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SHARK TANK: NEW TESTS FOR COVID–19

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING NEW TESTS FOR COVID-19

MAY 7, 2020

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 7, 2020

SHARK TANK: NEW TESTS FOR COVID–19

Thursday, May 7, 2020

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m., in room SD–106, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

Present: Senators Alexander [presiding], Enzi, Collins, Cassidy, Roberts, Murkowski, Scott, Romney, Braun, Murray, Casey, Baldwin, Murphy, Warren, Kaine, Hassan, Jones, and Rosen.

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. The hearing of the Health, Education, Labor, and Pensions Committee will please come to order. As we begin our hearing, I would like to explain a few of the changes that we have made to address the health and safety recommendations made by the Attending Physician and the Sergeant at Arms after they consulted with the Department of Health and Human Services and the Center for Disease Control and Prevention.

First, as you can see if you are watching, seating has been spaced so that we are 6 feet apart. Second, we have made it possible for Senators and witnesses to participate via videoconference if they choose to do so and several have. Third, to maintain social distancing we have very limited seating so we don't have room for members of the public to attend.

However, this hearing is available to watch live online and the recording will be available on the Committee's website, which is *www.help.senate.gov*. It is important to be clear that the hearing will be shown from gavel-to-gavel in its entirety, unedited by anyone from the moment we start until the very end when we stop.

Fourth, due to the limited seating, representatives from the press are working as a pool to relay their observations to their colleagues, and Senators and staff present have been reminded about the safety guidelines put in place by the Attending Physician. We all wore our masks. I am not going to wear mine during the hearing since we are 6 feet apart but Senators may do whatever they choose to do. I would like to thank the Senate Rules Committee, the Sergeant at Arms, the press gallery, the Architect of the Capitol, the Capitol Police, and our non-partisan Committee staff, Chung Shek and Evan Griffis, for all of their hard work to help keep all of us safe as we conduct these important hearings.

In April, the owners of a senior living facility gave a COVID–19 diagnostics test to 2,500 employees and residents, that is 26 communities in Tennessee and Kentucky. According to the owner Gary Keckley, there were "very few who tested positive of the 2,500." Those who tested positive were all without symptoms and they were all put in quarantine. This is what Mr. Keckley told the Tennessean newspaper, "Because of the fear, we decided the only way to make sure residents didn't have the virus was to test them. There is no substitute for testing everybody," Mr. Keckley said.

All roads back to work and back to school lead through testing. Our country will soon be doing 2 million diagnostic tests for COVID–19 a week, an impressive number. But to contain the disease and give Americans confidence that it is safe to go back to work or go back to school, we will need tens of millions of tests, many more than our current technologies can produce. Testing is necessary first to identify the small number of us who have the disease or have been exposed to it so those Americans can be quarantined, so we don't have to quarantine the whole country. And testing is important secondly because it will help Americans who are traumatized by the daily reports of the virus, it will help us gain confidence that will be necessary to go back to work and back to school.

This hearing is about how we will find those new technologies that are needed to rapidly produce tens of millions of tests in one of the most ambitious scientific enterprises in recent memory headed by one of our country's most distinguished scientists. Looking ahead, I want to mention two important oversight activities for this Committee.

Number one, next Tuesday our hearing will examine how we are dealing with this pandemic, COVID–19. Our witnesses will be Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease at the National Institutes of Health, Dr. Robert Redfield, Director of the Center for Disease Control and Prevention, Dr. Brett Giroir, Assistant Secretary for Health at the U.S. Department of Health and Human Services, and Dr. Stephen Hahn, Commissioner of the Food and Drug Administration.

The second oversight activity I would like to mention is that during the next few months, our Committee will examine what our country needs to do to prepare for the next pandemic, which will surely come. I believe that Congress should put in place the structures and the funding to be ready for that next pandemic during this year while the current crisis is still on our mind. Over the last 20 years, the last three presidents and several Congresses, including after 9/11, bird flu, Katrina, SARS, and Ebola, have passed seven major laws that created the national stockpile and assistant secretary for preparedness, provided incentives for development and manufacturing for diagnostics, treatments and vaccines, strengthen the Centers for Disease Control, and for the last time five years, thanks to the leadership of Senator Blunt and Senator Murray as well as others, have provided record funding for the National Institutes of Health.

We will talk about the importance of preparing for the next pandemic at our hearing next Tuesday as well. As a result of all of that effort by three Presidents and several Congresses over the last

20 years, the New York Times reported on March the 1st on its front page the following, "Most experts agree, the United States is among the countries best prepared to prevent or manage such an epidemic," but I think we would all agree that we would like to have been even better prepared for COVID–19. And it is everybody's responsibility to make sure that we are even better prepared for the next infectious disease.

I want to place in the record a remarkable speech by former Senate Majority Leader Bill Frist delivered in 2005 who saw very clearly then the problems we still have to deal with today. On April 13, the American Mind published Senator Frist's essay, "A Storm for Which We Were Unprepared," which I would also include in the record. The end of this crisis will be determined by three things, tests, treatments, and vaccines. There is promising news that we are likely to hear today from our witnesses that treatments and therapies will be available this summer.

The Administration's warp speed pursuit of a vaccine has a goal of 100 million doses by the fall and 300 million doses by January, a target that is much more ambitious than ever has been achieved before. And the private sector is demonstrating a capacity to turn out quickly tens of millions of serology tests. These are the tests that determine whether you have had the disease and have antibodies that might create some immunity, at least for a time, although that has not been proven yet.

The FDA this week is taking aggressive steps to make sure serology tests are accurate. After a bumpy start caused mainly by a faulty test developed by CDC, the United States is now conducting over 1 million diagnostic tests weekly. By mid-June, there will be 2 to 2.5 million available weekly according to Dr. Deborah Birx, Coordinator of the Coronavirus Task Force. And as of yesterday, according to President Trump and John Hopkins University, the United States has conducted over 7 million diagnostic tests. On May 1, The Wall Street Journal described the testing situation this way, "The Food and Drug Administration has now approved 70 coronavirus tests, about four times more than it approved for the H1N1 flu virus in 2009.

More tests per capita have been performed in New York City than in Singapore, South Korea, and Australia. Hospitals and labs have performed about 1.6 million tests in the past week, according to the COVID Tracking Project. Governor Andrew Cuomo last week said tests would be available at some 5,000 pharmacies across New York State. Abbott Lab says it has shipped 1 million tests for its 18,000 portable machines in the field that can return results in 5 minutes and is manufacturing 50,000 kits a day. U.S. hospitals have more than 5,000 Cepheid fast testing machines, which require no special training.

Some 93 percent of the U.S. population lives within 10 miles of a test site, according to the Wall Street Journal. "As testing has expanded," the Journal said, the choke point now is a shortage of no swabs and chemical reagents to process specimens, but those shortages are easing thanks to FDA flexibility and the resourcefullness of private industry. The FDA is allowing polyester swabs so that swab manufacturers can prioritize coronavirus tests." That is the end of the Wall Street Journal summary. The

Coronavirus Task Force reports that states have submitted their goals for testing for May and the administration is working to help supply media and swabs that states are not able to obtain on the commercial market so that states can meet those goals.

All that is very impressive but not nearly enough to test every nursing home, every prison, everyone in an operating room, and some entire classes and campuses and factories, teams at sports events. And to give those tests more than once, we will need millions more tests than we are producing today. This demand will only grow as the country goes back to work and some 100,000 public schools and more than 5,000 colleges plan to reopen this August. There are two ways to increase our testing capacity. Of course the first is to squeeze every possible test out of our current technologies, and the second which is to focus our—our focus today is on the need for new testing technology.

Throughout March and April, Senator Blunt, the chairman of the Senate Appropriations Subcommittee on Health, and I had many conversations with experts across the Government and the private sector. We couldn't find anyone who believed that current technology could produce the tens of millions of test necessary to put this virus behind us. So we worked to include in the most recent coronavirus legislation $1.5 billion for what we called a competitive Shark Tank. This is described, the name was described after the reality television show that pits entrepreneurs in a competition to see who can succeed.

This Shark Tank at the National Institutes of Health would utilize the capacities of Government itself, in coordination with the private sector, to pull out all the stops and fast-track new technologies designed to produce tens of millions of tests by August, or at least millions more tests by August, and even millions more than that by the flu season. We allocated another $1 billion to BARDA, the Biomedical Advanced Research and Development Authority, to work with the National Institutes of Health to accelerate production of those tests.

Talking with scientists across the country, there are many ideas, some utilize CRISPR, the gene editing technology. At least one allows you to use your cell phone to photograph your test swab result and send it to your doctor. Several may incorporate wearable technology. There is a lot of talk about antigen tests. The NIH, only five days after the funding was signed into law, announced the official start of its Shark Tank program to boost the most promising testing technologies. There were 400 requests for applications in the first 24 hours as of May the 5th, and I am sure Dr. Collins will update us on this, there were 850 expressions of interest and 50 applications have been submitted in review.

Many of these early stage concepts won't work or they won't be able to be scaled up quickly enough, but that is okay. Thomas Edison said that he tried 10,000 times, made 10,000 mistakes, before he produced the first incandescent light bulb. We hope we don't have that many failures, but all we need are two or three successes, or even one from this Shark Tank. The first place to find these technologies is at the National Institutes of Health. Dr. Francis Collins who leads the NIH, who once led the effort to map

the human genome, is here today to talk about the $1.5 billion Shark Tank program.

The second place is BARDA, a Division of the Department of Health. It has been working across Government and the private sector to invest in multiple innovative ideas to achieve accurate, fast, and easy testing capabilities to help build new capacity. Dr. Gary Disbrow, the Acting Director of BARDA is here to talk especially about BARDA's role in scaling up whatever new innovative test Dr. Collins finds. BARDA has another $1 billion for that purpose, bringing it to $2.5 billion the total effort for this acceleration of diagnostic tests. Nearly 80 years ago, in 1942, President Franklin D. Roosevelt invited Senator Kenneth D. McKellar of Tennessee, the chairman of the Senate Appropriations Committee, down to the White House for a private talk.

"Senator McKellar', President Roosevelt said, 'I would like for you to hide $2 billion in the Appropriations bill to create a project to win the war." Senator McKellar said, "Mr. President, that should be no problem, I just have one question, where in Tennessee will the project be built?" Well, that was Oak Ridge, Tennessee. That $2 billion funded the Manhattan Project that in record time produced two nuclear devices that won World War II. That effort assembled perhaps the greatest number of distinguished scientists working on one project in history.

Dr. Collins' Shark Tank is at least a mini Manhattan Project. It doesn't have to be in Tennessee but Tennesseans at the Oak Ridge National Laboratory will be helping it succeed with their supercomputers and their other assets. $2.5 billion does not go as far today as $2 billion did in 1942 but it is still a lot of money. And it is likely that at this moment, more scientists are working to create solutions to COVID–19 than on any other project in the world.

Their success in delivering new technologies to create simple diagnostic tests with quick results, and then safe and effective treatments and vaccines, is the only way this will end. There is no safe path forward to combat the novel coronavirus without adequate testing. Let us hope that out of Dr. Collins' Shark Tank will emerge at least one mighty great white shark that will help us combat this disease.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Chairman Alexander. Good to be here today with you. And I also want to thank our Committee staff who helped us set up this technology to make this hearing possible. And of course, thank you to our witnesses for being here today as well. Our Committee's last hearing on COVID–19 was March 3rd, and during that hearing I expressed my intense frustration at the administration's lack of preparedness, its failure to ramp up testing, the White House's constant contradictions of public health experts guidance and more. Now we are more than 60 days later.

I wish I could say I had better things to say about the administration's response but I do not. The only difference is that now over 800 people in my home state have died, nationwide now more than 73,000 are dead, and tens of millions are unemployed. Meanwhile,

the President is still denying the severity of this crisis, he is still insisting it is not his problem, and he is increasingly attempting to control and silence those who want the truth to be told. The President is afraid of the truth because here it is, he failed and continues to fail to protect lives and our economy and our way of life. And that brings me to our witnesses today.

I appreciate you being here and I expect you to tell the truth today. I will want to know your honest assessment of where we stand on testing capacity and whether we are preparing appropriately to have a safe, effective vaccine as soon as possible. I will want to understand how you are planning to prioritize public health over political influence and corporate profits, and I will want your commitment that you will protect workers at HHS who will speak out when they see that public health is not being put first.

Dr. Disbrow, you are here instead of Dr. Rick Bright who filed a complaint earlier this week detailing a shocking culture of corruption that prioritized cronyism over public health, including at an agency critical to vaccine development and distribution. You can expect a question from me on that and I expect the truth from you. And while I appreciate the interest in this "Shark Tank" initiative to develop new tests, we have to remember that the fight against this virus is reality—it is not reality television. It has to be led by scientists and it has to prioritize public health, not profits, not politics.

While innovation plays an important role in the development of vaccines and treatments and tests, there is no silver bullet. In fact, we have already innovated faster high throughput tests, at home collection tests, and point-of-care tests, and critically there is much more in the pipeline. The problem is not lack of innovation, it is lack of national leadership and a plan from this White House. You can innovate the fastest car in the world. It still won't get you to where you are going without a good driver and good directions. And when it comes to testing, this administration has had no map and no one at the wheel.

There is a reason they say failing to plan is planning to fail and it absolutely applies here because the fastest, most innovative test is not much use if we don't know how many tests we need, if we don't have a supply chain with capacity to manufacture all the tests and supplies that we need, and if we don't have the workforce and lab capacity to actually use those tests and supplies.

Even if we had enough tests and supplies and labs and workers, they can't have the necessary impact if they aren't distributed widely across the country, if they don't reach essential workers, and underserved communities, and tribes, people with disabilities, homebound seniors, communities of color, and high risk populations if test don't become available to asymptomatic people or if we don't enforce current law that requires free testing for everyone. And even addressing these issues won't be enough without plans to use testing results as effectively as possible to fight coronavirus like rapidly recruiting training and sustaining the workforce we need for public health efforts like contact tracing, and quarantine, and isolation, and using data to surveil and track this disease within our communities while protecting privacy.

Now, I was pleased the administration finally told Washington State last week it would be sending all states a significant number of supplies to help expand testing capacity. However, even if they finally deliver the supplies we have been asking for months, that is still not a plan, it is a piece of the puzzle. As long as the administration refuses to look at this full picture and develop a detailed, national plan to rapidly ramp up testing, we are not going to make the progress we need to get people safely back to school, back to work, and to some sense of normal life on a national scale because our experts won't have the visibility into transmission they need to ensure public health drives our efforts to reopen.

That is exactly why I fought to secure language in the latest COVID–19 package that Congress passed that requires the administration to submit a strategic testing plan no later than May 24th. I am going to be watching closely to make sure their plan addresses all of the questions we desperately need answered. And I am going to be pushing for more resources to build and sustain the testing efforts that we need, support contact tracing and other public health efforts, and to plan for vaccine production and distribution so that as soon as we have an effective vaccine, we can scale it up quickly and make it available and free for everyone.

While the $25 billion we passed for testing recently was a good start, it is going to take a lot more to get this job done. Yes, it will take innovation, but it will also take some semblance of leadership from the President because no matter how innovative our tests are, we cannot reopen our country safely until they are fast, free, and everywhere.

No matter how hard frontline workers and Governors and families work to do their part, we still need the Federal Government and its President to step up and finally do its part. Thank you, Mr. Chairman. It is great to be with you this morning.

The CHAIRMAN. Let me make sure my microphone is on. I am pleased to welcome our two witnesses. I want to give them a full introduction, and after they give us their statements, we will proceed back and forth from the parties in seniority. So technologically that is the way it is recommended that we do it.

We are very fortunate to have these two witnesses today on the subject of how do we create new technologies for diagnostic testing so that we can have millions more tests to help us go back to work and back to school and to contain the disease. Our first witness is Dr. Francis Collins. I have asked him to take up to 10 minutes for his opening remarks. He is the director of the National Institutes of Health and we are fortunate to have him in this position at this time. He oversees the work of the largest public funder of biomedical research in the world. He is a physician geneticist by training.

Prior to becoming the NIH Director 11 years ago in 2009, he served as Director of the agency's National Human Genome Research Institute from 1993 to 2008, during which he led the International Human Genome Project. He is an elected member of the National Academy of Medicine and the National Academy of Sciences, was awarded the Presidential Medal of Freedom in 2007, and received the National Medal of Science in 2009.

We are looking for a distinguished scientist to head this accelerated program. I think we are lucky to have one. He is a graduate of the University of Virginia, received a Ph.D. from Yale, his M.D. from the University of North Carolina School of Medicine, and he plays the guitar very well. Next we will hear from Dr. Gary Disbrow. He is broadly experienced as well. I have asked him to summarize his written testimony in 5 minutes. He serves as Acting Director of BARDA, the Biomedical Advanced Research and Development Authority. He is responsible for making sure BARDA is focused on the innovation, advanced research development, and procurement of medical countermeasures, such as diagnostic test subject today, critical to preventing and combating COVID–19 and other health threats we may face.

Dr. Disbrow has been at BARDA for more than 10 years. He joined in 2007. He began working on the smallpox vaccine program. Since then, he served as Deputy Assistant for Preparedness and Response, and Director of Medical Countermeasures at the U.S. Department of Health and Human Services. In 2014 and 2015, he was named Ebola Incident Coordinator for BARDA and played a key role in efforts that led to the first licensed Ebola vaccine.

Prior to joining BARDA, Dr. Disbrow was Assistant Professor of Oncology and Pathology at Georgetown University Medical Center where he focused on vaccines and therapeutics. He received his undergraduate from the University of Rochester and a Ph.D. from Georgetown. Welcome again to our witnesses. We will begin with you, Dr. Collins. Welcome.

STATEMENT OF FRANCIS COLLINS, M.D., PH.D., DIRECTOR, NATIONAL, INSTITUTES OF HEALTH, BETHESDA, MD

Dr. COLLINS. Well, thank you very much. Good morning, Chairman Alexander, Ranking Member Murray, and distinguished Members of this Committee both here in the room and joining virtually at this unusual time. I am glad to be here with my colleague Gary Disbrow from BARDA who has also just been introduced.

I want to thank you Senators for your sustained commitment to the National Institutes of Health, which has enabled us to be at the forefront of action in this time of a national public health crisis. I am grateful to have this opportunity to address how we at the NIH and our scientists across the country are harnessing innovation to diagnose, treat, and prevent the novel coronavirus. Can you hear me alright?

The CHAIRMAN. You are muffled either because of your mask or because of the microphone. I am not sure which it is.

Dr. COLLINS. Well, we are going to do an experiment here. I don't know if this is randomized but it is at least a comparison test——

The CHAIRMAN. You are still pretty—you are still pretty muffled. We did get advice from the Attending Physician of the Senate that it was appropriate for us not to wear our masks if we chose to when we were six feet apart and arranged this way.

Dr. COLLINS. Well, I see I am at a safe six-foot distance from everybody and I do want you to be able to hear the testimony so I will follow that direction. NIH has taken an all-hands-on-deck ap-

proach to bringing the best and the most innovative science to diagnosis, to treatment, and to prevention.

If I could have the slide up that I would like to be showing, that would be great, thank you. When the genetic sequence of SARS-COVID–2, the virus that causes COVID–19, was first released on January 10——

The CHAIRMAN. Dr. Collins, let me ask you to wait just a minute and let technicians try to work on your microphone.

Dr. COLLINS. Yes, we are having a little bit of a staticky thing, I think.

The CHAIRMAN. You are our principal witness so we want to hear what you have to say.

Dr. COLLINS. I am staticky enough without help. Maybe the other microphone was actually better. Now that I have the mask off, can we try that again?

The CHAIRMAN. Sure. We will take just a moment for a technical adjustment and see if that makes a difference. Yes, sir. You like my mask? Well, it didn't work for other things. I thought it might work for this.

[Laughter.]

Dr. COLLINS. How is this one?

The CHAIRMAN. That is a lot better——

Dr. COLLINS. Sounding better? No staticky thing? Okay. Thank you for your patience. Well, when the genetic sequence of SARS-COVID–2, the virus that causes COVID–19 was first released just on January 10th of this year, NIH worked quickly to identify possible therapeutic agents and to begin developing a fast-track vaccine. Within a month, the National Institute of Allergy and Infectious Diseases, NIAID, had launched a clinical trial on the Gilead drug remdesivir at sites across the Nation, as well as internationally, and that trial reported, as you heard, preliminary results just last week showing that patients that received remdesivir had a 31 percent faster time to recovery than those who received a placebo.

While this is not a home run, it does represent a landmark, the first rigorous demonstration of efficacy of a treatment for COVID–19. And on March 16th, just 63 days after receiving the viral genome sequence, NIAID completed all pre-clinical evaluation of a vaccine candidate and the first human patient was dosed in a phase 1 trial. That trial, I am happy to tell you, is going really well and I am excited to see how the timetable for full phase 3 testing of this vaccine and several other candidates has been advancing.

As more information has poured in from scientists and patients all over the world, we have been sifting and sorting, looking for the best ideas, funding everything from basic biology to clinical trials, while closely watching private sector efforts and seeking ways to collaborate. And it has been apparent that the biomedical research world has fully charged up to tackle the COVID–19 challenge. And that expression of American creativity also applied to the development of new and more powerful and accessible approaches to diagnostic testing, and that is the main topic of our hearing and I will come to that shortly.

But first if you will permit me, I wanted to share just a bit more about progress on therapeutics and vaccines for COVID–19. On April 17th, NIH announced the start of an unprecedented partner-

ship that now includes 18 pharmaceutical companies, multiple academic experts, the FDA, the CDC, BARDA, the European Medicines Agency, the Department of Veterans Affairs, and the Department of Defense. This partnership, which I am happy to co-chair with Paul Stoffels of Johnson & Johnson is called ACTIV, Accelerating COVID–19 Therapeutic Interventions and Vaccines.

You may be able to see on the slide the incredible selection of organizations across all sectors that have come together to speed up progress. To conduct its work, ACTIV has developed an executive committee made up of senior leaders from industry, NIH, and FDA, and four working groups, each working group is co-chaired by a senior scientist from industry and one from NIH. As just one example, that clinical therapeutics working group has been conducting a rigorous scientific review of approximately 170 therapeutic candidates already proposed, seeking to prioritize those that are of the greatest urgency to get into clinical trials. We can't do 170 clinical trials.

We want to be sure we used the resources for those that have the greatest promise. Another active working group is hard at work to make sure that the maximum clinical trials capacity is assembled and used for this purpose in order to test those highest priority candidates and standardized the evaluation methods to speed FDA review. We have never done it like this before to have this kind of coordinated approach across sectors to identify the highest priority candidates and figure out how to get them into trials efficiently and quickly.

I have to say a word about our industry partners here. Within two weeks, they embraced this partnership. They made unprecedented commitments. They agreed to abide by a prioritization of candidates no matter who owns the drugs, and even indicated their willingness to contribute their own clinical trial capacity irrespective of whether the drug being tested was one of their own. That is a partnership in the truest sense of the word, but there is more. The most recent endeavor of our COVID–19 effort spurred in part by you the Congress and representing the main topic for today's hearing is our diagnostic innovation initiative and I want to turn to that.

First, the National Cancer Institute is using their expertise in virology immunology and lab medicine, and supported by funding from this Congress, to evaluate and improve serology testing. Serology testing is based on the idea that we can look through your immune system's playbook to see whether your body has produced antibodies that respond to this virus. Such a serology test has the potential to tell generally how widespread a disease has been but it is critical that such a test be validated to make sure it is sufficiently sensitive and specific. You don't want a test out there that is giving wrong information. The tests are getting better and better.

At the moment we still do not know for sure, however, whether someone with a prior infection with SARS-COVID–2 and who is antibody positive is completely resistant to reinfection, and if so, how long such immunity will last. The answer to those questions are being intensively studied. Once that information is in hand, we will be in a better position to advise people about the meaning of

a positive antibody test. Second and most directly relevant for this hearing, NIH launched a COVID–19 initiative called Rapid Acceleration of Diagnostics or RADx just last week. As you heard from the Chairman, most current testing for the virus depends on detection of the viral RNA genome using the polymerase chain reaction or PCR.

A PCR test takes a small code of DNA or RNA, amplifies it millions of times over so that it can be detected, but that amplification process is time-consuming, requires a thermal cycling machine available only in laboratory settings in general, and needs personnel who know how to run the test and how to troubleshoot problems. This program, RADx, supported by the funding from the Congress, seeks to expand the range of diagnostic technologies to include a whole bunch of novel approaches that can rapidly expand access to testing.

RADx is engaging scientists across the country from the basement to the boardroom in an effort to improve current tests and advance completely new technologies. As America moves back into public spaces but seeks to avoid increased infections with COVID–19, tests have to be more accessible ideally to people at the point of care to make it easier for everyone to get tested. We need tests that don't require hours or days to determine results. The new types of tests need to be sensitive enough to flag asymptomatic individuals who may have just become infected and don't even know it yet. They must be reliable and have a user-friendly design. They must utilize various types of samples including saliva. And ideally, they should be able to integrate with mobile devices to process and show results and transmit data seamlessly.

Above all, they need to be accessible to everyone. So, how should we inspire this outpouring of new technologies? How can we unleash the legendary American ingenuity at this time of great public urgency? How will we provide the resources to accelerate development, scale up, and deployment of new and powerful testing platforms? Our approach, which Senators Alexander and Blunt recently compared to a Shark Tank, is diagrammed on this slide. You can see a bunch of light bulbs. Your comment from Thomas Edison seems relevant here. Light bulbs that maybe have promise or maybe they need some work. Well, this is what is going to be happening with this RADx initiative. It occurs in three phases.

First of all, there is a call for innovative technologies that went out last week on April 28. Phase 0, though, requires a review to be done of what the responses were to that call to be sure that they fit this model. Phase 0 is then a rapid evaluation of the technology over the course of only about a week by clinical technical business, regulatory, and manufacturing experts. Expert review boards covering scientific, clinical, regulatory, and business domains are going to rapidly evaluate these proposals, looking for the gems that provide real promise for COVID–19. Those promising early stage technologies will initially move into phase 1 where we will make a modest award of funds while simultaneously supporting that inventor or company with technical and clinical experts to address any scientific or business weaknesses identified in the review.

Already well developed technologies can actually go directly to phase 2. We don't want to hold anybody back and it is possible that

some of these arrivals in the Shark Tank are already big enough fish that they are ready to move on and we will support that as well, providing scale up for tests for validation. We have to know it works, meeting regulatory requirements, supporting manufacture and distribution, working closely with our colleagues at BARDA.

In that regard, we are interested in reproaches that can substantially increase throughput and accessibility of laboratory based tests even though the ultimate goal of RADx is to develop and deploy point-of-care tests. So to tell you the update, as you heard, the RADx solicitation was just announced last week. This is day eight since that came out. We are allowing submissions of proposals on a rolling basis. I got to say I am delighted and somewhat astounded that as of noon yesterday, there were 1,087 applications initiated, 79 of those already complete. They had to provide a lot of details.

In 27 years at NIH, I have honestly never seen anything move this quickly. The expert review team already in place has identified 20 of these completed applications that are ready to move into that first phase of intense scrutiny and the game is on and it is going to be a wild ride. Before I close though, I want to tell you about the third part of our initiative, a major focus on implementation of strategies to enable testing of rural, underserved, and underresourced populations, among the hardest hit by the coronavirus, and often those for which testing has been less available.

This effort which we are calling RADx-UP, as in underrepresented populations, will include the development of a centers program that will allow demonstration projects to be put in place across the country in places where COVID–19 has hit hardest and where testing has thus far been accessible. It will also include a program focused on the ethical, legal, and social issues associated with COVID–19 diagnostic testing and ways to try to avoid the inequities associated with unequal access.

To conclude, the goal of RADx is to help make millions more accurate and easy to use tests per week available to all Americans by the end of summer and even more in time for the flu season. I must tell you Senators that this is a stretch goal that goes well beyond what most experts think will be possible. I have encountered some stunned expressions when describing these goals and this timetable to knowledgeable individuals.

The scientific and logistical challenges are truly daunting, but I remain optimistic because of the track record of American ingenuity and the outpouring that has already happened of great ideas coming into this Shark Tank. So at NIH, we believe that putting the best minds in the world together is the only way to meet the challenge and to bring this virus under control. So I thank you for this opportunity to testify and to lead this initiative, and I look forward to your questions.

[The prepared statement of Dr. Collins follows:]

PREPARED STATEMENT OF FRANCIS COLLINS

Good morning, Chairman Alexander, Ranking Member Murray and distinguished Members of this Committee. It is an honor to appear before you today. I want to thank you for your sustained commitment to the National Institutes of Health (NIH) which has enabled us to be at the forefront of action in this time of a national public health crisis. I am grateful to have this opportunity to address how we at

the NIH and our funded scientists across the country are harnessing innovation to prevent, diagnose, and treat the novel coronavirus currently plaguing our Nation.

When the genetic sequence of SARS-CoV–2, the virus that causes COVID–19 was first released on January 10, 2020, NIH worked quickly to identify possible therapeutic agents and to begin developing a fast-track vaccine. Just one month later, the National Institute of Allergy and Infectious Diseases (NIAID) launched a clinical trial on the Gilead drug remdesivir at sites across the Nation, which reported preliminary results just last week, showing that patients who received remdesivir had a 31 percent faster time to recovery than those who received placebo. This is a landmark—the first rigorous demonstration of efficacy of a treatment for COVID–19.

On March 16th, just 63 days after receiving the viral genome sequence, NIAID completed all pre-clinical evaluation of a vaccine candidate and the first human patient was dosed in a Phase I trial.

As more information has poured in from scientists and patients all over the world, we have been sifting and sorting, looking for the best ideas, and funding everything from basic biology to clinical trials—while closely watching private sector efforts and seeking ways to collaborate. It soon became apparent that the biomedical research world is fully charged up to tackle the COVID–19 challenge, but what was needed was coordination of that vast community.

On April 17th, NIH announced the start of an unprecedented partnership with 16 biopharmaceutical companies, academic experts, and government partners that now include the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research Development Authority (BARDA), the Food and Drug Administration (FDA), the Department of Veterans Affairs (VA), and the Department of Defense (DoD). The partnership is called ACTIV—Accelerating COVID–19 Therapeutic Interventions and Vaccines. That initiative has moved quickly to accelerate progress by conducting a scientific review of the approximately 170 therapeutic compounds and more than 50 vaccine candidates already identified. Another ACTIV Working Group is hard at work to ensure the maximum clinical trials capacity is assembled, in order to test the highest priority candidates and standardize the evaluation methods to help FDA review.

I must say a word about our industry partners here. Within two weeks, they embraced this partnership and made an unprecedented commitment. They agreed to abide by a prioritization of therapeutic candidates, no matter who owns them, and indicated their willingness to contribute their clinical trial capacity irrespective of their potential for profit. It is a partnership in the truest sense of the word.

But there's more. The most recent endeavor of our COVID–19 effort is an initiative called Rapid Acceleration of Diagnostics, or RADx, which NIH launched just last week.

Most current testing for the virus depends on detection of the viral RNA, using a polymerase chain reaction or PCR. A PCR test takes a small code of DNA or RNA and amplifies it millions of times over so that it can be detected. This amplification process is time consuming, requires a thermal cycling machine available only in laboratory settings, and needs personnel who know how to run the test and troubleshoot problems.

RADx seeks to expand the range of diagnostic technologies to include novel approaches that can rapidly expand access to testing. RADx is engaging every scientist from the basement to the boardroom in an effort to improve current tests and advance completely new technologies. As America moves back into public spaces but seeks to avoid increased infections with COVID–19, tests must be accessible, ideally to people at the point of care to make it easier for everyone to get tested. We need tests that do not require hours or days to determine results. The new types of tests need to be sensitive enough to flag asymptomatic individuals who have just become infected but may not know it. They must be reliable and have a user-friendly design, must utilize various types of samples (nasal swabs, saliva, blood, exhaled breath, etc.), and ideally should be able to integrate with mobile devices to process and show results and transmit data seamlessly. Above all, tests need to be accessible to everyone who needs them.

Such tests sound like science fiction but are scientifically possible. One category we will pursue actively is called viral antigen testing. Antigen testing detects a part of the protein capsule of the virus itself and not its genetic code. This doesn't require PCR, and allows for immediate detection if the virus is present in the body. With time and effort, antigen tests can be modified to be done at home which would allow for easier and more frequent testing. They have traditionally been more difficult to develop to a sufficient level of accuracy, but that is where RADx comes in.

The RADx solicitation for applications was just announced last week, and proposals may be submitted on a rolling basis. The RADx technology assessment and potential scale up process will occur in three phases. Phase 0 is a rapid evaluation of the technology by clinical, technical, business, regulatory, and manufacturing experts. Expert review boards covering scientific, clinical, regulatory and business domains will rapidly evaluate technology proposals to find gems with promise for COVID–19.

Promising early stage technologies will initially move to Phase I, where NIH will make a modest award of funds while simultaneously supporting that inventor or company with technical and clinical experts to address any scientific or business weaknesses identified in the review. Already well-developed technologies may go directly to Phase II, where support will be provided for scale-up of tests for validation, meeting regulatory requirements, and support manufacture and distribution. We are also interested in approaches that can substantially increase throughput and accessibility of laboratory-based tests. While the ultimate goal of RADx is to develop and deploy of point-of-care tests, lab-based approaches can also be supported as intermediate solutions.

The goal is to help make millions of accurate and easy-to-use tests per week available to all Americans by the end of summer 2020, and even more in time for the flu season. To be completely honest, this is an ambitious goal. The scientific and logistical challenges are truly daunting. But I remain optimistic because of the track record of American ingenuity. At NIH, we believe that putting the best minds in the world together is the only way to meet the challenge and bring this virus under control.

Thank you again for this opportunity to testify. I look forward to your questions.

The CHAIRMAN. Thank you, Dr. Collins.

Dr. Disbrow, welcome.

STATEMENT OF GARY DISBROW, PH.D., ACTING DIRECTOR, BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY, OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. DISBROW. Thank you. Good morning, Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee. Thank you for the opportunity to testify today. I am Dr. Gary Disbrow, Deputy Assistant Secretary and Acting Director of the Biomedical Advanced Research and Development Authority, or BARDA, within the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services.

The CHAIRMAN. Could you put the slides back up for him, please?

Dr. DISBROW. Today, I want to highlight how BARDA is supporting efforts to develop vaccines, treatments, and diagnostics and response to the COVID–19 pandemic. HHS Secretary Alex Azar declared a public health emergency on January 31st, 2020. At nearly the same time, as per BARDA, established an interagency call with industry highlighting our high-level strategy for the development of vaccines, therapeutics, and diagnostics to address COVID–19, attracting over 1,500 participants.

That same day, BARDA opened a medical countermeasure or MCM portal to accept market research missions from stakeholders, receiving over 2,700 submissions to date. We are working with our interagency partners to quickly prioritize and review all submissions. Prior to receiving supplemental funds, BARDA modified our two solicitations to allow submissions of COVID–19 products. We have received 210 submissions under our Broad Agency Announce-

ment, or BAA, and 310 to our Easy BAA, which is a streamlined solicitation with a cap of $750,000 in funding.

This is what we do, we engage innovative stakeholders, establish partnerships, develop medical countermeasures, and bring them forward to the American people to save lives. Under the response structure, task forces were established to bring together experts from across the U.S. Government to address key challenges and find solutions. One task force is the Medical Countermeasure Task Force as shown on this first slide. The MCM task force includes representation from across the USG and working groups were established to address vaccines, therapeutics, and diagnostics.

BARDA is a key leader in the MCM task force working groups. The goals of the task force are to prioritize and align MCM development and share information across the USG in a transparent manner. BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past examples include H1N1, Ebola, and Zika. BARDA has unique authorities, allowing my organization to leverage and rapidly expand partnerships to push candidates forward to the review, testing, and approval phase. To date, BARDA has leveraged the $3.5 billion provided under the CARES Act COVID–19 supplemental and made investments in multiple vaccine candidates, multiple therapeutic candidates, and important for today's discussion, COVID–19 diagnostic programs.

The second slide shows diagnostic candidates supported by BARDA, CDC, and the Department of Defense. Starting at the top with molecular lab-based or near patient, then molecular point of care, and the last two rows highlight investments in antibody and antigen based tests. On the next slide, it is showing the BARDA specific products with emergency use authorization. To support the need for expanded diagnostic capacity, BARDA has made investments in molecular tests for commercial labs, near patient and point of care test to identify individuals who are infected. The slide shows lab-based and near patient molecular diagnostics on the left and point of care on the right.

The green stars indicate diagnostics that have been granted emergency use authorization or EUA by the Food and Drug Administration, FDA. BARDA has recently only shifted our focus to antigen and serological tests. BARDA is supporting a total of 19 diagnostic products and 8 have been granted EUA by the FDA. BARDA's efforts have helped ensure the availability of diagnostic testing in the U.S., with 2.7 million diagnostic tests shipped in the last seven weeks, and we expect our BARDA funded partners to continue to increase production in the coming weeks.

BARDA is proud to collaborate with NIH on two new efforts. First, we are integrated with the efforts established by Dr. Collins under the accelerated COVID–19 therapeutic interventions of vaccines or the ACTIV partnership. Second, we are collaborating with the rapid acceleration of diagnostics, or the RADx program, run by the National Institute of Biomedical Imaging and Bioengineering. BARDA will provide subject matter expertise as applications are reviewed, potential candidates are identified, and as teams are assembled to shepherd development.

NIH's initiative and BARDA's efforts are complementary, and together, we will make the RADx program a success. BARDA has over 300 industry partners, 13 years of product development experience, and 54 FDA approvals. BARDA's long-standing expertise in accelerating advanced research and development of candidate diagnostics, therapeutics, and vaccines is a testament to our dedicated and experienced team.

This Committee and Congress at large have been very supportive of the BARDA mission, and today more than ever we need your continued support and flexibility to ensure our staff can stay focused on the task at hand. Again, thank you for passing the recent supplemental appropriations that will aid in our overall response efforts.

We could not do our job without your partnership and support. I look forward to discussing how we can continue to work together on this important issue. Thank you.

[The prepared statement of Mr. Disbrow follows:]

PREPARED STATEMENT OF GARY DISBROW

Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee, thank you for the opportunity to testify today on our efforts to develop appropriate and effective medical countermeasures to prevent infection and test and treat those with or suspected of having COVID–19. I am Dr. Gary Disbrow, Deputy Assistant Secretary and Acting Director of the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response at the Department of Health and Human Services (HHS or Department). Today, I will provide a brief overview of the current response structure and then provide detail on BARDA's role in developing countermeasures and diagnostics to aid in the overall response.

As you all know, the Federal Government has been monitoring the spread and threat of the severe acute respiratory syndrome coronavirus, SARS-CoV2, the virus that causes COVID–19—since last December when cases began emerging in the city of Wuhan, Hunan province in China. COVID–19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. Immediately after the virus was detected, various HHS agencies to include the Centers for Disease Control and Prevention (CDC), the Assistant Secretary for Preparedness and Response (ASPR), the National Institute of Allergy and Infectious Diseases (NIAID) along with several other components of the National Institutes of Health, and the Food and Drug Administration (FDA) began coordinating and leveraging tools and resources to respond to COVID–19. Specifically, these agencies began implementing efforts to prevent and slow the spread of the disease, assisting repatriated Americans, protecting the supply of food, drugs, and devices, and developing diagnostics, therapeutics, and vaccines.

ASPR's Role in Response

ASPR's mission is to save lives and protect Americans from 21st century health security threats. During past response operations, ASPR has led, on behalf of HHS, Emergency Support Function #8: Public Health and Medical Services, under the National Response Framework. This means ASPR serves as the primary coordinator for public health information and deployment of assets to support the health components of a response.

For the current COVID–19 pandemic response, ASPR is participating in 14 Task Forces comprised of subject matter experts that are operating under the Federal response structure. ASPR has subject matter experts leading and/or serving on a number of the task force groups, including the Supply Chain Task Force, the Medical Countermeasures Task Force, the Healthcare Resilience Task Force, Laboratory Diagnostics Task Force, and the Data and Analysis Task Force to name a few. The purpose and goal of the various Task Forces is to explore policy issues, identify gaps in capabilities, and identify solutions to aid in the response. The Task Force structure supports streamlined communication across the Federal Government and expedites implementation of identified solutions as and when needed.

The Biomedical Advanced Research and Development Authority's Role in Medical Countermeasure Development

Outside of the current FEMA response structure, ASPR's BARDA continues to support the innovation, advanced research, development, manufacturing capacity improvements, and acquisition of medical countermeasures (MCM) (e.g., vaccines, medicines, diagnostics, and other necessary medical supplies). Since late January, BARDA has been collaborating with counterparts across the government, under the Medical Countermeasure Task Force, to continue to identify potential candidates and accelerate their advanced development.

Even before initial COVID supplemental funds were made available on March 6, 2020, BARDA initiated investments utilizing annual funding to quickly evaluate existing partnerships to determine those that had promising candidates and immediately made investments in vaccines, therapeutics, and diagnostics. Supporting this strategy, ASPR hosted an interagency call with industry on January 30, 2020, to inform external stakeholders of the high level strategy to pursue development of vaccines, therapeutics, and diagnostics. Over 1,500 attendees participated in the call. Shortly after the industry call, BARDA established the MCM Portal for Coronavirus, or Portal. This Portal which is accessible by NIH, CDC, FDA, the Department of Defense (DoD), and BARDA, ensures U.S. Government partners are able to stay current with the rapidly evolving landscape of promising, emerging technologies. Information and proposals from industry are submitted to the portal and then reviewed and prioritized by BARDA and interagency colleagues. After the initial review "CoronaWatch" meetings are scheduled. CoronaWatch is a unique tool that BARDA utilizes to ensure that those technologies that are ranked as highly relevant by interagency partners can be further evaluated and considered for funding across the U.S. Government. During the CoronaWatch meeting, BARDA and interagency experts discuss the specific proposal with the submitter, review data and other supporting information, and provide technical input for future submission for potential funding. As of May 1, 2020, over 2,590 applications have been submitted via the Portal and over 250 CoronaWatch meetings have been held with companies that were ranked at the highest priority level for the interagency, 99 of these for diagnostics.

In addition, BARDA continues to encourage applications to its two primary funding solicitations. To date, there has been 128 submissions under BARDA's Broad Agency Announcement (BAA) and 275 submissions under our Easy BAA (EZ BAA). The EZ BAA was established in 2018 to advance early stage innovative approaches to health security, with the ability to make awards in as few as 12 days.

Leveraging the funds provided in the first COVID–19 supplemental, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116–123), awards have already been made to promising candidates to date. Specifically, BARDA has made investments in three vaccine candidates, 8 therapeutic programs and 19 diagnostic programs. BARDA's COVID–19 portfolio is rapidly expanding, with daily awards and updates. For the most up-to-date information, please visit *https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx*.

BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past successes include the 2009 H1N1 influenza pandemic, Ebola outbreaks in 2014–2016 in West Africa and in 2018 the Democratic Republic of the Congo, as well as Zika in 2015. For these past response operations as well as the current response to COVID–19, Congress has provided emergency supplemental funding to support medical countermeasure development. For the current COVID–19 response, BARDA reviewed investments with Regeneron, Janssen, Sanofi Pasteur, and Genentech, all of which have previously shown success in the successful development of both prophylactic and therapeutic medical countermeasures for emerging infectious diseases. BARDA's leveraging of these existing partnerships and established platforms may help shave months off the development timelines for medical countermeasures and has been made possible because of flexible authorities and prior investment into these platforms.

Beyond medical countermeasure development, BARDA is also supporting efforts to strengthen domestic manufacturing capacity. Several years ago, BARDA established the Centers for Innovation in Advanced Development and Manufacturing (CIADMs). While these CIADMs provided such benefits as training opportunities for current and future industry and government scientists who engage in advanced development and manufacturing of medical countermeasures, there is great potential that they will aid the response to COVID–19 by supporting manufacturing as products are identified. Specifically, Janssen, a Johnson & Johnson company, has identi-

fied a lead candidate using their AdVac system. They have signed a partnering agreement with the BARDA CIADM at Emergent BioSolutions to help manufacture their vaccine.

The focus of today's Hearing is diagnostics. To support the anticipated need for expanded diagnostic capacity, BARDA initially invested in molecular tests to identify individuals who were infected with COVID–19. These tests specifically look for the virus RNA in respiratory samples. In March, BARDA invested in adding SARS-CoV–2 assays to systems that are routinely used in the commercial and clinical diagnostic space to rapidly expand high throughput capacity (Hologic, Luminex, DiaSoran, Cepheid). BARDA also invested in near patient/hospital based molecular diagnostics (Qiagen, GeneMark, Cepheid, Vela, Luminex). Finally, BARDA has supported hand-held and point of care molecular diagnostics (Mesa BioTech, Cue, Cepheid). The latter, point-of-care diagnostics are "sample-to-answer" systems that do not require the separate extraction reagents required by other systems that have been in short supply. BARDA's efforts have helped ensure the availability of diagnostic testing in the Unites States. In the last 6 weeks, 2 million diagnostic tests have been shipped by BARDA-funded test developers for use domestically and we expect our partners to continue to increase production and scale. As the pandemic has progressed, the need to develop antigen or antibody/serological tests is now the emphasis. These types of tests will allow for identification of individuals who were infected and now have antibodies against the virus. BARDA's investments include antibody/serological based tests (DiaSoren, InBios, Nanomix, Hememics) and antigen tests (OraSure, Nanomix, Hememics). BARDA has and will continue to work closely with interagency partners (FDA, CDC, NIH/NIAID, DoD) and with the Laboratory Diagnostics Task Force to help address existing and emerging technical and operational challenges related to COVID–19 diagnostics. BARDA is also currently supporting the Serology Project Team established by HHS to address the research, technical, and operational issues and gaps for utilization of antibody tests.

BARDA is proud to partner with the new NIH effort, Rapid Acceleration of Diagnostics (RADx). BARDA will provide subject matter expertise to review applications, evaluate potential candidates, and support development teams as they are assembled. NIH's initiative and BARDA's efforts are complimentary and will ensure RADx is as successful as possible to expedite development of new countermeasures. As products are developed, BARDA stands ready to aid in the manufacturing as needed, through established partnerships.

Conclusion

Since its inception, BARDA has entered over 300 industry partnerships, attained 13 years of clinical product development experience, and helped partners achieve 54 FDA approvals. BARDA's long standing expertise of accelerating the advanced research and development of candidate diagnostics, therapeutics, and vaccines through to FDA approvals, clearances, licensures and Emergency Use Authorizations, is unmatched across the government and underscores the overall capabilities that we have brought to bear on COVID–19.

Thank you for passing the recent supplemental appropriations that will aid our overall response efforts. We could not do our job without your partnership and support.

Thank you for your time and I look forward to discussing how we can continue to work together on this important issue.

The CHAIRMAN. Thank you, Dr. Disbrow. We will now go to 5 minute round of questions. We will go and seniority order including those Senators who are participating by video. And I will begin. Dr. Collins, you said that you would define the millions, tens of millions of tests that we need, diagnostic tests—first thing you are going to do is squeeze every test out of existing technology, but am I correct that existing technology won't produce that number of tests so we need a new technology?

Dr. COLLINS. I think it is both and, not either, or. I do think existing technologies have the potential for further scaling up and we are very interested in seeing that happen. And BARDA is also very

much in that space and we will work closely together on that, but most of the existing technologies are done in central laboratories.

They are not what you would call point of care and we want to see that feature very heavily emphasized in what we do with the new technologies so that they could be more accessible, give a more rapid turnaround as far as a result of the tests, and be generally distributed to places that currently don't have much access.

It is definitely the case—anything we can do that is going to increase the number of tests available by a factor of 5 or maybe even 10 is very worth what we would want to put into it. But we also believe that it is not just a matter of taking what we have and making it higher throughput, we need new technologies that have these more appropriate features.

The CHAIRMAN. I want to have a question for Dr. Disbrow, but let me ask you one first. Just before I came in here, I got off the phone with the chancellor of the University of Tennessee at Knoxville. They have invited their students to come back in August. Talked to the President of University of Middle Tennessee State University, South of Nashville.

They have done the same. What can you tell university presidents and principles? We have 5,000 colleges. We have 100,000 public schools. They would like to go back to school in August. What can you tell them about the availability of testing in August, including the possibility there may be some of these new tests that would expand the supply dramatically?

Dr. COLLINS. Well that would very much be our goal and you have made the point, I think repeatedly, how critical that is going to be in terms of getting us back into school and not having what would be another second or third wave of coronavirus at that very vulnerable moment when the flu season is starting up as well. What you want to have at that point is the ability in a community to know whether the virus is circulating. So that means being able to do surveillance, finding out whether the virus is around.

If so, then immediately identifying those who are infected and getting them quarantined. And obviously schools and colleges are a critical place to watch over. So having a great expansion in the number of point-of-care tests at that point so that university presidents or chancellors have a chance of knowing what are the risks of bringing people back. That is what we want to contribute to. That is what this project is all about.

The CHAIRMAN. Let me ask you and then Dr. Disbrow, if you will save him some time. Let's talk about scaling up. I am not a scientist and I am not going to pretend to be one but I have so much respect for our scientific community in the United States. I cannot imagine that out of the thousand applications that you have, or expressions of interest that you have received, that there won't come a few new ideas that will permit us the kind of quick, simple, inexpensive, easy to administer tests that will be widely available, and we are talking about tens of millions of tests.

But the question is, how do you manufacture all those? And when you select the survivors of your Shark Tank or your RADx experiment, are you taking into account whether you can scale them up? And then let me ask Dr. Disbrow within my minute and 20 seconds, what will BARDA do working with you to scale up

what you discover is a new technology for producing tens of millions of tests?

Dr. COLLINS. Great question. Very quickly, the review group that is going to be looking at these more than a thousand applications is well populated with people who are experts in business and commercialization and scale up. We are not going to invest in something that looks like it doesn't have that potential.

But then once you have decided it is going to have that potential, you got to get the resources together. These may come from small businesses. Most of the applications are. How do you find a large business partner? How do you provide the resources? BARDA is in a great spot there to assist with that scale up.

The CHAIRMAN. Dr. Disbrow.

Dr. DISBROW. Right. Thank you. So, as Dr. Collins mentioned, we envision this as a seamless transition. So BARDA does have experience, our 300 industry partners that we have, partnering with industry, bringing together engineers. So that as those products are moving through the funnel that you saw, it is a seamless transition and we assist with funding that we would have available to help scale up the manufacturing.

The CHAIRMAN. You will be involved in helping to identify promising technologies based upon their scalability——

Dr. DISBROW. Correct.

The CHAIRMAN. Then you will be coordinating with outside groups to see that the scaling is done so that we can——

Dr. DISBROW. To help partner them, correct.

The CHAIRMAN. That is right.

Senator Murray.

Senator MURRAY. Well, thank you very much, Mr. Chairman, and thank you again to our witnesses. You know, two months after the President claimed everyone who wants a test, gets a tests, we now have well over a million COVID–19 cases. As I said, there is more than 73,000 deaths and no plan to bridge the huge gaps in testing across the country. Instead take states are left to respond with limited Federal support and blind spots on how the disease has spread and fighting with each other for critical supplies.

To address those failures, Congress required the administration to submit a national strategic plan to increase testing by May 24th. On Tuesday, approximately 260,000 tests were performed in the United States. Experts have said we need anywhere from 500,000 tests per day right now to 5 million a day or even more going forward.

To reach those targets, states need more than vague musings from the White House. They actually need numbers and timelines and clear expectations of how the Federal Government intends to get us there.

Dr. Collins, I want to ask you just yes or no, in order for that plan to ensure America's Governors and public health leaders have enough testing to begin safely reopening, should that National strategic plan on testing include specific numeric targets testing capacity, supply chain capacity, and projections of shortages?

Dr. COLLINS. Senator, I am sorry. It is not my sweet spot because of course this is the job of the Coronavirus Task Force and the

CDC. Certainly, I know states are looking for those kinds of specific guidelines, and I totally understand that.

Senator MURRAY. Well, should a plan detail how to best allocate different tests for use in different settings? For example, at a hospital versus a workplace?

Dr. COLLINS. There is certainly scientific reasons why those kinds of decisions ought to be nuanced based on the circumstances. They can be quite different from one environment to the next. So I would hope yes, any plan would have that kind of specific recommendation about particular environments where testing is going to be offered.

Senator MURRAY. Okay. Thank you, doctor. Dr. Disbrow, thank you for testifying here so soon in your tenure in this role. This week, your predecessor, Dr. Bright, filed a complaint with the Office of the Special Counsel, detailing actually an alarming degree of corruption and incompetence among political leadership across HHS and the Trump administration. We learned from Dr. Bright yet again that the White House has largely ignored warnings about COVID–19, failed to take steps to adequately secure supplies of PPE, and otherwise prepare a response.

The White House failed to secure supplies for testing, they pushed untested and unproven drugs against the advice of experts, and political leaders put career public health officials in terrible positions where they had to decide between doing what they have been told versus doing what is right with people's lives on the line. Dr. Collins and Dr. Disbrow, I expect you to cooperate fully with any investigation into Dr. Bright's complaint and I am going to continue to look into these allegations.

There are so many workers across the Federal Government that are trying to do the right thing to help us get increased testing and generate a plan to develop and distribute a vaccine, putting science ahead of politics and refusing to put the public health at risk.

To those of you who are doing that who are watching, thank you. Dr. Disbrow and Dr. Collins, can you commit to me today, without reservation, that you will always prioritize the public health and never give in to pressure to do political favors and that you will speak out against corruption and incompetence and misconduct when you see it?

Dr. COLLINS. Yes.

Dr. DISBROW. Yes.

Senator MURRAY. Thank you. And I appreciate that. And do you both commit to doing everything in your power to protect HHS employees from political interference and doing their jobs, and especially to protect those who speak out to make sure public health efforts are guided by science and not personal profit or politics?

Dr. COLLINS. Yes.

Dr. DISBROW. Yes.

Senator MURRAY. Do either of you have any reason to doubt that Dr. Bright faced the political pressure that he described in this complaint?

Dr. COLLINS. It is Dr. Collins. I have to say I just don't have any personal primary information so I am only going by the things that I have read. It is not a circumstance that I can form my own opinion because I don't have the facts as a sort of personal experience.

Dr. DISBROW. Right. This is Gary Disbrow. So, now that this is a personnel matter being handled by the Office of Special Counsel, I can't really comment.

Senator MURRAY. Okay. Well, do you both commit to being transparent with Congress and the public regarding any partnerships your agencies engage in throughout this COVID–19 response, including regarding what guardrails are in place to make sure Government resources are devoted to the products most promising to public health and not those that will drive profits for politically connected companies?

Dr. COLLINS. Yes.

Dr. DISBROW. Yes.

Senator MURRAY. Did I hear yes from both of you?

Dr. DISBROW. Yes, you did.

Senator MURRAY. Alright. Thank you. I just have a few seconds left and I hope to ask a few more questions in the next round if that is possible, Mr. Chairman.

The CHAIRMAN. Sure. Thanks, Senator Murray. Good to see you even if at a distance.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman, and thank you, Senator Murray, for this hearing. I want to thank the witnesses for all of the information that they provided. It is very helpful.

This is a critical thing for our Nation and I hope this doesn't turn into a hearing about Trump. I noticed that the vaping one that was surprisingly turned into that but getting to my questions, the administration has announced a number of public, private partnerships are geared to bring the Federal agencies and private industry together to develop medical countermeasures.

The NIH is at the helm of most of these efforts. How is the agency's role different in the RADx and ACTIV partnership and Operation Warp Speed? Dr. Collins.

Dr. COLLINS. Yes, we are very much a fan of partnerships to get science to happen. When I had the privilege of leading the Human Genome Project, I learned how much can be gained by bringing groups together that have different skills and talents and not worrying too much about who is going to get the credit, just get the job done. More recently, I have had the privilege of leading several of these public-private partnerships focused on trying to develop the next generation of therapeutics for diabetes, for Alzheimer's disease, for rheumatoid arthritis and lupus, for Parkinson's disease, for cancer, and those have turned out to be enormously productive by bringing the best and brightest scientists around the same table to design the work, hold themselves accountable, and make sure all the data is accessible to everybody.

When the COVID–19 crisis came along. It was clear that we might benefit from that same kind of model. And by talking to my colleagues in all sectors, we did decide that this was worth a try. On April the 3d, which is just 34 days ago, convened senior leadership of pharmaceutical companies, of FDA, CDC, BARDA, and the NIH, and the European Medical Medicines Agency, came up with a series of things that we thought could be done better as a partnership than either of the sectors or either the companies or institutions could do on their own. And that is what ACTIV has become.

I must say, it has been astounding to see the way in which people have rolled up their sleeves and plunged in to this effort to advance therapeutics and vaccines for COVID–19. Some of those previous partnerships I mentioned took a couple years to sort of work out the details and finally get everybody sitting down at the same table. This took two weeks. And on April 17th, we announced the launch of this enterprise, and it has been 24/7 for these working groups that are trying to knock down the barriers that might otherwise get in the way.

The RADx effort is not the same kind of partnership. I might call it more of a bottom-up kind of partnership in the sense that the talent and the innovation and the creative ideas about new testing platforms is largely coming from small businesses. And so they become our partners because they are feeding these ideas into the Shark Tank.

Of those 1,087 that I told you that we have already received as far as responses to the solicitation, two-thirds of those are from small businesses. There is also a wonderful input from academics and a few middle sized businesses as well. That is just the kind of thing you would like to see for this kind of a partnership which is going to be intensely competitive.

Yes, I guess in my time at NIH, 27 years now, I learned over and over again, if you want to get something done, find all of the potential contributors who have skills, talents, energy, motivation, and resources, and let's do it together, and that is certainly what we have to do at a time like this with this global pandemic all around us.

Senator ENZI. Thank you. I now have a question of—it is kind of a who is in charge question. We are having to scramble to catch up and that means conducting the early stage of research at the same time that we are trying to move products through the advanced development stages.

Public health emergency MC mission statement identifies the National Institute of Health taking the lead role in the early research and BARDA as taking the lead role in advanced development and manufacturing. Do NIH or BARDA have primary authority for advanced manufacturing support or scale up?

Dr. COLLINS. I think this is what we are talking about at this hearing, the handoff that we are making sure happens in this space. We are really good at getting those early ideas started, figuring out how technologically they can be advanced. But when they get to the point of being ready for a real commercialization scale up, BARDA steps in with all their skills. Gary, you may want to say more about how that works.

Dr. DISBROW. Yes. I appreciate that, Francis. So this is not the first partnership between NIH and BARDA. We have partnered over the past decade or more with the National Institutes of Allergy and Infectious Diseases transitioning vaccines and therapeutics for some of the greatest threats that our Nation faces such as chemical, biological, radiological, and nuclear threats, and pandemic influenza.

I think this is, just a building of that natural partnership that occurs. We work hand in hand. You saw on Dr. Collins's slide that BARDA is integrated into the ACTIV partnership. You saw on the

slide that I presented that it is in a whole of Government where everybody is integrated and working across Government, sharing information, and helping to develop those medical countermeasures.

Senator ENZI. Thank you. The clock on my screen is behind my picture so I suspect that I have used my time and I thank you.

The CHAIRMAN. Thank you, Senator Enzi. your timing is very good. Senator Casey, who has done a lot of work in this area over the years with Senator Burr especially.

Senator Casey.

Senator CASEY. Can you hear me?

The CHAIRMAN. We can hear you.

Senator CASEY. Mr. Chairman, thanks very much. And I want to thank our witnesses, both the Dr. Collins and Dr. Disbrow. I want to start with the reality that so many communities are facing now that the case numbers and the deaths are overwhelming. As we all know the national numbers, those numbers translate in Pennsylvania to something on the order of more than 51,000 cases.

The death number in our state went up recently. We are now over 3,100 deaths. So we are thinking of those families that are suffering in so many ways. I want to start by commending the frontline workers in this crisis. The frontline healthcare workers as well as so many others, and I won't try to list all of the occupations, all of the work that is being done on those front lines.

Second, I want to commend those who are, throughout our country, the tens and tens of millions, who are doing their part by staying home and by social distancing and wearing masks and doing all the things that the experts tell us we should do to stop the spread of the virus. We are grateful for that. I think the administration's response so far has been inadequate and that might be an understatement. It is nowhere near the dedication of those frontline workers nor is it compliant or adhering to standards like people are at home.

I wanted to start with that in terms of just the what I think our failures that we have to recognize and try to mitigate in the short term, but make a pledge never to have such failures in the future. I think there are at least three, the testing failure, the failure to deliver adequate supplies of personal protective equipment, and then third the failure to effectively communicate over time. Sometimes the administration has been guided by science and expertise, and then that expertise is undermined by way the administration has communicated.

Finally, let me just say before I get to my questions, the Senate, as it has in the first four pieces of legislation, four being the Response Act, the Families CARES Act, the CARES Act, and then the—we have been focused on both stopping the spread of the virus, dealing with the public health challenge, but then second also helping those who are adversely impacted by the terrible economic consequences that flows in the wake of the virus.

I would say that is also concern or should focus our work on oversight. And I know the Chairman will be getting to that but we have to do a lot more oversight of the response so far. Dr. Disbrow, I want to pose a question to you about the next generation of PPE. You know BARDA's mission and part of BARDA's mission is to

make sure that when we have a pandemic, the agency, or BARDA itself, limits the harm of such a pandemic and PPE is obviously part of that.

You have heard, and you have read, and I am sure you are well aware of the limitations that the PPE has meant for so many workers. Sometimes out-of-date PPE, sometimes personal protective equipment that is causing harm to those workers. We have to get to the next generation of personal protective equipment and I would hope that you would work with us on preparing not just for the next couple of months but preparing for the next 50 years. And I hope we can have your commitment on that, both you personally as well as BARDA. Do we have that commitment from you?

Dr. DISBROW. Yes, you do.

Senator CASEY. Thank you very much. And Dr. Collins, in my remaining minute, let me just get to a question about evidence-informed policymaking. We have heard so much from public health experts and from scientists about how to stop the spread of the virus and how to deal with this pandemic. I would ask you, Dr. Collins, do you agree that science and peer-reviewed evidence should be what we implement by way of policy in our response to the pandemic?

Dr. COLLINS. Well, I have built my whole career on science and evidence and rigorous ways to derive that. In the hopes that, that would in fact be the way in which we as a society make decisions. So I certainly agree that ought to be the way in which we move ourselves forward in a fashion that we can be confident is based on real facts.

Senator CASEY. I hope you will continue to advocate for decisions that we make in the Senate based upon science and based upon the best possible expertise, not based upon arbitrary deadlines of politics or philosophy. So I thank you for that. We are grateful. Mr. Chairman, I might have some follow-up questions in the next round. Thank you.

The CHAIRMAN. Well, we will see Senator Casey, whether there will be a next round. We are going to try to end by 12:45 p.m. because the witnesses have to go on and we have votes at noon, I think.

Well, we have a vote at 1:30 p.m. So we will see if there is time for next round. Thank you. We will—Senator Roberts has an important engagement and has asked to go next and others have been kind enough to allow him to do that.

Senator Roberts.

Senator ROBERTS. Mr. Chairman, thank you very much. I apologize to my colleagues for going out of order. At 12 p.m., I am to speak on the floor of the Senate and it is in regard to the fact that the Eisenhower Memorial dedication has been delayed obviously because of circumstances. And this is on behalf of the Eisenhower Commission of which I am very privileged to be in the chair.

For that reason, I am going to proceed and I will try to make my remarks very succinct. Thank you to the witnesses for being here this morning and your tireless work. I want to talk about—I am sorry. I want to talk about—well, Okay. I hope you heard my—the reason that I am stepping forward here out of the recognition of the situation. I want to talk about a situation that is unique, that

we are going through right now, and that is the packing plant situation, the meatpacking plant situation.

Testing rates in Kansas have largely logged or lagged behind other states during this crisis, but that really changed here in the past couple of weeks. We have 23 percent of the cattle market. We have five packing plants in Kansas, Liberal Kansas, Garden City, Dodge City where I am from, and then also Emporia.

We have had quite a break out among the workers of the meatpacking plants. We are working with Governor Kelly of Kansas. We made an early decision and the Governor concurred that we would try to keep these plants open. We don't need not only a problem with our meat supply, but it was backing up the entire food chain. Others on the Committee can speak to that.

The same situation is happening at the pork industry and in the poultry industry. At any rate, the CEOs of the packing companies were very eager, and we are very pleased when the President initiated the Defense Production Act over three of them. I could have just gone up there and whispered in your ear——

[Laughter.]

Senator ROBERTS. It might have worked out. But at any rate, the CEOs at the packing houses have really stepped forward. The President initiated the Defense Production Act. He declared the meatpacking plants a national asset. Not only the guards to meat or pork, which is in a more serious situation, and poultry, but the backing up of our entire food chain.

Our consumers are discovering, finally, that their food doesn't come from grocery stores, it comes from farmers and ranchers and growers. So the CEOs have really stepped up. They wanted to invest in this kind of a situation before but now they are absolutely forced to but it is a willing kind of situation.

The problem is our workers. And just this morning they showed up at the plant, not numbers that we had hoped for, but we at least kept the meatpacking plant open. And what is happening is that they are not catching the virus at the meatpacking plant. It is afterwards. And so we have CDC, we have OSHA, and we have NIOSH. That is a fancy acronym for a team of people going out to inform the workers that the plant is safe and that they should practice social distancing, lack of congregation, etcetera, etcetera when they leave the plant and then at home. That has not been the case, at least up to date. So I think we are in a situation where if there is any need, that I can see, for an immediate test, right now they are having their temperature taken and when they go in and then when they come out.

My question to you is on a rapid test, this is the kind of situation that demands an answer now if in fact we had any kind of a situation where you could have an immediate test. By the way, that they are—in most making most meatpacking plants there are at least 15, 16 different languages that are spoken, and so to educate the workers and to alleviate their fears is a tall job as well. So you can see the need for the test.

Now I have gone on over time and I haven't left you any time to respond. But can we at least get something done on the rapid testing on something like this that is happening right today?

Dr. COLLINS. If I could take 10 seconds I would say, this is a very good example of why we need exactly, what this RADx program is trying to put forward which are rapid point-of-care tests that are readily accessible in any kind of place where there has been an outbreak because that is the only way you are going to identify who the people are who are infected and quickly get them quarantined so they don't spread it to others.

We know that people who have no symptoms sometimes and no fever can be carrying the virus. We need to have a test to identify that. That is what we are trying to do with RADx.

The CHAIRMAN. Thank you, Senator Roberts.

Senator ROBERTS. Appreciate it. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman, and Ranking Member, and to our witnesses. Dr. Collins, I think you are quite aware of how supportive I am of Federal investments in medical research and it is encouraging to hear about the work of the NIH during this really difficult time. You noticed—you noted in your testimony that above all, tests need to be accessible to everyone who needs them.

I agree and it is why I introduced the Medical Supply Transparency and Delivery Act with my colleague Senator Murphy, who you will likely hear from shortly, which requires the administration to develop a national testing plan and it unlocks the full authority of the Defense Production Act to increase the production of supplies needed for testing.

Dr. Collins, the goal of RADx is to develop and deploy tests for COVID–19. Each of the tests is likely to have supplies that will be needed in order to actually utilize and get specimens for these tests. We also need to know whether we will need personal protective equipment or swabs or reagents to actually conduct these tests. Can you describe sort of with your crystal ball looking forward to what might be produced by RADx, what sort of associated supplies will be needed to use these tests?

Dr. COLLINS. Senator, that is a great question. Every one of these various nominated platforms for technological advances is going to have a different set of requirements as far as those kinds of supply questions. And here again, we will be looking at that closely as we try to evaluate which of these ought to get the strong support in the Shark Tank to move forward quickly.

Many of them will require swabs in order to acquire the sample. We do, by the way, think that swabs that sample the front of the nose are maybe just about as good as the ones that have to go all the way in the back and most people would be glad to hear that. We also think that saliva may very well turn out to be an attractive alternative which might then not require a swab at all if you had a way of collecting just a saliva sample. But all those things have to be thought about and certainly we would not want to make a major investment in a particular diagnostic technology without having a very clear sense of what that supply chain need was going to be if this was going to be distributed and implemented all over the country.

Here again, as we are working closely with BARDA, is going to be critical because this is a sweet spot for them in terms of keeping

track of all of the details of how you make sure you don't end up with a success story that you can't actually implement because you forgot about some part of the supply chain.

Senator BALDWIN. Right. I thank you for that answer because what I am seeing with the available already testing platforms is that each has a different swab, a different reagent. They are sort of closed loop in many instances. And if that is going to be the case in the future, we need to anticipate that as we try to ramp up and make sure that we are supplying the reagents and the swabs and the specimen collection for each of the various tests that will be out there.

The second complication I see frequently is the—if I look at Wisconsin, for example, there is so many different entities that are trying to seek these tests for enhancing their testing capacity. Certainly the state. Some hospitals and systems, employers who want to test employees before they reopen for business when that time comes, K through 12 private and public schools, higher education, etcetera. There is no streamlined logistics right now.

Again, I return to this idea of having the full authority of the Defense Production Act involved with you at NIH and BARDA in order to make—to create a streamline system for testing. Would it help you to know at your stage at NIH what sort of facilities and institutions will need testing and when so that you can identify the gaps and actually be looking at tests that are likely to be able to fill those gaps?

Dr. COLLINS. Yes, of course we want to have a full sense of the needs that are out there from multiple institutions and particularly in places that are vulnerable. And we are aware that this is not evenly distributed. I mentioned these demonstration projects that we are going to try to put in place for places that don't have ready access to testing for underrepresented groups. And that is just one example of what you are referring to. So we do need to have our finger on that pulse.

The CHAIRMAN. Okay. Thank you very much, Senator Baldwin.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. Mr. Chairman, let me start by saluting you for your extraordinary leadership in putting together this initiative that is going to make such a difference for the health of our country. Dr. Disbrow, last year I introduced a bill called the MEDS Act after I reviewed alarming data that indicated how dependent our country's pharmaceutical market was on overseas suppliers of active pharmaceutical ingredients APIs.

I discovered that 72 percent of the facilities producing APIs were located overseas, 13 percent of the facilities where located in China. And sure enough in the midst of this pandemic, India took steps to restrict the export of 26 APIs to our American market.

Clearly we should not be so dependent on foreign nations for essential ingredients for our medications and that is going to be really important as we develop treatments for the coronavirus. As RADx leads to the development of promising new diagnostics, how will you ensure that we have the capacity to manufacture and scale up these innovations right here in the United States?

Dr. DISBROW. Thank you. So the global pandemic has highlighted the vulnerabilities in the supply chains for many products. PPEs

were one of the first things that we saw and now it is also raw materials for manufacturing active pharmaceutical ingredients. So for the active pharmaceutical ingredients and raw materials for drugs, we are currently looking at advanced manufacturing technologies.

We are evaluating multiple programs. Those are ongoing right now so I can't discuss that but it is to bring that into the U.S., use a much smaller footprint than you would for a typical or traditional manufacturing facility to try and bring that back. But again for these raw materials for the diagnostics is to partner them with U.S. companies that have the experience and know how to scale up diagnostics.

They have the engineers and work with them to acquire all those raw materials that they would need now so that we can scale that up. That is what we are doing for vaccines. Vaccine manufacturing is a very long process so we need to acquire those raw materials now so that our vaccine manufacturers can manufacture on scale.

Senator COLLINS. Well, part of the MEDS Act, which I authored, was included in the Cures Act, but I really think we do need to do more work in this area and I appreciate the fact that you are very aware of the problem and are working on it.

Dr. Collins, let me turn to you next. So you were just talking about swabs and how they are an essential part of diagnostic tests. I am proud of the fact that one of the two leading manufacturers of swabs is Puritan Medical Products, which is located in rural Guilford, Maine. And just last week, with support from the Defense Production Act and private investments, Puritan has teamed up with Cianbro, a large construction company, and Bath Iron Works, better known for building Naval destroyers, to open a new facility in record time that will double the production of swabs. So that obviously is very good news.

In addition, we have a laboratory, that is Abbott Labs, in Southern Maine that has helped produce the point of care rapid test. My question to you is what more could we be doing to tap in to the authority under the Defense Production Act so that when you do get a winner, we can be assured of a rapid scale up in manufacturing of the new test?

Dr. COLLINS. Would any of us imagined four or five months ago we would have talked about swabs at a Senate hearing? It is like this is coming in such an interesting and unexpected way and yet it has absolutely been critical to the availability of testing. But certainly, again, this comes back to needing to think ahead.

With any one of these new kinds of technologies that we are trying to encourage through the Shark Tank, what are all of the things that you are going to be short of and you should have plan for, and how can you take advantage of what BARDA has in terms of experience and resources to make sure that happens, deal with the supply chain and make sure that is not going to get cutoff by something international, and if necessary, come up with ways as you have done in Maine to double or triple the production.

Just what you need to do. We have to be thinking of everything in advance and not get caught by surprise. We won't—we will not make that mistake again.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Murphy.

Senator MURPHY. I thank you very much, Mr. Chairman. Thank you for being here today. A comment and then a couple of questions. We are just so grateful for all the work that you are doing and your efforts to inform us as to some of these innovative partnerships. But of course, you are only as good as the direction that you are given by the President of the United States and what you have effectively told us today is that this new effort to try to find widely available point-of-care test was launched eight days ago, largely at the urging of members of the Senate.

If we had a President who truly prioritized testing, this effort would have been launched the minute that we heard about the prospect for coronavirus coming to the United States. And instead literally in the middle of the epidemic, when some of our states have actually gotten through the worst of it, we are now launching this initiative. It shouldn't be lost on us how far behind we are on testing.

Frankly, it is not an accident. It is not an accident. The President told us early on that de didn't want to bring folks to the United States from a cruise ship because it would drive up our numbers not because of any public health risk. And then just yesterday he said this, by doing all this testing we make ourselves look bad.

That is the President's belief that the testing makes us look bad. And if you don't think that perception is important to this President, you haven't been paying attention for the last three years. And so we are playing catch-up and so the question is how we do that most effectively. And so Dr. Collins, let me ask you a question not so much about the new diagnostic project but ACTIV, which is the project to try to develop a vaccine and treatment.

I appreciate the fact that you have reached out to our European partners to be a part of this effort, but there are ready is an international effort designed to try to develop a vaccine, CEPI. In fact, it has been working on pandemic vaccines for three years and on Monday of this week, or maybe it was last week, the partners, our European partners all got together to try to rally the world to put more money not into ACTIV but into CEPI. And so my question is this, we should be running our own efforts to try to develop a vaccine, but why not also join CEPI?

Why not also make sure that we have a seat at the table when it comes to the biggest international effort to develop a vaccine? And maybe just my question is this because it is not necessarily your policy decision as to whether to join. We could do both, right. We could be developing our—leading our own efforts to develop a vaccine and also be a member of this international group, which by the way, all of our allies are part of, the Europeans are part of it, the Saudis are a part of, the Japanese, the Indians, the Australians, the Canadians, everybody is working on a vaccine together.

We are not part of that effort, which is just really hard to understand. We could do both, right?

Dr. COLLINS. I actually was present at the founding of CEPI at the World Economic Forum in Davos and that has been a wonderful contribution to try and prepare for pandemics, which we are

now in the middle of. And while we were not present in a direct way at this recent fundraising effort to try to put together additional support for vaccine development in Europe, we are certainly connected in multiple other indirect ways.

For instance, the companies that are part of ACTIV, many of them have strong European connection, some of them are in fact European companies, and CEPI is in a position also to contribute to the development of some of the vaccines that we are actually talking about getting into this master protocol this summer.

It is, I think—you are exactly right. This is a global crisis. We should approach it globally wherever the resources are and not get too wound up about what obstacles are in the way. I am a scientist. I want to see this project succeed.

Senator MURPHY. Mr. Disbrow one quick question. You referred to the allegations that Dr. Bright made as a personnel matter, but it is not a personnel matter. He didn't get fired for showing up late. He alleges he got fired because he was trying to talk to his superiors about a culture of corruption in which industry players and non-scientific input had influence over the decisions that BARDA was making.

That is not a personnel matter. That is a public policy matter. And so would you agree that getting to the bottom of the allegations that he makes is important for you as the temporary or acting head of this agency? And do you have any opinion as to whether outside industry groups have too much sway inside this operation?

Dr. DISBROW. I do think it is important and I am sure there will be an investigation. I stand by—I have been at BARDA for 13 years. All proposals that come in have to go through a scientific review. The review is based on science, technical merit, the feasibility of the actual program, and the ability of the company to potentially do the work.

We review those. They are done by interagency partners through the technical evaluation process. They are then reviewed and then we make awards. And so I am still confident in the way that we make our investment decisions that they are based on science and based on the best technology that we can bring forward.

Senator MURPHY. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Cassidy.

Senator CASSIDY. Dr. Collins. All three questions will be for you. Thank you both for your good work. I appreciate it. I was intrigued it wasn't in your testimony, but I would like to hear your kind of further thoughts about the RADx underserved population program. In Louisiana we have been hard hit. We have many populations underserved, and we—I am actually kind of working with my group, with people back home as to how we address this. So how do we apply for it? How do we get it? What resources, and you can reply to that as a QFR too.

[Laughter.]

Dr. COLLINS. Well very quickly, this is a program, again, because the funding for RADx just came along fairly recently, that is still in the formative spaces, but we will be in soliciting applications for centers that could be placed in locations where underrepresented

groups have been particularly hard hit and have not had access to testing in the way that you would ideally want to see. And that will be coordinated together along with an ethical, legal, and social implications program, and a coordinating center. So watch this space, it will be coming.

Senator CASSIDY. Who do I call, you can call me?

Dr. COLLINS. You can call me.

Senator CASSIDY. Sounds great. Second, next question. You spoke about having to look at the ability of antibodies to provide protection and the duration, etcetera. But if it is like flu, quite likely those antibodies will be completely protected in some, and mitigate the symptoms in others, and in a few it may just not have any effect whatsoever. And indeed, we may not know the duration of the benefit until three years from now.

I guess my question was all that. There is going to be uncertainty as we roll out this information. Are you suggesting that we wait for absolute certainty before we begin to make policy decisions based upon how useful anybody testing is both in terms of looking at the spread of disease, but more importantly I think as to its protection against reinfection?

Dr. COLLINS. It is a fundamentally important question and you as a physician have thought deeply about this as I have. We do know that coronavirus, the COVID–19, is one the immune system recognizes and eradicates the virus. We do know that people recover from it, and after a while, you can't recover the virus anymore. That is good. That tells you the immune system knows what to do with this. It is not like HIV.

At the same time, we do know that this virus can mutate. We have already been able to observe that. It is an RNA virus. Fortunately, it doesn't mutate the way influenza does so we don't think it will have this sort of very rapid seasonal change that we have to deal with influenza, which means last year's vaccine is maybe not the one you want this year.

We really don't know the answer though to a lot of your questions and they are fundamentally important. Can you get re-infected with this? There have been a few cases of that. They are not incredibly convincing. If you do develop immunity, how long does it last? We do not have a good reason to——

Senator CASSIDY. Can I ask you though, there is evidence both from rhesus monkeys that this antibody is protective and there is also from SARS–1, if you will—somebody writes about immunity being for 18 years. So it does seem as if the scientific evidence is pointing in that direction.

Dr. COLLINS. It is pointing in that direction. You are absolutely right and we are counting on that to be the answer here, but until we know—we will need to know.

Senator CASSIDY. Now, let me ask you though, what is defined as knowing? Because knowing may not be for one or two years and yet we have to make policy decisions hopefully before then.

Dr. COLLINS. Indeed and I think at the present time to be able to evaluate the meaning of a positive antibody test one should be quite cautious. I think it is going to help a lot to see if there is anybody who has such an antibody test that turns out to get infected again in the next six months or so because the virus is going to

be around. We will start to get an early warning sign there, but we won't know whether it is three years or five years or ten years for quite a long time.

Senator CASSIDY. You are suggesting that not only should we test but we should be tracking who is positive so that we can follow them longitudinally to see whether or not they develop once more.

Dr. COLLINS. With their appropriate consent, of course, and this is where the All of Us program that you and I have talked about which has enrolled now 300,000 Americans who are pre-consented for exactly this kind of follow-up is going to be very useful to track and see what happens.

Senator CASSIDY. Let me ask you as well, and to the Chairman, I would like to enter an article for the record, "COVID–19 has Shuttered Scientific Labs, Putting a Generation of Researchers At Risk."

The CHAIRMAN. So ordered.

[The information referred to can be found on page 52]

Senator CASSIDY. This is an issue that my universities back home have told me that they just had research projects shut down. The article, which I speak about specially raised genetically modified rats we have had to be euthanized because of the inability to access the lab, for example. And the expense of extending programs in want in just one of my university is $20 million for all the grad students who need to complete now.

I understand that NIH is a relaxed budgetary and spending guidelines and allowed no-cost extensions to grants and contracts but I'm also told that probably won't be enough. So I'm just asking you what is NIH's planning for all these scientists.

Dr. COLLINS. Well, I am deeply concerned about that. This is a heartache seeing the rest of the scientific enterprise pretty much put on hold. My own research laboratory has researchers who are at home trying to write papers and read literature, but they are not at the bench doing experiments they would be doing on diabetes or aging right now if we had the chance.

If you add up what this is going to cost just in terms of the lost productivity, the need to keep people employed, the estimates are something like $10 billions of NIH-funded research is going to disappear because of the way in which this virus has affected everybody, requiring this kind of distancing and sending people home. And universities, of course, are very much hoping that this is something that could somehow be ultimately compensated. I worry particularly about trainees who have lost time who are really quite concerned about what this does to their professional career.

We have to do everything we can to reassure them that we are going to get through this and that they will look back on this someday and say, well, that was a pretty bad time but we all managed to figure out a way to cope with it. But you put your finger on something that wakes me up at night a lot, what have we done to the rest of the research enterprise because of COVID–19.

Senator CASSIDY. I am not sure you though you gave me a plan. You sympathize with the issue, but didn't give a plan, but I am over my time. I yield back.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. Three months ago, America saw its first case of coronavirus, and President Trump's response has been a complete disgrace. Instead of using this time to drastically ramp up our testing supplier, make an actual plan to test as many people as possible, he has dawdled, he has peddled conspiracy theories, and he has bragged on television that U.S. cases would soon be close to zero. Today, over 70,000 people are dead, 1.2 million people are infected, and 30 million people have lost their jobs.

Meanwhile America is still racing to get its testing numbers up. I showed a detailed plan for how to do it. I am pleased that some pieces like funding to boost testing capacity and better reporting of demographic information are already logged, but there is more we need to do to correct for the President's failures, including using the power of the Federal Government to publicly manufacture testing supplies.

Dr. Disbrow, you are the Acting Director of BARDA which was set up 14 years ago to make sure that the Government has life-saving drugs on hand in a crisis even if it isn't profitable for drug companies to make those drugs on their own. Does that mean that the Federal Government is running drug factories all over the country with Federal employees inside and on the production line?

Dr. DISBROW. Thank you for the question. What we do at BARDA is we partner with companies and we form these public-private partnerships to help develop life-saving medical countermeasures vaccines, therapeutics, and diagnostics. We provide funding. The companies also in most cases provide funding.

There is a cost shared in some instances for the development of that, but we are providing the funds, and in particular for COVID–19, the Government will take the risk for developing those vaccines, therapeutics, and diagnostics because we need to expedite the development of those. No, Federal employees are not inside the factories, but we do work as a true partnership with our industry partners to bring those medical countermeasures forward.

Senator WARREN. Thank you, Dr. Disbrow. In other words, BARDA identify a public health threat, helps take a drug or other countermeasures from concept to reality, and then contracts with private companies to make it happen. So in other words, it uses the power of the Federal Government to ensure that the market uses what we need and when we need.

BARDA has already invested, I should point out, in dozens of companies including Moderna and Hello Check, both based in Massachusetts making therapeutics and vaccines and diagnostic tests to fight COVID–19. Our scientists are racing around the clock and they are going to get it done. But coming up with these life-saving innovations isn't the only challenge we face in this area.

Dr. Collins, let's say that science delivers all the tests we need and eventually a vaccine, what other basic medical supplies do we need to be able to actually produce and administer these tests and treatments?

Dr. COLLINS. Well again, I think we have to think about exactly what those supplies would need to be and whether that involves some kind of swab to collect the sample to do the test or some sort

of material, some sort of solution that you have to transmit to the laboratory.

All of those parts of the supply chain have to be thought about if we are going to make this as successful as it needs to be. Likewise with vaccines, people are worried about, do we have enough medical glass to be able to put all of these doses of the vaccines in vials so that they can be administered and that is a serious issue to think about. Right now, even as we are anticipating if all goes well, that such vaccines may be available in millions of doses as soon as this fall, again all of that requires thinking forward.

Senator WARREN. Alright, so thanks very much. I appreciate that, Dr. Collins. In other words to put it bluntly, even if we come up with vaccines or better tests, if we don't have the right supplies, if we don't have enough cotton swabs, if we don't have enough reagents, if we don't have enough glass, then it is not going to do us any good because we won't be able to get the job done. So let me ask this, Dr. Disbrow, is BARDA's job to supply the Nation with cotton swabs and reagents?

Dr. DISBROW. BARDA will do whatever is necessary to get the job done to protect our Nation. So, your question about vaccine. So BARDA is focusing on ancillary supplies. So making the bulk vaccine, which is the liquid, is only one staep . You need a vial to put the vaccine in, you need a stopper to, close the vile, and you also need needles and syringes. So we are responsible for making sure that all of those ancillary supplies to develop and administer that vaccine are taken care of.

Senator WARREN. Well, so in other words, we can't just wait for the cotton swabs and the—to roll off the assembly line from the cotton swab factory. We have really got to be planning this out as Dr. Collins was saying.

Dr. DISBROW. Correct.

Senator WARREN. I think that means that Congress should pass Senator Murphy and Senator Baldwin's bill to force the President to use every bit of his authority under the Defense Production Act and get private companies making what we need. And we can do more.

Last week, I announced the COVID–19 Emergency Manufacturing Act. My bill establishes an Office of Manufacturing for Public Health. It is modeled after BARDA. This office would publicly manufacture or enter into contracts for manufacturing everything the country needs to fight COVID–19, swabs, reagents, masks, face shields, intubation drugs, other COVID–19 products, and manufacture them at scale.

Congress should include it in the next coronavirus relief package so that we can save lives that are still being put at risk by the President. Thank you very much.

The CHAIRMAN. Thank you, Senator Warren.

Senator Murkowski.

Senator MURKOWSKI. Mr. Chairman, thank you. Gentlemen, thank you for your leadership. Greatly appreciate it. So this hearing is Shark Tank, a reality TV show. Alaska knows a little bit about reality TV shows and I have got a stress test for you today. And that stress test is Cordova, Alaska, a small fishing community, population about 2,000. In the winter, it doubles during the sum-

mer when the fisheries come on. It is a strong fishing community, 7th in volume of landings in Alaska, 16th nationwide, overall about $50 million in revenue plus so it is significant for us.

I mentioned that it is a small community. So that means it has a small hospital facility. We have got a license for 23 beds, 12 of those are long-term and are occupied. So we basically have 6 available beds for the community there. The fisheries begin, the big salmon season, the copper rivers are coming on, and that season begins May 14th. So we are moving onto it very, very quickly. We have got five processors that work in town. They bring in on average about 450 seasonal workers. Total workforce there is about 550. Yesterday, we had the first positive COVID test that we have seen in Cordova and it was a worker who had flown in to begin the fisheries season.

I want to share with you what the community of Cordova in collaboration with the processors has done to make sure that we keep this virus out. All out of state workers are gathered in Seattle. They are put up in a hotel room. There are security guards at the doors. They are tested and then they wait until the tests come back. If they are cleared, then they are put on an airplane, either a charter or Alaska Airlines, flown direct into Cordova, they are met at the airport, they are put in a special bus, they go directly to the processing facility where they are again administered a second test.

It was on that second test that this individual tested positive and they got the results just yesterday. The individual was asymptomatic. So we have got a situation here where you have got a community that is completely cutoff from the rest of the world. You only get in by airplane. There have been no ferries since the entire winter and you have got a situation where we now have three Abbott ID analyzers. We are waiting on a Cepheid test. All the other tests are completed by swab and those swabs are then flown to Anchorage, an hour's flight away and we have about 1,300 tests that are available in the community now.

I talked to the Mayor. I am texting back and forth with the Mayor last night speaking with our chief medical officer, Dr. Zinc last evening. What do you need? We have got this, we have got the Shark Tank going on. What does Alaska need? We need to have at point testing. We have to recognize that when you have these rural distances. It just doesn't work otherwise. It has to be easy to run.

Dr. Collins, you have mentioned the RADx-UP demonstration, and that sounds very intriguing and I will probably be calling you along with Senator Cassidy here, but you have indicated that it is intended for those areas that are hard hit. We don't want Cordova to be hard hit because if Cordova is hard hit, that fishery doesn't move forward. And it is not just Cordova's fishery that doesn't move forward, it is the Bristol Bay fishery that will be coming up in another month that is going through these same protocols here to try to determine if it's even possible to open up the fisheries. This is our economy.

I appreciate what you are saying about testing for those that are hard hit. This is your stress test in the Shark Tank. What are you going to give me?

Dr. COLLINS. That is a great story and a wonderful way to point out just how critical this is.

Senator MURKOWSKI. It is for real though and it is in real time.

Dr. COLLINS. Shark Tank aims to give you, by the end of the summer, it is not going to help you this month, a kind of point of care testing that you really would love to have where you have an immediate answer within an hour. And you can actually not just test people when they come in but maybe test everybody, every week to be sure that there is not something brewing there because you always worry about a negative test from somebody who actually has the virus but not enough of it yet to pop up on the tests. Maybe that is what happened with the individual you talked about a negative test and then it went positive.

You would want to be able to do this continually. And of course, as you say, you want to be able to do this in a way that doesn't require shipping the sample off to a central laboratory and waiting for the results to come back, if it does. You want something that is going to work right there. That is affordable. That is highly accurate.

It is a little bit of a knock on the Abbott test because it does have false negatives where you have somebody who probably is already infected but the test doesn't quite pick it up yet. We want to drive that number up to 100 percent. So that is what Shark Tank aims to do for you. Meantime, this whole business of RADx-UP, the idea of providing a special attention to places where testing has not been available, I think you make a very good point.

It doesn't mean they have to already be hard hit. It means they are vulnerable to becoming hard hit if the testing isn't accessible to them in a very special circumstance and you have just taught me about one of them. Thank you.

Senator MURKOWSKI. I look forward to speaking with you more about it. Thank you.

The CHAIRMAN. Thank you, Senator Murkowski.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman for the hearing and to our witnesses. The last time that we were here as a Committee was March 3 and 9 deaths had occurred in the United States of coronavirus when we were last together. And today the number is 74,665 in the days we have been apart. It has been an average of about 1,126 deaths a day. Personally, I am a well-off U.S. Senator.

I know four people who have died of coronavirus since we were last together. Jeanette Galliano, my brother Steve's mother-in-law, Dolson Anderson, a friend of 25 years in Richmond who was married to one of my agency heads when I was state Governor, Gerald Glenn a bishop and an Act of Faith leader in the Richmond community who was active and appointed by both Democratic and Republican Governors to juvenile justice positions, Louis Shaver who is my wife's best friend's mother who died in a nursing home here in Fairfax County couple weeks ago. My next-door neighbor Dean DeForest died, next door neighbor of 28 years in the last two weeks, not of coronavirus but of a long battle with lung cancer, but because of coronavirus, couldn't have visitors like he normally would, couldn't grieve with the family together like a family normally would.

Then Lorna Brie and I didn't know Lorna, but I have gotten to know her family. Lorna is from Charlottesville and was working in emergency medicine at Columbia Presbyterian Hospital and was trying to save as many people as she could. And she got coronavirus and went home, and then when she was well, she came back to the hospital and found it overwhelming, went back to be with her family in Charlottesville, and died 10 days ago by suicide.

I don't know who it was that said this brutal thing about a million deaths are a statistic and one death is a tragedy. The numbers are large, but we can't forget that each one is a tragedy. March 3d, we had nine deaths in this country. On March 3d, South Korea had 28 deaths on March 3d. The total death toll in South Korea today from coronavirus is 256. 19—I am sorry, 28 on March 3d and 256 today.

My question to you is why? South Korea is a messy, vigorous, robust democracy like us. It is not an authoritarian nation. South Korea is filled with super packed metropolitan areas, but also rural areas. So in that sense, it is like us. I am assuming, and this is a hearing about testing, I am assuming it has something to do with testing, but that is the only question I have, why on March 3 to today has the South Korean death toll gone from 28 to 256 and the U.S. death toll has gone from 9 to 74,665.

Dr. COLLINS. Senator, it is very sobering. I am glad you started talking about specific individuals because sometimes we get into these conversations about coronavirus as if it was an academic question or it is about statistics or it is about some fancy technology, which I confess I spend a lot of my time on that too, but this is really about people, real people who have lost their lives, have been terribly sick, whose families now have found the chance to grieve but not be able to grieve in the usual way.

My wife said to me a couple days ago, she said, you seem so burdened about this particular set of intense priorities and projects, you have done this before and you seem to just sort of sail along, what is going on? Said, when I was in charge of trying to lead the Human Genome Project it was incredibly competitive. It was comparably exciting. It had this historic nature to it.

But this time it is about people living or dying. It is different, and we have to think about that at every step in a conversation like this. South Korea did some amazing things. It is certainly helpful for them that they are a smaller country than we are with a whole lot less population to try to manage. They did figure out how to do the distancing thing and the testing thing and with great speed and rapidity.

South Korea, which I have visited, is an amazing technologically advanced country. If you haven't been there, it is like pretty breathtaking when you see what they have been able to do. And so they jumped in on this in a very effective way. A big, sprawling country is a whole other kind of challenge and obviously a challenge that we now grieve to see what has happened with those more than 75,000 deaths and we are not through this.

We are nowhere near through this and everything we have to do right now is to try to look at that experience and say we have got to put everything we have got into keeping this terrible tragedy from getting any worse. And that means testing and that means

therapeutics and that means vaccines. And I will tell you, for me personally, that is what I am doing 24/7 and I will continue as long as there is anybody still at risk.

Senator KAINE. Thank you, Dr. Collins. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman. Thank you to the panel for being here with us today. And I know that we have made significant progress over the last several weeks. And I am excited to see that I am also excited about the future prospects of your Shark Tank activities and efforts. So thank you for your willingness to spend 24/7, 7 days a week on trying to find ways to insulate America's health. Coming from the State like South Carolina we have around 6, 936 confirmed cases.

We assume that there is probably over 50,000 infected in South Carolina, but we haven't had the availability of testing, because as you already know, South Carolina is a state that is considered to be on the low side of the number of cases and therefore the testing resources are going in other directions. As you think about our future, we really want to make sure that as we serve America's needs, that those rural communities, and South Carolina is a fairly rural state, that we do indeed have more access to testing.

That is why I am encouraged by your, I think it is your RADx prospects. I would love to hear you talk a little bit more about the RADx prospects because in McCormick County, or Calhoun County, or in Newberry, or Greenville County, a larger county, the testing needs are very important in rural America and rural South Carolina. So would love to have you illuminate that a little bit more for us. The second question that I have is about the vulnerable populations in certainly rural America, and rural South Carolina is a part of that.

Are some minority groups like African Americans and Hispanics, in Alaska Native Americans as well, Native Alaskans, are all a part of the same type of grouping as it relates to the underlying health conditions that may make you more predisposed, having a significantly harder road through the coronavirus. Love to have you talk about the importance of having folks in control groups of minorities in our country participate there as well.

Dr. COLLINS. Great questions, Senator. And yes, it sounds like South Carolina and Alaska are both in the same situation here of not being able to have access to tests that you need right now to try to keep people in your state healthy. That is one of the main reasons that we are proposing this so-called RADx-UP program to try to put in places like that where there are vulnerable populations, some of which are getting sick at an alarming rate. The access to testing particularly needs to be focused on there.

I am particularly concerned when I look in across the country at the statistics about what is happening with African Americans where clearly the burden of COVID–19 in terms of the most serious illness and the deaths are falling disproportionately on the shoulders of black individuals.

Look at Georgia where something like 80 percent of the individuals with serious illness and hospitals are African American and

Georgia is only 30 percent African American. So that tells you right there, there is something going on. And a lot of that is the disproportion in terms of access to testing, making it much more difficult for many of those societies to be able to practice physical distancing just because of social circumstances and maybe can't really afford to stay at home and stay out of the public circulation because you have an hourly job and if you don't show up, you are not going to get paid.

We recognize that this is one of those moments where health disparities, which in this country have been a problem for decades, a bright light is being shown upon them and we should not miss the chance to react to that and come forward with solutions. And that is what in this area of trying to be sure that testing is accessible, maybe we can do something that hasn't quite been done this way before.

We imagine something like 10 or 20 of these demonstration projects located in places that are in particular need of access to these resources now populated by scientists who are dedicated to that goal with a very strong community outreach to try to be sure the community embraces what it is, that this can represent, and recognizes this may also be a way in which when vaccines come along, we make sure the vaccines are also distributed in a fashion that is not otherwise affected by going to the obvious places where there happened to be more resources.

We want to work through the federally qualified health centers for testing and for vaccine delivery, so I am right there with you. And I think South Carolina is a great example of a place that we could really benefit from working with.

Senator SCOTT. One comment, and I am sure I will be out of time but I will ask the question as the time ticks away and maybe the Chairman will allow you to answer that question.

One of the things that I found to be quite interesting is when you take a look at the prevalence of the coronavirus in nursing homes, look at the fact that the death rates are significantly higher there, you couple that with the fact that as I talked to the nursing home community, about 60 to 70 percent of their certified nursing assistants are African Americans, about 80 percent are female. You have a very vulnerable population serving another vulnerable population. If there is ever a case for more testing in nursing homes, not only for the residents but for the workers, this is a classic example.

Final question, perhaps to both the panelists, would be around the CRISPR and gene editing technologies to advance more testing and new types of testing. Any closing comments with my last 38 seconds?

The CHAIRMAN. The—if you can make your answers succinct, that would be appreciated. We have other Senators waiting.

Senator SCOTT. I apologize.

Dr. COLLINS. Well that is a question I loved but I will try to be quick. Yes, CRISPR which is this amazing new technology that allows you to find a very specific DNA or RNA sequence of letters in a complicated mixture is a really powerful way to find the presence of a little bit of a virus somewhere in a biological sample.

A number of the new protocols that are coming into the Shark Tank are based upon that and those are some of the ones I am most excited about because it is a totally different approach. It looks like it could be very point-of-care and very readily done but without requiring special technology.

Dr. DISBROW. I agree with that completely. I mean, it is a new technology that could look at a very low level of the virus in a sample and I think that is the true advantage of that and we look forward to pushing those forward.

Senator SCOTT. Thank you, Mr. Chairman, for your indulgence.

The CHAIRMAN. Thank you, Senator Scott.

Senator Hassan.

Senator HASSAN. Here we go. Thank you, Mr. Chairman, and thank you Ranking Member Murray for holding this hearing and allowing for remote participation. Thank you as well to the witnesses for being here today and for your ongoing work and that of your entire teams in responding to this pandemic. We do know how hard people are working.

I will just start by saying that yesterday in the small State of New Hampshire, a little under 1.4 million people, we lost 19 people all of whom were in long-term care facilities. Death rate is now about 8 per 100,000 from the coronavirus.

The need for testing has never been more clear and I think what is hanging over this entire hearing is that question, the question Senator Kaine so eloquently asked, but it is the question that we have all been really referencing is what would our trajectory look like right now if we had more testing where and when we needed it, accurate testing that could be done rapidly and why have some countries been able to do that testing and we haven't? So we need to discuss the near-term testing issues today to be sure and the other issues that the Chairman has talked about are also important too.

But I would like to just formally request that we also hold a hearing on COVID–19 vaccines as well because as it has already been discussed, we need to plan for the entire production and distribution of vaccines if we are fortunate enough to meet these intense and rapid goals or getting a vaccine up and operating. In my state, there is a manufacturer of hypodermic needles who says they have not been receiving the kind of purchase orders from the Federal Government that will allow them to have the kind of volume of hypodermic needles on hand when we are hoping this vaccine might be ready.

I hope very much that we will have a hearing just on vaccines and the manufacturing supply chain that we need to have up and ready because this administration has been slow to respond to the needs for testing and for personal protective equipment, and we need to learn from those mistakes and avoid this situation in the future.

Dr. Collins, a couple of questions for you because relatively few people can access testing and I would like it if we would start talking about the rate of testing we are doing per population in this country not just the wrong numbers. On advising those with potential COVID–19 symptoms who cannot access a test as to behave as though they have the virus has been an important part of our con-

tainment efforts. However, as states reopen and people are asked to return to work, it will become harder to comply with this advice. Meanwhile reports suggest some COVID–19 diagnostic tests are returning inaccurate results 15 to 30 percent of the time.

These quality issues may hinder containment of COVID–19 as individuals either correctly believe they aren't infected or incorrectly believe that they were infected and therefore they have developed immunity.

Dr. Collins, the goal of the Shark Tank initiative is to accelerate development and increase testing capacity. However, a reliable testing infrastructure depends as much on quality as it does on quantity. What steps will NIH take to ensure that any companies receiving funding or support through the Shark Tank initiative are producing high-quality products?

Dr. COLLINS. That is a critical question, Senator, and it is a critical step in the Shark Tank phase 1 too. The approach that we are taking, which is that along that, fairly early in that pathway, the technology has to be validated. That is, it has to be tested against a variety of gold standard samples of varying degrees of the presence of the virus to see whether it is sensitive enough to be able to detect the virus when it is there and specific enough so that it doesn't give a false positive on a sample that has no virus in it.

That is absolutely essential. Anything that fails at that point will basically fall out of the Tank and will not be taken forward unless there can be a technical solution to dealing with that performance issue. Once of course this does pass that gate and gets successfully moved forward into commercialization and scale up, the FDA will be in the strongest position then and they will look at this carefully to see whether it passes their muster. You may know in this current crisis, FDA has been authorizing tests with what is called EUA, emergency use authorization.

But in the longer term, they are going to be very determined to make sure that these tests pass all of the appropriate validation steps so you can count on that coming in there as well. So it is really critical question. We will make sure not to have this missed as an opportunity. It has got to not just be out there, but it has got to be accurate.

Senator HASSAN. Very quickly, and I know I am over time Mr. Chairman, what—how will you ensure, Dr. Collins, that in order to receive Federal funding these new diagnostic tests will represent a significant enough improvement over existing products that justify Federal investment?

Dr. COLLINS. That again will be something that BARDA will also be engaged in. We will not want to put taxpayers money into something that doesn't represent a significant advance over what is already there. I don't think we will have to worry though that there is going to already be enough testing that you don't want to think about bringing on board one of these new point-of-care platforms. If it is highly accurate and if it is quick and giving a response, it seems highly likely we will want to invest in it.

Senator HASSAN. Thank you very much. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman. I appreciate very much you holding this hearing. The first question is for Dr. Disbrow. It is a pretty quick question, which relates to probabilities. Those of us who have been in the business world have dealt with probabilities. People at NASA, I am sure do. Doctors certainly have to. What is the probability that we will have a generally available vaccine for the American public by the end of the year? What is your personal sense of what the probability is? 50/50, 90 percent, 20 percent? What is the likelihood?

Dr. DISBROW. I am not a betting person but if we don't set lofty goals, we will never achieve those goals. And so we are working very hard across the Federal Government to make sure that we were doing everything we can to expedite the development——

Senator ROMNEY. I know that. I know we all have lofty goals. I am not asking for goals. I am asking for the probability. What is the probability, 50/50, 90/10, 60/40? What is your sense of what the likelihood is that we will actually have a vaccine available for the general public let's say by the begining of the year for the population of our country. I know what our goal is, of course. Our goal is a 100 percent. But what is your sense of the probability. You have been in this vaccine world for a long time?

Dr. DISBROW. Yes.

Senator ROMNEY. What should we be thinking about?

Dr. DISBROW. That is why I don't like to set either timelines——

Senator ROMNEY. Never mind. Never mind. You won't answer the question, we will move on. Second question, Dr. Collins, which is the Abbott machine. It is already providing information I guess almost on a real-time basis. What is wrong with sort of making a lot more of those and using that as a machine that could be available at most businesses retailers and so forth? Is it just an inadequate? Is it the false negatives that gives? But it strikes me that we already have a technology that works. Am I wrong on that?

Dr. COLLINS. No, it is a great machine, Senator. This is the Abbott ID now approach. It does provide you point of care and it does it very quickly in the space of 15 minutes. It does require having this special machine. And of course, there is a limited number of those machines out there. I think it is 18,000 or something like that. And to be able to really meet the need, that would have to go up substantially, and the machines are not exactly inexpensive—I think the other concern has been that it does have about a 15 percent false negative rate.

If you are in a circumstance where you really, really don't want to miss a diagnosis of somebody who is already carrying the virus, you would like to have something that has a higher sensitivity than that, and I know they are working on how to make that happen. But, so it is great. It is certainly one of the most exciting things we have got right now, but we think we could even do better.

Senator ROMNEY. Yes, I am—your judgment is a lot better and more experienced than mine in this regard, but it does seem to me that given the fact we have a test that works, it can perhaps be made more sensitive. If we were to devote a lot of resources to making a lot of these machines, perhaps having some other people around the world or around the country at least making these ma-

chines on accelerated basis, while we could fulfill the need that we are talking about with technology that already exists because the probability of finding a new technology—I hope we can find that but it strikes me that this kind of machine has some potential.

Finally, the last question for you, Dr. Collins. You know, I have been sort of puzzled by the conflicting data that I see and I am sure you see the same thing. The reports that came out of Massachusetts as to the number of people there that were asymptomatic, the people that the course of the testing, and New York that suggested over 20 percent of the people there had already had COVID–19, the prisoners tests as well in five states in the South which is our recall 93 percent of the people who had tested positive never had any symptoms, and then the experience of Sweden, which said we are really not going to test everybody and we are going to let the economy keep going.

Do we really need to have a kind of testing we are talking about or does this information suggests that given so many people that are asymptomatic—this was in a hearing yesterday with the Homeland Security Committee, the suggestion was between 50 and 90 percent of the people that get COVID–19 have no symptoms. If that is the case, should we let this run its course through the population and not try and test every person? I am saying that a bit as a strong man, but I am interested in your perspective.

Dr. COLLINS. I appreciate your putting it forward as a strong man because while it is true that lots of people seem to get this virus without any symptoms at all and the estimates are that maybe 60 percent of new cases are transmitted by such people, it is still the case that 74,000 people have died from this disease. And so the people who are out there infected who may not themselves be suffering are passing this on and becoming a vector to others who were vulnerable with chronic illnesses or in the older age group. And sometimes young people too.

Let's not say that they are immune. There are certainly plenty of sad circumstances of young people who really you would not have thought would be hard hit by this, who have gotten very sick or even died. So I think it is extremely unusual to have a virus like this that is so capable of infecting people without symptoms, but having them then spread it on.

We just haven't encountered something like that before but it doesn't mean that it is not a terribly dangerous virus for those people who aren't so lucky and who get very sick and end up in the ICU and perhaps lose their lives. The only way we are really going to put a stop to that is to know who the people are who are infected even if they have no symptoms, get them quarantined, follow their contacts. It is just good, solid shoe leather public health and we have learned it over the decades and it applies here too.

Senator ROMNEY. Thank you, Dr. Collins, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Romney.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman, and thank you for having this hearing, you and Ranking Member Murray. It is very, very important. I have been monitoring this and decided to come down. But I have been listening to a number of things and I want to first follow-up a minute on what Senator Collins said and al-

luded to with regard to foreign dependence on vendors for healthcare equipment. She was talking more in terms of prescription drugs, but obviously we have seen a lot of problems with regard to PPE, other healthcare manufacturing.

I have been working on a bill that we hope to file next week that will give tax incentives and other things to try to get those manufacturing, healthcare manufacturing into this country so that in any future endeavors and as we replenish the national stockpile we can do so with American-made goods. And I would encourage my colleagues on the Committee to take a look at that and perhaps join me on that. I also listened carefully to Senator Murkowski and Senator Scott's questions regarding the rural areas of the country and how important that is in their particular states.

Senator Scott in particular stole my questions, Dr. Collins, but I appreciated your answers very, very much. And so I would like to follow-up just a little bit on that because with all candor, we talked about rural areas, but we also talked about vulnerable populations yet we—and I think your word is that this pandemic has shown a spotlight on the health disparities in this country.

It is a phrase I have been using as well in my home state and I don't think—it is not lost on me that ironically we are having this discussion this week when just within the last 24, 48 hours, the administration has issued briefs in the U.S. Supreme Court attempting to dismantle a health care program that has given good health care and insurance to millions of Americans in this country not only through the exchanges but also through Medicaid expansion in any number of states.

Unfortunately, my State Alabama is one of 14 states that did not expand Medicaid, and so as part of those vulnerable populations in Alabama and those rural areas, I have got some 326,000 Alabamians that are without healthcare and without healthcare insurance and access to good healthcare and I find that just appalling when we have the opportunities. And so as we go forward, number one, I am hoping that we, the Congress, in its next package will consider ways to incentivize states to expand Medicaid the way we did under the ACA.

I am obviously hoping that the ACA remains viable and intact, but I would like for you to comment just a little bit. We have spoken a lot on the your RADx and I really appreciate that, but I would also like to figure out what we can do now that we have shown this spotlight to make these vulnerable populations less vulnerable not just to this pandemic, but to all of the pre-existing conditions that we see in these populations, and I would appreciate you may be commenting on that and how specifically we are going to get some of these testing and the distributions into those areas. Thank you, Dr. Collins. Thank you all so very much.

Dr. COLLINS. I appreciate the question. This is a matter of great passion I think for virtually all of the institute directors at NIH and we have an entire institute, the National Institute of Minority Health and Health Disparities, which is focused on this issue. And increasingly, the research that we are doing is going beyond trying to identify what the factors are that are responsible for health disparities. We learned pretty much about those into what we could

actually do about it in terms of interventions and demonstration projects.

That is what we are thinking of in this space by having these demonstration projects where you introduce the access to testing, introduce therefore connection to vaccines, you can actually change the dynamic instead of just studying it. We have studied health disparities a lot. It is time to take some actions.

We think as the largest supporter biomedical research in the world, we have a chance to do those things and really learn what works and then try to see if that can be extrapolated to the whole country.

Senator JONES. Would you agree that if something like this happens in the future, that one of the things we also focus on and use a spotlight to try to make sure that people with pre-existing conditions, we reduce the number of the vulnerable population, we reduce the number of folks with the pre-existing conditions by doing all we can to get good, affordable access to healthcare throughout this country?

Dr. COLLINS. That is what we need as long, with all the other things you need to do to reduce the incidence of obesity and diabetes and cardiovascular disease, all of these things which at the present time take a heavy toll on people from certain subgroups and we ought to be doing everything we can to prevent that.

Senator JONES. Great. Well, thank you, Dr. Collins. Thank you, Mr. Chairman. I appreciate it.

The CHAIRMAN. Thank you, Senator Jones.

Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. Patience pays off. I may be the last one. I am not sure. Testing, you hear it so often, to me it repeats what we all agree with. I would like to find out as you said South Korea kind of was the standard to maybe try to aspire to. If there is a test that they used that was part of their protocol, is that—was that a significant part of it or was it their hygiene, their sheltering, and all the other things that all of us are doing anyway? Because if there is a test that anybody else used wouldn't we want to have access to it?

Dr. COLLINS. I don't recall the details of their particular technology, but I don't think it was anything out of the ordinary. It was based upon using this PCR reaction to be able to identify the presence of the viral RNA genome and certainly the kind of test that we are doing lots of those in this country as well. I think it was more the speed with which they were able to set this up their access to be able to test people very quickly who had any symptoms and their very strong enforcement of such things as physical distancing, doing this in a country where people were also quite amenable to those recommendations. Maybe not quite as much in the sort of American zone of not necessarily where Government has to tell you——

Senator BRAUN. Which tests and which company would be closest to what they use there that we have here?

Dr. COLLINS. I think the kinds of ones you see now in companies like LabCorp and Quest would be the sort of thing that you have where it's a fairly high throughput but it is done in a central laboratory.

Senator BRAUN. What is the timeframe, and talking to a pharmaceutical company one of the few headquartered in Indiana, the CEO said that about 40 companies across the country, that it has been at a breakneck pace to get there, especially for the one that is quick for a country our size that is going to have reliable results. We hear so often and we heard it today, that we dawdled and that we didn't get there.

I would really like your opinion, and from what I heard from the people that are actually doing it, they have been working at this in an entrepreneurial at a feverish pace and they didn't even have the genome to work with until what maybe four months ago or so. What is your comment on that?

Dr. COLLINS. I think there has been an incredible amount of energy put into trying to do this testing. I just gave you a small example. At NIH up here in Bethesda, I have 25,000 employees. I want to be sure that they are safe. We didn't have access to easy testing for our own employees and we wanted to be sure if they were coming to work, that they weren't going to be infecting other people.

I asked our laboratory in the clinical center, which is a research hospital, to set up a lab test. And they were able to do that but the most tests we can do in a given day is in the hundreds, it is not in the tens of thousands. It is not simple to do this.

Senator BRAUN. It is not that we dawdled. It is the fact that we have got a country that is scaled much larger than say South Korea and then it is going to take a point to get the equipment in place to do it. Is that fair?

Dr. COLLINS. I think that is part of it and part of it is bringing on board with some of these new technologies, which is what RADx is all about to try to do this at a scale——

Senator BRAUN. That is going to take time in and of itself.

Dr. COLLINS. But we haven't had the need to do this kind of scale of testing. I mean the kind of testing we do now even for something like HIV or for hepatitis C, which is a lot of tests, it pales by comparison to what we need now for this. So we didn't have in the laboratory community the kind of capacity to take on this number of tests and all of a sudden there it was.

Senator BRAUN. Very good. And answers one question for me. Last question would be, and we have touched on it a little bit here, Senator Romney, Senator Jones talked about it, that idea of the broad methodology where we took an approach say similar to Sweden where you let herd immunity be the approach. Yes, I know.

Could we have built an iron dome around the most vulnerable in some fashion with better protocol to where it would have been different from a one size fits all blanket approach that might have had difficulties to unfurl in this country just due to the nature of who we are as well? Could we have protected the most vulnerable if we had focused the available resources to where we could have contemplated a different approach since it seems to pass over so many people in a way where, they are asymptomatic. I am just throwing that out there as a question.

Dr. COLLINS. Yes, it would have to have been an iron dome that was pretty impenetrable because imagine that if just one case got in there and then again with the easy spread from people who

don't have symptoms pretty soon you have a nursing home situation in your iron dome. And in a certain way in this country we have been doing a version of the iron dome which is particularly with vulnerable people having them stay at home, keeping physical distance, making sure that other people around them are doing the same. It has been I would say a fairly successful enterprise when you see the flattening of the curves.

That has happened in many places. That didn't just happen because we got lucky. That happened because people went to considerable difficulties, and it did terrible damage to our economy, to try to save lives by this kind of sequestering of people so that they couldn't get fatal illnesses. But obviously what we really need to get back to where we all want to be is a circumstance where you don't have to do that anymore. That is why the vaccine is so prominent in our minds, and until we had the vaccine, the idea for the testing to identify people and get them quarantined if they are actually already incubating this virus.

It has got to be that mix, the diagnostics, the therapeutics, and vaccines. Don't let anybody tell you, what if we just did one of those it will be alright. We have to do all three.

Senator BRAUN. Thank you.

The CHAIRMAN. Thank you, Senator Braun.

Senator Rosen.

Senator ROSEN. Can everyone hear me Okay?

The CHAIRMAN. Yes, we can hear you.

Senator ROSEN. Thank you. I guess I think I get the luxury of being the last question. I hope it is a good one. I really appreciate Chairman that you set up this hearing and I appreciate the scientific research that the doctors are doing in their teams. I know how important it is. I know you have been working around the clock in Nevada. Of course, the seriousness of the pandemic is very real. We have had strict lockdown order, social distancing. We are beginning to flatten our curve. Our hospitals aren't overwhelmed and we seem to be doing alright there.

But of course everyone has talked about how we reopen our economy in a way that is thoughtful, that is science-based, how we need diagnostic testing capacity, antibody all of that. I spoke about this yesterday, but Senator Rubio and I have introduced legislation to start a longitudinal study for COVID with NIH and CDC. It is going to be reporting to us every three months and six months and further as we go down so we can point to scientists and us as policymakers with data into some better directions as we collect that.

Dr. Collins, have you seen any studies yet on your end or are you doing any that will track those individuals, so we talked about the have the positive antibody test, see how long they stay in their system, and what that means? That is my first question there and then I have I will just give them all so you can answer them.

The Shark Tank program doesn't include the antibody test, only acute testing. Are we going to add the antibody test to that? And then, I am very concerned about unintended consequences when you talk about the Shark Tank. In this instance, we need researchers to collaborate all around the world.

The competitive nature of Shark Tank is going to spur people on. What are their unintended consequences of putting people in silos

where collaboration that we so desperately need right now are not happening to get the best results? So those are my three questions for you.

Dr. COLLINS. Those are great questions. In terms of the need to track people and to see what happens, and particularly as was brought up earlier, is the presence of antibody actually something you can say makes you immune? I think maybe our best chance at this is this program that Congress has funded and it is part of 21st Century Cures Act.

I have to specifically give a shout out to this Committee about that and the Chairman. And that is this program called All of Us, which is tracking, when we get there, a million people over time. We are already up to over 300,000 that have signed up and those individuals answer lots of questions, their electronic health records are available for researchers to look at after they have been anonymized, they give blood samples over the course of time so you can track and see, oh, it didn't have the antibody, then, oh, now it does have the antibody, what happened there? We should be able to utilize that for this and many other purposes to try to get some of those answers and I totally agree we need those.

Your second question about antibody testing, our sense was that the commercial community has done a pretty good job of getting anybody tests out there. Our scientists at the National Cancer Institute were asked by FDA to do the validation and they have been able to do so and a bunch of those, which was just published a couple of days ago, actually are really good in terms of their sensitivity and specificity, so there seemed to be less of a need to make a big investment in the antibody testing area.

But I would say if we have a new technology that would give a twofer where you could get both a virus test and the antibody test at the same time for a really good price, that might be something we would be pretty interested in. And finally, in terms of the unintended consequences of Shark Tank resulting in silos, we are going to do our darnest not to let that happen.

Our kind of a Shark Tank actually kind of discourages that kind of siloing because the advisers who are going to be helping each of these platform developers that have new technology to succeed, they are very well connected. They come from the business community. They are going to be constantly looking for ways that the technology developer ought to meet this particular company that has the ability to do the scale up and we will not let those sort of opportunities go by. We will watch for that closely.

Obviously there will be competition and the successful companies are going to want to be on top and that is what American capitalism success, which is what we need in this space too, but not in the point where it becomes destructive and people don't share information that we could all learn from.

Senator ROSEN. Thank you very much for your time and your work. And I will yield my last few seconds back.

The CHAIRMAN. Thank you, Senator Rosen. I am going to call on Senator Murray just a moment for her closing remarks and then I am going to wrap up the hearing. We told our witnesses they could leave by 12:45 p.m. So if Senators could ask any other questions they have for the record and we will have an opportunity on

Tuesday because we have a hearing Tuesday on back to school and back to work which includes Dr. Fauci from NIH, Dr. Redfield, the head of CDC, the head of FDA, Dr. Hahn, and Admiral Giroir, who is in charge of testing.

The questions will be relevant to them. For those who might be watching, I want to assure you we are following the rules that the Attending Physician told us. We are socially distant. We have worn our masks and he said we could take them off while we were asking questions and we will put them back on as we leave.

I thank the Senators who have joined by video and I hope we have had an audience because this has been a very interesting time. Now, let me call on Senator Murray and after that we will conclude the hearing.

Senator MURRAY. Mr. Chairman, thank you so much for doing the hearing. I do have a number of other questions. I especially wanted to ask Dr. Collins about the racial and ethnic disparities and how he is going to ensure testing and diagnostics and the agency's partnerships are going to be deployed to communities in need and several others. I will submit those for the record, but Dr. Collins, I hope that you and I can talk about that in the future. And thank you to both of our witnesses today.

Mr. Chairman, I want to thank you. I do really want to thank our witnesses for coming in today circumstances, but I also really want to thank all the Senate employees, especially those who were required to come to the campus today. We really owe it to all of you and your families and your communities to take adequate safety precautions and I am pushing hard to make sure that happens. I also want to really thank everybody who helped set up the technology to make this hearing possible.

You know, our country has really grappled with a world of change since our last hearing on coronavirus and my gratitude goes out to our healthcare and public healthcare heroes to our essential workers, to our families across the country who have made sacrifices, both big and small to help slow the spread of this. And my heart goes out to everyone who is struggling with this awful disease themselves, the illness or loss of a loved one, or they are very real mental health effects of isolation and loneliness and stress and trauma.

But one thing has not changed since our last hearing, even though it has been over two months since President Trump said anyone who wants a test can get one, it still is not true. And that is not going to change if the President continues to deny the severity of this crisis to insist it is not his problem and to silence those who wanted the truth to be told.

While President Trump has yet to show the leadership or type of detailed national plan I think he should, I am not going to stop pushing on this because our families and our communities and our country cannot afford to keep waiting to finally get our response to this crisis on the right track. So thank you very much for having this hearing, Mr. Chairman, and I look forward to our next one as well.

The CHAIRMAN. Thank you, Senator Murray, and thanks for your cooperation and that of your staff and all the employees always in arranging for this hearing and the one on Tuesday. Just a few com-

ments as we wrap up. According to Johns Hopkins, as well as President Trump, the United States has conducted 7 million diagnostic tests. That is more per capita than South Korea, for example, and that is a very impressive total.

This hearing is about needing millions of more tests, but that is because of the uniqueness of the situation not because we don't conduct a lot of tests today. For example, my State of Tennessee, the Governor has been pretty aggressive on testing.

For example, he is testing everybody in the state prisons. He has drive-through testing on the weekends in many parts of our state. I began my testimony or my statement today with the nursing home in Franklin, Tennessee that has tested all 2,500 of its residents and staff. So we have been able to find that number of tests for those kinds of activities yet it is not enough for me to assure the president of the University of Tennessee, with whom I talked, that she will be able to have enough tests to assure students and faculty it is safe to come back.

On the other hand, I talked to a professor at University of California at Berkeley and he has converted his own laboratory into a laboratory that he believes can test everybody on the Berkeley campus within a week if they wish to be so tested. So while this is a hearing about needing tens of millions more tests, already having 7 million test, no country in the world has tested that many people for coronavirus.

I want to emphasize also the effort. I know that Senator Blunt, I, many others, we understand that in your RADx Shark Tank program there will be failures. In fact, if there are not failures, you are probably not doing your job because failure can mean it doesn't work or it doesn't work well enough to be scaled up fast enough to help the schools and to be ready for this education season and the flu season as it comes on.

We understand that and we support the idea that there may be failures. On the other hand, going to Senator Rosen's comment, the closest thing to this I remember is when I was the Education Secretary and David Kearns was the Deputy under H.W. Bush, we sent out a solicitation for ideas for new American schools.

There was a lot of money available. We were deluged with good ideas, only a few could win, but we gave a citation to so many others and we may have gotten more bang for our buck out of the ones that didn't win than the ones who did because it unleashed so much enterprise and opportunity. And as you said, maybe that will produce the test or the platform that can be used for the next virus or maybe it will introduce a really bright scientist to a manufacturing company that is looking for such a person.

I can see all sorts of dividends coming from this enterprise other than the one or two or three or four new technologies that will allow us to produce tens of millions of diagnostic tests so we can number one, identify all those with the disease—and they are not many of us. I don't know number. Maybe it is 3. Maybe it is 5. Maybe it is 7 percent. We really don't know. But those of us who are sick, those of us who are exposed, that will permit us to track and quarantine that percentage of us and then the rest of us can go back to work and back to school.

Right now, we have been quarantining the whole country because we are unable to identify just those who are sick or those who were exposed. We—that works, but it causes a terrible price to pay on our economy. I would like to also mention that tests are free. I mean Congress and the administration have made sure that if you take a COVID–19 test, it is free. You are—either your insurance company or the Government is going to pay for it. And that is also true with the antibody test.

First test is whether you have it and the antibody test is whether you have had it. And on those tests, at least in the conversations Senator Blunt and I had with a large number people, sounds like the private sector is well on their way with the serology are antibodies tests that we are not likely to have any problem with shortages of those over the next six months. Although the FDA has a job to do in making sure that we know which ones are accurate and which ones are not. So let me complete conclude the hearing with the appropriate words or I will be in trouble.

The hearing record will remain open for 10 days. I want to especially thank Dr. Collins and Dr. Disbrow for being here today. We are counting on you to do something that doesn't always happen in Government, which is unleashing the private sector, taking advantage of the best of it, and then letting our agencies collaborate and work together and not be sunk into their individual silos.

We need for Dr. Collins to find the new technology with the help of Dr. Disbrow who will say, well that may be a great idea, but I can't scale it up, and then we need for Dr. Disbrow to work with all the manufacturing people that he knows to make sure we can produce tens of millions of them so that we can go back to work and back to schools. Members may submit additional information for the record within the next 10 days if they would like.

The CHAIRMAN. As I have mentioned, we will meet again at 10 a.m. on Tuesday, May 12 for our hearing on COVID–19, safely getting back to work and back to school. Thank you for joining us today. The Committee will stand adjourned.

ADDITIONAL MATERIAL

Covid–19 has shuttered scientific labs. It could put a generation of researchers at risk

By Justin Chen May 4, 2020
Reprints *https://www.parsintl.com/publication/stat/*.

Scientists are skilled at tackling unexpected problems that threaten the integrity of their experiments—it comes with the territory. But the coronavirus pandemic poses a new—and entirely unprecedented—challenge.

The global health emergency has shut down scientific research labs across the country in a crisis that has left some scientists scrambling to save their work—and has left others grieving the loss of experiments they had dedicated months or even years to carrying out. Many are grappling with an overwhelming sense of uncertainty about how they'll continue their work.

The situation has hit early career researchers particularly hard. Their funding—and their futures—depend on quickly gathering data to publish in prestigious journals. Without additional financial support and an extension of tenure clocks, some scientists who have just started their own labs fear the delays to their studies may be too disruptive to overcome.

> "Early career scientists will be very vulnerable," said Cullen Taniguchi, assistant professor at University of Texas MD Anderson Cancer Center. Taniguchi said it will be crucial to properly support researchers when labs

> reopen—or, he warned, "we may lose a whole generation of researchers because of this."

Related: Patients, drug makers grapple with how to continue cancer trials during the coronavirus *https://www.statnews.com/2020/04/29/patients-drug-companies-grapple-cancer-trials-coronavirus/*.

Despite these struggles, many researchers say that shutting down the labs was necessary to stem the spread of the virus. And some labs are still up and running, though not all are doing so at full capacity. But for scientists whose work has been deferred, the closures have fueled a devastating ripple effect of consequences, both big and small.

Even when laboratories are reopened, it may take months to a year for research to resume as normal.

> "I have [new hires] in the lab that haven't even met each other physically," said Alice Soragni, a cancer researcher and assistant professor who runs a lab at the University of California, Los Angeles. "There is a lot of training that needs to have happened that hasn't happened," she added.

STAT spoke to scientists across the country to better understand the wide-ranging impacts of lab shutdowns.

In Portland, Ore., a scientist races to save her research—and then grieves its loss

Scientists have transitioned from long hours in the laboratory to working from home—but the abrupt halt to their research projects has left a lingering sense of disorientation for researchers like Kathleen Beeson, a sixth-year graduate student at Oregon Health and Science University.

Like many of her colleagues, Beeson was caught off guard by her lab's closure.

> "We were given a week's notice," she said. "Immediately, I and others were in a race to finish experiments, collect any data that we could, and get the lab prepared for a minimum of six weeks of shutdown."

Beeson had been completing a final experiment for a publication she needs to earn her Ph.D. and move onto a postdoc research position at Harvard Medical School.

The shutdown has upended Beeson's research, which involves measuring electrical activity in the brains of genetically engineered mice. Her work aims to describe how proteins at the junction of nerve cells help transmit chemical signals—an important step in understanding neurological dysfunctions such as epilepsy.

While other scientists were able to freeze cells or preserve tissue samples in formaldehyde, Beeson's research relied on analyzing freshly dissected brain tissue. Because she could no longer come into the lab, she had to sacrifice most of her mouse colony, which she had painstakingly raised from one male and one female to approximately 200 animals.

> "In the end, I found myself euthanizing mice by the masses in the university basement," she said. "It was the punctuation on a sad and disorienting week."

Beeson said it will likely take her months to raise enough animals for experiments again. In the meantime, she has been working on her Ph.D. dissertation and a second publication from home—although not at the pace that she had hoped for.

> "I applaud anyone making any progress, on anything, during this time," she said. "Sometimes my progress is processing my grief."

In Los Angeles, an early career researcher confronts 'exquisite challenges'

Disruptions to research and long startup times pose an especially daunting challenge to early career scientists who have just a few years to establish themselves as experts in their fields and obtain critical funding for their laboratories.

With experiments on hold, some early career scientists can't collect the kind of preliminary data that is crucial for them to compete with more established researchers who have a decade or more of experimental findings to build on.

> "[All researchers] are impacted but I think there are exquisite challenges for early career investigators like myself," said UCLA's Soragni.

To protect early career scientists, the NIH has extended the timeframe for which researchers can be considered "early stage investigators"—a status that helps gov-

ernment institutes and centers prioritize funding for scientists running new laboratories. The agency has also relaxed some of the eligibility requirements for maintaining grants and added additional flexibility for spending funds.

Despite these welcome efforts, early-career researchers—especially those lacking data needed to apply for new grants—remain in a precarious position. Soragni and others said they hoped the NIH would take the impact of Covid–19 into account and temporarily adjust its criteria for reviewing applications. However, the agency has recommended that scientists without enough preliminary data submit their applications at a later date.

For Soragni, the most difficult challenge has been the uncertainty.

"You are kind of left not knowing what you should do. . . . Should you be ramping up completely? But what if you are switched down again?"

ALICE SORAGNI, UCLA CANCER RESEARCHER

> "We really don't know if we are going to have a second wave of infections and what will be the consequences," she said. "You are kind of left not knowing what you should do. . . . Should you be ramping up completely? But what if you are switched down again? Should you be hiring? Will the economy bounce back? What is going to happen to your grants?"
>
> "We are just at a more vulnerable stage of our career," Soragni said. "I believe we may lose some laboratories to this, so that will be very painful to witness."

In Atlanta, a postdoc grapples with saying goodbye to a mentor

The shutdowns have taken a toll not only research, but also on the close professional relationships at the heart of scientific collaboration.

COURTESY STEPHANIE CAMPOS

For Stephanie Campos, Covid–19 meant that she would not complete her research or be able to say goodbye to her mentor, Walter Wilczynski, in person. Campos had come to Georgia State University for a postdoctoral fellowship with Wilczynski, a pioneer in the field of behavioral neuroscience and the first director of the university's Neuroscience Institute. But after 37 years of research, the lab was scheduled to close this summer after Wilczynski's cancer, once in remission, returned.

Campos and her colleagues were wrapping up their research—a study of the brain activity in lizards aimed at unraveling the neural underpinnings of social behaviors—when the pandemic hit. The lab shuttered earlier than expected.

Related: Covid–19 Drugs and Vaccines Tracker *https://w.w.statnews.com/2020/04/27/drugs-vaccines-tracker/*.

With the laboratory closed, Campos has been limited to writing manuscripts from home and analyzing old videos of lizard behavior. She can't see Wilczynski—who is immunocompromised—again in person before she moves to a new role as a visiting assistant professor at Swarthmore College.

> "[This experience] has really affected me emotionally in the way that I knew I was going to be his last student," Campos said. "And so I had really wanted to get as much as I could."

With Georgia easing restrictions on social distancing, there is a possibility that Campos could return to the lab late in the summer, but she is still unsure if returning to work would be socially responsible. Instead, she is planning on mailing the bulk of her delayed research project—which involves 68 lizard brains preserved in vials of paraformaldehyde—to Pennsylvania, where she will begin work in August.

Campos credits Wilczynski, who was at times too fatigued to read papers, for guiding her through the gauntlet of an academic job search and giving her the confidence to continue in academia.

> "His kindness during this time is what I'll remember the most," Campos said. "For me it is all about the personal connection, how well your mentors make you feel. Those are the things that I will take away."

In Boston and Baltimore, lab leaders plan for a new rhythm

Waiting for their labs to reopen, principal investigators are steeling themselves for the months of effort that will be needed to reestablish the rhythms of a productive laboratory.

There's a mountain of work to muddle through before experiments can get off the ground again.

> "We will have to first retest [our equipment] to make sure it is working, regrow our [bacterial] cultures, which takes a while, before we can even consider doing an experiment," said Eric Rubin, an immunology and infectious diseases researcher and professor at the Harvard T.H. Chan School of Public Health. Rubin also the editor-in-chief the New England Journal of Medicine.

Regrowing bacteria in Rubin's laboratory is not a job for the impatient. The focus of his studies, Mycobacterium tuberculosis, causes tuberculosis and kills more people worldwide than any other infectious pathogen. M. tuberculosis also grows approximately 50 times more slowly than other microorganisms. Experiments that would take a day with other commonly studied bacteria typically take weeks in the Rubin lab.

Related: Infect volunteers with Covid–19 in the name of research? A proposal lays bare a minefield of issues *https://w.w.w.statnews.com/2020/05/01/infect-volunteers-with-COVID-19-in-the-name-of-research-a-proposal-lays-bare-a-minefield-of-issues/*.

When laboratories closed, Rubin's team was in the midst of testing a batch of promising drug compounds for the ability to kill the bacteria. To resume the study, researchers will have to thaw out stocks of frozen bacteria and coax them to replicate in liquid broth.

> "We normally always have things growing so that we can grab them and do our next experiment," said Rubin. "[But now] it will likely take four months before we will have enough cells to do experiments at full tilt again."

Restarting research may take even longer—up to a year—for those working with laboratory animals, such as Subhash Kulkarni, a scientist and assistant professor at Johns Hopkins University School of Medicine.

In 2017, Kulkarni showed that, contrary to established dogma, nerve cells lining the intestines continue to grow and divide in adult animals. To understand how this discovery could lead to new treatments for digestive disorders, Kulkarni had begun analyzing how neurons behaved over the lifespan of a mouse. This project required raising genetically engineered mice at staggered times to have enough of each age group at the start of the study.

With his lab closed, the entire effort will have to be repeated once Kulkarni is allowed to work again. That timeline is daunting.

> "Think of this as the time when the planets are in perfect alignment," Kulkarni said. "Once that time is lost, making the next time requires [new] breedings, which can take anywhere from six to 12 months."

[Whereupon, at 12:54 p.m., the hearing was adjourned.]

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