practice, testing the system to find the weak spots and fix them.

Bits and pieces of what you'd want in a monitor-and-respond system exist. I've met people who have dedicated their lives to this work, and many put their lives on the line for it. But COVID did not happen because there were too few smart, compassionate people trying to prevent it. COVID happened because the world hasn't created an environment in which these smart, passionate people can make the most of their skills as part of a strong, well-prepared system.

At the country level, no Congress or Parliament ever told its top public health people: "Here's a proper budget for pandemic prevention. Stay vigilant. Make sure you're hiring the right people and preparing for these rare but massive outbreaks." Now we know they should have. The United States did some of this, but as we saw, the pieces didn't come together when

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the pandemic hit. In fact, the lack of coordination between the partially staffed groups became part of the problem.

What we need at both the global and country levels is a well-funded organization with enough full-time experts in all the necessary areas, the credibility and authority that come with being a public institution, and a clear remit to work on nothing but preventing pandemics.

I call the global team the GERM—Global Epidemic Response and Mobilization—team, and their job should be to wake up every day asking themselves the same questions: "Is the world ready for the next outbreak? What can we do to be better prepared?" They should be fully paid, regularly drilled, and prepared to mount a coordinated response to the next threat of a pandemic.

My back-of-the-napkin estimate is that GERM would need 2,000 to 3,000 full-time employees. Their skills should run the gamut: epidemiology, genetics, drug and vaccine development, data systems, diplomacy, rapid response, logistics, computer modeling, and communications. GERM should be managed by the World Health Organization, the only group that could give it global credibility. It should have a diverse workforce, with a decentralized staff working in places around the world but paid out of a central fund. Most of GERM's staff would be based in the countries where outbreaks are most likely to happen, though some would sit in the WHO's regional offices and at its headquarters in Geneva.

When there's a potential pandemic looming, the world needs expert analysis of early data points that can confirm the threat. GERM's data scientists would build a system for monitoring reports of clusters of suspicious cases. Epidemiologists would monitor reports from national governments and work with the WHO to identify anything that looks like an outbreak. Product-development experts would advise governments and companies on the highest-priority drugs and

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vaccines. People who understand computer modeling would coordinate the work of modelers around the world. And the team could take the lead on creating and coordinating common responses, such as how and when to implement border closures, recommend mask use, and so on

Diplomacy would inevitably be part of the job. After all, national and local leaders are the ones who understand the unique conditions in their country, who speak every local language, who know the key players, and to whom the public looks for leadership. People from GERM would have to work closely with them, making it clear that their job is to support, not supplant, local expertise. If GERM becomes—or even appears to be—something imposed from the outside, some countries will not follow its recommendations.

Finally, the GERM team would be responsible for testing the world's monitor-and-respond system to find the weak spots. Among other things, they could run practice drills. Just as militaries do complex exercises where they simulate different conditions and see how well they respond, the GERM team could organize outbreak response exercises. Not war games, but germ games. This will be the team's most important role, and we'll return to it in much more detail in Chapter 7.

***

The group I'm describing would be new, but not exactly unprecedented. It's based on a model I've seen work extremely well against another disease, one that we are achingly close to eradicating.

Polio—a paralyzing disease that usually affects the legs but can, in rare cases, affect the diaphragm and make it impossible to breathe—has probably been around for thousands of years. (An Egyptian tablet from the sixteenth century BCE portrays a priest with what appears to be a

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leg withered by polio.)[7] Even though polio vaccines were invented in the mid-1950s and early 1960s, for decades they didn't reach everyone who needed them. As recently as the late 1980s, there were still 350,000 cases of wild polio every year, in 125 countries.

But in 1988, the WHO and its partners—led by the volunteer group Rotary International—set out to eradicate polio. By adding a vaccine for it to the list of routine childhood immunizations, and by undertaking massive vaccination campaigns, the world cut cases of wild poliovirus* from 350,000 a year to fewer than a dozen in 2021.[8] That's a drop of more than 99.9 percent! And instead of existing in 125 countries, wild polio exists in only two: Afghanistan and Pakistan.

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Ending polio. A worldwide declaration initiated the dramatic reduction of wild polio cases globally, from nearly 350,000 in 1988, to just 4 in 2021. (WHO/GPEI)

A main ingredient in the secret sauce is what are known as emergency operations centers. These have existed in every country where there's been a big polio campaign.

Picture the office of a political campaign in the last days before the election, and you'll get an idea of what an EOC looks like. Maps and charts are pasted up on the walls—but instead of tracking poll numbers, they're staying on top of the polio campaign. They're organizing a network of community health workers who watch for signs of an outbreak and use a smartphone app to report cases. They're testing samples so they know exactly which version of the poliovirus might be present. They're maintaining relationships with community and religious leaders,

* I'm specifying "wild" poliovirus here to distinguish it from vaccine-derived cases, which are extremely rare.

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correcting misperceptions and misinformation about vaccines. They're using computer models to see where they might need to send vaccinators next.

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Maps like these from the communications and outreach division managing the pandemic in San Francisco filled the walls as city workers battled the impact of COVID-19 on the city.

They know exactly which houses in the area have been visited by vaccinators. They even know how many households refuse to have their children vaccinated. The measurement is incredibly precise: Last year, the national coordinator of Pakistan's national EOC reported that they had reduced the refusal rate from 1.7 percent in 2020 to 0.8 percent the next year, and that in one campaign, just 0.3 percent of households had refused the vaccine.9 And in March 2020, the EOC pivoted to focus much of its work on COVID.

In a sense, the GERM team would be a worldwide EOC on steroids. Just as emergency operations centers fight endemic diseases like polio while staying ready to pivot when something new emerges, the GERM team would do double duty as well—only with the focus reversed. Emerging diseases should be their top priority, but to keep their skills sharp, they would help out with polio, malaria, and other infectious diseases.

You might have noticed one obvious activity that's missing from GERM's job description: treating patients. That's by design. GERM wouldn't need to replace the rapid response clinical experts like those at Médecins Sans Frontières. Its job would be to coordinate their efforts and complement their work by doing disease surveillance, computer modeling, and other functions. No one from GERM would be responsible for caring for patients.

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I'd put the cost of running the GERM team in the neighborhood of $1 billion a year to cover salaries for 2,000 to 3,000 people plus equipment, travel, and other expenses. To put that number in perspective: $1 billion a year would be less than one one-thousandth of the world's annual spending on defense.[10] Given that it would be an insurance policy against a tragedy that costs the world trillions of dollars—as COVID has—and also drive down the human and financial burden caused by other diseases, a billion dollars a year would be a bargain.* Don't think of this spending as charity or even traditional development assistance. Just like defense spending, it would be part every nation's responsibility to ensure the safety and security of its citizens.

The GERM team is essential to running a proper monitor-and-respond system, I will come back to it repeatedly in the coming chapters. You'll see the crucial role it will play in every aspect of pandemic prevention: disease surveillance, coordinating the immediate response, advising on the research agenda, and running tests of systems to find its weak spots. Let's turn first to the problem of how you detect an outbreak to begin with.

* This organization should not be paid for by private citizens. It needs to be accountable to the public and have authority from the WHO.

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Chapter 3

Get better at detecting outbreaks early

How many times have you been sick in your life? Most people have probably suffered through a number of colds and stomach bugs, and if you're unlucky, you may have caught something worse like the flu, measles, or COVID. Depending on where you live in the world, you may have dealt with malaria or cholera.

People get sick all the time, but not every illness leads to an outbreak.

The task of watching for the cases that are merely troublesome, the ones that could be catastrophic, and everything in between—and ringing the alarm bell when necessary—is known as epidemic disease surveillance. The people who do disease surveillance aren't looking for a needle in a haystack; they're looking for the sharpest, deadliest needles in a mountain of somewhat duller ones.

The term "surveillance" has an unfortunate Orwellian connotation, but in this sense it just refers to the formal and informal networks of people around the world who keep track of what's happening with health day to day. The information they provide does everything from shaping public policy to informing which strain of flu you'll be vaccinated against each year. And as COVID has made clear, the world woefully underinvests in disease surveillance. Without a stronger system, we won't see potential pandemics soon enough to prevent them.

Fortunately, this is a solvable problem, and in the rest of this chapter I'll explain how we can solve it. I'll start with the local health care workers, epidemiologists, and public health

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officials who are the first people to see evidence of a pandemic in the making. Next, I'll explain some of the obstacles that make disease surveillance difficult for everyone—the fact that many births and deaths are never officially recorded, for example—and tell you about how some countries are overcoming these hurdles.

Finally, I'll explore the cutting edge of disease surveillance—the new tests that will radically change the way doctors detect diseases in their patients, and a novel citywide approach to studying the flu that was pioneered in my hometown of Seattle. (The twists and turns and ethical dilemmas in that story are intense.) By the end of this chapter, I hope to persuade you that, with the right investments in people and technology, the world can have the tools it needs to see the next pandemic coming before it's too late.

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January 30, 2020, marked a major milestone in the COVID pandemic: The director-general of the WHO declared the disease a "Public Health Emergency of International Concern." That's an official designation under international law, and when the WHO invokes it, every country in the world is supposed to respond by taking various steps.*

Although a few diseases, such as smallpox and new types of flu, are so alarming that they're supposed to be reported as soon they're detected, most of the time the system operates as it did with COVID. The WHO—trying to strike a delicate balance between protecting the public without setting off unnecessary panic—waits until it has enough data before setting a major international response into motion.

* There isn't yet any mechanism for making sure they actually take these steps, though.

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So how does that data make it up the chain, from a few people feeling sick to the WHO's decision to trigger a global response? To answer that question, we need to look in depth at how disease surveillance systems work. They're designed to gather data about health and illness in general, and so the better they run, the more likely they are to flag potential problems.

One source of information, as you might expect, is the everyday operations of a health care system: doctors and nurses interacting with their patients. With a few exceptions such as the ones I mentioned earlier, a single case of some disease isn't going to set off alarm bells; most staffers at a clinic won't be unnerved by one individual who shows up with a cough and a fever. Generally, it's the suspicious-looking clusters of cases that will draw attention.

This approach is called passive disease surveillance, and here's how it works. The staff at a clinic regularly pass information about the cases they're seeing up the chain to their public health agency. They won't share details about each case, but they will give the aggregate numbers of various illnesses. From there, ideally, the data will be fed into a regional or global database, which makes it easier for analysts to see patterns and respond accordingly. Countries in Africa, for example, enter aggregated data on certain diseases into something called the Integrated Disease Surveillance and Response system.[1]

Suppose their aggregate data shows an unusual number of patients with pneumonia whose cause couldn't be determined. That's a red flag, and hopefully an analyst for a state or national health agency who's monitoring the database will note the spike in cases and mark it for more investigation. In the world's most advanced health systems, the spike might be flagged by a computer system, which then notifies people at the health agency that they need to take a closer look.

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Once you suspect there is an outbreak, you need to find out far more than the number of cases. If the disease might spread fast, you need information such as exactly who was infected, the locations where they might have picked up the pathogen, and the people to whom they may have passed it. Gathering this information can be a time-consuming task, but it's an essential step in disease surveillance, and one of the many reasons that health systems need to be well funded and staffed.

Clinics and hospitals are primary sources of information about the diseases that are passing through a community, but they aren't the only ones. After all, they see only a small fraction of what's going on in the community. Some people who are infected don't feel sick enough to bother going to the doctor, particularly if getting to the clinic is expensive or time-consuming, as it is for many people in low- and middle-income countries. Others don't have any reason to see a doctor, because they don't feel the least bit sick. And some diseases spread so fast that it's a bad bet to wait for infected people to show up at the clinic. By the time you notice a jump in cases, it may be too late to stop a big outbreak.

That's why, in addition to monitoring the people who come to clinics and hospitals, it also helps to go looking for known diseases by meeting potential patients where they are. That's called active disease surveillance, and a great example is the outreach done by workers in polio campaigns. They go on rounds in the community not only to vaccinate children but also to be alert for kids with polio symptoms, such as unusually weak leg muscles or leg paralysis that can't otherwise be explained. And polio surveillance teams can often do double duty, as they did during the Ebola epidemic of 2014–15 in West Africa, when they were trained to watch for telltale signs of Ebola as well as polio.

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Some countries are developing smart ways to get even more eyes watching for signs of danger, whether they're coming from a known disease or a new one. Most of the major outbreaks in recent years also showed up in blog posts and social media. This data can be subjective, and there's a lot of noise surrounding the signal, particularly online, but it's often a useful supplement to the insights that health officials get from more traditional indicators.

In Japan, postal workers perform some health services and disease surveillance. In Vietnam, teachers are trained to file a report with local health authorities if they ever notice that several children are absent from school with similar symptoms in the same week, and 2 pharmacists are instructed to raise the alarm when they see a spike in sales of medicines for fever, cough, or diarrhea. The idea is to ensure that surveillance reaches as many communities as possible.

Another relatively new approach is to go looking for signals in the environment. Many pathogens, including poliovirus and coronaviruses, show up in human feces in such a huge quantity that you can detect even a few people who are shedding the virus if you take a sample from the sewage system. Workers take samples of wastewater from treatment plants or open sewers and take them to a lab where they're checked for these viruses..

If the sewage samples come back positive, someone will visit the community they came from to identify people who might be infected, step up vaccination efforts, and educate everyone on what to watch for. The idea of checking wastewater was first developed for polio surveillance, but in some countries the technique is also employed to study the use of illicit drugs and the spread of COVID. Studies have shown it can even act as an early warning system, letting officials prepare for a surge in cases before they show up in positive test results.

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In most rich countries, it is hard to be born or die without the government's recording it—the odds are high that the event will be entered into a birth or death registry. But in many low- and middle-income countries, that's not the case.

Many of them measure births and deaths using household surveys that are held several years apart, which means they only know statistics about deaths and births within some error range, such as plus or minus 5 percent.. According to the WHO, only 44 percent of children born in Africa show up in their government's registry. (In Europe and America, more than 90 percent do.) In low-income countries, just one out of every ten deaths is recorded by the government, and only a tiny fraction of those records includes a cause of death.

Given the challenge of recording major life events, it is hardly surprising that many cases of illness go undetected too. At the end of October 2021, estimates showed that about 15 percent of COVID infections worldwide were being detected. In Europe, the rate was 37 percent, but in Africa, it was only one percent. With so little precision, and with samples being taken only every few years, the deaths statistics won't help us detect an epidemic at all in those countries..

When I first got involved in global health, around 10 million children under the age of five were dying every year, the vast majority of them in low- and middle-income countries. That number was heartbreaking on its own, but even worse, the world knew shockingly little about why these children died. Official reports would show a huge percentage of deaths that was simply labeled "diarrhea," but lots of pathogens and conditions can cause diarrhea, and since nobody knew for certain which ones were the main causes of child mortality, it was nearly impossible to find a solution. Over time, the Gates Foundation and other organizations funded studies that pointed to rotavirus as a major cause, and researchers were able to develop an affordable rotavirus vaccine that saves the lives of nearly 30,000 children every year.3

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Yet identifying rotavirus as a chief culprit solved only one of the mysteries of child mortality. The places that experience the highest rates of child mortality are also, not coincidentally, the ones that are least well equipped with diagnostics and other tools that might help them understand what happened. A large share of the deaths happen at home, and not in a hospital where the staff could have recorded the child's symptoms. It has taken dozens of studies to gain an understanding of questions like why children die in their first 30 days of life and what is causing deaths from respiratory illnesses so we can learn how to save those lives.

Mozambique is a good example of how the system can work better. Until fairly recently, the government there counted deaths by surveying small parts of the country every few years and then using the data to estimate nationwide mortality. In 2018, though, the country began building what's known as a "sample registration system," which involves continuous surveillance in areas that are representative of the country as a whole. Data from these samples is fed into statistical models that make high-quality estimates about what's going on throughout the nation. For the first time, Mozambique's leaders can see accurate monthly reports on how many people died, how and where they died, and how old they were.

Mozambique is also one of several countries that are deepening their understanding of child mortality by participating in a program called the Child Health and Mortality Prevention Surveillance network, or CHAMPS, a global network of public health agencies and other organizations.4 The genesis of CHAMPS dates back nearly two decades to some of my earliest meetings on global health, when I was hearing from experts about the gaps in the field's understanding of why children die. I remember asking, "What do the autopsies reveal?" and being educated on how impractical they are in developing countries. A full autopsy is an

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expensive, time-consuming task, and the child's family often won't consent to such an invasive procedure.

In 2013, with funding from the Gates Foundation, researchers at the Barcelona Institute for Global Health developed a procedure called minimally invasive autopsy, or tissue sampling, which involves getting small samples from the child's body for testing.[5] Sometimes, of course, the family members find it too painful to allow a stranger to study their baby in this way. But many agree to the request.

As the name implies, the process is far less invasive than a full autopsy, but studies have shown that it produces comparable results. Although it is used in only a small number of cases and wasn't created with pandemic prevention in mind—the purpose was to give broader insights into child mortality—the information gleaned from minimally invasive autopsies can give researchers early evidence of an outbreak that is killing children.

I witnessed one of these autopsies during a trip South Africa in 2016. I had read about how the procedure worked, but I knew that watching one in person would help me understand it in a way that no memo or briefing document ever could. It's an experience that I will never forget.

On July 12, 2016, a baby boy had been born to a family in Soweto, outside Johannesburg. Three days later, he died. His heartbroken parents, hoping to spare other families the same grief, decided to allow doctors to perform the minimally invasive tissue sampling. They also graciously agreed to let me be present when it was done. (I was not there when the request was made.)

At a mortuary in Soweto, I watched as a doctor carefully used a long, narrow needle to remove small samples of tissue from the baby's liver and lungs. He also drew a small amount of

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the child's blood. The samples were stored safely and would later be tested for viruses, bacteria, parasites, and fungal pathogens, including HIV, TB, and malaria. It was over in just a few minutes. Throughout the entire procedure, the medical team treated the boy's body with great respect and care.

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This photo is from 2016, when I visited the Child Health and Mortality Prevention Surveillance network in Soweto, South Africa.

The parents were informed confidentially of the results. I never met them, but I hope they got some answers about what happened to their son, as well as a small measure of solace from the fact that their decision to participate in CHAMPS contributed meaningfully to the world's efforts to save children like their son.

Today, data on more than 8,700 cases from the CHAMPS network is giving researchers valuable insights into child mortality. The minimally invasive autopsy, and the systemic improvements that Mozambique and other countries are making, are deepening our understanding of why people die. We need to expand these innovative approaches to understand even better how we can intervene to save lives.

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Most people will never take a monthly household survey about births and deaths or, thankfully, have anything to do with a CHAMPS-type network. But in COVID, and in major outbreaks in the future, we want to sample the community to find out how many asymptomatic or unreported cases of sickness are out there. The field of diagnostics is rife with innovation to make the

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process cheaper and simpler—and therefore easier to implement at the scale that will be necessary—so let's go through the state of play and see what's in the offing.

Since the beginning of COVID, the U.S. government alone has approved more than 400 tests and kits for collecting samples. The one you might be most familiar with—the one that used to require the brain-tickling stick—is a PCR test, and it's the gold standard of diagnostics. If you've got a COVID infection, the virus will be in your airways and in your saliva, and the swab will catch a sample of it. To analyze your swab, a lab technician will add to your sample some specially designed DNA, which makes extra copies of any genetic material from the virus. This step ensures that if there's even a small amount of virus in the sample, it won't escape detection. (It is this process of duplication, which mimics the way nature copies DNA, that gives the polymerase chain reaction its name.) Then a dye is added, and if the viral genes are present, the dye will begin to glow. No glow, no virus.

Creating a PCR test for a new pathogen is a pretty easy task once you've sequenced its genome. Because you already know what its genes look like, you can create the special DNA, dye, and other necessary products very quickly—which is why researchers were able to establish PCR tests for COVID just 12 days after the first genome sequences were published.[6]

Unless the sample is contaminated, a PCR test is unlikely to give you a false positive—if the result says you're infected, you almost certainly are—but sometimes it can return a false negative, meaning that it says you're free and clear even though you're not. This is why if you're experiencing symptoms and get a negative PCR test, you may be asked to take the test again. The test may also pick up on genetic bits of the virus that remain in your blood or nose long after you've been sick, so you may test PCR-positive even if you're not infectious anymore.

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The main downside of PCR tests, though, is that they have to be run on special machinery in a lab, which makes them impractical in many parts of the world. The analysis itself takes only a few hours, but if there's a backlog—as there often has been during COVID—you may not get your results for days or even weeks. Given how easily COVID is passed from one person to another, any test result you get more than forty-eight hours after giving the sample is useless: If you're going to spread the virus, you've already done it by then, and if you need to start treatment with an antiviral or antibody medication, you have to do it within just a few days of the infection.

The other main category of tests looks not for the virus's genes, as PCR machines do, but for specific proteins on its surface. These proteins are known as antigens, and so the tests are called antigen tests. They're less accurate, but not egregiously so; they're especially good at detecting when you're capable of infecting others, and they produce results in less than an hour (and often within fifteen minutes).

Another benefit is that some antigen tests can be taken by anyone in the privacy of their home. If you've ever taken a pregnancy test by peeing on a stick and watching for the smiley face to appear, you've used a thirty-year-old technology called a lateral flow immunoassay—named that way, I suppose, because "test that uses liquid flowing over a surface" was too easy to understand. Many antigen tests work the same way.

During an outbreak, we've got to make it easier for everyone to get tested and get results fast—especially if it's a disease that you can transmit to others before you have any symptoms. And by "we," I mean the United States first and foremost. Other countries, including South Korea, Vietnam, Australia, and New Zealand, far outpaced the U.S. in testing and returning results, much to their benefit.

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Ideally, in the future, everyone's results will be linked into a digital data system—with the proper safeguards for privacy—so that public health officials can see what's going on in their community. It's especially important to identify the people who are most likely to spread the disease, since studies have shown that some COVID patients infect many others, while many COVID patients don't even infect people they're in constant contact with.

So let me tell you about some of the exciting work that's going on in diagnostics, with my usual bias for innovations that will benefit people in poor countries as well as wealthier ones.

The one I'm most enthusiastic about comes from the British company LumiraDx. It's developing systems that can be used to test for multiple diseases, all at once, in pharmacies, schools, and workplaces. These are antigen tests, so they provide rapid results and are easy to use, but they're far more accurate than other antigen tests, hitting the mark about as well as PCR machines do. They're designed for high volume; a single production line can produce hundreds of millions of tests in a year, and a new test for an emerging pathogen can be developed with little or no retooling.

LumiraDx's biggest contribution, though, is its ability to drive down costs exponentially. After you buy the machine—which, at $1,500, is still expensive—you can run each individual test for something like $1 to $1.50; the previous generation of tests cost roughly 10 times as much. That makes the marginal cost of each LumiraDx test nearly as low as the lateral flow approach, but with an accuracy approaching PCRs. In 2021, a group of partners that included the African Union and the Gates Foundation provided 1,500 LumiraDx machines to countries throughout Africa. That's a tiny fraction of the need, though, and I hope more funders step up.

For now, PCR tests remain the gold standard in terms of accuracy, but they also remain slow and expensive. Several companies, though, are out to change this through a process called

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ultra-high-throughput processing—basically, using robotic machines to exponentially increase the number of PCR tests that can be processed in a given time.

The fastest one I'm aware of is called Nexar, developed by Douglas Scientific. You put hundreds of samples on a long piece of tape—picture something like a filmstrip—and feed the tape into a machine that bathes the samples in a tiny pool of reagents called a water bath thermocycler [CHECK THIS]. After a couple of hours, you run the tape through a second machine, which quickly scans all the samples and flags the ones that are positive.

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Here's a picture of what the Nexar machine looks like.

Amazingly, the Nexar system can process more than 150,000 tests per day, which is about ten times what the largest high-throughput processors can do today.7 Biosearch and its partners are planning several pilot projects to see how Nexar machines can work in elementary schools and international airports. Other companies are working on different approaches, and I hope they all keep competing to make cheaper, faster, and more accurate tests. This is an area where the world still needs a lot of innovation.

Bottom line: We need to be able to design a new test very quickly that can be used in many different settings, including clinics, homes, and workplaces. Once that test is designed, we need to be able to make millions at ultra-low cost (perhaps less than a dollar per test). And many academic and private sector groups need to know how it will be manufactured so that they can get their tests scaled up in a few days.

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The Seattle area, where I live, has become something of a hub for the study of infectious diseases. The University of Washington has an excellent global health department and one of the best medical schools in the country. The Institute for Health Metrics and Evaluation, which I mentioned in Chapter 1, provides detailed statistics and computer models to governments around the world. The Fred Hutchinson Cancer Research Center, though focused primarily on cancer, is also home to top experts in infectious diseases. (It's high-profile enough that it's known around town simply as Fred Hutch.) PATH is a leading nonprofit dedicated to making sure that innovations in health reach the world's poorest people.

Put so many intelligent people who are passionate about the same field into one city, and they are practically guaranteed to start kicking around ideas. Over the past few decades, Seattle has become home to a thriving, informal network of researchers who exchange ideas within and across institutions.

It was through this network that, over the summer of 2018, a handful of people in genomics and infectious diseases came to a joint realization. Although they represented different institutions—the Fred Hutchinson center, the Gates Foundation, and another group called the Institute for Disease Modeling*—they were all worrying about the same problem: outbreaks of respiratory viruses. These outbreaks kill hundreds of thousands of people every year and are the most likely culprits for a pandemic, but the field needed to learn a lot more about how they move through communities. And the tools at scientists' disposal were, at best, limited.

For example, researchers have access to case counts from hospitals and clinics, but those statistics represent only a small share of the total. The Seattle scientists talked about how they needed to know much more before they could understand how a virus like influenza spreads

* The Institute for Disease Modeling is now part of the Gates Foundation.

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through a city—most importantly, they needed to know how many people actually got sick, not just how many were tested. And in an emergency outbreak, city officials would need to quickly identify the lion's share of people who might be sick, get them tested, and inform them about their results. But there was no systematic way to do any of those things.

Eventually, in June 2018, a few of the people who were driving this conversation met with me at my office outside Seattle to explain the problem as they saw it. They outlined a three-year project they called the Seattle Flu Study—a prototype for a citywide effort that could transform the way respiratory viruses were detected, monitored, and controlled—and asked whether I would fund it.

Here's how it would work. Beginning that fall, as the flu season ramped up, volunteers throughout the Seattle area would be asked to answer a few questions about their health. If they'd had at least two symptoms of a respiratory problem in the past seven days, they would be asked to submit a sample that would be tested for a range of respiratory diseases. (Despite the name of the project, it wouldn't be limited to flu—the tests would actually cover twenty-six different pathogens.)

Some people would give samples at kiosks set up in SeaTac Airport, the University of Washington campus, homeless shelters, and a few workplaces around town, but most of the samples would come from local hospitals that had already collected them from patients for other reasons. This is a common practice in medical research: When you get tested at a hospital, the results help the doctor decide how to treat you, but the mucus from your nasal swab might be saved for later. Researchers can then use that sample, after certain private data about you has been removed, to test for other pathogens and understand what's happening throughout the community. Just by being sick, you're contributing to science.

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In the Seattle Flu Study, the idea was that all the samples gathered from hospitals and from public places would be tested. When one tested positive for the flu, the case would be marked on a digital map showing, nearly in real time, how many people in Seattle had the flu. Then the virus would go through a further step: Its genetic code would be studied and compared with genes from other flu viruses found around the world.

This genetic work would be a key part of the Seattle Flu Study, because it would let the scientists understand how different cases were related to each other. How do different flu strains enter the city? If there was an outbreak at the university, how far would it spread within the community?

Genetic information is so useful due to a fortuitous flaw in the way genes work. Every time a pathogen makes a copy of itself (or forces the host cell to do the copying, as a virus does), it duplicates its genetic code, or genome. The genomes of all living things are made up of just four building blocks, which we represent as As, Cs, Gs, and Ts.* If you're a movie fan, you might remember a sci-fi film with Uma Thurman and Ethan Hawke about genetically enhanced humans, the title of which—*Gattaca*—is a clever arrangement of these building blocks.

The genome gets passed down from one generation to the next, ensuring that children resemble their biological parents. It is what makes a person a person, a virus a virus, and a pomegranate a pomegranate. The more complex an organism is, the longer its genome is. COVID's consists of about 30,000 As, Cs, Gs, and Ts, while yours and mine consist of several billion.

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* Viruses actually have Us instead of Ts, but the two substances are functionally identical, so I am sticking with Ts for the sake of simplicity.

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But the process of copying genes is imperfect, and it always introduces a few random mistakes, especially in viruses like COVID, influenza, and Ebola. Some As get copied over as Cs, and so on. Most of these mutations either have no effect or leave the copy unable to function, but once in a while they make the copy better suited to survive in its environment than the original that produced it. This is the evolutionary process that leads to COVID variants.

Figuring out the order in which an organism's genetic letters appear is what's known as sequencing its genome. By sequencing the genomes of many different versions of a virus and studying the different mutations among them, scientists can construct what amounts to its family tree. At the bottom of the tree is the latest generation. Further up the tree are that generation's ancestors, all the way up to the first known specimen. The places where the tree branches split indicate major evolutionary steps, such as the emergence of a new variant, and the tree can even be used to record related pathogens that have been found in animals and might make the leap to humans.

All this family tree information, in combination with a good testing regime, can provide invaluable insights into how a disease moves through a community. In South Africa, for instance, a good testing system paired with genetic analysis of HIV revealed that many young women who were living with the virus had acquired it by having sex with older men—information that led to changes in the way the country approached HIV prevention. More recently, genetic sequencing revealed that a 2021 outbreak of Ebola in Guinea started with a nurse who had been infected, astonishingly, five years earlier. Scientists were stunned to learn that the virus could remain dormant for so long, and based on this new information, many are now rethinking ways to prevent Ebola outbreaks.

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The problem that the Seattle scientists and their colleagues kept running up against was that in the United States key parts of the infrastructure needed for this kind of analysis were missing.

Think about the way we handle influenza here. Most people who think they have the flu don't bother going to the doctor—they just stock up on over-the-counter drugs and sweat it out. If they do end up at a clinic, the doctor might make a diagnosis based on the symptoms alone, without running a test. The only cases that get reported to public health officials are the ones in which a test is ordered by a doctor who works at a clinic that is participating in a voluntary influenza-reporting program.

The fact that so few tests are run has a ripple effect: Too few samples of the influenza virus are sequenced. Plus, many of the ones that do get sequenced are not accompanied by information about the people they came from—where they live, how old they are, and so on. You could have a million sequences of a virus, but if you don't know anything about who they came from, you won't be able to figure out where the disease started or how it spread from one place to another.

The Seattle Flu Study was designed to tackle this problem head-on. Not only would it create a system for testing lots of volunteers and sequencing lots of viral genomes, but—subject to privacy safeguards—the sequencing data would be linked to information about the volunteers it came from. And the near-real-time, citywide flu map that the project was going to create would be a game changer for detecting and stopping outbreaks.

I thought the Seattle Flu Study was an ambitious and unique idea, and it had a chance to make progress on some of the problems I had called out in my TED talk years before. I agreed to

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fund it through the Brotman Baty Institute, a research partnership between Fred Hutch, the University of Washington, and Seattle Children's.

The team quickly got to work on the infrastructure they had envisioned. They created a system to develop and prove a new diagnostic test, process and share the results, and perform quality checks to make sure all the work was valid. In the second year, they added a way to let participants take their own samples at home and return them in the mail. With this innovation, the Seattle Flu Study became the first medical study anywhere with a soup-to-nuts process that let people order a kit online, have it delivered to their home, ship it back to the lab, and receive a result. This was pioneering work and a point of pride for the team, but none of us had any idea just how crucial it was about to become.

In 2018 and 2019, the Seattle Flu Study tested more than 11,000 cases of flu and sequenced more than 2,300 influenza genomes—about one sixth of all flu genomes sequenced anywhere in the world in that time. They were able to show that flu in Seattle wasn't one homogenous outbreak, but actually a series of overlapping outbreaks of different flu strains.

Then, in the first few weeks of 2020, everything changed. Nearly overnight, influenza was no longer the virus we needed to worry about the most. The scientists who had spent countless hours planning and creating the flu study were now thinking about nothing but COVID.

By February, they had developed their own COVID test—once the virus was sequenced, this was an easy task for a diagnostician—and began running it on a few hundred samples that they had gathered for the flu study. Within two days, they had found a positive case, a sample submitted to the study by a local hospital that had treated a patient for flulike symptoms.

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After sequencing the virus from this positive sample, one of the team members—a computational biologist named Trevor Bedford—made a disturbing discovery: Genetically, it was closely related to another, earlier case in Washington state. By comparing mutations in the genomes of the two viruses, Bedford showed that the two people had been infected roughly three to six weeks apart. It was proof of what many scientists had long suspected—that the virus had been moving throughout the state for quite some time.

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When COVID arrived in Washington state. We now know COVID was spreading throughout communities undetected for several weeks before the first “non-traveler” cases were recorded. In this chart we can see the difference between confirmed cases of COVID and the estimated number of people infected in the first several weeks of 2020. (Institute for Health Metrics and Evaluation)

Then the group turned to the next logical question: Based on what they knew about the two cases they had sequenced, and how long they now knew the virus had been circulating, how many more people might be infected? A disease modeler named Michael Famulare ran the calculations and put the estimate at 570.*

At the time, only eighteen COVID cases had been confirmed through testing in all of Western Washington. With this work, Bedford, Famulare, and their colleagues showed that the country’s COVID testing system was utterly inadequate. In Washington state alone, hundreds of people had COVID but didn’t know it, and the disease was spreading fast.

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* To be more precise, Famulare put the number at 570, with 90 percent confidence that it was between 80 and 1,500.

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But there was a catch: They weren't sure they could tell anyone what they knew.

The patient at the hospital who had given the sample didn't know that it had been used in a research trial. Although it was well within standard practice to test the patient's sample for another disease such as COVID, revealing the results of that test to anyone—even to the patient, much less to public health officials—was another matter. It would be a violation of the flu study's research protocols.

Also, their COVID test had been approved for use in research studies, but not medical settings, in which the results are given to patients. Although the study team had been talking to government regulators for weeks, there was no way to get their test authorized for medical use. The rules for okaying COVID tests developed by anyone other than the CDC had not even been written yet.

It was a difficult dilemma. On the one hand, revealing the results would violate the standards under which they were operating as ethical researchers and could run afoul of government rules.

On the other hand, how could the team withhold test results from someone carrying a virus that was causing a pandemic? Or from public health officials who needed to know that COVID was spreading in the state, and had almost certainly infected hundreds more people than they realized?

One member of the group clarified the debate with a simple question: "What would a reasonable person do?" When he put it like that, the answer seemed obvious. A reasonable person would protect the individual and the community by revealing the results. So they did.

The news made a splash. "Coronavirus May Have Spread in U.S. for Weeks, Gene Sequencing Suggests," as one headline in *The New York Times* put it.[8]

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Although the decision generated some blowback from government officials and the team had to temporarily stop testing the hospital samples, I felt (and still feel) that they did the right thing. The University of Washington review board that was overseeing the project came to the same conclusion, noting that the team's actions were the responsible and ethical thing to do. And state and federal officials continued to work with them on ways to study COVID in the area.

In March 2020, the flu study group teamed up with the public health agency in King County, where Seattle is located, to create the Seattle Coronavirus Assessment Network, or SCAN. The pioneering system they had set up for gathering and processing flu samples and informing people of their results would be put to a new use: testing as many people for COVID as they could, mapping the results, and adding to the world's collection of genetic sequencing for this brand-new pathogen.

SCAN's efforts got a huge lift from another group of local researchers. Working with some scientists at the Gates Foundation, this group persuaded government regulators that wiping a swab in the tip of a person's nose produced results that were just as good as the brain-tickling jab that other COVID tests required. That was a major advance, because it let people swab themselves, while the previous approach had to be handled by a health care worker. It was also much less uncomfortable, removing a barrier that had kept some people from getting tested. The old way inevitably made the test subject cough, which raised the odds of exposure for whoever was administering it, and the world was in the unprecedented situation of running out of the longer swabs.

From March to May, things ran as smoothly as could be expected during a pandemic. The SCAN team collected samples from volunteers, told them whether they had COVID, started building a map of cases, and made sure the positive samples were sequenced. During that time,

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SCAN accounted for as much as a quarter of all testing in King County, and its maps helped local officials understand where the disease was most prevalent.

Then, in May, the federal government suddenly ordered them to stop. The team had run up against another problem: whether they were allowed to test samples that people had collected on their own (rather than by a health care worker). Up to that point, the federal government's rules regarding who could test self-collected samples had been murky. When they did clarify the rules, it was bad news for SCAN: They needed federal approval for their test. The team immediately started scrambling to find another way forward.

Then, two weeks later, the FDA changed its policy again. Researchers could test samples gathered by participants as long as they had approval from the review board overseeing the work. SCAN got the okay from theirs, and on June 10, the program took up testing again.

Over the rest of that year, the team toted up several accomplishments. They processed almost 46,000 COVID tests, nearly all of them from people who had enrolled online from home (as opposed to the kiosks in public places, which had largely shut down). They sequenced nearly 4,000 COVID genomes, more than half of all the sequences in Washington state that year, and they advised teams who were setting up similar studies in Boston and the San Francisco Bay Area.

As I write this toward the end of 2021, SCAN is still running, and the Seattle Flu Study continues to gather data on influenza and two dozen other pathogens. Trevor Bedford, the researcher who had discovered the genetic similarities between the two COVID samples and figured out their importance, is widely recognized for his groundbreaking contributions to COVID science. His genomic family trees are used throughout the world, and he has become an

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excellent public communicator, breaking down complex matters of epidemiology and genome sciences for his hundreds of thousands of Twitter followers.

The U.S.—and, really, any country with a similarly patchwork system of testing and sequencing—needs to invest in many more projects that build on what we've learned in SCAN. One lesson is that we need to be setting up response systems well ahead of the next big outbreak, as the Seattle Flu Study and SCAN tried to do. Governments need to establish working relationships with infectious disease experts in the public and private sectors. Regulations need to allow the rapid approval of tests when a pathogen emerges that we've never seen before. America's world-class research institutions and its private diagnostics companies have incredible talent and capacity to help, but they should be able to get involved right away, without jumping through all the hoops that the SCAN team went through.

The countries that get this done will be well positioned in the next major outbreak. It is no accident that South Africa, a country that has spent decades investing in testing and sequencing for its fight against HIV and TB, was the first to identify at least two major COVID variants.

There are some innovations coming in genomic sequencing equipment that will help a lot. For example, Oxford Nanopore, a spinoff from Oxford University, has developed a portable gene sequencer that eliminates the need for a full laboratory. It does require an online computer with a powerful processor, but some researchers from Australia and Sri Lanka are working on solving that problem too: They created an app that allows the information from the sequencer to be processed offline, on a standard-issue smartphone. In one test, the app/sequencer combination was able to sequence COVID genomes from two patients in less than thirty minutes each. Oxford

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Nanopore is now working with the Africa CDC and other partners to deploy similar advances throughout the continent.9

Another lesson is that setting up a platform similar to SCAN or the Seattle Flu Study—that is, making the test, creating the website where people can sign up, processing their samples, etc.—is only part of the challenge. It is another matter altogether to make sure that the results reflect the actual makeup of the community. Not everyone can navigate a website easily. Language barriers can get in the way. When demand for test kits is high and supplies are limited, people who can stay at home repeatedly checking a website have an advantage over essential employees who still have to go to work. Bridging these gaps has been a challenge in Seattle, and anyone who's looking to do something similar should keep them in mind.

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If I had to make a list of jobs that are both super-important and super-obscure, I'd probably put "disease modeler" near the top of the list. Or I would have before 2020. Once COVID came along, people who had been toiling in obscurity for decades found themselves thrust into the limelight. Disease modelers traffic in predictions, and during a pandemic there are few things that news reporters love more than predictions.

If you can name a disease model and you're not a specialist, the one you know about is probably from either Imperial College London or the Institute for Health Metrics and Evaluation (IHME). But there actually are dozens and possibly hundreds more models being run by academics all over the world.

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What each one tries to do, in essence, is to analyze all the available data—the sources I've described in this chapter, and many others, such as mobile phone data and Google searches—for two purposes. One is to determine why something happened in the past, and the other is to make an educated guess about what might happen in the future. It was computer modeling that showed, early on, that even if only 0.2 percent of the population got infected with COVID, hospitals would be overflowing with patients in no time.

My chief experience with disease modeling comes from working with IHME. * For me, one of COVID's chief lessons about modeling is the extent to which every model relies on good data, and just how hard it can be to get that data. How many tests are being done? How many are positive? IHME had all sorts of trouble finding out. Some U.S. states didn't break down their cases by location or gender. Sometimes, reporting would pause over a holiday weekend, and then all the cases would get submitted on the first day people were back in the office, and the modelers would be left to estimate what had really happened.

I also couldn't help noticing how often news reports about some modeler's latest findings would leave out important nuances and caveats. In March 2020, Neil Ferguson, a highly respected epidemiologist at Imperial College, predicted more than 500,000 COVID deaths in the U.K. and more than 2 million in the United States over the course of the pandemic.[10] That caused quite a stir in the press, but few reporters mentioned a key point that Ferguson had been very clear about: His predictions assumed that people wouldn't change their behavior—that no

* Like people in any profession, modelers have their disputes and disagreements. IHME was criticized early in the pandemic for making forecasts that were too optimistic. But they listened to the feedback and improved their model, as any good scientific organization would.

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one would wear masks or shelter in place, for instance—but of course that wouldn't be the case in reality. He wanted to show how high the stakes were, not drive everyone into a panic.

The next time you hear about some prediction made by a disease modeler, keep a couple of things in mind. First, all models have limitations, and the report you're hearing might have left out some important caveats. The level of uncertainty, for example, can be quite high. Remember Mike Famulare's estimate of 570 cases in Washington state, with a 90 percent certainty that it was between 80 and 1,500? Any report that omitted the range of possibilities left out some pretty important context.

Second, every variant is different, and it's hard to predict the impact of each one until there are a few weeks of data available. Finally, modeling needs to be done with a healthy dose of modesty, especially if the forecast stretches beyond four weeks or so. Modelers are on the most solid ground with predictions about the impact of certain steps: "How many cases could be prevented if a certain percentage of the population gets vaccinated? What if they mask up instead?"

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What everything in this chapter adds up to, I believe, is a clear agenda for the kind of disease surveillance that we need in order to prevent pandemics.

One step is to invest in all the elements of a robust health system that make it possible to detect and report diseases, as well as treat them. That's especially true in low- and middle-income countries, whose health systems are often underfunded. If the doctors and epidemiologists don't have the tools and training they need, or their national health agency is weak or nonexistent, we're going to keep seeing outbreak after outbreak.

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Another step is to expand on efforts to understand causes of death in adults and children alike. This work will have a double benefit, giving us new insights into health and illness as well as yet another window into emerging threats.

Third, we need to know the enemy we're up against. So governments and funders should back innovative ways to test mass numbers of people in a short time—especially high-volume, low-cost tests designed to work in low- and middle-income countries. New tests should make it possible to link the results back to the patient, with privacy safeguards, so the data can inform both individual care and public health measures. Genetic sequencing needs to expand dramatically. And in a major outbreak, when tests may be in short supply, maps that chart the prevalence of the disease should inform who gets priority—so that tests go to the people with the highest odds of being infected.

Finally, we need to invest in the promise of computer modeling. The forecasts produced during COVID have been extremely helpful, but they can be better. More data, more accurate data, and constant feedback on their models will make all of us safer.

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Chapter 4

Help people protect themselves right away

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I'm confused about what to do when I meet someone these days. Should we bump fists, shake hands, or just smile and wave? Depending on the nature of our relationship, I might want a combined handshake-and-hug, particularly if we haven't seen each for months.

And then there's the risk of misreading the signals, when one of us wants one thing but the other person thinks we want something else. Maybe one of us is inclined to hug, but the other would rather stay six feet away. It was hard enough to figure out before the pandemic, and it's even trickier now.

Of course, navigating hellos and goodbyes is just one of the many ways that COVID complicated our social interactions. Should you stay home if you've been exposed? Who should wear a mask, and when? Is it okay to have a party, can it be indoors or outside, and how far apart do people need to stand? Should you wash your hands more often? What about large public gatherings and public transit—should they keep going? Can schools, offices, and retail businesses stay open?

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Although not all of these decisions are up to individuals, many of them are. And during a pandemic, when your options seem more limited than ever, making a choice can be empowering. Even if you're not in a position to help scientists find a cure or a vaccine, you can still choose to wear a mask, stay home if you're feeling sick, and postpone your big parties.

It is unfortunate that in some places, especially in the United States, people have resisted making choices that will keep them and their families safer. I don't agree with these choices, but I also think it's unhelpful to simply label them "anti-science," as so many people do. In her book *On Immunity,* Eula Biss looks at vaccine hesitancy in a way that I think also helps explain the resentment we're seeing toward other public health measures.[1]

The distrust of science is just one factor, she says, and it is compounded by other things that trigger fear and suspicion: pharmaceutical companies, big government, elites, the medical establishment, even male authority. For some people, invisible benefits that might materialize in the future are not enough to get them over the belief that someone is trying to pull the wool over their eyes. This all took place in a period of strong political polarization.

It didn't help that, when COVID first hit, there wasn't enough evidence to weigh the costs and benefits of different measures. It was especially hard to make the case for painful measures like closing businesses and schools. Many of these steps hadn't been widely used since the 1918 pandemic, and while the costs associated with them were predictable and immediately apparent to anyone who thought about it, the benefits—especially given that we were dealing with a new pathogen—were not.

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Red Cross volunteers in Boston, Massachusetts, assemble masks made from gauze to prevent the spread of influenza during the 1918 pandemic.

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Part of the problem is that it's quite difficult to assess the impact of many of these measures—which are broadly called "nonpharmaceutical interventions," or NPIs—in a controlled environment. Drug and vaccine trials are expensive and time-consuming (as I'll explain in later chapters), but they allow us to run experiments that test the effectiveness of drugs and vaccines. By contrast, no one's going to run an experiment that shuts down all the schools and businesses in a city just to measure the costs and benefits.

Now, after two years of studying NPIs in the real world, we know a great deal about their effectiveness. COVID gave us real-world learning that no experiment ever could. At almost every level of government—city, county, state, provincial, and federal—officials have looked at data to see what was working, and hundreds and possibly thousands of academic studies have documented the impact of various NPIs. These efforts have dramatically improved our understanding of the field. The variations in policies among similar cities or countries allowed researchers to isolate the impact of individual NPIs in ways that had never been possible before.

This is good news, because NPIs are our most important tool in the early days of an outbreak. Unlike the situation with vaccines and drugs, there's no lab time to study when to put mask mandates in place, figure out when to cancel big public events, or limit how many people can sit in a restaurant. (Though we will need to make sure that whatever NPIs we deploy are appropriate to the pathogen we're trying to stop.)

These interventions are what we use to flatten the curve—that is, to slow down transmission so that hospitals don't get overwhelmed with patients—without having to identify everyone who's infected. If you catch it soon enough, you can find almost all the people who are infected and test everyone they have come in contact with. That's crucial, especially since it is

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notoriously difficult to find people who are carrying the pathogen but aren't showing symptoms; NPIs help prevent them from spreading COVID just as well as people who are symptomatic

I don't mean to suggest that NPIs are a painless solution. While some, such as wearing masks, have few downsides for most people, others—like closing businesses and stopping big public gatherings—have a huge impact on the public, and implementing them is a massive undertaking. But we can do them right away, and we know how to do them better than we did before.

Let's go through some of the top insights from the past two years.

"If it looks like you're overreacting, you're probably doing the right thing."

That's a quote from Tony Fauci, and I agree. The irony of NPIs is that the better they work, the easier it is to criticize the people who adopted them. If a city or state adopts them early enough, the case numbers will stay low, and critics will find it easy to say they weren't necessary.

For example, in March 2020, officials in the city and county of St. Louis took several steps to limit transmission, including a shelter-in-place order. As a result, the initial outbreak in St. Louis was not as severe as it was in many other U.S. cities, leading some to suggest that the policies were an overreaction. But one study found that if the government had implemented the very same interventions just two weeks later, the number of deaths would have shot up sixfold. St. Louis would have been on par with some of the hardest hit areas in the country.

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<~?~NO CAPTION FOR THIS ILLUSTRATION (Illustration describing the paradox of NPIs—when implemented measures work, fewer cases occur, which leads people to think the measures weren't necessary in the first place.)>

Nor was that the first time that St. Louis had led the way: Virtually the same thing had happened a century earlier. Shortly after detecting its first flu cases during the 1918 pandemic, St. Louis closed schools, banned large public gatherings, and put social distancing measures in place. Philadelphia, on the other hand, waited to do these things. For two weeks after its first case, it allowed large public gatherings, including a citywide parade.

As a result, Philadelphia's death rate was more than eight times higher than St. Louis's. Later, studies found that the pattern held across the country: Cities that put multiple measures in place, and did it early, had death rates that were half that of cities that had waited.

Compare countries instead of cities, and you'll get similar results. During the first wave of COVID, Denmark and Norway implemented strict lockdowns early on (when fewer than thirty people in the two countries had been hospitalized), while the government of neighboring Sweden relied more on recommendations than requirements, keeping restaurants, bars, and gyms open and only encouraging but not requiring physical distancing. One study found that if Sweden's neighbors had followed its lead instead of locking down stringently, Denmark would have had three times as many deaths as it did during the first wave, and Norway nine times as many as it did.[2] Another study estimated that NPIs in six large countries, including the United States, prevented nearly half a billion COVID infections in the first few months of 2020 alone.[3]

Not only should you appear to overreact at first, as Tony Fauci said, but you also have to be careful about relaxing NPIs too soon. When the most effective public measures are relaxed—such as restrictions on large gatherings—case numbers tend to go back up (all other things being equal). The problem with relaxing these measures early is that you end up with large numbers of people who are what experts call "immune-naïve"—since relatively few people have been

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infected, there's not much immunity, and so lots of people are susceptible to infection. That's why, just as it's important to keep taking antibiotics for a bacterial disease even when you start feeling better, in some cases we need to keep NPIs going until we get medical tools such as vaccines, drugs to treat the disease, or even drugs that could protect you from infection. (That's known as prophylaxis, and we didn't have it for COVID.) , Or at least until we're able to reduce transmission dramatically by testing lots of people and isolating the positive or suspected cases, as South Korea did.

Also, not all overreactions—or apparent overreactions—are created equal. Closing borders, for example, did slow the spread of COVID in some regions. But border closures are a hammer that needs to be wielded very carefully. By cutting off trade and tourism, they can crater a country's economy so badly that the cure becomes worse than the disease. This is particularly true if, as is often the case, the border controls come too late to significantly reduce the amount of disease getting across borders.

The cost/benefit analysis of targeted lockdowns within a country may be more clearly beneficial. [stat TK]

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Economies under lockdown. Shutting down local businesses, tourism, and trade hammered economies globally in 2020, but getting the virus under control has allowed many of them to bounce back in 2021. (World Economic Outlook 2021)

The cost of not locking down—at least at the height of the COVID pandemic—likely would have been even higher. The economy was bad when businesses shut down, but it could have been even worse if the virus were allowed to run rampant and kill millions more people

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than it already has. By saving lives, lockdowns can make it possible to start the economic recovery sooner.

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<~?~NO CAPTION FOR THIS ILLUSTRATION (Illustration suggesting the cost to economies of locking down at the beginning of a pandemic is far lower than the cost they will encounter if they don't lock down.)>

Long-term school closures might not be necessary in the future.

In the COVID era, if there's one issue that is debated almost as much as vaccines, it's whether to close schools. This is a bit perverse: There are good arguments on both sides of the school question, and good arguments on only one side of the vaccine question.* By all rights, we should spend way more time discussing what to do about schools than what to do with vaccines. Like many public debates, though, there are nuances to the school-closing question that don't get enough attention.

Between March 2020 and June 2021, virtually every country in the world closed schools because of COVID. The peak came in April 2020, when almost 95 percent of the world's schools had shut their doors. By June of the next year, all but 10 percent had reopened at least partially.4

The arguments in favor of closing schools are compelling. Teachers and staff aren't paid to risk their lives, which is exactly what the older ones are doing if they're required to teach in person without a vaccine during a pandemic. And schools, with their constant interactions among

* Just to be clear, I mean the pro-vaccine side.

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kids, are already known as breeding grounds for the common cold and the flu—why would they be any different for another pathogen?

On the other hand, when schools closed, students fell behind in their learning, and the achievement gap grew even bigger than it already was. The United Nations estimates that COVID robbed students of so much time with their teachers that 100 million of them have fallen below the minimum threshold for basic skills, and it will take years of remedial work to help them catch up.5 In the United States, Black and Latino third graders have fallen twice as far behind their classwork as white and Asian American students have. And third graders from high-poverty schools have lost three times more learning than their peers in wealthier schools.6

The pandemic also exposed one of the biggest myths about remote education—that it could ever replace classroom work for kids in the early grades. I'm a big fan of online learning, but I have always thought of it as a supplement to, not a substitute for, the work that young students and teachers do together in person. (In the United States, we mostly use the terms "remote learning" and "online learning" interchangeably, but many other countries provided lessons over the radio, television, and e-books as well as online.)

Few teachers have been trained to develop remote lessons, though this will change over time, as online toolkits and curricula improve. There are still many people who don't have Internet access—in South Asia, more than a third of the students forced to stay home were unable to do remote learning—and many of those who do have access found the experience less than engaging. In short, online learning was put to a test that it was never designed to pass. I'm still optimistic about its future when used appropriately, though, and will have much more to say about it in the Afterword.

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When schools close, the losses ripple out far beyond academic learning. Parents have to scramble for child care when their kids are suddenly at home during working hours. Millions of students in the United States and around the world rely on free and reduced-price meals provided at school. In school, kids learn how to interact with their peers, get exercise, and have access to mental health support.

Unfortunately, the debate over closing schools has been muddied by some initial data that turned out to be misleading. Early on, there were fewer COVID cases among children, leading many people (including me) to conclude that kids weren't susceptible to infection, or at least not as susceptible as adults are. That was an argument, I thought, for keeping schools open.

But it wasn't true. In the United States through March 2021, the rates of infection and illness in children were comparable to the rates in adults ages eighteen to forty-nine, and even higher than the rates in adults ages fifty and older.7 The initial view was probably affected by the fact that many schools were closed; there were fewer cases among children because kids weren't gathering at schools. They weren't less susceptible, they just had fewer opportunities to get infected. And when they did get infected, they were much less likely to show symptoms or get sick enough for their parents to get them tested—a problem that would have been rectified by large-scale testing.

Even with that in mind, what I think this all adds up to is that long-term school closures should not be necessary, especially if the world meets the goal of producing enough vaccines for everyone within six months. Once vaccines are available, teachers should be near the front of the line for them (as many were when COVID vaccines first came out). You will probably want to distinguish between younger teachers who don't live with older people and teachers who are older teachers or who do live with old people. (Remember that the age-related risks go down a

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lot for people under age fifty.) And in the meantime, many schools will be able to stay open while using various prevention strategies, including masks, distancing, and better ventilation. One study found that reopening schools in Germany did not cause cases to go up, but reopening them in the U.S. did.[8] The authors hypothesized that Germany's mitigation measures were more effective than America's.

I want to add a caveat to the idea that long-term school closures shouldn't be necessary. That will be true if the next outbreak is one with a profile like COVID's—in particular, one that rarely makes kids severely ill. But we have to be careful not to get caught fighting the last war. If a future pathogen is markedly different from COVID—for instance, if its impact on children is a lot worse—then the risk/benefit calculus could change, and closing schools might be prudent. We'll need to stay flexible and, as always, follow the data.

On the other hand, it is clear to me that locking down assisted living homes for older people was the right thing to do. It saved a lot of lives because the virus is so much deadlier for the elderly—and I say this knowing how deeply painful these lockdowns were for all the residents who were confined to their rooms, and to their loved ones. It was heartbreaking to hear stories about families who had to say goodbye to a dying parent or grandparent through a closed window or over the phone. My dad died of Alzheimer's disease in September 2020, and I feel very lucky that he was able to be at home, surrounded by family, in his last days.

The human suffering caused by these separations is incalculable, literally—we can't put a number on the pain of not being able to say goodbye in person. But the policy saved so many lives that it would be worth adopting again if the circumstances called for it.

What works in one place might not work in another.

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No matter where you are in the world, a mask is going to give you the same protection. Unfortunately, many other NPIs aren't so universal. Their effectiveness depends a lot not only on when they're used, but on where they're used too.

Lockdowns are a great example. The evidence is clear that they reduce transmission, and that stricter lockdowns reduce transmission more. But they're not equally effective everywhere, because not everyone is able to comply by staying in one place.

The difference is actually quantifiable. One ingenious study9 used anonymous cell phone data from throughout the United States to gauge the extent to which people living in different neighborhoods stayed at home. (Your cell phone checks in periodically with a service that establishes its location.)

Between January and March 2020, people who live in America's wealthiest neighborhoods were the most mobile—that is, they spent the most time out of their homes—and people in the lowest-income neighborhoods were the least mobile.

But in March, as lockdowns kicked in across the country, the situation swung upside-down. People in wealthy neighborhoods became the least mobile, and people in the poorest ones were the most mobile. The reason: They were much more likely to have jobs outside the home, and much less able to use delivery services for groceries.

A similar shift was driven by population density. Before lockdowns, the densest communities had the highest transmission rates. After lockdowns, they had the lowest transmission rates, and the less-crowded areas had not dropped nearly as much. That makes sense, of course, because when people aren't living and working in close quarters to begin with, telling them to stay home will naturally have less of an impact on transmission.

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Researchers have drawn other conclusions about the differences among and within countries. Contact tracing is more effective in places with a good system for reporting and processing the data about each person's contacts, though once the case numbers get high, it becomes much harder. Social distancing and lockdowns work better in richer countries than in poorer ones, for many of the same reasons as the disparity within the U.S. that I just described. In some countries, lockdowns can backfire, as the disease is spread by people who migrate (returning to their home community from a job in the city, for example). Lockdowns may not be necessary in places where the disease burden is modest. They're also more effective in countries where residents have less of a voice in the country's affairs, and the government is in a position to strictly enforce lockdowns and other mandates.

What this all means is that there is no single ideal mix of NPIs that works equally well everywhere. Context matters, and protective measures need to be tailored for the places where they'll be used.

The flu almost went away, at least for a while.

In the fall of 2020, as we got closer to flu season, I started to worry. Every year, influenza kills tens of thousands of Americans[10] and hundreds of thousands of people around the world, nearly all of them elderly.* Even more are hospitalized. At a time when COVID was overwhelming or

* The estimates of how many people get sick and how many die from the flu every year vary widely. Deaths in particular are probably undercounted, because not all flu deaths get reported to infectious disease center like the CDC, and because flulike symptoms might not be reported on a death certificate.

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at least sorely testing virtually every health system on the planet, a bad flu season could have been disastrous.

But there was not a bad flu season. In fact, there was hardly any flu season at all. Between the flu seasons of 2019–20 and 2020–21, cases dropped 99 percent. As I write this, in October 2021, one particular type of flu known as B/Yamagata has not been detected anywhere in the world since March 2020. Other respiratory viruses also dropped by quite a bit.

By the time you read this book, of course, many flu strains will be returning to their normal level. Flu strains have a way of disappearing for long periods and then suddenly recurring without explanation. But the huge decline in cases across the board is unmistakable, however long it lasts, and there is only one plausible explanation: Nonpharmaceutical interventions made a dramatic difference in reducing flu transmission when combined with the prior immunity and vaccinations that people had.

This is great news, and not only because it means we did not have a disastrous twindemic of flu and COVID in 2020–21. It's also reason to be hopeful that if there's an outbreak of a bad flu in the future, NPIs can help keep it from turning into a pandemic. While it's possible that we'll see an influenza so transmissible that it overwhelms our best efforts to contain it without a vaccine, it is reassuring to have more evidence that NPIs are effective against the common strains we know about today. And we now have solid evidence that, when paired with vaccines, NPIs could help us eventually eradicate every strain of flu, and every strain of coronavirus too.

We should use contact tracing to find superspreaders.

Depending on which country you live in, if you tested positive for the COVID virus, you may have been visited by someone asking about all the people you might have come into contact

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with. They probably focused specifically on the forty-eight hours before you first started feeling sick (if you did feel sick). This is the process known as contact tracing.

Although it felt new to many people around the world during COVID, contact tracing is actually an old strategy. It was essential to eradicating smallpox in the twentieth century and is also at the center of strategies to fight Ebola, tuberculosis, and HIV in the twenty-first.

Contact tracing works best in countries that excel at testing and processing data—among them, South Korea and Vietnam. But both of those countries did things that wouldn't fly in the United States. Under a law passed after the 2014 outbreak of Middle East Respiratory Syndrome, or MERS , the South Korean government used data from credit cards, mobile phones, and surveillance cameras to trace the movements of an infected person and identify people they had contact with. It published this information online, though it had to restrict some of the data after regional governments gave out too many details about people's movements. According to the journal *Nature,* one man "was wrongly accused of having an affair with his sister-in-law because their overlapping maps revealed they dined together at a restaurant."[11]

Vietnam also used posts on Facebook and Instagram, along with mobile phone location data, to supplement extensive face-to-face interviews. In March 2020, before the country was testing every passenger arriving from the U.K., a flight from London arrived in Hanoi with 217 passengers and crew.[12] Three days later, a patient went to the hospital with symptoms and tested positive for COVID. Vietnamese authorities tracked down all 217 people from the flight and identified 16 more cases among them. Everyone on the plane and more than 1,300 of their contacts were quarantined. In all, there were 22 cases related to the flight, a small fraction of the cases that would've happened if all those passengers and crew members had simply gone on their way.

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If you read the previous two paragraphs and thought, *if anyone calls me about contact tracing, I'm not picking up the phone,* you're not alone. In two counties in North Carolina, between a third and half of COVID-infected people who were reached claimed not to have had contact with a single person in the two days before they tested positive. And many of the contacts who were named never returned the tracer's phone call.13 But contact tracing is always going to be an important part of stopping the spread of a disease, so we have to figure out how to get people to share their contacts.

One of the reasons people hesitate to respond is the fear that their contacts will have to go into quarantine, but fortunately, broad quarantines of every single contact might not always be necessary. In England, some schools had their students stay home for ten days if they had come into contact with someone who had COVID. Other schools allowed the kids to keep attending school, as long as they tested negative every day. This daily testing, it turns out, was just as good at preventing outbreaks, but without having to keep students home from school.14

And contact tracing can still be effective even if it's not done as intensively as Vietnam and South Korea did. In general, if you start the program when only a small fraction of the population is infected, and if you identify a large share of cases in your country, contact tracing can cut transmission by more than half.15 And smartphone apps like the ones deployed by many states in the U.S. and around the world can help identify possible contacts while still protecting people's privacy.

One problem was that, with COVID, conventional contact tracing isn't an especially efficient use of resources, because the virus is not transmitted at the same rate by everyone who's infected. If you get the original COVID strain, the chances are not especially high that you'll pass it along to someone else. (About 70 percent of those cases may not transmit to anyone else

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at all.)[16] But if you *do* pass it along to someone else, you probably pass it along to many people. For reasons we don't entirely understand, 80 percent of COVID infections with early variants came from just 10 percent of the cases.[17](These numbers could be different for the omicron variant—as I write this, we don't have enough data to know.)

So with a virus like COVID, using the conventional approach means you'll spend a lot of time finding people who wouldn't have infected anyone else—epidemiologically speaking, you'll find yourself in a lot of cul-de-sacs. What you really want to do is find the main thoroughfares, the relatively small number of people who are causing the most infections.

Understanding this limitation, a few countries tried a newer approach to contact tracing.[18] Instead of working forward in order to find out whom they might have infected, these countries worked backward—identifying contacts up to fourteen days before the person started feeling sick. The goal was to find out who infected the patient, and then see who else that person may have passed the virus to.

Backward contact tracing is hard to pull off unless you have widespread testing, fast results, and a system for contacting people quickly. But where it was practical—like in places where people could use smartphone apps to notify them if they'd been exposed—the approach worked really well. It was used at locations in Japan, Australia, and other countries, and it proved quite effective at finding individuals who were superspreading the early COVID variants. One study found that it could prevent two to three times more cases than the traditional approach.[19]

Good ventilation matters more than you might think.

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Remember the advice early on to wash your hands a lot and to avoid touching your face? Or the way cashiers would clean a pen each time someone used it to sign a credit card receipt? Or how you'd feel safe if you stood far enough away from someone you were talking to?

It is a good idea to wash your hands, clean pens, and keep your distance: They're generally good health practices, and they help keep other pathogens like the flu and the cold at bay. And it's clear that soap and disinfectants do break down the COVID virus, rendering it harmless.

But after two years of COVID, scientists know a lot more than they did in early 2020 about how this particular virus spreads. One finding stands out: The virus can linger in the air longer and travel farther than most people thought in early 2020.

You may have heard some of the anecdotal evidence. In Sydney, Australia, an eighteen-year-old man singing in a church loft passed the virus to twelve others who were sitting fifty feet away.[20] At a restaurant in Guangzhou, China, a single person infected nine others, including some who were sitting at the same table but also some who were seated at tables several feet away.[21] In Christchurch, New Zealand, someone staying in a quarantine hotel picked up the virus through an open door nearly one minute after an infected person had walked past.[22]

None of this is speculation. Researchers looking at these cases have rigorously ruled out all the other ways the infection could have spread. One group of scientists who studied the Guangzhou incident used video footage to count thousands of times that waiters and customers in the restaurant touched the same surfaces; the number wasn't nearly high enough to explain all the cases. The case in New Zealand is supported by genetic analysis: By studying the genomes of the virus in both infected people, scientists determined that the second patient could only have gotten it from the person who walked past their room.

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The good news is that COVID's airborne proclivities could be a lot worse. It appears that the virus is able to stay in the air for several seconds, and perhaps up to a minute. The virus that causes measles, on the other hand, can stay in the air for hours.

To understand why viruses get transmitted through the air, we need to talk about your breath.

Whenever you talk, laugh, cough, sing, or simply breathe out, you exhale. We tend to think of the stuff we're exhaling as air, but it contains a lot more than air. Your breath is filled with tiny globs of liquid, a mix of mucus, saliva, and other secretions from your respiratory tract.

These globs are grouped into two categories by size: The larger ones are known as droplets, and the smaller ones are called aerosols. The dividing line between them is typically 5 micrometers, which is roughly the size of the average bacterium. Anything bigger than that is a droplet, and anything smaller is an aerosol.

Droplets, being on the larger side, typically contain more virus than an aerosol, which makes them a better mechanism for transmission. On the other hand, because they're relatively heavy, they don't make it more than a few feet from your mouth or nose before falling to the ground.

The surface that a droplet lands on becomes what's called a fomite, and how long the fomite is able to transmit the virus depends on several factors, including the type of pathogen and whether you sneezed or coughed it out (in which case it's more protected because it's covered in your mucus). Studies of COVID's ability to survive on fomites show a wide range of results, from an hour or two to a few days. There are undoubtedly some instances in which people picked up the virus by touching an infected surface, but they are certainly a small fraction of all cases.

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Once it was known that COVID spread mainly through the air, most experts thought it did so via droplets. This would have meant that anyone more than a few feet away, or sharing the same air space just a few seconds later, would've been safe. But further research showed that aerosols also contribute significantly to transmission. They're capable of containing quite a bit of virus, and because they weigh much less, they can travel farther and linger in the air longer than droplets. And for a time, at least, the virus was evolving to spread even more via aerosols—people with the Alpha variant exhale about eighteen times more virus in aerosols than people with the original virus do.[23]

Part of the reason aerosols were underestimated is that, because they're so small, they usually dry out quickly, which makes the virus particle inactive. One study used a computer simulation to show that COVID viruses—particularly the delta and omicron variants—have an electrical charge that attracts substances from the lungs that slow down the process of drying out aerosols.[24] We need to study transmission dynamics a lot more so that next time we understand quickly how transmission is taking place.

Depending on the conditions in the room—temperature, airflow, humidity, and so on—aerosols may stay in the air for as long as a minute, and they can travel several feet. It's not clear yet what share of cases is caused by aerosol transmission, but it could be more than half.

What does this all add up to? Airflow and ventilation matter, probably quite a bit. You should install high-quality air filters to remove aerosols if you can, and if that's not possible, there's also a simpler and cheaper option: opening the windows. In a study done in Georgia, schools that opened doors or windows and used fans to dilute airborne particles had 30 percent fewer COVID cases than those that didn't. Schools that also installed air filters had 50 percent fewer cases.

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It's good to wash your hands and wipe down surfaces, and in a future outbreak that might be your first choice for staying safe. But when it comes to preventing COVID, if you have to choose between spending time and money on cleaning things or improving airflow, improve the airflow.

Social distancing works, but there's nothing magical about six feet.

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<~?~NO CAPTION FOR THIS ILLUSTRATION (Illustration showing how confusing social distancing can be. This example suggests a distance of 28 tennis balls between people.)>

By now, I've lost count of how many signs I've seen reminding me to stay six feet away from others. My favorite is the one at the club where I play tennis, which hilariously explains that six feet is the width of twenty-eight tennis balls. Who on earth is so tennis-oriented that they understand twenty-eight tennis ball widths better than they understand six feet? If you get too close, do they say, "Hey, you're only nineteen tennis balls away, please step back nine more?" I guess that if such people exist, you'll find them at a tennis court. But I play a lot of tennis and I have no clue what twenty-eight tennis balls looks like.

In any event, there's nothing magical about the six-foot rule (or the twenty-eight-tennis-balls rule). The WHO and many other countries recommend distancing of 1 meter, or about 3 feet. Others recommend 1.5 to 2 meters, which is around 6½ feet.

In truth, there is not some stark cutoff where you're at high risk of getting COVID within a certain distance and zero risk beyond that distance. There's a continuum of risk, and it depends on the specific situation you're in: how big the droplets you're exposed to are, whether you're

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inside or outside, and so on. Six feet is better than shorter distances, but we don't know just how much better. Before the next pandemic, scientists need to dig into this question and help us understand the role of ventilation and air movement so we can get a clearer answer.

In the meantime, the six-foot rule is a good one to follow, unless it's very difficult to maintain, such as in a classroom`. People need clear, easily remembered guidelines. It is not a helpful public health message to say, "Keep your distance, but the exact distance depends on the situation, so it might be three feet, or six feet, or maybe more."

It's mind-blowing how cheap and effective masks are.

This is a little hard to admit, because my worldview is centered on solving problems by inventing new things. But it's true: We may never devise a cheaper, more effective way to block the transmission of certain respiratory viruses than a cheap piece of cloth with a couple of elastic straps sewn onto it.

The idea of controlling a disease by promoting the widespread use of masks is both simple and old. It dates from 1910, when Chinese authorities called on a pioneering physician named Wu Lien-teh to lead the response to an outbreak of plague in the region then known as Manchuria, in the northeast part of the country.25 The plague had a fatality rate of 100 percent—every single infected person died, sometimes within twenty-four hours—and was thought to be spread by infected fleas that lived on rats.

Wu believed that it was airborne, not rodent-borne, and he insisted that medical staff, patients, and even members of the general public cover their faces with masks. He was partly right—you can get the infection from a flea carried by rats, but the more dangerous situation is when people have plague in their lungs and then transmit it through the air to other humans. .

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Although 60,000 people died before the outbreak had run its course, the consensus was that Wu's strategy had prevented it from being much worse. He was celebrated as a national hero, and thanks in large part to his leadership, masks became a common sight—as protection against disease, air pollution, or both—throughout China. Even if COVID had not happened, they would still be part of the region's social fabric today.

Just as Chinese experts were initially mistaken about how the 1910 plague was transmitted, much of the scientific community in the West was initially wrong about how COVID spread. ("The big mistake in the U.S. and Europe," the head of the Chinese CDC said in March 2020, "is that people aren't wearing masks.")

For many people who were following the research—people in the West, at least—the case in favor of masks was sealed by an incident involving two hairstylists in Springfield, Missouri.[26]

Both stylists developed symptoms and tested positive for COVID in May 2020. Their records indicated that they had exposed 139 clients. But everyone had masked up during the haircuts, and not a single client developed symptoms.

Was that because the stylists weren't transmitting the virus? No. One of them had four close contacts outside the salon—when the stylist wasn't wearing a mask—who developed symptoms and tested positive. That settled the question. Like a good set of barber shears, masks were cutting transmission.

The Springfield incident shows how masks can actually serve two purposes: to prevent an infected person from spreading the disease, and to protect an uninfected person from getting it. The first is called source control, and the beauty of it is that almost any mask of any type is good at source control, at least for certain diseases. Even a cotton T-shirt over your nose and mouth

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will stop a large majority of the droplets that are a chief source of transmission for COVID and other coronaviruses.

Whereas just about any material covering your mask will do a pretty good job of source control, protecting yourself from someone else's germs is a whole other matter. Any mask will give you some security, but the level of protection you get depends greatly on the material and the way the mask fits your face. This is because now you want to capture both the larger droplets, which are short-lived, and the smaller aerosols, which can linger longer and travel farther.

(By the way, some of the experiments used to test this kind of thing are wonderfully creative. One research team[27] padded the inside of mannequin's head to simulate the nasal cavities of a human skull, set it at a height of 5 feet 8 inches—near the global median height for men—and hooked it up to a smoke machine and a pump. Then they measured how far the droplets traveled when the mannequin coughed in various scenarios: with its mouth uncovered, with its mouth covered by a bandana made from a T-shirt, with a folded handkerchief, and finally with a stitched mask. Another group of researchers set two mannequins next to each other, simulated a cough from one of them, and then measured how many particles made it from the cougher to coughee.)[28]

As long as your mask fits snugly, then a decent rule of thumb is that the denser the material, the more filtration you get. A mask cut from a T-shirt provides substantial protection, but not as much as a surgical one, and the surgical one doesn't protect you as much as an N95. A few numbers from one study that looked at the effectiveness of different masks:[29] If two people are talking to each other at a distance of six feet, and if one of them is infected with COVID, the odds that the other will be infected within a few minutes are as high as 90 percent. If they both

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wear surgical masks, the odds drop to 30 percent or less. And if they both wear N95s or KN95s, the odds drop to 0.4 percent or less.

(In case you're wondering, the 95 indicates that, in testing, the mask's material blocked 95 percent of very small particles blown with enough force to simulate a human doing hard work. On an N mask, the elastic straps go around the back of your head, while the straps on a KN mask go around your ears.)*

Of course, every chain is only as strong as its weakest link, and masks can only stem an outbreak if enough people wear them. In America, unfortunately, resistance to wearing masks is almost as old as masks themselves.

During the 1918 flu epidemic, just a few years after Wu's breakthrough finding, several U.S. cities adopted mask mandates. In San Francisco, anyone who failed to wear a mask in public could be fined or put in jail.30 Protests broke out across the city. In October 1918, a "mask slacker" beat a health inspector with a bag of silver dollars for insisting that he cover up. The health inspector pulled out a pistol and shot him.†

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* Masks like the N95 and KN95 are, confusingly, also referred to as "respirators." I'll just call them masks, to avoid confusion with the machines that help patients breathe.

† Both men survived. According to the *The New York Times,* the shooter "was charged with disturbing the peace, resisting an officer and assault. The inspector was charged with assault with a deadly weapon."

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It is unfortunate that Americans have not grown more accepting of masks in the intervening century. The protests were at least as vocal and occasionally violent in 2020 as they were in 1918.

Missing the value of masks is indeed, as the head of China's CDC said, one of the biggest mistakes made during the pandemic. If everyone had masked up early on—and if the world had had enough supplies to meet the demand—it would have blunted the spread of COVID dramatically. As a public health expert from the Gates Foundation told me over dinner one night, "*How to Prevent the Next Pandemic* would be a very short book if everyone would just wear masks."

The benefit of masks has been proven around the world. In Bangladesh, for example, researchers ran a study involving nearly 350,000 adults in 600 villages.[31] One group, about half of the people, were given free masks (some cloth, some surgical), information on the importance of using them, in-person reminders, and encouragement from religious and political leaders. The second group didn't get any of those things. After two months, proper mask use in the first group was up 42 percent, versus just 13 percent in the second group. People in the first group also had a lower COVID infection rate, and even five months later, they were still more likely to be using masks.

It'll be interesting to see whether the social standards on wearing masks change much as a result of COVID. In March 2020, I went to an in-person meeting while I was feeling under the weather. Because the CDC hadn't recommended masks yet, I didn't wear one. Luckily, I later found out that I'd had the flu and not COVID, but I feel bad that I was there with respiratory symptoms without taking a measure that might have reduced the chance of spread. Knowing what I know now, I would either join that meeting virtually, or I'd wear a mask.

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But will that catch on more widely? It's hard to say. My guess is that most Americans will eventually go back to attending meetings and big sporting events without masks. So we'll need to get the word out about masking up if you're experiencing respiratory symptoms, and we'll need the public warning systems to kick into high gear as soon as there's a sign of a problem. It could be the difference between an outbreak and a pandemic.

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Chapter 5

Find new treatments fast

Early on, rumors and misinformation about COVID seemed to be spreading faster than the disease itself. In February 2020, a month before it had declared COVID a pandemic, the WHO was already contending with false claims about various substances that supposedly cured or prevented the disease. Its director-general said, "We're not just fighting an epidemic; we're fighting an infodemic,"[1] and its website began featuring a myth-busting section that had to be constantly updated to debunk false claims.

In just the first half of 2020 alone, doctors had to shoot down false rumors that COVID could be cured by:[2]

- Black pepper
- Antibiotics (COVID is caused by a virus, and antibiotics don't affect viruses)
- Vitamin and mineral supplements
- Hydroxychloroquine
- Vodka
- Sweet wormwood

Although none of these substances has any effect on COVID, I can see why people would want to believe otherwise. Some of them are legitimate medical interventions:

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Hydroxychloroquine is used to treat malaria, lupus, and other diseases, and ivermectin—which had a moment in the spotlight in 2021—is a standard treatment for various parasitic diseases in people and other animals. Obviously, just because a drug treats one condition doesn't mean it will work on COVID, but it's not irrational to hope that it might.

I can even see why people might be drawn even to purported cures that are closer to a folk remedy than to modern medicine. At a time when a frightening new disease is making its way around the world, and our phones are sending us the latest scary stories about it by the day or even by the hour, it's natural to look for immediate help anywhere you can find it. Especially when there's no scientifically proven cure to fill the need for a treatment, and when the alternative being proposed is already in your bathroom cabinet or under your kitchen sink.

There is nothing new, of course, about people clinging to the false hope of an easy cure. Humans probably started doing it as soon as they were aware enough of their own mortality to look for ways to fend it off. But medical misinformation is more dangerous now than ever, because it can travel faster and farther than ever, with tragic consequences for many of the people who believe it.

I don't have a complete solution to this problem. But I do think there would have been fewer wrong ideas going around about COVID if science had found an actual treatment sooner—something that everyone could point to as a legitimate therapeutic—and if it had become widely available around the world.

Early on in COVID, that's what I thought would happen. I was confident that a vaccine would be developed eventually, but I expected that a treatment would come along well before that point. I wasn't alone: Most people I know in the public health community felt the same way.

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Unfortunately, that's not what happened. Safe, effective COVID vaccines were available within the year—a historic feat that will get its due in the next chapter—but treatments that could keep large numbers of people out of the hospital were surprisingly slow out of the gate.

It wasn't for lack of trying. Doctors began prescribing a drug called hydroxychloroquine off-label—that is, for something other than its approved purpose—almost from Day 1. Early reports suggested that it could be effective against COVID, and the FDA gave the provisional green light known as emergency-use authorization.

The early evidence for hydroxychloroquine came from lab studies of its effect on cells taken from the kidneys of the African green monkey. These cells are often used to screen potential antiviral drugs because viruses replicate very quickly in them, and in fact the method did surface some promising treatments, including the antiviral drug remdesivir.

In early studies, hydroxychloroquine was able to block one pathway by which the COVID virus entered the monkey cells, suggesting that it might do the same in humans. Hundreds of clinical studies tried to replicate these promising results,[3] but in early June a definitive randomized study in the U.K. found that the drug provided no benefit for patients who'd been hospitalized with COVID. Ten days later, the FDA revoked the emergency-use authorization, and two days after that the WHO dropped hydroxychloroquine from a trial it was running.

The problem, it turns out, was that human cells have a different pathway from the one that the drug blocked in monkey cells—so the promising results didn't translate from animals to people. As far as treating COVID goes, the drug was a dead end. Meanwhile, the hydroxychloroquine craze caused a run on the drug, and many patients who needed it to treat lupus and other chronic conditions couldn't get it.

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By that summer, dexamethasone had become the primary treatment for severe COVID, having been found to reduce mortality among hospitalized patients by up to a third.[4] Dexamethasone, a steroid that has been in use since the 1950s, works on COVID somewhat counterintuitively: by suppressing some of the immune system's defenses.

Why would you want to suppress your immune system? Because once you're past the early stages of infection, the biggest danger of COVID doesn't actually come from the virus, it comes from the immune system reaction that's triggered by the virus.

In most people, the immune system is able to reduce the amount of virus within five or six days of getting infected, but the it becomes so activated that it can cause a phenomenon known as a cytokine storm—a flood of signals to send massive amounts of fluids and blood to various organs, which in turn can cause organ failure and death. It's your body's overreaction to the invasion that makes you sick.

Dexamethasone was a significant success: It was effective, easy to deliver, cheaper than any of the alternatives, and widely available even in many developing countries. (In fact, even before COVID, the WHO deemed it an essential medicine for use in pregnant women.) Less than a month after it was shown to work well, a nonprofit called the African Medical Supplies Platform had acquired 9 million tablets that would be available free for every country in the African Union.[5] British researchers estimated that by March 2021, dexamethasone had saved as many as one million lives around the world.[6]

Even so, the drug does have its downsides—chiefly, that if used too early, it will mute your immune response at the very moment when it needs to be at full strength so it can stop the virus from replicating. When that happens, you become more susceptible to complications and

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opportunistic infections. The second wave of COVID in India was accompanied by a spike in cases of a gruesome and deadly disease called mucormycosis, also known as “black fungus”—some people had this fungus in their lungs, but it was held in check until their immune system was suppressed, unleashing it and causing the disease. In most countries, almost no one had this fungus, so the problem was mostly limited to India..

Hoping to find another existing drug that might help, researchers tried other potential treatments that were already at hand. Remdesivir, the antiviral that showed promise in monkey cells, was originally developed to fight off hepatitis C. There are also various ways to take antibodies from the blood of people who have recovered from a disease and give them directly to someone who’s still sick, an approach known as convalescent plasma. Unfortunately, neither convalescent plasma nor remdesivir was effective enough to warrant using them broadly for COVID.

There was, however, a different approach to giving people antibodies that held more promise. It’s called monoclonal antibodies, or mAbs for short, and it worked well enough to be approved for use in COVID cases in November 2020—only a month before the first vaccines became available.

Instead of preventing a virus from taking over healthy cells, or from reproducing once it does take over a cell—which is how most antiviral drugs work—mAbs are the same thing your immune system generates to mop up the virus. (Antibodies are a protein with variable regions that allow them to grab onto unique shapes on the surface of the virus.) To make mAbs, scientists either isolate a powerful antibody from a patient’s blood or use software modeling to come up with an antibody that grabs the virus. Then they clone it billions of times. (This cloning from a single antibody is why they’re called monoclonal.)

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If you're infected with COVID and get mAbs at the right time (and if they're adapted for the variant you have), they reduce the risk that you'll end up in the hospital by at least 70 percent.7 I had high hopes for mAbs in the early days of COVID—so much so that the Gates Foundation paid to have up to 3 million doses set aside for high-risk patients in poor countries. But we soon learned that mAbs weren't going to be a game changer for COVID: The Beta variant of the virus, which was especially prevalent in Africa, had changed its shape enough that the antibodies we had supported no longer grabbed onto it enough to help. We could have started over to develop another mAb that would have been effective for the new variant, but manufacturing them takes three to four months, which makes it hard to keep up with a virus that evolves as quickly as COVID does. In the future, there may be better ways of manufacturing mAbs that reduce this lead time, or ways to pick mAbs that grab onto a piece of the virus that is unlikely to change.

Other downsides became clear as wealthier countries tried to roll out mAbs treatments. COVID antibodies were expensive to make, they had to be administered at facilities capable of infusing them into your blood, and they helped only those patients who could be identified early in the course of the disease. The lack of infusion centers was a particularly big problem in developing countries. As of [XX date], mAbs are estimated to have saved [XX lives]—a significant number, but not the big breakthrough we had hoped for. Because of these problems, we wrote off our investment in mAbs and increased our focus on antiviral drugs—particularly the ones that patients could take orally rather than requiring an infusion..

As soon as COVID was identified, many researchers started looking for the holy grail of treatments: an antiviral drug that's cheap, easy to administer, effective for different variants, and

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capable of helping people before they get terribly sick. In late 2021, a few of these efforts paid off—not as soon as would have been ideal, but still in time to have a big impact..

Merck and its partners developed a new antiviral called molnupiravir, which could be taken orally and was shown to reduce the risk of hospitalization or death by 30 percent in certain cases. In fact, the drug worked well enough that the clinical trial was stopped early. (This is a common practice in trials—they'll wrap up early if it would be unethical to continue because there's definitive evidence either that the drug is a success, in which case the participants who aren't getting it are receiving clearly inferior treatment, or that the drug is a failure, in which the participants who are getting it are the ones receiving inferior treatment.)

Soon, the study of a second oral antiviral, Paxlovid (made by Pfizer), was stopped for even better reasons. When used in combination with another drug and administered soon after symptoms kicked in, it reduced the risk of severe illness or death by nearly 90 percent.8

By the time these announcements came out in late 2021, a large share of the world's population had received at least one dose of a vaccine. But that's no reason to think that therapeutics aren't important, in COVID or any other outbreak. In fact, it's a mistake to think of vaccines as the star of the show and therapeutics as the opening act you would just as soon skip.

Consider the time line. In the next epidemic, even if the world is able to develop a vaccine for a new pathogen in 100 days, it will still take a lot of time to get the vaccine to most of the population. This is especially true if you need two doses for full protection. . If the pathogen is especially transmissible and deadly, tens of thousands or more could die without a therapeutic drug.

And we'll still need good therapeutics even once there is a vaccine. As we've seen with COVID, not everyone who can take a vaccine will choose to do so. Unless the vaccine

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completely prevents breakthrough cases, some vaccinated people will still get sick. If a variant comes along that the vaccine doesn't protect you from, we'll want to have treatments on hand until the vaccine can be tweaked. And, along with nonpharmaceutical interventions, therapeutics can reduce the strain on hospitals, which would prevent the overcrowding that ultimately means that some patients die who otherwise wouldn't.

With good enough therapeutics, the risk of severe illness and death will drop dramatically, and countries can decide to loosen restrictions on schools and businesses, reducing the disruption to education and the economy.

All of which is to say: Therapeutics are fundamentally important in an outbreak. We're lucky that scientists made COVID vaccines as quickly as they did—if they hadn't, and considering the slow progress toward effective treatments in the first two years of the pandemic, the death toll from COVID would have been far worse.

To understand how we can avoid what happened with COVID, we need to take a tour through the world of therapeutics: what they are, how they get from the lab to the market, why they didn't fare better in this pandemic, and how innovation can set the stage for a better response in the future.

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We tend to think of medicines as mysterious and complex substances, but the most basic ones are remarkably simple—clusters of carbon, hydrogen, oxygen, and other elements that can be described using nothing more than high school chemistry. Just as water is H_20 and salt is NaCl, the formula for aspirin is $C_9H_8O_4$. Tylenol is $C_8H_9NO_2$. Because their mass is so tiny—one

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molecule of aspirin is just 180 times more massive than a single atom of hydrogen—they belong to a class of drugs known as small molecules.

Small-molecule drugs have several advantages that make them especially appealing in an outbreak. Because their chemical structure is so easy to describe, they're easier to manufacture, and thanks to their minuscule size, they don't get broken down by your digestive system, so you can take them as a pill. (This is why you've never had an injection of aspirin.) And most of them can be kept at room temperature and have a long shelf life.

Larger molecules are more complicated in just about every respect. Monoclonal antibodies, for example, are 100,000 times larger than aspirin. Because large molecules are broken down by your digestive system if you swallow them, they need to be injected or given by an IV drip. This means you'll need medical personnel and equipment to make sure it is done properly, and you'll need to isolate infected patients when they come in for treatment so they don't pass the virus to other people at the facility. Large molecules also require far more complex manufacturing—they're produced using live cells—which means they're more expensive, and it takes more time to scale them up.

In short, during an outbreak, you'd rather have small-molecule treatments than large ones, all other things being equal. But we may not be able to find a small-molecule drug that works well against a particular pathogen (or works without causing bad side effects), so our pandemic plan should have us ready to do both and pursue them in parallel. We can do research and development over the next decade to shorten the steps required when a potential pandemic is detected..

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We'll also need to deliver other lifesaving tools that aren't drugs, but help keep patients alive long enough for their bodies to recover. Oxygen is a prime example: According to the WHO, about 15 percent of COVID patients get so sick that they need supplemental oxygen.9

Oxygen is an important component in any health system—it's used in cases of pneumonia and premature birth, among others—and although rich countries have run short of it during COVID, low- and middle-income countries have struggled even more. One survey found that only 15 percent of health facilities in developing countries had any oxygen equipment, and only half of that equipment was functional. Hundreds of thousands of people die every year because they can't get medical oxygen—and this was before the pandemic.10

Bernard Olayo, a health specialist at the World Bank, is trying to do something about it.

After graduating from medical school in the mid-2000s, he worked at a rural hospital in his native Kenya, where many of the patients were children with pneumonia who needed oxygen for treatment. But there was never enough oxygen available. Often, several patients had to share a single cylinder of oxygen. When there wasn't enough to go around, Olayo and his colleagues would have to decide who would get it and who would go without—a gut-wrenching choice that often meant one child would live and another would die.

Olayo set out to learn why something as seemingly basic as oxygen was so hard to come by in Kenya. One problem, he learned, was that there was only one oxygen supplier for the entire country, and because there was no competition, the supplier could charge exorbitant prices. (At the time, oxygen in Kenya cost about thirteen times more than in the United States [CHECK THIS FACT].) Plus, many Kenyan health facilities are hundreds of miles from the nearest oxygen plant, which caused two other problems: Transportation costs added to the price, and

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poor roads added to the delivery time. New supplies were often delayed, and sometimes never arrived at all.

In 2014, Olayo created an organization called Hewatele—the Swahili word for "abundant air"—to try a different approach. With funding from local and international investors, Hewatele built oxygen plants at several of the busiest hospitals in the country, where demand is highest and reliable electricity for production is available. It devised a milkman model: Oxygen cylinders would regularly be dropped off at remote hospitals and clinics and the empty cylinders returned for a refill. Using this new approach, Hewatele has cut the market price for oxygen in Kenya by 50 percent and reached some 35,000 patients. And as I write this, the group is looking to expand within Kenya and to other parts of Africa.[11]

In addition to needing oxygen, patients who are severely sick might need to be intubated—have a tube put down their windpipe—and use a ventilator to help them breathe. In extreme cases, people's lungs might be so badly damaged that they can no longer oxygenate the blood, and a machine will need to do it for them. Just like oxygen supplies, the medical expertise and equipment needed to do these things was already hard to come by in many lower-income countries before COVID, a problem that the pandemic has multiplied many times over.

A recurring theme of this book is that we don't have to choose between preventing pandemics and improving global health more broadly—they reinforce each other. This is a classic example: If we do a better job of equipping the world's health systems with oxygen and other tools, as Hewatele is doing, then more health care workers will have the equipment they need to deal with everyday problems like pneumonia and premature births. And during a crisis, like an outbreak that's threatening to become a pandemic, they'll be able to save lives and stop the disease from overwhelming the entire health system. Each makes the other stronger.

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Treating disease is nothing new to humans. The practice of using roots, herbs, and other natural ingredients as healing agents dates to ancient times. Some 9,000 years ago, Stone Age dentists in modern-day Pakistan drilled into their patients' teeth with pieces of flint.12 The ancient Egyptian physician and scientist Imhotep catalogued treatments for 200 diseases around 5,000 years ago, and the Greek physician Hippocrates prescribed a form of aspirin—extracted from the bark of the willow tree—more than 2,000 years ago.13

But it's only in the past couple of centuries that we've been able to synthesize medicines in the lab rather than by extracting them from things we found in nature. One of the earliest synthesized drugs came about in the 1830s, when several scientists and physicians working independently all managed to make chloroform, the powerful anesthetic and sedative that, among other uses, would help Queen Victoria through the pain of childbirth.

Sometimes a drug has been invented because some enterprising scientist set out to do it, but sometimes it happens by pure accident, as in 1886, when two young chemistry students at the University of Strasbourg stumbled on a solution to a problem they weren't even looking to solve.14 Their professor was investigating whether a substance called naphthalene—a by-product of making tar—could be used to cure intestinal worms in humans. They administered the naphthalene with surprising results: It didn't get rid of the worms, but it did break the person's fever. After further investigation to figure out what had happened, they realized that they hadn't used naphthalene at all, but rather a then-obscure drug called acetanilide, which the pharmacist had handed them by mistake.

Soon, acetanilide was on the market as a cure for fevers and as a pain reliever, but doctors found that it had an unfortunate side effect: It made some patients' skin turn blue. After

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additional research, they learned that a substance could be derived from acetanilide that would have all the benefits without the blue hue. It was called paracetamol, which Americans know as acetaminophen, an active ingredient in Tylenol, Robitussin, Excedrin, and a dozen other products that you may have in your medicine cabinet right now.

Even in modern times, drug discovery still relies on a mixture of good science and good luck. In the early 1990s, scientists at Pfizer started a clinical trial to see whether a drug called sildenafil could be used to treat cardiovascular problems by dilating the blood vessels around the heart. It worked, though men involved in the trial found that the heart wasn't the only place in their body where blood vessels were expanding. Today, in addition to treating some forms of high blood pressure, sildenafil is the active ingredient in Viagra.

Unfortunately, when an outbreak appears to be headed toward a pandemic, there's no time to count on luck. We'll need to develop and test treatments as fast as possible, much faster than we did for COVID.

So let's suppose we're in that situation: There's a new virus that looks like it could go global, and we need a treatment. How will scientists go about making an antiviral?

The first step is to map the virus's genetic code and then, armed with that information, figure out which proteins are the most important in the life cycle of the virus. These essential proteins are known as the targets, and the search for a treatment essentially boils down to defeating the virus by finding things that will keep the targets from working the way they should.

Until the 1980s, researchers trying to identify promising compounds had to get by with only a rudimentary understanding of the targets they were seeking. They would make their best educated guess and run an experiment to see if they were right; most of the time, they weren't, and they would move on to the next molecule. But the tools available for identifying the right

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drug have gotten much better in the past thirty years, with the advent of a field called structure-guided discovery.

In structure-guided discovery, instead of testing each possible compound in a lab, scientists can program computers to create 3D models of vulnerable parts of the virus and then design molecules that attack those targets. Moving the search for compounds from laboratory experiments to structure-guided discovery is like playing chess on a computer instead of a board—the game still happens, but not in a physical space. And just as with chess, structure-guided discovery has become more sophisticated with the growing processing power of computers and advances in artificial intelligence.

Here's how it worked for Paxlovid, the antiviral announced by Pfizer in late 2021. Scientists had identified how COVID hijacks parts of your cells to make more copies of itself (these parts are sequences of amino acids, the building blocks of proteins). Using this knowledge, they designed a molecule that operates like an undercover cop conducting a sting operation. It mimics most of the sequence of amino acids that COVID will seek out, but it's missing key pieces of the sequence, so it disrupts the life cycle of the virus. There are several stages of the life cycle that can be disrupted. In the case of HIV antivirals, by far biggest category of antivirals, we have ones that attack each stage, and we combine three of them so that the virus is very unlikely to mutate to stop them from working all at once..

Even though we can now run virtual experiments very quickly on a computer, sometimes researchers still need to do the real thing—to match a compound with the protein from a virus in a lab and see what happens. But technology is changing this approach too.

In a process known as high-throughput screening, robotic machines can run hundreds of experiments at a time, mixing compounds and proteins and then using various methods to

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measure the reaction. With high-throughput screening, companies can now test millions of compounds in a matter of weeks, a task that would take a normal team of humans years to complete. Many of the major pharmaceutical companies have collected millions of compounds; if each collection is a library, then high-throughput screening is the fast, methodological way to search through every book on the shelf for just the right word.

And even if there isn't a good match—if there isn't an existing compound that looks as if it might make a good treatment—that's helpful information. The faster we can rule out the compounds we already have, the faster we can move on to making new molecules.

Regardless of the method involved, once a promising compound is identified, the scientific teams will analyze it to determine whether it's worth further exploration. If it is, a different team—the medicinal chemists—will try to optimize the compound in a process that's a bit like squeezing a balloon. They might tweak it in one way to make it more potent, but then discover that the higher potency also made it more toxic.

Once we've found a promising candidate in the exploratory phase, we'll spend a year or two in the preclinical phase, studying whether our candidate is safe and whether it actually triggers the expected response in animals. Finding the right test subject is not as easy as it sounds, because animals don't always respond to a drug the way that humans will. Researchers have a saying: "Rats lie, monkeys exaggerate, and ferrets are weasels."

If all goes well in the preclinical phase, we'll move into the riskiest and most expensive part of the process: clinical trials in humans.

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In May 1747, a physician named James Lind was serving as a ship's surgeon in the British Royal Navy vessel *Salisbury*.[15] He was horrified by the number of sailors who were suffering from scurvy, a condition that causes muscle weakness, exhaustion, bleeding from the skin, and eventually death. No one knew at the time what caused scurvy, but Lind wanted a cure, so he decided to try various options and compare the results.

He selected twelve patients on board who had similar symptoms. They all ate the same food—gruel sweetened with sugar in the morning, mutton broth or barley and raisins for dinner—but were given different treatments. Two drank a quart of cider each day. Two others were given vinegar. Other pairs of patients got either seawater (the poor souls), oranges and a lemon, a medicine concocted by a hospital surgeon, or a mixture of sulfuric acid and alcohol known as elixir of vitriol.

The citrus treatment won out. One of the two men who received it was back on duty in six days, and the other recovered quickly enough to begin tending to the rest of the patients. Although the British navy wouldn't make citrus a required part of a sailor's diet for another fifty years, Lind had found the first real evidence of a cure for scurvy. He had also run what is widely regarded as the first controlled clinical trial of the modern era.*

Other innovations in clinical trials would follow in the decades after Lind's experiment: the use of placebos in 1800, the first double-blind trial (in which neither the patient nor the physician knows who is getting what treatment) in 1943, and the first international guidance on

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* We now know that scurvy is caused by a deficiency of vitamin C. May 20, the day Lind began his trial, has been designated International Clinical Trials Day.

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the ethical treatment of trial participants in 1947, following revelations of the Nazis' horrific experiments during World War II.

In the United States, a series of laws and court rulings over the course of the twentieth century slowly built up the testing and quality assurance regime that exists today. It's this regime that our hypothetical treatment for a new pathogen will have to go through. Let's track how it typically works, phase by phase.

Phase 1 trials. With permission from your government's regulator—in the U.S., it's the Food and Drug Administration—to run clinical trials in humans, you'll start with a small trial involving a few dozen healthy adult volunteers. You're looking to see whether the drug causes any adverse effects and to zero in on a dosage that's high enough to have the effect you want but not so high that it makes the patient sick. (Some cancer drugs are tested only on volunteers who already have the disease because they're too toxic to be given to healthy people.)

Phase 2 trials. If everything goes well and you know your drug is safe, you're allowed to move on to larger trials. Here you'll give it to several hundred volunteers in the target population—people who are sick and otherwise fit the profile—and you'll look for proof that the drug does what you hope it will. Ideally, at the end of Phase 2, you know whether the drug works and perhaps the right dosage as well, because the next phase is so expensive that you only want to move ahead if you've got a good chance of success.

Phase 3 trials. If all goes well up to this point, you'll run even larger trials involving hundreds of sick volunteers—half of whom get your drug candidate, the other half of whom get either the standard treatment for their condition or, if there isn't a treatment yet, a placebo. This is a lot smaller than Phase 3 trials for vaccines, which I'll explain in the next chapter. Everyone is already sick with the disease you're trying to treat, so you can see whether the drug is working

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a lot faster. (If there's already a treatment on the market, you'll have to enroll more volunteers, because you'll need to show that your product is at least as effective as the competition.)

Another hurdle in Phase 3 is finding enough volunteers to make sure your drug candidate is safe and effective for everyone who might take it. You need to find people who are sick—obviously at this stage there's no point in giving your potential cure to people who don't have the disease—but for the reasons we covered in Chapter 4, it's hard enough to identify those people, much less to identify the ones who are not only sick but also willing to volunteer to try out a new drug. And because everything from age to race to overall health can affect how a drug works in a person's body, it's important to study how a lot of different people react to it. Recruiting a diverse set of volunteers for a clinical trial can sometimes take more time than running the trial itself.

Regulatory approval. If you get out of Phase 3, you go back to the regulatory agency and apply for approval. The application can run literally hundreds of thousands of pages, and in the U.S., the FDA's review can take months or even years. The agency will also inspect the factory where you're going to make the drug, and they'll review the label you want to put on the vial as well as the printed information that's included in the packaging. Even after you're licensed, you might be required to run another phase of trials among certain groups of people, and in any case, regulators will continue to check your production line to make sure the doses you're making are safe, pure, and potent. And as more people take your drug, you'll keep watching out for adverse effects (an especially rare problem might only show up once lots of people are taking it), and you'll also be on the lookout for signs that the pathogen is building up a resistance to your drug.

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Now, this is how it works in nonpandemic times. In the emergency that COVID was, it needed to happen much, much faster. The U.S. government and other funders put up the money for some of the Phase 3 trials—the most expensive step in the process, because it involves so many people—even before drug candidates had been approved. Scientists also put off studying facets of the drugs that weren't crucial in an emergency. It was akin to proving that a car will get you where you need to go without exploding halfway there, but being a little unsure about its gas mileage or how well the tires will handle snow.

For COVID, there wasn't an agreement in advance on a standard protocol for doing trials and deciding what data to collect within or across countries. During COVID, a lot of time and money was wasted because multiple, poorly designed clinical trials tested the same products but didn't produce conclusive evidence either way. We need to standardize the approach to trials ahead of time, ensuring that they're well designed and set up to provide definitive evidence as fast as possible. One of the few trials that was done well was the RECOVERY trial in the U.K, which looked at a number of drugs, including dexamethasone: It was ready to go within six weeks and included 40,000 participants at 185 sites.16

Some new ideas may push the limits of what regulators are comfortable with. One is that, if you test positive, you could get an immediate text message giving you the chance to volunteer for a clinical trial that needs people with profiles like yours. Simply click "Enroll Me" and you'll start the process; if you're selected, you'll get access to treatment—either the one being studied or the best one already in use—and you'll be helping speed up the clinical trial. Another innovation I hope to see is putting regulatory submissions in the cloud and in a standard format, so it can be reviewed by all the regulatory groups without duplication.

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So let's return to our hypothetical example of a new pathogen. We've now developed a treatment, run trials to prove that it's safe and effective, and gotten the green light to make and sell it. It's time to start manufacturing. Although making a small-molecule drug is easier than making an antibody, which in turn is generally easier than making a vaccine for reasons I'll explain in the next chapter, it's still worth taking a moment to walk through the challenge of scaling up manufacturing.

First, a team of chemists will work on finding the most effective way to produce the key part of our drug—known as the active pharmaceutical ingredient—by setting off a series of reactions using chemicals and enzymes. The best path might involve four or five separate steps: Our chemistry team will start with certain ingredients, spark a reaction among them, capture the by-products, use some of those in another reaction, and so on, until they have the active ingredient we're after. Then they'll turn it into the form in which patients will take it—such as a pill, nasal spray, or injection.

Quality control is relatively easy for small-molecule medications, as opposed to vaccines. Because the product is just a string of molecules, and not a living thing, we can use analytical tools to confirm that it has all the necessary atoms in all the right places.

It's hard to overstate the importance of this one fact. It is a godsend for everyone who cares about equity in global health, because it gave rise to one of the most important global health innovations in the past several decades: generic drug manufacturers committed to creating low-cost versions of lifesaving drugs.

Historically, the companies that invent new drugs have been based in higher-income countries. Because it costs so much to develop a new product, they try to recoup their costs as quickly as possible by selling doses at the higher prices that rich countries can afford. It doesn't

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make sense to tinker with the manufacturing process to lower the cost of making the product—by reducing the number of steps involved, for example—because that would require going through some of the regulatory process again. This can mean that the cost stays too high for developing countries, and it's why it sometimes takes decades for drugs that are widely available in the rich countries to reach poor ones.

This is where low-cost generic manufacturers come in. Their mission is to help people in poor countries get access to the same drugs and other lifesaving inventions that are widely available in rich countries.*

Generics made their mark on global health around two decades ago. At the time, lifesaving HIV drugs were too expensive for countries like Brazil and South Africa, which meant millions of people living with HIV were priced out of the market. So, the governments in those countries had generic manufacturers duplicate the drugs, violating the intellectual property rights of the companies that had invented them. At first, the companies resisted, but they eventually backed off after realizing that a tiered pricing approach would work better. They made all the information about their drugs available to low-cost generic manufacturers, which were allowed to sell to developing countries without paying any royalties. This is what's known as tiered pricing: the highest price for rich countries, a lower price for middle-income countries, and the lowest possible price—one that matches the cost of manufacturing—for low-income countries..

One problem is that once a drug is made generic, no one has an incentive to invest in reducing the manufacturing cost since other companies could immediately copy their

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* Generic manufacturers are also the reason why you might be able to get significantly cheaper versions of some of the prescriptions you take.

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improvements. To resolve this, donors such as the Gates Foundation will hire experts and fund the optimization work and the upfront costs of implementing a new process. In 2017, for example, the foundation and a number of partners helped create a generic form of a more effective version of an HIV drug cocktail. The pharmaceutical companies that invented the drugs provided a free license to enable this work.

The generic firms were able to reduce the cost so much that today nearly 80 percent of people who get HIV treatment in low- or middle-income countries are receiving the improved cocktail. The new drug requires a much lower dose—and a smaller pill—to be effective than previous treatments did, which means it's a lot easier for people to take. It also causes fewer side effects and is less likely to cause drug resistance..

It's hard to overstate the impact of these low-cost, high-volume generic manufacturers. Months before studies proved that molnupiravir is an effective antiviral, Merck had already negotiated licensing deals with several generic manufacturers in India, allowing them to make and sell generic versions in India and more than 100 other low- and middle-income countries. Researchers funded by the Gates Foundation developed ways to drive down the cost of making it, and our grantees helped the generic companies get ready to make the drug and apply for approval from the WHO. Beginning in January 2022—just two months after molnupiravir's successful results had been announced—generic companies would make 11 million doses available to low- and middle-income countries, a first step to producing many more.

Generic manufacturers such as Aurobindo, Cipla, and Sun (all based in India), Teva (based in Israel), and Mylan and Sandoz (in the U.S. and Europe) produce the large majority of medicines used by people in low- and middle-income countries.17 One WHO program that

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works largely with generic manufacturers estimated that they will eventually help 200 million people get drugs to treat malaria who wouldn't have otherwise.[18]

I wish that making antibodies were as straightforward as making drugs. To produce antibodies for the hypothetical pathogen we're trying to contain, we'll need to find patients who've survived the disease, draw their blood, and identify the antibodies that their bodies developed to fight this particular disease. Since their blood will contain antibodies for essentially every disease they've ever encountered, we'll have to isolate the one we're looking for by introducing the virus to a bit of their blood, and then watching to see which antibodies stick to the virus. Those are the ones we want. (An alternative is to do the same process but with blood from humanized mice—rodents in which human cells or tissues have been implanted.)

Once we've isolated the right antibody, we'll need to copy it billions of times over. We'll likely do that by growing them on the CHO cell platform, which consists, as you surely guessed, of ovarian cells from Chinese hamsters.

These cells are so useful because they're especially hardy, they can be maintained indefinitely, and they grow quickly. The story of how they came to hold this lofty position has more twists and turns than I have space for in this book. According to one history of CHOs, most of the cells in use around the world today are clones of a cell line created by a geneticist at the University of Colorado Medical School in 1957. He had managed to get his hands on a single female whose ancestors had been smuggled out of China in 1948, on one of the last flights out of Shanghai before the Communist Party came to power.

Unfortunately, the CHO platform doesn't produce antibodies fast enough to meet much of the need during a pandemic. The world produces around 6 billion doses of vaccines every

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year, and only about 30 million doses of antibodies. CHO antibodies are also expensive to make—the current cost of goods and services to make them is in the range of $70 to $120 per patient, too much for many low- and middle-income countries. But scientists are working on ways to solve these problems.

For example, some are looking into different host cells that would produce antibodies more efficiently than CHOs, and other potential improvements in the process. They are also studying ways to find more potent and highly selective antibodies, so that you wouldn't need as much product per patient. Already there are ideas being tested but not yet commercialized that would get the cost down to more like $30 or $40 per dose. But the ideal would be to cut costs by a factor of ten—getting them below $10 per person—while also being able to produce ten times as many doses in the same amount of time. It will take a number of improvements to achieve that.

Companies are also developing solutions to the problem of variants. One approach involves making antibodies that target parts of the virus that don't change, even across different variants—meaning they're just as effective against the variants as they are against the original virus. Another approach involves mixing a cocktail of antibodies that attack different parts of the virus, making it much harder for the virus to develop resistance to them.

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Back to the hypothetical disease that we're making treatments for. Let's assume we get a treatment approved and are able to manufacture lots of doses. How do we make sure it actually reaches everyone who needs it?

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Even if the cost is low, some countries will need donations to be able to get enough for all their people. For twenty years, low- and middle-income countries have been getting help from a nonprofit called the Global Fund to buy medicines and other tools to fight HIV, TB, and malaria. The Global Fund is now the world's largest financer of these efforts, reaching more than 100 countries, and in 2020 it expanded its purview to include COVID supplies.

A newer approach that could inform our efforts is the partnership known as the Access to COVID-19 Tools Accelerator. Led by the WHO and other groups, its goal is to herd all the cats involved in global health, making sure that developing countries are consulted—and their needs considered—when new COVID drugs are developed and delivered.

Of course, cost isn't the only hurdle we'll need to overcome. Even once we have a cheap treatment, it may be hard to get it to the patients who need it. And we'll need to make sure they get the right treatment at the right time. (Remember, for example, that mAbs and antibodies need to be given shortly after symptoms start, while a steroid like dexamethasone is only appropriate later in the disease, when someone is severely ill.)

Even then, something as seemingly basic as the packaging of the medicine might make people reluctant to take it. Some HIV drugs also help prevent people from getting infected in the first place—the approach called pre-exposure prophylaxis—but many patients don't want to take an AIDS medicine out of fear that others will think they're HIV-positive. That problem can be solved, but not without some effort, because you can't just start making pills that look different. You have to test every element, including the shape, size, and even the color of the pill.

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I feel sure we will have better treatment options in the next big outbreak than we did for COVID. One of the keys to making that happen will be big libraries of drug compounds that let us quickly scan to see if existing therapies work against new pathogens. We have some of these libraries already, but we need more. This will require substantial investment to bring together academia, industry, and the latest software tools.

We need libraries that cover many types of drugs, but there are some types that should be a top priority. The most promising, in my view, are the ones known as pan-family and broad-spectrum therapies—either antibodies or drugs that can treat a wide range of viral infections, especially those that are likely to cause a pandemic. We could also have better ways of activating what's known as innate immunity, which is the part of your immune system that kicks in just minutes or hours after it detects any foreign invader—it's your body's first line of defense. (It stands in contrast to the adaptive immune response, which is the part that remembers the pathogens you've encountered before and knows how to fend them off.) By boosting your innate immune response, a drug could help your body stop an infection before it takes hold.

To deliver on these promising approaches, the world needs to invest more into understanding how various dangerous pathogens interact with our cells. Scientists are working on ways to mimic these interactions so that they can quickly figure out which drugs might work in an outbreak. A few years ago, I saw a demonstration of a "lung on a chip," an experimental device you could hold in your hand that operated just like a lung, allowing researchers to study how different drugs, pathogens, and human cells affect each other.

With advances in artificial intelligence and machine learning, it's now possible to use computers to identify weak spots on pathogens that we already know about, and we'll be able to do the same when new pathogens arise. These technologies are also speeding up the search for

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new compounds that will attack those weak spots. With adequate funding, different groups could take the most promising new compounds through Phase 1 studies even before there's an epidemic, or at least have several leads that can be turned into a product quickly once we know what the target looks like.

In short, although therapeutics didn't rescue us from COVID in 2020, they hold a lot of promise for saving lives and preventing future outbreaks from crippling health systems. But to make the most of that promise, the world ought to invest in the research and systems we'll need to find treatments much faster, and to deliver them to people who need them, wherever they are. If we do, we'll save millions of lives and minimize the disruption the next time the world faces an outbreak.

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Chapter 6

Get ready to make vaccines

It is easy to forget, now that billions of people have received at least one dose of a COVID vaccine, that the odds were not in humanity's favor. I mean they were *really* not in our favor.

The fact that scientists were able to create multiple successful COVID vaccines is itself unusual in the history of disease. The fact that they did it in roughly a year is miraculous.

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Vaccines for COVID-19 were developed at an unprecedented pace. It took scientists only one year to create safe and effective vaccines for COVID-19. As a comparison, nearly eighty years passed between identifying whooping cough as a disease and immunizing 35 percent of the population against it. (Our World in Data)

Pharmaceutical companies, being the data hounds that they are, have a way of measuring the chance that a drug or vaccine candidate will make it all the way through the arduous process of being approved for use in humans. This measure, which is called the Probability of Technical and Regulatory Success, depends on several factors, including whether similar products have proved successful. If you're testing a vaccine that works more or less the same way as one that has already been approved, your odds are better.

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Historically, the average probability of success for vaccine candidates* is 6 percent.[1][2] What this means is that if you start with 100 candidates, only 6 of them will make it all the way to full regulatory approval. The others will fail for any number of reasons—they might not give people enough immunity, or clinical trials might not give you the conclusive results you need, or they might have unintended side effects.

Of course, this 6 percent figure is just an average. The odds for drugs and vaccines created using tried-and-true methods would be a few percentage points higher. And they're a few points lower when you're trying a new approach. First you have to prove that the basic approach works, then you might also have to prove that the vaccine you make using that approach also works. You have to run massive trials, which can involve hundreds of thousands of people, and later you'll have to watch for side effects in millions of people. There are hurdles everywhere.

Fortunately, the COVID virus is relatively easy to target with a vaccine. That's partly because it has few of the tricks that make some viruses especially hard to go after—such as the ability of two strains to create a third one by swapping genes—and the spike on its surface is not as camouflaged as the proteins on some other viruses are. COVID is fairly good at replicating itself accurately, which means it hasn't produced as many variants as, say, HIV.

As a result, the success rate for COVID vaccines has been unusually high. .

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* A vaccine candidate is just what you'd imagine: something that might turn out to be a safe, effective vaccine, but is still in the development stages. It's like a bill that is making its way through Congress or Parliament and may or may not become law.

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Yet the greatly underappreciated miracle of COVID vaccines is not the fact that they were created and approved. It's that they were created and approved faster than any other vaccines ever.

In fact, it happened even more rapidly than many people, including me, were willing to predict in public. In April 2020, although I thought we could have a vaccine by the end of the year, I wrote on my blog that it could take as long as twenty-four months—I thought it wouldn't be responsible to raise the prospect of quick successes if there was a decent chance they wouldn't happen. In June, after seeing initial data on some promising vaccine candidates, a former commissioner of the Food and Drug Administration told *The New York Times,* "Realistically, the 12 to 18 months that most people have been saying would be a pretty good marker but still optimistic."3

What did in fact happen was the best-case scenario. The vaccine made by Pfizer and BioNTech was approved for emergency use at the end of December,4 just eleven months after the first cases were identified.

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Making a vaccine. All vaccines go through a rigorous process to make sure they're safe and effective. Incredibly, several vaccines were created for COVID-19 within one year. To do this, scientists and manufactures consolidated costly development stages without sacrificing safety. (NEJM 2020)

To get a sense of just how fast this was, consider that the vaccine development process—from the first discovery in a lab, through proving that it works and getting it licensed—typically takes between six and twenty years.5 It can take as many as nine years simply to get a product

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into humans for clinical testing, and even with a lot of time, there's no guarantee of success. The first vaccine trial for HIV began in 1987, and we still don't have one that's licensed.

Before COVID, the land speed record for developing a vaccine was four years. This remarkable feat was achieved with a vaccine for mumps by a scientist named Maurice Hilleman, who was one of the most productive vaccine makers ever. Of the fourteen vaccines currently recommended for children in the U.S., he and his team at Merck Pharmaceutical developed eight, including ones that protect you from measles, hepatitis A and B, and chickenpox.6

In 1963, his five-year-old daughter, Jeryl Lynn, came down with a sore throat. Suspecting that she had mumps—for which there wasn't yet a licensed vaccine—he took a sample from her throat using a swab, went to his lab, and isolated the virus. Eventually he used it to create the first licensed mumps vaccine in 1967. This strain of mumps is still in use today, and it's named for his daughter. If you've received the MMR vaccine—for measles, mumps, and rubella—you got the Jeryl Lynn strain.

In Hilleman's time, making a vaccine in four years was a fantastic accomplishment. But one of the reasons he was able to move relatively fast is that there weren't the same stringent ethical standards for gaining consent or assuring quality that we have today. In any case, when an outbreak is threatening to become a pandemic, four years would be an eternity and longer would be a disaster.

The implications for preventing pandemics are clear: We need to raise the odds of success for vaccines, and we need to reduce the time it takes to get them out of the lab and into humans, without sacrificing safety or effectiveness. We also need to manufacture so many of them so quickly that they'll be available to everyone in the world within six months.

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That's an ambitious goal, and as I mentioned in the Introduction, one that will strike some people as crazy. But I'm convinced that it's possible, and in the rest of this chapter, I want to make the case that we can do it.

Getting a vaccine out of the lab and into patients takes four steps—developing it, getting it approved, manufacturing it at high volumes, and delivering it—and we'll look at the opportunities to accelerate the process along the way. We'll look at why it's usually so hard to create and test a vaccine and why it takes so long. What exactly is happening in those five or ten years before it's ready for the market? We'll also explore why scientists were able to move so much faster this time—it's a fascinating story of farsighted planning, dogged research by two heroic scientists, and more than a little luck.

Unfortunately, as we've seen with COVID, it's one thing to get a vaccine created and approved. It's another challenge entirely to avoid creating a system of vaccine haves and have-nots—to make and distribute enough doses to quickly reach everyone who needs them, including people in low-income countries who have a high risk of getting severely sick.

The distribution of COVID vaccines in 2020 and 2021 was, to quote Hans Rosling again, both bad and better. Vaccines reached more people faster than any other vaccination effort ever. They also reached many people in poor countries faster than ever—but not fast enough. So we'll look at ways to distribute vaccines more fairly.

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These two images are a reminder of how uneven vaccine availability can be. In the U.S. rows of cars lined up at predetermined locations, while people living in more remote

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parts of the world waited for limited doses to arrive by someone traveling by foot to their region.

Finally, we'll wrap up this chapter with a new kind of drug that would complement vaccines –ones that you could inhale and would keep the virus from getting into your body in the first place. Protecting yourself and others would be no more complicated than treating your hay fever.

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My initiation into the world of vaccines came in the late 1990s, as I was learning about global health. When I discovered that children in poor countries were dying of diseases that kids in rich countries never died of—and that the main reason was that one group got certain vaccines and the other group didn't—I read up on the economics of immunization. It was a classic case of a market failure: Billions of people needed the great inventions of modern medicine, but because they had so little money, they had no way of expressing their needs in ways that matter to markets. So they went without.

One of our first major projects at the Gates Foundation was to help create and organize Gavi, the Vaccine Alliance,* an organization that pools donations to help poor countries buy vaccines. Gavi created a market where there wasn't one: Since 2000, it has helped vaccinate more than 820 million children and prevented some 14 million deaths.7 It's also the home for COVAX, the program created to provide COVID vaccines for low- and middle-income countries. It's safe to say that Gavi is one of the foundation's contributions that I am most proud of.

* Formerly known as the Global Alliance for Vaccines and Immunization, or GAVI, they changed their name a few years ago to Gavi, the Vaccine Alliance.

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Gavi saves lives. Since its formation in the year 2000, Gavi has helped vaccinate more than 800 million children in 77 countries, with 324 million children being vaccinated in the past five years alone. We see the direct impact in the chart on the right, which shows the reduction in child deaths under age 5 over the same time period. (Gavi Progress Report 2020)

The more we got into vaccines, the more I started learning about the science as well as the economics. It wasn't just that poor countries couldn't afford existing vaccines—they also didn't have the market power to demand new vaccines for diseases that primarily affected them. So the foundation started hiring people who were experts in making vaccines (and drugs). I had to learn a lot more about chemistry, biology, and immunology, I've spent countless hours in conversations with scientists and researchers from all over the world, and I've toured more vaccine factories than I can count.

In short, I've spent a lot of time learning about the finances and operations of the vaccine industry, and I can say confidently that it is quite complex.

That's partly because we've decided as a society that we'll tolerate very little risk when it comes to vaccines. This cautious approach makes sense: After all, you give vaccines to healthy people, and giving them a vaccine that has bad side effects defeats the purpose. (People won't take a vaccine if it's likely to have severe side effects.) As a result, the industry is highly regulated, and vaccines go through a lengthy, rigorous process of being tested and monitored. I'll explain shortly how it differs from the drug-approval process, but here's just one example of how rigorous the process is: If you build a vaccine factory, you have to meet standards that touch on

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nearly every aspect of the building, from the temperature of the air and the volume of airflow to the curvature of the wall corners.

Another reason the industry is so challenging is the nature of the product. Vaccines are made up of massive molecules, on the order of a million times heavier than the molecules that make up aspirin. Many are created in living cells—flu vaccines, for instance, are typically grown in chicken eggs—and since living things are inherently unpredictable, you don't necessarily get exactly the same result each time. Yet getting almost exactly the same result each time is crucial to making a vaccine that's safe and effective. You need highly specialized equipment, and you need trained technicians to run it, and even then, there are half a dozen or more variables that could change the final product in subtle but important ways, every time you make a new batch.

Once you've found a method for making a vaccine and developed one that's safe for humans, you have to reproduce this method every time you make it—that's the only way a regulator can confirm that you've gotten the same result you got previously. In contrast with checking a small molecule—where someone can examine it and say, "I don't particularly care how you made this thing; I can tell it has the right atoms in the right places"—checking a vaccine requires the regulator to watch how you make it and then, on an ongoing basis, make sure you don't change anything. By comparison, reproducing something like software is a cinch. Once you've debugged your code, you can copy it as many times as you want without fear that something new will suddenly go wrong with it. If making copies of software occasionally introduced new problems, the industry wouldn't have been nearly as successful.

It also costs a lot of money to develop a vaccine: Estimates for the total cost to get one developed and licensed range from $200 million to $500 million. The number goes even higher

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if you factor in the cost of all the failures you'll have along the way: One widely cited but debated study on drugs (not vaccines) put the total figure at $2.6 billion.[8]

During an outbreak, vaccine companies also have to contend with high expectations from the public. People want to have a new vaccine that's safe and effective, they want it fast, and they want it to be cheap. Some have argued that vaccines should be free.

I'm not defending every decision that a pharmaceutical company has ever made about pricing a product, and I'm not asking anyone to feel sorry for the industry. But if we're going to tap into their expertise in developing testing, and manufacturing drugs and vaccines—and there's no way to prevent or even stop pandemics unless we do—then we need to understand the challenges they face, the process they go through when they're deciding what products to work on, and the incentives that push those decisions in one direction or another.

You may have noticed that I keep using words like *business, industry,* and *markets,* with the implication that much of the work on vaccines is done by private companies. That's intentional. Although nonprofits and governments have essential roles to play—funding basic research and deploying vaccines widely among them—the private sector is almost always responsible for the final stages of developing vaccines and manufacturing them at scale.

This has important implications for our efforts to keep future outbreaks from going global. Remember that our goal is to have no more pandemics, so although we definitely need to be able to produce enough vaccines for everyone on the planet in case a disease goes global before we can contain it, we would rather keep a disease from turning into a pandemic in the first place. So we'll need vaccines for regional outbreaks, in which potential patients will number in the hundreds of thousands, rather than the millions or billions. This will change the pharmaceutical companies' incentives dramatically. Why spend all the effort and funding

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required to develop a vaccine with only a small pool of potential buyers, especially if you have to set the price so low that you're unlikely to ever make money?

Simply relying on market forces won't do the trick. The world needs a plan for getting vaccine factories ready in advance and financing new vaccines. This plan should include money to prepare for vaccine trials and approvals, as the U.S. government did with $20 billion during COVID.

It should also include significant funding for research and development on vaccines and other tools, some of which should go to CEPI, the organization I mentioned in the Introduction that gives grants to academic centers and private companies to get them to develop vaccines and vaccine technologies. . By the summer of 2021, CEPI had raised $1.8 billion for its COVID response, but it struggled to get funding for work on future pandemics.9 That's understandable—when one disease is killing people around the world, it's hard to get donors to think about the disease that may emerge at some point in the future—but this is part of the billions we need to spend to save millions of lives and prevent trillions of dollars of economic losses in the future. .

One area in which CEPI can contribute is the creation of vaccines that would be effective against entire families of viruses, also known as universal vaccines. Today's COVID vaccines teach your immune system to attack part of the spike protein on the surface of one specific Coronavirus. But researchers are now working on vaccines that would target shapes that show up on all coronaviruses, including COVID and its cousins, and would even be likely to appear on ones that evolve in the future. With a universal coronavirus vaccine, your body would be ready to fight viruses that don't even exist yet. SARS* and influenza viruses should be the targets of these vaccines, since they were responsible for t the worst outbreaks of the past twenty years. .

* Severe Acute Respiratory Syndrome.

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Finally, the world's vaccine plan should establish a way to allocate doses rationally, so that they provide the greatest benefit for public health and don't simply go to the highest bidders. COVAX was intended to solve this problem during COVID, but for reasons that were mostly out of its control, it fell far short of its goals. There were bureaucratic barriers, delivery problems in countries with struggling health systems, and rich-country governments negotiating their own deals, which put them first in line. The world will need to do better next time, a subject I'll return to in Chapter 9.10

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Of course, financing scientific work on new vaccines is only part of the equation. Those vaccines actually have to be made— even faster than the COVID vaccines were—and by far, the most promising technology to do that is mRNA vaccines. For most people, these seemed to come out of the blue, but in fact they were the product of decades of dogged work by researchers and product developers, including two who had to fight tooth and nail for their revolutionary idea.

From the time she was sixteen years old, Katalin Karikó knew that she wanted to become a scientist. She had a particular fascination with messenger RNA, or mRNA, molecules that (among other things) direct the creation of proteins in your body. In the 1980s, while working on her PhD in her native Hungary, she became convinced that tiny strands called messenger RNA could be injected into cells to allow the body to make its own medicines.

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Katalin Karikó, a Hungarian biochemist, co-discovered RNA technology that is now used in the development of mRNA vaccines.

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Messenger RNA, or mRNA, functions as a kind of middleman—it carries the directions for making proteins from your DNA to the factories in your cells where the proteins will be assembled. It's a bit like the waiter who writes down your order and takes it to the kitchen, where the cooks will make your meal.

Using mRNA to make vaccines, Karikó knew, would be a major departure from the way most vaccines work. They all boost your immune system, but mRNA vaccines would do the job unlike any vaccine before.

When you're infected by a virus, it invades certain cells in your body, uses the cells' machinery to make more copies of itself, and then releases the newly made viruses into your blood. These new viruses go off in search of more cells to invade, and the process continues in a cycle.

Meanwhile, your immune system is primed to look for anything in your body with a shape that it hasn't seen before. When it encounters something it doesn't recognize, it says: "Hey, there's a new shape floating around. It's probably bad news. Let's get rid of it."

Ingeniously, your body is capable of going after both the viruses that are floating freely in your bloodstream and the cells that they have invaded. To defeat the ones in your blood, your immune system makes antibodies that grab onto that specific shape. (The cells that produce antibodies are known as B cells, and the ones that attack infected cells are called killer T cells.) Once you're producing antibodies and T cells, your body also produces memory B cells and memory T cells, which as the name implies, help your immune system remember what the new shape looked like.*

* I'm simplifying things somewhat.

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This system eventually stops the first attack of a virus and allows your body to do a better job the next time it sees that virus. . But for viruses that make you sick—like COVID or influenza—it's better to prime your immune system so it can attack the virus the first time it shows up. That's what vaccines do.

Conventional vaccines operate by injecting a weakened or dead form of the virus you're trying to stop. Your immune system sees the new shapes on the virus, kicks into gear, and builds up immunity. With a weakened virus, there is always the question of whether it was weakened enough—if it wasn't, it might mutate back into a form that can cause disease. But if it was weakened too much, it won't activate a strong immune response in your body. Likewise, killed viruses often don't trigger much of an immune response.

The idea behind mRNA vaccines was ingenious. Since mRNA takes the orders for proteins from the DNA and delivers them to the cooks in your cells' kitchen, what if we could change those orders in a very targeted way? By teaching your cells to make shapes that match shapes on the actual virus, the vaccine would trigger your immune system without having to introduce the virus itself.

If they could be made, mRNA vaccines would be a huge advance over conventional vaccines. Once you had mapped out all the proteins that make up the virus you wanted to target, you'd identify the one that you want antibodies to grab. Then you'd study the virus's genetic code to find the instructions for making that protein, and you'd put that code into the vaccine using mRNA. If, later, you wanted to attack a different protein, you'd just change the mRNA. This design process would take at most a few weeks. You would ask the waiter for fries instead of a side salad, and your immune system would do the rest.

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There was just one problem: It was only a theory. No one had ever actually made an mRNA vaccine. What's more, most people in the field thought it was crazy to even try, not least because mRNA is inherently unstable and prone to degrading quickly. It was far from obvious that you could keep your modified mRNA together long enough to do its job. Also, cells have evolved to avoid being hijacked by foreign mRNA, and there would need to be a way of getting around this defense system.

In 1993, while doing research at the University of Pennsylvania, Karikó and her boss managed a feat that told them they were on to something: They got a human cell to produce a tiny amount of new proteins using a modified version of mRNA that had been cleverly altered so it could get past the cell's defense system.

This was a breakthrough, because it meant that if they could scale up the production dramatically, the would be able to make a vaccine. In theory, it would be possible to make mRNA vaccines not just for flu or coronaviruses, but also for various forms of cancer.

Unfortunately, their work lost momentum when Karikó's boss left academia for a biotech firm. She no longer had a lab or financial support for her work; although she applied for grant after grant, every application was rejected. The year 1995 Nineteen ninety-five was particularly dispiriting: She had a cancer scare, she was taken off the tenure track at work, and her husband was stuck in Hungary because of a problem with his visa.

But Karikó was undeterred. In 1997, she began working with Drew Weissman, a new colleague who came to Pennsylvania with a promising background; he had done a fellowship at NIH under the supervision of Anthony Fauci.

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Together Karikó and Weissman kept pursuing the idea of creating vaccines using mRNA that had been engineered in a lab. But they still had to get more mRNA past the cell's defense systems, a problem that other scientists helped solve.

In 1999, a cancer researcher named Pieter Cullis and his colleagues proposed that lipids—basically, tiny bits of fat—could be used to encase and protect a more delicate molecule, such as mRNA.[11] Six years later, working with Cullis, biochemist Ian MacLachlan did it for the first time. The lipid nanoparticles he developed paved the way for the first mRNA vaccines.[12]

As late as 2010, hardly anyone in the federal government or private industry was interested in trying to make vaccines using mRNA. Major pharmaceutical companies had tried and failed, and some scientists felt that mRNA would never trigger enough of a response in the body. But an official at DARPA, the little-known research program for the U.S. military, saw enough promise in the technology that he started funding mRNA vaccines for infectious diseases.*

As pioneering as this work was, it didn't lead immediately to new vaccines. Accomplishing that would be the task of companies dedicated to translating the breakthrough into a product that could be approved and sold; the U.S.-based Moderna and Germany-based Curevac and BioNTech were founded to do just that. In 2014, Karikó joined BioNTech, where she turned her attention to developing an mRNA vaccine for flu.

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* DARPA is the Defense Advanced Research Projects Agency, and the DARPA official is a cancer researcher named Dan Wattendorf. He now works at the Gates Foundation.

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Early efforts didn't work, although a test of a rabies vaccine showed promise. Still, Karikó and her BioNTech colleague persevered, as did scientists at Moderna. When COVID hit, they immediately set out to make a vaccine for the new virus.

It was a good bet. The notion that mapping a virus's genome would allow you to create an mRNA vaccine in a matter of weeks proved to be exactly right.

In March 2020, just six weeks after scientists sequenced the COVID virus's genome, Moderna announced that it had identified an mRNA-based candidate and begun making it for clinical trials. On December 31, the mRNA vaccine made by BioNTech in partnership with Pfizer was approved for emergency use by the World Health Organization. When Karikó received the first dose of the vaccine she had done so much to create—a few days before it was officially approved—she wept.

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<~?~NO CAPTION FOR THIS ILLUSTRATION (This illustration shows how information coded in an mRNA vaccine can imitate components of a virus and then inform human cells about the potential threats it may encounter, effectively boosting the immune system.)>

It is hard to overstate the impact that mRNA vaccines have had on COVID. In many places, they account for virtually all of the COVID vaccinations. As of late 2021, more than 83 percent of vaccinated people in the European Union had received a vaccine made by either Pfizer or Moderna, both of which use mRNA. In the U.S., 96 percent had. Japan used *only* mRNA vaccines.[13]

To me, the moral of the mRNA story is this: Be willing to bet on crazy-sounding ideas, because they might be just the breakthrough you need. It took years of work to advance our understanding of mRNA far enough that we could use it to develop vaccines. We are lucky COVID didn't come along five years earlier.

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The agenda for mRNA researchers now is to keep making the technology better and broader—for instance by going after vaccines for HIV, and creating new ways to treat diseases. It may be possible to create a single mRNA vaccine that gives protection against several pathogens, rather than just one. And if we can find additional sources for the raw materials involved in making mRNA vaccines, their prices will go down.

In future outbreaks, we'll be measuring the time between the first case and the first vaccine candidate not in years or months, but in weeks. And mRNA will almost certainly be the technology that makes this possible.

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If mRNA vaccines are the cool new kid on the block, viral-vectored vaccines are the equally cool kid who doesn't get quite as much attention because her family moved in a few years earlier.

Like mRNA, the viral-vectored approach was the subject of years of research and only recently produced vaccines that could be used in people. It works by delivering the spike or other target protein that your immune system needs to recognize as foreign. The delivery mechanism is a version of another virus—such as one that causes the common cold—that has been modified so it's harmless to humans; this virus, the carrier of the surface protein that the immune system will learn to make antibodies for, is what's known as the vector.

If you got a vaccine manufactured by Johnson & Johnson or Oxford/AstraZeneca, if you got Serum Institute of India's Covashield, you got a viral-vectored dose. Although making the surface protein is harder than making the mRNA, these vaccines were still developed very quickly; the first two COVID vaccines that used viral vectors reached the market in just fourteen

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months, smashing the previous record for this approach. Before COVID, the only licensed viral-vectored vaccines were for Ebola, and those took five years to be approved.

As optimistic as I am about these technologies, I need to add a caveat: *We were good, but we were also lucky.* Because coronaviruses had already caused two previous outbreaks (SARS and MERS), scientists had learned quite a bit about the structure of the virus. Especially important was the fact that they had identified its characteristic spike protein—the crownlike thing you've seen a dozen pictures of—as a potential target for vaccines. When it came time to modify mRNA for a COVID vaccine, they had a sense of what the target should be.

The lesson here is that we need to keep up basic research on an even wider array of known viruses and other pathogens, so we understand as much as possible before the next outbreak. We should also be stepping up research on the broad-spectrum therapies that I mentioned in the previous chapter.

But no matter how quickly we make a new vaccine during an outbreak, it won't do any good if it takes years to get through the approval process. So let's look in detail at how that process works, and how we might accelerate it without sacrificing safety or effectiveness.

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Humans invented vaccines long before they invented ways to make sure they worked. The British physician Edward Jenner is considered the founder of modern vaccines, having shown in the late eighteenth century that inoculating a young boy with cowpox—a disease related to

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smallpox, but not nearly as deadly—made him immune to smallpox too.* (The word *vaccine* comes from name of the cowpox virus, *vaccinia,* which in turn is derived from *vacca,* the Latin word for cow.)14

By the end of the nineteenth century, you could get immunized against smallpox, rabies, plague, cholera, and typhoid. But you wouldn't be sure whether the vaccine was any good, or even whether it was safe.

This unregulated market had tragic consequences. In 1901, a contaminated smallpox vaccine caused an outbreak of tetanus is Camden, New Jersey. That same year, a contaminated serum that was supposed to offer protection from the bacterial infection diphtheria killed thirteen children in St. Louis.15

Spurred by outrage over these incidents, the U.S. Congress began regulating the quality of vaccines and drugs, creating the Hygienic Laboratory of the U.S. Public Health Service in 1902. The job of regulation eventually moved over to the Food and Drug Administration, and responsibility for federal research stayed with the Public Health Service, which we know today as the National Institutes of Health.16

In the previous chapter, I walked through the process for getting a drug approved. It works largely the same way for vaccines, so I'll give just a quick summary here and note the major differences between getting approvals for drugs versus vaccines.

The exploratory stage. Two to four years of basic laboratory research designed to identify candidates.17

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* Like a lot of scientists at the time, Jenner had wide-ranging interests. He was an ornithologist and also studied the hibernation of hedgehogs.

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Preclinical studies. A year or two assessing your candidate's safety and studying whether it actually triggers an immune response in animals.

Phase 1 trials. If you get permission from your government's regulator to run clinical trials in humans, you'll start a small one involving a few dozen volunteers, some of whom also get a placebo. At this point you're just looking to see if it causes any adverse effects.

Phase 2 trials. You'll give the vaccine candidate to several hundred people and measure whether it's safe, check whether it bolsters their immune systems in the right way, and calculate the proper dosage.

Phase 3 trials. You'll run even larger trials involving thousands or tens of thousands of people, half of whom get a placebo or the most effective vaccine that's currently available. In Phase 3, you want to do two things, both of which require lots of volunteers from various communities where the disease you want to block is prevalent. One goal is to prove that the vaccine significantly reduces disease when compared with a placebo. Once the trial is under way, you have to wait until you have enough cases of sickness to know whether most of the infections are among people who get the placebo rather than those who get the vaccine. The other goal in this phase is to identify relatively rare bad side effects, which might show up in, say, one in every 1,000 cases. So even with 10,000 participants, you'll see the side effect in just 10 of them.

Just as in a drug trial, you'll also need a diverse pool of volunteers from both sexes and different communities, races, ethnicities, and age groups. Stephaun Wallace, an epidemiologist at Fred Hutch in Seattle, is one of many people around the world who are trying to deepen the pool of potential volunteers.

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Growing up Black in Los Angeles, he experienced firsthand how race shapes every part of how society treats people—including the medical system. After moving to Atlanta in his twenties, he created an organization that provided assistance to young Black men who were HIV-positive. That experience ignited his interest in health inequities and led him to a career working to address them.

Wallace's work at Fred Hutch is particularly focused on improving the way clinical trials are run. He and his colleagues make a point of reaching out to diverse groups of people, including consulting with leaders from different communities, tailoring communications for those communities, making scheduling more flexible, and writing consent forms with accessible, nonscientific language.

Wallace was working on trials of potential HIV vaccines when the pandemic hit and quickly shifted to trials for most of the major COVID vaccine candidates (as well as some treatments). He even participated in one of the clinical trials himself, hoping that it would convince more people who look like him that the vaccines are safe. As a result, more people of color participated in those trials than in any previous one that Wallace had been involved in.

Even though vaccine trials had to be sped up during COVID—just as drug trials were—the standards for safety and effectiveness didn't change. Each vaccine approved by the WHO was tested for safety in at least 3,000 volunteers in clinical trials, and in most cases, thousands more than that. In fact, because COVID vaccines have been given to so many people and their safety records tracked so closely, scientists now have extensive safety data on the various vaccines on the market—even in groups like pregnant women, who are usually not prioritized in clinical trials for vaccines.

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You may recall that after COVID vaccines hit the market, there were reports that some of them appeared to raise very slightly the risk of a condition in which small blood clots form in the blood vessels, causing bruises, fever, and shortness of breath. The risk turned out to be tiny: Out of 100,000 vaccinated people, the first dose of a vaccine might cause this condition in one person. The second dose didn't cause any extra risk. You were more likely to be killed by lightning than to get a clot from a vaccine.[18]

After reviewing the evidence, even the most stringent regulators decided that this risk was outweighed by the benefits of getting a vaccine—especially because the odds of developing similar blood clots were much higher in people who caught COVID. The vaccine manufacturers added a warning label to the labels on the vaccines, and both of them stayed on the market.

Some people saw this incident as proof that the safety system wasn't working. But I see it as proof that the system *did* work—because we were able to detect an extremely rare side effect, assess the evidence, and weigh the risks and benefits.

Another reason COVID vaccines got approved so quickly is that the people responsible for approving them worked insanely hard, reducing a process that can take years into a matter of months. Government employees in Washington, D.C., Geneva, London, and other cities worked around the clock to examine data from vaccine trials and go through those hundreds of thousands of pages of documents. Keep this in mind the next time you hear someone bad-mouthing government bureaucrats. If you were one of the people who got a COVID vaccine fast, and if you felt confident that it wouldn't seriously hurt you, you have many unsung heroes at the FDA working over the Christmas holidays to thank for it.

As for how we might accelerate trials and approvals even faster next time, the efforts that I mentioned in Chapter 5 to prepare for trials ahead of time—agreeing on protocols and setting

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up the infrastructure for running them, for instance—will help with vaccines just as much as with drugs. In addition, during COVID, researchers and regulators have learned a great deal about how safe mRNA and viral vector vaccines are, and they'll be able to use this understanding to evaluate candidates even faster in the future.

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Let's continue the hypothetical outbreak example from Chapter 5. Suppose the world wasn't able to contain it in time, and it's going global, so we'll need to vaccinate billions of people. Several vaccines have made it through the approval and review process and are licensed for use in humans. Now we need to solve a whole other set of problems: How do we make enough of it and distribute the doses so they do the most good?

To give you a sense of how many more doses we'll need to make: The world typically produces around 5 billion doses of vaccines every year—that's counting all childhood vaccinations, flu shots, polio vaccines, and more. If there's a huge outbreak, we'll need to make nearly 8 billion doses of a new vaccine (one for just about every person on earth), and maybe as many 16 billion (if it's a two-dose vaccine). And we need to do it without backsliding on other lifesaving vaccines. Our goal should be to do it in six months.

And, if you're a vaccine manufacturer, you're going to face challenges at each step in the manufacturing process:

- In the first step—producing the active ingredient that makes your vaccine work—you might need to grow cells or bacteria, infect them with the pathogen you want to stop, and harvest the substances they produce for your vaccine. To do this, you'll need a container called a bioreactor—either a reusable steel vat

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or a single-use plastic bag—but the supplies of both are limited. Early in the pandemic, bioreactors were bought up en masse by various companies hoping for an early breakthrough. If you couldn't find toilet paper at the store, you know how they felt.

- Next, you'll mix your vaccine with other things to make it more effective or stable. If it's an mRNA vaccine, you'll need a lipid. If it's another type, you might need what's known as an adjuvant, a substance that sets off red alerts in your immune system and shouts: "Hey, come look at this new shape over here! You'd better learn to attack it." Believe it or not, one of the most effective adjuvants in the world is derived from the inner bark from the Chilean soapbark tree. Unfortunately, these trees are relatively rare, so your manufacturing may be held up while you stand in line for your allotment of bark. In the future, we need to be able to make synthetic versions of adjuvants so we can scale up manufacturing quickly.
- Finally, you'll need to pour your doses into vials. You'll need sterile, highly precise equipment, and each part of the vials you use will have to meet exacting specifications, down to the type of glass and stopper. (At one point during COVID, there were fears that the world would run out of the high-grade sand used to make the necessary glass.) You'll need to label your vials according to rules set by the country in which you'll sell it, including which

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languages can be used, and those rules will vary from place to place.*

For years, there has been a debate in global health about when waiving companies' intellectual property rights is an effective way to get more vaccines or drugs produced. In some cases, waivers have helped make low-cost drugs available, such as the story of the HIV treatments I mentioned in Chapter 5. This history got a lot of attention again in 2021, as advocates called on the World Trade Organization to waive the intellectual property protections for COVID vaccines.

Unfortunately, this movement came too late to help close the supply gap. There are a limited number of facilities and people in the world who can produce vaccines that meet all the national and global requirements for quality and safety. And, because most vaccines are made using very specific processes, you can't simply switch a facility from making, say, viral vectors to making mRNA vaccines. You'll need new equipment, and even then, your facility will still need to be approved to make the new product.

Suppose the WHO has required companies to release their recipes for approved vaccines, and now Company A wants to duplicate Company B's approved vaccine and meet all the necessary standards. But just getting B's recipe won't be enough—they'll also need information from B like specifics about their manufacturing processes, data from clinical trials, and details about what they've told regulators. Because some of this information applies to B's other

* During COVID, the Gates Foundation was involved in many efforts to streamline and standardize labeling requirements.

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products—maybe they want to use the same process to make a cancer vaccine—they will hesitate to release it.

If A proceeds anyway but deviates from B's manufacturing process in even the slightest way, they'll have to go through new clinical trials, defeating the purpose of getting B's recipe in the first place. And in the end, the two companies will release two seemingly similar products that may have different levels of safety and effectiveness—creating confusion about vaccines at a time when what everyone needs is clarity. Company A benefits because it can't be sued by B, but otherwise, it has not gained much.

What's more, making a vaccine is typically more complicated than making a drug. Remember that many drugs are made using chemical processes that are well defined and measurable. But many vaccines don't work that way. Manufacturing them often involves living organisms—anything from bacteria to chicken eggs.

Living things don't necessarily act exactly the same way every time, which means that even if you follow the same process twice, you might not get the same product both times, and it's much harder to tell whether the generic version matches the original in all the important ways. The process of making a vaccine typically involves thousands of steps! Even an experienced vaccine maker finds it difficult to duplicate another company's process and is most successful when it gets technical assistance from the original producers.

This is why we have generic drugs but not generic vaccines. Although the situation might change in the future, particularly as the mRNA vaccine technology matures, it's not a realistic possibility right now. In 2021, waiving intellectual property protections would not have meaningfully increased the supply of COVID vaccines.

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The key decisions that determined how quickly there would be enough vaccine supply for the entire world were made in 2020. In the first half of that year, the Gates Foundation worked with many of the companies in the vaccine ecosystem on ways to maximize the number of vaccines produced. The approach used wasn't simply to make the intellectual property available and ask manufacturers to do their own factory design and trials, but rather to cooperate and share all the information—including factory design and methods for verifying the quality of the vaccines—and work together with regulators. Until 2020, such deals were rare, but given the urgency of producing lots of vaccines quickly, they were the best way to get additional factories into production without compromising regulatory approval or quality.

These deals are known as second sourcing. In a second-source deal, one company with a viable candidate agrees to work with another company to make that vaccine in its own facility.19 They share not only the recipe but also the knowledge about how to use it, as well as personnel, data, and biological samples.

These are complex arrangements that involve accounting for the costs and time associated with the transfer, negotiating the necessary licenses, and settling on terms that will be acceptable to both parties. And there are lots of incentives pushing against them for both companies: Imagine Ford inviting Honda to use its factories for making Accords.

But when they work, these arrangements are remarkable: It was a second-source deal with AstraZeneca—not a government-mandated intellectual property waiver—that allowed Serum Institute of India to produce 100 million doses at a very low cost and in record time.

Before COVID, most vaccines destined for low- and middle-income countries were created not via second-source agreements, but by low-cost manufacturers who got philanthropic funding to do some of the development on their own.

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But during the pandemic, companies accelerated the deals. In less than two years, a single manufacturer, AstraZeneca, signed second-source deals involving twenty-five factories in fifteen countries. (Recall that AZ also agreed to forgo its profits on the COVID vaccine.) Novavax signed one with Serum Institute of India, or SII—leading to a vaccine now being widely used in many countries—and Johnson & Johnson inked one with the Indian company Biological E. Limited. All told, second-source deals led to the production of hundreds of millions of additional COVID vaccine doses. And in the future, they could be done even faster if companies that have them now can maintain their relationships with each other, so they don't have to start from square one in the next outbreak.

I'm also hopeful that this is yet another type of problem that mRNA vaccines will help solve. Many of the conventional ways to make vaccines are pretty arcane, which means there are many Is to dot and Ts to cross in making a second source deal. But because the basic approach to mRNA is pretty much the same—you just swap out your old mRNA for the new one—it should be easier to transfer between companies. There are also some new technologies in the pipeline that, if they prove out, will make it cheaper and easier to build and run factories. This would make them more flexible, able to adapt as needed to make different types of vaccines.

Finally, there are a couple of steps that a global body like the WHO could take. One is to standardize the labels that go on vials, so companies don't have to make bunches of different labels for the same vaccine. The other is to buy up raw materials for making vaccines and vials ahead of time, and distribute them later to the manufacturers with the most promising candidates. CEPI did this with glass vials during COVID, ensuring that there would be a reserve supply if any companies hadn't acquired enough on their own.

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Vaccines significantly reduce the risk of severe disease and death. Yet vaccination rates have divided, heartbreakingly, along income lines. In 2021, more than half of the world's population received at least one dose of a COVID vaccine. In low-income countries, only 7 percent did—and even worse, young, healthy people in rich countries who aren't likely to get sick or die from COVID were getting vaccines before older people and frontline workers in poorer countries, who were at much higher risk.[20]

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Vaccine inequity. As of October 2021, people living in wealthier countries had far greater access to COVID-19 vaccines than people living in poorer ones. (Our World in Data, UN Population Division)

It's natural to think we could close these inequities by allocating the doses we have more fairly. Certainly, rich countries deserve credit for sharing more than a billion doses with poorer countries during COVID, as do COVAX and the WHO for their efforts. But the gaps they tried to fill were enormous. And sharing doses in itself is not a permanent solution—we can't assume that countries will always do that. How many politicians would be willing to tell young voters they can't be vaccinated because the doses are going to another country, at a time when schools were still closed and people were still dying?

That's why I think that, rather than focusing primarily on reallocation, the more practical approach is to focus on making more doses—so many that the question of who should be able to draw from a limited supply is no longer an acute issue. In 2021, the White House published a smart plan with ambitious goals:[21] Develop and test a safe, effective vaccine within 100 days of recognizing a threat, and be able to produce enough for all Americans 30 days after that and for

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the entire world another 70 days after that. If it's a two-dose vaccine, that means producing some 16 billion doses roughly six months after getting approval.

Because it costs so much to develop a new product, the companies that invent new vaccines try to recoup their costs as quickly as possible by selling doses at the higher prices that rich countries can afford. Even if their original production process results in a treatment that's quite expensive, they have little incentive to redesign it, because then they would have to go through a new regulatory review.

For a number of vaccines, the solution has been to work with manufacturers in developing countries to come up with a new vaccine for the same disease, while also making sure that the cost of manufacture is very low. This is far easier than inventing the vaccine in the first place because you know it's possible to make a vaccine, and you understand the immune response that you need to provoke.

The pentavalent vaccine—which protects against five diseases—is a great example. The most widely used one was invented in the early 2000s, but there was only one manufacturer, and at more than $3.50 per dose,[22] it was quite expensive for low- and middle-income countries. Our foundation and its partners worked with two vaccine companies in India—Bio E. and Serum Institute, the same two that more recently started producing COVID vaccines—to develop a pentavalent vaccine that would be affordable everywhere. Today that vaccine costs about $1, and it is given to 80 million children a year. That's a sixteen-fold increase since 2005.[23]

Similar deals have led to new vaccines for two major killers of children: rotavirus (which causes diarrhea) and pneumococcal disease (a severe respiratory illness). As I was writing this book, India announced that it would expand access to the pneumo vaccine from less than half the

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country to the entire country—a decision that will save tens of thousands of children every year.[24]

What we've learned is that creating an entire vaccine-making ecosystem is a long walk down a hard road. But the obstacles can be overcome.

For one thing, there's the issue of regulatory approvals. The WHO has to green-light every vaccine factory before it can start production. If you built your factory in a country with what's known as a "gold-standard" regulator, then the WHO review is relatively speedy. If not, then the WHO review is a lot more thorough and time-consuming.

Today, only a handful of developing countries have gold-standard regulators, and most are in South Asia or Southeast Asia., but regional agencies in Africa are working with the WHO and the European Union to improve the quality of regulation on the continent. Governments are also collaborating on regional standards for vaccines, so manufacturers don't have to meet different safety and efficacy requirements in each country.

There's another challenge in addition to the approval process: Vaccine manufacturers need other products to make between outbreaks, or they'll go out of business. As new vaccines become available for diseases like malaria, tuberculosis, and HIV, they'll increase the overall size of the vaccine market, potentially making room for new producers. And in the meantime, countries can take on the fill-and-finish process—putting vaccines made elsewhere into vials and distributing them.

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In the mid-2000s, during a trip to Vietnam, I visited a rural health clinic, hoping to get a firsthand look at some of the challenges the staff there were dealing with. As a big fan and

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funder of vaccines, I was especially interested in what it took to deliver a vaccine over what people in the field call “the last mile”—the journey from a storage facility to a remote clinic and finally to a patient.

The WHO had recently approved a new vaccine funded by the Gates Foundation to protect children from rotavirus. At the time, more than 400,000 children were dying of rotavirus every year. This clinic had received a shipment of the new rota vaccine, but there was a problem. To make a point, one of the health workers took a few of the vials and tried to put them a portable cooler. (These coolers are what vaccinators carry vaccines in when they go into the field.)

The point of the demonstration was to show me a problem: The new vials didn’t fit in the cooler.

This may seem like a minor detail, but it’s a big problem. Vaccines will spoil if they aren’t kept cold—typically between 2 and 8 degrees C, or roughly 35 to 46 degrees F—during the trip from the factory to their final destination. If a health clinic can’t keep the vials cold, the doses are spoiled. (Keeping them at the right temperature throughout the process is known as *maintaining the cold chain.*)

The manufacturer of the rotavirus vaccine soon fixed the problem by changing the size of the vials, but it was a vivid illustration of a fundamentally important point about vaccines: Delivering them to every part of the world where they’re needed is an enormous logistical challenge, and seemingly small decisions like the size of a container can throw everything off.

The good news is that the cold chain and other hurdles in delivering vaccines have been solved in most parts of the world. Today, 85 percent of children get at least three doses of the

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routine infant vaccines. But getting to the remaining 15 percent is a big challenge. (If it were easy, it would've been done by now.)

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Global vaccination coverage at its highest. The percentage of children who receive three doses of diphtheria-, tetanus-, and pertussis-containing vaccines (DTP3) has improved substantially since 1980. (WHO)

For the sake of making sure every child gets the basic vaccines that most of the world enjoys, and preparing to stop outbreaks before they go global, we need to be able to deliver vaccines everywhere, even in the most remote places. Let's look at what it takes to get a vaccine from the factory all the way to the patient.

Depending on where a container of vaccines is headed, there might be as many as seven way stations along the route. The container arrives in a country by boat or plane and is taken to a national storage facility. From there, it will be shipped to a regional facility, then a district one, then a subdistrict one, and then a community facility. From there, a health worker will load up a pack of vaccines and go around the local area, vaccinating people in and around their homes.

At every step of the way, the container has to maintain just the right temperature, not just at each storage facility, but on the road from one facility to another as well. The power could go out at any one of the facilities, shutting down refrigerators and putting the vaccines at risk of spoiling.

Ultimately, vaccines only reach the people who need them because of the health workers who are dedicated to taking them that last mile. Their work requires precision and stamina—they often have to walk many miles every day on their rounds—and can be risky. Depending on which vaccines they're administering, they might have to prepare each dose by diluting a powder

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in a liquid, carefully using just the right proportions of each. They might get stuck by a needle during the process. They have to watch out for counterfeit vaccines. They must keep good records of who has been vaccinated.

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A health worker travels several miles each day, often through rigorous terrain, to deliver vaccines to people living in remote locations.

There's phenomenal work going on to solve these problems. Vaccinators in India are already using a new portable cooler that prevents the vaccines from freezing if the ice in the cooler is too cold. Researchers are also working on new vaccine formulations that wouldn't need to be kept as cold at every step of the journey. They're reducing shipping costs and saving refrigerator space by making the packages smaller, and they're simplifying the process for health workers by getting rid of powders that have to be mixed with liquid on site.

Bar codes printed on the vials will let vaccinators use their cell phones to confirm that the vaccines are legitimate, just as you might scan a QR code to pull up the menu at a restaurant. Advanced methods for delivering vaccines, such as replacing the needle and syringe with a small patch containing microneedles—picture something that looks superficially like the nicotine patches that people use to stop smoking—are making the process safer for everyone, and they might make vaccines easier to deliver too.

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You've probably read (in this book if not somewhere else) that the goal of vaccines is to prevent severe sickness and death, not to prevent infection. But that's not ideal, of course: A perfect vaccine would in fact keep you from getting infected, which would make a big difference

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in cutting down transmission—no one who was vaccinated could pass the pathogen to other people.

Perfecting vaccines to block infection entirely is a long-term goal, and in the meantime, we should also create a new type of drug called a transmission blocker. These drugs could be used in combination with vaccines to protect you completely from infection: The vaccine would give you long-term protection from severe disease, and the drug would provide shorter-term protection from any infection. You would use the drug during intense periods of transmission, but if it didn't work or you didn't take it often enough, you would still have the vaccine's protection from severe sickness and death.

Rather than attacking the virus in your blood, transmission-blocking drugs would keep it from getting into your blood in the first place. In your mucus—yes, I'm mentioning mucus a lot!—there are particular immune cells that have four binding sites they can use to grab a pathogen and neutralize it. A blocker would teach these cells to watch out for a particular virus (flu or COVID, for example) and latch on to it. Because they have so many binding sites, these mucosal immune cells can attack viruses much more efficiently than the immune cells in your blood. One unpublished paper I've seen suggests that, in mice at least, these cells might provide ten times as much protection.25

The technology behind these blockers is still in its early days, but if we could get blockers to the point where they can be developed quickly—the way mRNA vaccines now can—and delivered by nasal spray or pill, they'd be a phenomenal tool for keeping an outbreak at a low level. .

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And if they were cheap and long-lasting enough—a few pennies for a dose that lasts thirty days or more—it might make sense to use them to block seasonal respiratory infections. Every schoolchild could get a dose at the beginning of each month. You could even set up sniffing stations where people stop by every few weeks for another dose.

There's some exciting work being done on blockers. The company Vaxart, for example, has produced promising data on an oral transmission blocker for flu and is working on one for COVID. On the whole, though, transmission blockers aren't getting nearly enough attention, given what a breakthrough they would be for new and existing diseases alike. Governments and companies need to invest a lot more in them, with a particular focus on making them affordable and practical in low-income countries as well as rich ones.

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None of these tools will matter, though, if people refuse to use them. Whenever I talk to someone about blockers or vaccines, whether it's a scientist, politician, or journalist, there's one subject hanging over everyone's heads: vaccine hesitancy. I imagine that someday we'll have to confront blocker hesitancy too.

Researchers who are studying vaccine hesitancy have gained a few insights. One is that there isn't one single reason for it. Fear and suspicion are certainly factors. So are things like how much people trust the government and their ability to get information that's timely and accurate. Many Black Americans, for example, are generally skeptical of the government's good intentions when it comes to health, and understandably so. For forty years, the U.S. Public Health Service ran the infamous Tuskegee Study—a horrific experiment in which it looked at the

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effect of syphilis on hundreds of Black men, without giving them their true diagnosis, and even withholding treatment once it became available eleven years into the study.

There are also socioeconomic factors that don't have anything to do with fear, mistrust, or misinformation—like whether you're able to get to an immunization site. Many people don't have the transportation to get to a clinic that's miles away. Maybe they can't afford to stop working or get someone to watch their kids. In some parts of the world, it's not safe for women to travel long distances by themselves.

But the research also shows that you're not going to persuade uncertain people by simply throwing more facts at them. You need to meet them where they are—literally and figuratively.

That means vaccines need to be affordable or free, and available nearby at a time when people can get to them. It helps when people see politicians and celebrities getting vaccinated. And maybe most of all, they need to hear the truth from trusted sources, like religious leaders and local health workers they already know.

In Zambia, anyone in search of good information can tune the radio to FM 99.1. Once a week, Catholic nun and social worker Sister Astridah Banda hosts the "COVID-19 Awareness Program," a talk show where she and her guests discuss health topics—with a focus on preventing COVID—and answer questions from callers.Sister Astridah is not a doctor, but she is passionate about public health. When COVID arrived in Zambia, she noticed that most of the public health bulletins were being written in English. Although English is an official language in Zambia, many people speak one of the country's local languages, and they were missing out. She approached Yatsani Community Radio and asked to start broadcasts on which she could translate the bulletins into local languages and share other information about the virus. Her show now reaches more than 1.5 million people.

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Sister Astridah Banda is a Catholic nun and social worker from Zambia. Here we can see her delivering important information about COVID-19 on Yatsani Community Radio in Lusaka, Zambia.

In any outbreak, the world needs many Sister Astridahs, and other efforts too. Driving up vaccination rates requires both supply and demand—you need to have enough vaccines, and people need to want them. As I've argued in this chapter, innovative policies and technologies will help us make and deliver enough vaccines for everyone. Making sure the demand is there too, by helping the uncertain become certain—and by persuading the unwilling as well—will be just as important.

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This chapter boils down to two key points. First: As awful as COVID is, the world is lucky to have made vaccines as quickly as we did. And second: We've only touched the surface of how good vaccines can be. Because we can't assume we'll be so lucky next time—and because there are phenomenal opportunities for saving lives beyond the threat of pandemics—the world should be pursuing an ambitious agenda to make vaccines even better.

I see seven areas that should be priorities for funding and research:

- **Universal vaccines.** Thanks to the advent of the mRNA vaccine, it should be possible to create injections that target several variants of the same pathogen, or even multiple pathogens. We could have vaccines that protect you from

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coronaviruses, flus, and the respiratory virus known as RSV—and with some luck, we could even eradicate all three virus families.

- **No more second doses.** One of the big hurdles in COVID vaccination has been the need to deliver two doses. It's an inconvenience for people who can get to a clinic or pharmacy easily, who don't have to worry about child care, and who can get time off work, but for others, it's a huge barrier. New formulations of vaccines would give you the same protection with one shot as you now get with two; given the work that's already under way, I think this is an achievable medium-term goal.
- **No more boosters.** Although COVID vaccines help keep you out of the hospital if you get sick, their benefits in reducing infection and sickness wane over time. An ideal vaccine would protect you for your whole life, rather than requiring yearly boosting; research into the immune system should allow us to figure out how to provide such long-lasting protection.
- **Total protection.** The best COVID vaccines available (as I write this, at any rate) cut your risk of infection by about 50 percent. If we could get that number closer to 100 percent, then we would shut down the spread of the disease substantially—breakthrough cases would be a thing of the past. We need to generate more protection in your mucosal tissues including the mouth and nose.
- **No more ice chests.** Vaccines would be far easier to deliver, particularly in the developing world, if they didn't have to be kept cold all the time. Researchers have been working on this problem since at least 2003, and we still don't have

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a complete solution. If we did, it would revolutionize the field of global health.

- **No more needles and syringes.** Vaccines and transmission-blocking drugs that you could inhale with a nasal spray would be much easier to administer than ones that have to be injected. And the micro-needle patches I wrote about earlier would make needles and syringes obsolete. You could pick one up at the grocery and apply it yourself, without help from a health care worker who has to put a needle in your arm, and it might not even need to be kept cold. Researchers are already testing prototypes that deliver measles vaccines, and although this work is moving ahead fast, we need more time and effort to get them ready for market, produce huge volumes of them, and use the patch technology as a platform for going after other diseases.
- **Expanded manufacturing.** For all these advances to have an impact, developing and approving them won't be enough. We'll also need to manufacture them in massive volume—enough for the entire world—and within six months. To do that, we'll need production capacity throughout the world, including in regions with the worst disease burden. And we'll need to be creative about how all this new infrastructure can stay in business even when there isn't a pandemic threatening to emerge.

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Chapter 7

Practice, practice, practice

In July 2015, *The New Yorker* published an article that got attention up and down the West Coast of the United States.1 I live just outside of Seattle, and I remember emailing the article to friends just as it was arriving in my inbox from other friends. It became a regular source of dinner-table conversation that summer.

The headline on the article was, "The Really Big One: An earthquake will destroy a sizable portion of the coastal Northwest. The question is when." The author, a Pulitzer Prize–winning journalist named Kathryn Schulz, explained that a huge stretch of coastline, from Canada into Washington state, Oregon, and northern California, sits near what's known as the Cascadia Subduction Zone. Cascadia is a fault hundreds of miles long beneath the Pacific, where two tectonic plates meet and one is sliding underneath the other.

Subduction zones are inherently unstable and tend to cause earthquakes. Seismologists figure that massive earthquakes occur along the Cascadia zone an average of every 243 years, and that the last one occurred around 1700. The 243-year average is debated, and Cascadia may go much longer than that between two quakes, but reading the article, none of us locals could dismiss the fact that the last Cascadia quake happened more than 315 years ago.

The article cited horrific projections: A Cascadia quake, and the tsunami that would result from it, could kill nearly 13,000 people, injure 27,000 more, and displace a million people from

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their homes. And the toll could be much worse if the quake occurred during the summer, when tourists crowd the beaches of the West Coast.

To test how ready the Pacific Northwest is for the really big one, the federal government oversees a series of periodic full-scale exercises known as Cascadia Rising. The 2016 exercise involved thousands of people[2] from dozens of government agencies, the military, nonprofits, and businesses.[3] A lengthy after-action report detailed the results and issued a series of lessons learned during this real-life exercise. Among other things, the report noted, "Catastrophic response requirements are fundamentally different than any response we have seen before. . . . A *massive* response will be required." Another Cascadia Rising exercise is scheduled for summer 2022.

I wish I could report that Cascadia Rising has led to major changes and the Pacific Northwest is now as ready as it can be for a catastrophic quake. Unfortunately, that's not the case. For one thing, retrofitting the region's buildings to make them seismically sound would be prohibitively expensive.

But the exercises are still worthwhile. At least the government is trying to get people to focus on the problem.

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We tend to use words like "drill" and "exercise" interchangeably, but in the world of disaster preparation, they don't mean the same thing at all.

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A drill, for example, is a test of just one part of a system—say, whether the fire alarm in your building works, and whether everyone knows how to get out quickly.

Then, moving up the scale of complexity, there's the tabletop exercise, a discussion designed to identify and solve problems. More complicated still is the functional exercise, a simulated disaster that tests how well the whole system operates, but without moving people or equipment.

Finally, there are full-scale exercises, such as Cascadia Rising. These are designed to get as close to the real thing as possible—complete with actors pretending to be sick or injured and vehicles moving people and equipment around.

For as long as I've been learning about pandemic preparedness and prevention, I've been amazed that there isn't an ongoing series of full-scale exercises designed to test the world's ability to detect and respond to an outbreak. As the WHO's flu preparedness program put it in a 2018 guide to running outbreak exercises, "Considerable efforts and resources have been invested by countries around the world in developing national pandemic influenza preparedness plans and the capacities needed to respond to an influenza pandemic. However, to be effective, plans need to be tested, validated and updated periodically through simulation exercises."4

There have been many tabletop and functional exercises for disease outbreaks, but perhaps only a handful of country-scale ones designed to simulate an outbreak of flu or coronavirus.* Credit for running the first one seems to belong to Indonesia, which held a full-

* Exercises related to animal-borne diseases aren't unheard of. For example, four years after a disastrous outbreak of foot-and-mouth disease in 2001, the United Kingdom and five

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scale outbreak exercise in Bali in 2008.[5] Taiwan followed with a full-scale simulation involving the arrival of passenger with avian flu at the national airport. There have been none involving entire regions or the world.

Although details are sometimes murky because governments classify some of the results—especially of full-scale exercises—it appears that the history of these simulations is spotty. On the positive side are countries like Taiwan and Vietnam, which have held frequent simulations at various levels of complexity, taken action to fix problems that were revealed, and set themselves up to respond especially well to COVID.

But just as often, in other countries, these exercises end with a series of what-ifs and missed opportunities.

For example, the United Kingdom ran an exercise called Winter Willow in 2007 and another, Cygnus, in 2016, both focused on flu outbreaks. Cygnus in particular highlighted problems with the government's readiness and produced a series of classified recommendations that went unheeded—and which caused a scandal when *The Guardian* revealed them during the first year of the COVID pandemic.[6]

The United States had a similar experience of its own. In 2019, the U.S. government ran Crimson Contagion, a series of exercises designed to answer one question: Was the country ready to respond to an outbreak of a novel flu virus from China?[7]

Overseen by the Department of Health and Human Services, Crimson Contagion occurred in two phases. The first involved a series of seminars and tabletop exercises held

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Nordic countries ran simulations to test their readiness.

(**https://www.sciencedirect.com/science/article/pii/S2212420921002119?via%3Dihub**)

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between January and May, in which people from all levels of government, plus the private sector and nongovernmental organizations, got together to discuss existing plans for responding to an outbreak.

In the second phase, they put these plans to the test in a functional exercise. Over four days in August 2019, participants worked through a scenario in which tourists visiting China have become ill with a respiratory illness caused by a virus. They fly out of the airport in Lhasa and travel to other cities in China before flying home to their respective countries.

The virus turns out to be just as contagious as the 1918 flu strain, and only slightly less deadly. It rapidly spreads from one human to another, making its first U.S. appearance in Chicago and quickly moving to other major cities.

At the beginning of the exercise, it has been forty-seven days since the first U.S. case. There are moderate or high caseloads across the Southwest, Midwest, and Northeast. Models are predicting that the virus will make 110 million people in the U.S. sick, put more than 7 million in the hospital, and kill 586,000 Americans.

Over the next four days, the participants would debate decisions that would have been unfamiliar to anyone not already versed in outbreak response work: quarantines, personal protective gear, social distancing measures, school closures, public communications, the purchase and distribution of vaccines, and more. Today, of course, these terms are part of our everyday vocabulary.

The scope of Crimson Contagion's functional exercise was enormous. It involved 19 federal departments and agencies, 12 states, 15 tribal nations and pueblos, 74 local health departments, 87 hospitals, and more than 100 groups from the private sector. When it was all over, the participants got together to discuss how it had gone. While they found a few things that

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worked well, they found many more that did not. I'll mention just a few, which will sound eerily familiar.

No one in the exercise understood what the federal government was responsible for, versus what others would do. The Department of Health and Human Services didn't have clear authority to lead the federal response. There wasn't enough money to buy vaccines (in this scenario, there was already an available vaccine for the strain in question, but it hadn't been administered). State leaders didn't know where to turn for accurate information. There were huge discrepancies in how states planned to deploy scarce resources, such as ventilators, and some had no plan at all.

Some of the troubles were almost comically mundane, like something out of the TV show *Veep.* Federal agencies confused participants by unpredictably changing the names of conference calls. Sometimes the name of the meeting used some unrecognizable acronym, so people wouldn't show up. State governments, already understaffed, struggled to keep up with all the calls while also handling the response itself.

It is telling that in the official government report on the results of Crimson Contagion—dated January 2020, just as COVID cases were starting to mount—the word "diagnostics" appears only three times over fifty-nine pages. The report simply notes that diagnostics will be one of many supplies that will be hard to come by in a pandemic. Just a few weeks later, of course, the United States' inability to ramp up testing in a serious way would become tragically apparent. It bears repeating: America's failure to test people at anything near the scale that other nations achieved is the biggest mistake any country has made during the pandemic.

Crimson Contagion was not the first simulation designed to test America's readiness to handle an outbreak. That honor likely goes to a tabletop exercise with the ominous name Dark

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Winter, which was held over the course of three days in June 2001 at Andrews Air Force Base in Washington, D.C.

Surprisingly, Dark Winter wasn't organized by the federal government, but by independent organizations whose leaders were growing increasingly concerned about the potential of a bioterror attack on the United States and wanted to draw attention to the problem.

Dark Winter supposed that a terrorist group releases smallpox in Philadelphia, Oklahoma City, and Atlanta, infecting a total of 3,000 people. Less than two months later, the disease had spread to 3 million people and killed one million, with no end in sight.8 An observer I know commented that the outcome was: Smallpox 1, Humanity 0.

Other exercises followed: Atlantic Storm in 2005 (another smallpox attack), Clade X in 2018 (an outbreak of a novel influenza virus), Event 201 in 2019 (an outbreak of a novel coronavirus), a simulation at the Munich Security Conference in 2020 (a bio-attack involving an engineered influenza virus).*

Even though each of these U.S. exercises imagined different scenarios, were run in different ways, and used different methods, they had three things in common. One is that their conclusions are fundamentally the same—there are huge gaps in America's and much of the world's ability to contain outbreaks and prevent a pandemic—and they propose various ways to fill those gaps.

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* The Gates Foundation was one of the funders of the Event 201 exercise. Some conspiracy theorists suggested that it predicted COVID. As the organizers made clear, it wasn't a prediction, and they said so at the time. You can find a statement about this at centerforhealthsecurity.org.

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The second thing these exercises have in common is that virtually nothing was done as a result to make America more ready to handle an outbreak. Although some adjustments were made at the federal and state levels, we only need to look at what's happened since December 2019 to see that whatever changed was not enough.

The third is that, with the exception of Crimson Contagion, each of the U.S. simulations took place exclusively in conference rooms, and none of them involved moving real people or equipment from one place to another.

Full-scale exercises aren't run as often as tabletop and functional ones for the obvious reason that they're expensive, time-consuming, and intrusive. In addition, some public health leaders have argued that the best way to prepare for a pandemic is to simulate smaller outbreaks, which means not preparing for things that happen only in an epidemic or pandemic—problems like supply chains being disrupted, economies shutting down, and heads of state interfering for political reasons. It's also likely that, until 2020, the threat of a worldwide contagion seemed remote to most people, and therefore not worth the trouble and cost of a full-scale, real-life exercise.

Two years into COVID, the argument is much easier to make. The world needs to be running far more full-scale exercises that test its readiness for the next major outbreak.

In most countries, these exercises can be run by national public health institutions, emergency operations centers, and military leaders, with the GERM team that I described in Chapter 2 acting as an advisor and reviewer. For low-income countries, the world will have to bring in resources to help out.

Here's how a full-scale outbreak exercise might work. The organizers would pick a city and act as if it's experiencing a bad outbreak that could spread nationally or globally. How

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quickly can a diagnostic test for the pathogen be developed, manufactured at a high volume, and delivered wherever it is needed? How well, and how quickly, can the government get accurate information out to the public? How do local health officials handle quarantines? And—as we now know can happen—what if supply chains are cut, local health agencies make poor decisions, and political leaders interfere?

They would establish a system for reporting cases and running genetic sequencing on the pathogen. They would recruit volunteers to try out nonpharmaceutical measures, modify them based on how the disease spreads, and understand the economic impact they would have during a real emergency.

And if the pathogen spreads through human contact with animals, the exercise would evaluate a government's ability to dispose of the animals. Suppose it's an avian flu spread by chickens:* Because so many people rely on chickens for their livelihood, they'll be reluctant to slaughter the birds on the off chance they might spread a flu. Does the government have the money to compensate them for their losses, and a system for doing so?†

To make the exercise even more realistic, software would generate surprise events from time to time, throwing a wrench into the plan to see how everyone responds. Software would also be used to track the oerall simulation and record actions for later review.

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* In November 2020, the Danish government ordered the culling of 15 million mink out of concern about a COVID mutation that might move from them to humans.

† If you want more detail from experts on what an exercise might involve, see the WHO document "A Practical Guide for Developing and Conducting Simulation Exercises to Test and Validate Pandemic Influenza Preparedness Plans," available at **who.int**.

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In addition to advising countries on their exercise plans, the GERM team would measure readiness in other ways, for example by looking at how well a given country's health system is detecting and responding to non-pandemic diseases. If it's a place where malaria is a problem, how early does the system there detect big outbreaks? Or with tuberculosis, how well are they tracing the recent contacts of people who test positive? On their own, these proxies wouldn't tell researchers everything they need to know, but they would offer clues about weaknesses in the system that need more attention. The countries that do a good job of watching for, reporting, and managing endemic diseases are in a good position to respond to pandemic threat.

The GERM team's most important role will be to distill the findings from exercises and other measures of preparedness, and record the recommendations that come out of them—ways to strengthen supply chains, better methods for coordinating across governments, agreements to improve the distribution of medicines and other supplies—and then try to keep the pressure on world leaders to translate these findings into action. We've already seen how little things changed after Dark Winter, Crimson Contagion, and the other outbreak simulations. Unfortunately, there's no innovation that can make sure that after-action reports don't simply get stored on some website and then forgotten. Political leaders and policymakers will need to change this.

To get a sense of the different scales at which full-scale exercises can be run, let's look at two examples from disaster preparedness, starting with a relatively small one.

In the summer of 2013, Orlando International Airport in Florida simulated a horrific aviation-related disaster, an exercise designed to meet the federal government's requirement that all U.S. airports run a full-scale exercise once every three years. 9 In the scenario, according to an article in *Airport Improvement* magazine, a hypothetical jetliner carrying ninety-eight

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passengers and crew members experiences hydraulic problems and crashes into a hotel a mile from the airport.

The exercise involved 600 volunteers pretending to be victims, 400 first responders, and staff from sixteen hospitals, and it took place in a training facility with three aircraft and a four-story building designed to let firefighters practice on real fire. Officials had to establish who was in command. First responders had to triage patients, treat the ones they could, and transport others to the hospital. Security had to manage a crowd of observers. Friends and family of the victims had to be notified. News reporters needed updates. The exercise identified some necessary improvements and cost about $100,000.

At the other end of the complexity spectrum, there's the full-scale exercise run by U.S. military forces in August 2021.[10] Over the course of two weeks, personnel from the Navy and Marine Corps participated in the largest naval training event in a generation. The name of this exercise—Large-Scale Exercise 2021—understated its scope. Simulating concurrent wars with two world powers, LSE 2021 spanned seventeen time zones and involved more than 25,000 personnel, using virtual reality to allow participants to join remotely and to link units from around the world so they could share information in real time.

The analogy between war games and germ games is not perfect. Stopping an outbreak, after all, is different from fighting a war. Countries should be working together, not against one another. And unlike military exercises, outbreak simulations can involve the public and be highly visible so they're no more out-of-the-ordinary than a fire drill.

Still, the ambition of the LSE is impressive. The exercise created the opportunity for organizations spread around the world to share data and make fast, informed decisions together. It is hard to read about that and not think: *We need something like this for pandemic prevention*.

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So far in this book, I've stuck to writing about naturally occurring pathogens. But there is another, even more unsettling scenario that disease exercises must account for, a pathogen that's intentionally deployed with the goal of killing or maiming huge numbers of people: bioterrorism.

The history of turning viruses and bacteria into weapons stretches back for centuries. In 1155, Frederick I, the Holy Roman Emperor, lay siege to the town of Tortona (in modern-day Italy) and is said to have poisoned the local water wells with dead human bodies. More recently, in the eighteenth century, British soldiers distributed blankets used by smallpox patients to Native Americans. In the 1990s, members of the Aum Shinrikyo cult released sarin gas in the Tokyo subway, killing thirteen people, and reportedly released botulinum toxin and anthrax four times without causing any casualties. And in 2001, a series of attacks using anthrax sent through the U.S. mail left five people dead.

Today the natural pathogen that would make the most fearsome weapon is surely smallpox. It's the only human disease that has ever been eradicated from the wild, though samples are still kept in government labs in the United States and Russia (and possibly in other countries too).

What makes smallpox especially scary is that it spreads fast and has an extremely high mortality rate—killing around one third of everyone who's infected—it spreads very easily through the air, and because most vaccination programs stopped when it was eradicated in 1980, almost no one is immune to it anymore. (The United States does have a stockpile of smallpox vaccines large enough to protect everyone in the country, but as we've seen with COVID vaccines, distributing the doses would not be a simple matter—especially when people are panicking about an attack—and it's unclear how the rest of the world could be protected.)

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Part of the risk stems from the fall of the Soviet Union. As my friend Nathan Myhrvold notes in his paper "Strategic Terrorism," an international treaty banned bioweapons in 1972, but the Soviet Union continued its program into the 1990s—"thereby producing thousands of tons of weaponized anthrax, smallpox, and far more exotic biological weapons based on genetically engineered viruses. No one can be certain how far either the germs or the knowledge has spread since the collapse of the Soviet Union."

The chances that terrorists will get their hands on these existing weapons are compounded by the fact that the science behind engineering pathogens is no longer the sole province of highly trained scientists working in secretive government programs. Thanks to the advances in molecular biology of the past few decades, undergraduate students at hundreds of colleges and universities around the world can learn everything they need to know to engineer a biological weapon. And some scientific journals have published information that a terrorist could use to concoct a new pathogen, decisions that have led to vigorous debate about how to share research knowledge without adding to the risk.

We haven't yet seen a mass attack using an engineered bioweapon, but it is certainly not out of the question. In fact, during the Cold War, Soviet and American labs produced bioengineered anthrax that was resistant to antibiotics and evaded every vaccine. A nation-state or even a small terrorist group that developed smallpox that resisted treatment and vaccines would be capable of killing over a billion people.

A new pathogen could be designed that is highly communicable and lethal, but doesn't cause symptoms right away. Such a pathogen would spread quietly around the world, perhaps for years, before arousing suspicion. HIV, which evolved naturally, works this way; although people can infect others very quickly after acquiring it, their health doesn't fail for almost a decade,

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allowing the virus to go undetected while they spend years passing it to others. A pathogen that operated this way but didn't require intimate contact to spread, as HIV does, would be far worse than the AIDS pandemic.

"To put it in perspective," Nathan writes, a single attack that caused 100,000 casualties "would kill more people than were killed cumulatively in all terrorist actions by all parties throughout history. It might take anywhere from 1,000 to 10,000 typical suicide bombings to equal it." It is this scale of catastrophe—the kinds of events that can kill hundreds of thousands, millions, or even billions of people—that deserves far more attention than it gets.

Now, I am an optimistic person who's naturally inclined to focus on solutions. But even I have to admit that it's hard to write a list of responses that feels adequate to the threat of bioterrorism. Unlike a natural pathogen, an intentionally made disease can be designed to get around our tools of prevention..

All of the things we need to do to prepare for a deliberate attack are a super-set of the things we need to do to prepare for a natural one. Outbreak exercises can focus on attack scenarios and test our readiness. Better treatments and vaccines are important, no matter what the source of the pathogen is. Better diagnostics that return a result in thirty seconds would make it more practical to screen people at airports or public events, where we'd be likely to see the most spread of an engineered pathogen, and of course would be extremely useful for everyday testing as well. Mass-scale genomic sequencing of pathogens will help in an ordinary flu outbreak and during an attack. Even if an attack never comes, we'll be glad to have all of these tools.

We also need some approaches that are specifically designed to deal with deliberate attacks. I am hopeful that we'll have devices in airports and other big gathering places that detect pathogens in the air and sewage, but the technology is still years away. The U.S. government

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made an attempt at a much larger-scale version of this approach in 2003 with a program called BioWatch, which placed devices designed to detect airborne anthrax, smallpox, and other pathogens in cities throughout the country.

Although BioWatch still operates in twenty-two states, it is widely regarded as a flop. Among other faults, it relies on the wind blowing in exactly the right direction and takes up to thirty-six hours to confirm a pathogen. Sometimes the detectors fail to work for the most basic reason—they get unplugged.

Regardless of whether air-sniffing machines have a future, the possibility of a bioterror attack is another reason why the world should be putting far more money and effort into research on detecting, treating, and preventing diseases that can go global. Given the national security implications of an attack and the chance that the number of casualties could reach into the millions, more of this research should come from defense budgets. The Pentagon's budget is roughly $600 billion a year, while the National Institutes of Health budget is about $40 billion a year [CHECK THESE FIGURES]. As far as resources are concerned, the Department of Defense operates on a whole other level.

Although I'm optimistic that science will deliver better tools for stopping outbreaks from any source, governments should also consider a defense that is as low-tech as they come: a reward. There's precedent for it—governments frequently offer to pay people for information leading to the arrest of criminals and terrorists. Considering the scale of damage that can be done these days, governments should be willing to pay quite a bit to an informant who gave information to thwart a bio-attack.

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As governments work with the GERM team to plan their outbreak exercises, they would be smart to include purposeful attacks in their scenarios. The consequences of not doing so could be catastrophic.

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A good model of a country-level simulation is the one developed by Vietnam for a full-scale exercise in August 2018, designed to see how well the system identified a potentially worrisome pathogen.[11] I'm impressed by how meticulous it was.

Four actors were hired to play patients, family members, and their contacts, and they were given scripts with key information for the medical staff (who knew they were participating in an exercise). On Day 1, the actor portraying a fifty-four-year-old businessman arrived at the emergency room of a hospital in the northeastern province of Quang Ninh, complaining of a dry cough, fatigue, muscle pain, and shortness of breath. The doctor questioned him thoroughly enough to discover that he had recently traveled to the Middle East, where he could have picked up the MERS virus—a fact that, in combination with his symptoms, was enough to get him admitted to the hospital and isolated.

News of the worrisome case made its way up the chain of command within minutes, and soon the members of a rapid response team had arrived at the hospital and at the man's residence. The actors were tested using throat swabs, which were then replaced with samples that had been spiked with the virus that causes MERS. Although the samples weren't actually driven to the lab, the organizers waited the length of time it would have taken to transport them before lab staff ran real tests and correctly identified the positive MERS cases.

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The exercise didn't go off flawlessly—the organizers noticed a number of gaps in the process—but it would be surprising if it had been flawless. The point is that the gaps were identified and, most importantly, fixed.

This full-scale exercise was relatively limited compared to the national and regional ones that the world needs, but it had many of the necessary components. If exercises like this one were run by more countries and in more regions, they would keep us from making a classic mistake: preparing for the last war.

It will be tempting to assume that the next major pathogen will be as transmissible and as lethal as COVID, and as susceptible to innovations like mRNA vaccines. But what if it isn't? There is no biological reason why the next pathogen couldn't be far more lethal. It could quietly infect millions of people before a single person starts feeling sick. Our bodies might not be able to knock it out with neutralizing antibodies. With germ games, we'll be able to test against the wide range of pathogens and scenarios that the next outbreak might present.

Since the risk of a pandemic is higher than the risk of an all-out war, we should be running an LSE-sized global exercise organized by the GERM team at least once a decade. Each region should run another major exercise in the same decade, with advice from GERM, and countries should undertake smaller simulations with their neighbors. Military exercises such as Thailand's Cobra Gold and the international RIMPAC have been going for decades, and they've likely improved regional responses to typhoons and tsunamis.

There is one reason to hope that the reports generated by future exercises won't be ignored: experience. In the early days of COVID, many experts thought the countries that had gone through a previous coronavirus outbreak in 2003 were better prepared for COVID. Having experienced how bad it was, the theory went, they were ready—politically, socially, and

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psychologically—to do what it took to protect themselves. The theory proved true. The places hit hardest in 2003 included China, Taiwan, Hong Kong, Canada, Singapore, Vietnam, and Thailand. When COVID emerged, most of these governments responded quickly and decisively, limiting the numbers of COVID cases for more than a year.

Maybe Crimson Contagion, Dark Winter, and the rest didn't have more impact because their scenarios seemed so remote at the time—at least to most people and most politicians. Now, though, the idea of a virus spreading around the world, killing millions of people and doing trillions of dollars in damage, is very real for all of us. We should take the outbreak of a disease at least as seriously as we take earthquakes and tsunamis. To keep COVID from happening again, we need to practice stopping pathogens early, learn which parts of the system need to improve, and be willing to change even when it's difficult to do so.

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Chapter 8

Go after malaria, HIV, and TB too

The world's response to COVID has been exceptional. In December 2019, no one had heard of the disease. Within eighteen months, multiple vaccines had been developed, proven safe and effective, delivered, and given to more than 3 billion people, or roughly 40 percent of the earth's population. Humans have never responded faster or more effectively to a global disease. We accomplished in a year and a half something that normally takes a half a decade or more.

Yet within these phenomenal numbers, there were, and are, startling disparities.

To begin with, the pandemic has not affected everyone equally. As you may remember from Chapter 4, Black and Latino third graders in the United States have fallen twice as far behind in their classwork as white and Asian American students have.[1] Across every age group, Black and Latino people and Native Americans are twice as likely to die from COVID as white people in the U.S. are.[2]

The pandemic's overall impact was toughest in the world's low- and middle-income countries. In 2020, it pushed nearly 100 million people around the world into extreme poverty, an increase of about 15 percent and the first time the number had increased in decades.[3] And only a third of low- and middle-income economies are expected to return to pre-pandemic income levels in 2022, while virtually all advanced economies are expected to.

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As is so often the case, the people around the world who suffered the most got the least help. Those in poor countries were far less likely to get tested or treated for COVID than those in rich countries. The difference was most dramatic, though, with vaccines.

In January 2021, as COVID vaccines were rolling out, the director of the WHO opened a board meeting with a grim assessment. “More than thirty-nine million doses of vaccine have now been administered in at least forty-nine higher-income countries,” said Dr. Tedros Adhanom Ghebreyesus. “Just 25 doses have been given in one lowest-income country. Not 25 million; not 25 thousand; just 25.”[4]

By May of that year, the gap that Tedros had warned of had become front-page news. “The Pandemic Has Split in Two,” ran a headline in *The New York Times.* “Zero deaths in some cities. Thousands in others. The pandemic’s fault lines continue to widen as vaccines flow toward rich countries.”[5] One WHO official denounced the inequity as “a moral outrage.”[6]

There were countless examples. In March, 7.6 percent of Americans had been fully vaccinated, while 0.2 percent of Indians and 0.1 percent of South Africans had been. By July, the numbers had shot up to 49 percent in the U.S., but to just 5.8 in India and 2.8 in South Africa. Worst of all, people in wealthy countries who were at low risk of becoming severely sick were being vaccinated before people in poorer countries who were at a much higher risk.

To many observers, these facts were both infuriating and shocking. How could the world have billions of doses of a lifesaving vaccine and yet distribute them so unequally? Protesters marched, and politicians gave heartfelt speeches and pledged to donate doses.

Inside the world of global health, though, among people who work in the field, the reaction was different. Of course they were angry about the injustices of COVID. But they knew

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that COVID did not happen in a vacuum. Far from being the only inequity in global health, COVID wasn't even the *worst* inequity in global health.

Consider that, as of November 2021, COVID had caused some 19 million excess deaths—that's counting people who died of the disease itself, plus those who died from its ripple effects, for example tuberculosis patients who couldn't get treatment because their local health system was overwhelmed by the pandemic.

It is impossible not to be horrified by this number. But compare it with the deaths in developing countries over the past decade*: 24 million women and babies died before, during, or shortly after childbirth. Intestinal diseases killed 19 million people. HIV killed nearly 11 million people, and malaria more than 7 million, most of them children and pregnant women.7 And this is just in the past ten years—these diseases have been killing people for far longer than that, and they won't end when the pandemic does. They happen year after year, and unlike COVID, stopping them is not at the top of the world's agenda.

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Preventable deaths. In 2019, there was a significant gap in health disparities between countries in sub-Saharan Africa and high-income North America. (Institute for Health Metrics and Evaluation)

The vast majority of people who die from these conditions live in low- and middle-income countries. Where you live and how much money you have determines—to a great extent—your chance of dying young or growing up to become a thriving adult.

* From 2010 to 2019, the most recent year for which data is available as this book goes to press.

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Some of these diseases exist primarily in low-income tropical countries, which is why they are often ignored by much of the world. During the past decade, when malaria has killed 4 million children in sub-Saharan Africa, it has killed fewer than 100 people in the United States.

A child born in Nigeria is about twenty-eight times more likely to die before her fifth birthday than a child born in the United States.

A child born in the U.S. today can expect to live for seventy-nine years, but one born in Sierra Leone can expect to live just fifty-five years.8*

In other words, health inequities are not rare. I think many people in rich countries were shocked by the world's unequal response to COVID not because it was out of the ordinary but because health inequities are not visible to them the rest of the time. Through COVID—a condition the whole world was experiencing—everyone can see how unequal the resources are.

The point is not to depress you, or to wag a finger at the people who haven't dedicated their lives to global health. The point is that all these problems deserve more attention. The fact that most of the people who suffer from these diseases live in low- and middle-income countries doesn't make them any less awful.

My dad had a beautiful way of elevating the moral dimensions of this phenomenon. Years ago, in a speech to the United Methodist Conference, he put it like this: "People suffering from malaria are human beings. They are not national security assets. They are not markets for our exports. They are not allies in the war against terrorism. They are human beings who have

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* Differences in health usually hold true within countries as well as between them. In the U.S., Black women are three times more likely to die in childbirth than white women.

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infinite worth without any reference to us. They have mothers who love them and children who need them and friends who cherish them—and we ought to help them."

I could not agree more. When Melinda and I started the Gates Foundation two decades ago, we decided that providing resources to reduce and eventually get rid of this inequity would be our biggest focus.

The moral arguments do not fully persuade the governments of most rich countries to spend enough money to reduce or eliminate diseases that aren't killing their own people. Fortunately, there are also practical arguments that make the case even stronger, including the idea that better health makes the world more stable and improves international relations. I've been making that case for years, and now, in the COVID era, we have the additional benefit that investments in new medicines and developing-country health systems will help us stop pandemics before they engulf the world.

Virtually everything we should do to fight infectious diseases like malaria is also broadly helpful for future pandemics, and vice versa. It's not a binary choice in which we must decide whether to put money into pandemic prevention or infectious disease programs. It is just the opposite. Not only *can* we do both, we *should* do both, because they are mutually reinforcing.

Let's review the progress that the world has made in global health, and what made that progress possible. As bad as the disparities I've mentioned above are, they are smaller today than at any point in history; when it comes to basic measures of health, we're moving in the right direction. How this progress happened is a thrilling story, and it bears directly on the world's ability to prevent pandemics.

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I could cite dozens of statistics to show you the extent to which disparities in health have shrunk over the years. But I'm going to narrow it down to just one: child mortality.

From a clinical point of view, there's a good reason for using child mortality as a measuring stick for the health of the world. Improving child survival requires some interventions such as maternity care for their mothers, childhood vaccines, better education for women, and better diets. When more children survive, it's an indication that a country is getting better at doing these things.

But there's also another reason I use this statistic: When you look at health through the lens of child mortality, you can't help realizing just how high the stakes are. It is gut-wrenching to think about the death of a child. As a parent, I can't imagine anything worse, and I would give my life to protect my kids. For every child saved, there is a family that does not have to live through the worst anguish imaginable.

So let's look at how the world is doing on this fundamental measure of the human condition.

In 1960, nearly 19 percent of children died before their fifth birthday. Think about that for a moment: ***Almost one in every five children on earth did not live to see the age of five.*** And the disparity was enormous: In North America, the rate was 3 percent, while it was 21 percent in Asia and 27 percent in Africa. If you lived in Africa and had four children, you probably had to bury one of them.

Thirty years later, in 1990, the worldwide child mortality rate had dropped by half, to just under 10 percent. In Asia it was under 9 percent. Africa saw a similar but less dramatic improvement.

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Now skip ahead another three decades to 2019, the latest year for which data is available. That year, less than 4 percent of the world's children died before age five. In Africa, less than 7 percent did, and in Asia, less than 3 percent did.

I know this is a lot of numbers. To keep it simple, you can think of it as 20-10-5. In 1960, 20 percent of the world's children died. In 1990, it was 10 percent. Today it's less than 5 percent. The world keeps cutting the child mortality rate in half, and we're on track to do it again by [YEAR].

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More children are surviving today than at any other point in history. In the year 1950, roughly 20 percent of children born did not reach their fifth birthday. Today, that number is below 5 percent. (UN World Population Prospectus 2019)

This is one of the great stories in human history, one that every high school student should know by heart. If you remember only one fact that illustrates the trajectory of human health over the past half century or so, it should be 20-10-5.

And yet, 5 percent is still heartbreakingly high. It amounts to more than 5 million children a year. Taken in isolation, preventing 5 million deaths sounds like impossible task. But when you see the number in context, when you understand how far the world has come, it becomes a challenge and an inspiration to do even better. At least it did for me. It's the main focus of my work since I transitioned to working full-time at the Gates Foundation.

Over the years, I've given enough speeches on 20-10-5 and seen enough tweets and Facebook comments to know the question that inevitably comes next: Won't saving all these children lead to overpopulation?

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It's a natural concern. It just seems like common sense that if more children survive, the global population will go up faster. In fact, I used to worry about this problem myself.

But I was wrong. The answer is, emphatically and without a doubt, no—lower rates of child mortality do not lead to overpopulation.

The best explanation of why this is true was given by my friend Hans Rosling, whose influence on me is evident by the number of times I mention him in this book. I first became aware of Hans when he gave an unforgettable TED talk in 2006 called "The Best Stats You've Ever Seen."* Hans had spent decades working in public health, with a focus on poor countries, and he used his talk to share some surprising facts about how health was getting better.

Eventually, I got to meet Hans and spend a lot of time with him. I admired the way he showed people that the countries with the highest child mortality rates—places like Somalia, Chad, Central African Republic, Sierra Leone, Nigeria, and Mali—are also the countries where women have the most children.9

When the child mortality rate drops, so does the size of the average family. It happened in France in the 1700s, Germany in the late 1800s, and in Southeast Asia and Latin America in the second half of the twentieth century.10

There are various reasons that explain why this is the case; one factor is that parents tend to want enough children so that they'll have someone to take care of them when they're older. If the odds are high that some of their children won't survive to adulthood, they'll make the perfectly rational decision to have more kids.

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* It's at **https://www.ted.com/talks/hans_rosling_the_best_stats_you_ve_ever_seen**. I promise that you won't regret watching it.

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The drop in family size has led to a remarkable fact: The world recently passed what Hans called "peak child"—that is, the number of children under five hit its maximum and is going down. The benefit? As the United Nations Population Fund explains on its website, "Smaller numbers of children per household generally lead to larger investments per child, more freedom for women to enter the formal workforce, and more household savings for old age. When this happens, the national economic payoff can be substantial."[11]

So: Health is improving nearly everywhere, with big dividends for human welfare. The global health gap is still large, but it is narrowing.

As dramatic as this story is, it's only the background for what we need to know now. What caused these changes? And how can accelerating them also help prevent pandemics?

Trying to explain a decades-long global phenomenon involving billions of people is a risky endeavor. Entire books have been written on single aspects of the decline in child mortality and the march toward global health equity, and I'm covering the subject in just one chapter. I'm going to focus on the factors that are most directly relevant to the problem of preventing pandemics, with the understanding that I'm leaving out a host of others, including agricultural yields, global trade, economic growth, and the spread of human rights and democracy.

It is no accident that many of the tools used against COVID have their roots in global health. In fact, at virtually every step in the COVID response, there is an essential tool or system or team that exists only because the world has invested in improving health for the poor. The fingerprints of the global health movement are all over the COVID response.

Here's a list—and just a partial list at that—of ways that the two overlap.

Understanding the virus

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Early in the pandemic, scientists needed to know what they were dealing with. To find out, they turned to genetic sequencing, the technology that sped up vaccine development (by quickly revealing the genetic code of the COVID virus) and made it possible to detect and monitor variants as they spread around the world.

It's no accident that the first COVID variants were not discovered in the United States. The reason has little to do with where variants were emerging, and a lot to do with which countries were prepared to look for variants: The U.S. didn't put enough money and time into gathering virus samples and getting them sequenced. (The lab capacity existed—it just wasn't used.) . Compared with other countries, the U.S. was flying blind.

Fortunately, several countries in Africa—most especially South Africa and Nigeria—were better prepared, having spent years building up a robust network of sequencing labs. The original intent was to help with diseases like malaria that affect the continent disproportionately, but when COVID came along, these labs were ready to pivot; having been nurtured for years, they were able to produce more results, and faster, than their counterparts in the United States. South Africa's labs were the first to discover the Beta variant of COVID, as well as the subsequent Omicron variant.

Similarly, as I wrote in Chapter 3, computer modeling has helped us learn a lot about this pandemic, and it needs to be an even bigger part of our pandemic-prevention efforts. But the notion of using computer modeling to understand infectious diseases did not emerge suddenly with COVID.

The Institute for Health Metrics and Evaluation—whose computer models were widely cited by the White House and reporters during the pandemic—was created in 2007 to give the world insight into causes of death in poor countries. Imperial College London established its

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modeling center in 2008 with an eye toward assessing the risk of outbreaks and the effectiveness of different responses. That same year, I funded and recruited people for the Institute for Disease Modeling, which was designed to help researchers understand malaria better and to advise on the most effective paths to eradicating polio–and is now helping governments understand the impact of various COVID policies. The fact that these groups—and many others like them—turned out to be useful for COVID is a testament to the fact that investing in global health helps with pandemics too.

Getting lifesaving supplies

Another crucial early step, before vaccines were available, was to get preventive equipment (such as masks), oxygen, and other lifesaving equipment to people who needed it. This wasn't easy for anyone—even the United States struggled to acquire and deliver these things early on—and poor countries were in an even worse position. Luckily, many of them could turn to the Global Fund for support.

Created in 2002 to bolster the fight against HIV, TB, and malaria in low- and middle-income countries, the Global Fund has been a rousing success. It's now the world's largest funder of HIV, malaria, and TB work that is not a government. Today it makes sure that more than 21 million people living with HIV/AIDS get the medicines they need to stay alive. Every year, it distributes more than 180 million malaria-preventing bed nets—nets you hang over your bed at night to keep mosquitoes from biting while you sleep. In two decades, it has saved some 44 million lives. Years ago, I called the Global Fund the kindest thing that humans have ever done for one another. I still believe that today.

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To do all this work, the Global Fund had to establish a solution for reaching people in need. It set up financing mechanisms so it could raise money and get it out the door quickly. It built systems to deliver medicines in some of the most remote places on the planet. It established networks of laboratories and set up supply chains

When the Global Fund turned all these assets toward COVID, the results were impressive. It raised almost $4 billion for the COVID response in a single year, and it worked with more than 100 governments and more than a dozen programs that help multiple countries.12 Thanks to the fund, countries were able to buy COVID tests, oxygen, and medical supplies. They got protective equipment for their frontline health workers and stepped up their contact tracing efforts. Although about a sixth of the additional money supplemented the work on HIV, TB, and malaria to deal with pandemic issues, there were still big setbacks; because of COVID, TB deaths rose in 2020 for the first time in more than a decade.13

Making and testing new vaccines

When the effort to develop a vaccine went into high gear, it relied heavily on work that had been done for infectious diseases. For instance, mRNA technology had been in the pipeline for decades, with a lot of commercial funding to explore its potential as a cancer treatment. (It works by causing cells to express proteins that can do many things, such as activating the immune system against an infectious disease or against cancer cells.)

Then, when it came time for human trials of vaccines—which is typically a long and expensive process, as you'll recall from Chapter 6—researchers turned to the HIV Vaccine Trials Network. As the name suggests, it was established to create an infrastructure that could speed up trials on HIV vaccines, a system that proved crucial in COVID vaccine trials. Although very few

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COVID vaccine trials took place in Africa, the ones that did relied on South Africa's strong clinical trial infrastructure, which had been built with funding for HIV. The first evidence about how effective COVID vaccines would be against a COVID variant came from trials in South Africa.

Buying and delivering vaccines

Years ago, someone started a meme claiming that if I walked past a $100 bill lying on the sidewalk, it wouldn't be worth my time to pick it up. Although I've never had the opportunity to test this theory, I'm sure it's not true. I would absolutely pick up a $100 bill! First, I'd look around to see if I could find the person who dropped it, because someone is probably sad about losing their $100. And if I didn't see anyone, I'd take that money and send it where it could do the most good: Gavi, the Vaccine Alliance.

Gavi has a phenomenal impact. It finances and organizes vaccines systems for children in low- and middle-income countries and has helped vaccinate more than 880 million children and prevented 15 million deaths in the past two decades.14 Part of its mission is to help poor countries buy vaccines, but it does much more than that.

Gavi helps countries gather data to measure the effectiveness of their work and make improvements. It helps them build supply chains so that vaccines, syringes, and all the other necessary pieces reach the clinics where they're needed. It offers training for leaders in the health sector so they can manage their countries' vaccine programs more effectively and increase the public's demand for vaccines.

The Gates Foundation helped create Gavi in 2001, with the goal of making vaccines available to all the world's children. We did not foresee the role that Gavi would play in

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combating a pandemic like COVID, but looking back, it now seems obvious: Gavi was a fantastic investment for saving children that was also a fantastic investment for dealing with COVID. Having spent the better part of two decades helping poor countries improve their systems for delivering vaccines, Gavi had skills and experience to help when global disaster struck.

Gavi is one of three partners running COVAX, the program designed to get COVID vaccines to people in developing countries. COVAX has missed its volume goals for getting vaccines out, but it deserves credit for two important things. It delivered hundreds of millions of doses of a vaccine that had not even existed a year before, and it accomplished this feat faster than anything like it had ever been done before. (This was even more complex than it sounds: Although Gavi and UNICEF have built lots of infrastructure for delivering vaccines, their job is to immunize children and, in some cases, teenagers. They had to retool their systems to reach adults during COVID.)

It's not just global vaccination programs that are paying off for COVID. Countries that made a point of improving their own immunization efforts were also well positioned to respond. Let's look at one of them.

Beginning after it won independence from the U.K. in 1947, India undertook a massive campaign to eliminate smallpox—a project that required improving its health system, training vaccinators, buying cold chain equipment, reaching even the most remote parts of the country, and creating a surveillance network for vaccine-preventable diseases. It took decades, but it worked. India's last case of smallpox was reported in 1975.15

Then, in the early 1980s, India turned to another problem: low rates of routine childhood immunizations. At the time, the percentage of children born in India who received these basic

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vaccines ran in the single digits. Building on the systems that had been put in place for smallpox, the government set out to raise immunization rates by an order of magnitude. It succeeded wildly: Vaccination rates soared, and case numbers plummeted. In 2000, for example, the country reported more than 38,000 cases of measles, and twenty years later, it reported fewer than 6,000.16 Every year, India's immunization program gives primary doses to more than 27 million newborns, and booster doses to more than 100 million children between the ages of one and five years.

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Stamping out measles in India. Cases of measles plummeted in India as vaccination rates soared. The first vaccine dose (MCV1) was introduced in India in the mid-1980s, with a second dose (MCV2) being recommended later. (WHO)

Building up a strong immunization program was a fantastic investment for India long before COVID came along, and when the virus did arrive, the investment paid off again. Because it had a system already in place, India rapidly established nearly 348,000 public centers and over 28,000 private centers to administer COVID-19 vaccines—including many in the tough mountain regions in the country's north and northeast. By mid-October 2021, the country had administered one billion doses of COVID vaccines.

India still had work to do—only about 50 percent of the population there had received at least one dose—but there is simply no way they could have achieved as much as they did, as quickly as they did, without a well-run immunization program already in place.

One of India's next-door neighbors has a similar story. Pakistan's vaccine coverage numbers have gone up dramatically in the past few decades,17 thanks to major investments in its health system. And as soon as COVID vaccines became available, the government was ready to

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roll them out. By late summer 2021, the country was vaccinating roughly a million people a day, a much higher share of its population than most other lower-middle-income countries.18

Bringing it all together with logistics

Countries that had recently been running large polio campaigns—as both Pakistan and India had done—had another advantage: their national and regional emergency operations centers. (You may remember these nerve centers of public health campaigns from Chapter 2.) When COVID hit, these EOCs were a natural model for coordinating COVID-related activities.

In Pakistan, for example, health officials paused polio vaccination campaigns early in 2020 because of the transmission risk posed by vaccinators moving from one community to another. In March, though, they saw an opportunity: set up an emergency operations center for COVID modeled on the one for polio.

Within a few weeks, more than 6,000 health workers who had been trained to watch for signs of polio were taught about COVID symptoms as well.19 A call center that had been set up to take reports of possible polio cases was repurposed for COVID; that anyone in the country could call a toll-free number to get reliable information from a trained professional. The EOC also logged case numbers, coordinated contact tracing and genetic sampling, and used its existing data-transmission systems to share this information throughout the government—all functions that had been built up during the polio campaign. The maps, charts, and statistics pasted all over the walls now counted COVID.20

This brings me to a criticism that I've been hearing for years. Trying to eradicate a disease is what people in the field call a vertical approach—that is, it goes deep on trying to end one disease. By contrast, a horizontal approach is one that can drive progress across many

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different problems at once. If you strengthen health systems, for example, you can expect to see improvements in malaria, child mortality, maternal health, and so on.

The criticism is that vertical efforts come at the cost of horizontal ones, and that those horizontal efforts are, by their nature, the more effective way to save and improve people's lives with limited money and effort.

I don't agree with the criticism, though. The vast majority of the resources goes to horizontal programs, including the global polio program's funding of routine immunization work. Targeted vertical programs such as house-to-house polio campaign vaccination or distributing drugs for tropical diseases are integrated into the horizontal system.

The way polio campaigns have shifted to help with COVID shows that horizontal and vertical capabilities are not a zero-sum game. And COVID is not the only example: During the 2014 Ebola outbreak in West Africa, polio workers in Nigeria were able to step in and help with the Ebola response. Without them, the country's 180 million citizens would have been at far greater risk—and in fact, in countries without the polio-eradication infrastructure, the outbreak was much worse.

Strengthening one muscle does not have to come at the expense of weakening another. As we build up the world's ability to detect and respond to outbreaks—the most dangerous of which will be respiratory diseases—the investments we make will benefit the entire health system. The opposite is also true: When health care workers are well trained and have the tools they need, and when everyone gets good care, health systems will be able to stop outbreaks before they spread far and wide.

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In my foundation work, I often advocate for increasing health aid to developing countries. Most people don't follow this subject, and they're surprised when they learn how little funding is involved.

If you added up all the money from governments, foundations, and other donors that helps low- and middle-income countries improve the health of their people, what would it amount to? We're counting everything: money for COVID, malaria, HIV/AIDS, child and maternal health, mental health, obesity, cancer, smoking, and so on.

In 2019, the answer would've been $40 billion a year—that was the annual total of what's called development assistance for health.[21] In 2020, when rich governments stepped up generously to deal with COVID, the answer was $55 billion. (As I write this, the number for 2021 isn't available yet, but I anticipate . . . [Foundation team: do you think DAH will be roughly the same?].)

Whether $55 billion a year strikes you as a lot of money for global health depends on the context. It amounts to roughly .005 percent of the world's annual economic output. People spend almost that much on perfume every year.[22]

Of that $55 billion annual figure, the United States contributes about $7.9 billion a year. That's less than 0.2 percent of the federal government's budget.

If you're a citizen in a donor country, you can feel good about the impact of this spending. The bang for your buck is tremendous.

Remember the 20-10-5 story from a few pages ago? That's what this money is paying for.

This pie chart shows how many children died in 1990, and what they died from:

[chart]

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Now look at the progress the world has made in the past 30 years. Here's the same chart for 2020:

[chart]

See how much smaller the diarrhea and pneumonia sections are? That's Gavi. See how the malaria section also shrank? That's the Global Fund.

This is historic progress on a global scale that translates into many millions of families who haven't had to bury a son or daughter. And, as we have now discovered, these efforts will provide another benefit: They will help prevent pandemics too.

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Chapter 9

Make—and fund— a plan for preventing pandemics

For decades, people told the world to get ready for a pandemic. Now that we're in one, the top priority is to get out of it. What I worry about, though, is that once we do get out of it, the world's attention will turn to other problems, and pandemic prevention will once again get moved to the back burner—or taken off the stove entirely.

But ending the immediate crisis and getting ready to prevent the next one have a lot in common. The things we need to do to bring an end to the COVID crisis are also some of the key things we need to do to start shoring up our defenses for the future:

1. Make better tools for preventing, detecting, and treating infectious diseases.
2. Start to develop a dedicated team to help with germ games and data systems. A key activity will be working with countries to improve disease surveillance so every country can know what's going on within its borders and can alert the world to new variants or viruses.
3. And strengthen primary health care systems, especially in low- and middle-income countries.

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That's why I approach this not as two different sets of activities, but as two points on the same line: end this pandemic while creating the tools and systems we need prevent the next one. Save lives now *and* avoid disasters in the future.

Commented [FA([1]: This is acritical statement since even now as we are struggling to end this pandemic, resources are being taken away from our pandemic preparedness as "offsets" for other programs due to budgetary constraints. You should strongly warn against this near-sightedness
Fauci, Anthony (NIH/NIAID) [E]
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But it's possible to take this idea too far—to assume that the next pandemic threat will look exactly like COVID. It may not. It could be more infectious, passing more easily from one person to another. Or it could, unfortunately, be deadlier. Worst of all, it could be both.

The key is to be ready to adapt our response to the problem at hand. In the next major outbreak, the pathogen might not be so much worse for older people as COVID is, or it might spread by lingering on surfaces or be transmitted through human feces.

Let's go through the plan, step by step.

1. Make better tools.

All my work in software and philanthropy stems from a simple idea: Innovation can improve lives and solve important problems, whether it's reducing childhood deaths or making education more accessible to more people. When Microsoft cofounder Paul Allen and I imagined a day when there would be a computer on every desk and in every home, that struck many people as a pipe dream. But we got to be part of the digital revolution that made it happen.

The same goes for health. The advances in biology and medicine in the past few decades alone have unlocked phenomenal new ways to treat and prevent disease, including new vaccines. But these advances do not simply happen on their own. As the decades-long story of mRNA vaccines shows, ideas and research must be nurtured, sometimes for more than a decade, before they produce anything of practical use.

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So a key step in my pandemic-prevention plan is to invest in three main areas: vaccines, diagnostics, and treatments. Of course, none of these advances will mean much if there isn't a system to deliver them, a subject I'll come to later in this chapter.

Vaccines

The world surpassed all expectations by developing multiple effective and safe COVID vaccines faster than it has ever made any vaccine, and by churning out billions of doses within a year. But almost as soon as we started rolling out vaccines, the virus fought back, mutating in ways that made our current vaccines less effective. And the vaccines' protective effect started going down within six months of patients' receiving them.

In the short term, I see three key steps:

Adapt today's vaccines for variants. This includes coordinating testing of current vaccines against new variants as soon as they emerge, to see which ones stay most effective, and then smoothing the path for improved versions to be approved as quickly as possible. Scientists can also work to get ahead of the variants by coordinating their efforts to sequence genomes, which will help researchers understand how the virus might evolve in the future. With this knowledge, vaccine manufacturers could be preparing in advance.

Adjust vaccination strategies to reflect reality on the ground. Not every country's COVID profile is exactly the same. In one place, most people might have been given a previous vaccine. In another, most people might have natural immunity because they've already been infected. What this means is that updated vaccines can't be used in the same way everywhere. Health officials will need

Commented [FA([2]: Besides sequencing we need to continue to study viruses in the animal populations to get a better feel for the evolution of viruses in animals. People confuse this with gain of function research and inhibiting the study of the animal human interface could impede our ability to understand the plasticity of the virus
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to adjust their strategies based on what the data says will be most effective in the place where they're working.

Keep working on backup vaccines. There are many COVID vaccines still in the pipeline. We should continue developing them if they have a chance of protecting people for longer, reducing the number of breakthrough infections, or attacking parts of the virus that aren't likely to change in future variants. Although mRNA~~na~~ vaccines have proven to be the most effective so far, other platforms such as nanoparticles, -virus-like particles (VLPs) and vector-expressed immunogens should also be pursued, since they might provide a vaccine that's better in one of these areas. And even though during 2022 volume of supply won't be the problem that it was before, the world still needs to expand its manufacturing capability so we can provide improved versions to everyone and be ready for the next pandemic.

At the same time, we need to invest in four goals that will let us stop future outbreaks before they infect so many people:

Develop novel vaccines that fully protect against entire families of viruses particularly respiratory viruses. These universal vaccines hold a lot of promise—including the prospect of eliminating the flu and the entire family of coronaviruses from humans. The has been referred to by some as the "prototype pathogen" approach to vaccine development.

Create transmission blockers that people can give themselves to get immediate protection from a respiratory pathogen.

Make it easier to deliver vaccines. Micro-needle patches, for example, would

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solve the cold chain problem, make it less painful to get a vaccine, and allow people to vaccinate themselves. The technology is being finalized for a measles vaccine, but a lot of work remains to make it cheap, and high volume. Other promising ideas include mucosally-delivered vaccines to protect against infection and transmission, vaccines whose protection lasts for decades, time-release vaccines that are given in a single shot and eliminate the need for follow-up doses, and combination vaccines that work against multiple pathogens (a combined flu-and-COVID shot, for example).

Get ready to make lots of doses fast. The world needs large-scale manufacturing capacity—enough to provide everyone on the planet all the necessary doses of a new vaccine within six months of creating it. During COVID, when countries that make lots of vaccines were hit hard by the pandemic, they restricted exports of their vaccines to make sure they had enough for their own people. The world's interest, though, is in vaccinating everyone, so we'll need to account for this complicating factor by investing in more manufacturing capacity and in innovations that make it easier to do technology transfers and second sourcing. Other steps include research to drive down the cost of vaccines and standing up~~making~~ new factories sustainable by inventing vaccines for them to produce when there isn't a pandemic threat. With the right investments, the world can create vaccines for TB, HIV, and malaria, use new factories to make them when there isn't a pandemic threatening, and stockpile extra doses so we won't run out when they have to switch to vaccines for a new pathogen.

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Treatments

Despite the early hopes for treatments like remdesivir and monoclonal antibodies, it took nearly two years to find effective antiviral treatments for COVID. In a pandemic, two years is an eternity: If the virus had been deadlier, that kind of delay would have been catastrophic. As we roll out the treatments that we now have, we should also be building the systems that will allow us to develop and deliver future treatments much faster.

Right now, we need to:

> *Expand access to antiviral treatments,* including ~~Merck's molnupiravir~~ and Pfizer's Paxlovid, Merck's molnupiravir, and Gilead's Remdesivir. ~~.~~ The Gates Foundation is placing advance orders on behalf of low- and middle-income countries so that generic drugmakers will start to manufacture them even when they're still going through regulatory approvals—these orders eliminate the risk that the generic companies will lose money if the approvals don't come through. Every country needs to figure out the logistics of treating anyone who tests positive and is at significant risk of severe disease, which will add a powerful incentive for people to get tested in the first place.

Over the longer term, I see three more areas of innovation in therapeutics that deserve the world's attention.

> *Prepare a library of millions of antiviral compounds that are designed to attack common respiratory viruses,* including ones that work on a wide range of variants. If we have three or more of these compounds, we will combine them

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together to reduce the chances that a drug-resistant variant will emerge. (This is done now with HIV treatments: Three antivirals are combined, limiting the spread of resistant viruses.) These libraries need to be accessible to all researchers so they can use different approaches to find out what should be added to the library.

Use artificial intelligence and other software to develop antivirals and antibodies faster. Several companies are doing great work in this field. Essentially, you would build a 3D model of the pathogen that you want to target—it could even be one we've never seen before—and also models of various drugs that you think might work against it. The computer would quickly run these models against each other and then tell you which drugs look promising. It can figure out how to improve drugs or even design them from scratch.

Speed up clinical trials. A few efforts, such as the RECOVERY trial in the U.K., set up ready-to-go protocols and built up infrastructure that made it much easier to get started once COVID hit. We should build on those models, improving the ability to do trials around the world so we can learn what works even when a new disease is present in just a few countries. Regulators need to agree in advance on how people will be enrolled and on the software tools that will enable enrollment globally, as soon as the disease strikes. And by connecting diagnostic reports into the trial system, we can automatically suggest to doctors that their patients should join a large-scale trial.

Diagnostics

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Testing people for a disease should serve two purposes: letting them know very quickly whether they're infected so they can take action (including isolating themselves), and also informing public health officials so they know what's happening in the community. Some portion of positive tests should be gathered and sequenced so that variants can be seen as soon as they emerge. The quick rollout of PCR tests and quarantine policies explains in large part why some countries, such as Australia, had dramatically fewer infections and excess deaths than others.

In addition to making systemic changes in disease surveillance, which I'll cover in the next section, we need to continue pursuing innovations in diagnostics. Two key steps are to:

Keep improving the gold standard of testing. High-throughput PCR testing has all the benefits of a typical PCR test but is also remarkably fast, processing 100,000 tests per machine per day. It is also very cheap and doesn't require the supplies of reagents that limited our diagnostic capacity in this pandemic. PCR is easily adapted to detect any new pathogen as soon as the sequence is known.

Deploy and improve new types of tests that make it easier to collect samples and turn around results quickly. Low-cost lateral flow immunoassays—the ones that resemble a pregnancy test—unlock the possibility of testing throughout entire communities. So does the LumiraDx system, which I mentioned in Chapter 3; the LumiraDx machines need to be made cheaper and more durable. And now that we know that self-swabbing is an effective way to get a sample, more people in more places should have the opportunity to take advantage of it.

2. Improve disease surveillance.

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After a lifetime of neglect by the public at large, disease surveillance is finally having its moment. The world has a lot of catching up to do.

In the immediate future, we should:

Get better data on COVID's incidence. If you don't know how widespread the virus is in your community, it's hard to make good decisions about vaccination strategies and things like closing schools and businesses. Often, especially in developing countries, the government's data on COVID comes from testing—which isn't being done widely enough in many places—and from outdated data gathered in single surveys conducted in particular populations, such as health care workers or blood donors. Given the extraordinary fluid dynamics of the current outbreak with multiple successive waves of infection , it is critical that surveillance data be available in real time. This may be true of future pandemics. Outdated data are not only often not helpful, they can frequently be misleading. With timely, representative surveys of the population at large, countries can gain crucial insights that will guide efforts to slow the spread of COVID, including the most effective ways to use nonpharmaceutical interventions while accelerating economic recovery and targeting lockdowns to only the places where they're necessary.

Expand genomic sequencing. Africa's ability to sequence genomes has alerted the world to at least two COVID variants. We will be able to do this even better than we can now if we build up the world's sequencing capacity by supporting the Africa Pathogen Genomics Initiative, a network of labs across the continent that are able to share genomic data with each other. This model is being

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expanded to South and Southeast Asia, but it should go even further. The field would also benefit from advances like the Oxford Nanopore sequencer and smartphone app from Chapter 3, which make it possible to do genomic sequencing in many more places. And some researchers are using viral genomes to predict when and where the next variant may emerge, work that deserves much more support.

Start building the GERM team. The team I envisioned in Chapter 2 won't be stood up overnight. But by working on COVID, they will gain valuable experience so they can be ready for the next major outbreak while also helping reduce the burden of other infectious diseases, including measles and malaria. [possible mention of a foundation commitment here, with emphasis that ultimately it needs to be fully funded by rich governments]

For the longer term:

Create and fund the GERM team, coordinated by (and accountable to) the WHO.

Improve civil registration and vital statistics in the developing world. At a minimum, developing countries need stronger registries of births and deaths, information that would feed into national disease surveillance work, like the effort in Mozambique that I described in Chapter 3. Then, building on that foundation, they could expand into genomic sequencing, autopsies that use minimally invasive tissue sampling, wastewater surveillance, and other practices. Ultimately, the goal for nearly every country is to be able to detect and respond to outbreaks within its borders—whether the disease is TB, malaria, or one we've never seen before.

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Run an ongoing census of circulating respiratory viruses in as many patients as possible, looking at not only people with respiratory symptoms but also hospital admissions and increases in deaths. This will allow officials to know which respiratory diseases are circulating at any given moment.

Make diagnostics more a part of the health system. Today, testing for disease is an expensive proposition, whether you're picking up a flu test at the drugstore or your doctor is ordering a more advanced diagnostic. In the U.S., that's because the system doesn't give anyone an incentive to drive the price down, or to make testing widely available throughout a community. But that's exactly what we'll need to detect and stop an outbreak, because testing allows you to keep the disease from spreading out of control. And the results need to feed into the public health system, along the lines of what the scientists behind the Seattle Flu Study were piloting.

Commented [FA([3]: You might want to make mention of the fact that the health care infrastructure in the United states with the lack of uniformity and interchangeability of health records makes an endeavor such as this very difficult , and this should be a high priority of improvement looking forward
Fauci, Anthony (NIH/NIAID) [E]
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3. Strengthen health systems.

When I first got involved with global health, I was focused like a laser on developing the kinds of new tools I've been describing. *Make a new rotavirus vaccine,* I thought, *and no kids will die of rotavirus.* Over time, though, I've seen how limitations in the health care delivery system—particularly the basic level, which is called the primary health care system—prevent vaccines and other new tools from reaching all the patients who need them. The Gates Foundation and our partners are helping improve these systems and ensuring that they can reach all kids with new vaccines.

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These national systems are part of regional networks, and beyond that, there's a global system for health too: When a genome is sequenced in South Africa, leading to a vaccine that's developed in Europe, manufactured in India, and delivered to people in Nigeria, that is the global health system at work.

Who pays for these systems? As a country moves out of poverty and achieves middle-income status, its government can start funding health care on its own. Many countries have made this transition over the past few decades, and today, only 15 percent [CHECK THIS] of the global population lives in low-income countries that still need help financing basic health care.

Tragically, the pandemic was a huge setback to these systems. The WHO estimates that more than 115,000 health workers died of COVID between January 2020 and May 2021. [1] So for the sake of saving lives, making the world a fairer place, and preventing pandemics, we need to invest in these systems.

In the short run, the world needs to:

Distribute vaccines fairly—especially ensuring that people at high risk, such as the elderly and people who are immunocompromised, don't end up standing in line behind young, healthy adults. It is both inefficient and unfair to give a booster to a twenty-five-year-old with a clean bill of health before a fifty-year-old nurse and a person living with HIV get their first doses.

Solve in-country delivery problems. In the early days of the pandemic, when there weren't enough vaccines to go around, high-income countries got the bulk of them. But that began to change as the world ramped up vaccine manufacturing, and the main limiting factor became not how few doses were reaching the developing world, but how few doses actually reached the people in need. The

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reasons ran the gamut: It was hard to maintain the cold chain, there weren't enough health care workers to deliver doses, high-income countries often donated doses that were about to expire, existing in-country infrastructure such as that built up over the years through the President's Emergency Plan for AIDS Relief (PEPFAR) was not optimally utilized to distribute vaccines, and even when the vaccines were available, some people were hesitant to take them. But some countries have excelled: By December 2021, for example, more than 80 percent of people in Cambodia had been vaccinated—that's better than most high-income countries had done by that time.[2]

Measure the gaps. We can use COVID as a real-time test of the world's health systems. Who did well, and in what ways? What gaps did it expose? I'm not just talking about low- and middle-income countries, either: America's response was hardly a shining model, and it revealed gaping holes in the country's preparedness. Understanding these holes and finding ways to fill them should be an immediate priority.

In the longer run, the fundamental challenge is that most low-income countries don't have the funding, technical support, or institutions they need to offer basic health services to all their people, let alone manage a major outbreak.

At the risk of oversimplifying an extremely complex subject, here is one opportunity I see to strengthen health systems:

Rebuild and rethink. During COVID, many rich governments have cut foreign aid or redirected it to COVID from work on other diseases. I'm a big believer in foreign aid—it's formally known as overseas development assistance—and

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will always make the case that wealthy governments should be as generous as Sweden and Norway, both of which give more than one percent of their GDP in aid. But in tough times especially, we should also make sure that the spending achieves many things at once: For example, if money goes into buying more machines for diagnosing COVID or signing up more community health workers, it can be spent in ways that will still be useful once COVID subsides. (Diagnostic machines like LumiraDx will also be used to test for other diseases, including new respiratory pathogens.)

[foundation team: What else would you add here?]

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The world's richest countries have a proud history of leading the way on innovation. The U.S. government, for instance, supported the research that led to the creation of the microchip, unleashing a flurry of advances that made the digital revolution possible. Without those investments, Paul Allen and I would never have been able to even imagine a company like Microsoft, much less actually make it happen.

Or take a more recent example: the groundbreaking work being done on zero-emissions energy sources at national labs across the country. If the world can manage to eliminate greenhouse gas emissions by 2050, as I think it can, the energy research supported by the U.S. and its peers will be one reason why.

When COVID struck, even the fumbling responses by some high-income countries couldn't hold back the innovations that would prove to be essential in fighting the disease. Crucial advances in vaccines were made by academics and companies in the United Kingdom

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and Germany. One part of the U.S. government supported the academic work on mRNA, another part supported the effort to translate the basic research into marketable products, and another part funded vaccine companies that were working with mRNA and other vaccine technologies when the pandemic struck.

Now rich countries' governments must lead the way on pandemic prevention: funding more research into better vaccines, better diagnostics, and better treatments; backing the GERM team; investing more in disease surveillance; and helping low-income countries improve their health systems.

More funding is necessary, but not sufficient. For the GERM team to become a reality, wealthy governments will need to voice their support for it, and be ready to supply some of its staff members. Another key contribution will be to ease the path to approval for new tests, treatments, and vaccines, without sacrificing safety. As the scientists behind the Seattle Flu Study and SCAN saw firsthand, it's too difficult and time-consuming to put breakthrough ideas to work, especially during an emergency, when every hour counts.

For their part, leaders of low- and middle-income countries can do more to fund their health systems—including staff, supplies, and facilities. They can also make it a priority to detect and stop outbreaks, seeking outside technical support and funding when they'll be helpful. They can support efforts to expand low-cost, high-volume manufacturing of drugs and vaccines in their regions. And by joining projects like the global system for sharing health data, they can give the world more insight into what's happening on the ground in every region.

As the organization responsible for coordinating the GERM team, the WHO can help by keeping that group focused solely on its core mission: detecting outbreaks and sounding the alarm, hopefully preventing most from becoming pandemics. As part of that mission, the WHO

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can encourage governments to be more open about potential outbreaks within their borders, and member countries of the WHO can hold each other accountable for doing so—while recognizing that there are incentives to do to just the opposite. If sharing news of a possible outbreak means that a country will be singled out for travel restrictions, it could hurt the economy, which is a strong reason not to do it. But the global community has an interest in getting this information and has committed to sharing it as part of the International Health Regulations under the WHO's constitution. The WHO should work with its member states to strengthen the IHR and its implementation.

A few other groups have important roles to play. Pharmaceutical and biotechnology companies, for example, can commit to more tiered pricing and second-source deals to make sure that even their most advanced products are available to people in developing countries. Technology companies can develop new digital tools, such as ways to make it easier and cheaper to collect samples for diagnostic tests, or software that monitors the internet for signs of an outbreak.

More broadly, foundations and other nonprofits should support research on better tools that can be used both for today's infectious diseases and future pandemic threats. And because other ongoing global problems do not pause nor do new ones stop arising~~don't stop coming~~ during a pandemic, philanthropy also needs to keep supporting efforts to avoid a climate disaster, help low-income farmers grow more food, and improve education around the world.

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Finally, there's each of us. It can be hard to feel like you have any ability to affect the course of a pandemic. A mysterious new disease is frightening, and it can also be frustrating, because it seems like we have so little power to do anything about it.

But there are things each of us can do. Elect leaders who will take pandemics seriously and make good, science-based decisions when the time comes. Follow their advice about masking up, staying home, and keeping your distance when you're out. Get vaccinated when you can. Get your information regarding public health practices from reliable sources such as the WHO and national public health agencies such as the CDC in the United States and it's equivalent in other countries. Avoid destructive disinformation and misinformation that we often find flooding social media.

Most of all, once COVID is no longer an acute threat, don't forget about what it has done. Do whatever you can to keep pandemics on the agenda—locally, nationally, internationally—so we can break the cycle of panic and neglect that makes them the most important thing in the world for a time, until we forget about them and go back to our daily lives. We're all eager to return to the way things were before, but there is one thing we cannot afford to go back to—our complacency about pandemics.

We don't need to live in fear of another global catastrophe. But we do need to be aware of the possibility and willing to do something about it. The fact that we now understand the threat like never before should inspire the world to take action—to invest billions now so we won't lose millions of lives and trillions of dollars in the future. This is an opportunity to learn from our mistakes and ensure that no one ever has to live through another disaster like COVID. But we can be even more ambitious than that: We can work toward a world where everyone has a chance at a healthy and productive life. The opposite of complacency isn't fear. It's action.

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Afterword

How COVID changed the course of our digital future

While I was writing this book, I spent a lot of time thinking about how the COVID pandemic accelerated innovation on the infectious disease front. But it also ushered in a new era of rapid change that goes way beyond health innovations.

In March 2020, when most of the world adopted strict lockdown rules, many people were forced to find ways to replicate in-person experiences from the safety of their homes. In places like the United States,* we turned to digital tools like videoconferencing and online grocery shopping to fill the gap, using them in new, creative ways. (I remember thinking that the concept of a virtual birthday party seemed so strange back in the early days of the pandemic.)

I think we'll look back at March 2020 as an inflection point when digitization began to accelerate rapidly. Although the world has been becoming more and more digitized for decades, the process has been relatively gradual. In the U.S., for example, smartphones seemed to become

* The pandemic has accelerated digitization all over the world in different ways, but I'm going to focus on high-income countries where the pace of change has been the most dramatic.

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ubiquitous overnight, but it took ten years to go from 35 percent of Americans owning one to today's level of 85 percent.[1]

March 2020, on the other hand, was an unprecedented moment when digital adoption took a huge leap forward in many areas. The changes weren't limited to any demographic or specific technology. Teachers and students turned to online platforms to keep learning. Office workers began holding brainstorming sessions over Zoom or Teams before hosting virtual trivia nights with their friends in the evening. Grandparents signed up for Twitch accounts to watch their grandkids' wedding ceremonies. And just another everyone started shopping online a lot more, causing e-commerce sales in the United States to jump by 32 percent in 2020 compared to the year before[2].

The pandemic forced us to rethink what is acceptable for many activities. Digital alternatives that were once viewed as inferior were suddenly seen as preferable. Before March 2020, if a salesperson offered to make a pitch over a video conference, many customers would have taken that as a sign he or she wasn't serious about winning their business.

Pre-pandemic, I wouldn't have dreamt of asking a political leader to spend 30 minutes on a video call discussing how to improve their primary health care system, because it would have been seen as less respectful than meeting in person. Now, when I suggest a video call, they understand how effective it can be and set time aside to meet virtually. Once people learn the digital approach, they generally stick to it.

In the early days of the pandemic, many technologies were merely "good enough." We were using them in ways that weren't exactly their intended purposes, and the results were sometimes bumpy. But over the last couple of years—as it's become clear that the need for these

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digital tools is here to stay—we've seen huge improvements in quality and features. These advancements will only continue in the years ahead as both the hardware and software get better.

We're just at the beginning of this new era of digitization. The more we use digital tools, the more feedback we get about how to make them better—and the more creative we'll be about how we can use them to improve our lives.

The first book I wrote, *The Road Ahead,* was all about how I thought personal computers and the internet would shape the future. It came out in 1995, and although I didn't nail all of my predictions (I thought digital agents would be almost as good as human assistants by now), I also got some key things right (we now have video on demand and computers that fit in our pockets).

This is a very different book. But just like *The Road Ahead,* it is fundamentally about how innovation can solve big problems, and so I wanted to share some thoughts about how technology will change our lives even faster because we had to rethink our approaches during the pandemic.

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One of my favorite authors, Vaclav Smil, has this riff he uses in several books. He tells you about a young woman who wakes up and drinks a mug of instant coffee before taking a subway to work. When she gets to the office, she takes an elevator to the tenth floor and stops to grab a Coca-Cola from the vending machine on the way to her desk. The plot twist is that the situation he's describing takes place in the 1880s, not the modern era.

When I first heard his riff years ago, I was struck by how familiar the scene Smil described was. But when I read it again during the pandemic, it felt for the first time as if he was describing the past (although not the part about drinking a Coke in the middle of the workday!).

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Of all the areas that are forever changed by the pandemic, I suspect that office work will see the most dramatic shift. The pandemic disrupted work in virtually every industry, but office workers were in the best position to take advantage of digital tools. The situation Smil describes—where you commute somewhere every day and work from a desk in an office—sounds increasingly like a relic of the past, even though it was the norm for more than a century.

As I write this at the end of 2021, many companies and workers are still figuring out what their "new normal" looks like. Some have already returned to full in-person work. Others have committed to being entirely remote. Most are somewhere in between, still trying to figure out what works best.

I'm excited about the potential for experimentation. Expectations around traditional work have been upended. I see lots of opportunity to rethink things and find out what is effective and what isn't. Although most companies will likely opt for a hybrid approach in which people come into the office part of the week, there's a good deal of flexibility around what exactly that looks like. What days do you want everyone to be in the office for meetings? Do you let people work remotely on Mondays and Fridays, or do you let them stay home in the middle of the week? In order to minimize traffic, it would be best if every company in an area didn't pick the same days.

One prediction I made in *The Road Ahead* was that digitization would create more choices about where to live and lead to many people moving further out of cities. It looked like this wasn't going to pan out—until the pandemic hit. Now, I am doubling down on that prediction. Some companies will decide that time in the office is only required one day a week or one week a month. This will allow employees to live farther away, since a long commute is easier to tolerate if you aren't doing it most days. Although we've seen some early signs of this

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transition, I think we'll see a lot more of it in the decade ahead as employers formalize remote work policies.

If you decide that employees are required to be in the office less than 50 percent of the time, you can share your workspace with another company. Office space is a significant expense for businesses, which could be cut in half. If enough companies do this, it would reduce the demand for expensive office space.

I don't see any reason why companies need to make firm decisions right away. This is a great time to take an A/B testing approach. Maybe you have one team try one configuration while a different team tries another, so that you can compare the results and find the right balance for everyone. There will be tension between managers who tend to be more conservative about new approaches and employees who want more flexibility. Resumes in the future will likely include information about preferences for being able to work away from the office.

The pandemic has forced companies to rethink productivity in the workplace. The boundaries between once discrete areas—brainstorming, team meetings, quick conversations in the hallway—are collapsing. Structures that we thought were essential to office culture have begun to evolve, and the changes will only intensify in the years to come as businesses and employees settle into new permanent ways of working.

I think most people will be surprised by the pace of innovation over the next decade now that the software industry is focused on remote working scenarios. Many of the benefits of working in the same physical space—like running into people at the water cooler—can be recreated with the right user interface.If you use a platform like Teams for work, you're already using a much more sophisticated product than you were in March 2020. Features like breakout

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rooms, live transcription, and alternate viewing options are now standard across most teleconferencing services. Users are just beginning to take advantage of the rich features available to them. For example, I've started using the chat function in many of my virtual meetings to add comments and ask questions. When I meet in person now, I miss the ability to have this kind of high-bandwidth interaction without distracting the group.

Eventually, digital meetings will evolve beyond simply duplicating an in-person meeting. Live transcription may one day allow you to search for a topic across all meetings at your company. You might be able to have action items automatically added to your to-do list as they're mentioned and analyze a meeting's video recording to learn how to make your time more productive.One of the greatest drawbacks of online meetings is that video doesn't let you see who is looking where. A lot of the non-verbal exchanges get lost, and it eliminates a human element. Moving from the rectangular squares to other "seating" arrangements makes things a bit more natural, but it doesn't solve the loss of eye contact. This is about to change as we move participants into a 3D space. A number of companies—including Meta and Microsoft—have recently unveiled their visions for the "metaverse," a digital world that both replicates and enhances our physical reality. (The term was coined by Neal Stephenson, one of my favorite modern science fiction authors, in 1992.)

The idea is that you will use a 3D avatar—a digital representation of yourself—to meet with people in a virtual space that mimics the feeling of being together in real life. This feeling is often referred to as "presence," and a lot of tech companies have been working on capturing it since before the pandemic started. When done well, presence can not only replicate the experience of an in-person meeting but enhance it: Picture a meeting where engineers at a car

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company who live on three different continents pull apart a 3D model of a new vehicle's engine to make improvements.

This type of meeting could be accomplished through either augmented reality (where you superimpose a digital layer on top of our physical environment) or virtual reality (where you enter a completely immersive world). The change won't come right away, since most people don't own tools to enable this kind of capture yet, in contrast to the way the switch to video meetings was enabled by the fact that many people already had PCs or phones with cameras. Right now, you can use virtual reality goggles and gloves to control your avatar, but more sophisticated and less obtrusive tools—like lightweight glasses and contact lenses—will come along over the next few years.

Improvements in computer vision, display technology, audio, and sensors will capture your facial expressions, eyeline, and body language with very little delay. Think about any time you've tried to jump in with a thought in a spirited video meeting, and how hard that was when you couldn't see the way people's body language shifts as they're wrapping up a thought.

A key feature in the metaverse is the use of spatial audio, which makes speech sound like it's actually coming from the direction of the person talking. True presence means that technology captures what it *feels* like to be in a room with someone, not just what it *looks* like.

In the fall of 2021, I got to put on a headset and join a meeting in the metaverse. It was amazing to hear how people's voices seemed to move along with them. You don't realize how unusual it is to have meeting audio only coming from your computer's speaker until you try something else. In the metaverse, you'll be able to lean over and have a quiet side conversation with a coworker just like when you're in the same room.

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I'm particularly excited to see how metaverse technologies will enable more spontaneity with remote work. This is the biggest thing you lose when you're not in the office. Working from your living room isn't exactly conducive to having an unplanned discussion with your manager about your last meeting or starting a casual conversation with your new coworker about last night's baseball game. But if you're all working together remotely in a virtual space, you'll be able to see when someone is free and approach them to chat.

We're nearing a threshold where the technology is beginning to truly replicate the experience of being in the office. The changes we've seen in the workplace are precursors to changes that I think we'll eventually see in many areas. We're moving toward a future where we will all spend more time around and within digital spaces. The metaverse may feel like a novel concept now, but as technology gets better, it will evolve into what feels more like an extension of our physical world.

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There are, of course, huge sectors of the economy where workplaces won't change as much or will shift in different ways from what I'm describing here. If you're a flight attendant, your job has probably evolved a lot in recent years but not because of increased digitization. If you're a server in a restaurant, your customers might now use a QR code menu to decide what they want before placing orders through their phones. And if you work on a factory floor, technology has been changing your job since long before the pandemic*.

Digitization will eventually transform all of our lives in one way or another, though. Consider how the way you take care of your health may have changed since 2020. Have any of

* In addition to the rise of automation, augmented reality is catching on so that workers can be trained in complex tasks and quickly see the status of a piece of equipment with just a glance.

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your doctor's appointments in the last couple of years been virtual? Had you ever done a virtual health appointment before the pandemic? The number of people using telehealth services increased by a factor of 38 during the pandemic.[3]

The benefits of telehealth are clear during a disease outbreak. People who might have been skeptical about virtual appointments before suddenly saw a tangible upside to them: If you're not feeling well, it's a lot safer to do your appointment from home where you don't have to worry about infecting anyone or getting sick.

Once you try telehealth, though, it becomes clear that the benefits go way beyond limiting your exposure to people who are sick. Going to the doctor can be a time-consuming activity, as you have to take time off work or find someone to watch your kids, travel to the doctor's office, sit in a waiting room, check out after your appointment, and then commute back home or to work. That might be worth it for some types of visits, but it feels increasingly unnecessary for others—especially behavioral health visits.

Seeing your therapist is a lot less time-consuming and easier to fit in your day when you only need to turn a laptop on. Sessions can be as long or as short as needed. A fifteen-minute session might not feel worth it if you have to go to someone's office, but it makes a lot more sense from home. Plus, many people feel more comfortable in their own space than in a clinical setting.

Other types of doctor's visits might become more flexible as new tools emerge too. Right now, when it's time for your annual physical, you probably need to go into your doctor's office to get your vitals taken and your blood drawn—but what if you had a private, secure device at home that your doctor could control remotely to test your blood pressure?

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One day soon, he or she might be able to look at data collected from a smartwatch—with your permission—to see how you're sleeping and how your active heart rate differs from your resting heart rate. Instead of going into an office to get blood drawn, you could get your blood tested instead at a convenient place in your neighborhood—maybe at your local pharmacy—that sends the results directly to your doctor. And if you move to another state, you could still see the same primary care physician you've trusted for years.

These are all real possibilities in the future. There will always be health care specialties that require in-person visits—I can't imagine a future where a robot removes your appendix in your living room—but most routine care will eventually be something you can do from the comfort of your own home.

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I don't, however, think that virtual alternatives will replace existing structures in K–12 education the way they are likely to in office work and health care. But change is coming to education all the same. Although the COVID pandemic made it clear that young people learn best when they can work face-to-face with their teachers, digitization will lead to new tools that supplement what happens in the classroom.

If you were the parent of a school-age child during the pandemic, chances are you became very familiar with the concepts of synchronous and asynchronous learning. Synchronous learning attempts to mimic the normal experience of going to school: A teacher uses a videoconferencing service to teach a class live, and students can jump in to ask questions, just like in a real classroom. This will remain a good option for many postsecondary students, especially those who require more flexibility. But I don't see synchronous K–12 learning

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sticking around much in a post-pandemic world except maybe for the oldest high school students or on snow days. It just doesn't work well for younger students.

Asynchronous learning, on the other hand, is here to stay—although in a different form from what we saw during the height of the pandemic. In this type of instruction students watch prerecorded lectures and complete assignments on their own schedule, and teachers can post prompts on a discussion board and ask their class to weigh in for credit.

I know that both forms of remote learning were frustrating for many teachers, parents, and students, and that the idea of keeping any version of them might not seem appealing. But there's remarkable potential for some of the tools used in asynchronous learning to supplement the work that students and teachers already do together in the classroom.

Just think about how digital curricula can make homework more enriching and engaging. If you're a student, you'll be able to get feedback in real time while you do your homework online. The days of turning in your homework and then waiting to see what you got right should be behind you. The content will be more interactive and personalized to you, helping you focus on areas where you need a bit more help while boosting your confidence by giving you problems you're comfortable solving.

If you're a teacher, you'll be able to see how quickly your students worked and how often they needed hints, giving you a deeper understanding of how your kids are doing. A simple button click will show you that Noah might need more help on a particular type of question and that Olivia is ready to take on a more advanced reading assignment.

Digital tools can facilitate more personalized learning in the classroom too. One example I'm familiar with is the Summit Learning Platform. Students work together with teachers to pick a goal—maybe you want to get into a specific university or prepare for a certain career path—

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and create a digital learning plan. In addition to receiving traditional instruction in the classroom, they use the platform to test their knowledge and assess their own performance. Letting kids take control of their learning in this way helps build confidence, curiosity, and persistence.

These technologies have been in the works for a while, but progress was accelerated when demand skyrocketed during the pandemic. In the years ahead, the Gates Foundation will will invest heavily in these tools and measure what works.

Some of the biggest leaps forward have been in math curricula—especially algebra. Algebra I is a key milestone on the road to graduation, but it has the highest failure rate of any high school course.4 Students who don't pass have just a one-in-five chance of graduating from high school. This is a statistic that particularly affects students who are Black, Latino, English language learners, or experiencing poverty, putting them at a disadvantage for future careers and higher earnings. Kids who struggle with algebra often develop a self-image of not being good at math that haunts them through the rest of their time in school. They get frustrated by problem sets that are perhaps too hard for their current skill level and never catch up as classes become more advanced.

A company called Zearn is working on a new math curriculum for grade school students that helps them shore up concepts that are key to more advanced math, like fractions and the order of operations. They provide teaching materials to help educators create lesson plans, and they've created digital lessons and assignments that make doing homework more fun.

I'm hopeful that tools like this will help more students succeed in school while also easing the burden on teachers. Unlike the way things were at the height of the pandemic—when remote learning meant that teachers had to juggle more work than normal—software will eventually free up more time for them to focus on where they add the most value.

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Of course, the ability of new digital education tools to transform the classroom is dependent on kids having access to technology at home. The gap has narrowed since the start of the pandemic[5] and will continue to narrow, but a lot of kids still don't have a decent computer or reliable, fast internet at home. (This is especially true for students of color[6] and those from low-income families, who stand to benefit the most from digital tools that can help close educational outcome gaps.) Finding ways to expand access is just as important as the development of new innovations. Ultimately, the extent to which digitization takes hold—whether it's in education or any other area—depends on how widespread adoption is.

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In 1964, Bell Telephone exhibited the first-ever video phone at the World's Fair. The Picturephone looked like something from *The Jetsons,* with a small live image embedded in a futuristic-looking oval tube. I was eight years old at the time. I saw pictures of the phone in the newspaper and couldn't believe that what I was looking at was possible. Little did I know that, decades later, I'd spend hours of my day on video calls.

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Virtual meetings have come a long way since this early prototype of AT&T's Picturephone in 1964.

It's easy to see technology as mundane when it's just part of our day-to-day life. When you take the time to think about them, though, today's digital capabilities are miraculous. We're now able to connect with each other and with the world in a way that once seemed like pure fantasy.

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For many people—especially older people who lived in assisted living facilities—video calls have become a lifeline to the world. Even if you're tired of virtual happy hours and birthday parties, you can't deny that the connections they've provided helped get us through the darkest days of the pandemic.

As devastating as the COVID pandemic has been, imagine how much worse the isolation would have been even a decade ago. Video calls existed, but broadband speeds weren't fast enough yet to support lots of people doing video meetings from home. The reason broadband infrastructure improved so rapidly over the last decade was because people wanted to be able to watch Netflix at night. By the time the pandemic started, bandwidth had increased enough to let people work remotely during the daytime.

The truth is, it's impossible to predict exactly how breakthroughs will shape the future. You can come up with all these scenarios for ways in which a new technology will change the world, and then something like COVID comes along and forces everyone to use the tools at their disposal in new ways. For all her amazing foresight, I doubt even Katalin Karikó imagined that mRNA vaccines would one day play an essential role in ending a pandemic.

I can't wait to see how digital breakthroughs continue to evolve in the years ahead. The technological advances we've seen over the last couple of years have the potential to create more flexibility and options that improve people's lives. They'll even put us in a better position to prevent the next pandemic. When we look back at this period, I suspect history will view it as a time of terrible devastation and loss that also sparked massive changes for the better.

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Terms, acronyms, and abbreviations

Antibodies: Proteins created by the immune system that grab onto the surface of a virus, bacterium, or parasite and attempt to neutralize it.

Breakthrough case: an infection that occurs in a person who has been vaccinated against the disease. Breakthrough cases may eventually be prevented by transmission blockers.

CEPI: the Coalition for Epidemic Preparedness Innovations, a non-profit created in 2017 to accelerate work on vaccines against new infectious diseases and help those vaccines reach people in the poorest countries.

Gavi, the Vaccine Fund: a non-profit created in 2000 to encourage manufacturers to lower vaccine prices for the poorest countries in return for long-term, high-volume and predictable demand from those countries. Formerly known as the Global Alliance for Vaccines and Immunization.

Genome, genomic sequencing: The genome is the genetic code of a specific organism. All living things have genomes, and every genome is unique. Sequencing an organism's genome is the process of figuring out the order in which the genetic information appears.

Global Fund: officially the Global Fund to Fight AIDS, TB, and Malaria, a non-profit partnership designed to end the epidemics of those three diseases.

IHME: the Institute for Health Metrics and Evaluation, a research organization based at the University of Washington that develops evidence to guide decisions about public health.

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mRNA (messenger RNA): genetic material that carries the directions for making certain proteins to the factories in your cells where the proteins will be assembled. mRNA vaccines work by introducing mRNA that teaches your cells to make shapes that match shapes on a given virus, triggering your immune system to produce antibodies against that virus.

Monoclonal antibodies (mAbs): a form of treatment for some diseases. mAbs are antibodies that have been isolated from a patient's blood or designed in a lab and then cloned billions of times to create a treatment for someone who has been infected.

Pathogen: an organism that causes disease. Viruses, bacteria, and parasites are examples of pathogens.

Transmission blocker: a new type of drug that could be used together with vaccines to protect people completely from infection, preventing breakthrough cases. Transmission blockers are still in development.

WHO: the World Health Organization, the United Nations agency that's responsible for international public health.

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Index

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GATES BOOK COMMENTS

General comments, to be followed by chapter-specific comments.

This is a powerful book that is very well written, to be understood by average people. It is well organized, clear, conversational, sometimes folksy, and it respects its readers and engages in an intimate way. The science is explained at a level that is probably optimal, "not too hot, not too cold", and the opinions reflect serious understanding of the scientific, public health, and societal issues associated with trying to prevent and control pandemics.

Many of my comments relate to addressing the complexities of the challenges. While I am sure that some problems can be solved by money, organization, and an entrepreneurial spirit, there are other challenges that currently seem, and may well prove to be, intractable. This might be addressed in a sober way.

In this vein, many of the stated goals, in Chapter 9 and elsewhere, are aspirational, but readers may wonder: OK, yes, but how do we get there? This is most apparent in the several discussions of the GERM force. It's a great idea that many have already floated in the past 5+ years, but the key question is: HOW DO WE ESTABLISH IT? Some specific ideas about this would be very helpful. Such a force must be international, cooperative, collegial, and with broad national and public buy-in. In an era in which international squabbling and non-cooperation is more notable than international cooperation for the common good (see for example, climate change), how to proceed with this idea?

Introduction

Page 16, bottom para: a 5-year time frame seems far too optimistic for respiratory pathogens

Page 17, top few lines: an issue here to be addressed is that many pandemic pathogens probably spread silently for many weeks or months before the first detection (e.g., pandemic flu, SARS and SARS-CoV-2), so how do you find something like this before a single case of symptomatic or out of the ordinary disease is detected? It is worth noting that had we been doing extremely enhanced viral surveillance in 2009, detecting multiple genomes of the pandemic flu virus, we would have had no way of recognizing it as such, because we have no way of recognizing viral properties such as pandemic transmissibility from the genomes alone.

Page 17, para 6, approval of drugs and vaccines requires a minimal time frame rarely less than 6 months, even when the recipe is agreed on, as with seasonal flu vaccines. There isn't much that can be done to lessen that time frame short of approval based on incomplete data that might miss catching serious problems.

Page 18, line 7, the time frame was LESS than 12 months, I think closer to 11 months

Page 18, general, I think it desirable to pull back a bit on implying that success with the two mRNA vaccines provides lessons for future pandemics. The mRNA success, while real, may be a one-off thing, since other mRNA vaccines haven't worked. Moreover, the short-term protection, easy breakthrough, and need for boosters, makes that vaccine more of a quick interim solution, not an ultimate solution for pandemic disease control. Even successes have important limitations that should be appreciated. This

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is addressed somewhat later in the book by discussing universal vaccines: the mRNA vaccines are the opposite in being non-universal but very strain specific, highly problematic for a virus that easily mutates into new strains the vaccine can't cover.

Chapter 1

Page 26, the whole page, brings up some very important issues. The 2020 US federal COVID response is rightly criticized, BUT….. A larger problem not directly addressed here is the relationship between the political and public health/scientific spheres. For example, in criticizing CDC it is worth remembering that unlike every single developed nation in the world, the US has no national health department or health ministry. Way back in 1783 our founding fathers set up a system in which public health sovereignty resided entirely at the State and local level. With the limited exception of a 1798 act establishing several quarantine stations at east coast ports, PH sovereignty today remains at the State and local level. CDC has to GET PERMISSION to go to a State, look at their data, etc., and basically what CDC gets is only what 50 States and numerous cities and counties agrees to give them, in a variety of formats and degrees of detail. Attempts to fix this situation stretch back to 1870, but all have failed.

So, the failed system we have with respect to pandemic response is the one we set up more than 235 years ago. Blaming the agencies does not fix the problem.

A second point touched on here, that is mentioned tangentially later, is the control over national PH by politicians. Until 1977 CDC had always had expert scientific leaders. When David Sencer was fired over the "swine flu affair" there was an international outcry attacking then-HEW Secretary Califano, who retreated by replacing Sencer with his young protégé Bill Foege. But in subsequent years CDC directors have more often been political appointees, often with little PH expertise. (There are exceptions: you mention Bill Foege and Tom Frieden, but you could also add Jeff Koplan). You could make a stronger point here that CDC directors and other health agency directors should be top scientists widely respected as such by experts, and they should be allowed to function independently, without political interference.

This is a pull-no-punches book, and it might be worth going out on a limb to say that over the past century, around the world, political coopting of national health and science leaders has too often led to disasters.

Page 30, para 1, line 4: the flu vaccine DOESN'T always need not be update annually, although even when it doesn't, we still need to get vaccinated a year later because protection is transient. These are 2 different issues.

Page 30, para 2, line 6: Delta's arrival was a surprise only in its specifics. Most experts believed that problematic variants were likely to arise in one form or another. Some predicted a delta-like virus, and others predicted a different phenotype.

Page 32, bottom, and top of page 33: it might be worth noting that the value of masks was not only well appreciated in 1918 but that residents of many big Asian cities have been wearing them in public ever since. Here too, it might be worth saying more about the superiority of N95 asks, which offer an order of magnitude greater protection than paper masks. Why do we not highly recommend or even mandate

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them? Cost? They are more expensive than paper masks, but at scale could be made for a very low price, and some could be used multiple times.

Page 34, line 6: CDC whiplash. Again, I think this may be more a function of political interference than CDC incompetence.

Page 34, bottom two paras: I completely agree that David Sencer was a great leader, and I have always admired him. HOWEVER, it is worth being aware that, however unfairly, Sencer was during his lifetime severely criticized as one of those leaders who did not end the old Tuskegee syphilis studies (which you mention later on) when he could have. This is a complicated story, usually portrayed unfairly, but lauding Sencer might provoke some push back. If it were me, I would certainly sing his praise, but there could be a downside.

Page 35, para 3. This was not purely Sencer's decision but a consensus decision of all but one of the top US flu and PH experts Sencer convened, made in conjunction with Califano and the Ford White House. The one dissenter was Russ Alexander, but as I recall Russ later said he thought it was the call Sencer had to make. Regarding the firing of Sencer, and the statement that he did know exactly why he was fired. He knew, as did everyone else. It's worth noting that many years later it came out that the damning 1977 book "The Swine Flu Affair", authored by Neustadt and Fineberg, was actually an HEW-instigated hatchet job designed as a pretext to fire Sencer, another reason to hope for a return to independence of HHS agency directors.

Page 37, para 4, line 3, the profit motive isn't always determinative. The original polio vaccine, the Salk vaccine, was funded by the private NFIP (National Foundation for Infantile Paralysis) at a time when NIH had limited funds.

Page 38, line 1. Many would say the response to SARS in 2003 was faster and more effective: it actually PREVENTED a pandemic-in process.

Chapter 2

Page 40, para 2. The fire brigade analogy is instructive. It might also be said that in the US and elsewhere we had city boards of health, sometimes set up and dismantled as circumstances dictated, throughout the 1880s, with occasional examples going back centuries. Thus, the concept is old.

Page 45, para 2. The GERM idea is fantastic and should be fleshed out in greater detail. Many similar ideas arose spontaneously during and after the 2015 Ebola epidemics. I argued at the time, and some others agreed, that such a force needed a "strike force" with a "military-like" component. NOT a military, but a force that could quickly deploy to remote areas and bring in teams, water purification, electrical generators, set up temporary buildings and compounds, etc. The Ebola epidemic began in a remote Guinea border area where access is limited, roads are washed out in the rainy season, no electricity (to run PCR machines, for example) or safe water, and no safe facilities to treat infected patients.

Page 46: there may be a disproportionate emphasis on the supposed magic of computer modeling for predictions, as opposed to biostatistical study. The 4-decade history of predicting various diseases with computer modeling is actually not very good, e.g., for early HIV and for BSE. Modeling used to be called

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"theoretical epidemiology" and was used only for teaching, not prediction. Modeling has to some extent replaced more expensive epidemiological study with real people on the ground, but isn't as good because it relies on assumptions, some, if not many of which, turn out to be wrong.

Page 46, bottom of paras 2. An extremely important missing piece on setting up a GERM like entity is how to get international buy-in and participation. No one has the authority to set up something like this "top down". It would have to come from a mixture of top down and bottom up, and requires consensus building as to the "how". Who can make this happen? The international politics doomed the League of Nations and has crippled the WHO since its beginning so that it is woefully underfunded, understaffed, and unable to do much except persuade and organize.

Page 46, bottom. The polio example is both good and bad. The good part is well stated. The bad part is that the original goal of eradication has been missed for 22 years now, and the reasons are well known and likely to apply to almost every other international health endeavor. I think this needs to be discussed.

Page 49, top line. You could compare the GERM cost to the cost we now accept for preventing nuclear war: pandemics over the years since 1945 have killed far more people, and are thus in the same league of existential threats as nuclear warfare, yet we spend a pittance on pandemic prevention.

Chapter 3.

Page 3, middle para. It's surprising here to see little mention of the use of smart phones and other devices to get health and epi data in many areas.

Page 55, bottom para. That we knew "shockingly little" about why these kids died is debatable, but, as the author knows, there is a sad irony not addressed in this para that we HAD an efficacious rotavirus vaccine in 1999 and failed to deploy it internationally because of largely false scientific claims about side effects. In the interval between this episode and the development of the next 2 rotavirus vaccines, an estimate 4-6 million childhood lives were needlessly and tragically lost. Having the right tech to make the best vaccines isn't always enough. We need to be sure we don't have systems that encourage us to shoot ourselves in the foot.

Page 59, para 2, line 3: I think most virologists would say that PCR is NOT the gold standard but rather that viral isolation is. Viral isolation is more expensive and doesn't always work, but it is generally agreed to be the gold standard, and we need to do more of it in addition to PCR and other rapid tests.

Page 61, para 1, line 4: should be "most likely to spread the infection", not disease.

Page 67, para 2, line 4: it's not true that the only cases that get reported are when a test is ordered by a doctor. Even in the US, some diseases are reported without tests, some based on syndromic presentations, and some are reported directly from labs without a doctor seeing a patient. Also, in poorer countries there is reporting based on entirely syndromic surveillance, and this can be critically important.

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Page 71, para 3: the term “brain-tickling” is here used for the second time, and I don’t recall that this jocular usage is explained so that regular folks will understand. Actually, the olfactory nerve is a projection of the brain, and physically close to it, so “brain-tickling” comes close to being true.

Page 74, para 3. See comments above about not over-praising the role of disease modeling compared with on the ground epi and science studies. Big data from computer models don’t replace common sense. Studies in the past have shown that model predictions do no better than the old fashioned “Delphi method”.

Chapter 4.

Page 80, para 3. Nobody ever says this, but it is worth saying. “If only” we could convince people to use NPIs and standard PH interventions known for over a century (isolation of cases and contacts, masks, social distancing, disbanding crowding situations, etc.), we could STOP ALL PANDEMICS in their tracks. The problem isn’t that we don’t have the tools, it’s that we aren’t able to arrive at consensus about using them. If COVID was 100% fatal instead of 1% fatal, we would have been able to stop it completely using stringent PH measures even before we had vaccines. It’s worth remembering this because vaccines should be viewed as the second line of defense, not the first. When native societies first encountered Westerners and their diseases in the 1700s and 1800s, they instinctively understood isolation of the sick and self-isolation of the well to prevent getting sick, even without any concept of infection. Common sense, not rocket science.

Page 82, top few lines. While there is general agreement about this point, going back to 1918, it’s worth remembering that all these data (on cities with better PH policies faring better in pandemics) are based on unscientific ecologic studies. It all makes sense, and more public health is always a good thing, but we don’t have hard science to back this up.

Page 85, top of para 2. The figure of 100 million school students falling behind, is that number correct? Off the top of my head there are only something in the range of 65 million total kids (18 and under) in the US, so how can 100 million be falling behind?

Page 91, para 3: should perhaps have more discussion of both cell phone data and the privacy issues we have in the US, here and/or elsewhere (and see above comment), and also with contact tracing

Page 92: more on contact tracing, see above.

Page 93: The introduction of the concept of super-spreaders could be defined fleshed out here. It us hugely important because the combination of crowds + super-spreaders leads to super-transmission, and probably accounts directly and indirectly for a large percentage of total cases and rapidity and completeness of spread. The public should know that super-spreaders are of little greater risk to most of us than other infected people in the home and work environments, at least when we use good PH practices, but when we go into crowded bars, etc., during times of community transmission, the chance that there will be one or more super-spreaders not only increases, but their ability to infect many v. just a few increases as well. Linear spread becomes logarithmic spread when these folks go into crowded places. And they don’t know who they are, nor does anyone else.

Why is no one studying the biology of super-spreaders?

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Page 95, line 2. I don't think it's true that SARS-CoV-2 usually only stays in the air for seconds or a minute. It depends on all sorts of things from droplet sizes, airflow, temp, humidity, etc., but in many if not most cases, it is surely much longer than that.

Page 96, para 4, line 1, airflow and ventilation do matter, and especially in the context of crowds.

Page 98, para 4, here it is good to remember that 8 years later, many around the world sought to control pandemic flu with masking. In fact, the issue of masking goes back to the late 1800s as a method of TB control, and leather masks (probably minimally effective, if at all) were used during plague and other epidemics in the Middle Ages.

Page 100, bottom para: here as above, a chance to discuss the advantages of N95 masks and why are they not used universally? Same at the top of page 101.

Page 101, see above. Parenthetically there is a great color photo of a group of masked men and women standing on a California train platform during the flu pandemic in early 1919. One woman wears a placard saying something like mask or go to jail or be fined, or something to that effect.

Chapter 5

Page 109, line 1 and elsewhere: isn't the preferred abbreviation MAbs? Maybe there are several accepted abbreviations, but that's the one I've been seeing for 40 years.

Page 111: might be worth mentioning combination antivirals as well as screening of single new compounds. HIV is an obvious example, mentioned here, but it may be that antiviral combos that hit the virus at different stages of the infection cycle will turn up successes missed by single drug screening.

Page 119: Re the Lind trial, there is a clinical trial of sorts mentioned in the Book of Daniel, written circa 100-200 BCE but describing events 400 years earlier.

Page 120, line 1: a reference for this ethics work might be good

Page 120, para 2: it might be worth pointing out that in addition to drugs to treat new pathogens there may also be drugs (the same ones or different ones) to prevent infection or symptoms from new pathogens. Some immune serums have this property and probably monoclonal antibody cocktails for many new pathogens will as well.

Page 121, line 3: regarding the above, finding and testing drugs for prophylactic rather than treatment use is sometimes, in some ways, easier.

Page 125, top para, the mention of the HIV drug cocktail again brings up the issues alluded to in comments above.

Page 126. Para 2: that's not the only way to make MAbs. In the 1980s, before human MAbs, they were made in mouse secretor cells, and in vitro development without human materials still could be done.

Chapter 6.

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Page 132, para 3, line 1: the statement that COVID is easy to target with a vaccine is debatable in some senses of "easy". The mRNA vaccines have short duration protective effects, so they are not vaccines to control COVID completely, just stopgaps to buy more time. Their fast approval, mentioned on top of page 133 is great, but we don't yet know that this approach will work as well in future pandemics with other agents. That some mRNA vaccines for other agents have failed is not encouraging. While we celebrate the triumph of these vaccines, we need also to be studying their limitations. Maybe not the panacea we want? Time will tell.

Page 136, para 4: mRNA vaccines arose from cancer vaccine research, an example of why basic research needs to go on, in addition to managed and targeted research. See comments below.

Page 137, top 3 lines: Partially redundant with a few sentences earlier.

Page 140, line 3: WHAT plan? More specifics about this would be great, as it's hard to envision a plan that will work.

Page 140, para 4. Re universal vaccines: in most cases no one has any workable idea about how to go about this, and most of the ideas tested (e.g., for glycoprotein stem antigens) have failed. Here and in some other areas, the science "isn't there", and no amount of money can fix it. Although we should keep trying!

Page 143, para: again, mRNA vaccines probably won't prove to be the holy grail. They have been great over the last year, but their future value remains to be determined, and we need to forge ahead with other approaches.

Page 147, first 3 lines: again, may be too optimistic.

Page 149, para 3: it might be worthy of note that it was around this time that the US Marine Hospital Service embarked upon the 3rd of 3 initiatives (the control over biological products directly resulting from the St. Louis incident) that eventually led to the FDA, NIH, and CDC. They all arose from a "national health department in waiting" that was eventually broken up into discrete federal agencies.

Page 158, para 2: again, I am uneasy at the overly optimistic view of the upcoming role of mRNA vaccines. I see their considerable value as being in the realm of early stopgaps, but not final solutions to pandemic control. I hope I am wrong, but I suggest some additional perspective on this.

Page 166, bottom para: here is mention of the Tuskegee studies, alluded to above in the context of David Sencer's role. I would recommend not even getting into these experiments, which I would never defend, but at the same time regret that they have, because of one popular hatchet-job of a book some decades ago, come to stand for scientific evil. The truth is far more complex, and not necessary, in my view, for inclusion here.

Page 168-170: these points are all desirable, and aspirational, but they shouldn't prevent us from finding the best vaccines possible that DON'T meet all these goals, because in all likelihood the best vaccines of the foreseeable future will fail these tests. I would think of these not as "how to make future vaccines" but rather "how to perfect great vaccines once we have them". That is, the perfect shouldn't be the enemy of the good.

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Chapter 7

Page 176, para 2. Again, this is an issue of where lies PH sovereignty in the US. DHHS didn't have clear authority because our mechanism doesn't give it authority. And, as every PH worker in the US knows, or soon finds out, PH is grossly underfunded when there are no pandemics, and then when a pandemic appears, PH is blamed for not preventing it. PH workers live their whole careers caught in this Catch-22.

Page 178, top para and elsewhere: the discussion of these exercises, which is excellent, brings to mind an issue raised earlier and also later, regarding the GERM idea. In the US we have an ICS (Incident Command Structure) for rapid responses to crises such as mass shootings and natural disasters. The public never sees it, but we all see the effects when we turn on the news and see a breaking incident like a shooting. Within an hour or so, there, on national TV behind a microphone, will be the governor, mayor, police chief, maybe the FBI, and various other local officials, all coordinating and reporting on the activities of their agencies, representing hundreds or even thousands of people getting on top of the problem. This happens because of long years of intensive planning, coordinating, exercises and drills, and a tight organizational chain of command in which everyone knows his or her roles and responsibilities. It also includes stockpiling and forward placement of equipment and supplies, designation of triage sites, medical facilities for casualties, and so on. In the US, this is one of the few governmental things that works REALLY WELL. With respect to the GERM idea, is it possible to do this on an international level?

Page 182, para 2: the smallpox blanket story has never been proved. Some regarded it as probably true, or possibly true, while others regard it as apocryphal.

Page 183, top para: actually, we DO know alot about these Soviet bioweapons. Through various programs including BTEP (Biotechnology Engagement Program) coordinated by the State Department, American scientists went to Russia and examined their bioweapons plants, including the notorious Vektor lab in Novosibirsk, which contains smallpox and once contained weaponized Marburg and other deadly agents (I was part of that team). We also brought some of the Soviet bioweapons scientists back to the US and gave them science jobs. (I now work with 2 of them in NIAID, NIH). While we need to always be aware of the potential for bioterrorism, we must at the same time recognize that Mother Nature is the ultimate bioterrorist.

Page 187, bottom para: may be a good place to flesh out the GERM idea. How to make it happen? Who leads? What steps need to be taken and who takes them?

Chapter 8

Page 189, para 1: as mentioned above, many would say our response to SARS was faster and more effective: whatever else one might say, we DID prevent a likely pandemic. Maybe we should study once more how we succeeded than but failed with COVID-19.

Page 190, para 5: to many observers these things were not shocking at all, but completely and tragically expected. Has anything changed since we had HIV therapy but, for years, until PEPFAR and other programs, couldn't find a way to deliver these life-saving drugs to millions who needed it? Rather than being shocked, I think many more are just depressed by the "déjà vu all over again".

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Page 194, para 5: this brings to mind the devastating book by Chinua Achebe: "Things Fall Apart", in which he explains that because of high childhood mortality many parents won't name a child until it reaches its 8th birthday, but then will say that "he or she has come to say".

Chapter 9

Page 208, para 3: once again, readers may ask, yes, but HOW do we do these things when lack of international cooperation is a roadblock to so many things (e.g., climate change, territorial water rights, trade wars, etc.)

Page 209, bottom para: this really touches on the old but very important question of investigator-initiated v. managed or directed research, and what role these two approaches should play in going forward to prevent pandemics. The book seems to assume that directed research is the way to go (e.g., "let's all try to make a universal coronavirus vaccine"). But this may be short-sighted. In many cases, scientists don't have very good clues about how to proceed, in part because of lack of basic knowledge. For example, we know that influenza can result in fatal viral pneumonia but, shockingly, in a typical influenza infection that might or might not go on to be fatal, we don't know where the virus is, how and where the immune system encounters it, and why that infection, even if it's a severe one, fails to elicit long term protective immunity. Without these clues, how can we hope to make a successful universal vaccine?

Moreover, most of the momentous breakthroughs have come NOT from directed research but from serendipity in the hands of scientists curious about arcane stuff: PCR, monoclonal antibodies, CRISPR cas9, mRNA immunogenicity, even the discovery of the "double helix", all came about because unknown scientists were studying obscure things with little or no funding and few expectations of success. So, where in the big picture of pandemic prevention do these two different approaches to science fit? This was a question faced successfully by Basil O'Connor in the 1940s, as he hoped the NFIP could come up with a polio vaccine. It did.

Page 210: para 3, sequencing more genotypes is good but not sufficient, because "genotype does not equal phenotype", meaning that looking at a genetic sequence, even if modeled to guess its protein's tertiary structure, tells us very little other than epidemiology of viral circulation. Ideally, sequencing should lead to study of the infectious virus in animals and in some situations, if safe, even in people, including pathogenesis studies and what has been called pejoratively "gain of function" studies. In this era of genomics, we seem to have forgotten the importance of the biology of infection. It is worth repeating that if we had had the entire genome of the 2009 pandemic H1N1 flu virus beforehand, we wouldn't have been able to predict that it had a chance of becoming pandemic. Had we grown it up into live virus and studied it in the lab, we might at least learned that it was highly transmissibly and not prevented by population H1N1 immunity, derived from infection with highly drifted H1N1 viruses. That would have allowed us to surveil for it and identify a pandemic at its earliest stages.

Page 211, para 4, re vaccines against viral families, this is a great aspirational goal, but all attempts have failed so far, and few if any have good ideas about how to proceed. Can this goal be made realistic, and how?

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Page 11, para 5: re creating transmission blockers, it's worth remembering we have great ones now: N95 masks. In pursuing the high tech it's worth remembering the low tech "first lines of defense".

Page 213, para 4: again, the idea of drug combinations could be stressed, see comments above

Page 214, para 3: speeding up clinical trials would be great, but there is a real limit to how much time can be saved. This is for biological reason such as the fact that it takes time to see whether you have a protective immune response that isn't transient, and to look for late side effects. There is a limit to how much "fat" can be trimmed.

Page 215, para 3: again, viral isolation is the real gold standard, and many will argue we should be doing much more of it, as it provides important data we don't get from PCR and, to reiterate, genotype does not equal phenotype

Page 216, para 1: not only incidence but also prevalence and transmissibility. That is, rather than models we need to be doing more "shoe leather" on-the-ground population epidemiology in real time, including population prospective studies which are expensive, but which yield critically important data.

Page 216, para 2: as above, genome sequencing should lead to study of the live virus in experimental animals so we know what all of these genotypes can do.

Page 216, last line. The GERM team idea is so important that one wishes it could be fleshed out with more specifics. Most importantly, how to set it up so that it will work collaboratively and be "owned" and valued by every country. I don't think something like this will just happen spontaneously, just because it's a good idea. How to birth it?

Page 217, first two paras: more fleshing out of the details would be good.

Page 217, para 3: in addition, we need to try to get a census of the viruses circulating in "non-patients", those who are infected but don't know it, and may nevertheless transmit. This is probably a significant, if unknown, component of pandemic spread. It may be worth reviewing the classic "Virus Watch" studies of the mid-1900s, which intensively surveilled whole large open communities. Can this be done in the modern era? I think it can, although it's expensive.

Page 222, para 2: here, a lot more international scientific exchanges including workshops and training exchanges would be helpful. Science thrives on lots of in-person contact, and more so with international collaborative science.

Page 222, para 3: but as noted, WHO has no money and few staff, it is basically an organizing entity with a staff of bureaucrats. This raises again the question of how to set up the GERM idea.

<u>Afterword</u>

While this chapter is really interesting, it seems to be independent and not closely related to the rest of the book. I worry it might detract from the powerful impact of the previous 9 chapters.

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From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "'Bill Gates'" [redacted]@gatesventures.com>
Cc: "Larry Cohen" [redacted]@gatesventures.com>, "Ian Saunders" [redacted]@gatesventures.com>, "Josh Daniel" [redacted]@gatesventures.com>
Subject: RE: My new book "How to Prevent the Next Pandemic"
Date: Sat, 08 Jan 2022 13:29:29 -0500
Importance: Normal
Attachments: Gates_document_with_Fauci_comments_and_edits_on_Chapter_9.docx; BG_book_comments_from_David_Morens_01_06_2022.docx

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Bill:

Thanks for sending this. I have done 3 thing: 1) I skimmed the book in its entirety; 2) I very carefully read Chapter 9 very carefully and provided tracked edits and several comments; and 3) I gave the manuscript in close confidence to a trusted colleague who destroyed it after reading it. His name is Dr. David Morens and he has read the entire book and have provided comments on every chapter. His comments are a bit granular and you might not be able to address them in the limited time frame; however, I am providing them in the attached document for your interest and use if you wish. Regarding the book (especially chapter 9), I agree completely with Dr. Morens. This is really well-done and easily understandable with crisp and clear messages for the general public. Chapter 9 is very well done and my comments are in the attached document. I am sorry that I did not have time to read the entire book carefully (except for Chapter 9), but I have another Senate HELP hearing on Tuesday and I need to prepare over the weekend. I hope our comments are helpful. Thank you for giving me the opportunity to read the manuscript. Again, well done!

Warm regards,

Tony

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From: Bill Gates [redacted]@gatesventures.com>
Sent: Monday, January 3, 2022 11:57 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Larry Cohen [redacted]@gatesventures.com>; Ian Saunders [redacted]@gatesventures.com>; Josh Daniel

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[redacted]@gatesventures.com>
Subject: [EXTERNAL] My new book “How to Prevent the Next Pandemic”

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Tony,

Happy New Year! I hope this note finds you well.

I have been working on a book entitled “How to Prevent the Next Pandemic” - and I am getting ready to submit it to the publisher.

It would mean a lot to me if you would be able to find time to look it over before I submit.

I will be curious to hear your ideas for improving it, especially chapter 9, which is the plan I am proposing for the world.

It may be too much to ask, but if you had time to look over the book before this Sunday the 9th, it would allow me to incorporate your thoughts into the manuscript I submit. Even if you don’t have time this week, I would appreciate any thoughts you have at any time.

The book is scheduled to be released on May 3, 2022.

Bill

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From: "Conrad, Patricia (NIH/NIAID) [E]" </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7EA3E3EA7DAA432887495D6825C9E588-CONRADPA>
To: "Christa Bowles" [redacted]@gatesfoundation.org>
Subject: Re: Connect with Bill Gates
Date: Wed, 01 Apr 2020 06:16:56 -0400
Importance: Normal

Got it and yes - will be back later today with availability.

Sent from my iPhone

On Apr 1, 2020, at 12:17 AM, Christa Bowles [redacted]@gatesfoundation.org> wrote:

Dear Patricia,

Trevor sent the below message to Dr. Fauci but got an autoreply. Would you be able to assist in arranging a call with Bill Gates tomorrow (Wednesday) evening? Or connecting us to someone in his office that can assist?

Thank you,
Christa Bowles

Christa Bowles
Executive Assistant to Trevor Mundel
Global Health Office of the President
Office [redacted]
Mobile [redacted]
E [redacted] gatesfoundation.org

Bill & Melinda Gates Foundation
www.gatesfoundation.org

From: Trevor Mundel [redacted]@gatesfoundation.org>
Sent: Tuesday, March 31, 2020 7:02 PM
To: Tony Fauci [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>
Subject: Connect with Bill

Hi Tony, great work in keeping things on such an even keel. Bill was keen to catch up with you and I wondered if you might have 30-45 min any time between 5:30pm and 8pm EST tomorrow to chat with him. Regards, Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Christa Bowles

Released by Chairman Rand Paul

Executive Assistant
Office of the President, Global Health
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

APPENDIX B

NIH-BMGF Collaboration to Cure HIV and Sickle Cell Disease

EXECUTIVE COMMITTEE ROSTER

MARCH 4, 2020

National Institutes of Health

Francis S. Collins, M.D., Ph.D. (*as available*)
[redacted], NIH
[redacted]h.gov

Anthony S. Fauci, M.D. (*Co-Chair*)
[redacted]or, NIAID
[redacted]ih.gov

James M. Anderson, M.D., Ph.D.
Director, Division of Program Coordination, [redacted]ategic Initiatives (DPCPSI)
[redacted]@nih.gov

Gary H. Gibbons, M.D.
[redacted]LBI
[redacted]nih.gov

Lawrence A. Tabak, D.D.S., Ph.D.
[redacted]y Director, NIH
[redacted]@nih.gov

Bruce J. Tromberg, Ph.D.

[redacted]@nih.gov

Carrie Wolinetz, Ph.D.
[redacted]tor for Science Policy, NIH
[redacted]@nih.gov

Bill and Melinda Gates Foundation

Bill Gates (*as available*)
[redacted]stee, BMFG

Trevor Mundel, Ph.D. (*Co-Chair*)
President
[redacted]Program
[redacted]@gatesfoundation.org

Emilio A. Emini, Ph.D.
Director
[redacted]gatesfoundation.org

Toni Hoover, Ph.D.
Director
[redacted]anning, and Mgmt for Global Health
[redacted]atesfoundation.org

Mike McCune, M.D., Ph.D.
Senior Advisor
[redacted]chnology Solutions
[redacted]gatesfoundation.org

Dan Wattendorf, M.D.
Director
[redacted]nology Solutions
[redacted]@gatesfoundation.org

Ex officio

Peter Marks, M.D., Ph.D.
Director, Center for Biologics and Evaluation Research

[redacted]fda.hhs.gov

Released by Chairman Rand Paul

From: "Eiss, Robert (NIH/FIC) [E]" [redacted]@mail.nih.gov>
To: "Simon, Ian (NIH/NIAID) [E]" [redacted]@nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: RE: Proposed structure of NIH-Gates Foundation panel on Omicron variant
Date: Mon, 13 Dec 2021 20:38:22 -0500
Importance: Normal
Attachments: BG_FINAL_NIH_speech_12102021.docx

Here is the "close hold" advance copy of Bill Gates' talk shared by his office, with the minor caveat that he tends to run off-script a bit and improvise

---

From: Simon, Ian (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, December 13, 2021 10:45 AM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: RE: Proposed structure of NIH-Gates Foundation panel on Omicron variant

Thanks, Rob. Do you know if others are using slides?

From: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Sent: Friday, December 10, 2021 11:38 AM
To: Simon, Ian (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Hi Ian,

It would be ideal if Dr Fauci's remarks could be around 4 minutes, given the number of panelists and need to give a reasonable margin of time for Q's and A's before concluding the session Also, the audience of course will be reasonably current and informed, constituting some 280 senior BMGF and NIH scientists

I hope this abbreviated timeframe is workable and happy to accommodate Dr Fauci's preference if more time is desired No problem

As you will note, we have given over much of this platform to the African perspective, given both the preliminary findings in South Africa and their outstanding effort to share data rapidly

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From: Simon, Ian (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, December 10, 2021 11:18 AM
To: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Cc: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Hi Rob,

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Thank you for sending this proposed structure. I see Tony is set here to deliver some opening remarks. How long is he expected to speak? 1 min, 3 min, 5 min? And I assume there's no expectation of slides, correct?

Thank you,
Ian

From: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Sent: Thursday, December 9, 2021 4:34 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; MOETI, Matshidiso Rebecca [redacted]@who.int>; [redacted]@usaid.gov; [redacted]@mrc.ac.za; Trevor Bedford [redacted]@bedford.io>
Cc: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Simon, Ian (NIH/NIAID) [E] [redacted]@nih.gov>; Folkers, Greg (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; [redacted]@usaid.gov; CAELERS, Diana Ann [redacted]@who.int>; KIAWOIN, Rita Eleanor [redacted]@who.int>; Thato Mkhwanazi | SAMRC [redacted]@mrc.ac.za>; [redacted]@usaid.gov; Wood, Gretchen (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: Proposed structure of NIH-Gates Foundation panel on Omicron variant

Dear colleagues,

On behalf of Dr. Francis Collins, attached is a proposed structure for the panel you are joining on December 15, to open the 8th Annual National Institutes of Health/Bill & Melinda Gates Foundation workshop. We are very grateful for your participation on what promises to be an outstanding session. As you might anticipate, the focus of the panel has pivoted to the deeply topical subject of the Omicron variant and landscape of variants.

Francis would welcome your comments on the proposed session structure.

The audience will be compromised of some 260 senior scientists from the NIH and the Gates Foundation, as well as several HHS officials. These include Janet Woodcock, Acting Commissioner at the FDA; Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER) at FDA; and Gary Disbrow, Director of the Biomedical Advanced Research and Development Authority (BARDA).

As noted, Bill Gates will attend, and immediately prior to the panel, deliver a talk on the need to "focus scientific inquiry on two important sides of the research agenda - *survive and thrive* - looking past the pandemic to achieving further progress on human health and development, with equity in mind from the outset."

I also attach the agenda for the full meeting, which presents an annual opportunity for various NIH-Gates Foundation established working groups to discuss status of present joint activities and future plans.

Please don't hesitate to have your office contact me with any questions or needed clarifications.

Again, many thanks for your willingness to join this important discussion, and your global leadership in the Covid-19 response.

Best regards,

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Barasch, Kimberly (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: FW: Proposed structure of NIH-Gates Foundation panel on Omicron variant
Date: Tue, 14 Dec 2021 07:51:21 -0500
Importance: Normal
Attachments: BG_FINAL_NIH_speech_12102021.docx

Fyi-

Kim pls add to folder

From: Eiss, Robert (NIH/FIC) [E] [redacted]@mail.nih.gov>
Sent: Monday, December 13, 2021 8:38 PM
To: Simon, Ian (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
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Released by Chairman Rand Paul

Best regards,

Released by Chairman Rand Paul

From: Bill Gates [redacted]@gatesventures.com>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Cc: Trevor Mundel [redacted]@gatesfoundation.org>
Subject: Pandemic Innovation memo
Date: Wed, 22 Apr 2020 23:46:37 -0400
Importance: Normal
Attachments: Pandemic_I_-_The_First_Modern_Pandemic.pdf

Tony,

The attached memo sets out how I'm thinking about the COVID pandemic in its various aspects.

I plan on sharing it in its full length with some key audiences (like WHO, policymakers) and might do a shorter version for the broader public.

It's been great getting your feedback over the last few weeks, so if you think changes or additions are needed, please let me know.

Bill

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Pandemic Innovation memo
Date: Thu, 23 Apr 2020 07:06:37 -0400
Importance: Normal
Attachments: Pandemic_I_-_The_First_Modern_Pandemic.pdf

The email below is from Bill Gates.

Robert W. Eisinger, Ph.D.
Special Assistant for Scientific Projects
Immediate Office of the Director
National Institute of Allergy and Infectious Diseases
National Institutes of Health
31 Center Drive, Room 7A-03
Bethesda MD 20892
Telephone: [redacted]
Email: [redacted]@nih.gov

From: Bill Gates [redacted]@gatesventures.com>
Sent: Wednesday, April 22, 2020 11:47 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Trevor Mundel [redacted]@gatesfoundation.org>
Subject: Pandemic Innovation memo

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It's been great getting your feedback over the last few weeks, so if you think changes or additions are needed, please let me know.

Bill

Released by Chairman Rand Paul

Pandemic I: The First Modern Pandemic

BILL GATES

Released by Chairman Rand Paul

The coronavirus pandemic pits all of humanity against the virus. The damage to health, wealth, and well-being has already been enormous. This is like a world war, except in this case, we're all on the same side. Everyone can work together to learn about the disease and develop tools to fight it. I see global innovation as the key to limiting the damage. This includes innovations in testing, treatments, vaccines, and policies to limit the spread while minimizing the damage to economies and well-being.

This memo shares my view of the situation and how we can accelerate these innovations. The situation changes every day, there is a lot of information available—much of it contradictory—and it can be hard to make sense of all the proposals and ideas you may hear about. It can also sound like we have all the scientific advances needed to reopen the economy, but in fact we do not. Although some of what's below gets fairly technical, I hope it helps people make sense of what is happening, understand the innovations we still need, and make informed decisions about dealing with the pandemic.

Exponential growth and decline

In the first phase of the pandemic, we saw an exponential spread in a number of countries, starting with China and then throughout Asia, Europe, and the United States. The number of infections was doubling many times every month. If people's behavior had not changed, then most of the population would have been infected. By changing behavior, many countries have gotten the infection rate to plateau and start to come down.

Exponential growth is not intuitive. If you say that 2 percent of the population is infected and this will double every eight days, most people won't immediately figure out that in 40 days, the majority of the population will be infected. The big benefit of the behavior change is to reduce the infection rate dramatically so that, instead of doubling every eight days, it goes down every eight days.

We use something called the reproduction rate, or R0 (pronounced "are-nought"), to calculate how many new infections are caused by an earlier infection. R0 is hard to measure, but we know it's below 1.0 wherever the number of cases is going down and above 1.0 wherever the number of cases is going up. And what may appear to be a small difference in R0 can lead to very large changes.

If every infection goes from causing 2.0 cases to only causing 0.7 infections, then after 40 days you have one-sixth as many infections instead of 32 times as many. That's 192 times fewer cases. Here's another way to think about it: If you started with 100 infections in a community, after 40 days you would end up with 17 infections at the lower R0 and 3,200 at the higher one. Experts are debating now just how long to keep R0 very low to drive down the number of cases before opening up begins.

Exponential decline is even less intuitive. A lot of people will be stunned that in many places we will go from hospitals being overloaded in April to having lots of empty beds in July. The whiplash will be confusing, but it is inevitable from the exponential nature of infection.

Released by Chairman Rand Paul

As we get into the summer, some locations that maintain behavior change will experience exponential decline. However, as behavior goes back to normal, some locations will stutter along with persistent clusters of infections and some will go back into exponential growth. The picture will be more complex than it is today, with a lot of heterogeneity.

Have we overreacted?

It is reasonable for people to ask whether the behavior change was necessary. Overwhelmingly, the answer is yes. There might be a few areas where the number of cases would never have gotten large numbers of infections and deaths, but there was no way to know in advance which areas those would be. The change allowed us to avoid many millions of deaths and extreme overload of the hospitals, which would also have increased deaths from other causes.

The economic cost that has been paid to reduce the infection rate is unprecedented. The drop in employment is faster than anything we have ever experienced. Entire sectors of the economy are shut down. It is important to realize that this is not just the result of government policies restricting activities. When people hear that an infectious disease is spreading widely, they change their behavior. There was never a choice to have the strong economy of 2019 in 2020.

Most people would have chosen not to go to work or restaurants or take trips, to avoid getting infected or infecting older people in their household. The government requirements made sure that enough people changed their behavior to get the reproduction rate below 1.0, which is necessary to then have the opportunity to resume some activities.

The wealthier countries are seeing reduced infections and starting to think about how to open up. Even as a government relaxes restrictions on behavior, not everyone will immediately resume the activities that are allowed. It will take a lot of good communication so that people understand what the risks are and feel comfortable going back to work or school. This will be a gradual process, with some people immediately doing everything that is allowed and others taking it more slowly. Some employers will take a number of months before they require workers to come back. Some people will want the restrictions lifted more rapidly and may choose to break the rules, which will put everyone at risk. Leaders should encourage compliance.

Differences among countries

The pandemic has not affected all countries equally. China was where the first infection took place. They were able to use stringent isolation and extensive testing to stop most of the spread. The wealthier countries, which have more people coming in from all over the world, were the next to be affected. The countries that reacted quickly to do lots of testing and isolation avoided large-scale infection. The benefits of early action also meant that these countries didn't have to shut down their economies as much as others.

Released by Chairman Rand Paul

The ability to do testing well explains a lot of the variation. It is impossible to defeat an enemy we cannot see. So testing is critical to getting the disease under control and beginning to reopen the economy.

So far, developing countries like India and Nigeria account for a small portion of the reported global infections. One of the priorities for our foundation has been to help ramp up the testing in these countries so they know their situation. With luck, some factors that we don't understand yet, like how weather might affect the virus's spread, will prevent large-scale infection in these countries.

However, our assumption should be that the disease dynamics are the same as in other countries. Even though their populations are disproportionately young—which would tend to mean fewer deaths from COVID—this advantage is almost certainly offset by the fact that many low-income people's immune systems are weakened by conditions like malnutrition or HIV. And the less developed a country's economy is, the harder it is to make the behavior changes that reduce the virus's reproduction rate. If you live in an urban slum and do informal work to earn enough to feed your family every day, you won't find it easy to avoid contact with other people. Also, the health systems in these countries have far less capacity, so even providing oxygen treatment to everyone who needs it will be difficult.

Tragically, it is possible that the total deaths in developing countries will be far higher than in developed countries.

What we need to learn

Our knowledge of the disease will help us with tools and policies. There are a number of key things we still don't understand. A number of studies are being done to answer these questions, including one in Seattle done with the University of Washington. The global collaboration on these issues is impressive, and we should know a lot more by the summer.

- **IS THE DISEASE SEASONAL OR WEATHER DEPENDENT?**
  Almost all respiratory viruses (a group that includes COVID) are seasonal. This would mean there are fewer infections in the summer, which might lull us into complacency when the fall comes. This is a matter of degree. Because we see coronavirus spreading in Australia and other places in the Southern hemisphere, where the seasons are the opposite of ours, we already know the virus is not as seasonal as influenza is.

- **HOW MANY PEOPLE WHO NEVER GET SYMPTOMS HAVE ENOUGH OF THE VIRUS TO INFECT OTHERS? WHAT ABOUT PEOPLE WHO ARE RECOVERED AND HAVE SOME RESIDUAL VIRUS—HOW INFECTIOUS ARE THEY?**
  Computer models show that if there are a lot of people who are asymptomatic but infectious, it is much harder to open up without a resurgence in cases. There is a lot of disagreement about how much infection comes from these sources, but we do know that many people with the virus don't report symptoms, and some portion of those might end up transmitting it.

- **WHY DO YOUNG PEOPLE HAVE A LOWER RISK OF BECOMING SERIOUSLY ILL WHEN THEY GET INFECTED?**
  Understanding the dynamics here will help us weigh the risks of opening schools. It is a complicated subject because even if young people don't get sick as often, they might still spread the disease to others.

Released by Chairman Rand Paul

- **WHAT SYMPTOMS INDICATE YOU SHOULD GET TESTED?**
  Some countries are taking the temperature of lots of people as an initial screening tool. If doing this helps us find more potential cases, we could use it at airports and large gatherings. We need to target the tests we have at the people at greatest risk since we don't have enough tests for everyone.

- **WHICH ACTIVITIES CAUSE THE MOST RISK OF INFECTION?**
  People ask me questions about avoiding prepared food or door knobs or public toilets so they can minimize their risk. I wish I knew what to tell them. Judgments will have to be made about different kinds of gatherings like classes or church going and whether some kind of spacing should be required. In places without good sanitation, there may be spread from fecal contamination since people who are infected shed the virus.

- **WHO IS MOST SUSCEPTIBLE TO THE DISEASE?**
  We know that older people are at much greater risk of both severe illness and death. Understanding how gender, race, and comorbidities affect this is a work in progress.

The Gates Foundation's role

In normal times, the Gates Foundation puts more than half of its resources into reducing deaths from infectious diseases. These diseases are the reason why a child in a poor country is 20 times more likely to die before the age of five than one in a rich country. We invest in inventing new treatments and vaccines for these diseases and making sure they get delivered to everyone who needs them. The diseases include HIV, malaria, tuberculosis, polio, and pneumonia. Whenever there is an epidemic like Ebola, SARS, or Zika we work with governments and the private sector to help model the risks and to help galvanize resources to create new tools to stop the epidemic. It was because of these experiences that I spoke out about the world not being ready for a respiratory epidemic in my 2015 TED talk. Although not enough was done, a few steps were taken to prepare, including the creation of the Coalition for Epidemic Preparedness Innovation, which I will discuss below, in the vaccine section.

Now that the epidemic has hit, we are applying our expertise to finding the best ideas in each area and making sure they move ahead at full speed. There are many efforts going on. More than 100 groups are doing work on treatments and another 100 on vaccines. We are funding a subset of these but tracking all of them closely. It is key to look at each project to see not only its chance of working but also the odds that it can be scaled up to help the entire world.

One urgent activity is to raise money for developing new tools. I think of this as the billions we need to spend so we can save trillions. Every additional month that it takes to get the vaccine is a month when the economy cannot return to normal. However, it isn't clear how countries will come together to coordinate the funding. Some could go directly to the private sector but demand that their citizens get priority. There is a lot of discussion among governments, the World Health Organization, the private sector, and our foundation about how to organize these efforts.

Released by Chairman Rand Paul

Innovation to beat the enemy

During World War II, an amazing amount of innovation, including radar, reliable torpedoes, and code-breaking, helped end the war faster. This will be the same with the pandemic. I break the innovation into five categories: treatments, vaccines, testing, contact tracing, and policies for opening up. Without some advances in each of these areas, we cannot return to business as usual or stop the virus. Below, I go through each area in some detail.

TREATMENTS

Every week, you will be reading about new treatment ideas that are being tried out, but most of them will fail. Still, I am optimistic that some of these treatments will meaningfully reduce the disease burden. Some will be easier to deliver in rich countries than developing countries, and some will take time to scale. A number of these could be available by the summer or fall.

If in the spring of 2021 people are going to big public events—like a game or concert in a stadium—it will be because we have a miraculous treatment that made people feel confident about going out again. It's hard to know precisely what the threshold is, but I suspect it is something like 95 percent; that is, we need a treatment that is 95 percent effective in order for people to feel safe in big public gatherings. Although it is possible that a combination of treatments will have over 95 percent effectiveness, it's not likely, so we can't count on it. If our best treatments reduce the deaths by less than 95 percent, then we will still need a vaccine before we can go back to normal.

One potential treatment that doesn't fit the normal definition of a drug involves collecting blood from patients who have recovered from COVID, making sure it's free of the coronavirus and other infections, and giving the plasma to people who are sick. The leading companies in this area are working together to get a standard protocol to see if this works. They will have to measure each patient to see how strong their antibodies are. A variant of this approach is to take the plasma and concentrate it into a compound called hyperimmune globulin, which is much easier and faster to give a patient than unconcentrated plasma. The foundation is supporting a consortium of most of the leading companies that work in this area to accelerate the evaluation and, if the procedure works, be ready to scale it up. These companies have developed a Plasma Bot to help recovered COVID patients donate plasma for this effort.

Another type of potential treatment involves identifying the antibodies produced by the human immune system that are most effective against the novel coronavirus. Once those antibodies have been found, they can be manufactured and used as a treatment or as a way to prevent the disease (in which case it is known as passive immunization). This antibody approach also has a good chance of working, although it's unclear how many doses can be made. It depends on how much antibody material is needed per dose; in 2021, manufacturers may be able to make as few as 100,000 treatments or many millions. The lead times for manufacturing are about seven months in the best case. Our grantees are working to compare the different antibodies and make sure the best ones get access to the limited manufacturing capacity.

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There is a class of drugs called antivirals, which keep the virus from functioning or reproducing. The drug industry has created amazing antivirals to help people with HIV, although it took decades to build up the large library of very effective triple drug therapies. For the novel coronavirus, the leading drug candidate in this category is Remdesivir from Gilead, which is in trials now. It was created for Ebola. If it proves to have benefits, then the manufacturing will have to be scaled up dramatically.

The foundation recently asked drug companies to provide access to their pipeline of developed antiviral drugs so researchers funded by the Therapeutics Accelerator can run a screen to see which should go into human trials first. The drug companies all responded very quickly, so there is a long list of antivirals being screened.

Another class of drugs works by changing how the human body reacts to the virus. Hydroxychloroquine is in this group. The foundation is funding a trial that will give an indication of whether it works on COVID by the end of May. It appears the benefits will be modest at best. Another type of drug that changes the way a human reacts to a virus is called an immune system modulator. These drugs would be most helpful for late-stage serious disease. All of the companies that work in this area are doing everything they can to help with trials.

VACCINES

Vaccines have saved more lives than any other tool in history. Smallpox, which used to kill millions of people every year, was eradicated with a vaccine. New vaccines have played a key role in reducing childhood deaths from 10 million per year in 2000 to fewer than 5 million per year today.

Short of a miracle treatment, which we can't count on, the only way to return the world to where it was before COVID showed up is a highly effective vaccine that prevents the disease.

Unfortunately, the typical development time for a vaccine against a new disease is over five years. This is broken down into: a) making the candidate vaccine; b) testing it in animals; c) safety testing in small numbers of people (this is known as phase 1); d) safety and efficacy testing in medium numbers (phase 2); e) safety and efficacy testing in large numbers (phase 3); and f) final regulatory approval and building manufacturing while registering the vaccine in every country.

Researchers can save time by compressing the clinical safety/efficacy phases while conducting animal tests and building manufacturing capacity in parallel. Even so, no one knows in advance which vaccine approach will work, so a number of them need to be funded so they can advance at full speed. Many of the vaccine approaches will fail because they won't generate a strong enough immune response to provide protection. Scientists will get a sense of this within three months of testing in humans by looking at the antibody generation. Of particular interest is whether the vaccine will protect older people, whose immune systems don't respond as well to vaccines.

The issue of safety is obviously very important. Regulators are very stringent about safety, to avoid side effects and also to protect the reputation of vaccines broadly, since if one has significant problems, people will become more hesitant to take any vaccines. Regulators worldwide will have to work together to decide how large the safety database needs to be to approve a COVID vaccine.

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One step that was taken after the foundation and others called for investments in pandemic preparedness in 2015 was the creation of the Coalition for Epidemic Preparedness Innovations (CEPI). Although the resources were quite modest, they have helped advance new approaches to making vaccines that could be used for this pandemic. CEPI added resources to work on an approach called RNA vaccines, which our foundation had been supporting for some time. Three companies are pursuing this approach. The first vaccine to start human trials is an RNA vaccine from Moderna, which started a phase 1 clinical safety evaluation in March.

An RNA vaccine is significantly different from a conventional vaccine. A flu shot, for example, contains bits of the flu virus that your body's immune system learns to attack. This is what gives you immunity. With an RNA vaccine, rather than injecting fragments of the virus, you give the body the genetic code needed to produce lots of copies of these fragments. When the immune system sees the viral fragments, it learns how to attack them. An RNA vaccine essentially turns your body into its own vaccine manufacturing unit.

There are also at least five leading efforts that look promising and that use other approaches to teach the immune system to recognize and attack a viral infection. CEPI and our foundation will be tracking efforts from all over the world to make sure the most promising ones get resources. Once a vaccine is ready, our partner GAVI will make sure it is available even in low-income countries.

A big challenge for vaccine trials is that the time required for the trials depends on finding trial locations where the rate of infection is fairly high. While you are setting up the trial site and getting regulatory approval, the infection rate in that location could go down. And trials have to involve a surprisingly large number of people. For example, suppose the expected rate of infection is 1 percent per year and you want to run a trial where you would expect 50 people to be infected without the vaccine. To get a result in six months, the trial would need 10,000 people in it.

The goal is to pick the one or two best vaccine constructs and vaccinate the entire world—that's 7 billion doses if it is a single-dose vaccine, and 14 billion if it is a two-dose vaccine. The world will be in a rush to get them, so the scale of the manufacturing will be unprecedented and will probably have to involve multiple companies.

I am often asked when large-scale vaccination will start. Like America's top public health officials, I say that it is likely to be 18 months, even though it could be as short as nine months or closer to two years. A key piece will be the length of the phase 3 trial, which is where the full safety and efficacy are determined. When the vaccine is first being manufactured, there will be a question of who should be vaccinated first. Ideally, there would be global agreement about who should get the vaccine first, but given how many competing interests there are, this is unlikely to happen. The governments that provide the funding, the countries where the trials are run, and the places where the pandemic is the worst will all make a case that they should get priority.

TESTING

All of the tests to date for the novel coronavirus involve taking a nasal swab and processing it in a Polymerase Chain Reaction (PCR) machine. Our foundation invested in research showing that having patients do the swab themselves, at the tip of the nose, is as accurate as having a doctor push the swab further down to the back of your

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throat. Our grantees are also working to design swabs that are cheap and able to be manufactured at large scale but work as well as ones that are in short supply. This self-swab approach is faster, protects health care workers from the risk of exposure, and should let regulators approve swabbing in virtually any location instead of only at a medical center. The PCR test is quite sensitive—it will generally show whether you have the virus even before you have symptoms or are infecting other people.

There has been a lot of focus on the number of tests being performed in each country. Some, like South Korea, did a great job of ramping up the testing capacity. But the number of tests alone doesn't show whether they are being used effectively. You also have to make sure you are prioritizing the testing on the right people. For example, health care workers should be able to get an immediate indication of whether they are infected so they know whether to keep working. People without symptoms should not be tested until we have enough tests for everyone with symptoms. Additionally, the results from the test should come back in less than 24 hours so you quickly know whether to continue isolating yourself and quarantining the people who live with you. In the United States, it was taking over seven days in some locations to get test results, which reduces their value dramatically. This kind of delay is unacceptable.

There are two types of PCR machines: high-volume batch processing machines and low-volume machines. Both have a role to play. The high-volume machines provide most of the capacity. The low volume machines are better when getting a result in less than an hour is beneficial. Everyone who makes these machines, and some new entrants, are making as many machines as they can. Adding this capacity and making full use of the machines that are already available will increase the testing capacity. The foundation is talking to the manufacturers about different ways to run the big machines that could make them more than twice as productive.

Another type of test being developed is called a Rapid Diagnostic Test (RDT). This would be like an in-home pregnancy test. You would swab your nose the same way as for the PCR test, but instead of sending it into a processing center, you would put it in a liquid container and then pour that liquid onto a strip of paper that would change color if it detects the virus. This form of test may be available in a few months. Even though it won't be as sensitive as a PCR test, for someone who has symptoms it should be quite accurate. You would still need to report your test result to your government since they need visibility into the disease trends.

A lot of people talk about the serology test, where you give blood and it detects whether you have antibodies against the virus. If you do, it means you have been exposed. These tests only show positive results late in your disease, so they do not help you decide whether to quarantine. Also, all the tests done so far have problems with false positives. Until we understand what level of antibodies is protective and have a test with almost no false positives, it is a mistake to tell people not to worry about their exposure to infection based on the serology tests that are available today. In the meantime, serology tests will be used to see who can donate blood and to understand the disease dynamics.

A lot of countries did a good job focusing the PCR capacity on the priority patients. Most countries had their government play a central role in this process. In the United States, there is no system for making sure the testing is allocated rationally. Some states have stepped in, but even in the best states, the access isn't fully controlled.

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Testing becomes extremely important as a country considers opening up. You want to have so much testing going on that you see hot spots and are able to intervene by changing policy before the numbers get large. You don't want to wait until the hospitals start to fill up and the number of deaths goes up.

Basically, there are two critical cases: anyone who is symptomatic, and anyone who has been in contact with someone who tested positive. Ideally both groups would be sent a test they can do at home without going into a medical center. Tests would still be available in medical centers, but the simplest is to have the majority done at home. To make this work, a government would have to have a website that you go to and enter your circumstances, including your symptoms. You would get a priority ranking, and all of the test providers would be required to make sure they are providing quick results to the highest priority levels. Depending on how accurately symptoms predict infections, how many people test positive, and how many contacts a person typically has, you can figure out how much capacity is needed to handle these critical cases. For now, most countries will use all of their testing capacity for these cases.

There will be a temptation for companies to buy testing machines for their employees or customers. A hotel or cruise ship operator would like to be able to test everyone even if they don't have symptoms. They will want to get PCR machines that give quick results or the rapid diagnostic test. These companies will be able to bid very high prices—well above what the public health system would bid—so governments will have to determine when there is enough capacity to allow this.

One assumption is that people who need to get tested will isolate themselves and quarantine those in their household. Some governments police this carefully, whereas others simply assume people will follow the recommendation. Another issue is whether a government provides a place for someone to isolate themselves if they can't do it at their home. This is particularly important if you have older people in close quarters at your house.

CONTACT TRACING

I mentioned in the testing section that one of the key priorities for testing is anyone who has been in close contact with someone who has tested positive. If you can get a list of these people quickly and make sure they are prioritized for a test like the PCR test (which is sensitive enough to detect a recent infection), then these people can isolate themselves before they infect other people. This is the ideal way of stopping the spread of the virus.

Some countries, including China and South Korea, required patients to turn over information about where they have been in the last 14 days by looking at GPS information on their phone or their spending records. It is unlikely that Western countries will require this. There are applications you can download that will help you remember where you have been; if you ever test positive, then you can voluntarily review the history or choose to share it with whoever interviews you about your contacts.

A number of digital approaches are being proposed where phones detect what other phones are near them. (It would involve using Bluetooth plus sending a sound out that humans can't hear but that verifies that the two

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phones are reasonably close to each other.) The idea is that if someone tests positive then their phone can send a message to the other phones and their owners can get tested. If most people voluntarily installed this kind of application, it would probably help some. One limitation is that you don't necessarily have to be in the same place at the same time to infect someone—you can leave the virus behind on a surface. This system would miss this kind of transmission.

I think most countries will use the approach that Germany is using, which requires interviewing everyone who tests positive and using a database to make sure there is follow-up with all the contacts. The pattern of infections is studied to see where the risk is highest and policy might need to change.

In Germany, if someone is tested and confirmed positive, the doctor is legally required to inform the local government health office. The doctor must provide all personal data—name, address, phone number—so that the health office can contact the person and ensure they isolate themselves.

Then the local health office begins the process of contact tracing. They interview the infected person, find out how to contact all the people he or she has met in the past couple of weeks, and contact those people to ask them to self-isolate and get a test.

This approach relies on the infected person to report their contacts accurately, and also depends on the ability of the health authorities to follow up with everyone. The normal health service staff can't possibly do all this work even if the case numbers are fairly low. Every health system will have to figure out how to staff up so that this work is done in a timely fashion. Everyone who does the work would have to be properly trained and required to keep all the information private. Researchers would be asked to study the database to find patterns of infection, again with privacy safeguards in place.

OPENING UP

Most developed countries will be moving into the second phase of the epidemic in the next two months. In one sense, it is easy to describe this next phase. It is semi-normal. People can go out, but not as often, and not to crowded places. Picture restaurants that only seat people at every other table, and airplanes where every middle seat is empty. Schools are open, but you can't fill a stadium with 70,000 people. People are working some and spending some of their earnings, but not as much as they were before the pandemic. In short, times are abnormal but not as abnormal as during the first phase.

The rules about what is allowed should change gradually so that we can see if the contact level is starting to increase the number of infections. Countries will be able to learn from other countries that have strong testing systems in place to inform them when problems come up.

One example of gradual reopening is Microsoft China, which has roughly 6,200 employees. So far about half are now coming in to work. They are continuing to provide support to employees who want to work at home. They insist people with symptoms stay home. They require masks and provide hand sanitizer and do more intensive

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cleaning. Even at work, they apply distancing rules and only allow travel for exceptional reasons. China has been conservative about opening up and has so far avoided any significant rebound.

The basic principle should be to allow activities that have a large benefit to the economy or human welfare but pose a small risk of infection. But as you dig into the details and look across the economy, the picture quickly gets complicated. It is not as simple as saying "you can do X, but not Y." The modern economy is far too complex and interconnected for that.

For example, restaurants can keep diners six feet apart, but will they have a working supply chain for their ingredients? Will they be profitable with this reduced capacity? The manufacturing industry will need to change factories to keep workers farther apart. Most factories will be able to adapt to new rules without a large productivity loss. But how do the people employed in these restaurants and factories get to work? Are they taking a bus or train? What about the suppliers who provide and ship parts to the factory? And when should companies start insisting their employees show up at work?

There are no easy answers to these questions. Ultimately, leaders at the national, state, and local levels will need to make trade-offs based on the risks and benefits of opening various parts of the economy. In the United States it will be tricky if one state opens up too fast and starts to see lots of infections. Should other states try to stop people moving across state boundaries?

Schools offer a big benefit and should be a priority. Large sporting and entertainment events probably will not make the cut for a long time; the economic benefit of the live audience doesn't measure up to the risk of spreading the infection. Other activities fall into a gray area, such as church services or a high school soccer game with a few dozen people on the sidelines.

There is one other factor that is hard to account for: human nature. Some people will be naturally reluctant to go out even once the government says it is okay. Others will take the opposite view—they will assume that the government is being overly cautious and start bucking the rules. Leaders will need to think carefully about how to strike the right balance here.

Conclusion

Melinda and I grew up learning that World War II was the defining moment of our parents' generation. In a similar way, the COVID pandemic—the first modern pandemic—will define this era. No one who lives through Pandemic I will ever forget it. And it is impossible to overstate the pain that people are feeling now and will continue to feel for years to come.

The heavy cost of the pandemic for lower-paid and poor people is a special concern for Melinda and me. The disease is disproportionately hurting poorer communities and racial minorities. Likewise, the economic impact of

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the shutdown is hitting low-income, minority workers the hardest. Policymakers will need to make sure that, as the country opens up, the recovery doesn't make inequality even worse than it already is.

At the same time, we are impressed with how the world is coming together to fight this fight. Every day, we talk to scientists at universities and small companies, CEOs of pharmaceutical companies, or heads of government to make sure that the new tools I've discussed become available as soon as possible. And there are so many heroes to admire right now, including the health workers on the front line. When the world eventually declares Pandemic I over, we will have all of them to thank for it.

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From: Bill Gates [redacted]@gatesventures.com>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Subject: My End-of-Year Letter
Date: Tue, 07 Dec 2021 17:43:56 -0500
Importance: Normal
Attachments: My-End-of-Year-Letter_2021.pdf

Tony,

You may have seen that my Year in Review was published on Gates Notes today.

Every year around this time, I like to take stock of the last twelve months. It's a great opportunity to reflect on what has gone well and what hasn't over the past year, and what I'm expecting for the year ahead. I recently sat down to write about some of the things that are top of mind for me as 2021 comes to a close, from when the pandemic might end to how digitization will shape the future.

Attached is a copy of the letter. I'll be interested to hear what you think.

Happy holidays,

Bill

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MY END-OF-YEAR LETTER 2021

December 7, 2021

Reasons for optimism after a difficult year
By Bill Gates

When Paul and I were starting Microsoft, we had a vision that personal computers would one day play a significant role in people's lives. But I don't think either of us ever foresaw a future where they would be your only connection to the world. Like many people, there were entire days this year when the only human interaction I had was through a screen.

The result has been the most unusual and difficult year of my life. (I suspect a lot of the people reading this might say the same.) 2020 had a brief period of relative normalcy before COVID-19 upended everything. In 2021, the pandemic has dominated our lives since day one. We've all had to adapt to a "new normal," although what that looks like is different for every person. For me, the result has been a year spent mostly online.

I had stretches of time without any face-to-face social interaction. If I had a break between meetings, I'd walk around my yard just to see something different. After work, I'd play bridge with friends online or hang out with them over video chat. Once I got vaccinated, I started having some small in-person get-togethers, but my social life is still a lot more digital than it used to be.

It's been a strange and disorienting experience. My personal world has never felt smaller than it did over the last twelve months.

At the same time, this year was a reminder that our world is more connected than ever. 2021 was full of monumental events with global repercussions, including extreme weather events, the ongoing effects of the pandemic, and America's withdrawal from Afghanistan. Every time you looked at the news, you were reminded of just how significantly something happening on the other side of the world could affect you at home. (Just look at how one container ship stuck in the Suez Canal for a week caused shipping delays around the world.) It's never been clearer that tackling big problems requires people working together across borders and sectors.

(Left) People rest in a cooling center in Portland, Oregon, during a heatwave in June. (Kathryn Elsesser/AFP) (Right) A large cargo ship became lodged in the Suez Canal, halting global commerce for six days in March. (Songphol Thesakit/Getty Images)

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Collaboration has been a constant theme with my work this year. The foundation continues to take up the bulk of my time, and I'm blown away by the amazing progress made by our team and our partners in 2021. Most weeks, we have a virtual get-together with everyone who's working on our COVID response. Each meeting focuses on a different topic, like disease modelling or vaccine distribution. It's inspiring to hear how groups are working together to find solutions.

Although COVID-19 has been a huge focus, the foundation continues to make progress in other areas. Our U.S. Program is working with partners to help students and teachers navigate the strange new world of pandemic-era education, and my colleagues working on gender equality are fighting for a more equitable global recovery. The global health and development teams have found creative ways to protect advancements on diseases like polio, TB, and HIV and continue progress in reducing childhood mortality. (This year's Goalkeepers Report outlines how the pandemic hasn't set us back as badly as feared.)

One of the most exciting things that happened was WHO approval of the first malaria vaccine. Malaria kills nearly 650,000 people every year—more than half of them children under five—and remains one of the leading causes of death in low-income countries. We funded late-stage clinical development of the vaccine between 2001 and 2015 and continue to support research into how to optimize its effectiveness. This new vaccine is giving us insights into how to develop second-generation vaccines and preventative tools that can be used on all ages, are even more effective, and can help us reach the goal of eradication.

This year also saw the start of a new chapter in my climate work. I released my book *How to Avoid a Climate Disaster* and launched the Breakthrough Energy Catalyst and Fellows programs to support financing, producing, and buying new clean-energy technologies. The reason I felt confident enough to expand our efforts so significantly was the incredible progress I've seen from Breakthrough Energy Ventures, where we are now supporting over 70 amazing companies.

I've been working on climate and energy issues for a long time, but the area has become a bigger part of my focus over the last twelve months. I also found time to work on some non-foundation and non-climate-related areas, like Alzheimer's research and expanding free educational resources for teachers.

Even though I think the things I've been working on are by far the most interesting part of my year, I know a lot of people are curious about a subject closer to home: my divorce. Melinda and I continue to run our foundation together and have found a good new working rhythm, but I can't deny that it's been a year of great personal sadness for me. Adapting to change is never easy, no matter what it is. I've been impressed by how resilient my loved ones—especially my kids—have been in this challenging time.

My family also experienced a lot of changes beyond what you probably saw in the news. My oldest daughter, Jenn, got married this fall, and her wedding was the highlight of my year. Our youngest, Phoebe, graduated from high school and went off to college. Since my son Rory is also away at school, that means I'm officially an empty nester. The house is a lot quieter without a bunch of teenagers hanging around all the time. I miss having them at home, even if it is easier to focus on reading a book or getting work done these days.

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2021 has been a year of big transitions for me, but it hasn't changed why I love the work I do. As it comes to a close, I wanted to sit down and write about four things that are top of mind heading into 2022: the latest progress toward ending the COVID-19 pandemic, why decreased trust in institutions might be the biggest obstacle standing in our way, what the climate conversation can teach us about making progress, and how the rapid digitization brought on by the pandemic will shape our future.

Why I'm hopeful the end of the COVID-19 pandemic is finally in sight

In my previous end-of-year post, I wrote that I thought we'd be able to look back and say that 2021 was an improvement on 2020. While I do think that's true in some ways—billions of people have been vaccinated against COVID-19, and the world is somewhat closer to normal—the improvement hasn't been as dramatic as I hoped. More people died from COVID in 2021 than in 2020. If you're one of the millions of people who lost a loved one to the virus over the last twelve months, you certainly don't think this year was any better than last.

Because of the Delta variant and challenges with vaccine uptake, we're not as close to the end of the pandemic as I hoped by now. I didn't foresee that such a highly transmissible variant would come along, and I underestimated how tough it would be to convince people to take the vaccine and continue to use masks.

I *am* hopeful, though, that the end is finally in sight. It might be foolish to make another prediction, but **I think the acute phase of the pandemic will come to a close some time in 2022**.

(Left) A barista announces the reopening of her coffee shop. (Getty Images) (Right) Employees practice safety procedures at Suvarnabhumi International Airport in Thailand. (Lillian Suwanrumpha/Getty Images)

There's no question that the Omicron variant is concerning. Researchers—including a network called GIISER that is supported by our foundation—are working urgently to learn more about it, and we'll have a lot more information (like how well vaccines or previous infection protect you against it) soon. But here's what we do know: The world is better prepared to tackle potentially bad variants than at any other point in the pandemic so far. We caught this variant earlier than we discovered Delta because South Africa has invested heavily in genomic sequencing capabilities, and we're in a much better position to create updated vaccines if they're needed.

It's troubling any time a new variant of concern emerges, but I'm still hopeful that, at some point next year, COVID-19 will become an endemic disease in most places. Although it is currently about 10 times more lethal than flu, vaccines and antivirals could cut that number by half or more. Communities will still see occasional outbreaks, but new drugs will be available that could take care of most cases and hospitals will be able to handle the rest. Your individual risk level will be low enough that you won't need to factor it into your decision-making as much. It won't be primary when deciding whether to work from the office or let your kids go to their soccer game or watch a movie in a theater. In a couple years, my hope is that the only time you will really have to think about the virus is when you get your joint COVID and flu vaccine every fall.

Now that we're starting to move toward the end of this pandemic, I've been spending a lot of time thinking about what went right and what went wrong over the last two years. We can learn important lessons from the world's COVID-19 response that will make us better prepared next time.

Even though the pandemic has dragged on longer than anticipated, a lot has gone well. To start, **the progress we've made on vaccines is remarkable**. The world has never made and distributed a vaccine for a disease faster than it did for COVID-19. The fact that we had one—let alone multiple!—vaccines during the first year of the pandemic is miraculous. That success is a tribute to how many candidates the world had in the pipeline. Vaccine development relies on a little bit of luck, and we hedged our bets by trying so many different approaches.

I think **mRNA vaccines will ultimately be seen as the most consequential breakthrough of the pandemic.** Proving that mRNA works as a vaccine platform has been a massive gamechanger—not just for this pandemic, but for the next one too. Now that mRNA is well established, we'll be able to develop safe and effective vaccines super-fast in the future.

We also learned a lot about nonpharmaceutical interventions (or NPIs) that will inform disease response moving forward. NPIs include things like mask mandates, quarantine procedures, and travel restrictions. The last two years have given us the opportunity to see how effective different strategies are against a respiratory disease like COVID. Next time, the world will be ready to deploy cheap and easy tools like masks much quicker, and governments will have a greater understanding of when and how to deploy more burdensome strategies like lockdowns.

(Top left) A community health worker speaks with families about COVID-19 prevention in Afghanistan. (Top right) Students participate in an outdoor class in India. (Majority World/Getty Images) (Bottom left) A sign urges drivers to stay home during the early days of the pandemic. (Asurobson/Getty Images) (Bottome right) Catholic nuns prepare face masks for community distribution in Lusaka, Zambia.

Although stopping a pandemic is something that ultimately falls on systems and governments, **the last two years have shown us that individuals can make a real impact.** We've seen incredible people from around the world step up to do heroic work protecting their communities—from teachers who took time to drop off class materials on their students' doorsteps to health workers who went house to house making sure everyone had the opportunity to get vaccinated. I wrote a separate post profiling several of those heroes from the African continent. You can read about them here.

One area that's been a mixed bag is **therapeutics**. Up until the last couple of months, I was disappointed by the lack of progress we'd made on the treatment front. Remdesivir is expensive, and it just didn't have that big an effect. Dexamethasone is cheaper and helped a bit, but not enough to make a huge dent in stopping disease early. Monoclonal antibodies—which I was quite optimistic about at one point—were too complicated logistically to get out and save that many people earlier in the pandemic, and they weren't very effective against variants.

The reason I'm now feeling much better about therapeutics is the recent news about two new antiviral drugs. These are the therapeutics we needed in 2020. One of them—a drug called molnupiravir from Merck—just got the seal of approval from the FDA for people at high-risk last week. It significantly reduces your chances of being hospitalized or dying from COVID-19 (although not as much as we'd initially hoped), it's relatively cheap to make, and it's an oral medication that's easy to distribute.

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Earlier this year, before we knew the drug worked, the foundation supported an effort to streamline the process of producing molnupiravir in order to bring costs down. Merck is letting generic manufacturers make this simplified formulation, which will make the drug accessible to a lot more people. We also recently committed $120 million to making sure the drug is available in lower-income countries where it will save a lot of lives. I just wish it had come along sooner.

The area I see as the biggest disappointment is **the inequity of vaccine allocation**. This is something I've written about at length and something I'm going to keep talking about any chance I get, because it didn't have to be this way. The world has done an outstanding job manufacturing and distributing billions of doses of vaccine, but the fact that so few people at high risk in low-income countries have received them is unacceptable. It just doesn't make sense that so many low-risk people got vaccinated before we reached everyone who's older or had an underlying medical condition. Moving forward, we need to change how the world allocates doses and find ways to ramp up manufacturing even faster, including by expanding global vaccine-making capacity and helping more countries develop, manufacture, and approve vaccines themselves.

The other area where there is huge room for improvement is in **finding ways to combat disinformation.** As I mentioned, I thought demand for vaccines would be way higher than it has been in places like the United States. It's clear that disinformation (including conspiracy theories that unfortunately involve me) is having a substantial impact on people's willingness to get vaccinated. This is part of a larger trend toward distrust in institutions, and it's one of the issues I'm most worried about, heading into 2022.

Declining trust makes it harder to tackle big challenges

I've had a lot of people ask me recently if I'm still optimistic about the future. While the answer is yes, being an optimist doesn't mean ignoring problems. I am deeply troubled by one challenge in particular.

The pandemic has been a massive test of governance. When the pandemic finally comes to an end, it will be a tribute to the power of global cooperation and innovation. At the same time, this era has shown us how declining trust in public institutions is creating tangible problems and complicating our efforts to respond to challenges. Based on what I've seen over the last

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couple of years, I'm more worried than I've ever been about the ability of governments to get big things done.

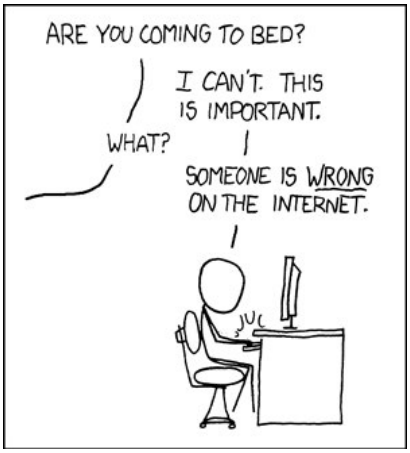
We need governments to take action if we're going to make progress on challenges like avoiding a climate disaster or preventing the next pandemic. But declining trust makes it harder for them to be effective. If your people don't trust you, they're not going to support major new initiatives. And when a major crisis emerges, they're less likely to follow guidance necessary to weather the storm.

This decline in trust is happening all over the world. The 2021 Edelman Trust Index shows worrying drops across the globe. Part of it is understandable: Any time you have a really big crisis like a pandemic, people look for someone to blame. Governments are an obvious target.

But this trend toward less trust in government didn't start in 2020. The pandemic only made clearer what had already been happening.

So, who or what is to blame? It's clear that increased polarization is a significant driver. This is especially evident here in the United States, although we're far from alone. Americans are becoming more divided and more deeply entrenched in their political beliefs. The gap between the left and the right is becoming a gulf that's harder and harder to bridge.

There are many reasons for this growing divide, including a 24-hour news cycle, a political climate that rewards headline generation over substantive debate, and the rise of social media. I'm especially interested in understanding the latter, since it's the most technologically driven.



(xkcd.com)

Digital communication has profound benefits in terms of helping people collaborate, stay in touch, and share things with each other. But social media has played a huge role in spreading misinformation that makes people suspicious of their governments. Social media feeds have become so personalized that you don't see factual information if it doesn't align with your profile.

I believe that governments need to regulate what you can and can't use social media for. In the United States, this topic has raised a lot of free speech questions. But the reality is that our government already has all sorts of norms around communication.

You can't slander someone or trick them out of their money by promising something you don't deliver on. Network TV shows can't show explicit sex scenes or use certain profane language before 10 p.m., in case children are watching. These rules exist to protect people. So why couldn't our government create new rules to protect them from the most tangible harms created by social media? They wouldn't be easy to enforce, and we'd need public debate about exactly where the lines should be, but this is doable and really important to get done. A video falsely claiming that the COVID-19 vaccine makes you infertile should not be allowed to spread widely under the guise of being news.

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As people become more polarized on both sides of the aisle, politicians are incentivized to take increasingly extreme positions. In the past, if you didn't like the way a government agency was operating, you'd run on a platform of fixing it. Today, we're seeing more people get elected on the promise of abandoning institutions and norms outright.

When your government leaders are the ones telling you not to trust government, who are you supposed to believe? This creates a compounding effect where people lose confidence in government, elect politicians who share their distrust, and then become even more disillusioned as their leaders tell them how bad the institutions they now run are.

This is usually where I'd lay out my ideas for how we fix the problem. The truth is, I don't have the answers. I plan to keep seeking out and reading others' ideas, especially from young people. I'm hopeful that the generations who grew up online will have fresh ideas about how to tackle a problem that is so deeply rooted in the internet.

This problem requires more than just innovation to solve, although there are some steps we can take (especially around e-governance and making data more available to the public) to make modest improvements. There are all sorts of ways that great scientific ideas get published and tested. For great political ideas, the pathways are not as clear. Thinktanks and academics can point in the right direction, but at the end of the day—in a democracy at least—it seems to me like you need to pick the right leaders and give them the space to try new ideas.

What we can learn about progress from the climate conversation

There's a phrase we like to use at the foundation: Progress is possible, but not inevitable. Change happens because groups of people get together and decide to make things better. It might not happen as quickly as you want or need it. But if you have enough smart, thoughtful, and passionate people pushing for it, progress will eventually come.

I was reminded of this at the recent COP26 climate conference in Glasgow, Scotland. The climate conversation is often singled out as an area stymied by disagreement. In the past, there was a lot of debate about whether we had all the tools we needed to solve this problem. Now, there's a lot more agreement that we have some of what we need, but not all of it—and that we need to prioritize closing that gap if we're going to avoid a climate disaster.

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I was blown away by the enthusiasm and intense engagement in Glasgow, especially compared to the last major COP conference in 2015. Everywhere you looked, you saw leaders from around the world—including lots of government officials and CEOs—eager to make real commitments.

The biggest change I saw compared to 2015 was the focus on innovation. There is now a broad understanding that innovation needs to be at the forefront of any plan to get to zero emissions by 2050. The private sector is playing a central and necessary role alongside governments and nonprofits. It was encouraging to hear leaders from various industries that need to be part of the transition—including shipping, mining, and financial services—talk about their practical plans to decarbonize and to support innovation.

I spent a lot of time at the conference talking to people about how new green technologies need to be affordable enough for the whole world to use them. If we're going to scale the innovations that get us to zero, we need to reduce the cost difference between things that emit greenhouse gases and things that don't. I call this difference the Green Premium, and addressing it needs to be an essential part of any climate plan.

I was also excited to see so much attention paid to adaptation. We will lose the global fight against poverty if we don't help the world's poorest adapt to climate change, especially subsistence farmers who rely on the food they grow to feed their families and are the most at risk. Even if the world hits its goal of net-zero by 2050, we'll still experience significant warming. That will create huge problems for people in low- and middle-income countries unless we take steps now to help them, such as developing new crops that are more productive and can withstand weather changes.

In short, this conference made it clear that the world is engaged and making progress. The result was a number of important concrete steps, like new commitments to investing in clean technologies, pledges to cut methane emissions and end deforestation by the end of the decade, and the creation of a coalition that will help farmers adapt.

None of this happened by accident. The improvements made over recent years are a testament to the activists, elected officials, business leaders, philanthropists, and engaged citizens fighting to move climate change up the global agenda. We still have a lot more work to do—even if every commitment made at the COP is fulfilled, we still won't hit our target of limiting global warming to less than 2 degrees—and I hope the world builds on the progress made in Glasgow. But I'm optimistic that we have the momentum necessary to avoid a climate disaster.

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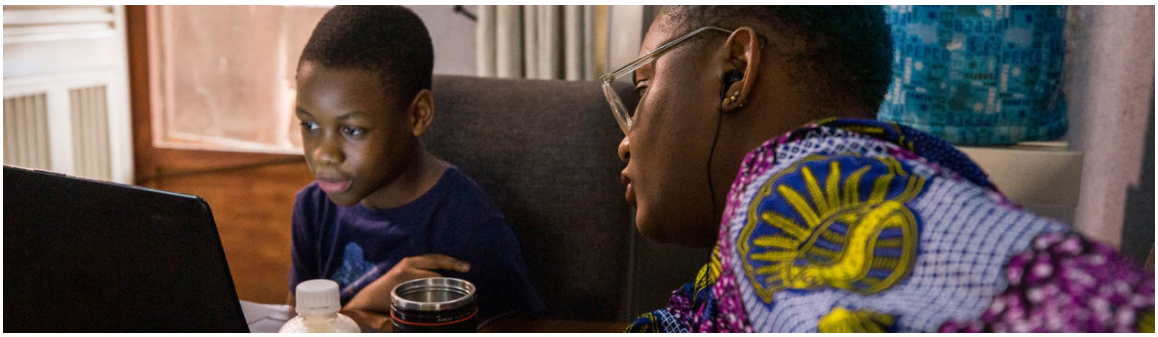

2021 gave us a preview of our more digitized future

Even after this pandemic ends, it's clear that much of the digitization it brought on is here to stay. The last two years have led to monumental leaps forward in how we use technology, accelerating changes that would've taken years—if not a decade or longer—otherwise. We've seen rapid, widespread adoption of services that already existed, like ordering groceries online or having meetings over video chat. And we've seen the creation of new innovations that I think only represent the tip of the iceberg of what's to come in the years ahead.

Digitization is here to stay, but the technologies we're using will continue to get better over time. We're just at the start of how software will enable innovation. The more we use digital tools, the more feedback we get about how to make them better. It'll take at least a decade to understand the full scope of the pandemic's impact on digitization, but I predict we'll see big changes in three areas.

The first and perhaps most significant is office work. The pandemic has revolutionized how companies think about productivity and presence in the workplace. The boundaries between once-discrete areas of work—brainstorming, team meetings, casual conversations in the hallway—are collapsing. We're starting to see structures evolve that we thought were essential to office culture, and those changes will only intensify in the years to come as businesses and employees settle into new permanent ways of working.

I'm really excited about the potential for experimentation. Expectations around what productivity looks like have been upended. I see lots of opportunity to rethink things and find out what is working and what isn't.

For example, there has been a lot of debate about whether companies should stay completely remote, plan a full return to the office, or find some compromise between the two. Although most companies will likely opt for the hybrid approach, there's a good deal of flexibility around what exactly that approach might look like. What if your employees set their own schedule? Do you have people work from the office on Mondays and Fridays, or do you ask them to work remotely on those days knowing that traffic might be worse around the weekend?

I don't see any reason why companies need to make firm decisions right away. As the pandemic ends and things start to become more normal, this is a great time to take an A/B testing

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approach to remote work. Maybe you have one team try one configuration while a different team tries another, so that you can compare the results and find the right balance for everyone.

(It's worth repeating that I'm talking about office jobs. The pandemic disrupted work in virtually every industry. There are huge sectors of the economy where things won't change as much or will change in different ways from what I'm describing here.)

I'm also really interested in how technology can create more spontaneity with remote work, moving forward.

This is the biggest thing you lose when you're not in the office. Let's say you used to work in an open space with six other people. You could look up at any time and see what they were up to. You could tell whether they felt like talking, giving you advice, or just taking a break to chat about nonwork stuff. That kind of spontaneous interaction stopped when many of us began working from home—you aren't exactly going to have an unplanned conversation with a colleague about your last meeting in your living room. But there are a lot of innovations in the pipeline to replicate that experience at home.

If you had a second screen that was very cheap and a physical place to put it, you could have a feed of all six of you sitting in your home offices working. You could look at the screen to see what everyone is doing (except when someone wants privacy and turns the camera off). When someone seems like they're free to talk, you could just click on their video, zoom in, and start chatting. This isn't radically different from how collaboration tools work today, and it's something we have the bandwidth and software power to do now.

I think we'll soon start to see an even bigger shift. People shouldn't assume that the quality of the software that lets you have virtual experiences will stay the same. The acceleration of innovation is just starting.

Within the next two or three years, I predict most virtual meetings will move from 2D camera image grids—which I call the *Hollywood Squares* model, although I know that probably dates me—to the metaverse, a 3D space with digital avatars. Both Facebook and Microsoft recently unveiled their visions for this, which gave most people their first view of what it will look like.

The idea is that you will eventually use your avatar to meet with people in a virtual space that replicates the feeling of being in an actual room with them. To do this, you'll need something like VR goggles and motion capture gloves to accurately capture your expressions, body language, and the quality of your voice. Most people don't own these tools yet, which will slow adoption somewhat. (One of the things that enabled the rapid change to video meetings was the fact that many people already had PCs or phones with cameras.) Microsoft plans to roll out an interim version next year, which uses your webcam to animate an avatar that's used in the current 2D setup.

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I had a lot of fun trying out a 3D avatar earlier this year.

There are a ton of companies working on 3D avatars, and I recently had the opportunity to test out some of their prototypes. I was super impressed by what I saw. One of the biggest improvements over what we use now is the use of spatial audio, where speech sounds like it's actually coming from the direction of the person talking. You don't realize how unusual it is to have meeting audio only coming from your computer's speaker until you try something else. There's still some work to do, but we're approaching a threshold where the technology begins to truly replicate the experience of being together in the office.

The second area where we'll see the lasting effects of digitization is education. Unlike offices, schools will go back to only in-person instruction except maybe for some limited remote options for older high school students. What will change, though, is how we use digital tools to enhance the way kids learn.

The ability of new digital education tools to transform the classroom is, of course, dependent on kids having access to technology at home. The access gap has narrowed since the start of the pandemic and will continue to narrow, but a lot of kids still don't have a decent computer or reliable, fast internet at home. Finding ways to expand access is just as important as the development of new innovations.

The pandemic accelerated the development of dynamic curricula, as more teachers had to rely on digital tools to give students assignments during the periods when schools were closed. We're starting to see that curriculum become more responsive as demand goes up, and it will only become more tailored to the individual needs of students and teachers in the years ahead. The intention is that these new tools will supplement classroom learning rather than replace it. (If there's one thing the last two years made clear, it's that many kids—especially younger ones—don't do well sitting in front of a screen doing classwork all day.)

If you're a student, you'll be able to get feedback from the software while you do your homework online. The content will be more interactive and personalized to you, helping you focus on areas where you need a bit more help while boosting your confidence by giving you problems you're more comfortable solving.

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(Left) A college student does homework on her laptop. (Carol Yepes/Getty Images) (Right) A teacher records himself explaining a math problem to his students in Jilin, China. (TPG/Getty Images)

If you're a teacher, you'll gain a deeper understanding of how your students are doing. A simple button click will show you that student X might need more help on a particular type of question while telling you that student Y is ready to take on a more advanced reading assignment.

The foundation has been working on innovative new tools like this for years, and it's been great to see so much progress made over the last two years in response to the pandemic.

Some of the biggest leaps forward have been in math curricula. A lot of kids develop a self-image of not being good at math. They struggle with problem sets that are perhaps too hard for their current skill level, and they never catch up as classes become more advanced. It's a big problem that I'm optimistic we can solve with technology.

The foundation is working with partners on new curricula that help kids become more confident in their math skills. I'm so excited about this work—and have so much to say about it—that I wrote a separate post detailing some of the most promising examples. You can read it here.

The final area where digitization is here to stay is in health care. Telehealth isn't new, but its popularity during the pandemic was. Over the last two years, we've seen more people opting for virtual appointments instead of in-person care. The technologies that facilitate these appointments are already getting much better, and I expect huge improvements over time.

Although some medical fields have gone back to mostly in-person visits, one area that I predict is forever changed is behavioral health. Virtual appointments have so many upsides that I think the new model is here to stay.

Seeing your therapist is a lot less time-consuming and easier to fit in your day when you only have to turn your laptop on. Sessions can be as long or as short as needed—a 15-minute session might not feel worth it if you have to go to a doctor's office, but it makes a lot more sense from home. Plus, many people feel more comfortable in their own spaces than in a clinical setting.

Other types of doctor's visits might become more flexible as new tools emerge, too. Right now, when it's time for your annual physical, you probably need to go into your doctor's office to get your vitals taken and your blood drawn. But what if you had a device at home that your

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doctor could control remotely to test your blood pressure? What if he or she could look at data collected from your smart watch to see how you're sleeping and what your active heart rate is? What if you could get your blood tested at a convenient place in your neighborhood—maybe at your local pharmacy—that sends the results directly to your doctor? What if you could keep seeing a primary care physician you like even if you moved to another state?

(Left) Health workers pose with a robot that helps with consultations, therapies, and mental health evaluations of COVID-19 patients. (Claudio Crus/Getty Images) (Right) A dad checks his daughter's temperature while a doctor watches over a video call. (Maskat/Getty Images)

These are all real possibilities in the future, and I'm curious to see how they transform health care. Beyond the technology and privacy limits, there are also regulatory hurdles we need to figure out before digital health care becomes truly mainstream. Some states still make it hard to see patients virtually in a different state because of how licensing currently works.

As unbelievable as it sounds, we're only starting to see how digitization is going to change our lives. There is so much potential for technology to create more flexibility and options for people. I'm hesitant to suggest that anything about the COVID-19 pandemic has been positive. But when we look back at this period, I suspect history will view it as a time of terrible devastation and loss that also sparked lots of massive changes for the better.

Reasons for optimism in 2022

My work has always been driven by a simple idea: The world can get better. A big setback like the pandemic makes it harder to believe that progress is possible. I'm still optimistic, though, about our ability to build a world where everyone has the chance to live a healthy and productive life.

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But that ability is dependent on whether we can stop the next pandemic. We can't afford to repeat the suffering of the last two years. The world had a chance to invest in the tools and systems that could've prevented the COVID-19 pandemic, and we didn't take it. Now is the time to learn from our mistakes and take steps to prevent this terrible experience from ever happening again.

The good news is that the world no longer needs to be persuaded that stopping a pandemic is important. I'm hopeful that we'll see broad support for pandemic preparedness efforts, and I plan on spending a lot of time advocating for them. **This is the biggest and most important thing I'm going to work on in 2022.** I'm currently writing a book that will come out some time next year, which lays out my plan for making sure that COVID-19 is the last pandemic.

I think we'll see plenty of other reasons for optimism in 2022 as well, especially on the innovation front. I expect lots of progress as R&D that was put on hold by the pandemic picks up steam.

One of the things I'm most excited to track is the clinical trials for a promising new HIV preventative called islatravir. Today, you can reduce your risk of getting infected by either taking a pill every day or what's called "on-demand prophylaxis." Although both current options provide terrific protection, the former relies on the ability to take it regularly, and the latter requires planning ahead.

Islatravir is a pill that you take just once a month. The first results from the Phase II trials were released this summer, and they're terrific so far. I look forward to seeing more next year, as well as following progress on Phase III trials. Our foundation helped fund a Phase III trial of the drug in Africa, which started in early 2021 and will study how effective the drug is for young women for the next several years.

Another area to watch for in 2022 is Alzheimer's diagnostics. Huge progress has been made on this front recently, and there's a decent chance that the first affordable, accessible blood test for Alzheimer's will get approved next year. Although this won't be a game changer yet for people who have the disease—which currently has no cure or even a way to slow it down—this test will accelerate progress in the quest for a treatment breakthrough.

I'm also looking forward to continuing the work of Breakthrough Energy Ventures, Catalyst, and Fellows to make clean-energy innovations more available and affordable for everyone. They're enabling breakthroughs across a broad range of areas, many of which are still years away. One area where we might see some real progress soon is in making green hydrogen fuels more affordable. This would be a huge step forward, because hydrogen fuels would enable long-duration energy storage and could be used to run things like large planes and industrial processes.

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Settling into a new normal

I've never been a big New Year's resolution person. I don't have any specific goal in mind for 2022 (although I guess I still have a couple more weeks to think of one). But what I do hope is that next year is a lot more settled than this one.

Human beings are naturally resistant to change. Whether it's the massive global upheaval of the last two years or transitions closer to home, it's never easy to adjust to new ways of living.

I think 2022 will be a year when many of us finally settle into a post-pandemic new normal. For me, that will mean going into the office a bit more as COVID cases hopefully go down. I want to find a new rhythm at home now that all three of my kids have moved away and my day isn't as structured around finding time to spend with them. I'm looking forward to spending more time engaging with people through my blog and other channels. I'd like to keep up my COVID-era habit of watching lots of educational videos on YouTube and subscription services like Wondrium, because they're a really great way to learn about obscure topics. (I now know more about glassmaking, birdwatching, and the history of American Samoa than I ever expected.)

I hope you and your loved ones also find a way to create new routines. There's no question that the pandemic will create huge, lasting changes that will take years to fully understand, which can feel scary. One of my favorite authors, Yuval Noah Harari, once wrote that, "people are usually afraid of change because they fear the unknown. But the single greatest constant of history is that everything changes."

The world has adapted to big disruptions before, and we'll do it again. In the meantime, I wish you a very happy holiday season.

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From: Trevor Mundel [redacted]@gatesfoundation.org>
To: "Bill Gates (Gates Ventures)" [redacted]@gatesventures.com>, Tony Fauci [redacted]@niaid.nih.gov>
Cc: Robert Nabors [redacted]@gatesfoundation.org>
Subject: Low Dose Moderna
Date: Mon, 26 Jul 2021 15:23:08 -0400
Importance: Normal

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https://www.medrxiv.org/content/10.1101/2021.06.30.21259787v1.full.pdf

Bill, Tony, this is the low (1/4) dose Moderna data which looks quite strong - I know Sette has a lot of additional data he presented over the weekend and I'm trying to get this from him.

Regulatory authorities (EMA and MHRA thus far) have agreed to immunogenicity phase 3 trials for the new vaccines coming along due to the inability to do standard phase 3 - in the 2 case I know of the endpoint will be NA superiority to the AZ vaccine. By this standard we can be sure that Moderna low dose already meets this standard and of course going with a lower dose of an approved vaccine means that safety issues are off the table.

This is the only pathway to immediately double capacity from Moderna and even if only part of their supply was allocated to this it could mean a few hundred million additional vaccines in 2021.

Trevor

Get Outlook for iOS

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From: Trevor Mundel [redacted]@gatesfoundation.org>
To: Tony Fauci [redacted]@niaid.nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>
Subject: Connect with Bill
Date: Tue, 31 Mar 2020 22:02:12 -0400
Importance: Normal

Hi Tony, great work in keeping things on such an even keel. Bill was keen to catch up with you and I wondered if you might have 30-45 min any time between 5:30pm and 8pm EST tomorrow to chat with him. Regards, Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Christa Bowles
Executive Assistant
Office of the President, Global Health
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

From: "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Fwd: Connect with Bill
Date: Wed, 01 Apr 2020 01:02:05 -0400
Importance: Normal

Hi Larry,
Do you know if Patti Conrad is the best person to get this in front of ASF? Thanks.

Best,
Cyndi

Begin forwarded message:

From: Jennifer Weisman [redacted]@gatesfoundation.org>
Date: March 31, 2020 at 10:17:30 PM EDT
To: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>, "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>
Subject: FW: Connect with Bill

Gretchen, Cyndi,
I hope you both are faring well in these crazy and challenging times! Trevor sent the below message to Tony F but got an autoreply. Do you know how we might get through to his office about arranging a call with Bill Gates tomorrow evening?
Thank you!!
Jenni

From: Trevor Mundel [redacted]@gatesfoundation.org>
Sent: Tuesday, March 31, 2020 7:02 PM
To: Tony Fauci
Cc: Christa Bowles
Subject: Connect with Bill

Hi Tony, great work in keeping things on such an even keel. Bill was keen to catch up with you and I wondered if you might have 30-45 min any time between 5:30pm and 8pm EST tomorrow to chat with him. Regards, Trevor

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Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Connect with Bill
Date: Wed, 01 Apr 2020 06:11:17 -0400
Importance: Normal

Let me try. If not, I'll send to Patti

From: "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
Date: Wednesday, April 1, 2020 at 1:02 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Fwd: Connect with Bill

Hi Larry,
Do you know if Patti Conrad is the best person to get this in front of ASF? Thanks.

Best,
Cyndi

Begin forwarded message:

From: Jennifer Weisman [redacted]@gatesfoundation.org>
Date: March 31, 2020 at 10:17:30 PM EDT
To: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>, "Burrus-Shaw, Cyndi (NIH/OD) [E]" <cyndi.burrus-[redacted]@nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>
Subject: FW: Connect with Bill

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Thank you!!
Jenni

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Sent: Tuesday, March 31, 2020 7:02 PM
To: Tony Fauci
Cc: Christa Bowles
Subject: Connect with Bill

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President, Global Health Program
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E [redacted]@gatesfoundation.org

Released by Chairman Rand Paul

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M [redacted]
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Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: Anthony Fauci [redacted]@niaid.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Bcc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Connect with Bill
Date: Wed, 01 Apr 2020 06:13:49 -0400
Importance: High

Tony –
We all hope that you are hanging in there!
Please see note from Trevor re. Bill wanting to touch base with you.
Larry

From: Trevor Mundel [redacted]@gatesfoundation.org>
Sent: Tuesday, March 31, 2020 7:02 PM
To: Tony Fauci
Cc: Christa Bowles
Subject: Connect with Bill

Hi Tony, great work in keeping things on such an even keel. Bill was keen to catch up with you and I wondered if you might have 30-45 min any time between 5:30pm and 8pm EST tomorrow to chat with him. Regards, Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Christa Bowles
Executive Assistant
Office of the President, Global Health
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

From: "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Connect with Bill
Date: Wed, 01 Apr 2020 07:26:15 -0400
Importance: Normal

Thanks.

From: Larry Tabak [redacted]@nih.gov>
Date: Wednesday, April 1, 2020 at 6:11 AM
To: Cyndi Burrus-Shaw [redacted]@nih.gov>
Subject: Re: Connect with Bill

Let me try. If not, I'll send to Patti

From: "Burrus-Shaw, Cyndi (NIH/OD) [E]" [redacted]@nih.gov>
Date: Wednesday, April 1, 2020 at 1:02 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Fwd: Connect with Bill

Hi Larry,
Do you know if Patti Conrad is the best person to get this in front of ASF? Thanks.

Best,
Cyndi

Begin forwarded message:

From: Jennifer Weisman [redacted]@gatesfoundation.org>
Date: March 31, 2020 at 10:17:30 PM EDT
To: "Wood, Gretchen (NIH/OD) [E]" [redacted]@od.nih.gov>, "Burrus-Shaw, Cyndi (NIH/OD) [E]" <cyndi.burrus-[redacted]@nih.gov>
Cc: Christa Bowles [redacted]@gatesfoundation.org>
Subject: FW: Connect with Bill

Gretchen, Cyndi,
I hope you both are faring well in these crazy and challenging times! Trevor sent the below message to Tony F but got an autoreply. Do you know how we might get through to his office about arranging a call with Bill Gates tomorrow evening?
Thank you!!
Jenni

From: Trevor Mundel [redacted]@gatesfoundation.org>
Sent: Tuesday, March 31, 2020 7:02 PM
To: Tony Fauci
Cc: Christa Bowles
Subject: Connect with Bill

Released by Chairman Rand Paul

Hi Tony, great work in keeping things on such an even keel. Bill was keen to catch up with you and I wondered if you might have 30-45 min any time between 5:30pm and 8pm EST tomorrow to chat with him. Regards, Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
V [redacted]
F [redacted]
E [redacted]@gatesfoundation.org

Christa Bowles
Executive Assistant
Office of the President, Global Health
V [redacted]
M [redacted]
E [redacted]@gatesfoundation.org
Bill & Melinda Gates Foundation
www.gatesfoundation.org

Released by Chairman Rand Paul

From: Bill Gates [redacted]@gatesventures.com>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Cc: Melinda French [redacted]@mfgates.com>
Subject: Our Annual Letter
Date: Thu, 28 Jan 2021 22:29:02 -0500
Importance: Normal

Tony,

We are writing to share a copy of our 2021 Annual Letter. We decided to focus entirely on the topic at the top of everyone's mind: the pandemic.

We hope the letter gives you some reasons for optimism.

Bill & Melinda

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Bill Gates" [redacted]@gatesventures.com>
Cc: "Melinda French" [redacted]@mfgates.com>
Subject: RE: Our Annual Letter
Date: Fri, 29 Jan 2021 14:48:36 -0500
Importance: Normal

Thanks, Bill.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Bill Gates [redacted]@gatesventures.com>
Sent: Thursday, January 28, 2021 10:29 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Melinda French [redacted]@mfgates.com>
Subject: Our Annual Letter

Tony,

We are writing to share a copy of our 2021 Annual Letter. We decided to focus entirely on the topic at the top of everyone's mind: the pandemic.

We hope the letter gives you some reasons for optimism.

Bill & Melinda

Released by Chairman Rand Paul

From: Bill Gates [redacted]@gatesventures.com>
To: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>
Cc: [redacted]@niaid.nih.gov" [redacted]@niaid.nih.gov>, [redacted]@nih.gov" [redacted]@nih.gov>
Subject: Thank you
Date: Fri, 23 Oct 2020 19:36:38 -0400
Importance: Normal

Dear Tony,

I want to thank you for taking the time out of your incredibly busy schedule to join Rashida and me as a guest on our podcast recently. We both appreciated your clear explanations about the state of the pandemic.

It would be an understatement to say the work you have been doing around COVID is critical to managing this pandemic. I don't know if anyone can fully comprehend the magnitude of your care and commitment to the health and safety of this country. For that, I am deeply grateful.

I wish you and your family good health.

Bill

Released by Chairman Rand Paul

From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Fwd: Thank you
Date: Fri, 23 Oct 2020 20:20:26 -0400
Importance: Normal

Sent from my iPhone

Begin forwarded message:

From: Bill Gates [redacted]@gatesventures.com>
Date: October 23, 2020 at 7:36:51 PM EDT
To: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Barasch, Kimberly (NIH/NIAID) [C]" [redacted]@nih.gov>
Subject: Thank you

Dear Tony,

I want to thank you for taking the time out of your incredibly busy schedule to join Rashida and me as a guest on our podcast recently. We both appreciated your clear explanations about the state of the pandemic.

It would be an understatement to say the work you have been doing around COVID is critical to managing this pandemic. I don't know if anyone can fully comprehend the magnitude of your care and commitment to the health and safety of this country. For that, I am deeply grateful.

I wish you and your family good health.

Bill

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Bill Gates" [redacted]@gatesventures.com>
Subject: RE: Thank you
Date: Fri, 23 Oct 2020 21:50:51 -0400
Importance: Normal

Bill:
Thank you for your kind note. It is much appreciated.
Best regards,
Tony

From: Bill Gates [redacted]@gatesventures.com>
Sent: Friday, October 23, 2020 7:37 PM
To: Fauci, Anthony (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Barasch, Kimberly (NIH/NIAID) [C] [redacted]@nih.gov>
Subject: Thank you

Dear Tony,

I want to thank you for taking the time out of your incredibly busy schedule to join Rashida and me as a guest on our podcast recently. We both appreciated your clear explanations about the state of the pandemic.

It would be an understatement to say the work you have been doing around COVID is critical to managing this pandemic. I don't know if anyone can fully comprehend the magnitude of your care and commitment to the health and safety of this country. For that, I am deeply grateful.

I wish you and your family good health.

Bill

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Bill Gates - Bill and Melinda Gates Foundation
Date: Fri, 23 Oct 2020 21:52:11 -0400
Importance: Normal
Attachments: unnamed

Released by Chairman Rand Paul

Formatted Name

Bill Gates

Email

[redacted]@gatesventures.com

Name

Bill Gates

VCard Version

3.0

COMPANY

Bill and Melinda Gates Foundation;

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Hodes, Richard (NIH/NIA) [E]" [redacted]@31.nia.nih.gov>, [redacted]@bgc3.com" [redacted]@bgc3.com>
Cc: "Niranjan Bose" [redacted]@bgc3.com>, "Jonah Goldman" [redacted]@bgc3.com>
Subject: RE: Thank you
Date: Sat, 12 May 2018 11:29:48 -0400
Importance: Normal

Dear Bill,

We at NIH are very glad to work with you on this critical issue – and we're delighted that you have identified this as a major priority.

All the best, Francis

From: Hodes, Richard (NIH/NIA) [E]
Sent: Friday, May 11, 2018 9:52 PM
To: [redacted]@bgc3.com
Cc: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Niranjan Bose [redacted]@bgc3.com>; Jonah Goldman [redacted]@bgc3.com>
Subject: FW: Thank you

Dear Bill,
Thank you for the message and for the opportunity to work with you and the bgc3 team. Following our meeting with you last October, we have met with Bose, Scott, and Jonah in Bethesda, Santa Barbara, and last Friday in San Francisco. We strongly share your perspective on the critical importance of optimizing the generation, sharing, and analysis of data through interoperable platforms, and we look forward to working toward this priority as a part of the global coalition that is forming around this Alzheimer's effort. Thank you again for your leadership.
Best regards
Richard

From: Bill Gates [redacted]@bgc3.com>
Sent: Friday, May 11, 2018 9:36 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Hodes, Richard (NIH/NIA) [E] [redacted]@31.nia.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>; Jonah Goldman [redacted]@bgc3.com>
Subject: Thank you

Dear Francis and Richard,

I wanted to thank both of you for your support and engagement as my team and I have explored opportunities to accelerate the discovery of scientific breakthroughs by enhancing access to Alzheimer's disease research data.

I was great that Richard and Eliezer could participate in the working session last week. I understand that their input and engagement was extremely helpful. I appreciate the NIA's participation in this coalition of like-minded funders to help strengthen the data ecosystem for Alzheimer's disease. I am convinced that better leveraging the data being generated by studies funded by the NIH can accelerate the development of an effective treatment for Alzheimer's disease. I was excited to hear that the discussion was productive and that the group agreed to work together to improve data access, drive interoperability across existing Alzheimer's disease data platforms, and strengthen the data ecosystem for Alzheimer's.

Released by Chairman Rand Paul

I know that NIH and NIA are already making strong efforts to promote data sharing, and I believe these will provide a strong foundation on which we can build. Your partnership has been invaluable, and I thank you for joining the effort to driving a more coordinated data ecosystem. We are already benefiting greatly from your leadership and insight.

I look forward to our continued collaboration.

Sincerely,

Bill Gates

Released by Chairman Rand Paul

From: Niranjan Bose [redacted]@bgc3.com>
To: [redacted]@od.nih.gov'" [redacted]@od.nih.gov>
Subject: Visiting the NIA offices
Date: Tue, 18 Sep 2018 18:43:43 -0400
Importance: Normal

Dear Francis,

Hope you are doing well. Not sure you remember me – we have met a few times, including most recently at the American Society for Human Genetics (ASHG) learning sessions that Dan Wattendorf helped curate for Bill Gates. I am with bgC3, the private offices of Mr. Gates and lead out health & life sciences work including the most recent engagement in Alzheimer's disease. Your partnership and Dr. Hodes' partnership have been extremely helpful to us and it turns out that I will be at your campuses on the 24th of September for a set of meetings with Dr. Hodes & his team.

In case your schedule permits (realize your calendar probably gets packed months in advance), I would greatly welcome the opportunity to stop by and say hello to you in person. Completely understand if schedules don't allow.

Best,
Bose

Niranjan Bose, PhD
Senior Director, Health & Life Sciences
bgC3, LLC

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Niranjan Bose" [redacted]@bgc3.com>
Subject: RE: Visiting the NIA offices
Date: Tue, 18 Sep 2018 20:27:52 -0400
Importance: Normal

Hi Bose,

Yes, of course I remember you! And I would love to have the chance to say hello – but unfortunately it won't work this time, as I'll be on the west coast on Sept 24. Please let me know if you come back at another time. I am glad you are working so effectively with Richard Hodes.

Best, Francis

From: Niranjan Bose [redacted]@bgc3.com>
Sent: Tuesday, September 18, 2018 6:44 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: Visiting the NIA offices

Dear Francis,

Hope you are doing well. Not sure you remember me – we have met a few times, including most recently at the American Society for Human Genetics (ASHG) learning sessions that Dan Wattendorf helped curate for Bill Gates. I am with bgC3, the private offices of Mr. Gates and lead out health & life sciences work including the most recent engagement in Alzheimer's disease. Your partnership and Dr. Hodes' partnership have been extremely helpful to us and it turns out that I will be at your campuses on the 24th of September for a set of meetings with Dr. Hodes & his team.

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Best,
Bose

Niranjan Bose, PhD
Senior Director, Health & Life Sciences
bgC3, LLC

Released by Chairman Rand Paul

From: Niranjan Bose [redacted]@bgc3.com>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: Visiting the NIA offices
Date: Wed, 19 Sep 2018 12:50:29 -0400
Importance: Normal

Dear Francis,

Thank you for the quick response. Sorry to miss you on this trip but will look forward to the next opportunity.

Best,
Bose

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Tuesday, September 18, 2018 5:28 PM
To: Niranjan Bose [redacted]@bgc3.com>
Subject: RE: Visiting the NIA offices

Hi Bose,

Yes, of course I remember you! And I would love to have the chance to say hello – but unfortunately it won't work this time, as I'll be on the west coast on Sept 24. Please let me know if you come back at another time. I am glad you are working so effectively with Richard Hodes.

Best, Francis

From: Niranjan Bose [redacted]@bgc3.com>
Sent: Tuesday, September 18, 2018 6:44 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: Visiting the NIA offices

Dear Francis,

Hope you are doing well. Not sure you remember me – we have met a few times, including most recently at the American Society for Human Genetics (ASHG) learning sessions that Dan Wattendorf helped curate for Bill Gates. I am with bgC3, the private offices of Mr. Gates and lead out health & life sciences work including the most recent engagement in Alzheimer's disease. Your partnership and Dr. Hodes' partnership have been extremely helpful to us and it turns out that I will be at your campuses on the 24th of September for a set of meetings with Dr. Hodes & his team.

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Best,
Bose

Niranjan Bose, PhD
Senior Director, Health & Life Sciences

Released by Chairman Rand Paul

bgC3, LLC

Released by Chairman Rand Paul

From: Bill Gates [redacted]@bgc3.com>
To: [redacted]@od.nih.gov'" [redacted]@od.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>, Jonah Goldman [redacted]@bgc3.com>
Subject: Alzheimer's update
Date: Tue, 17 Jul 2018 00:55:50 -0400
Importance: Normal

Dear Francis,

Thank you for your continued support and guidance as I continue to think through how I can be helpful in the fight against Alzheimer's disease. I appreciate the partnership we continue to develop with NIA on the data initiative. We are also working on a number of other areas related to the disease. I'm excited to share my next step.

As you may remember, when I announced my engagement in Alzheimer's disease last fall, early detection and diagnosis stood out as a key unmet need if we are going to substantially alter the course of the disease. Since then, I've learned a lot about the exciting developments in the search for a blood-based biomarker, but I've also learned about the challenges that scientists face while trying to bring these tools to market.

That has informed the blog post I'll share tomorrow (I've pasted it below), which announces a new project to advance bold ideas for earlier and better diagnosis of Alzheimer's disease. This project—called the Diagnostics Accelerator—is a partnership I'm excited to be part of with Leonard Lauder, the Alzheimer's Drug Discovery Foundation (ADDF), the Dolby family, the Charles and Helen Schwab Foundation, and other donors. We are adopting a new approach that brings together philanthropic capital with a venture mindset to accelerate the discovery and development of transformative tools for diagnosis of the disease.

I hope this initiative can build on the good work that the community, including NIH and NIA, has done. Through this partnership, we are committed to bringing the funding, focus, and urgency required to solve this important problem. I'm eager to see what comes of it and motivated by the real potential for a breakthrough Alzheimer's diagnostic – ultimately helping us move closer to a cure. I hope you share this news with others in the field who can help bring us there.

Thank you again and I am happy that our teams continue to work together. I look forward to our future collaboration and your continued leadership.

Bill

Why diagnosing Alzheimer's today is so difficult – and how we can do better
By Bill Gates

When I announced that I was investing in Alzheimer's research for the first time last fall, I thought I knew what to expect. I knew I would get to engage more deeply with the brilliant scientists and advocates working to stop Alzheimer's – and I haven't been disappointed. The things I've seen over the last seven months make me more hopeful than ever.

What I didn't see coming was the amazing response I got from the Alzheimer's community at large. Because my family didn't talk publicly about my dad's diagnosis before the announcement, I had yet to experience how remarkable the support community is. So many of you have shared your personal experiences with me, both in person and online (including here on TGN). It helps to hear from others who are going through the same thing.

Alzheimer's research is a frontier where we can dramatically improve human life – both the lives of people who have the disease and their loved ones. I'm optimistic that we can substantially alter the course of Alzheimer's if we make progress in several key areas. One of the biggest things we could do right now is develop a reliable, affordable, and accessible diagnostic.

Released by Chairman Rand Paul

The process of getting diagnosed with Alzheimer's today is less than ideal. It starts with a cognitive test. If you don't perform well, your doctor needs to rule out all other possible causes for memory loss, like stroke or a nutritional deficiency. Then your doctor can order a spinal tap or PET scan to confirm you have Alzheimer's. Although these tests are fairly accurate, the only way to diagnose the disease definitively is through an autopsy after death.

There are two big problems with this process. First, it can be expensive and invasive. Most insurance plans in the United States won't reimburse tests for Alzheimer's. Patients often pay thousands of dollars out of their own pockets. Meanwhile, spinal taps can be scary and uncomfortable, and PET scans require the patient to stay perfectly still for up to 40 minutes. That's difficult for anyone to do – but especially someone with Alzheimer's.

Second, patients aren't being tested for the disease until they start showing cognitive decline. The more we understand about Alzheimer's, the clearer it becomes that the disease begins much earlier than we previously thought. Research suggests Alzheimer's starts damaging the brain more than a decade before symptoms start showing. That's probably when we need to start treating people to have the best shot at an effective drug.

This delay is a huge problem in the quest for a scientific breakthrough. It's currently so difficult to find enough eligible patients for a clinical trial that it can take longer to enroll participants than to conduct the study. We need a better way of diagnosing Alzheimer's – like a simple blood test or eye exam – before we're able to slow the progression of the disease.

It's a bit of a chicken and egg problem. It's hard to come up with a game changing new drug without a cheaper and less invasive way to diagnose patients earlier. But most people don't want to find out if they have the disease earlier when there's no way to treat it. The commercial market for Alzheimer's diagnostics simply isn't there. There's promising research being done, but very few companies are looking at how to turn that research into a usable product.

That's why my next investment in Alzheimer's research is in a new fund called Diagnostics Accelerator. This project of the Alzheimer's Drug Discovery Foundation (ADDF) aims to accelerate bold new ideas for earlier and better diagnosis of the disease. Today I'm joining Leonard Lauder, ADDF, the Dolby family, the Charles and Helen Schwab Foundation, and other donors in committing more than $30 million to help launch Diagnostics Accelerator.

Diagnostics Accelerator is a venture philanthropy vehicle, which means it's different from most funds. Investments from governments or charitable organizations are fantastic at generating new ideas and cutting-edge research – but they're not always great at creating usable products, since no one stands to make a profit at the end of the day. Venture capital, on the other end of the spectrum, is more likely to develop a test that will actually reach patients, but its financial model favors projects that will earn big returns for investors.

Venture philanthropy splits the difference. It incentivizes a bold, risk-taking approach to research with an end goal of a real product for real patients. If any of the projects backed by Diagnostics Accelerator succeed, our share of the financial windfall goes right back into the fund.

My hope is that this investment builds a bridge from academic research to a reliable, affordable, and accessible diagnostic. I expect to see lots of new players come to the table, who have innovative new ideas but might not have previously had the resources to explore them. If you think you're one of these bold thinkers, we want to hear your great ideas. I encourage you to apply for funding on the new Diagnostics Accelerator website here.

Imagine a world where diagnosing Alzheimer's disease is as simple as getting your blood tested during your annual physical. Research suggests that future isn't that far off, and Diagnostics Accelerator moves us one step closer.

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Hodes, Richard (NIH/NIA) [E]" [redacted]@31.nia.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" [redacted]@nih.gov>, "Burklow, John (NIH/OD) [E]" [redacted]@OD.NIH.GOV>
Subject: FW: Alzheimer's update
Date: Tue, 17 Jul 2018 06:40:41 -0400
Importance: Normal

Hi Richard,

I don't know whether you knew this was coming. Seems like a good thing, especially given Bill's intention to work closely with NIA.

Francis

From: Bill Gates [mailto[redacted]@bgc3.com]
Sent: Tuesday, July 17, 2018 12:56 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>; Jonah Goldman [redacted]@bgc3.com>
Subject: Alzheimer's update

Dear Francis,

Thank you for your continued support and guidance as I continue to think through how I can be helpful in the fight against Alzheimer's disease. I appreciate the partnership we continue to develop with NIA on the data initiative. We are also working on a number of other areas related to the disease. I'm excited to share my next step.

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I hope this initiative can build on the good work that the community, including NIH and NIA, has done. Through this partnership, we are committed to bringing the funding, focus, and urgency required to solve this important problem. I'm eager to see what comes of it and motivated by the real potential for a breakthrough Alzheimer's diagnostic – ultimately helping us move closer to a cure. I hope you share this news with others in the field who can help bring us there.

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The process of getting diagnosed with Alzheimer's today is less than ideal. It starts with a cognitive test. If you don't perform well, your doctor needs to rule out all other possible causes for memory loss, like stroke or a nutritional deficiency. Then your doctor can order a spinal tap or PET scan to confirm you have Alzheimer's. Although these tests are fairly accurate, the only way to diagnose the disease definitively is through an autopsy after death.

There are two big problems with this process. First, it can be expensive and invasive. Most insurance plans in the United States won't reimburse tests for Alzheimer's. Patients often pay thousands of dollars out of their own pockets. Meanwhile, spinal taps can be scary and uncomfortable, and PET scans require the patient to stay perfectly still for up to 40 minutes. That's difficult for anyone to do – but especially someone with Alzheimer's.

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It's a bit of a chicken and egg problem. It's hard to come up with a game changing new drug without a cheaper and less invasive way to diagnose patients earlier. But most people don't want to find out if they have the disease earlier when there's no way to treat it. The commercial market for Alzheimer's diagnostics simply isn't there. There's promising research being done, but very few companies are looking at how to turn that research into a usable product.

That's why my next investment in Alzheimer's research is in a new fund called Diagnostics Accelerator. This project of the Alzheimer's Drug Discovery Foundation (ADDF) aims to accelerate bold new ideas for earlier and better diagnosis of the disease. Today I'm joining Leonard Lauder, ADDF, the Dolby family, the Charles and Helen Schwab Foundation, and other donors in committing more than $30 million to help launch Diagnostics Accelerator.

Diagnostics Accelerator is a venture philanthropy vehicle, which means it's different from most funds. Investments from governments or charitable organizations are fantastic at generating new ideas and cutting-edge research – but they're not always great at creating usable products, since no one stands to make a profit at the end of the day. Venture capital, on the other end of the spectrum, is more likely to develop a test that will actually reach patients, but its financial model favors projects that will earn big returns for investors.

Venture philanthropy splits the difference. It incentivizes a bold, risk-taking approach to research with an end goal of a real product for real patients. If any of the projects backed by Diagnostics Accelerator succeed, our share of the financial

windfall goes right back into the fund.

My hope is that this investment builds a bridge from academic research to a reliable, affordable, and accessible diagnostic. I expect to see lots of new players come to the table, who have innovative new ideas but might not have previously had the resources to explore them. If you think you're one of these bold thinkers, we want to hear your great ideas. I encourage you to apply for funding on the new Diagnostics Accelerator website here.

Imagine a world where diagnosing Alzheimer's disease is as simple as getting your blood tested during your annual physical. Research suggests that future isn't that far off, and Diagnostics Accelerator moves us one step closer.

Released by Chairman Rand Paul

From: "Hodes, Richard (NIH/NIA) [E]" [redacted]@31.nia.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>, "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>, "Hallett, Adrienne (NIH/OD) [E]" [redacted]@nih.gov>, "Burklow, John (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: Alzheimer's update
Date: Tue, 17 Jul 2018 07:01:43 -0400
Importance: Normal

Hi Francis,
I agree, and we continue to work closely with Bill and staff. We will be meeting with BgC3 colleagues in Chicago at the Alzheimer's International Congress next week to pursue big data efforts.
Richard

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, July 17, 2018 6:41 AM
To: Hodes, Richard (NIH/NIA) [E] [redacted]@31.nia.nih.gov>
Cc: Tabak, Lawrence (NIH/OD) [E] [redacted]@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] [redacted]@nih.gov>; Hallett, Adrienne (NIH/OD) [E] [redacted]@nih.gov>; Burklow, John (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: FW: Alzheimer's update

Hi Richard,

I don't know whether you knew this was coming. Seems like a good thing, especially given Bill's intention to work closely with NIA.

Francis

From: Bill Gates [mailto[redacted]@bgc3.com]
Sent: Tuesday, July 17, 2018 12:56 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>; Jonah Goldman [redacted]@bgc3.com>
Subject: Alzheimer's update

Dear Francis,

Thank you for your continued support and guidance as I continue to think through how I can be helpful in the fight against Alzheimer's disease. I appreciate the partnership we continue to develop with NIA on the data initiative. We are also working on a number of other areas related to the disease. I'm excited to share my next step.

As you may remember, when I announced my engagement in Alzheimer's disease last fall, early detection and diagnosis stood out as a key unmet need if we are going to substantially alter the course of the disease. Since then, I've learned a lot about the exciting developments in the search for a blood-based biomarker, but I've also learned about the challenges that scientists face while trying to bring these tools to market.

That has informed the blog post I'll share tomorrow (I've pasted it below), which announces a new project to advance bold ideas for earlier and better diagnosis of Alzheimer's disease. This project—called the Diagnostics Accelerator—is a partnership I'm excited to be part of with Leonard Lauder, the Alzheimer's Drug Discovery Foundation (ADDF), the Dolby family, the Charles and Helen Schwab Foundation, and other donors. We are adopting a new approach that brings

together philanthropic capital with a venture mindset to accelerate the discovery and development of transformative tools for diagnosis of the disease.

I hope this initiative can build on the good work that the community, including NIH and NIA, has done. Through this partnership, we are committed to bringing the funding, focus, and urgency required to solve this important problem. I'm eager to see what comes of it and motivated by the real potential for a breakthrough Alzheimer's diagnostic – ultimately helping us move closer to a cure. I hope you share this news with others in the field who can help bring us there.

Thank you again and I am happy that our teams continue to work together. I look forward to our future collaboration and your continued leadership.

Bill

Why diagnosing Alzheimer's today is so difficult – and how we can do better
By Bill Gates

When I announced that I was investing in Alzheimer's research for the first time last fall, I thought I knew what to expect. I knew I would get to engage more deeply with the brilliant scientists and advocates working to stop Alzheimer's – and I haven't been disappointed. The things I've seen over the last seven months make me more hopeful than ever.

What I didn't see coming was the amazing response I got from the Alzheimer's community at large. Because my family didn't talk publicly about my dad's diagnosis before the announcement, I had yet to experience how remarkable the support community is. So many of you have shared your personal experiences with me, both in person and online (including here on TGN). It helps to hear from others who are going through the same thing.

Alzheimer's research is a frontier where we can dramatically improve human life – both the lives of people who have the disease and their loved ones. I'm optimistic that we can substantially alter the course of Alzheimer's if we make progress in several key areas. One of the biggest things we could do right now is develop a reliable, affordable, and accessible diagnostic.

The process of getting diagnosed with Alzheimer's today is less than ideal. It starts with a cognitive test. If you don't perform well, your doctor needs to rule out all other possible causes for memory loss, like stroke or a nutritional deficiency. Then your doctor can order a spinal tap or PET scan to confirm you have Alzheimer's. Although these tests are fairly accurate, the only way to diagnose the disease definitively is through an autopsy after death.

There are two big problems with this process. First, it can be expensive and invasive. Most insurance plans in the United States won't reimburse tests for Alzheimer's. Patients often pay thousands of dollars out of their own pockets. Meanwhile, spinal taps can be scary and uncomfortable, and PET scans require the patient to stay perfectly still for up to 40 minutes. That's difficult for anyone to do – but especially someone with Alzheimer's.

Second, patients aren't being tested for the disease until they start showing cognitive decline. The more we understand about Alzheimer's, the clearer it becomes that the disease begins much earlier than we previously thought. Research suggests Alzheimer's starts damaging the brain more than a decade before symptoms start showing. That's probably when we need to start treating people to have the best shot at an effective drug.

This delay is a huge problem in the quest for a scientific breakthrough. It's currently so difficult to find enough eligible patients for a clinical trial that it can take longer to enroll participants than to conduct the study. We need a better way of diagnosing Alzheimer's – like a simple blood test or eye exam – before we're able to slow the progression of the disease.

It's a bit of a chicken and egg problem. It's hard to come up with a game changing new drug without a cheaper and less invasive way to diagnose patients earlier. But most people don't want to find out if they have the disease earlier when there's no way to treat it. The commercial market for Alzheimer's diagnostics simply isn't there. There's promising research being done, but very few companies are looking at how to turn that research into a usable product.

That's why my next investment in Alzheimer's research is in a new fund called Diagnostics Accelerator. This project of the Alzheimer's Drug Discovery Foundation (ADDF) aims to accelerate bold new ideas for earlier and better diagnosis of the disease. Today I'm joining Leonard Lauder, ADDF, the Dolby family, the Charles and Helen Schwab Foundation, and other donors in committing more than $30 million to help launch Diagnostics Accelerator.

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Released by Chairman Rand Paul

From: Bill Gates [redacted]@bgc3.com>
To: [redacted]@od.nih.gov'" [redacted]@od.nih.gov>, [redacted]@31.nia.nih.gov'" [redacted]@31.nia.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>, Jonah Goldman [redacted]@bgc3.com>
Subject: Thank you
Date: Fri, 11 May 2018 21:35:53 -0400
Importance: Normal
Attachments: 5-11-18,_Francis_Collins_and_Richard_Hodes,_NIH-NIA.PDF

Dear Francis and Richard,

I wanted to thank both of you for your support and engagement as my team and I have explored opportunities to accelerate the discovery of scientific breakthroughs by enhancing access to Alzheimer's disease research data.

I was great that Richard and Eliezer could participate in the working session last week. I understand that their input and engagement was extremely helpful. I appreciate the NIA's participation in this coalition of like-minded funders to help strengthen the data ecosystem for Alzheimer's disease. I am convinced that better leveraging the data being generated by studies funded by the NIH can accelerate the development of an effective treatment for Alzheimer's disease. I was excited to hear that the discussion was productive and that the group agreed to work together to improve data access, drive interoperability across existing Alzheimer's disease data platforms, and strengthen the data ecosystem for Alzheimer's.

I know that NIH and NIA are already making strong efforts to promote data sharing, and I believe these will provide a strong foundation on which we can build. Your partnership has been invaluable, and I thank you for joining the effort to driving a more coordinated data ecosystem. We are already benefiting greatly from your leadership and insight.

I look forward to our continued collaboration.

Sincerely,

Bill Gates

Released by Chairman Rand Paul

bgC3

May 11, 2018

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Sincerely,

Bill

Bill Gates

main/[redacted] fax/[redacted] / 4700 Carillon Point / Kirkland, WA 98033

Released by Chairman Rand Paul

From: "Hodes, Richard (NIH/NIA) [E]" [redacted]@31.nia.nih.gov>
To: [redacted]@bgc3.com" [redacted]@bgc3.com>
Cc: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, Niranjan Bose [redacted]@bgc3.com>, Jonah Goldman [redacted]@bgc3.com>
Subject: FW: Thank you
Date: Fri, 11 May 2018 21:51:38 -0400
Importance: Normal
Attachments: 5-11-18,_Francis_Collins_and_Richard_Hodes,_NIH-NIA.PDF

Dear Bill,
Thank you for the message and for the opportunity to work with you and the bgc3 team. Following our meeting with you last October, we have met with Bose, Scott, and Jonah in Bethesda, Santa Barbara, and last Friday in San Francisco. We strongly share your perspective on the critical importance of optimizing the generation, sharing, and analysis of data through interoperable platforms, and we look forward to working toward this priority as a part of the global coalition that is forming around this Alzheimer's effort. Thank you again for your leadership.
Best regards
Richard

From: Bill Gates [redacted]@bgc3.com>
Sent: Friday, May 11, 2018 9:36 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Hodes, Richard (NIH/NIA) [E] [redacted]@31.nia.nih.gov>
Cc: Niranjan Bose [redacted]@bgc3.com>; Jonah Goldman [redacted]@bgc3.com>
Subject: Thank you

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I look forward to our continued collaboration.

Sincerely,

Bill Gates

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: [redacted]@mfgates.com" [redacted]@mfgates.com>
Cc: "Jennifer Weisman" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: NIH Director hoping to bring you and your book to NIH
Date: Fri, 31 Jan 2020 04:54:38 -0500
Importance: Normal

Dear Melinda,

It has been a truly gratifying experience working closely with the Bill & Melinda Gates Foundation over the decade that I have served as NIH Director. My senior staff and yours have become wonderfully effective colleagues, team members, and friends across a wide range of projects and themes, from HIV/TB/malaria to maternal and child health. But I write now with a different kind of outreach that I hope will appeal to YOU.

I write to invite you to NIH as the featured author for the NIH "Big Read" in 2020. This innovative program was developed to foster engaging discussions throughout the NIH community on a single book over several months, culminating with a special event featuring the author of the book.

After significant consideration, the Planning Committee has selected your book, *The Moment of Lift: How Empowering Women Changes the World*, as our top choice for this year's NIH Big Read. Your engaging writing style and the book's compelling message would undoubtedly connect with a wide audience at NIH, especially since we have made the empowerment of women a major theme over the last year. Through the personal stories in your book, we hope to generate stimulating discussions that inspire conversation and personal discovery. In addition, I think our staff would benefit immensely from your articulation of the values and strategy that serve as the bedrock for the Bill & Melinda Gates Foundation.

Should you accept this invitation, the NIH Big Read would kick off here in the next couple of weeks with an announcement to engage the NIH community and encourage participation in small-group discussions. The activities would lead to a major event during which you and I would talk about your book, on stage, in an interview-style setting, in our largest auditorium (capacity about 500, with the likelihood of overflow space). A reception where you would have the opportunity to meet and interact with NIH scientists and staff will follow the main event. The scheduling of that event is very flexible and can be guided by your availability – but ideally we are thinking of a date sometime in May.
Prior best-selling authors featured for the NIH Big Read include Siddartha Mukherjee (*The Gene*) and Ed Yong (*I Contain Multitudes*). But this would be a perfect year to feature *The Moment of Lift*, and I sincerely hope you will accept this invitation to be the featured author. Please let me

Released by Chairman Rand Paul

know of your willingness and availability, and I will ask the planning group to follow up with you to arrange the details.

With warm personal regards,

Francis

Released by Chairman Rand Paul

From: Melinda French [redacted]@mfgates.com>
To: [redacted]@od.nih.gov" [redacted]@od.nih.gov>
Cc: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, [redacted]@od.nih.gov" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Wed, 05 Feb 2020 18:02:31 -0500
Importance: Normal

Francis,

Thank you for the kind note and invitation. NIH is a valued partner to our foundation and a leader in the field, especially on promoting gender equality. The example you set is not only changing the dynamic at NIH, but the broader research ecosystem. I want to thank you for being such a prominent and vocal male ally, and hope you know how touched I am that the planning committee selected *The Moment of Lift* for this opportunity.

My schedule is quite full this spring but I've passed on your invitation to my team to see whether it can work. They should be in touch soon.

In the meantime, I'm incredibly excited to see what our new collaboration will accomplish for sickle cell disease and HIV.

All the best,
- Melinda

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto[redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto[redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto[redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto[redacted]@od.nih.gov>>
Subject: NIH Director hoping to bring you and your book to NIH

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After significant consideration, the Planning Committee has selected your book, The Moment of Lift: How Empowering Women Changes the World, as our top choice for this year's NIH Big Read. Your engaging writing style and the book's compelling message would undoubtedly connect with a wide audience at NIH, especially since we have made the empowerment of women a major theme over the last year. Through the personal stories in your book, we hope to generate stimulating discussions that inspire conversation and personal discovery. In addition, I think our staff would benefit immensely from your articulation of the values and strategy that serve as the bedrock for the Bill & Melinda Gates Foundation.

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With warm personal regards,

Francis

_____

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Cc: [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Bcc: "Wolinetz, Carrie (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Wed, 05 Feb 2020 18:31:49 -0500
Importance: Normal

Dear Melinda,

Many thanks for your kind response – we will await a decision from your team, with great hopes that this could work out. Once again, we can be VERY flexible about the date.

Warm personal regards, Francis

From: Melinda French [redacted]@mfgates.com>
Sent: Wednesday, February 5, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Subject: NIH Director hoping to bring you and your book to NIH

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From: Emily Libresco [redacted]@pivotalventures.org>
To: [redacted]@od.nih.gov" [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>
Subject: NIH Director hoping to bring you and your book to NIH
Date: Wed, 19 Feb 2020 12:56:00 -0500
Importance: Normal

Hi Francis,

Thanks very much for being in touch. We manage Melinda's communications and events, and would like to learn more about what you propose below.

Could you please share a bit more about the event? Also, I see that you mentioned aiming for May timing. If we could arrange something, would late June work as well?

Thanks again for this kind invitation.

All the best,
Emily

Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

(+1) [redacted]
[redacted]@pivotalventures.org

PIVOTAL VENTURES
A MELINDA GATES COMPANY

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
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Francis

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ref:_00D36uJsU._5001Rv428X:ref

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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: FW: NIH Director hoping to bring you and your book to NIH
Date: Wed, 19 Feb 2020 16:14:41 -0500
Importance: Normal

Hi Jackie,

This looks promising. Do you have a formal description of the Big Read program that would go beyond my initial letter to Melinda? If so, can you send to me so I can respond to Emily. I assume we'd be fine with a date in late June.

FC

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Wednesday, February 19, 2020 12:56 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>
Subject: NIH Director hoping to bring you and your book to NIH

Hi Francis,

Thanks very much for being in touch. We manage Melinda's communications and events, and would like to learn more about what you propose below.

Could you please share a bit more about the event? Also, I see that you mentioned aiming for May timing. If we could arrange something, would late June work as well?

Thanks again for this kind invitation.

All the best,
Emily

Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

(+1) [redacted]
[redacted]@pivotalventures.org

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A MELINDA GATES COMPANY

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>

Released by Chairman Rand Paul

Subject: NIH Director hoping to bring you and your book to NIH

Dear Melinda,

It has been a truly gratifying experience working closely with the Bill & Melinda Gates Foundation over the decade that I have served as NIH Director. My senior staff and yours have become wonderfully effective colleagues, team members, and friends across a wide range of projects and themes, from HIV/TB/malaria to maternal and child health. But I write now with a different kind of outreach that I hope will appeal to YOU.

I write to invite you to NIH as the featured author for the NIH "Big Read" in 2020. This innovative program was developed to foster engaging discussions throughout the NIH community on a single book over several months, culminating with a special event featuring the author of the book.

After significant consideration, the Planning Committee has selected your book, The Moment of Lift: How Empowering Women Changes the World, as our top choice for this year's NIH Big Read. Your engaging writing style and the book's compelling message would undoubtedly connect with a wide audience at NIH, especially since we have made the empowerment of women a major theme over the last year. Through the personal stories in your book, we hope to generate stimulating discussions that inspire conversation and personal discovery. In addition, I think our staff would benefit immensely from your articulation of the values and strategy that serve as the bedrock for the Bill & Melinda Gates Foundation.

Should you accept this invitation, the NIH Big Read would kick off here in the next couple of weeks with an announcement to engage the NIH community and encourage participation in small-group discussions. The activities would lead to a major event during which you and I would talk about your book, on stage, in an interview-style setting, in our largest auditorium (capacity about 500, with the likelihood of overflow space). A reception where you would have the opportunity to meet and interact with NIH scientists and staff will follow the main event. The scheduling of that event is very flexible and can be guided by your availability - but ideally we are thinking of a date sometime in May.

Prior best-selling authors featured for the NIH Big Read include Siddartha Mukherjee (The Gene) and Ed Yong (I Contain Multitudes). But this would be a perfect year to feature The Moment of Lift, and I sincerely hope you will accept this invitation to be the featured author. Please let me know of your willingness and availability, and I will ask the planning group to follow up with you to arrange the details.

With warm personal regards,

Francis

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From: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Re: NIH Director hoping to bring you and your book to NIH
Date: Wed, 19 Feb 2020 21:45:13 -0500
Importance: Normal
Attachments: NIH_Big_Read_program_details.docx; Draft_Detailed_Agenda_Big_Read_M._Gates_.docx

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Hi Dr. Collins,

Great – we are getting closer! We have two dates held on your calendar and Masur's calendar: June 19 and June 22. Can you check with Emily on those dates? If those don't work, we can definitely find other options in June.

See attached for the formal description of the NIH Big Read program as well as a draft detailed agenda for you to forward to Emily.

Please let me know if you need anything else.

Thanks,
Jackie

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Date: Wednesday, February 19, 2020 at 4:14 PM
To: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: FW: NIH Director hoping to bring you and your book to NIH

Hi Jackie,

This looks promising. Do you have a formal description of the Big Read program that would go beyond my initial letter to Melinda? If so, can you send to me so I can respond to Emily. I assume we'd be fine with a date in late June.

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To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>
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Thanks again for this kind invitation.

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All the best,
Emily

Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

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Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
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Francis

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Draft Agenda for The NIH Big Read
Melinda Gates

Lunch is optional. Shift arrival time to 12:30 pm if not available for lunch.

11:45 am	Mrs. Gates arrives at the South Drive and Rockville Pike entry gate *NIH Police will escort car to Bldg. 10 South Entrance*
11:50 am	Mrs. Gates arrives at the south entrance of Building 10 and is welcomed by NIH Library and FAES staff.
11:55 am	Mrs. Gates escorted to FAES suite for lunch.
12:00 pm	Lunch with NIH postdoctoral fellows, FAES suite (Bldg. 10/Room 1N241)
12:45 pm	Lunch ends. Dr. Collins greets Mrs. Gates at FAES suite (Bldg. 10/Room 1N241) • ***NIH Photographer takes photographs with Dr. Collins, Mrs. Gates, NIH Library Director, FAES Director at FAES Suite***
12:50 pm	Proceed to Masur Auditorium, Green Room
12:57 pm	Dr. Collins and Mrs. Gates exit the Green Room and receive their lavaliere microphones.
1:00 pm	Dr. Collins introduces the NIH Big Read and Mrs. Gates. • ***NIH Photographer takes photos during the event***
1:05 pm	Dr. Collins and Mrs. Gates proceed to center stage and take their seats for discussion. Questions will come from Dr. Collins, NIH staff (pre-selected), book discussion groups, and Facebook Live.
2:00 pm	The discussion ends. Dr. Collins escorts Mrs. Gates out of Masur's side door and up the hallway to the FAES terrace for the meet and greet and reception. • ***NIH Photographer takes photos during the meet and greet and reception***
3:00 pm	The meet and greet ends. Mrs. Gates proceeds to NIH Library for thank you from the from NIH Library and FAES staff. • ***NIH Photographer takes photos at the Library, including group photos***
3:15 pm	The NIH Big Read ends and the NIH Library staff escort Mrs. Gates to Building 10 south lobby, where her driver is waiting to pick her up.

Released by Chairman Rand Paul

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Emily Libresco" [redacted]@pivotalventures.org>
Cc: "Courtney Wade" [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Thu, 20 Feb 2020 06:35:42 -0500
Importance: Normal
Attachments: NIH_Big_Read_program_details.docx; Draft_Detailed_Agenda_Big_Read_M._Gates_.docx

---

Dear Emily,

Thanks for your follow up note. I am delighted to know that this invitation is under consideration. Attached please find a more detailed description of the NIH Big Read program, and a possible draft agenda for what the visit might look like (though that is entirely open to revision, depending on how Melinda would most like to spend her time at NIH).

A June visit would be just fine. Looking at calendars, June 19 and 22 would work particularly well, but there are lots of other options. Just let me know what would work best for Melinda.

We are truly excited at the possibility of being able to host Melinda for this year's Big Read. She would have the chance to inspire many scientists, from young trainees to senior leaders, both women and men.

Best, Francis

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Sent: Wednesday, February 19, 2020 12:56 PM
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Cc: Courtney Wade [redacted]@pivotalventures.org>
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Thanks again for this kind invitation.

All the best,
Emily

Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

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(+1) [redacted]
[redacted]@pivotalventures.org

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A MELINDA GATES COMPANY

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
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With warm personal regards,

Francis

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NIH Big Read

The NIH Big Read was created by the NIH Library and FAES to foster collaboration and community at NIH around a topic of interest to the NIH community through reading a book that is related to the work of NIH. The program also encourages interaction between the author of the book and the NIH community as a way of exploring and enriching the overall community's understanding of the topic(s) in the selected book.

The NIH Big Read begins with an announcement to engage the NIH community and encourage participation in small-group discussions over the course of several weeks. The book is available for NIH staff to read through the OverDrive platform, or through the FAES bookstore.

The book discussions lead up to a final event during which the author and Dr. Collins talk about themes in the book, on stage, in an interview-style setting. The talk includes selected questions forwarded from the book discussion groups as a way of incorporating the community in the conversation. Following the on-stage discussion, FAES hosts a meet and greet reception with the author, during which NIH staff have an opportunity to meet the author.

The whole program takes place over approximately 6 weeks. The final event is scheduled as a one-hour event in Masur Auditorium, followed by a one-hour reception and book signing. Optional lunch, tours of NIH and other activities can be included before or after the main event.

For additional information about the program, see the NIH Big Read 2019 webpage, which also has links to the NIH Big Read 2018 and 2017 programs.

Videocasts of the last two on-stage discussions with Dr. Collins can be seen at:
2019: https://videocast.nih.gov/watch=31900
2018: https://videocast.nih.gov/watch=27765
2017: available via the NIH network only

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Possible Draft Agenda for The NIH Big Read

Melinda Gates

The Moment of Lift:
How Empowering Women Changes the World

Lunch is optional. Shift arrival time to 12:30 pm if not available for lunch.

11:45 am — Mrs. Gates arrives at the South Drive and Rockville Pike entry gate
NIH Police will escort car to Bldg. 10 South Entrance

11:50 am — Mrs. Gates arrives at the south entrance of Building 10 and is welcomed by Dr. Collins, Dr. Fauci, and NIH Library and FAES staff.

11:55 am — Mrs. Gates escorted to FAES suite for lunch.

12:00 pm — Lunch, FAES suite (Bldg. 10/Room 1N241) -- possible options:
- Postdoctoral fellows with interest in global health research
- Senior NIH leadership with focus on maternal/child health, reproductive health

12:45 pm — Lunch ends. Dr. Collins returns.
- ***NIH Photographer takes photographs with Dr. Collins, Mrs. Gates, NIH Library Director, FAES Director at FAES Suite***

12:50 pm — Proceed to Masur Auditorium, Green Room

12:57 pm — Dr. Collins and Mrs. Gates exit the Green Room and receive their lavaliere microphones.

1:00 pm — Dr. Collins introduces the NIH Big Read and Mrs. Gates.
- ***NIH Photographer takes photos during the event***

1:05 pm — Dr. Collins and Mrs. Gates proceed to center stage and take their seats for discussion. If desired, Mrs. Gates may begin with a 15 – 20 minute presentation. Or can go straight to a conversation and Q&A. Questions will come from Dr. Collins, NIH staff (pre-selected), book discussion groups, and Facebook Live.

2:00 pm — The discussion ends. Dr. Collins escorts Mrs. Gates out of Masur's side door and up the hallway to the FAES terrace for the meet and greet, book signing, and reception.
- ***NIH Photographer takes photos during the meet and greet and reception***

3:00 pm — The meet and greet ends. Mrs. Gates proceeds to NIH Library for thank you from the from NIH Library and FAES staff.
- ***NIH Photographer takes photos at the Library, including group photos***

3:15 pm — The NIH Big Read ends and the NIH Library staff escort Mrs. Gates to Building 10 south lobby, where her driver is waiting to pick her up.

Released by Chairman Rand Paul

From: Jennifer Weisman [redacted]@gatesfoundation.org>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Thu, 20 Feb 2020 08:55:51 -0500
Importance: Normal

Thanks for the visibility, Francis. Glad that her team is seriously exploring this! Jenni

---

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, February 20, 2020 3:36 AM
To: Emily Libresco (Pivotal Ventures) [redacted]@pivotalventures.org>
Cc: Courtney Wade (Pivotal Ventures) [redacted]@pivotalventures.org>; Jennifer Weisman [redacted]@gatesfoundation.org>; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

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Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Thu, 20 Feb 2020 14:38:56 -0500
Importance: Normal

Hi Francis,

Thank you for this helpful information. We will review the documents you shared and check Melinda's calendar and come back with follow-up questions.

All the best,
Emily

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, February 20, 2020 3:36 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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EXTERNAL: *This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.*

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Emily Libresco
Senior Associate, Executive Communications and Media
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I write to invite you to NIH as the featured author for the NIH "Big Read" in 2020. This innovative program was developed to foster engaging discussions throughout the NIH community on a single book over several months, culminating with a special event featuring the author of the book.

After significant consideration, the Planning Committee has selected your book, The Moment of Lift: How Empowering Women Changes the World, as our top choice for this year's NIH Big Read. Your engaging writing style and the book's compelling message would undoubtedly connect with a wide audience at NIH, especially since we have made the empowerment of women a major theme over the last year. Through the personal stories in your book, we hope to generate stimulating discussions that inspire conversation and personal discovery. In addition, I think our staff would benefit immensely from your articulation of the values and strategy that serve as the bedrock for the Bill & Melinda Gates Foundation.

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With warm personal regards,

Francis

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ref:_00D36uJsU._5001Rv428X:ref

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From: Emily Libresco [redacted]@pivotalventures.org>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Wed, 04 Mar 2020 17:23:23 -0500
Importance: Normal

Hi Francis,

Thanks again for this kind invitation and thorough proposal. We have a few follow-up questions:

- How much flexibility do you have in the programming? We'd be working with a pretty tight time frame. I noticed that you listed the lunch as optional. Would the meet/greet/book-signing time also be negotiable, if we were able to make this work? Do authors ever pre-sign books for Big Read participants instead?
- How many people typically attend your book talks? And what's the typical book buy size?
- Would 6/23 in the afternoon work for timing? I know you mentioned you have some flexibility.

Thanks in advance for your thoughts on these questions.

All the best,
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From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, February 20, 2020 3:36 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Thanks again for this kind invitation.

All the best,
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Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

(+1) [redacted]
[redacted]@pivotalventures.org

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From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
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To: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: FW: NIH Director hoping to bring you and your book to NIH
Date: Thu, 05 Mar 2020 05:37:05 -0500
Importance: Normal

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From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Wednesday, March 4, 2020 5:23 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
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From: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: Re: NIH Director hoping to bring you and your book to NIH
Date: Thu, 05 Mar 2020 10:43:53 -0500
Importance: Normal

Yes, we had a pre-signing with Eric Kandel and it worked well. He signed the books just before his lecture. In the past FAES has sold around 100-150 books for each Big Read event, but they are projecting to sell 200 books for this event. Keep in mind those numbers are just FAES sales since some folks may have purchased the book elsewhere. We can be very flexible in the programming and timing of the events. And we can definitely make June 23 afternoon work. I've placed a hold on Masur Auditorium's calendar for that afternoon. Is your schedule open that afternoon?

I answered the questions below in blue. Let me know if you need any additional information in order to reply back to Emily. Thanks. - Jackie

- How much flexibility do you have in the programming? We'd be working with a pretty tight time frame. I noticed that you listed the lunch as optional. Would the meet/greet/book-signing time also be negotiable, if we were able to make this work? Do authors ever pre-sign books for Big Read participants instead? We are very flexible in the timing of the programming and could arrange a pre-signing session if that works best with Melinda's schedule.
- How many people typically attend your book talks? And what's the typical book buy size? We are anticipating a full house in Masur Auditorium which accommodates 480 people. Typically the books sales are in the 100-150 range, but FAES is projecting to sell 200 copies of Melinda's book.
- Would 6/23 in the afternoon work for timing? I know you mentioned you have some flexibility. Yes, June 23 in the afternoon would work great!

From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Date: Thursday, March 5, 2020 at 5:37 AM
To: "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: FW: NIH Director hoping to bring you and your book to NIH

Have we ever done pre-signing? Any concern about this? And what are the answers to the second and third bullets?

FC

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Wednesday, March 4, 2020 5:23 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

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All the best,
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From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, February 20, 2020 3:36 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Sent: Wednesday, February 19, 2020 12:56 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>
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Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

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[redacted]@pivotalventures.org

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From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Emily Libresco" [redacted]@pivotalventures.org>
Cc: "Courtney Wade" [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Thu, 05 Mar 2020 12:49:19 -0500
Importance: Normal

Hi Emily,

Thanks for reaching back out. We can be pretty flexible here. Here are responses to the queries you posed:

- How much flexibility do you have in the programming? We'd be working with a pretty tight time frame. I noticed that you listed the lunch as optional. Would the meet/greet/book-signing time also be negotiable, if we were able to make this work? Do authors ever pre-sign books for Big Read participants instead? *Yes, lunch is optional, as is the meet/greet/book-signing. We have had authors do pre-signing in the past, and we could arrange a private pre-signing session if that works best with Melinda's schedule.*
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I write to invite you to NIH as the featured author for the NIH "Big Read" in 2020. This innovative program was developed to foster engaging discussions throughout the NIH community on a single book over several months, culminating with a special event featuring the author of the book.

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With warm personal regards,

Francis

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from your system.

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From: Emily Libresco [redacted]@pivotalventures.org>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Thu, 12 Mar 2020 14:01:41 -0400
Importance: Normal

Hi Francis,

Thanks for all of this helpful information. We will review it with our scheduling team and let you know what might be possible.

All the best,
Emily

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, March 5, 2020 9:49 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Senior Associate, Executive Communications and Media
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From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
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Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Tue, 21 Apr 2020 12:44:05 -0400
Importance: Normal

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All the best, and hope you are all staying well,
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Sent: Thursday, March 12, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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[redacted]@pivotalventures.org

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Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>;
Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
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From: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
To: "Emily Libresco" [redacted]@pivotalventures.org>
Cc: "Courtney Wade" [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Tue, 21 Apr 2020 12:48:09 -0400
Importance: Normal

Dear Emily,

Given the COVID-19 crisis, I certainly understand. I am hopeful that we might be able to revisit this plan when all of us are able to move around more freely.

Please give my very best to Melinda.

Francis

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Tuesday, April 21, 2020 12:44 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
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Prior best-selling authors featured for the NIH Big Read include Siddartha Mukherjee (The Gene) and Ed Yong (I Contain Multitudes). But this would be a perfect year to feature The Moment of Lift, and I sincerely hope you will accept this invitation to be the featured author. Please let me know of your willingness and availability, and I will ask the planning group to follow up with you to arrange the details.

With warm personal regards,

Francis

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Released by Chairman Rand Paul

ref:_00D36uJsU._5001Rv428X:ref

Released by Chairman Rand Paul

From: Emily Libresco [redacted]@pivotalventures.org>
To: "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, "Roberts, Jacqueline (NIH/OD) [E]" [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH
Date: Tue, 21 Apr 2020 12:53:48 -0400
Importance: Normal

Certainly – thanks for understanding.

All the best,
Emily

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Tuesday, April 21, 2020 9:48 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

EXTERNAL: Do not click links or open attachments that appear suspicious.

Dear Emily,

Given the COVID-19 crisis, I certainly understand. I am hopeful that we might be able to revisit this plan when all of us are able to move around more freely.

Please give my very best to Melinda.

Francis

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Tuesday, April 21, 2020 12:44 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

Hi Francis,

I wanted to get back in touch to let you know that due to the current situation, Melinda won't be traveling to D.C. in June. We very much hope that she'll make a trip in the near future, and we'll let you know when that happens, if you'd still be willing to try to arrange a visit to the NIH.

All the best, and hope you are all staying well,
Emily

Released by Chairman Rand Paul

From: Emily Libresco
Sent: Thursday, March 12, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

Hi Francis,

Thanks for all of this helpful information. We will review it with our scheduling team and let you know what might be possible.

All the best,
Emily

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, March 5, 2020 9:49 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

EXTERNAL: Do not click links or open attachments that appear suspicious.

Hi Emily,

Thanks for reaching back out. We can be pretty flexible here. Here are responses to the queries you posed:

- How much flexibility do you have in the programming? We'd be working with a pretty tight time frame. I noticed that you listed the lunch as optional. Would the meet/greet/book-signing time also be negotiable, if we were able to make this work? Do authors ever pre-sign books for Big Read participants instead? *Yes, lunch is optional, as is the meet/greet/book-signing. We have had authors do pre-signing in the past, and we could arrange a private pre-signing session if that works best with Melinda's schedule.*
- How many people typically attend your book talks? And what's the typical book buy size? *We are anticipating a full house in Masur Auditorium which accommodates 480 people. Typically the books sales are in the 100-150 range, but our bookstore is projecting to sell at least 200 copies of Melinda's book.*
- Would 6/23 in the afternoon work for timing? I know you mentioned you have some flexibility. *Yes, June 23 in the afternoon would work great!*

Best, Francis

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Wednesday, March 4, 2020 5:23 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

Hi Francis,

Released by Chairman Rand Paul

Thanks again for this kind invitation and thorough proposal. We have a few follow-up questions:

- How much flexibility do you have in the programming? We'd be working with a pretty tight time frame. I noticed that you listed the lunch as optional. Would the meet/greet/book-signing time also be negotiable, if we were able to make this work? Do authors ever pre-sign books for Big Read participants instead?
- How many people typically attend your book talks? And what's the typical book buy size?
- Would 6/23 in the afternoon work for timing? I know you mentioned you have some flexibility.

Thanks in advance for your thoughts on these questions.

All the best,
Emily

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Sent: Thursday, February 20, 2020 3:36 AM
To: Emily Libresco [redacted]@pivotalventures.org>
Cc: Courtney Wade [redacted]@pivotalventures.org>; [redacted]@gatesfoundation.org; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov>
Subject: RE: NIH Director hoping to bring you and your book to NIH

EXTERNAL: *This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.*

Dear Emily,

Thanks for your follow up note. I am delighted to know that this invitation is under consideration. Attached please find a more detailed description of the NIH Big Read program, and a possible draft agenda for what the visit might look like (though that is entirely open to revision, depending on how Melinda would most like to spend her time at NIH).

A June visit would be just fine. Looking at calendars, June 19 and 22 would work particularly well, but there are lots of other options. Just let me know what would work best for Melinda.

We are truly excited at the possibility of being able to host Melinda for this year's Big Read. She would have the chance to inspire many scientists, from young trainees to senior leaders, both women and men.

Best, Francis

From: Emily Libresco [redacted]@pivotalventures.org>
Sent: Wednesday, February 19, 2020 12:56 PM
To: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>
Cc: Courtney Wade [redacted]@pivotalventures.org>
Subject: NIH Director hoping to bring you and your book to NIH

Hi Francis,

Thanks very much for being in touch. We manage Melinda's communications and events, and would like to learn more about what you propose below.

Released by Chairman Rand Paul

Could you please share a bit more about the event? Also, I see that you mentioned aiming for May timing. If we could arrange something, would late June work as well?

Thanks again for this kind invitation.

All the best,
Emily

Emily Libresco
Senior Associate, Executive Communications and Media
Pronouns: She/her/hers

(+1) [redacted]
[redacted]@pivotalventures.org

PIVOTAL VENTURES
A MELINDA GATES COMPANY

From: Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Sent: Friday, January 31, 2020 1:55 AM
To: Melinda French [redacted]@mfgates.com<mailto [redacted]@mfgates.com>>
Cc: Jennifer Weisman [redacted]@gatesfoundation.org<mailto [redacted]@gatesfoundation.org>>; Roberts, Jacqueline (NIH/OD) [E] [redacted]@od.nih.gov<mailto [redacted]@od.nih.gov>>
Subject: NIH Director hoping to bring you and your book to NIH

Dear Melinda,

It has been a truly gratifying experience working closely with the Bill & Melinda Gates Foundation over the decade that I have served as NIH Director. My senior staff and yours have become wonderfully effective colleagues, team members, and friends across a wide range of projects and themes, from HIV/TB/malaria to maternal and child health. But I write now with a different kind of outreach that I hope will appeal to YOU.

I write to invite you to NIH as the featured author for the NIH "Big Read" in 2020. This innovative program was developed to foster engaging discussions throughout the NIH community on a single book over several months, culminating with a special event featuring the author of the book.

After significant consideration, the Planning Committee has selected your book, The Moment of Lift: How Empowering Women Changes the World, as our top choice for this year's NIH Big Read. Your engaging writing style and the book's compelling message would undoubtedly connect with a wide audience at NIH, especially since we have made the empowerment of women a major theme over the last year. Through the personal stories in your book, we hope to generate stimulating discussions that inspire conversation and personal discovery. In addition, I think our staff would benefit immensely from your articulation of the values and strategy that serve as the bedrock for the Bill & Melinda Gates Foundation.

Should you accept this invitation, the NIH Big Read would kick off here in the next couple of weeks with an announcement to engage the NIH community and encourage participation in small-group discussions. The activities would lead to a major event during which you and I would talk about your book, on stage, in an interview-style setting, in our largest auditorium (capacity about 500, with the likelihood of overflow space). A reception where you would have the opportunity to meet and interact with NIH scientists and staff will follow the main event. The scheduling of that event is very flexible and can be guided by your availability - but ideally we are thinking of a date sometime in May.

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With warm personal regards,

Francis

_____

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ref:_00D36uJsU._5001Rv428X:ref

Released by Chairman Rand Paul

From: Dan Wattendorf [redacted]@gatesfoundation.org>
To: Trevor Mundel [redacted]@gatesfoundation.org>, [redacted]@quantigen.com" [redacted]@quantigen.com>, Mark Suzman [redacted]@gatesfoundation.org>, Robert Nabors [redacted]@gatesfoundation.org>, [redacted]@od.nih.gov" [redacted]@od.nih.gov>, [redacted]@nih.gov" [redacted]@nih.gov>, [redacted]@nih.gov" [redacted]@nih.gov>, [redacted]@mail.nih.gov" [redacted]@mail.nih.gov>, [redacted]@thermofisher.com" [redacted]@thermofisher.com>, "Bill Gates (Gates Ventures)" [redacted]@gatesventures.com>
Subject: Options to Maximally Scale Up Laboratory Capacity for Molecular Diagnostics (12:00-12:30 pm PT / 3:00-3:30 pm ET)
Date: Sat, 25 Apr 2020 11:15:35 -0400
Importance: Normal
Attachments: unnamed

Join Microsoft Teams Meeting

[redacted] United States, Seattle (Toll)
[redacted] United States (Toll-free)

Conference ID: 357 872 777#

Local numbers | Reset PIN | Learn more about Teams | Meeting options
Join with a video conferencing device
[redacted]@teams.bjn.vc VTC Conference ID: 1140049702
Alternate VTC dialing instructions

Gary Feldman, *ITS Senior Program Assistant to:*
-Dan Wattendorf, MD *(Director)*
-Mike McCune, MD, PhD *(Senior Advisor, HIV Frontiers)*
-Sumin Koo, PhD *(Deputy Director, Strat. Planning & Mgmt.)*
-Emily Turner, PhD , MScPH *(Senior Program Officer)*
-Brian Doehle, PhD *(Senior Program Officer)*
-Omar Vandal, PhD *(Senior Program Officer)*

(ITS) Innovative Technology Solutions \ Global Health (GH)
Co-Lead of **Out for Good** employee resource group
Pronouns: He/Him/His

Bill & Melinda Gates *foundation*
Seattle Office
www.gatesfoundation.org

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Event: Options to Maximally Scale Up Laboratory Capacity for Molecular Diagnostics (12:00-12:30 pm PT / 3:00-3:30 pm ET)

Start Date: 2020-04-25 15:00:00 -0400

End Date: 2020-04-25 15:30:00 -0400

Organizer: Dan Wattendorf [redacted]@gatesfoundation.org>

Location: Microsoft Teams Meeting

Class: X-PERSONAL

Date Created: 2021-04-28 13:23:37 -0400

Date Modified: 2021-04-28 13:23:37 -0400

Priority: 5

DTSTAMP: 2020-04-25 11:15:34 -0400

Attendee: Trevor Mundel [redacted]@gatesfoundation.org>; [redacted]@quantigen.com [redacted]@quantigen.com>; Mark Suzman [redacted]@gatesfoundation.org>; Robert Nabors [redacted]@gatesfoundation.org>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Tromberg, Bruce (NIH/NIBIB) [E] [redacted]@nih.gov>; Heemskerk, Jill (NIH/NIBIB) [E] [redacted]@nih.gov>; Merchak, Todd (NIH/NIBIB) [E] [redacted]@mail.nih.gov>; [redacted]@thermofisher.com [redacted]@thermofisher.com>; Bill Gates (Gates Ventures) [redacted]@gatesventures.com>

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Start Date: 2020-04-25 15:00:00 -0400

End Date: 2020-04-25 15:30:00 -0400

Organizer: Dan Wattendorf [redacted]@gatesfoundation.org>

Location: Microsoft Teams Meeting

Class: X-PERSONAL

Date Created: 2021-04-28 13:18:40 -0400

Date Modified: 2021-04-28 13:18:40 -0400

Priority: 5

DTSTAMP: 2020-04-25 11:15:34 -0400

Attendee: Trevor Mundel [redacted]@gatesfoundation.org>; [redacted]@quantigen.com [redacted]@quantigen.com>; Mark Suzman [redacted]@gatesfoundation.org>; Robert Nabors [redacted]@gatesfoundation.org>; Collins, Francis (NIH/OD) [E] [redacted]@od.nih.gov>; Tromberg, Bruce (NIH/NIBIB) [E] [redacted]@nih.gov>; Heemskerk, Jill (NIH/NIBIB) [E] [redacted]@nih.gov>; Merchak, Todd (NIH/NIBIB) [E] [redacted]@mail.nih.gov>; [redacted]@thermofisher.com [redacted]@thermofisher.com>; Bill Gates (Gates Ventures) [redacted]@gatesventures.com>

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-Omar Vandal, PhD *(Senior Program Officer)*

(ITS) Innovative Technology Solutions \ Global Health (GH)
Co-Lead of **Out for Good** employee resource group
Pronouns: He/Him/His

Bill & Melinda Gates *foundation*
Seattle Office
www.gatesfoundation.org

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From: Melinda French [redacted]@mfgates.com>
To: [redacted]@od.nih.gov" [redacted]@od.nih.gov>
Cc: [redacted]@nih.gov" [redacted]@nih.gov>
Subject: With admiration
Date: Thu, 07 Oct 2021 16:55:36 -0400
Importance: Normal

Francis,

I saw the news of your stepping down from the helm of the NIH and wanted to send a note of gratitude for all you've done as Director.

I know you've been a tremendous colleague and valued partner to the foundation. I've admired and appreciated your leadership both over the course of our collaboration and during the extraordinarily challenging moments the pandemic has brought.

Your ability to take on vastly varied challenges and to lead across division has done so much for the world and for the inclusivity of your field. What a bar you've set for whoever comes next, and what a distance you've carried the baton they'll pick up.

Thank you, for your partnership and your leadership,

- Melinda French Gates

Released by Chairman Rand Paul

From: "Kraigsley, Alison (NIH/NIAID) [E]" [redacted]@nih.gov>
To: "Embry, Alan (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Cc: "Eichelberg, Katrin (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: TBRU Summary for teh Gates Meeting tomorrow
Date: Thu, 20 Sep 2018 15:29:44 -0400
Importance: Normal
Attachments: 2018_09_TBRU_Accomplishment_Summary.docx; TBRU_summary_slide_(2018).pptx

---

Dear Alan and Katrin,

I've put together a brief summary from the TBRUs. The attached document includes the 4 responses from the individual TBRUs imbedded in the word files.

There's a summary of the TBRU awards, their grant numbers, and project expiration dates. There's also a high-level summary of some metrics (# publications, # trainees, # funded spin-off grants). Page 2 has a summary of some of the vaccine-related work being done by the TBRUs. Page 3 has a bulleted summary of work being done that can be categorized into drugs and diagnostics. Page 4 describes some of the work being done to refine animal models.

Also attached is the one-page slide describing all 4 TBRUs.

ASTRa is the more vaccine relevant TBRU. Since Katrin will be in the room, I think you'll be well-covered.

Please let me know if you have any questions or if there is anything additional needed.

Best regards,
Alison

Alison Kraigsley, Ph.D.
Program Officer
NIH/NIAID/DMID/RDB
[redacted]@nih.gov
Office: [redacted]
Mobile: [redacted]

Released by Chairman Rand Paul

TBRU Summary

September 20, 2018

Below you will find a compiled summary of the information provided by the 4 TBRU centers.
Here are the original files:

Center Name	PIs	Grant Number	Accomplishment File	Expires
ASTRa	Henry Blumberg Joel Ernst	AI111211	2018 TBRU Annual Meeting_Pre-	7/31/2021
CLEAR-TB	Jerry Ellner David Alland Padmini Salgame	AI111276	2018 TBRU Updates and	7/31/2021
LIMAA	Branch Moody Megan Murray	AI111224	TBRU LIMAA 2018 PI survey.docx	01/31/2022
Tri-I	Carl Nathan Mike Glickman	AI111143	2018 Tri-I TBRU Updates and	6/30/2021

- TBRUs were awarded in 2014 and run until 2021 (LIMAA continues until Feb 2022)
- Total value over 7 years: ~$105M (~$15M/year for 7 years)
- Annual cross-collaborative supplement program supports cross-collaborative projects, many led by early career investigators (Projects are ~$200K each/year/center)

High-Level Data as of 9/17/2018. Grant years completed: 4; Grant years remaining: 3

- **Number of Publications = 144**
    I. *there may be redundant publications in the list if the same publication was listed under two centers*
    II. *this number includes both reviews as well as research publications*
- **Number of Trainees = 87**
    - Number of trainees seeking TB-related independent careers = 33
        I. Defined: new faculty position, on the job market, late post-docs
- **Number of Spin-Off Grants FUDNED = 43**
    - Number of funded spin-off grants for NI/ESI = 18
    - Number of grants waiting review or funding decision: 7
    - Funders of spin-off grants: NIH, DoD, Gates, Foundations, etc.
- **Number of projects in translational categories for all 4 centers**
    - Vaccines: 7
    - Drugs: 15
    - Diagnostics: 5
    - Animal Models: 7
        I. *These numbers aren't reflective of the full spectrum of work being conducted by the TBRU Network, just an overview summary*
        II. *While the TBRU Network has a focus on Paucibacillary disease, there are a number of projects in the translational space*

TBRU Summary September 20, 2018

Research Highlights: **VACCINES**

- **Development and Publication of a Novel Response Spectrum Assay (RSA). [ASTRa]**
  The 60-*Mtb* antigen "Response Spectrum Assay (RSA)" performed on whole blood has been developed by the TBRU-ASTRa team and validated in Emory Vaccine Center laboratories. Assay development and optimization of the a 7-day diluted whole blood assay to measure antigen-specific T cell responses was of this novel assay was recently published in *The Journal of Immunology* (J Immunol 2018; 200(8):3008-3019) with Cheryl Day (co-PD of Project 1) as the senior author. Interim data analysis from a cohort of patients with latent TB infection (LTBI) that accepted treatment at the DeKalb County Board of Health were presented at NIAID at the TBRU-Network Meeting in April 2018 and further data analysis from this cohort as well as patients enrolled at a clinical site in Kenya is ongoing in collaboration with the TBRU-ASTRa Data Management Center (DMC).

- **Completion of enrollment and follow up of the LTBI "Accepted Treatment" Cohort. [ASTRa]**
  A total of 112 study subjects with latent TB infection (LTBI) who accepted treatment for LTBI (with the weekly isoniazid plus rifapentine regimen delivered by the DeKalb County Board of Health via directly observed therapy for 12 weeks [3HP]) were enrolled into TBRU-ASTRa Project 1. Enrollment occurred at the DeKalb County Board of Health clinics in Metro Atlanta and was completed in March 2017; the final 12-month follow-up visits completed for all enrolled participants in March 2018. The 60-antigen Response Spectrum Assay (RSA) was performed on each blood sample collected at baseline, and 3-, 6-, 9- and 12-month follow-ups. PBMCs were isolated and cryopreserved, and EDTA and Sodium Heparin plasma aliquots stored at Emory Vaccine Center/Yerkes site. PAXgene blood DNA tubes were also collected from each participant enrolled. In total, 72 participants with LTBI completed LTBI treatment and all 5 study visits including 4 follow-up visits with blood sample collection for the RSA and PBMC cryopreservation. Data analyses are ongoing.

- **Tetramer Production and Development. [ASTRa]**
  Dr. John Altman (TBRU ASTRa Immunology Core PD) in collaboration with the NIH-funded Emory Tetramer Facility (PI: Altman) and Drs. Michael Glickman and Jeffrey Aube of the Tri-I TBRU in New York who provided key ligands for MR1 tetramers has generated mouse, human, and rhesus macaque MR1/5-OP-RU tetramers. These reagents have been made available to the research community via the NIAID Tetramer Facility. HLA typing was performed on specimens from 68 subjects from the DeKalb County "Accepted Treatment" cohort and the TBRU-ASTRa Immunology Core is currently using the allele frequency data, with a focus on class II, to reprioritize tetramer development plans. We anticipate that a recent discovery by the Altman lab/Tetramer Facility that soluble HLA-DM greatly accelerates peptide loading to a wide-range of class II MHC alleles from humans (including HLA-DR and -DQ alleles), at least one class II allele from rhesus macaques (Mamu-DRB-w201), and one class II allele from mice will help us accelerate tetramer development. We expect that DM will significantly assist loading for most class II alleles, and that HLA-DM will work in a cross-species manner on alleles from rhesus macaques.

- **Human responses to MR1 and CD1 reactive T cells [LIMAA]**
  Whereas most vaccine work focuses on MHC-restricted T cells, we are studying the in vivo human responses to MR1 and CD1 reactive T cells, including tests of T cell expansion during acute and chronic TB infections. We are seeking diagnostic tests that rely on antigens (tuberculosinyl adenosine, sulfoglycolipid) that are present in *M. tuberculosis* but absent in BCG. This approach could minimize false positive diagnostic tests in the setting of BCG vaccination, especially in the setting of NIH interest in new approaches to systemic BCG vaccination via routes other than skin, as well as renewed interest in other experimental whole cell vaccines.

- **Immune responses of the earliest point of initial TB infection [Tri-I]**
  To develop a vaccine that may prevent infection, we need to understand the immune responses that occur at the earliest point of initial TB infection, yet this phase of infection has received much less attention than latent or active disease. Our studies of genetics, transcriptomics and microbiomics in defined clinical cohorts can shed light on this phase.

Other Research Highlights

DRUGS

- Development and application of novel mass spectrometry-based profiling technologies with the potential to increase the lesion 'penetrance' of new drug candidates
- Used TRIP screens to ID new regulators and effectors of sensitivity to INH. Developed an experimentally-derived *in silico* approach to predicting drug:drug interactions.
- Biphasic efficacy in combination treatment with isoniazid and bedaquiline identified through a biochemical screening, network modeling and machine learning approach. We find that early antagonism is shared with other electron transport chain inhibitors and that late potentiation is explained by collateral sensitivity to bedaquiline resulting from acquisition of isoniazid resistance.
- PET/CT could prove a novel means to assess novel preventive therapy regimens in Experimental Medicine studies involving far fewer (2 orders of magnitude) participants than traditional trials of preventive therapy that are largely based in any case on equivalence, not superiority.
- Developing novel models of *M. tuberculosis* persistence to enable better drug-screens that are active against persisting/latent stage bacteria.
- Our data inform new approaches to host directed drug therapy including vitamin A supplementation and anti-hyperglycemic treatment with Metformin and related drugs.
- New beta-lactams with improved functional properties.
- The first phosphopantetheinyl transferase inhibitors.
- Identification of new high-value targets for drug development, including the transcription termination factor Rho, thioredoxin reductase and biotin protein ligase.
- Identification of risks in targeting *Mtb*'s respiratory chain for drug development.
- Development and application of genetic approaches for drug MOA analyses.
- Identification of human genetic defects in TB patients that could lead to the development of new treatments aimed at restoring immunity. As an example, patients with a genetic defect of IFN-γ production, such as those homozygous for the P1104A *TYK2* missense variant, may benefit from treatment with recombinant IFN-γ.
- Development and application of novel mass spectrometry-based intrabacterial profiling technologies with the potential to increase the efficiency of TB drug development and enable rational engineering of phenotypic antimicrobial activity into chemical compounds in a target- and species-selective manner.
- Discovery of novel approaches for development of mechanism-based drug combinations, including the elucidation of treatment shortening activities of pyrazinamide and identification of targets in pyrazinamide-susceptible Mtb.
- Studies of Mtb aerobiology with potential for development into novel transmission blocking strategies.

DIAGNOSTICS

- A primary aim of the project is to develop biosignatures of risk of transition to active tuberculosis. This will allow targeting of interventions such as treatment of "latent" TB infection to those most likely to benefit
- Identification of bacterial factors that predict TB relapse is the first step to develop a pre-treatment sputum test that can assign individualized treatment length to each patient, most likely identifying the majority of patients who can be safely treated for 4 months or less without increased relapse risk.
- We are working on diagnostic approaches that involve detection of biomarkers of infection and have preliminarily identified altered phospholipids in the blood and urine of acute TB infection. We have developed lipid specific ELISAs based on tuberculosinyl adenosine that show promise in detecting infection in "resistors" and patients with prior or active tuberculosis.
- Biologically unbiased discovery and identification of novel urinary small molecule biomarkers of disease and treatment response from primary human samples.
- Development of methods that detect ~1 order of magnitude more viable Mtb per mL of patient sputum than standard methods and demonstrate their differential response to initiation of therapy.

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ANIMAL MODELS

- **Development of a Novel and Robust Model for LTBI in non-human primates (NHPs) – Project 3**
  A novel model for evaluating treatment of latent TB infection (LTBI) in the NHP has been developed. In this model, weekly isoniazid plus rifapentine (INH/RPT) was used to mirror the treatment regimen used among patients in the DeKalb cohort described above. Manuscript preparation is ongoing. The model should prove highly valuable in assessing new and shorter regimens for the treatment of LTBI in humans.
- Development, optimization and validation of a rabbit model of latent TB.
- Development of the C3H mouse model to study immunopathogenesis.
- The two strongest areas are TB drug development and implementation of improved therapies to shorten TB chemotherapy with work on rabbit and mouse models but with an interest in their applications to human treatments. The second major area is that of developing better animal models as work on the rabbits provides a different perspective than work on the mice. It is clear from looking at the human situation that there is great variability and each of the animal models reflects some aspect of that.
- TBRU supplement funding has supported the successful development of a new guinea pig model of dietary vitamin A deficiency and metformin treatment through projects led by Brendan Podell.
- Development of paucibacillary mouse models for TB.

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TBRU-N

NIAID Tuberculosis Research Units Network

"Conduct research to address pauci-bacillary stages of TB (latency and persistence) through integration of human studies and animal models"

www.niaid.nih.gov/research/tuberculosis-research-units-network

Tri-I TBRU
Weill Cornell Medical College

- Human genetics of reactivation pulmonary TB
- Innate, transcriptomic, and microbiomic correlates of TB infection
- Viable but non-culturable *M. tuberculosis*
- Biomarkers of Pyrazinamide activity and its target bacterial populations
- Mouse models for pauci-bacillary persistence
- **CETR Supplement:** Identify drugs and chemical probes targeted to inhibit bacterial persistence

GHESKIO
Port-au-Prince, Haiti

TBRU-ASTRa
Emory University

- Identification of human Mtb-specific T cell signatures that are associated with resolved and persistent Mtb infection
- Human T cell responses permissive for progression to active TB disease
- Macaque T cell signatures of Mtb control

Armauer Hansen Research Institute
Addis Ababa, Ethiopia

KEMRI/CDC
Kisumu, Kenya

TBRU- LIMAA
Brigham and Women's Hospital

- Multi-disciplinary analysis of host metabolic determinants of the spectrum of TB clinical phenotypes
- Identification of host genetic determinants of immune response and TB control
- Discovery of diagnostic biomarkers for acute and recurrent *M. tuberculosis* disease in humans with parallel mechanistic studies in guinea pigs

Socios en Salud
Lima, Peru

CLEAR-TB TBRU
Boston Medical Center

- Biomarkers to stratify risk of progression from latent TB infection to disease
- Validation and application of a model of human TB – like latency in rabbits
- Bacterial mechanisms and host pharmacokinetic factors that determine persistence in pauci-bacillary TB

Núcleo de Doenças Infecciosas
Vitória, Brazil

Released by Chairman Rand Paul

Also attached is the one-page slide describing all 4 TBRUs.

ASTRa is the more vaccine relevant TBRU. Since Katrin will be in the room, I think you'll be well-covered.

Please let me know if you have any questions or if there is anything additional needed.

Best regards,
Alison

Alison Kraigsley, Ph.D.
Program Officer
NIH/NIAID/DMID/RDB
[redacted]@nih.gov
Office: [redacted]
Mobile: [redacted]

Released by Chairman Rand Paul

From: "Anthony Fauci" <[redacted]@gmail.com>
Sent: Wed, 20 Jul 2022 22:30:18 -0400 (EDT)
To: [redacted]@oig.hhs.gov
Subject: Fwd: Tweet Analysis
Attachments: fauci_analysis_0701_sm.pptx

From my friend Stewart Simonson.

---------- Forwarded message ---------
From: **STEWART SIMONSON** <[redacted]@icloud.com>
Date: Wed, Jul 20, 2022 at 8:36 PM
Subject: Tweet Analysis
To: <[redacted]@gmail.com>

Tony: This is the analysis I mentioned the other day. When we get together, I will explain its relevance, as I see it, to planning for the future.

Stewart

Sent from my iPhone

--
Anthony S. Fauci, M.D.
Editor, *Harrison's Principles of Internal Medicine*

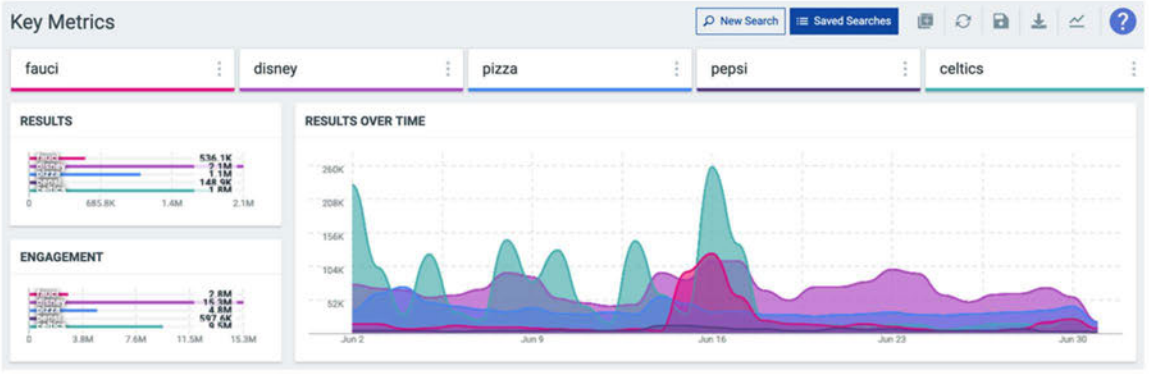
Released by Chairman Rand Paul

To illustrate the level of social media activity relating to Dr. Fauci relative to other topics and news cycles, we created the image below, which shows the total number of mentions of the keywords "fauci", "Disney", "pizza", "pepsi" or "Celtics" on Twitter in the U.S. from June 1 to July 1, 2022.

We can see that on the average day, there are 10-15,000 mentions of "fauci", on par with conversations mentioning Pepsi and are about half of those mentioning "pizza". Disney is another entity that generates consistent conversation but has also recently drawn significant attention from right-wing activists.

We can see that there is an overall larger volume of activity associated with Disney, but that the news cycle around Dr. Fauci's Covid-19 infection drove a spike in activity similar to what Disney experiences on a daily basis (as well as what the Boston Celtics saw during their NBA Playoff performance). Significant global keywords like "Ukraine" drove about six million mentions during the same time period, or about 230,000 mentions per day. "Bill Gates" mentions drove about 8,000 mentions per day or about 260,000 during this time period.

INSIGHT
The keyword "Fauci" can generate as much social media activity on any given day as major brands or pop culture events.



Confidential

Released by Chairman Rand Paul

To more deeply understand the activity around Dr. Fauci on Twitter, we performed a network analysis using AI models designed to detect propaganda-like behavior and the presence of bots.

The image at right is a network graph visualizing all English mentions of "Fauci" and "monkeypox" for the time period of May 31st to June 14, 2022.

The circles ("nodes") represent individual users (e.g. @SallySmith) or concepts (e.g. #vaccines). The lines between them ("edges") represent interactions between nodes (likes, retweets, replies, etc).

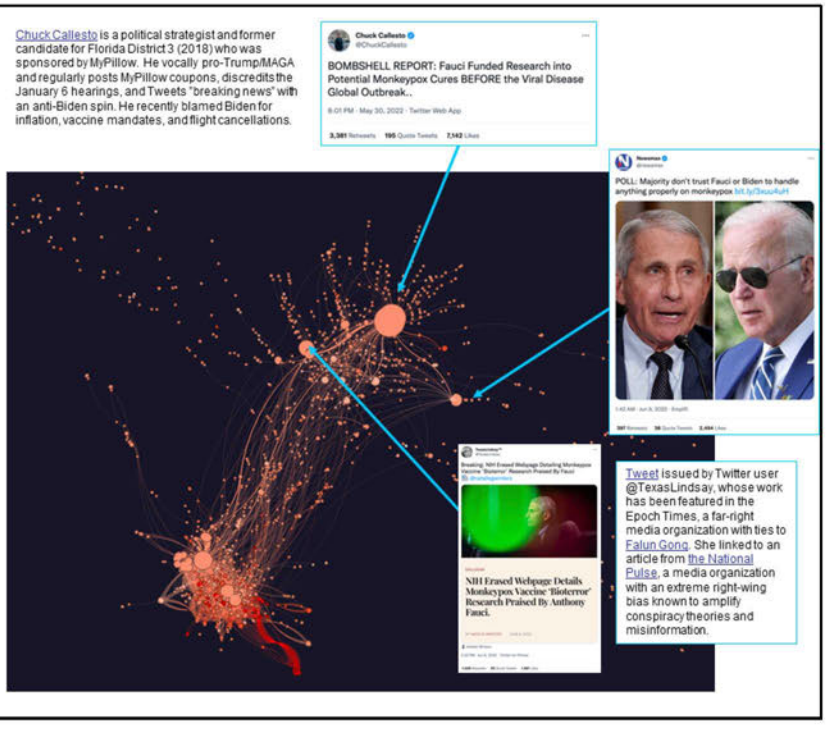
The red shading of the graphic displays the intensity of "anomalous behavior" for a given user or post; this measures the degree of propaganda-like or bot- like behavior present (e.g. overuse of hashtags, excessive posting on the same subject, etc). Darker red signifies more manipulative behavior.

ANALYSIS

While Dr. Fauci is frequently the target of mainstream right-wing news organizations, a loosely coordinated network of provocateurs and conspiracy theorists with significant followings are using his name and general sentiment against him to grab attention for themselves by stoking outrage, day in and day out.

For example, some of these actors (top right of the graph) are actively worked to discredit Dr. Fauci by referencing that the NIAID funded research into a monkey pox vaccine years ago, without noting that monkeypox is a disease that has been around since the 1950s.

We also observed connections being sown between Dr. Fauci and Bill Gates within the monkeypox conversation, indicating that there's a concerted effort to connect him with other conspiracy theories discussed in the cloud of activity at the bottom left of the graph.



Released by Chairman Rand Paul

Chuck Callesto is somewhat typical of the right-wing influencer activists propagating conspiracy theories and other forms of online harassment against Dr. Fauci.

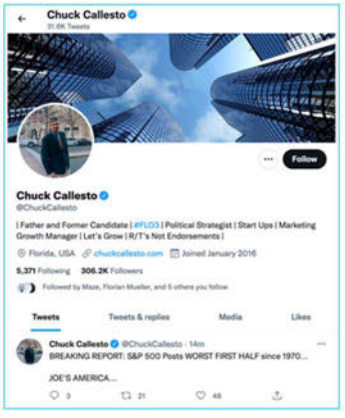
He refers to himself as "a political strategist", is verified as an authentic user by Twitter, and has over 300,000 followers on the network. He also refers to himself as a "former candidate" for Florida's 3rd congressional district. He posts content supporting a wide range of right-wing narratives, including misinformation about Dr. Fauci, but also well beyond.

However, he also has no discernable business/consultancy connections, and did not raise any funding for his "congressional bid", according to OpenSecrets.

He also frequently posts coupons and affiliate marketing links for notable "big lie" proponent Mike Lindell's MyPillow.

INSIGHT
Chuck Callestro is what is commonly referred to as a "troll"; an online bully that deliberately tries to offend, cause trouble or directly attack people in order to gain attention.

While any given post from any given troll can usually be dismissed or ignored, in aggregate, the overall volume and coordination of these trolls appears to be successfully manipulating public opinion against Dr. Fauci.



None of the links to Callesto's services or biography are active on his website; it is essentially blank. He does refer to being "sponsored" by MyPillow, a key funding source of the campaign promoting 2020 election fraud conspiracies.

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Released by Chairman Rand Paul

The image immediately at right is a network graph visualizing all English mentions of "Fauci" and "gates" for the time period of May 31st to June 14, 2022 on Twitter.

The red shading represents the confidence level of a bot-detection algorithm; the dark red nodes are users that are very likely to be bots used to programmatically generate the appearance of support for a given theme or narrative.

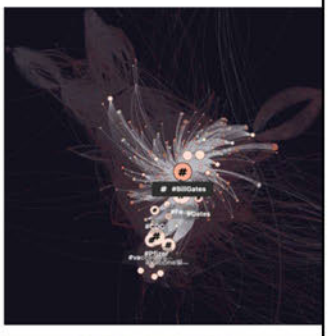
ANALYSIS

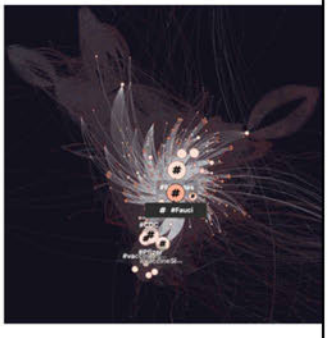
A moderate level of activity in the dataset (~15%) is attributable to bot accounts who are propagating conspiratorial connections between Dr. Fauci and Bill Gates. Twitter claims that ~5% of all activity on their platform is generated by bots.

Combined with the close linkage and overlap of Gates and Fauci mentions in the dataset (images at far right), we can infer that there is a coordinated effort to involve Dr. Fauci in many other conspiracy theories relating WEF, Bill Gates and other Western elites, such as the Great Reset.

We have seen from other analyses that Gates and his foundation are the target of a large quantity and intensity of conspiracy theorizing, alongside George Soros, often calling for actions like imprisonment to be taken against them.

Confidential





Released by Chairman Rand Paul

Example content from users that are likely to be bots.

There is no clear connection among the themes or conspiracies that suggest a clear motive for the bots engaged with Dr. Fauci, perhaps other than sowing division, confusion, and doubt among institutions and institutional leaders.

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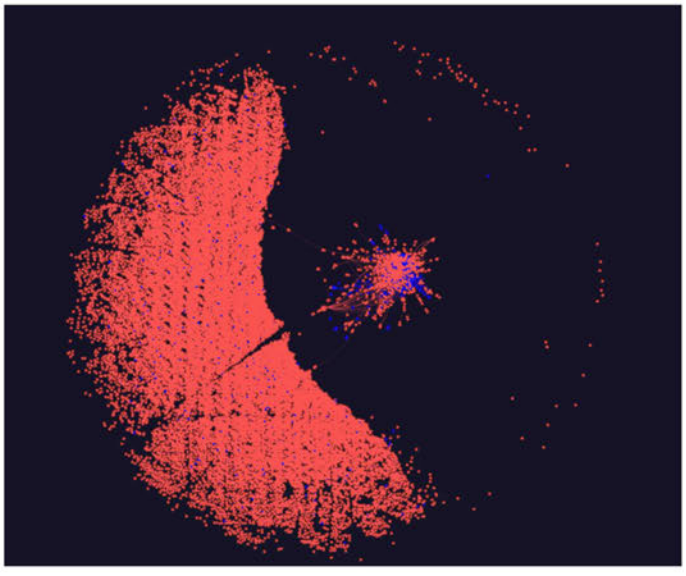
The nodes in the network image at the right visually depict the distribution of Twitter users and hashtags as well as their network connections, as it pertains to mentions of Dr. Fauci and prominent news/media organizations and prominent hosts/writers within these organizations. This includes Tweets/retweets tags, replies, and links.

The conversation playing out on Twitter is, unsurprisingly, very partisan. Conservative to far-right individuals and media organizations such as Fox, OANN, and Breitbart (noted in red on the graph) dominate online narratives with 98% of results, drowning out both non-partisan and left-leaning narratives advocating for Dr. Fauci, which make up 2% of results (noted in blue on the graph).

Mentions of Dr. Fauci have transcended health narratives; he is now positioned as a political figure who is part of the "elites" and has been pulled into highly politicized narratives (January 6 insurrection and associated hearings, Russia/Ukraine conflict, inflation, etc.). The right is calling for Dr. Fauci's arrest and aims to discredit him at every turn.



RED= Fox News, OANN, Breitbart
BLUE = ABC, NBC, NYTimes

Tweet issued by Olivia Troye, former White House Homeland Security Advisor to VP Pence

Tweet issued by Tim Young, a Washington Times columnist and Sirius XM DJ

Released by Chairman Rand Paul

1/4/2022 4 3 0

chat [redacted]

Participants: [redacted] **David M. Morens**; +[redacted] **Greg Folkers**; +[redacted] Anthony Fauci (Owner); +[redacted] Hugh Auchincloss

First Message: 1/4/2022 1:51:56 PM

Last Message: 1/4/2022 1:59:13 PM

[redacted] **Greg Folkers** 1/4/2022 1:51:56 PM

David --- new assignment from asf that we did not want to put in email. Bill gates sent him a manuscript on pandemic preparedness and wants feedback esp on chapter 9. Can u eyeball 👁 with a focus on chapter 9 and send your comments to asf by the end of week ? A couple pages of notes would suffice Pls keep confidential. I will send u a link

---

[redacted] **David M. Morens** 1/4/2022 1:53:53 PM

Sure, can do. Plz send asap as i am at the hosp at the moment but will be on campus soon. My printer at home is having issues and i will need to print this out. TY, D

[redacted] **Greg Folkers** 1/4/2022 1:59:13 PM

Sent a link to email thx 🙏

[redacted]

Released by Chairman Rand Paul

1/5/2022 4 1 0

chat [redacted]

Participants: + [redacted] **David M. Morens**; + [redacted] Greg Folkers; [redacted] Anthony Fauci (Owner); + [redacted] Hugh Auchincloss

First Message: 1/5/2022 6:22:40 PM

Last Message: 1/5/2022 6:22:40 PM

+ [redacted] **David M. Morens** 1/5/2022 6:22:40 PM

Greg, went thru entire book today and made line by line notes in the margins. Will hopefully get comments typed up tomorrow. Much that might be said but i will try not to be too verbose. Very good, well organized, clear, and readable book aimed at layman's level. The science is mostly explained

well but might benefit from some fleshing out and caveats on various "enthusiasms" that sound great as aspirations but lack perspective and lack approaches that get you from A to Z. d

---

[redacted]

Released by Chairman Rand Paul

1/7/2022 4 3 0

chat [redacted]

Participants: +1 [redacted] **Greg Folkers**; + [redacted] **Hugh Auchincloss**; [redacted] David M. Morens; [redacted] Anthony Fauci (Owner)

First Message: 1/7/2022 1:21:54 PM

Last Message: 1/7/2022 2:49:48 PM

+ [redacted] **Greg Folkers** 1/7/2022 1:21:54 PM

Asf I wud suggest u use gmail to write back to bill g. David's response in OD is very good

---

+ [redacted] **Hugh Auchincloss** 1/7/2022 2:33:50 PM

Greg. I got this message. Did you send to ASF also? Hugh

+ [redacted] **Greg Folkers** 1/7/2022 2:49:48 PM

Yes

[redacted]

Released by Chairman Rand Paul

2/21/2022 3 4 0

+[redacted]

Participants: +1[redacted] **Anthony Fauci (Owner)**; +[redacted]; [redacted]@outlook.com Anthony Fauci (Owner)

First Message: 2/21/2022 3:58:39 PM

Last Message: 2/21/2022 5:01:13 PM

+[redacted] 2/21/2022 3:58:39 PM

Sorry to bother you on a holiday. Any chance you have a few minutes to talk today

---

+[redacted] **Anthony Fauci (Owner)** 2/21/2022 4:19:18 PM

About what?

+[redacted] 2/21/2022 4:27:15 PM

I'm in Geneva. Met with Bill Gates and Richard Hatchett and others about pandemic preparedness and vaccines. Wanted to get your off the record view on a few things.

+1[redacted] **Anthony Fauci (Owner)** 2/21/2022 5:01:13 PM

Tried your phone but no answer. Let us try to connect tomorrow. Thanks, Tony

---

[redacted]

Released by Chairman Rand Paul

5/1/2022 2 1 0

+[redacted]

Participants: +[redacted] **Francis Collins**; [redacted] Anthony Fauci (Owner)
First Message: 5/1/2022 6:29:38 PM
Last Message: 5/1/2022 6:29:38 PM

+[redacted] **Francis Collins** 5/1/2022 6:29:38 PM

Hey Tony,

I'm going to see Bill Gates in two hours, and it would be good to know any points to raise with him. Have you got a few minutes to chat?

Francis

[redacted]

Released by Chairman Rand Paul

From: Jeremy Farrar [redacted]@wellcome.ac.uk>

To: [redacted]@usaid.gov" [redacted]@usaid.gov>, [redacted]@thieme.de" [redacted]@thieme.de>, [redacted]@scienceopen.com" [redacted]@scienceopen.com>, [redacted]@rockfound.org" [redacted]@rockfound.org>, [redacted]@pensoft.ne" [redacted]@pensoft.ne>, [redacted]@plos.org" [redacted]@plos.org>, [redacted]@inmi.it" [redacted]@inmi.it>, [redacted]@microbide.com" [redacted]@microbide.com>, [redacted]@medecinsdumonde.net" [redacted]@medecinsdumonde.net>, [redacted]@amed.go.jp" <makoto-[redacted]@amed.go.jp>, [redacted]@gmail.com" [redacted]@gmail.com>, [redacted]@ndm.ox.ac.uk" [redacted]@ndm.ox.ac.uk>, [redacted]@ins.gob.pe" [redacted]@ins.gob.pe>, [redacted]@butantan.gov.br" [redacted]@butantan.gov.br>, [redacted]@pasteur.fr" [redacted]@pasteur.fr>, [redacted]@live.com" [redacted]@live.com>, [redacted]@fiocruz.br" [redacted]@fiocruz.br>, [redacted]@f1000.com" [redacted]@f1000.com>, [redacted]@embo.org" [redacted]@embo.org>, [redacted]@ecohealthalliance.org" [redacted]@ecohealthalliance.org>, [redacted]@cdc.gov" [redacted]@cdc.gov>, [redacted]@cifar.ca" [redacted]@cifar.ca>, [redacted]@gulbenkian.pt" [redacted]@gulbenkian.pt>, [redacted]@who.int" [redacted]@who.int>, [redacted]@bmj.com" [redacted]@bmj.com>, [redacted]@bnitm.de" [redacted]@bnitm.de>, [redacted]@aaas.org" [redacted]@aaas.org>, [redacted]@aka.fi" [redacted]@aka.fi>, [redacted]@acmedsci.ac.uk" [redacted]@acmedsci.ac.uk>, [redacted]@zonmw.nl" [redacted]@zonmw.nl>, [redacted]@nsf.gov" [redacted]@nsf.gov>, [redacted]@nwo.nl" [redacted]@nwo.nl>, [redacted]@royalsociety.org" [redacted]@royalsociety.org>, [redacted]@nature.com" [redacted]@nature.com>, "Mark J Walport [redacted]@beis.gov.uk)" [redacted]@beis.gov.uk>, [redacted]@mrc.ac.za" [redacted]@mrc.ac.za>, Charlotte Watts [redacted]@dfid.gov.uk>, [redacted]@dbt.nic.in" [redacted]@dbt.nic.in>, [redacted]@nejm.org" [redacted]@nejm.org>, "Collins, Francis (NIH/OD) [E]" [redacted]@od.nih.gov>, [redacted]@gmail.com" [redacted]@gmail.com>, [redacted]@ndm.ox.ac.uk" [redacted]@ndm.ox.ac.uk>, [redacted]@fondation-merieux.org" [redacted]@fondation-merieux.org>, "Dzau, Victor J." [redacted]@nas.edu>, [redacted]@lancet.com" [redacted]@lancet.com>, [redacted]@gatesfoundation.org" [redacted]@gatesfoundation.org>, [redacted]@aasciences.ac.ke" [redacted]@aasciences.ac.ke>, [redacted]@nature.com" [redacted]@nature.com>, Paul Stoffels [redacted]@its.jnj.com>, George Gao [redacted]@im.ac.cn>, Maria Van kerkhove [redacted]@who.int>, "Redfield, Robert R. (CDC/OD)" [redacted]@cdc.gov>, Fiona Watt - UKRI MRC [redacted]@mrc.ukri.org>, [redacted]@esrc.ukri.org" [redacted]@esrc.ukri.org>, Barbara Kerstiens [redacted]@ec.europa.eu>, [redacted]@ec.europa.eu" [redacted]@ec.europa.eu>, Mercedes TATAY [redacted]@geneva.msf.org>, Rebecca GRAIS [redacted]@epicentre.msf.org>, [redacted]@ecohealthalliance.org" [redacted]@ecohealthalliance.org>, Julie Gerberding [redacted]@merck.com>, "Venkayya, Rajeev" [redacted]@takeda.com>

Cc: Josie Golding [redacted]@wellcome.ac.uk>, Teresa Miller de Vega [redacted]@wellcome.ac.uk>, David Carr [redacted]@wellcome.ac.uk>, Jeremy Farrar [redacted]@wellcome.ac.uk>

Subject: Joint statement on sharing research data and findings relevant to the novel coronavirus (nCoV) outbreak

Date: Tue, 28 Jan 2020 18:17:09 +0000

Importance: Normal

Dear All,

[redacted]

Released by Chairman Rand Paul

Joint statement on sharing research data and findings relevant to the novel coronavirus (nCoV) outbreak

I am writing to ask your organisation to recommit to a joint statement to rapid and open sharing of research data and findings relevant to the coronavirus (2019-nCoV) outbreak in China. The text of the joint statement follows below. Please do also share with others who may not be on this list.

This statement updates the 2016 joint statement on data sharing in public health emergencies, to which your organisation was a signatory.

In light of the urgent global health threat presented by this outbreak, we are asking signatories to reaffirm their commitment to these principles and pledge to also ensure research findings of relevance are shared rapidly with WHO. This statement reflects the public commitments already made by several leading journals over the last few days. It is aimed at researchers globally, and is necessary because of the unprecedented speed and number of research papers in response to the outbreak.

We plan to publish this statement before the end of the day on Thursday 30 January, so please let us know by 14:00 GMT on Thursday if you would like to sign.

Please reply to my colleague David Carr at Wellcome [redacted]@wellcome.ac.uk), who will also be happy to answer any questions you have.

With best wishes,

Jeremy Farrar

PROPOSED JOINT STATEMENT

Sharing research data and findings relevant to the novel coronavirus (nCoV) outbreak

The outbreak of the novel coronavirus in China (2019-nCoV) represents a significant and urgent threat to global health.

We call on researchers, journals and funders to ensure that research findings and data relevant to this outbreak are shared rapidly and openly to inform the public health response and help save lives.

We affirm our commitment to the principles set out in the 2016 Statement on data sharing in public health emergencies, and pledge to ensure that the World Health Organization has rapid access to emerging findings that could aid the global response.

Specifically, we commit to work together to ensure:

- all peer-reviewed research publications relevant to the outbreak are made immediately open access
- research findings relevant to the outbreak are shared immediately with the WHO upon journal submission, with author approval
- research findings are made available via preprint servers at or before journal submission, or via platforms that make papers openly accessible before peer review – with clear statements regarding the availability of underlying data
- interim and final research data relating to the outbreak are shared as rapidly and widely as possible, including with public health and research communities and the WHO
- journals are clear that data or preprints shared ahead of submission will not pre-empt its publication in these journals

[redacted]

We will apply the principles of this statement to similar outbreaks in the future where there is a significant public health benefit to ensuring data is shared widely and rapidly. We urge others to make the same commitments. If your organisation is committed to supporting these principles, please contact us [redacted]@wellcome.ac.uk) and we will add your organisation to the list of signatories

SIGNATORIES TO THE STATEMENT ON EBOLA

- Academy of Finland
- Academy of Medical Sciences, UK
- Bernhard Nocht Institute for Tropical Medicine
- Bill and Melinda Gates Foundation
- Biotechnology and Biological Sciences Research Council (BBSRC)
- The British Medical Journal (BMJ)
- Bulletin of the World Health Organization
- Calouste Gulbenkian Foundation – Gulbenkian Science Institute
- Canadian Institutes of Health Research
- The Centers for Disease Control and Prevention (to include Morbidity and Mortality Weekly Report [MMWR])
- Chinese Academy of Sciences
- Chinese Centre for Disease Control and Prevention
- The Department of Biotechnology, Government of India
- The Department for International Development (DFID)
- Deutsche Forschungsgemeinschaft (DFG)
- eLife
- EcoHealth Alliance
- The Economic and Social Research Council (ESRC)
- EMBO Press
- F1000
- Fondation Mérieux
- Fundação Oswaldo Cruz (Fiocruz)
- The Global Health Network
- Global Virus Network
- GlaxoSmithKline (GSK)
- The Institut Pasteur
- Instituto Butantan, Brazil
- Instituto Nacional de Salud, Peru
- International Severe Respiratory and emerging Infection Consortium (ISARIC)
- International Society for Infectious Diseases
- Japan Agency for Medical Research and Development (AMED)
- The JAMA Network
- The Lancet
- Médecins du Monde/Doctors of the World (MdM/DoW)
- Médecins Sans Frontières/Doctors Without Borders (MSF)
- Microbide Limited
- National Academy of Medicine
- National Institutes of Health, USA
- National Institute for Infectious Diseases Lazzaro Spallanzani (INMI), Italy
- National Science Foundation, USA
- The New England Journal of Medicine (NEJM)
- PLOS
- ProMED
- Research Ideas and Outcomes (RIO) Journal

[redacted]

- The Rockefeller University Press
- The Royal Society
- SAB Biotherapeutics
- Science Journals
- ScienceOpen
- South African Medical Research Council
- Springer Nature
- Thieme Publishers
- UK Medical Research Council
- Universidade Jean Piaget de Capo Verde
- USAID
- Wellcome Trust
- ZonMw – The Netherlands Organisation for Health Research and Development

Wellcome exists to improve health by helping great ideas to thrive. We support researchers, we take on big health challenges, we campaign for better science, and we help everyone get involved with science and health research. We are a politically and financially independent foundation.

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[redacted]

Released by Chairman Rand Paul

From: Jennifer Weisman [redacted]@gatesfoundation.org>
To: "Schwetz, Tara (NIH/OD) [E]" [redacted]@nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations
Date: Fri, 08 Apr 2022 08:30:14 -0400
Importance: Normal
Attachments: BMGF-Accelerator-Introduction.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Hi Larry, Tara,

Following up on our recent chats, I wanted to confidentially share with you a draft overview of our new effort. Please note that this continues to be a work in progress, so I'd ask that you please not share this material. This is meant to give you a sense of the programmatic areas we are currently pursuing – what is missing in this version is the incentives element that I think is incredibly important for discussion and I'll build into the next iteration.

I'm currently targeting May 2-4 to visit the DC area for exploratory meetings. I'd love to meet with you during that time if possible, and also welcome your recommendations on additional potential partners – perhaps in the BARDA ecosystem? I'm not connected there and would appreciate your advice/introduction.

Many thanks and have a great weekend!
Jenni

From: Schwetz, Tara (NIH/OD) [E] [redacted]@nih.gov>
Sent: Monday, March 21, 2022 5:34 PM
To: Jennifer Weisman [redacted]@gatesfoundation.org>
Cc: Simon, Dina (NIH/OD) [C] [redacted]@nih.gov>
Subject: Re: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

Jenni,

Good to hear from you! Thanks, and congrats to you as well! Yes, absolutely—happy to connect. I'm looping in Dina Simon, who can help us find some time to meet. Please let us know if there's someone she should work with on your side.

I look forward to connecting!

Best,

Tara A. Schwetz, PhD
Acting Principal Deputy Director, NIH
A: Building 1, Room 138
[redacted]

From: Jennifer Weisman [redacted]@gatesfoundation.org>
Date: Monday, March 21, 2022 at 8:11 PM

Released by Chairman Rand Paul

To: Tara Schwetz [redacted]@nih.gov>
Subject: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Hi Tara,
Congrats on your Acting Principal Deputy Director appointment! I spoke with Larry earlier today and he noted how pleased he was to have you working in this capacity. I had the chance to share with him a new venture that we've launched at the foundation and he recommended that I connect with you. I plan to do some targeted outreach in the DC area in the next couple of months and would love your perspectives before I start to initiate contact. Would you have time for a chat in the next week or two?
Best,
Jenni

Jennifer Weisman, PhD
Head of Strategic Alliances
Biotech Accelerator
[redacted]@gatesfoundation.org

Released by Chairman Rand Paul

BioInnovation Accelerator

Bill & Melinda Gates foundation

Released by Chairman Rand Paul

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Note that name, branding, and identity are in development.

Released by Chairman Rand Paul

ACCELERATOR TEAM LEADERSHIP

DAN WATTENDORF, MD
DIRECTOR

Dan is the Director of the Accelerator and leads the Activator Unit, focused on exploring and funding seedling efforts across a wide variety of topics for proof-of-concept potential. He joined the Foundation following a successful tenure at DARPA, where his funded technologies formed the basis of multiple mRNA, mAb, and cellular therapeutics companies. Dan is a clinically trained physician with multiple genetics fellowships and a retired USAF Colonel.

JENNI WEISMAN, PHD
HEAD OF STRATEGIC ALLIANCES

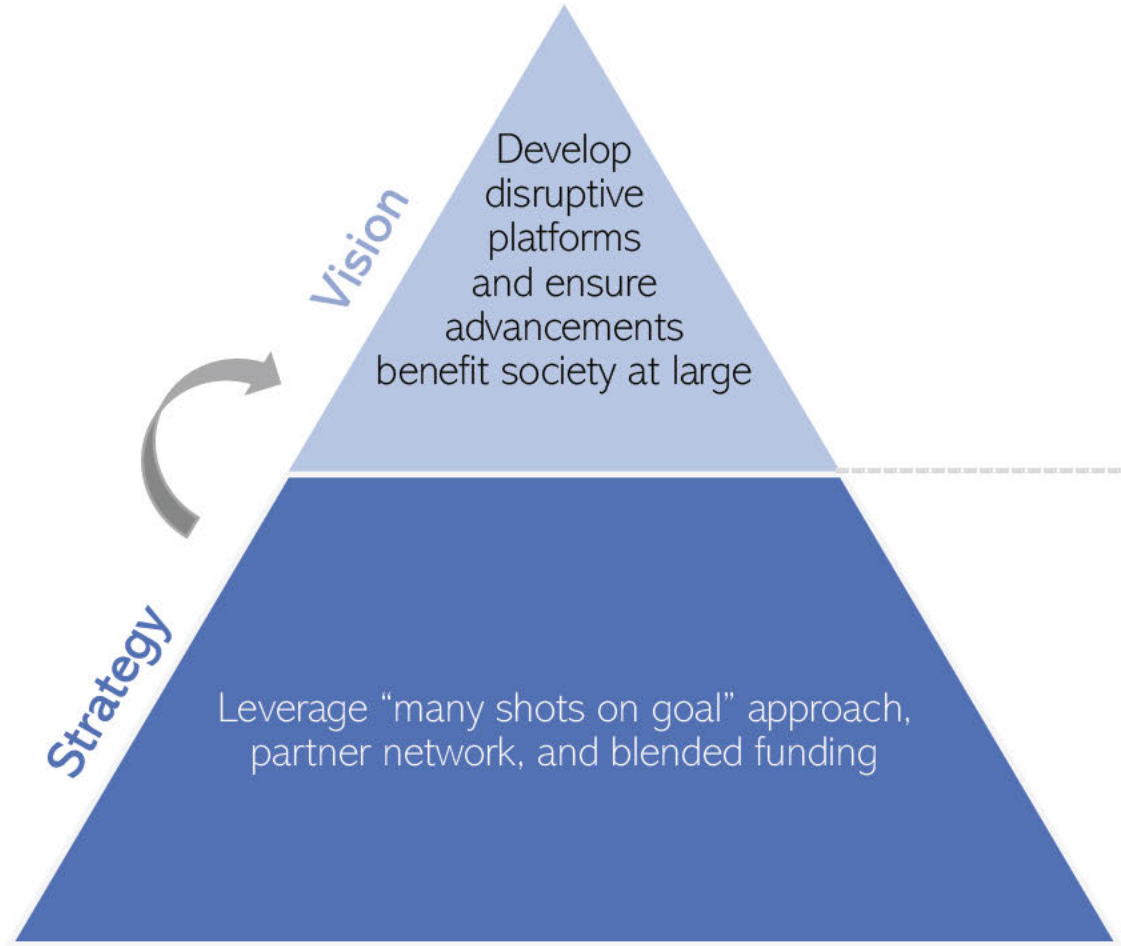
Jenni leads the Partnerships Unit, focusing on strategic external alliances, internal partnerships, and portfolio management to enable the maximum leverage and capacity for the Accelerator's programmatic goals. She joined the Foundation after a decade of US Government service at NIH, HHS, and DARPA. Jenni is a physical chemist by training with antimalarial drug discovery experience.

MIKE MCCUNE, MD, PHD
HEAD OF HIV FRONTIERS

Mike leads the HIV Frontiers Unit, the flagship unit of the Accelerator that aims to discover, develop, and deliver cures for HIV and SCD for global implementation. He joined the foundation with over 30 years of research experience in HIV pathogenesis, prevention, and treatment. Mike is a physician scientist and co-founder of multiple companies in addition to his long and decorated career in academia.

Released by Chairman Rand Paul

SUPPORT DEVELOPMENT OF DISRUPTIVE PLATFORMS BY ENABLING "MANY SHOTS ON GOAL" APPROACH



VISION STATEMENT:

- Fund the creation and development of new technological capabilities for **broad societal benefit** that are unaddressed in current government and private sector funding

STRATEGIC APPROACH:

- Use portfolio approach to pursue "many shots on goal" for a given technology capability to reduce overall risk
- Collaborate with academia, commercial entities, philanthropic partners, government agencies, and more
- Leverage $50M annual grant fund + $50M annual equity fund + uniquely aligned syndicate partner funds

Released by Chairman Rand Paul

OUR VISION

The overarching goal of the **Accelerator** is to foster platforms and capabilities that will eventually underpin future global health, agriculture, climate, and ecological interventions in support of the Foundation's mission.

GLOBAL HEALTH

- Detect contagious people in the community (including non-invasive detection)
- Prevent inflammation
- Cure HIV with a single-shot scalable solution
- R_0 Prevent disease transmission
- Create more potent, durable, and targeted vaccines
- Cure sickle cell disease (SCD) with a scalable solution
- Calculate individual disease risk linking measurements with public health
- Provide optimal immune protection first to infants (and eventually to others)
- Predict effective insecticides for infectious disease

+ MORE

- Maintain and expand crop diversity
- Adapt agriculture to climate change
- Promote ecological sustainability

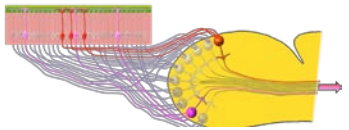
Additional goals

Released by Chairman Rand Paul

THE ACCELERATOR WILL INVEST IN MANY PLATFORM CAPABILITIES TO ENABLE OUR VISION

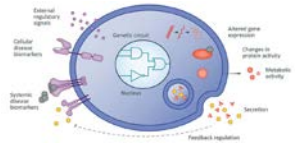
CURRENT PORTFOLIO

1 DETECT THE VOLATILOME WITH BIOSENSORS

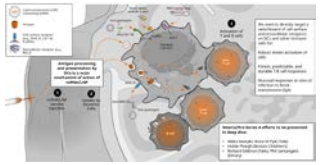


2 PREDICT AND DESIGN *DE NOVO* ODORS

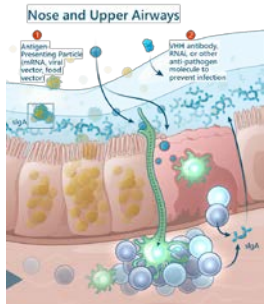
3 MANIPULATE CELL STATE AND FATE



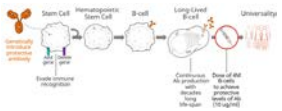
4 PROGRAM IMMUNITY



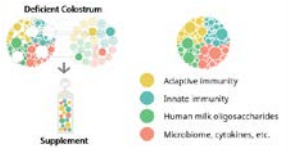
5 BLOCK TRANSMISSION



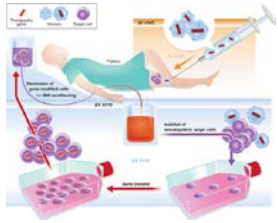
6 ENGINEER B CELLS



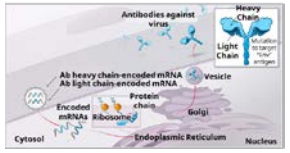
7 DEVELOP ORAL BIOLOGICS



8 OPTIMIZE *IN VIVO* GENE THERAPY



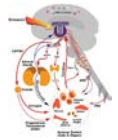
9 TREAT BY VACCINE



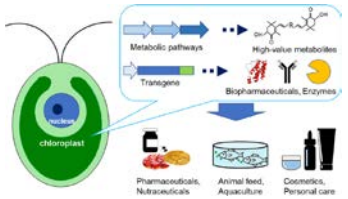
Source: Moderna Blog Post

POTENTIAL TOPICS

DEVELOP BIOPHYSICAL THERAPEUTICS



EDIT ORGANELLES



+ OTHERS

(e.g., synthetic biology platforms with climate, energy, and agriculture applications)

Released by Chairman Rand Paul

WE BUILD PLATFORM CAPABILITIES THROUGHOUT COMPANY JOURNEY; OPPORTUNITY FOR LEVERAGED PARTNER SUPPORT

	CAPABILITIES		
	CONCEIVE	CREATE	CARRY THROUGH
WHAT BIOINNOVATION ACCELERATOR DOES	• Work with academics / companies to develop groundbreaking technologies and fund early-stage experiments • Ensure forward looking global access and global health license agreements	• Provide funding to enable platform science development for early stage/ new companies • Offer guidance on global health applications	• Form syndicates with government and commercial entities to increase funding • Work with governments to develop market incentives • Participate in later funding rounds
OPPORTUNITIES FOR LEVERAGED PARTNERS	• **Source:** Find targeted partners working on new technology platforms • **Collaborate:** Share information across syndicate • **Incentivize:** Assist with early market-shaping incentives (as is relevant)	• **Fund:** Support platform scale up through early capital investment • **Advise:** Advise company on early commercial strategy	• **Fund:** Join syndicate and fund company • **Incentivize:** Develop incentives for continued global health sustainability • **Advise:** Continue to advise company on commercial strategy

Released by Chairman Rand Paul

EXAMPLES OF PREVIOUS WORK IN THESE AREAS

CAPABILITIES

CONCEIVE

- 85+ investments across the Accelerator's portfolio from 2016-2022

Sample Partners

University of York, Novartis, Seattle Children's, bluebirdbio, Boston Children's Hospital (Until every child is well), VIR, FRED HUTCH (CURES START HERE™), University of Washington, Stanford, Intellia Therapeutics, The Rockefeller University, Emory University, CRISPR Therapeutics

And many more

CREATE

- Multiple companies launched after receiving grants from the Accelerator

Select Examples

ensoma
Gene therapy
Raise $70M in Series A

BE BIOPHARMA
Engineering B cells
Raised $52M in Series A

WALKING FISH THERAPEUTICS
Engineering B cells
Raised $50M and $73M in Series A funding

CARRY THROUGH

- Syndicates: Multiple leveraged funding partnerships across both commercial and government entities
- Government incentives: BMGF experience starting GAVI

NOVARTIS
Gene-based cure for sickle cell disease
Significant 1:1 leveraged funding

NIH
Collaboration on gene-based cures for HIV and sickle cell disease
$100M leveraged funding

Gavi The Vaccine Alliance
Org development for vaccine distribution
$5.8B in grant funding from BMGF committed to date

Not for distribution

Released by Chairman Rand Paul

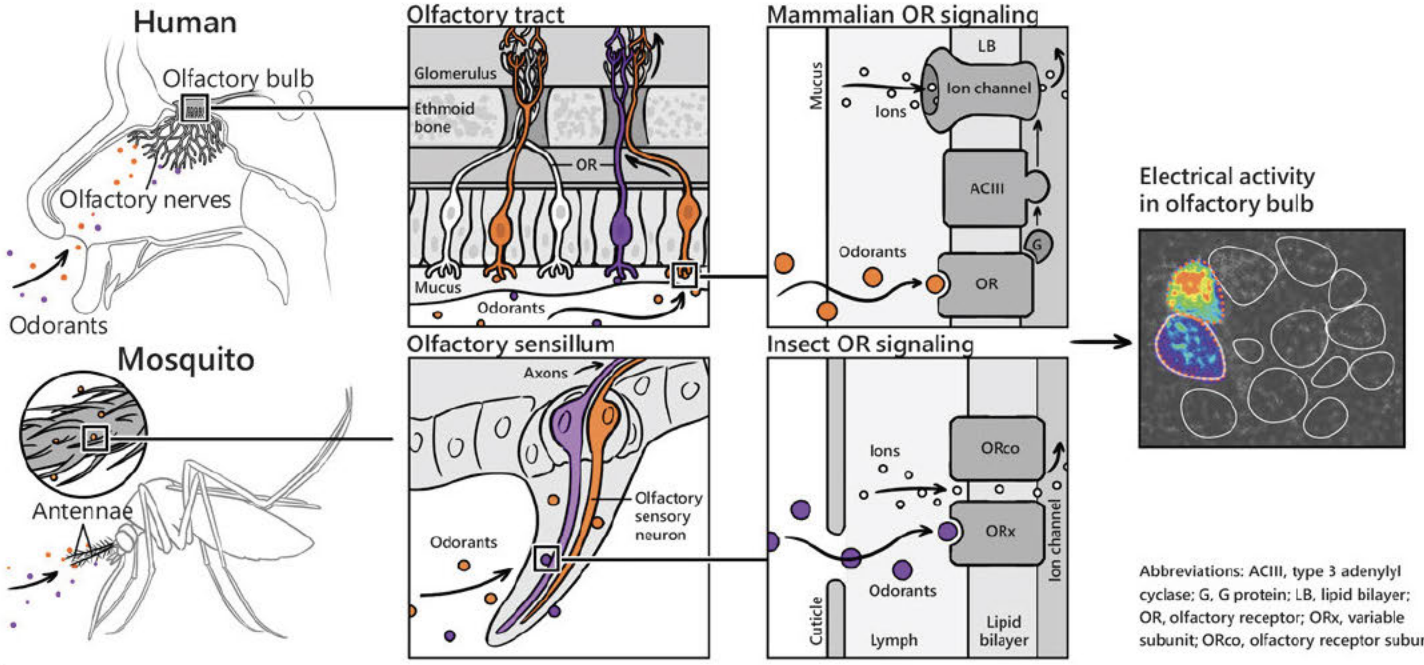
PLATFORM CAPABILITIES

Technical summaries of current portfolio

Released by Chairman Rand Paul

DETECT THE VOLATILOME WITH BIOSENSORS

A HOW DOES CHEMO-SENSING WORK?



Abbreviations: ACIII, type 3 adenylyl cyclase; G, G protein; LB, lipid bilayer; OR, olfactory receptor; ORx, variable subunit; ORco, olfactory receptor subunit

C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

Oxford NANOPORE Technologies · cardea · SCHRÖDINGER · canaery · The Rockefeller University · Duke · Caltech

+ And more, including new companies

B

KEY QUESTION(S)

How do we understand the relationship between odors and olfactory receptors? Which receptors respond to which chemicals?

FUTURE STATE

Develop olfactory receptor (OR)-based biosensors to detect volatile or soluble chemicals

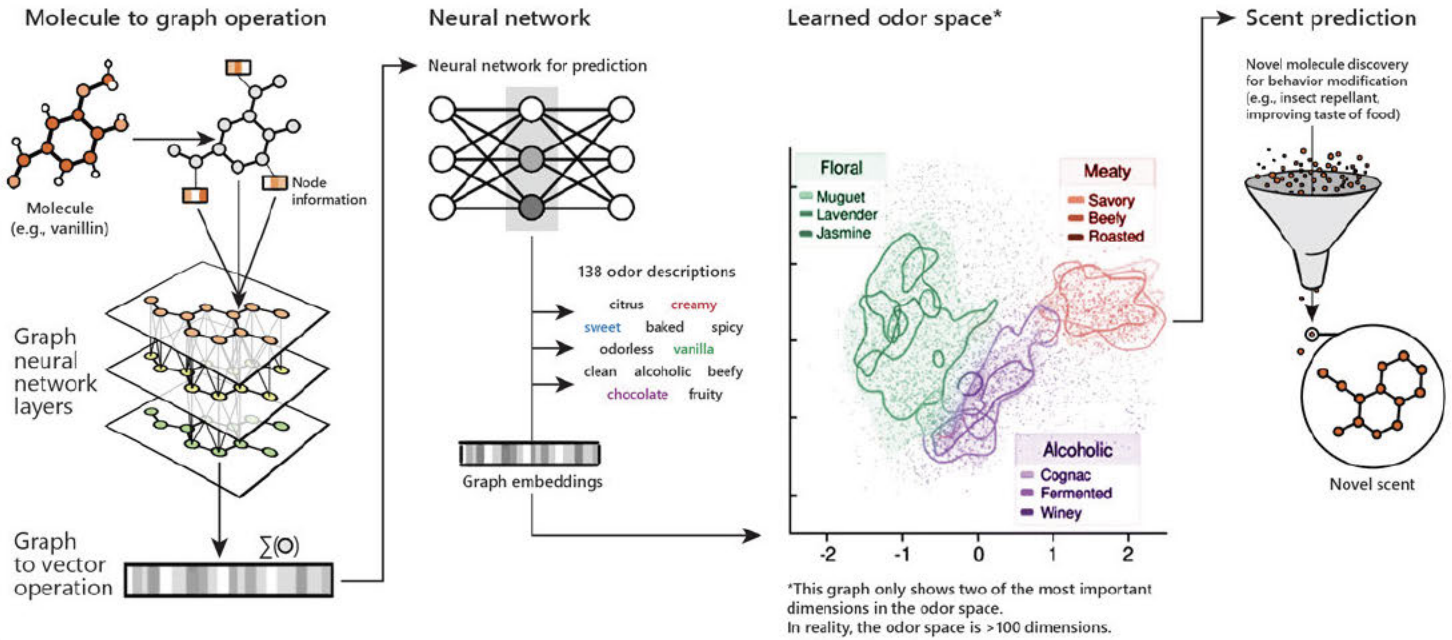
POSSIBLE APPLICATION(S)

Chip technology to detect odors with ultra-high sensitivity

Released by Chairman Rand Paul

PREDICT AND DESIGN *DE NOVO* ODORS

A HOW ARE BEHAVIOR-MODIFYING ODORANTS IDENTIFIED?



C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

TROPIQ HEALTH SCIENCES

SCJohnson USDA

And more, including new companies

B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
Can we redesign and retune olfactory receptors to detect volatiles of human interest and importance?	Identify new behavior-modifying chemicals and odors	New classes of mosquito repellants/ attractants that protect humans/ animals from vector born infections

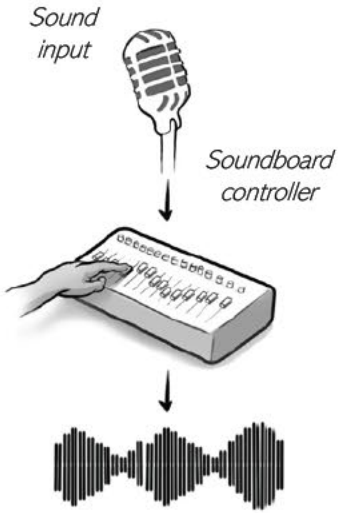
Released by Chairman Rand Paul

MANIPULATE CELL STATE AND FATE

A

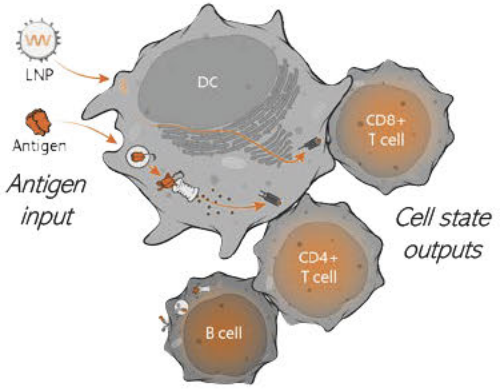
CAN WE APPLY RATIONAL CONTROLS TO IMMUNE AND STEM CELLS?

Music analogy

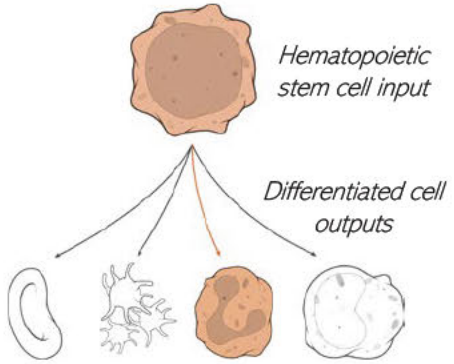


Rational controls in biological systems

Immune cells



Stem cells



What controls can be used to define these varied outputs?

C

WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

CarryGenes

The Alan Turing Institute

The University of Melbourne

California Institute of Technology

And more, including new companies

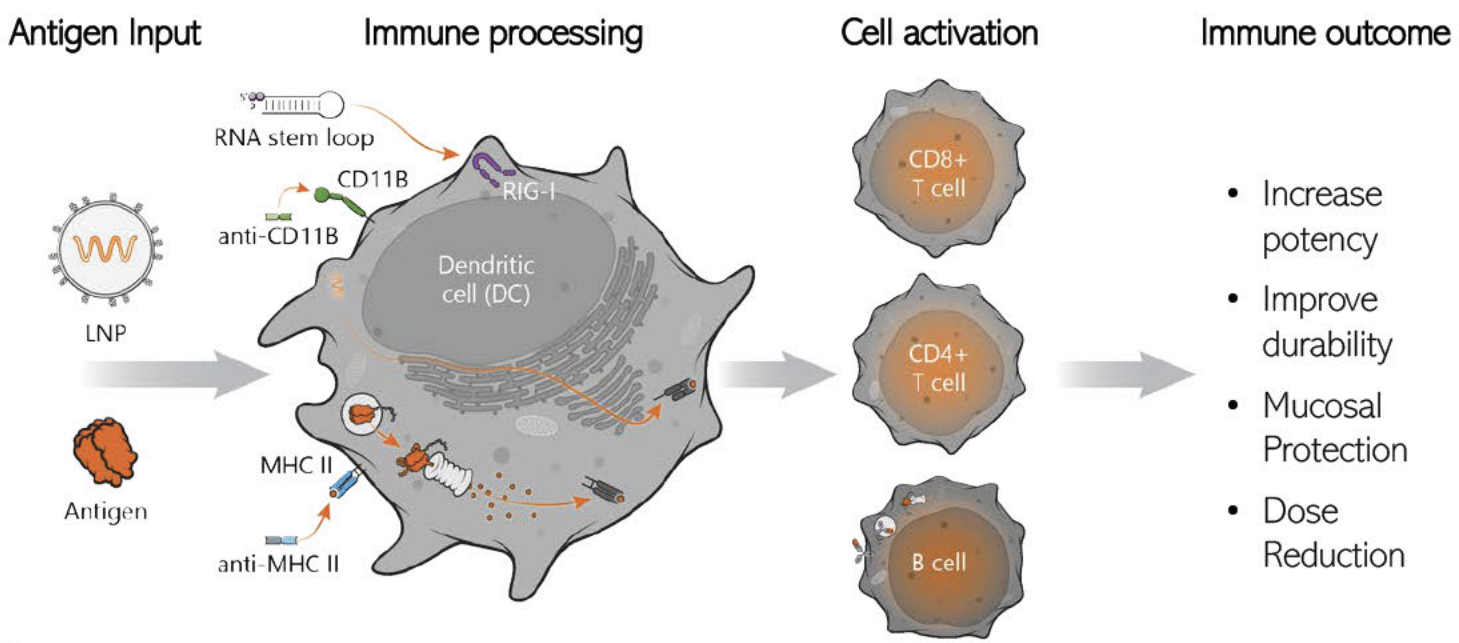
B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
What non-genetic perturbations influence cell state and fate?	Identify models and frameworks to define biological controls of immunity and stem cell differentiation	Programmable design of next-generation vaccines and therapeutics to control specific immune responses

Released by Chairman Rand Paul

PROGRAM IMMUNITY

A WHAT IS PROGRAMMING IMMUNITY?



C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

TRANSIMMUNE
HelixNano
Yale SCHOOL OF MEDICINE
HARVARD
EMORY UNIVERSITY SCHOOL OF MEDICINE

+ And more, including new companies

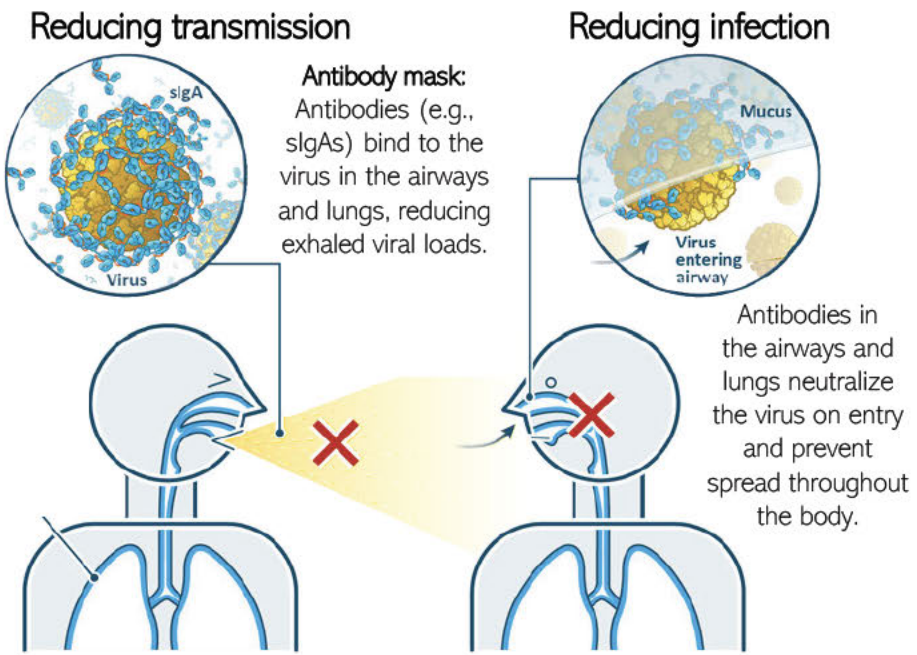
B

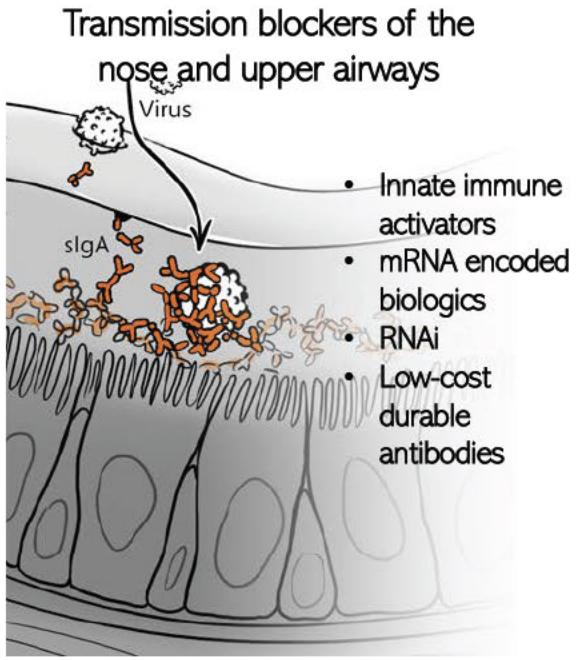
KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
How and where are immune signals transduced & processed?	Know and control the location, duration, and specific immune responses	cell — Fit for purpose, directed vaccines that lead to durable protection from severe disease

Released by Chairman Rand Paul

BLOCK TRANSMISSION

A WHAT IS TRANSMISSION BLOCKING?





C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

LUMEN BIOSCIENCE
RIGImmune
eleven THERAPEUTICS
Tether Therapeutics
Yale SCHOOL OF MEDICINE
EMORY UNIVERSITY SCHOOL OF MEDICINE
And more, including new companies

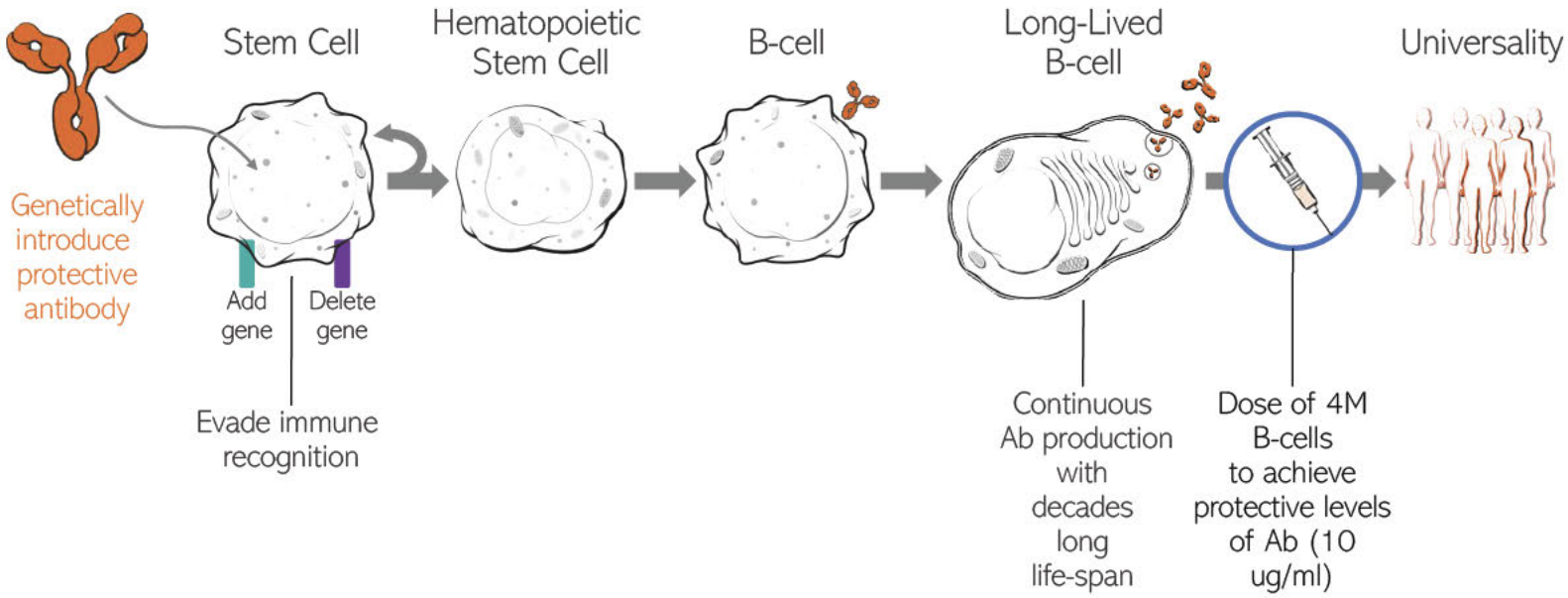
B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
How do we induce protective responses at sights of pathogen entry?	Understand how to block infection at the epithelium (e.g., GI tract)	Mucosal vaccine or antibody inhaler to prevent transmission

Released by Chairman Rand Paul

ENGINEER B CELLS

A WHAT DOES ENGINEERING B-CELLS INCLUDE?



C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

TABBY · WALKING FISH THERAPEUTICS · STEMCELL TECHNOLOGIES · BE BIOPHARMA · Seattle Children's · Scripps Research · The Rockefeller University · ARIZONA · Mount Sinai Hospital · EMORY UNIVERSITY

And more, including new companies

B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
How can we use stem cell engineering to produce long-lived B-cells?	Know the qualities necessary for differentiation and delivery of B-cells	Designer B cells delivered by injection

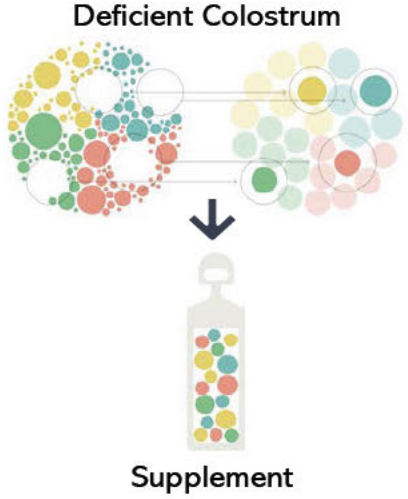
Released by Chairman Rand Paul

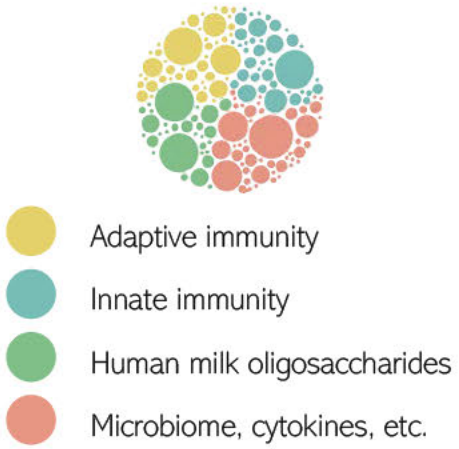
DEVELOP ORAL BIOLOGICS

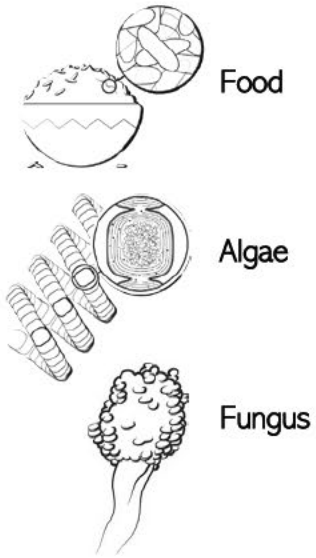
A

WHAT ARE ULTRA LOW-COST BIOLOGICS (OR FOOD-GROWN ANTIBODIES)?

Solving immune deficiencies → What will this contain? → Potential platforms







C

WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

BACTOLIFE · MassBio Massachusetts Biotechnology Council · VENTRIA BIOSCIENCE · LUMEN BIOSCIENCE · KU The University of Kansas · Tufts University

And more, including new companies

B

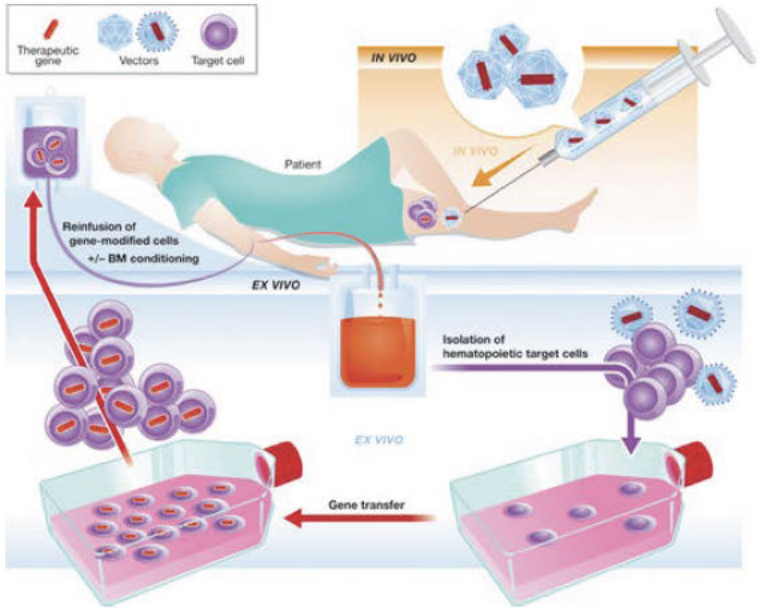
KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
How do we produce and deliver biologics into the gut such that they are stable, active, and durable?	Scalable platform that allows for production of gut-directed interventions	Synthetic colostrum as a supplement to improve gut health of infants and children

Released by Chairman Rand Paul

OPTIMIZE *IN VIVO* GENE THERAPY

A WHAT IS *IN VIVO* GENE THERAPY AND HOW DOES IT DIFFER FROM *EX VIVO* GENE THERAPY?

Ex vivo gene therapy can now treat sickle cell disease, but the approach requires (i) expensive manufacturing facilities and (ii) sophisticated clinical infrastructure



We aim to transform the approach to an *in vivo* method for editing blood and immune cells – using emerging technologies associated with CRISPR and mRNA vaccines – to create a safe and durable "single-shot" therapy

C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

Intellia THERAPEUTICS · GreenLight BIOSCIENCES™ · NIH National Institutes of Health · CRISPR THERAPEUTICS · NOVARTIS · FRED HUTCH CURES START HERE™ · EMORY UNIVERSITY · Boston Children's Hospital Until every child is well™ · BROAD INSTITUTE

+ And more, including new companies

B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATIONS
What combination of gene editing technologies and nucleic acid delivery vehicles will optimally reach blood and immune cells and their stem cell progenitors?	Understand how to safely and durably edit hematopoietic stem cells *in vivo*	Single-shot cure for diseases like HIV (infectious) and sickle cell disease (inherited)

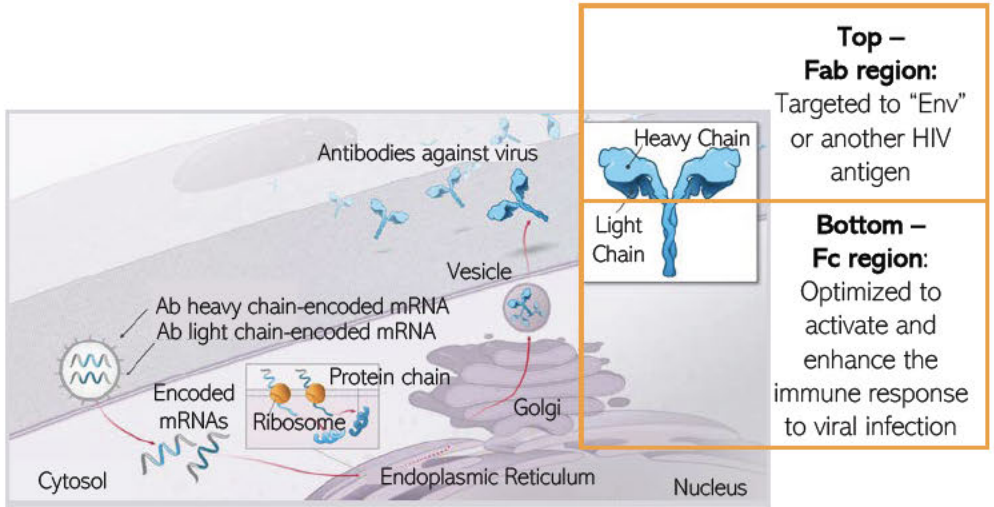
Source: Kaufmann, et al., *EMBO Mol Med*, 2013.

Released by Chairman Rand Paul

TREAT BY VACCINE

A WHAT DOES IT MEAN TO TREAT BY VACCINE?

Therapeutic vaccination might be accomplished in several ways: first, by providing an mRNA vaccine that induces immune responses targeting cells that are infected; and secondly, by providing engineered broadly neutralizing antibody (bNAbs) that would, upon contact with the virus, result in secondary induction of an antiviral immune response.



Example therapeutic vaccine method

C WHAT POTENTIAL RELATIONSHIPS COULD ACCELERATE THIS WORK?

Duke · VIR · The Wistar Institute · The Rockefeller University · Imperial College London · Emory University · University of Oxford · Ragon Institute of MGH, MIT and Harvard

+ And more, including new companies

B

KEY QUESTION(S)	FUTURE STATE	POSSIBLE APPLICATION(S)
How can mRNA vaccines and/or bNAbs be engineered to induce effective antiviral immune responses?	Launch one or both approaches off an mRNA/lipid nanoparticle	Single-shot mRNA therapeutic cure for viral infections

Source: Moderna Blog.

Released by Chairman Rand Paul

THANK YOU

Please contact Dan Wattendorf and Jenni Weisman to learn more

Released by Chairman Rand Paul

From: Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>
To: "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>, "Schwetz, Tara (NIH/OD) [E]" <tara.schwetz@nih.gov>
Cc: "Simon, Dina (NIH/OD) [C]" <dina.simon@nih.gov>, "McManus, Ayanna (NIH/OD) [E]" <ayanna.mcmanus@nih.gov>
Subject: RE: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations
Date: Thu, 28 Apr 2022 15:25:01 -0400
Importance: Normal
Attachments: BMGF_Accelerator_Intro_Overview_Pre-read_May_2022.pdf
Inline-Images: image001.png

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Larry, Tara,

Looking forward to meeting with you both next week. In advance, please find attached an updated overview of our efforts (still a work in progress, so I'd appreciate if you don't share further). It would be great to touch on the incentives concept that is now included. We've had some interesting conversations with European funder colleagues on this front and I'd like to see what you think about it with respect to ARPA-H, while of course recognizing that the Director has not yet been named and much is yet to be determined. Given your roles in its stand-up, I'm interested to see what you think.

Separately, I'll also have a chance to connect with Bruce T on any potential portfolio areas of overlapping interest. He's traveling next week but I'll have a chat with him and Taylor G the following week. Many thanks for that suggestion/connection!

Best,
Jenni

From: Tabak, Lawrence (NIH/OD) [E] <lawrence.tabak@nih.gov>
Sent: Monday, April 11, 2022 3:12 AM
To: Schwetz, Tara (NIH/OD) [E] <tara.schwetz@nih.gov>; Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>
Cc: Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>; McManus, Ayanna (NIH/OD) [E] <ayanna.mcmanus@nih.gov>
Subject: Re: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

Jenni
pleased to meet with you. I have cc'd Ayanna McManus who can find a mutually convenient time.
best wishes,
Larry

From: "Schwetz, Tara (NIH/OD) [E]" <tara.schwetz@nih.gov>
Date: Monday, April 11, 2022 at 12:08 AM
To: Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>, "Tabak, Lawrence (NIH/OD) [E]" <lawrence.tabak@nih.gov>
Cc: "Simon, Dina (NIH/OD) [C]" <dina.simon@nih.gov>
Subject: Re: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

Jenni,

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This looks great—thanks for sharing! Happy to meet when you are in town, and I'm looping in Dina, who can work with your folks to find some time.

Regarding BARDA, I would recommend reaching out to Sandeep Patel (Sandeep.Patel@hhs.gov), who was instrumental in getting BARDA Ventures up and running. Happy to facilitate an introduction, if helpful.

Best,

Tara A. Schwetz, PhD *(she/her)*
Acting Principal Deputy Director, NIH
A: Building 1, Room 109
P: 301-402-3965

Executive Assistant: Caroline Dzokoto-Pomenya (caroline.dzokoto-pomenya@nih.gov)
Scheduler: Dina Simon (dina.simon@nih.gov)

From: Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>
Date: Friday, April 8, 2022 at 8:30 AM
To: Tara Schwetz <tara.schwetz@nih.gov>, Larry Tabak <lawrence.tabak@nih.gov>
Subject: RE: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

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Hi Larry, Tara,

Following up on our recent chats, I wanted to confidentially share with you a draft overview of our new effort. Please note that this continues to be a work in progress, so I'd ask that you please not share this material. This is meant to give you a sense of the programmatic areas we are currently pursuing – what is missing in this version is the incentives element that I think is incredibly important for discussion and I'll build into the next iteration.

I'm currently targeting May 2-4 to visit the DC area for exploratory meetings. I'd love to meet with you during that time if possible, and also welcome your recommendations on additional potential partners – perhaps in the BARDA ecosystem? I'm not connected there and would appreciate your advice/introduction.

Many thanks and have a great weekend!
Jenni

From: Schwetz, Tara (NIH/OD) [E] <tara.schwetz@nih.gov>
Sent: Monday, March 21, 2022 5:34 PM
To: Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>
Cc: Simon, Dina (NIH/OD) [C] <dina.simon@nih.gov>
Subject: Re: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

Jenni,

Good to hear from you! Thanks, and congrats to you as well! Yes, absolutely—happy to connect. I'm looping in Dina Simon, who can help us find some time to meet. Please let us know if there's someone she should work with on your side.

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I look forward to connecting!

Best,

Tara A. Schwetz, PhD
Acting Principal Deputy Director, NIH
A: Building 1, Room 138
P: 301-402-3965 | **M:** 301-538-4920

From: Jennifer Weisman <Jennifer.Weisman@gatesfoundation.org>
Date: Monday, March 21, 2022 at 8:11 PM
To: Tara Schwetz <tara.schwetz@nih.gov>
Subject: [EXTERNAL] Biotech Accelerator - potential NIH and ARPA-H collaborations

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Hi Tara,
Congrats on your Acting Principal Deputy Director appointment! I spoke with Larry earlier today and he noted how pleased he was to have you working in this capacity. I had the chance to share with him a new venture that we've launched at the foundation and he recommended that I connect with you. I plan to do some targeted outreach in the DC area in the next couple of months and would love your perspectives before I start to initiate contact. Would you have time for a chat in the next week or two?
Best,
Jenni

Jennifer Weisman, PhD
Head of Strategic Alliances
Biotech Accelerator
V +1.202.997.9890
E Jennifer.Weisman@gatesfoundation.org

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BIOINNOVATION ACCELERATOR

BILL & MELINDA GATES foundation

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Note that name, branding, and identity are in development.

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ACCELERATOR LEADERSHIP

DAN WATTENDORF, MD
DIRECTOR

Dan is the Director of the Accelerator and leads the Activator Unit, focused on exploring and funding seedling efforts across a wide variety of topics for proof-of-concept potential. He joined the Foundation following a successful tenure at DARPA, where his funded technologies formed the basis of multiple mRNA, mAb, and cellular therapeutics companies. Dan is a clinically trained physician with multiple genetics fellowships and a retired USAF Colonel.

JENNI WEISMAN, PHD
HEAD OF STRATEGIC ALLIANCES

Jenni leads the Partnerships Unit, focusing on strategic external alliances, internal partnerships, and portfolio management to enable the maximum leverage and capacity for the Accelerator's programmatic goals. She joined the Foundation after a decade of US Government service at NIH, HHS, and DARPA. Jenni is a physical chemist by training with experience across drug discovery, health data privacy protections, and policy development.

MIKE MCCUNE, MD, PHD
HEAD OF HIV FRONTIERS

Mike leads the HIV Frontiers Unit, the flagship unit of the Accelerator that aims to discover, develop, and deliver cures for HIV and SCD for global implementation. He joined the foundation with over 30 years of research experience in HIV pathogenesis, prevention, and treatment. Mike is a physician scientist and co-founder of multiple companies in addition to his long and decorated career in academia.

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SUPPORT DISRUPTIVE PLATFORMS THROUGH "MANY SHOTS ON GOAL" APPROACH

VISION STATEMENT

Fund the creation and development of new technological capabilities for broad societal benefit that are unaddressed in current government and private sector funding

STRATEGIC APPROACHES

- Use portfolio approach to pursue "many shots on goal" for a given technology capability to reduce risk
- Ensure shared global access terms and goals across each platform capability portfolio
- Collaborate with academia, commercial entities, philanthropic partners, government agencies, and more
- Leverage blended grant and equity fund + uniquely aligned syndicate partner funds
- Prioritize rapid investment actions and early exits to "fail fast" on unpromising approaches

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OUR VISION

The overarching goal of the **ACCELERATOR** is to foster platforms and capabilities that will eventually underpin future global health, agriculture, climate, and ecological interventions in support of the Foundation's mission.

GLOBAL HEALTH

- Detect contagious people in the community (including non-invasive detection)
- Prevent inflammation
- Cure HIV with a single-shot scalable solution
- R_0 Prevent disease transmission
- Create more potent, durable, and targeted vaccines
- Cure sickle cell disease (SCD) with a scalable solution
- Calculate individual disease risk linking measurements with public health
- Provide optimal immune protection first to infants (and eventually to others)
- Predict effective insecticides for infectious disease

+ MORE

- Maintain and expand crop diversity
- Adapt agriculture to climate change
- Promote ecological sustainability

+ ADDITIONAL GOALS

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DEVELOP NOVEL, STEP CHANGE SOLUTIONS

/ Select examples	Continuous progress is fundamental	We focus on radical new options
Detect contagious people in the community	Improving sensitivity of existing diagnostic technologies	Develop bio-sensing chip technology to detect odors with ultra-high sensitivity
Provide optimal immune protection first to infants (and eventually to others)	Improve existing vaccines for infants	Create ultra-low-cost synthetic colostrum cocktails
R_0 Prevent disease transmission	Improve existing vaccine technologies	Cultivate mucosal antibody inhaler to prevent transmission

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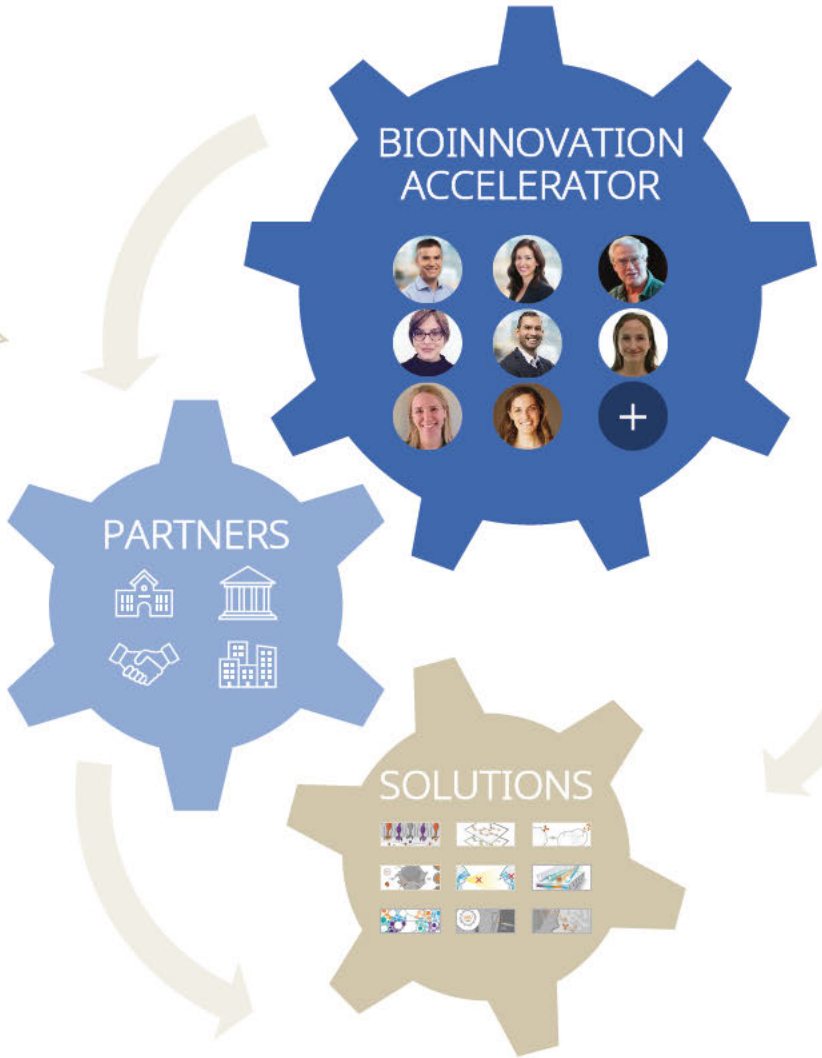
PLATFORM CAPABILITY NEEDS/SOLUTIONS ACTIVELY SOURCED THROUGH ACCELERATOR

BioInnovation Accelerator team actively engages external partners and builds platforms by funding new companies



External partners include academics, government entities, philanthropies, and private sector entities

BioInnovation Accelerator and partners work together to support technical capability and incentives development

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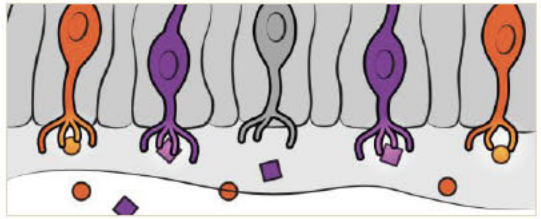
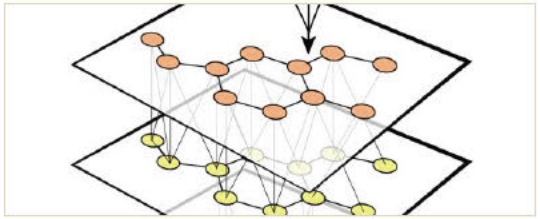
THE ACCELERATOR WILL INVEST IN MANY PLATFORM CAPABILITIES TO ENABLE VISION

CURRENT PORTFOLIO

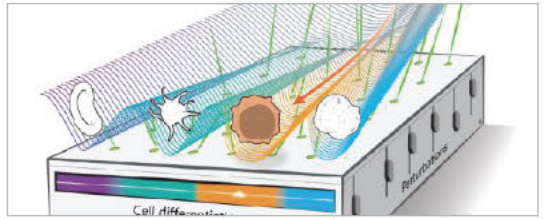
1 **SMELL THE VOLATILOME WITH BIOSENSORS**



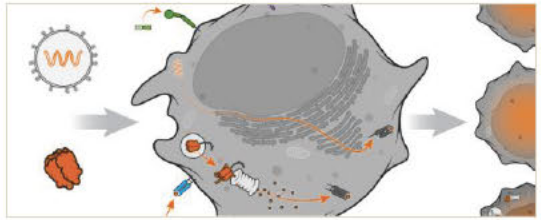
2 **PREDICT AND DESIGN *DE NOVO* ODORS**



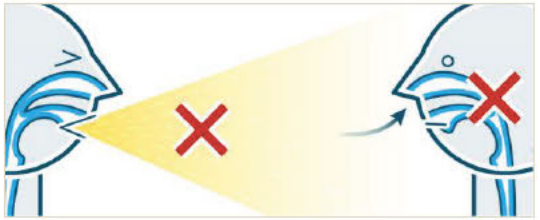
3 **MANIPULATE CELL STATE AND FATE**



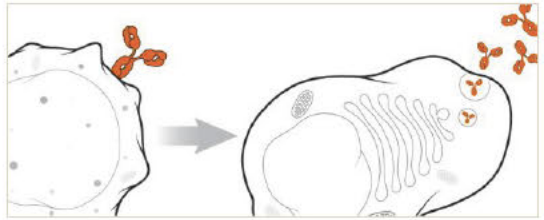
4 **PROGRAM IMMUNITY**



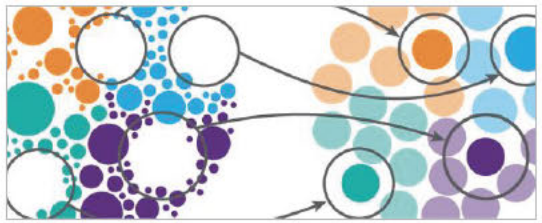
5 **BLOCK TRANSMISSION**



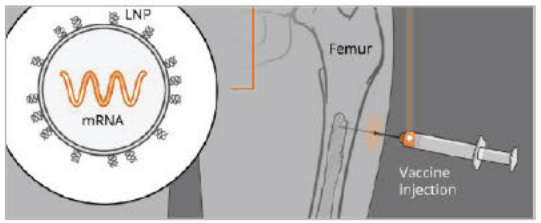
6 **ENGINEER B CELLS**



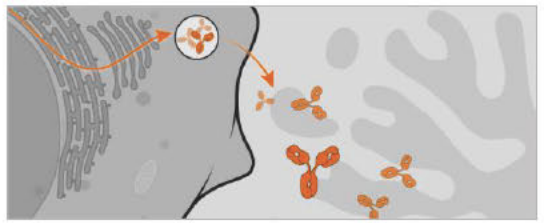
7 **DEVELOP ORAL BIOLOGICS**



8 **OPTIMIZE *IN VIVO* GENE THERAPY**

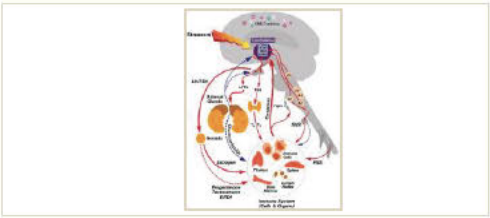


9 **TREAT BY VACCINATION**

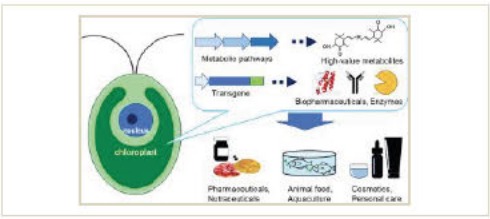


POTENTIAL TOPICS

DEVELOP BIOPHYSICAL THERAPEUTICS



EDIT ORGANELLES



+ OTHERS

(e.g., synthetic biology platforms with climate, energy, and agriculture applications)

HIV FRONTIERS

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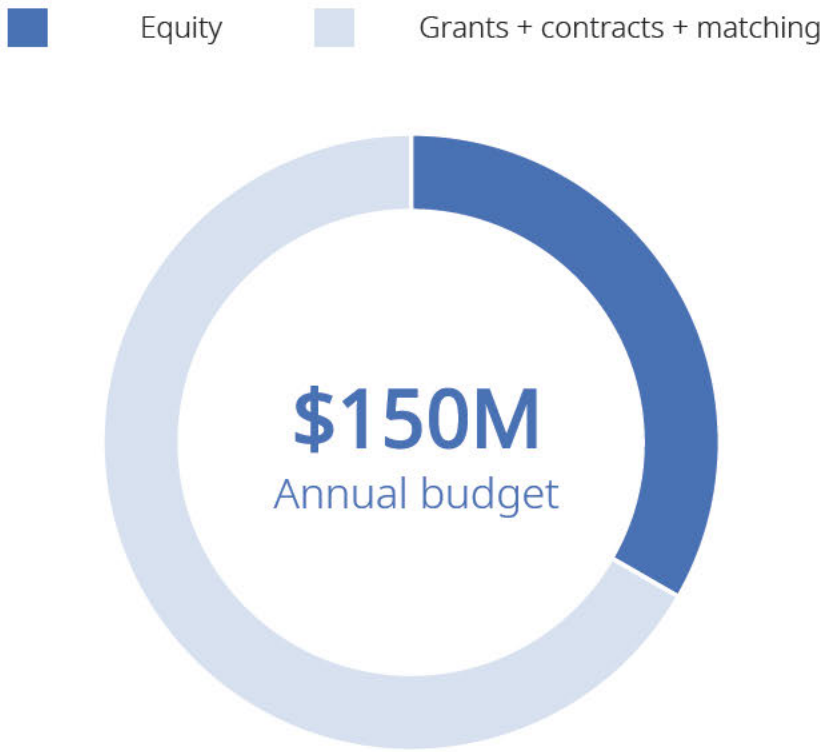
BIOINNOVATION VENTURE ENHANCES PAST SUCCESSES WITH NEW TOOLS & APPROACH

HISTORICAL EFFORTS*

150+ Investments	**100** Investment recipients
~5 Commercial platforms enabled	**$50M** Annual budget
$20k-5M Investment range	**$1M** Average investment
30-40% Investments to companies	**2-8 weeks** Average time to execute investment

BIOINNOVATION ACCELERATOR



(*) Includes Disruptive technology and HIV frontiers investments

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OPPORTUNITY FOR PARTNER INVOLVEMENT

	CAPABILITIES		
	CONCEIVE	CREATE	CARRY THROUGH
WHAT BIOINNOVATION ACCELERATOR DOES	• Work with academics / companies to develop groundbreaking technologies and fund early-stage experiments • Ensure forward looking global access and global health license agreements	• Provide funding to enable platform science development for early stage/ new companies • Offer guidance on global health applications	• Form syndicates with government and commercial entities to increase funding • Work with governments to develop market incentives • Participate in later funding rounds
OPPORTUNITIES FOR STRATEGIC PARTNERS	• Source: Find targeted partners working on new technology platforms • Collaborate: Share information across syndicate	• Fund: Support platform scale up through early capital investment • Advise: Advise company on early commercial strategy	• Fund: Join syndicate and fund company • Advise: Continue to advise company on commercial strategy

PARTNERS CRITICAL TO DRIVING INCENTIVES FOR PLATFORM CAPABILTY SUCCESS

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PLATFORM CAPABILITIES

Technical summaries of current portfolio

Gf

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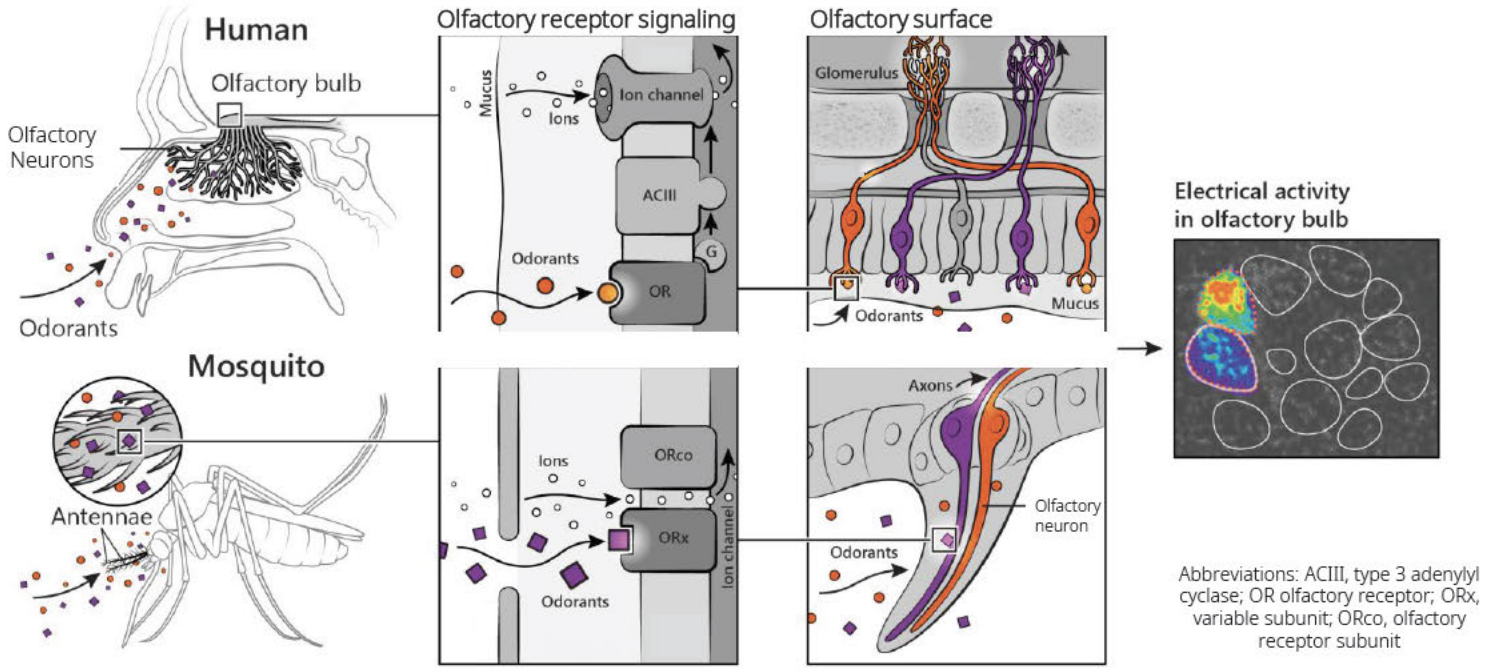
1

SMELL THE VOLATILOME WITH BIOSENSORS

A HOW DOES CHEMO-SENSING WORK?



Abbreviations: ACIII, type 3 adenylyl cyclase; OR olfactory receptor; ORx, variable subunit; ORco, olfactory receptor subunit

B KEY QUESTION(S)

Can we redesign and retune olfactory receptors to detect volatiles of human interest and importance?

FUTURE STATE

Develop olfactory receptor (OR)-based biosensors to detect volatile or soluble chemicals

POSSIBLE APPLICATION(S)

Chip technology to detect odors that are signatures of disease/ health of humans, animals, and plants

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: Oxford NANOPORE Technologies; SCHRÖDINGER; canaery; The Rockefeller University; Duke; Caltech; cardea

INCENTIVES: Regulatory approval pathways for multiplexed biosensing of volatiles for disease signatures, creation of large public-private human volatile biomarker datasets, orphan drug status equivalency for pandemic preparedness targets, additional costing structures (to be developed)

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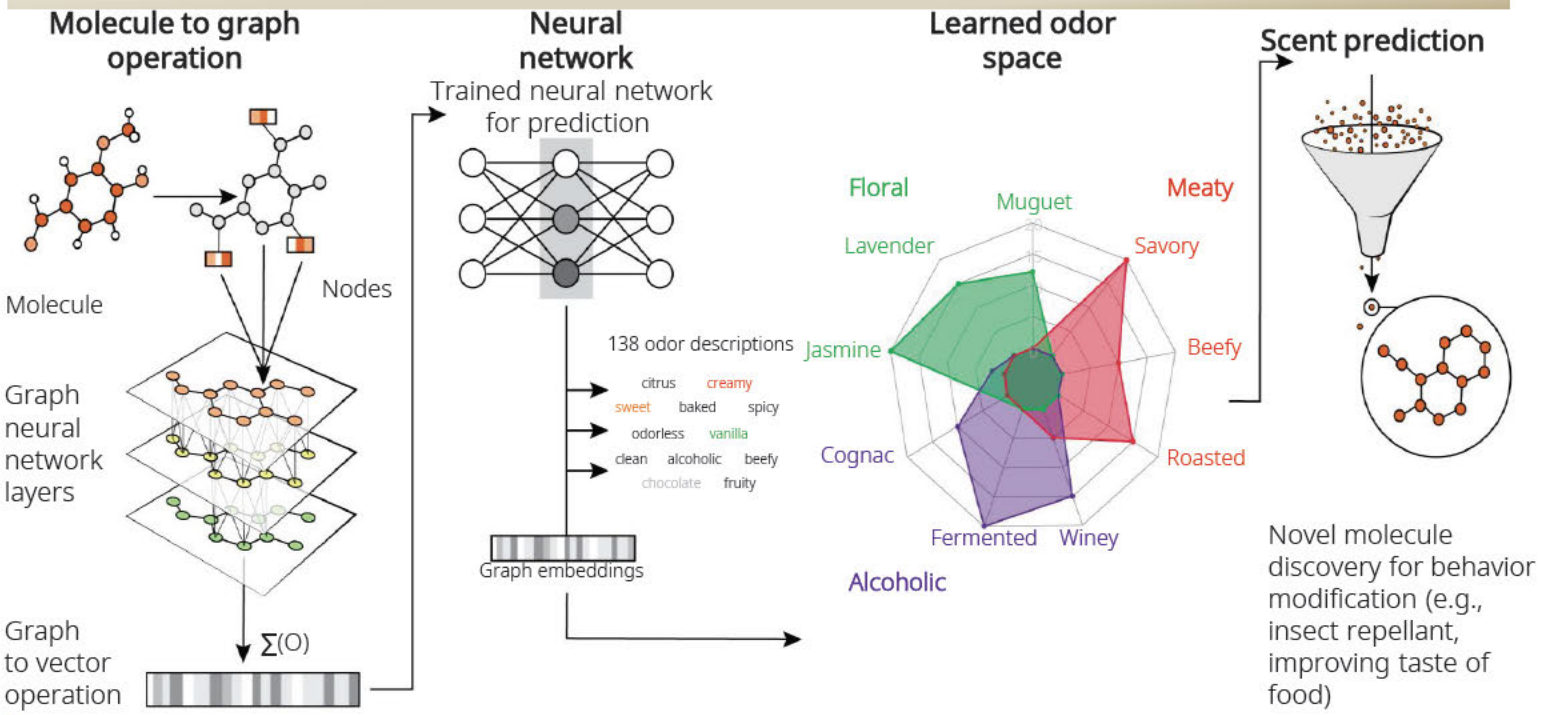
2

PREDICT AND DESIGN *DE NOVO* ODORS

A HOW ARE BEHAVIOR-MODIFYING ODORANTS IDENTIFIED?



B KEY QUESTION(S)

Can we accelerate the discovery of novel odors using AI and ML?

FUTURE STATE

Rapid identification of entirely new classes of chemicals and odors that have impact on human health and experience

POSSIBLE APPLICATION(S)

New classes of pest repellants that protect against vector-borne infections or attractants that enhance crop health

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: TROPIQ HEALTH SCIENCES, G, scJohnson, USDA

INCENTIVES: Fast-tracked approval pathways for odorant-controlled behaviors, costing structures for low- and middle-income contexts (to be developed)

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3

MANIPULATE CELL STATE AND FATE

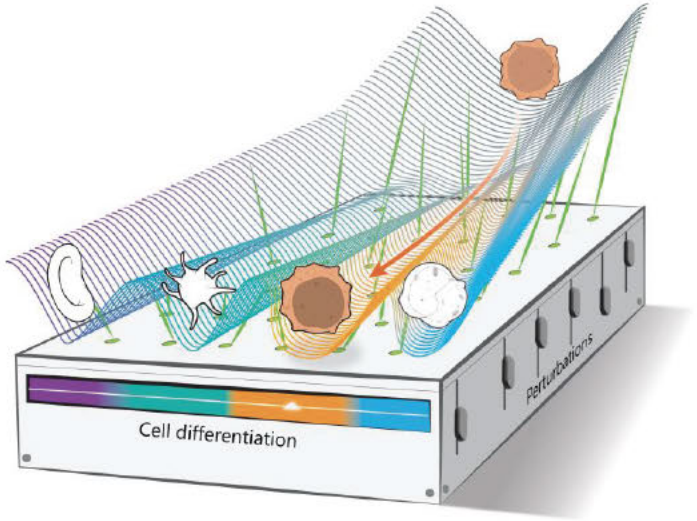
A CAN WE APPLY RATIONAL CONTROLS TO IMMUNE AND STEM CELLS?

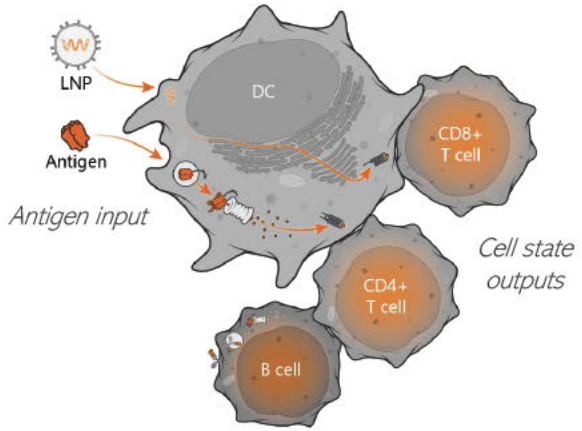
Waddington's epigenetic landscape

Rational controls in biological systems

Stem cells

Immune cells





What controls can be used to define these varied outputs?

B KEY QUESTION(S)

What non-genetic perturbations influence cell state and fate?

FUTURE STATE

Identify models and frameworks to define biological controls of immunity and stem cell differentiation

POSSIBLE APPLICATION(S)

Programmable design of next-generation vaccines and therapeutics to control specific immune responses

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: California Institute of Technology · The Alan Turing Institute · The University of Melbourne · CarryGenes

INCENTIVES: (to be developed)

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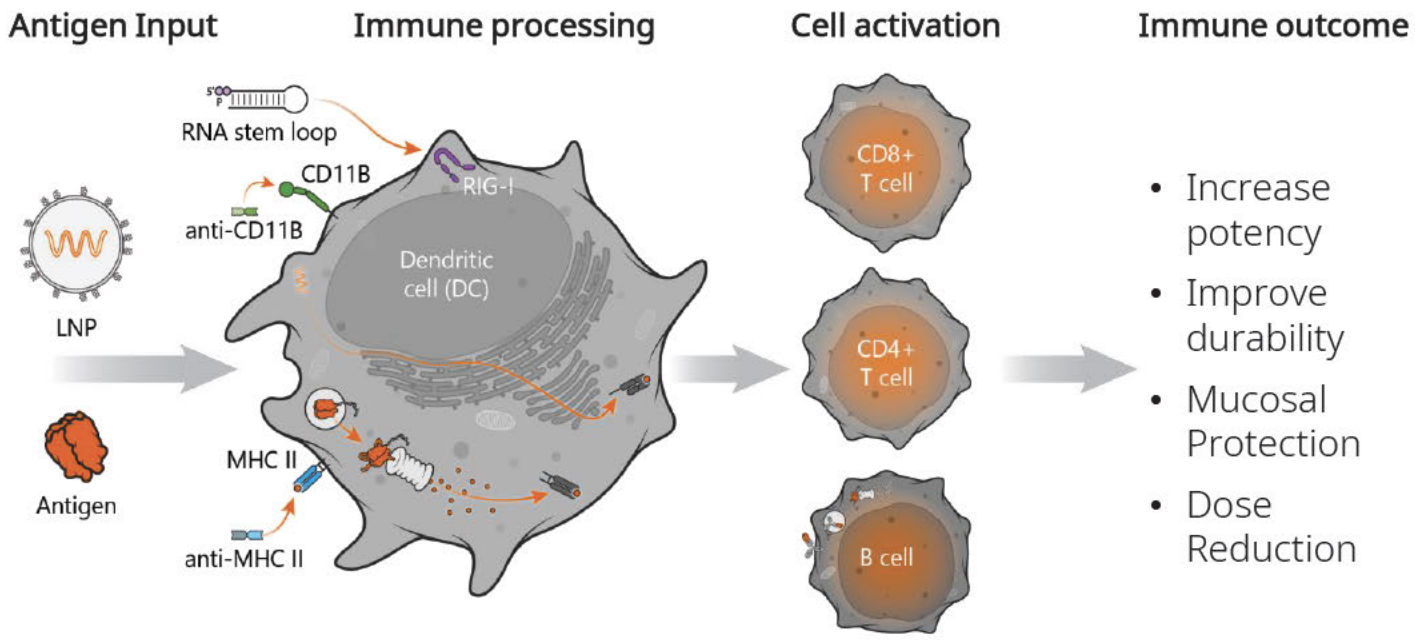
PROGRAM IMMUNITY

A WHAT IS PROGRAMMING IMMUNITY?



B KEY QUESTION(S)

How and where are immune signals transduced & processed?

FUTURE STATE

Know and control the location and duration of specific immune responses

POSSIBLE APPLICATION(S)

Fit for purpose, directed interventions that lead to durable protection from severe disease

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: TRANSIMMUNE · GT · HelixNano · Yale SCHOOL OF MEDICINE · VE CU TAS HARVARD · EMORY UNIVERSITY SCHOOL OF MEDICINE

INCENTIVES: Regulatory guidance/clarity for approval processes on severe disease endpoints, costing infrastructures (to be developed)

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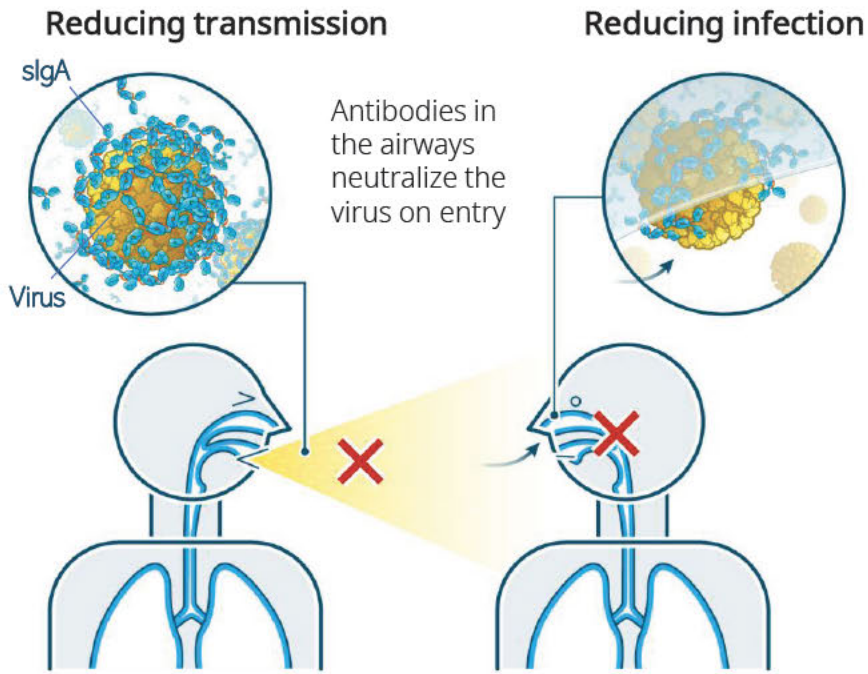
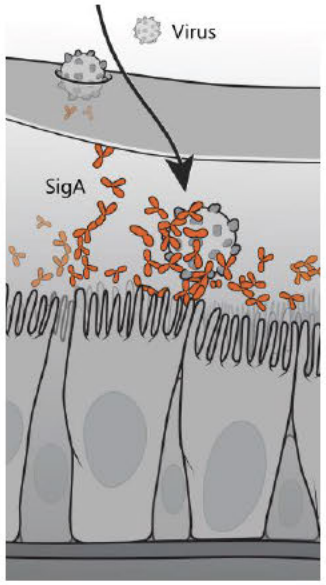
5

BLOCK TRANSMISSION

A WHAT IS TRANSMISSION BLOCKING?



Transmission blockers applied to the nose and upper airways



For example:

- Innate immune activators
- mRNA encoded biologics
- RNAi
- Low-cost durable antibodies

B KEY QUESTION(S)

How do we protect the nose and upper airways from pathogens, so they are unable to infect and spread?

FUTURE STATE

New platforms for potent, durable, and low-cost approaches that can be applied at scale to prevent pathogen transmission

POSSIBLE APPLICATION(S)

Blocking transmission of respiratory or enteric pathogens

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: LUMEN BIOSCIENCE; RIGImmune; eleven THERAPEUTICS; Tether Therapeutics; Yale SCHOOL OF MEDICINE; EMORY UNIVERSITY SCHOOL OF MEDICINE

INCENTIVES: Regulatory measures/endpoints for approval of transmission-reducing interventions, payment codes/infrastructure for transmission reduction, price/ volume guarantees (to be developed)

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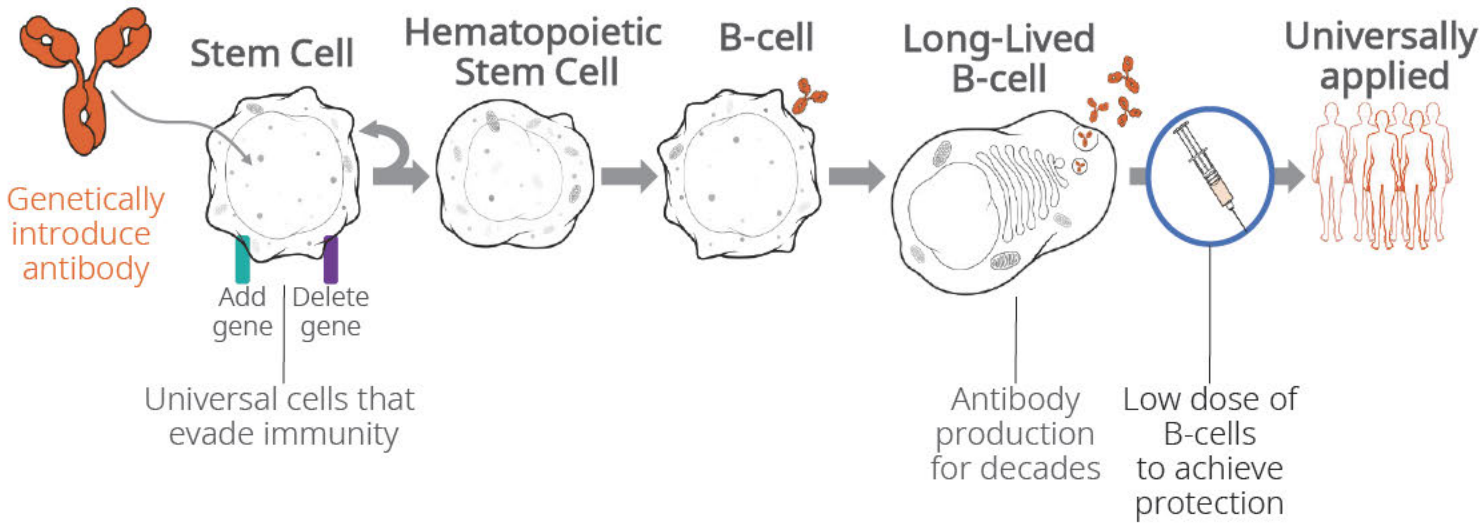
6

ENGINEER B CELLS

A WHAT DOES ENGINEERING B-CELLS INCLUDE?



B KEY QUESTION(S)

Can we use stem cell engineering and differentiation technologies to produce long-lived B-cells?

FUTURE STATE

Designer B cells producing antibody / therapeutic protein delivered by injection

POSSIBLE APPLICATION(S)

Infectious disease and other applications that require long-term, stable antibody production

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: TABBY, Walking Fish Therapeutics, STEMCELL Technologies, be BIOPHARMA, Seattle Children's, Scripps Research, The Rockefeller University, Arizona, Mount Sinai Hospital, Emory University

INCENTIVES: Regulatory guidance/clarity for approval processes on severe disease endpoints, costing infrastructures (to be developed)

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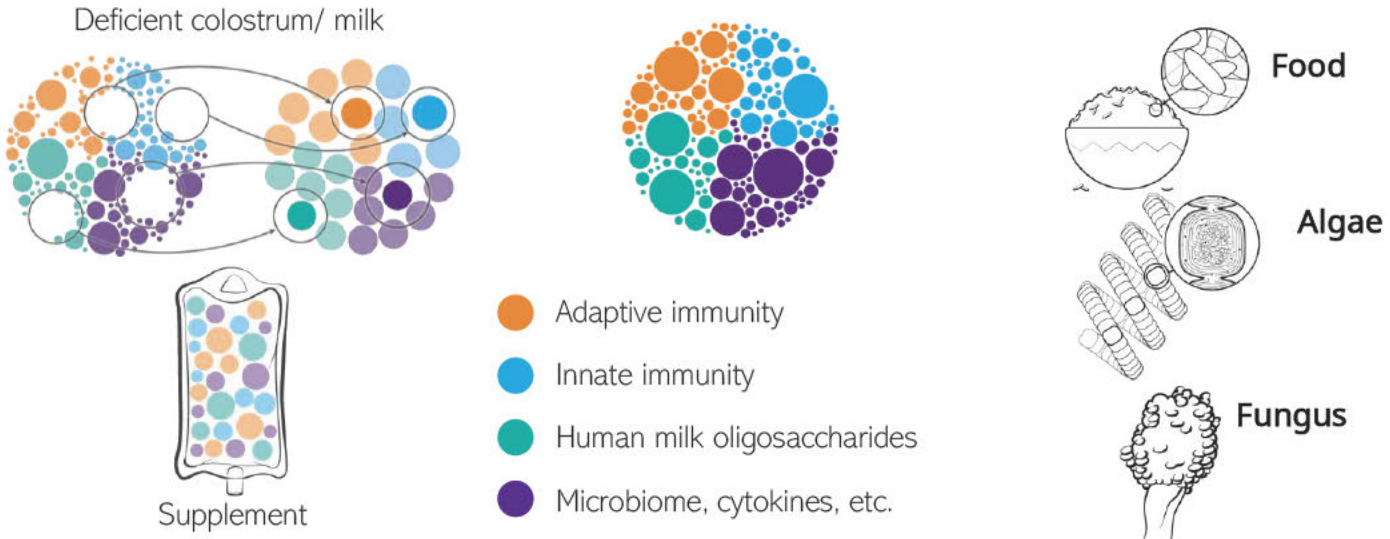
DEVELOP ORAL BIOLOGICS

A WHAT ARE ULTRA LOW-COST BIOLOGICS (OR FOOD-GROWN ANTIBODIES)?

Solving immune deficiencies → **What will this contain?** → **Potential platforms**



B KEY QUESTION(S)

How do we produce and deliver biologics into the gut such that they are stable, active, and durable?

FUTURE STATE

Scalable platforms that allow for production of low-cost, gut-directed interventions

POSSIBLE APPLICATION(S)

Synthetic colostrum/ milk as a supplement to improve gut health of humans and animals

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

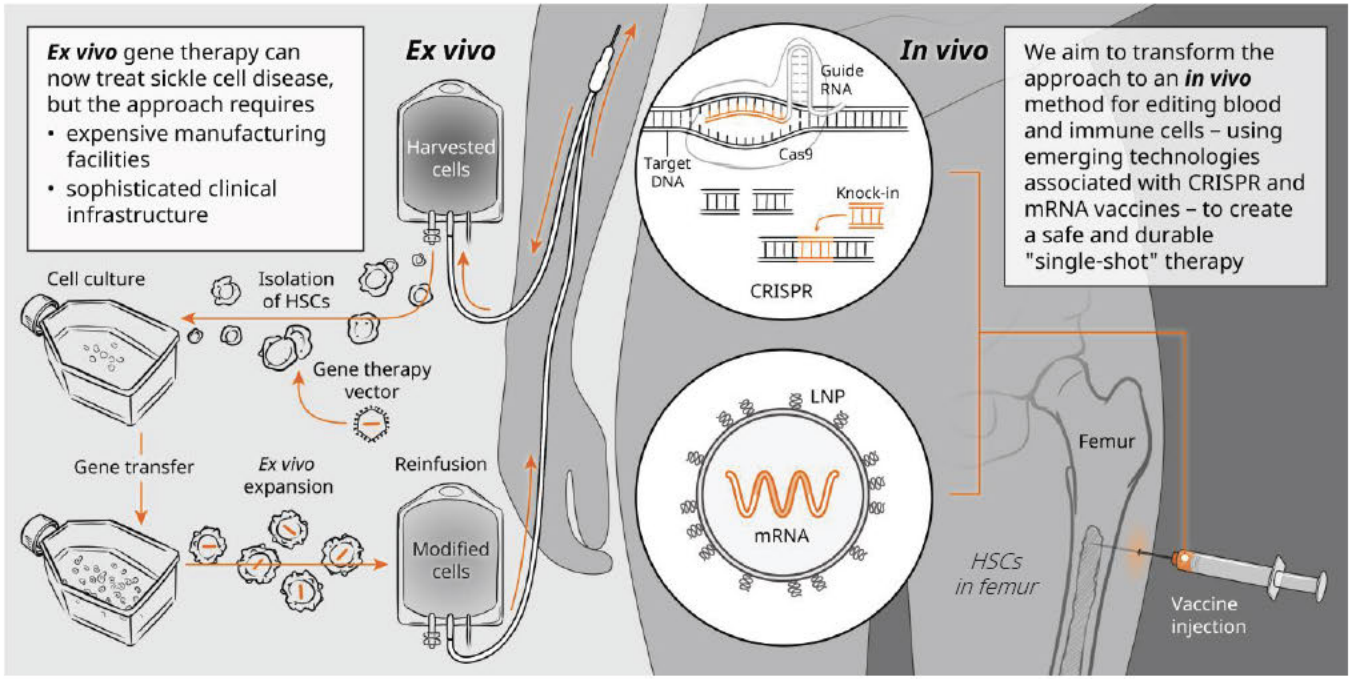
PARTNERS: BACTOLIFE, MassBio, VENTRIA BIOSCIENCE, LUMEN BIOSCIENCE, KU KANSAS, Tufts University

INCENTIVES: Regulatory measures/endpoints for approval of oral antibody cocktails, price/ volume guarantees (to be developed)

Released by Chairman Rand Paul

OPTIMIZE *IN VIVO* GENE THERAPY

A WHAT IS *IN VIVO* GENE THERAPY AND HOW DOES IT DIFFER FROM *EX VIVO* GENE THERAPY?



B KEY QUESTION(S)

What combination of gene editing technologies and nucleic acid delivery vehicles will optimally reach blood and immune cells and their stem cell progenitors?

FUTURE STATE

Understand how to safely and durably edit hematopoietic stem cells *in vivo*

POSSIBLE APPLICATION(S)

Single-shot cure for diseases like HIV (infectious) and sickle cell disease (inherited)

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: FDA, NIH (National Institutes of Health) — CRITICAL PARTNERS; Intellia Therapeutics; GreenLight Biosciences; Novartis; CRISPR Therapeutics; Fred Hutch Cures Start Here; Emory University; W; Boston Children's Hospital; Broad Institute

INCENTIVES: Regulatory pathways for approval of in vivo gene therapies, orphan drug status equivalency for populations in low- and middle-income countries, costing infrastructures (to be developed)

Source: Kaufmann, et al., *EMBO Mol Med*, 2013.

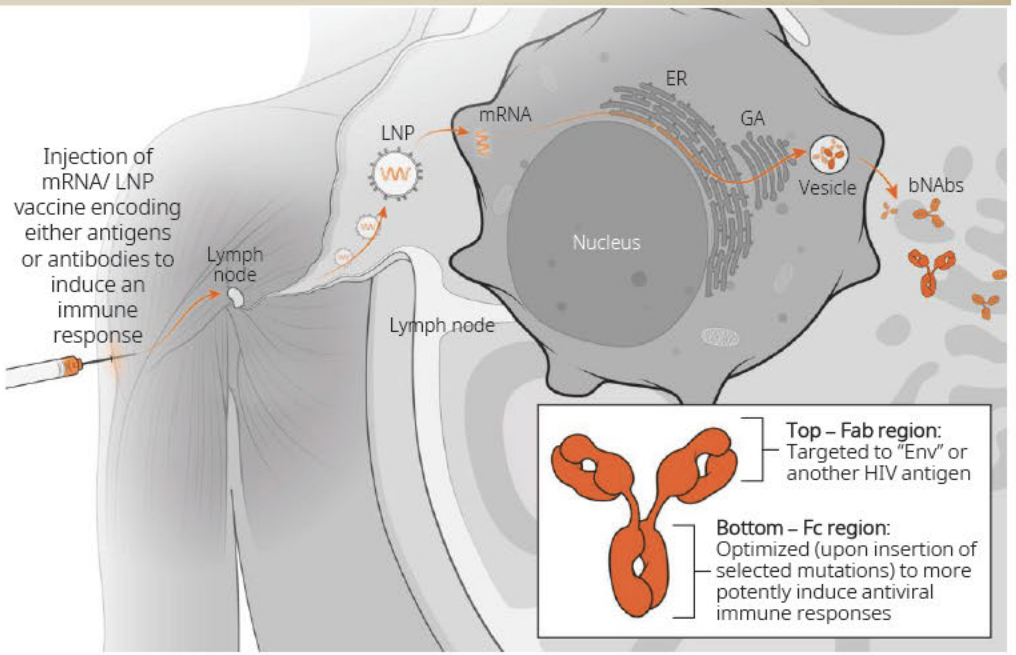
Released by Chairman Rand Paul

TREAT BY VACCINATION

A WHAT DOES IT MEAN TO TREAT HIV DISEASE WITH A VACCINE?

Therapeutic vaccination might be accomplished in several ways:

- **Method 1**: mRNA vaccine encoding antigens that induce immune responses targeting cells that are HIV-infected
  AND/ OR
- **Method 2**: mRNA vaccine encoding antibodies optimized to result in secondary antiviral immune responses upon binding to virus



Abbreviations: bNAbs, broadly neutralizing antibodies; ER, endoplasmic reticulum; Fab, "variable" region of antibodies that confers specific binding to antigens like HIV; Fc, "constant" region of antibodies that confers effector functions; GA, Golgi apparatus; LNP, lipid nanoparticle

B KEY QUESTION(S)

How can mRNA vaccines and/or bNAbs be engineered to induce effective antiviral immune responses?

FUTURE STATE

Launch one or both approaches off an mRNA/lipid nanoparticle

POSSIBLE APPLICATION(S)

Single-shot mRNA therapeutic cure for viral infections

C WHAT PARTNERS/INCENTIVES COULD ENABLE THIS WORK?

PARTNERS: Duke, VIR, The Wistar Institute, The Rockefeller University, Imperial College London, Emory University, University of Oxford, Ragon Institute of MGH, MIT and Harvard

INCENTIVES: Regulatory measures/endpoints for induced antiviral immune responses, costing infrastructures (to be developed)

Source: Moderna Blog.

Released by Chairman Rand Paul

THANK YOU

Please contact Dan Wattendorf and Jenni Weisman
to learn more

Released by Chairman Rand Paul

From: "Lehrman, Sandra \(NIH/NIAID\) [E]" [redacted]@niaid.nih.gov>

To: "Fauci, Anthony \(NIH/NIAID\) [E]" <AFAUCI@niaid.nih.gov>, "Auchincloss, Hugh \(NIH/NIAID\) [E]" [redacted]@niaid.nih.gov>, "Dieffenbach, Carl \(NIH/NIAID\) [E]" [redacted]@niaid.nih.gov>, "Lane, Cliff \(NIH/NIAID\) [E]" [redacted]@niaid.nih.gov>

Subject: Gates/Microbicides

Date: Sun, 17 Sep 2006 15:50:38 -0400

Importance: Normal

Thought you might be interested in this message relative to our conversation Friday afternoon.

Bottom line - Sharon is setting up discussions to explore Gates co funding of MTN studies. I will speak to her tomorrow at the Gates/Forum meeting on Biomedical Approaches to Prevention and keep you up to date. Let me know if you have any specific issues you would like me to raise with Sharon or the Gates representatives.

Sandi

-----Original Message-----
From: Hillier, Sharon L. [redacted]@mail.magee.edu]
Sent: Saturday, September 16, 2006 11:22 AM
To: Lehrman, Sandra (NIH/NIAID) [E]
Subject: RE: Time to talk

Hi Sandi-

Just wanted to follow up about finding a time to talk. Looks like between your schedule and mine this month might be tough for a face-to-face meeting but perhaps we could se up a time to talk by phone.
Bobbi told me that she would deliver one of our MTN Leadership meeting binders to you this week. I do have a short list of issues to talk about. Probably the most fun is a meeting I have set up with the Gates Foundation at the end of this month to discuss, among other things, the possible co-funding of our planned trial of oral vs vaginal tenofovir under the MTN. Our clinical trial sites will have capacity in mid 2008 and we will have to move fast to identify new PIF for this study. My agenda during the meeting with Gates this time is to briefly outline the MTN and explain what our infratrsucture could provide. I know that Gates is very interested in such a partnership but needs to understand how the Gates money could flow through the DAIDS network structures. I am hoping that our follow-up meeting with Gates would include you and John Mellors, who is the head of our Virology Core and is a major proponent in moving this study forward from the Pittsburgh MTN CORE team. I was at the OAR yesterday co-chairing the WHIN review with Joe Margolick and had the opportunity to meet briefly with Jack Whitescarver after we adjourned. He was also enthusiastic about approaching Gates about this and I told him that I hoped that you could accompany us on our next visit with them.

Have a great weekend, Sandi. Soory for the long email but will try to find a time for us to talk next week.

Sharon Hillier

Released by Chairman Rand Paul

From: Trevor Mundel [redacted]@gatesfoundation.org>
To: "Fauci, Anthony (NIH/NIAID) [E]" <afauci@niaid.nih.gov>
Cc: Robert Nabors [redacted]@gatesfoundation.org>, Christa Bowles [redacted]@gatesfoundation.org>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Jennifer Weisman [redacted]@gatesfoundation.org>
Subject: Following up
Date: Sat, 16 Jan 2021 09:59:07 -0500
Importance: Normal

Hi Tony,

Thanks for connecting with Bill and myself on Wednesday - there were a couple of areas we had discussed for potential follow on collaboration. First was any work you are doing through the VRC to adapt the Spike/other antigens in response to the new variants (I think Barney's work that was picked up by Novavax and some of the other companies will be very important). Let me know if there is anything we can help out with in this work. I'll also be in touch with Francis around the sequencing in the US and in Africa - we've had a lot of help here from Illumina and other companies.

Warm regards,
Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
[redacted]@gatesfoundation.org

Christa Bowles
Executive Assistant
Global Health Office of the President
[redacted]@gatesfoundation.org

Released by Chairman Rand Paul

From: "Mascola, John (NIH/VRC) [E]" [redacted]@mail.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <afauci@niaid.nih.gov>, Trevor Mundel [redacted]@gatesfoundation.org>
Cc: Robert Nabors [redacted]@gatesfoundation.org>, Christa Bowles [redacted]@gatesfoundation.org>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Jennifer Weisman [redacted]@gatesfoundation.org>, "Marston, Hilary (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: RE: Following up
Date: Mon, 18 Jan 2021 10:17:19 -0500
Importance: Normal

Tony, Trevor,

I am touching base with Emilio tomorrow to bilaterally catch up on several areas of mutual interest, including the emerging variants and their potential impact.

Several groups, including VRC/Moderna, have made mRNA based on UK and RSA variant and will soon do preclinical studies; E.g. Syrian Hamster model where we can immunize with current vaccine and challenge with UK or RSA viral challenge; and then vice versa. It will take 4-6 weeks for these data to emerge.

A related discussion would be when we would know enough to consider funding a clinical lot of a new variant for phase 1. We don't want to be chasing our tail with every new variant – but a case could be made based on some key criteria; level of antigenic variation seen, impact on vaccine sera, preclinical datda, global prevalence.

Importantly - Phase 3 clinical data will be key. In that regard, OWS is funding Janssen study that is enrolling in Brazil and RSA. These data would read in by end of this month.

BMGF has funded phase 2b Novavax study being conducted in RSA – I understand Novavax may be doing interim analysis soon - and it would be great of the Foundation and NIH could stay in close touch on these data. The clinical data my be our most informative insight into impact of the new variants.

Best,
John

From: Fauci, Anthony (NIH/NIAID) [E] <afauci@niaid.nih.gov>
Sent: Sunday, January 17, 2021 10:35 PM
To: Trevor Mundel [redacted]@gatesfoundation.org>
Cc: Robert Nabors [redacted]@gatesfoundation.org>; Christa Bowles [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Jennifer Weisman <[redacted]@gatesfoundation.org>; Mascola, John (NIH/VRC) [E] [redacted]@mail.nih.gov>
Subject: RE: Following up

Thanks, Trevor. I am copying John Mascola on this e-mail. He can fill you in on what we are doing at the VRC.
Best regards,
Tony

From: Trevor Mundel [redacted]@gatesfoundation.org>
Sent: Saturday, January 16, 2021 9:59 AM

Released by Chairman Rand Paul

To: Fauci, Anthony (NIH/NIAID) [E] <afauci@niaid.nih.gov>
Cc: Robert Nabors [redacted]@gatesfoundation.org>; Christa Bowles [redacted]@gatesfoundation.org>; Conrad, Patricia (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Jennifer Weisman [redacted]@gatesfoundation.org>
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Warm regards,
Trevor

Trevor Mundel, MD, PhD
President, Global Health Program
[redacted]
E [redacted]@gatesfoundation.org

Christa Bowles
Executive Assistant
Global Health Office of the President
[redacted]
E [redacted]@gatesfoundation.org

Released by Chairman Rand Paul

To: Dugan, Kerri[redacted]@darpa.mil]; Jordan, Kristen[redacted]@darpa.mil]
Cc: Schorr, Timothy (contr-bto)[redacted]@darpa.mil]; van Opstal, Edward (contr-bto)[redacted]@darpa.mil]; Willis, Samira (contr-bto)[redacted]@darpa.mil]; Martin, Charles (contr-bto)[redacted]@darpa.mil]
From: Ripp, Angela (contr-bto)
Sent: Mon 5/2/2022 12:50:56 PM
Subject: BMGF Briefs
Received: Mon 5/2/2022 12:50:59 PM

PREEMPT Overview for Bioinnovation Accelerator BMGF-Distro A_JORDAN.pptx
05032022_FoF_DISTAR.pptx
2022-05 BMGF INTERCEPT Briefing.pptx
ReVector -BMGF wo VT.pptx
BMGF Accelerator Intro Overview Pre-read May 2022.pdf
smime.p7s

Hi Kerri and Kristen,

Here are the briefings for tomorrow's BMGF meeting if you'd like to take a look at them prior. Tim will be in the room logged-in/projecting the decks in 11-300 for the briefers and Chuck will escort them up to the room. We are still on schedule for the following agenda:

3:30-4:00pm BMGF Overview (Kerri, Kirsten, Cathy dialing-in)
4:00-4:05pm Briefers arrive to 11-300/Intros (Clare, Tiffany, Linda)
4:05-4:15pm INTERCEPT Overview – Dr. Clare Rowland
4:15-4:25pm PREEMPT Overview – Dr. Kristen Jordan
4:25-4:35pm Friend or Foe Overview – Dr. Tiffany Prest
4:35-4:45pm ReVector Overview – Dr. Linda Chrisey
4:45-5:00pm Q&A/Wrap-up

Angela

Angela Ripp
Biological Technologies Office
Defense Advanced Research Projects Agency
Contractor, Strategic Analysis
[redacted]
[redacted]@darpa.mil

[redacted] [redacted]

Released by Chairman Rand Paul

PREventing EMerging Pathogenic Threats PREEMPT

Kristen Jordan, Ph.D.
Biological Technologies Office

Bioinnovation Accelerator
Bill and Melinda Gates Foundation

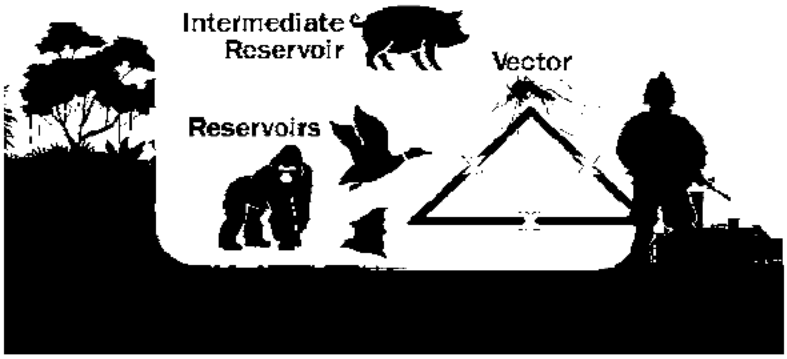
May 3, 2022

Released by Chairman Rand Paul

DARPA

Program Overview

DoD Problem: DOD Problem: Military personnel are regularly deployed to areas at high risk of acquisition of emerging infectious diseases



Fact: About 60-80% of infectious diseases in humans originate in animals and are transmitted by animals or insects

Global Virome Project: There are on the order of 600-800K unknown viruses among mammals and birds that have the potential to make a zoonotic leap (Science, 2018)

Vision: Significantly reduce viral threat surprise by preemptively blocking new outbreaks via targeting viruses in animals before they emerge in humans

[redacted] [redacted]

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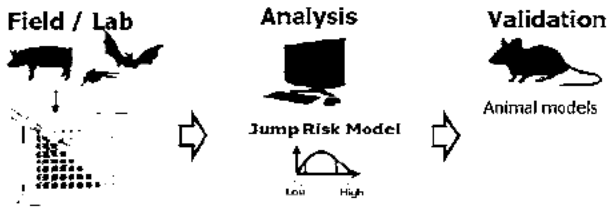
DARPA

PREEMPT Technical Areas

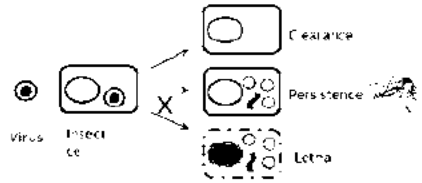
DARPA's Approach: Preemptively *block spillover of viral pathogens* by targeting and intervening at the animal / insect reservoir

TA1: Develop new tools to *predict* virus jump into humans



TA2: Develop and validate methods to *prevent* species jump

Example preemptive method:



Target insect immunity to eliminate persistent infection that results in transmission to humans

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DARPA

Technical Approach – Montana State University (MSU)

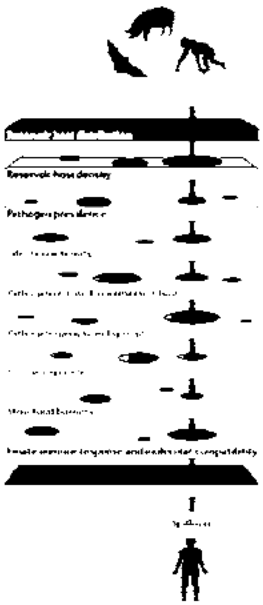
MONTANA STATE UNIVERSITY Rocky Mountain Labs

BAT

Generate the key pieces of data and models needed to understand all the layers.

Integrate data and models across scales to predict spillover.

Develop novel ecological and immunological solutions to prevent spillover at the level of the reservoir host.



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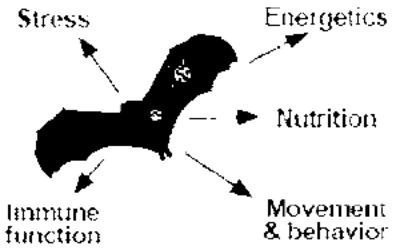
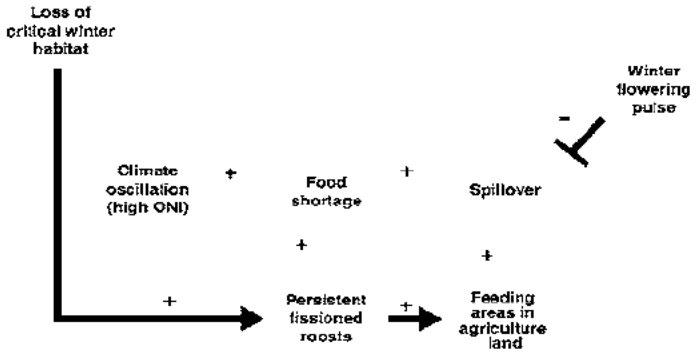
DARPA

MSU TA1-Modeling Virus Spillover Dynamics

- Spatiotemporal sampling of bats in 4 countries (1000+ samples)
- Multi-scale data pipeline and models to quantify zoonotic potential of bat viruses using Henipaviruses as proof of concept





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Technical Approach– University of California Davis (UCD)

Developing animal species-specific cytomegalovirus (CMV)-based transmissible vaccines for Lassa virus (LASV) and Ebola virus (EBOV)

Three Interwoven Strands

Virus Ecology

- What animal species serve as the major reservoir host?
- What CMV and pathogen virus lineages are co-circulating in these reservoir hosts?
- What is the incidence and prevalence of pathogen in these animals?

Modelling

- When and where is the highest risk for spillover?
- When is it optimal to introduce transmissible vaccine, and at what dose?
- When are animals most susceptible to vaccine intervention?

Vaccine Development

- Can the vaccine vector be isolated from reservoir animals?
- Can the vaccine have a limiting half-life "i.e., off-switch" to control environmental dissemination?
- Does the vaccine prevent infection and shedding virus?

[redacted] [redacted]

Released by Chairman Rand Paul

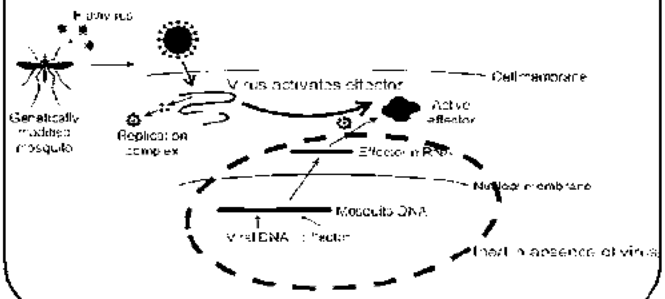
DARPA

Additional Program Accomplishments

The Pirbright Institute

Pirbright

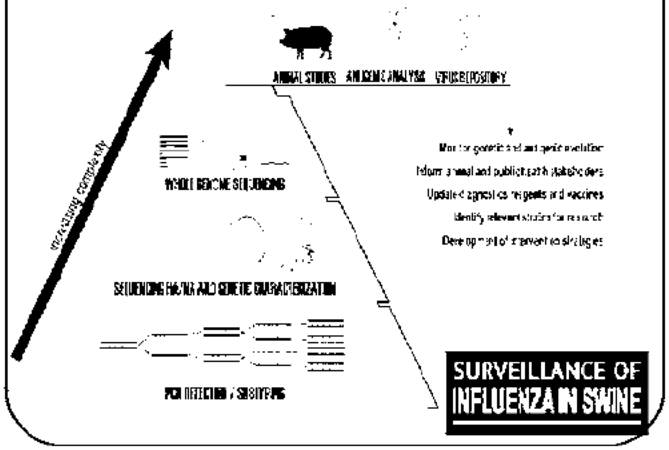
- Developed novel broad-spectrum, virus-resistant mosquito vectors.
- Protease—Cre/loxP design: virus-responsive (VR) effector induces mosquito death upon Flavivirus infection.



Iowa State University

STATE
USDA

- Identified N1 evolutionary diversification and preferential HA/NA pairings.
- Developed machine learning tools for prediction of antigenic drift in H3 influenza A viruses in swine.



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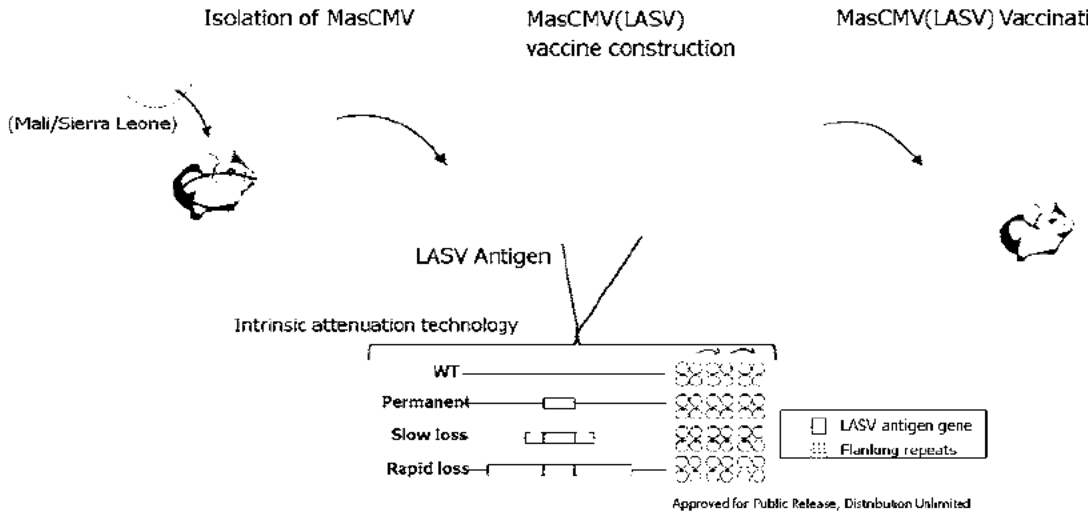
www.darpa.mil

[redacted] [redacted]

Released by Chairman Rand Paul

UCD TA2: Transmissible Vaccine for Lassa Virus

- Generated a scalable, species-specific cytomegalovirus (CMV)-based transmissible vaccine for Lassa virus (LASV) with internal off switch



Potential Vaccine Deployment Regions – UCD Sierra Leonne, Guinea and other countries in West Africa