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COVID–19: SAFELY GETTING BACK TO WORK AND BACK TO SCHOOL

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING COVID-19, FOCUSING ON SAFELY GETTING BACK TO WORK AND BACK TO SCHOOL

MAY 12, 2020

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C O N T E N T S

STATEMENTS

TUESDAY, MAY 12, 2020

COVID–19: SAFELY GETTING BACK TO WORK AND BACK TO SCHOOL

Tuesday, May 12, 2020

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

The Committee met, pursuant to notice, at 10:03 a.m., in room 106, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. Well, good morning. The Committee on Health, Education, Labor, and Pensions will please come to order.

First, some administrative matters. Based on the advice of the attending physician and the Sergeant at Arms, after we consulted the Department of Health and Human Services and the Centers for Disease Control and Prevention, individuals in the hearing room are at least 6 feet apart. As a result, there is no room for the public to attend in person. Representatives of the press are working as a pool to relay their observations to colleagues.

The hearing may be watched online. An unedited recording will be available on the Committee's website, *www.help.senate.gov*

Witnesses are participating by videoconference in a one-time exception. Some Senators, including the Chairman, are participating by videoconference. Senators, we have been advised, may remove their masks, talk into the microphone when they are in the hearing room as they are 6 feet apart.

I am grateful to the Rules Committee, Sergeant at Arms, the Press Gallery, the Architect of the Capitol, the Capitol Police, Committee staff Chung Shek and Evan Griffis, all for their hard work to keep us safe.

At our hearing last Thursday, I said that all roads back to work and back to school run through testing, and that what our Country has done so far on testing is impressive, but not nearly enough. Over the weekend, Senator Schumer, the Democratic leader, was nice enough to put out a Tweet quoting half of what I said. He left out the other half, the impressive part.

Let me say again what I meant by that. When I said impressive, I meant that, according to the Johns Hopkins University study, the

United States has tested over nine million Americans for COVID–19. That is twice as many as any other country. We do not know what China has done. And, it is more per capita than most countries, including South Korea, which many Members of our Committee had cited as an example of a country that had tested well. According to Dr. Deborah Birx, the United States will double testing in the month of May, which should get us up to about 10 million tests conducted.

Now, here is what I mean by impressive here in Tennessee, where I am today. First, anyone who is sick, first responder, or healthcare worker, can get tested. Our Governor, Bill Lee, is also testing every prisoner, every resident and staff member in a nursing home. He has offered weekend drive-through testing. He has done specific outreach for testing to low-income communities. A Tennessean can get a free test at the local public health department. The Governor's slogan is, "If in doubt, get a test."

Governor Lee sent his testing goals in May to the Federal Government, as every state has done. The Federal Government is helping him make sure that he has enough supplies in case he has trouble getting them through the labs and the other commercial sources. As a result, our state has tested about 4 percent of the population. The Governor hopes to increase that by 7 percent in May. That is one of the best in the country.

This impressive level of testing is sufficient, we believe, to begin Phase 1 of going back to work. But, as I said last week, it is not nearly enough to provide confidence to 31,000 students and faculty members that we hope will show up at the University of Tennessee campus in August when school starts.

Last week, I talked with U.T. Knoxville Chancellor, Donde Plowman, about that. We said, what would persuade those 31,000 students, as well as the 50 million K through 12 students in the country and the other 5,000 university students, what will persuade them to go back to campus in August?

That is where the new Shark Tank comes in. Dr. Collins at the National Institutes of Health calls it RADx. We had our hearing about that on Thursday. It is a really remarkable scientific exercise to take a few early stage concepts that are swimming around in what we call that competitive Shark Tank to see if Dr. Collins and his associates can find a few new technologies to create millions of new tests that will scale up rapidly and make it more likely that students will go back to school in August.

For example, the FDA authorized last week its first diagnostic test using saliva that a person provides at home instead of a nose swab or blood. It authorized its first antigen test—we are hearing a lot about those—like the ones used for flu or strep throat, which involves the swabbing of a nose, and you can get the result in just a few minutes.

Another proposal not yet approved is to put in your mouth a sort of lollipop sponge, take a photo of that with your cell phone, and send that to your doctor. If it lights up, you are positive. Or, the university might send that saliva lollipop to a nearby laboratory, which could be a gene sequencing laboratory, which can deal with thousands of those samples overnight. That same process could occur at a middle school. It could occur at a factory.

Of course, anyone testing negative one day can test positive the next. But, such widespread screening of entire campuses, schools, or places of work will help identify those who are sick, trace down those who are exposed. That, in turn, should help persuade the rest of us to go back to school and back to work.

In addition to more testing, I expect Dr. Fauci to talk to us about additional treatments that will be available to reduce the risk of death, and the administration's plan to do something that our Country has never done before, which is to start manufacturing a vaccine before it actually has been proven to work in order to speed up the result in case it does work.

Those vaccines, those treatments, are the ultimate solution. But, until we have them, all roads back to work and school go through testing. The more tests we conduct, the better we can identify those who are sick and exposed, and we can quarantine the sick and exposed instead of trying to quarantine the whole country.

Now, in my opinion, this requires millions of new tests, many from new technologies. Some of these will fail, but we only need a few successes to get where we want to go. That is why I said on Thursday that what our Country had done so far in testing is impressive, but not nearly enough. First, squeeze all the tests we can out of current technologies. Next, try to find new technologies to help us contain the disease and persuade us to go back to work.

Now, one other thing. This is a bipartisan hearing to examine how well we are preparing to go safely back to work and to school, and to determine what else we need to do in the U.S. Senate. Such an exercise sometimes encourages finger pointing. Before we spend too much time finger pointing, I would like to suggest that almost all of us, the United States and almost every country so far as I can tell, underestimated this virus; underestimated how contagious it would be; underestimated how it can travel silently in people without symptoms to infect other people; how it can be especially deadly for certain segments of our population—the elderly, those with pre-existing conditions, minority populations.

Let me go back to the March 3d hearing that we had in our Committee on coronavirus. Six weeks after the first case was discovered in the United States, a day when only two deaths were recorded in this country, I read at that hearing this paragraph from the *New York Times* two days earlier on March the 1st.

They reported this. "Much about the coronavirus remains unclear," the *Times* reported, "and it is far from certain"—this is March 3rd—March 1—"that the outbreak will reach severe proportions in the United States or affect many regions at once. With its topnotch scientists, modern hospitals, and sprawling public health infrastructure, most experts agree, the United States is among the countries best prepared to prevent or manage such an epidemic." That was the New York Times on March 1.

A lot of effort has gone into trying to make our Country well prepared. Over the last 20 years, four Presidents, several Congresses, in response to 9–11, bird flu, Katrina, Ebola, H1N1, MERS, passed nine major laws to try to help get this country ready for what we are going through today. These laws stood up the strategic national stockpile, created an Assistant Secretary for Preparedness. It created incentives for the developments of vaccines and medicines that

we are using today, strengthened the Centers for Disease Control, created BARDA. Thanks to the leadership of Senator Blunt and Senator Murray for five straight years, we have significantly increased funding for the National Institutes of Health.

All of this was part of a shared goal—Democrats, Republicans, four Presidents, several Congresses—to try to get ready for what we are going through today, whether it was known, like anthrax, or unknown, like COVID–19. But, despite all that effort, even the experts underestimated COVID–19.

This hearing is about how we improve our response to this virus, as well as the next one. During the Oversight hearing, I also intend to focus on, as I just said, the next pandemic, which we know is coming.

What can we learn from this one to be ready for the next one? Can we—what can we learn from the fast-tracking of vaccines and treatments that we are about to hear about that will make it even faster the next time? How can we keep hospitals and states from selling off protective equipment when their budget gets tight? How can we make sure Congress does our share of the funding responsibility? How do we provide enough extra hospital beds without canceling elective surgery or hurting other patients and bankrupting hospitals? Whose job should it be to coordinate supply lines so that protective equipment and supplies get where they are supposed to go when they are supposed to go? What is the best way to manage the stockpile?

My preacher once said, I am not worried about what you do on Sunday; it is the rest of the week that concerns me. I am afraid that during the rest of the week, between pandemics, we relax our focus on preparedness. We become preoccupied with other important things. Our collective memory is short. Just 3 months ago, this country was preoccupied with impeaching a President. Now that seems like ancient Roman history.

Now, while this crisis has our full attention, I believe we should put into law this year whatever improvements need to be made to be well prepared for the next pandemic. If there is to be finger pointing, I hope they are pointed in that direction.

We are fortunate today to have four distinguished witnesses who are at the heart of the response to the coronavirus. We are grateful for their service to our Country. I have asked them each to summarize their remarks in 5 minutes. Then we will have 5-minute rounds of questions from each Senator. I have agreed we will end our hearing about 12:30, after we have a full round of questions. Every Senator will have a chance to have his or her 5 minutes. Senator Murray will then have an opportunity to ask the last question or to close the hearing, and I will then close the hearing. There will be other hearings to follow this hearing, like last Thursday's hearing, and Senators may submit their questions in writing within the next 10 days.

Staying at home indefinitely is not the solution to this pandemic. There is not enough money available to help all those hurt by a closed economy. All roads back to work and back to school lead through testing, tracking, isolation, treatment, and vaccines. This requires widespread testing, millions more tests, created mostly by new technologies, to identify those who are sick and who have been

exposed so they can be quarantined. And, by containing the disease in this way, give the rest of America enough confidence to go back to work and school.

For the near term, to help make sure those 31,000 U.T. students and faculty members show up in August, we need widespread testing. Millions more tests, created mostly by new technologies, to identify those who are sick and who have been exposed so they can be quarantined. By containing the disease in this way, give the rest of America enough confidence to go back to work and back to school.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. My thoughts are with you and your team right now as you try to navigate the same challenge so many in our Country are worried about. We all wish your staff member a speedy recovery. And, as everyone works to take appropriate safety precautions today, I would like to thank not only our witnesses for joining us today, but also our Committee staff for working to set up a safe format for Members and witnesses and the public to participate in this hearing remotely.

Families across the country are counting on us for the truth about the COVID–19 pandemic, especially since it is clear they will not get it from President Trump. Truth is essential so people have the facts, so they can make decisions for themselves and their families and their communities. Lives are at stake. If the President is not telling the truth, we must, and our witnesses must, and we are counting on you today.

Families need us to take this opportunity to dig into the facts about where things did go wrong so we can finally get them on track because the Trump administration's response to this public health emergency so far has been a disaster all on its own.

Delays, missteps have put us way behind where we need to be on diagnostic tests and allowed inaccurate antibody tests to flood the market. Corruption and political interference have impeded efforts to secure desperately needed personal protective equipment and promoted dangerous, unproven treatments. And, we recently learned that after experts at the Centers for Disease Control and Prevention spent weeks developing a detailed guide to help our communities understand how to safely reopen when the time comes, the Trump administration tossed it in the trash bin for being too prescriptive.

But, this is far from the first time this administration has silenced experts who were doing their job and putting public health first. The fact of the matter is, President Trump has been more focused on fighting against the truth than fighting this virus, and Americans have sadly paid the price.

Since this Committee last heard from these witnesses on March 3d, we have seen over 900 deaths in my home State of Washington, over 80,000 deaths nationally, and the numbers continue to climb. Still, President Trump is trying to ignore the facts and ignore the experts, who have been very clear we are nowhere close to where we need to be to reopen safely. My hope today is that we can cut

through this and have a serious discussion about what is needed to safely open, how close we are as a country to meeting those needs, and how we actually get there.

One thing that is abundantly clear, we need dramatically more testing. It is unacceptable we still do not have a national strategic plan to make sure testing is free, fast, and everywhere. That is why I fought to make sure our last COVID–19 package included an initial $25 billion testing fund and a requirement that the administration submit a plan by May 24th.

When I say a plan, I do not mean a PR plan. I mean a plan with specific timelines and numeric goals for supply and funding needs; one that actually addresses the issues we are seeing on testing capacity and distribution and disparities and building out our public health system; and makes clear to states and tribes and employers and the American people what they can expect and what the administration will do to keep Americans safe.

But, testing alone will not be enough to reopen our Country. We still need far more personal protective equipment than has been available for our healthcare workers on the front lines, and we will need far more for other workers as we reopen.

We desperately need this administration to step up and get that equipment to states, who are doing everything in their power to purchase supplies but simply cannot get nearly enough. Because, the reality is, unlike states, the Federal Government has the tools to actually fix the problem, if only the administration would use them.

We also need that equipment to actually work, and for the FDA to act promptly if it does not; not weeks later when people may have already been exposed.

Just as importantly, we cannot expect people to go back to work or to restaurants or to confidently send their kids to school if there is not clear, detailed guidance about how to do that safely.

Schools, from early childhood through college, need to know how to keep their students, their staff, and their educators safe. When should they wear masks? How do you run a school cafeteria or a school bus? And, if they cannot reopen classrooms, schools and families need to know we are working to ensure every student gets an education.

Tools like online learning can only get us so far if we do not address the digital divide that—so that every student can access them. And, even then, there will be learning loss that could deepen existing educational disparities among low-income students, students with disabilities, English language learners, and other vulnerable populations if we do not make sure they get equal access to resources and support.

Of course, schools are not the only workplaces we have to be thinking about. We need to make sure that industries across the country know how to safely reopen and that people know their workplace is safe. Secretary Scalia needs to stop dragging his feet and do his job and have the Department of Labor set forward a rule that makes clear worker safety is not optional.

Mr. Chairman, I hope this Committee can hear about those critical issues from Secretary Scalia and Secretary DeVos, as well as other experts in the space in the days ahead.

This is especially important to protect workers and residents at our nursing homes and other congregate care facilities where we have seen some of the most deadly outbreaks. And, as the rash of outbreaks at meatpacking plants shows, this is not just an issue for the healthcare industry. It is an issue for everyone.

Just as we need a plan before we can start to reopen, we also need a plan well before we have a safe and effective vaccine to guarantee that we can quickly produce and distribute it on a global scale, and make it free and available for everyone. So, I will be asking about our progress on those issues today.

Today, safely reopening our Country may be a ways off, and the administration's planning may be way behind, but there is still a lot that Congress needs to do. There is not time to spare. Some, including the White House, say we have already provided enough economic relief. Well, my question to them is, what good is a bridge that only gets you to the middle of the river? We do not need to wait around to see if people need more help. We know they do. We need to work quickly on another aggressive relief package, and we need to make sure our priorities in that bill are protecting our workers, our students and our families, and addressing this public health crisis, not bailing out corporations or protecting big business from accountability.

People across the country are doing their part. They are washing their hands and wearing masks and social distancing and staying home. They need their Government to do its part, too. They need leadership. They need a plan. They need honesty, and they need it now, before we reopen, so they can rest assured that we are doing things safely and competently with their health and well-being as a top priority.

Thank you, Mr. Chairman.

The CHAIRMAN. This hearing, it is an important hearing, and I know lots of people may be watching it for the first time. If they are, I hope they notice that we have 23 Members of this Committee, I believe, one more Republican than Democrat. We have some very strong views, but we are able to work together and to express those views and respect each other and our witnesses, and I—and a big part of that goes to Senator Murray and her staff. So, thank you for that.

Each witness will have up to 5 minutes to give his testimony. Thank you for making an exception and agreeing to testify by video because of these unusual circumstances. And, thank you for what you are doing for our Country.

Our first witness is Dr. Anthony Fauci. He is director of the National Institutes of Allergy and Infectious Diseases at the National Institutes of Health. He has held that position since 1984, which meant he has advised six Presidents and worked on HIV-AIDS, influenza, malaria, Ebola, and other infectious diseases. He was involved in treating Ebola patients at NIH, and also worked on vaccine trials for Ebola.

Next, we will hear from Dr. Robert Redfield. He is director of the U.S. Centers for Disease Control and Prevention, which has its headquarters in Atlanta. More than 30 years, he has been involved with clinical research related to chronic human viral infections and infectious diseases, especially HIV. He was the founding director of

the Department of Retroviral Research within the U.S. Military's HIV Research Program. He spent 20 years with the U.S. Army Medical Corps.

Third, Admiral Brett Giroir. Admiral Giroir is Assistant Secretary for Health at the U.S. Department of Health and Human Services. That puts him in charge of development of public health policy recommendations. He has taken on the responsibility for coordinating testing and focused on the increasing number of tests that we can do with existing technology. His Federal service includes a variety of activities with our Defense Department in advanced research, threat reduction, and he was part of the Blue Ribbon Panel to reform the U.S. Veterans Health System.

Finally, we will hear from Dr. Stephen Hahn. He is Commissioner of the Food and Drug Administration. Before joining FDA, he was the chief medical executive of the University of Texas MD Anderson Cancer Center. He was chair of the Department of Radiation Oncology at the University of Pennsylvania. He was a senior investigator at the National Institutes of Health. He was commander of the U.S. Public Health Service Commissioned Corps from 89 to 95.

Now we will ask each of our witnesses to summarize their remarks in 5 minutes. Following that, each Senator will have 5 minutes for questions and answers in order of seniority.

Dr. Fauci, let us begin with you. Welcome.

STATEMENT OF ANTHONY FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD

Dr. FAUCI. Thank you very much, Mr. Chairman, Ranking Member Murray, and Members of the Committee. Thank you for giving me the opportunity to discuss with you today the role the National Institutes of Health has in research addressing COVID–19.

The strategic plan that we have is fourfold: One, to improve our fundamental knowledge of the virus and the disease it causes; next, to develop new point-of-care diagnostics; next, to characterize and test therapeutics; and finally, to develop safe and effective vaccines.

First, with regard to diagnostics. As you probably heard from Dr. Francis Collins last Thursday, the NIH has developed a Rapid Acceleration of Diagnostics Program, called RADx, with an award to that specific program up to a half a billion dollars to support the development of COVID–19 diagnostics. It is a national call for innovative technologies that will be evaluated in a Shark Tank-like selection process to get to either success or failure rapidly.

Moving on to therapeutics. I will talk a bit about the Remdesivir success antiviral in a moment, but let me emphasize that there are a number of broad-spectrum antivirals that are in various stages of testing.

In addition, we will be looking at convalescent plasma, which is plasma from individuals who have recovered from COVID–19, to be used in passive transfer either in prevention or treatment. In addition, hyperimmune globulin, which could be used as a gammaglobulin shot. We will be looking at repurposed drugs, as well as immune-based therapies and host modifiers. And finally, monoclonal antibodies.

Let me take a moment to describe the Remdesivir placebo-controlled, randomized trial, which was done internationally with the power of more than a thousand individuals in sites throughout the world. It was in hospitalized patients with lung disease. The endpoint was primarily time to recovery. The result was statistically significant, but really modest. And, we must remember it was only a modest result showing that the drug made a 31 percent faster time for recovery. We hope to build on this modest success with combinations of drugs and better drugs.

Moving on to vaccines. There are at least eight candidate COVID–19 vaccines in clinical development. The NIH has been collaborating with a number of pharmaceutical companies at various stages of development. I will describe one very briefly, which is not the only one, but one that we have been involved in heavily developing with Moderna. It is a messenger RNA platform.

You might recall in this Committee that in January of this year, I said that it would take about one year to 18 months if we were successful in developing a vaccine. The NIH trial moved very quickly. On January 10th, the sequence was known. On January 11th, the Vaccine Research Center met to develop a plan. On the 14th of January, we officially started the vaccine development. Sixty-two days later, we are now in Phase 1 clinical trial with the two doses already fully enrolled. There will be animal safety. The Phase 1 will directly go into Phase 2/3 in late spring and early summer. And, if we are successful, we hope to know that in the late fall and early winter.

There are some important issues, however, in COVID–19 vaccine development. We have many candidates and hope to have multiple winners. In other words, it is multiple shots on goal. This will be important because this will be good for global availability if we have more than one successful candidate.

We also, as the Chairman mentioned, will be producing vaccine at risk, which means we will be investing considerable resources in developing doses even before we know any given candidate or candidates work. I must warn that there is also the possibility of negative consequences, where certain vaccines can actually enhance the negative effect of the infection. The big unknown is efficacy. Will it be present or absent, and how durable will it be?

Finally, I want to mention the NIH has launched a public-private partnership called Accelerating COVID–19 Therapeutic Interventions and Vaccines. The purpose of that is to prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential.

Hopefully, our research efforts, together with the other public health efforts, will get us quickly to an end to this terrible ordeal that we are all going through.

Thank you very much. Happy to answer questions later.

PREPARED STATEMENT OF ANTHONY FAUCI

NIH is the HHS agency leading the research response to COVID–19 and the novel coronavirus that causes it, SARS-CoV–2. Within NIH, NIAID is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID–19.

NIAID responds rapidly to threats of infectious diseases as they emerge, by accelerating fundamental basic research efforts, engaging a domestic and international

basic and clinical research infrastructure that can be quickly mobilized, and leveraging collaborative and highly productive partnerships with industry. NIAID also provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research on emerging and re-emerging infectious diseases. These research resources help bridge gaps in the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by product developers and incentivizing companies to partner with us in developing safe and effective countermeasures including vaccines, therapeutics, and diagnostics.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has improved our fundamental understanding of coronaviruses and provides a strong foundation for our accelerated efforts to address the challenge of COVID–19 by developing vaccines, therapeutics, and diagnostics.

Developing Vaccines to Prevent SARS-CoV–2 Infection

A safe and effective vaccine for SARS-CoV–2 will be essential to stopping the spread of infection, reducing rates of morbidity and mortality, and preventing future outbreaks. NIAID is supporting development of several SARS-CoV–2 vaccine candidates, including vaccines based on platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

The NIAID Vaccine Research Center has collaborated with the biotechnology company Moderna, Inc., to develop a vaccine candidate using a messenger RNA (mRNA) vaccine platform expressing the SARS-CoV–2 spike protein. On March 16, 2020, NIAID initiated a Phase 1 clinical trial of this experimental vaccine at the Kaiser Permanente Washington Health Research Institute, and later added clinical sites at Emory University and the NIH Clinical Center. This trial was recently expanded to enroll older adults to better define the safety of and immune response to the vaccine across various age groups. The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA plans to support advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories (RML) are collaborating with University of Oxford researchers to develop a SARS-CoV–2 chimpanzee adenovirus-vectored vaccine candidate, now in a Phase 1/2 clinical trial supported by the University of Oxford. RML investigators also have partnered with University of Washington scientists to investigate another mRNA vaccine candidate against SARS-CoV–2. NIAID is working with additional academic and industry partners to develop several other vaccine concepts.

The rigorous clinical testing required to establish safety and efficacy means that it might take some time for a licensed SARS-CoV–2 vaccine to be available to the general public. The COVID–19 response currently is focused on the proven public health practices of containment and mitigation.

Identifying Therapeutics to Treat COVID–19

Effective therapeutics for COVID–19 are critically needed to treat many patients globally who have been infected with SARS-CoV–2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial to evaluate the safety and efficacy of therapeutics for COVID–19, initially examining the antiviral drug Remdesivir for treatment of COVID–19 in hospitalized adults. The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the immunosuppressive drug baricitinib, which was recently added to the study. An analysis of preliminary data from 1,063 patients enrolled in the trial indicated that those who received Remdesivir had a 31 percent faster time to recovery, 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that Remdesivir may benefit survival, though the mortality data did not reach statistical significance. A mortality rate of 8 percent was observed for the group receiving Remdesivir versus 11.6 percent for placebo. NIAID is developing and testing other novel and repurposed therapies, including monoclonal antibodies (mAbs). NIAID also is planning clinical trials to evaluate hydroxychloroquine (HCQ) and azithromycin in patients with mild to moderate COVID–19, and hyperimmune intravenous immunoglobulin (IVIG) for treatment of COVID–19.

On April 6, 2020, the National Heart, Lung, and Blood Institute (NHLBI) launched a clinical trial of HCQ in hospitalized COVID–19 patients through its Prevention and Early Treatment of Acute Lung Injury (PETAL) clinical trials network. NHLBI also sponsored the addition of a U.S. site for a Canadian Institutes for Health Research-funded trial of colchicine—an anti-inflammatory drug commonly

used to treat gout—for treating COVID–19 in the outpatient setting. Additionally, NHLBI is leveraging the NIH-funded Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) to study whether convalescent plasma, or blood plasma from individuals who have recovered from COVID–19, can help reduce the progression of COVID–19 in patients with mild symptoms.

The National Center for Advancing Translational Sciences (NCATS) is leveraging the NCATS Pharmaceutical Collection, a compilation of every drug approved for human use by major regulatory agencies worldwide, and other collections of small molecules and compounds to identify potential SARS-CoV–2 therapeutics for further investigation. Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the development and testing of mAbs and antiviral drugs for potential treatment of COVID–19. NIAID, the National Cancer Institute (NCI), NHLBI, NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke are all engaged in this critical effort.

NIH, in collaboration with the Foundation for the NIH, recently launched an innovative public-private partnership to speed the development of COVID–19 therapeutics and vaccines. The Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership brings together stakeholders from across the U.S. Government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID–19 pandemic. Other Federal partners include BARDA, the Department of Defense (DOD), the Department of Veterans Affairs, CDC, and FDA.

NIH also has convened the COVID–19 Treatment Guidelines Panel, comprised of representatives of NIH and five other Federal agencies along with representatives of eight professional organizations, academic experts, and treating physicians including providers from high incidence areas. On April 21, 2020, the panel issued the first release of COVID–19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments currently available and address considerations for special populations, including pregnant women and children. The guidelines will be updated regularly as new credible information emerges.

Enhancing Diagnosis and Understanding the Pathogenesis of COVID–19

NIH is supporting an HHS-wide effort to promote the development and commercialization of diagnostic tests to detect current SARS-CoV–2 infection. On April 29, 2020, NIH announced the Rapid Acceleration of Diagnostics (RADx) initiative, which will work to identify, support, and make innovative strategies for COVID–19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. RADx will leverage the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for potential roll out of new products by fall 2020. This initiative expects to award up to $500 million to support development of point-of-care and home diagnostic devices, as well as innovations that make current laboratory tests faster, more efficient, and more widely accessible. Innovators will be matched with technical, clinical,

regulatory, business, and manufacturing experts to increase the odds of success. In addition, NIAID is using CARES Act funds to support diverse SARS-CoV–2 diagnostic platforms including RT-PCR and enzyme-linked immunosorbent assays, and facilitating development of sensitive, specific, and rapid diagnostic tests by providing critical SARS-CoV–2 isolates and reagents to test developers. In addition, NCI is coordinating with FDA and NIAID to assess the sensitivity and specificity of marketed SARS-CoV–2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV–2.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the U.S. without a confirmed history of infection with SARS-CoV–2 have antibodies to the virus, indicating prior infection. In addition, NIH is supporting COVID–19 natural history studies to understand the clinical course of infection, including incidents of thrombosis, strokes and heart attacks, and other sequelae of infection. Some of these studies will examine the quality and durability of the immune response to SARS-CoV–2; this information may be leveraged to develop SARS-CoV–2 therapeutics or vaccines. Natural history studies also will inform our understanding of COVID–19 pathogenesis, including factors that may predict disease progression and will help to identify individuals or groups at high risk.

NIH continues to expand efforts to elucidate the viral biology and pathogenesis of SARS-CoV–2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIH is focused on developing safe and effective COVID–19 vaccines and therapeutics, and sensitive, specific, and rapid

point-of-care diagnostic tests. These efforts will improve our response to the current pandemic and bolster our preparedness for the next, inevitable emerging disease outbreak.

The CHAIRMAN. Thank you, Dr. Fauci.

Dr. Redfield, welcome.

STATEMENT OF ROBERT REDFIELD, M.D., DIRECTOR, UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. REDFIELD. Good morning, Chairman Alexander and Ranking Member Murray and Members of the Committee.

Our Nation is confronting the most serious public health crisis in more than a century, yet we are not defenseless. We have powerful tools to fight this enemy. We have tried and true, effective public health interventions, such as early case identification, isolation, and contact tracing, combined with important mitigation strategy, including social distancing, frequent hand washing, and face covering. These public health tools have and will continue to slow the spread of COVID–19.

I appreciate the opportunity this morning to provide a brief overview of some of CDC's ongoing work in response to COVID–19. CDC has been working 24/7 to combat the pandemic.

CDC's Emergency Operations Center is supporting state, tribal, local, and territorial public health partners in building core capabilities, particularly workforce, laboratory, and data and predictive analytics.

Epidemiologists are conducting surveillance for COVID–19, as well as conducting health system surveillance.

Community mitigation teams are providing guidance on infection control and contact tracing, and our laboratory experts are performing serological testing to better define the extent of asymptomatic populations.

As local leadership makes decisions to reopen, they will require varying degrees of Federal support. Each location will be different and will face unique circumstances. CDC has conducted a state-by-state assessment of public health testing capacity and contact tracing capacity, as well as surge plans.

CDC is providing technical assistance and funding to the states provided through the Supplemental CARES Act and the Paycheck Protection Program and Healthcare Enhancement Act. We are working directly with the state public health leaders to define their needs for testing and testing devices, supplies, and manpower, surveillance, data collection and reporting, contact tracing, infection control, and outbreak investigation.

I want to spend a moment to focus on several key elements. First, testing. Rapid, extensive, and widely available, timely testing is essential for reopening America. CDC's role in testing continues to support diagnosis and contact tracing, surveillance, and outbreak. We work with the public health partners to define their particular testing strategy for their jurisdiction. Admiral Giroir will address the testing components of the response in greater detail.

Contact tracing. Increasing state, tribal, local, and territorial contact tracing capacity is critical. It is a critical part to stop the

chains of transmission and prevent the occurrence of sustained community transmission. CDC's role is to provide technical training, assistance, and support for the states as they hire and build a workforce necessary to be fully prepared to effectively respond to the public health challenges posed by the ongoing COVID pandemic. This will be an expansive effort.

Surveillance. Our Nation's surveillance program is built on a combination of systems, including existing syndromic influenza and respiratory viral disease surveillance systems, have been combined with commercial and research lab platforms in our case reporting form system. CDC is adapting these and optimizing it to have a surveillance system in response to COVID–19.

Importantly, in light of the significant occurrence of asymptomatic infection, the surveillance for asymptomatic infection becomes an important public health tool for early case identification. CDC is working with each public health jurisdiction to develop a prospective surveillance program to include active surveillance among those that are most vulnerable, such as individuals in long-term care facilities, inner-city clinics, and homeless shelters.

We need to rebuild our Nation's public health infrastructure, data and data analytics, public health laboratory resilience, and our Nation's public health workforce. Now is the time to put it in place for the generations to come, not only for the public health system that our Nation needs, but for the public health system that our Nation deserves.

Before I close, I want to recognize the tireless commitment of the dedicated CDC staff, who have deployed to every corner of this Nation to fight COVID–19. More than 4,000 employees have deployed here and globally. Science and data continue, with technical expertise and public service, to be the backbone of CDC's contributions to the U.S. response.

I extend my serious gratitude to the healthcare workers on the front lines, as well as their family, and the essential emergency personnel, as well as the American people, to say thank you for adhering to the stay-at-home guidelines and protecting the most vulnerable.

It is important to emphasize that we are not out of the woods yet. The battle continues, and we must, but we are more prepared. We need to stay vigilant with social distancing. It remains an imperative. We are a resilient Nation, and I am confident that we will emerge from this pandemic stronger, together.

Thank you.

PREPARED STATEMENT OF ROBERT REDFIELD

CDC is America's health protection agency, and works 24/7 to save lives and protect America from health, safety and security threats, both foreign and in the United States. Addressing infectious diseases like COVID–19 is fundamental to our mission and is our highest priority. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and pandemic influenza to meet new challenges presented by COVID–19. These challenges are many, and they are historic. Every single American is affected by this pandemic, and CDC is leaning into this public health crisis with every applicable asset we have. CDC is drawing on its emergency response capacity and its relationships with State, tribal, local, and territorial (STLT), global, and private sector partners; and is leveraging our workforce's strengths in public health surveillance, and laboratory capacity, to address this public health emergency. CDC is developing guidance for healthcare professionals and the public to en-

courage safer practices, improve health outcomes, and save lives. CDC is also working with partners to develop guidance and decision tools to assist State and local officials and other stakeholders in adjusting mitigation strategies. Importantly, CDC is preparing the Nation's public health system and the private sector for a vaccine when one is available. Abroad, CDC is leveraging investments in global health security, pandemic influenza preparedness and public health infrastructures and capacities built through programs like the President's Emergency Plan for AIDS Relief to support countries in mitigating and containing COVID–19. The emergence and rapid spread of COVID–19 confirms that an infectious disease threat anywhere is a threat to Americans everywhere, including here at home.

When, in late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered in Wuhan, China, CDC began monitoring the outbreak. At the beginning of January, CDC began developing situation reports, which were shared with HHS, and reaching out to the Chinese Center for Disease Control and Prevention to offer CDC support. By January 7, 2020, CDC began expanding its incident management (IM) and response structure to facilitate staffing and communications. On January 21, 2020, CDC officially activated its Emergency Operations Center for COVID–19. Using the IM structure, CDC immediately set up task forces to address key needs and reached out frequently to our State and local partners. On March 17, 2020, CDC joined other HHS components and the Federal Emergency Management Agency (FEMA) in coordinating activities through FEMA's National Response Coordination Center. Addressing COVID–19 is taking an all-of-government effort.

Congress has addressed the urgent need to respond to this pandemic at home and abroad and has allocated substantial resources for CDC's COVID–19 activities through the statutes mentioned above. This funding supports a federally guided, State managed, and locally implemented response to COVID–19 in the United States. With support provided by Congress for global disease detection and emergency response through COVID–19 appropriations, CDC is supporting prevention, preparedness, and response efforts in partnership with public health agencies, health ministry counterparts and multilateral and non-governmental agencies worldwide. Here in the United States, CDC is working with STLT partners to focus use of these resources to establish and enhance case identification; conduct contact tracing; implement appropriate containment and community mitigation measures; improve public health surveillance; enhance testing capacity; control COVID–19 in high-risk settings; protect vulnerable and high-risk populations; and work with healthcare systems to manage and monitor capacity. As of May 1, 2020, CDC has announced or obligated $1.627 billion in awards to jurisdictions across America from the funds provided by Congress.

CDC is providing direct technical assistance and support to STLT partners as they consider approaches to mitigate and contain COVID–19. The White House, and Federal partners including CDC, have convened calls with all 50 states, Puerto Rico and the District of Columbia to identify State capacities and needs. The Federal Government has committed to ensuring that states can meet testing objectives for the month of May, as identified by each State. Through these calls and other outreach efforts, CDC has worked with jurisdictions to identify needs and develop plans to enhance testing capacity, State surveillance, contact tracing, and surge staffing. These discussions and plans for action will emphasize the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

In addition, CDC has launched a multifaceted approach to enhance and complement STLT efforts and expand support to communities during the current public health emergency. The COVID Response Corps is a new, nationwide community-focused initiative to identify surge staffing and resources to STLT health departments on the frontlines of the fight against COVID–19. Response Corps members will augment health department teams and engage in core public health functions including contact tracing, testing, infection prevention and control, call center activities, COVID–19 education, and public health surveillance.

CDC relies on timely and accurate public health surveillance data to guide public health action and inform the nationwide response to COVID–19. This crisis has highlighted the need to continue efforts to modernize the public health data systems that CDC and states rely on for accurate data. Public health data surveillance and analytical infrastructure modernization efforts started in fiscal year 2020 using funds provided by Congress, which have been augmented by $500 million provided for these efforts under the CARES Act. Timely and accurate data are essential as CDC and the Nation work to understand the impact of COVID–19 on all Americans, particularly for populations at greater risk for severe illness, such as older Americans, those with chronic medical conditions, and some racial and ethnic minorities.

CDC is also working to understand the impact of COVID–19 on healthcare workers, first responders, and other essential workers. Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is capitalizing on multiple existing surveillance systems run in collaboration with STLT partners, including influenza and viral respiratory disease systems. In collaboration with STLT partners, CDC is committed to making data available to the public, while protecting individual privacy. CDC's population-based COVID-NET system monitors COVID–19 associated hospitalizations that have a confirmed positive test in greater than 250 acute care hospitals in 99 counties in 14 states. Data gathered are used to estimate age-specific hospitalization rates on a weekly basis and describe characteristics of persons hospitalized with COVID–19 illness. CDC is using these data to monitor hospitalizations by race, ethnicity, underlying condition, age, and gender, and is now including this information in CDC's weekly COVIDView summary. CDC is now receiving more granular data on deaths by State and locality, allowing us to identify and address where there may be racial and ethnic disparities in morbidity and mortality. CDC also is augmenting the existing National Healthcare Safety Network to monitor and analyze the capacity of the healthcare system daily—including hospitals and nursing homes—so that Federal, State, and local officials can adjust their response and mitigation efforts as needed.

Regarding laboratory support, from the outset, CDC laboratories have been applying sequencing technologies to SARS-CoV–2 and have made the data available through domestic and global data bases. CDC is leading the SARS-CoV–2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES), a new national genomics consortium to coordinate SARS-CoV–2 sequencing across the United States to do large-scale, rapid genomic sequencing of the virus. These advanced molecular detection and sequencing activities are being ramped up at the State and local levels to give us a clearer picture of how the virus outbreak is evolving and how cases are connected. CDC is engaged with the National Institutes of Health (NIH), the FDA, and the Biomedical Advanced Research and Development Authority (BARDA) to evaluate serology tests, and CDC is supporting serological surveys to help determine how laboratory testing can contribute to decisions about enabling Americans to return to work.

CDC has developed a new serologic laboratory test to assist with efforts to determine how much of the U.S. population has been infected with SARS-CoV–2, the virus that causes COVID–19. The serology test looks for the presence of antibodies, which are specific proteins made in response to infections. It typically takes one to 3 weeks after someone becomes sick with COVID–19 for their body to make antibodies; some people may take longer to develop antibodies. The antibodies detected by this test indicate that a person has had an immune response to SARS-CoV–2, regardless of whether symptoms developed from infection or the infection was asymptomatic. However, it is important to point out that, at this point, we do not know whether the presence of antibodies provides immunity to the virus. Currently, CDC's serologic test is designed and validated exclusively for broad-based surveillance and research that is giving us information needed to guide the response to the pandemic and protect the public's health.

During the week of March 30, CDC and public health partners began the first stage of studies of community transmission of SARS-CoV–2. These initial studies use serum samples collected in the State of Washington and New York City. In April, the second stage expanded to include serologic testing in more areas with high numbers of people with diagnosed infections. It also includes studies of households in some states. By using seroprevalence surveys, CDC can learn about people who have been infected, including those infections that might have been missed due to lack of symptoms or testing not being performed for other reasons. These surveys can also track how infections progress through the population over time. This is done by taking "snap shots" of the percentage of people from the same area who have antibodies against SARS-CoV–2 (also called the seroprevalence) at different time points.

On April 27, 2020, CDC updated testing prioritization and focused testing guidelines for those who may have or who are at risk for active SARS-CoV–2 infection. Clinicians considering testing of persons with possible COVID–19 should continue to work with their local and State health departments to coordinate testing through public health laboratories or use clinical laboratory viral tests for COVID–19 that has been issued an Emergency Use Authorization (EUA) by FDA or are being offered as outlined in FDA's policy regarding COVID–19 tests. Increasing testing capacity will allow clinicians to consider the medical necessity of COVID 0919 testing for a wider group of symptomatic patients and persons without symptoms in certain situations. CDC recommends that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID–19 and whether the

patient should be tested. Most patients with confirmed COVID–19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing) but some people may present with other symptoms as well. Other considerations that may guide testing are epidemiologic factors such as the occurrence of local community transmission of COVID–19 infections in a jurisdiction.

The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID–19. CDC develops and disseminates guidance for individuals and communities. These recommendations include actions that every American should take, such as following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. CDC guidance is available here *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick-prevention.html.*

First responder and healthcare guidance documents cover a range of topics—from addressing potential work-related exposures, implementing infection prevention and control measures in health facilities, and optimizing the supply of personal protective equipment to clinical evaluation, testing, and clinical care. CDC is providing these recommendations to support communities' efforts, while recognizing that each sector and community is unique and will need to consider these in the context of their community-level data and circumstances. CDC teams on the ground and those aiding from Atlanta are and will continue working with State and local officials to integrate these recommendations into COVID–19 plans.

Mitigation and containment of COVID–19 are the key to public health strategies and CDC is committed to using our expertise and partnering with others on the frontlines. While surveillance, testing, contact tracing, and community mitigation interventions are the best tools we have right now, looking to the future, CDC continues to work to prepare our Nation's public and private health systems to deliver effectively a COVID–19 vaccine once it is available. This includes working with CDC's 64 immunization awardees to help ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking. CDC remains committed to supporting the COVID–19 response with all available resources.

The CHAIRMAN. Thank you, Dr. Redfield.

Admiral Giroir, welcome.

STATEMENT OF ADMIRAL BRETT GIROIR, M.D., ASSISTANT SECRETARY FOR HEALTH, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Admiral GIROIR. I am here to provide you with an update on the Nation's progress in testing for COVID–19.

On March 12th, Secretary Azar requested that I lead the COVID–19 testing efforts within HHS, including oversight and coordination of the FDA and CDC with regard to testing. Since then, the Nation has performed more than nine million COVID–19 tests, a number far greater than any other country, and double the per capita tests performed to date in South Korea. To reach this point, we implemented a phased approach to meet testing needs during mitigation, and now during Phase 1 reopening of America.

Beginning March 20th, we pioneered 41 community-based, drive-through testing sites in locations prioritized by the CDC. These sites have been a profound success, testing over 167,000 high-risk individuals and demonstrating a prototype that is being duplicated multifold in nearly every state.

Next, the administration leveraged trusted retailers, including CVS, Rite Aid, Walgreens, Walmart, Kroger, and Health Mart, who are now providing testing at 240 locations in 33 states, 69 percent of which are in communities with moderate to high social vulnerability.

To meet the need for collection supplies, like swabs and media tubes, we first secured the global supply chain through a military

air bridge. We worked directly with manufacturers to increase domestic production. We collaborated with the private sector and the FDA to validate multiple swab and media types that vastly expanded supplies, while minimizing the need for PPE.

Finally, we used Title III of the Defense Production Act to further invest in domestic manufacturing to prepare us for reopening.

To support the need for surveillance testing during reopening, on April 27th, we issued a new testing framework that also prioritized testing for persons without symptoms, who are prioritized by health departments or clinicians for any reason, including screening of asymptomatic individuals, according to state and local plans.

Next, our Federal multidisciplinary team conducted multiple calls with leadership from each state to set state-specific testing objectives. Collectively, states and territories established an overall goal to perform 12.9 million tests over the next 4 weeks. The Federal Government is able to, and will, support the achievement of this goal. Specifically, the Federal Government is shipping to states 12.9 million swabs and over 9.7 million tubes of media in May alone.

Last month, we also detailed the location and capacity of every lab machine in every state that could potentially run COVID–19 assays, and our team has worked with test suppliers to match reagents to these machines.

Looking forward, between now and the end of 2020, the Federal Government will procure over 135 million swabs and 132 million tubes of media and distribute these to states, as requested, to supplement the now robust commercial supply.

We anticipate marked increases in current tests, as well as a dramatic expansion of new point-of-care tests, like the first in class Quidel antigen test, authorized by the FDA just last Friday. Quidel anticipates being able to distribute 300,000 tests per day within just a few weeks.

By September, taking every aspect of development, authorization, manufacturing, and supply chain into consideration, we project that our Nation will be capable of performing at least 40 to 50 million tests per month if needed at that time. And, if new technologies are authorized, like whole genome sequencing approaches or any novel solutions uncovered by NIH's new diagnostics initiative, that number will be much higher.

Finally, I want to acknowledge and express my heartfelt gratitude to the officers of the U.S. Public Health Service Commission Corps, the uniformed service I am honored to lead. Three thousand, four hundred and seventy-one men and women have deployed in support of this pandemic; on the cruise ship in Japan; to our military bases, repatriating Americans; to our community-based testing sites and international airports; to FEMA and our task forces; to nursing facilities, including King County Washington; and to field hospitals in hard-hit communities across our Nation. I thank each and every one of these officers and their families. And, on their behalf, I thank the Members of this Committee for supporting our training needs and the establishment of a ready reserve to supplement our ranks in future national emergencies.

Thank you for the opportunity to provide these remarks.

PREPARED STATEMENT OF BRETT GIROIR

Diagnostics and Testing

Testing for the presence of SARS-CoV–2 is an essential component of our Nation's response to the COVID–19 pandemic; its importance will be further magnified as states enter Phase–1 of reopening. The indications for viral testing depend heavily on the stage of the pandemic and the extent of mitigation employed. In general, testing may be indicated for diagnosis of those who are symptomatic, tracing of those in contact with those who are infected, and surveillance testing of those who are asymptomatic or mildly symptomatic to achieve infection control and/or other public health objectives.

The focus of this testimony is on testing for the presence of the virus, in contrast to testing for the presence of antibody to the virus. The former determines whether the individual is actively infected, and presumably infectious. The latter determines whether the individual has been infected, has developed an immune response, and may be protected from subsequent SARS-CoV–2 infections.

It is useful to understand the overall testing strategy in terms of its chronology and sequential objectives, and to understand that this virus was a new human pathogen for which no diagnostic tests had previously been developed. In addition, the predominant type of test relies on sophisticated RNA amplification technology that can only be done in a laboratory certified to perform moderate or high complexity testing. New point-of-care (POC) tests are an exception in that they are low complexity; however, this class of test still represents a minority of available testing capability and has limited utility because of its low throughput. Finally, the pandemic caused an unprecedented demand for all supplies and materials, such that overall demand in a single month approximated total annual demand of some components. This reality represented substantial challenges, but Federal leadership has guided efforts to combat these challenges in close collaboration with states, local jurisdictions, and the private sector. Our overall strategy for testing includes:

- Assuring that those who need testing, receive testing
- Prioritizing testing to meet the stage of the pandemic
- Increasing the number and diversity of tests
- Enhancing states' ability to collect specimens through novel "front ends" like drive-through sites
- Organizing and galvanizing the industry on an unprecedented scale
- Enhancing testing to underserved communities
- Providing surge testing capacity during local outbreaks
- Supporting critical infrastructure and national security needs
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

The overall testing strategy is outlined chronologically as we met the needs of each evolving stage of the pandemic.

Stage 1: Launch: Engaging the Emerging Crisis

In the beginning stages of the COVID–19 pandemic, CDC was engaged in building the foundation for diagnostic testing in the United States. On January 10, 2020, Chinese researchers deposited the 2019-nCoV genome sequence to GenBank and CDC began development of the CDC 2019-nCoV Real-Time PCR Diagnostic Panel. On January 24th, CDC publicly posted its assay for the CDC's newly developed diagnostic panel, allowing the global community to develop their own assays using the CDC design. On February 3d, CDC submitted an EUA request, and the FDA issued an EUA on February 4th, enabling use of the CDC's COVID–19 diagnostic Panel.

Understanding the importance of increased testing, the FDA moved swiftly to engage with more than 470 test developers that indicated their intent to submit requests for EUAs. In mid-January, BARDA convened a meeting of leading diagnostic companies from across America to encourage development of COVID–19 tests. In the ensuing months, multiple funding opportunities for the development of COVID–19 diagnostic tests were announced and NIH provided COVID–19 RNA to diagnostic companies to expedite private-sector test development. With a desire to ensure high quality diagnostic testing but also ensure rapid development and dissemination of COVID–19 tests, the FDA has provided EUA templates for laboratories and manufacturers in an effort to streamline the entire process, and works with developers who wish to use alternate approaches to the templates. FDA has issued a record number of EUAs for COVID–19 tests. This has contributed greatly to the dramatic increases in testing the Nation has seen in the past months. The amount and expediency in which EUAs were issued for COVID–19 tests far exceed past viral out-

breaks. For example, in response to the 2016 Zika Virus outbreak, FDA issued 20 test EUAs; in response to the 2009 H1N1 outbreak, FDA issued 17 test EUAs. Currently, FDA has issued more than 70 COVID–19 test EUAs. The timeliness and number of EUAs issued by FDA for COVID–19 tests is unprecedented and has been critical to improving the testing scale and capacity in our Country.

Throughout the COVID–19 outbreak, the Administration has encouraged diagnostic test manufacturers, commercial laboratories, and professional societies to expand capacity and scale for existing nucleic acid testing platforms. Through the efforts of the Administration, the United States has developed a multilayered, multifaceted approach to testing that is capable of providing the right test to the right person at the right time. This approach includes contributions from State public health labs, high-throughput commercial labs, academic and hospital labs, labs at CDC, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs. In addition, the ecosystem now includes POC testing that can be done in rural areas at high risk without sophisticated supporting infrastructure, or as a tool to investigate outbreaks in nursing homes or other confined settings.

As of the beginning of May, our Nation is performing more than 200,000 tests per day, and this number will continue to increase. Commercial laboratories are working more efficiently, processing tests in rapid succession, which ensures patients receive their results, on average, within 3 days. Hospital and academic laboratories typically provide results within 2 days, and often much sooner. POC tests provide results within 15 minutes.

Concurrent to the Federal Government's efforts to expand capacity and scale of laboratories testing capabilities across the country, the Administration also worked with State and local partners to establish Community Based Testing Sites (CBTS). At the inception of this effort, the 41 federally supported sites were developed and established by the U.S. Public Health Service Commissioned Corps (Corps), in CDC-prioritized locations across the country and 14 sites remain open with Federal support. These sites are located in Colorado, Texas, Illinois, New Jersey, and Pennsylvania. The Corps had unique expertise in COVID–19 testing, since many officers had deployed to Japan and elsewhere to assist in infection control, diagnosis, and eventual repatriation of American citizens. The initial objectives of CBTS were to screen and test healthcare facility workers and first responders, as prioritized by local jurisdiction. The CBTS model has been a success, having tested over 140,000 individuals, and with an overall COVID–19 test positive rate of approximately 17 percent, meaning that the CBTS are testing the right individuals at the right time. This effort has also supported and co-evolved with technological advances such as the validation of nasal self-swabbing, which minimizes the need for trained health professionals and personal protective equipment. The CBTS initiative was an early example to states and localities on how to conduct community based COVID–19 testing, and this model has been replicated throughout the country to screen and test hundreds of thousands more Americans.

From the onset in January, and continuing to the present, the President, Vice President, and senior Administration officials have held numerous briefings with Governors and their State leadership. Many of these briefings have focused on joint Federal-State efforts to expand testing throughout the country. In addition to these calls with the Nation's Governors, the White House and senior Administration officials have organized numerous calls to enhance State, local, territorial and tribal testing coordination efforts. The constant communication between the Administration and State leadership has helped provide guidance to states on how to best utilize testing capacity in their own states. Another product that was produced by the Administration to assist the states to leverage the full testing capacity at their disposal was a data base of nationwide lab locations and capacity, including the specific testing platforms at each laboratory.

Stage 2: Scaling and Technological Innovation

The identification and expansion of public and private sector testing infrastructure has been, and continues to be, a priority. One example of expanding testing infrastructure through public-private partnerships is the engagement of the Administration with well-known retailers that have a regional or nationwide footprint. As of May 5 and with the assistance of the Federal Government, United States retailers have opened and are operating 102 testing sites in 31 states. In an effort to expand testing further, the Federal Government is building upon the public-private partnerships to increase the number of testing sites offered at commercial locations across the country. The public-private partnerships with these retailers are being expanded to support many more testing sites that will be opened and operating in the coming weeks. These commercial testing locations are also uniquely situated to meet the testing needs of communities with moderate to high social vulnerability,

which was the focus of the original sites. Going forward, retailers have indicated their intent to open hundreds more of these sites depending on local needs.

Another effort of the Administration to further support and expand the testing infrastructure in the United States has been strengthening the testing supply chain. The Administration has massively increased the availability of laboratory and testing supplies by engaging directly with distributors and manufacturers to increase production capacity through direct procurement, application of the Defense Production Act, formation of various public-private partnerships, and improved allocation criteria that ultimately help ensure that supplies meet the state's needs and reach the locations where the supplies are needed most. In addition, validation of additional supply types has led to a dramatic broadening of available supplies and reagents.

As of April 30, the Federal Government had directly procured 6.7 million swabs, 3.3 million vials of transport media, 15 million lancets, and 15 million alcohol pads. As of March 27th, the Federal Government had also facilitated the nationwide delivery of 175.2 million masks, 14.7 million gowns, and 793.8 million gloves. Through the mechanisms mentioned above, we are unlocking the full potential of laboratories in the United States and this is allowing testing capacity to expand consistently.

Stage 3: Support Opening Up America Again

Current efforts are focused on further scaling up testing capabilities to guarantee that each State has the testing supplies and capabilities they need to reopen according to their own individual State plans. For example, the Federal Government is procuring over 21 million swabs and 13 million collection tubes with transport media (or saline) in May. These supplies will be shipping out to states over the course of the month. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million extraction and PCR kits in May, enabling states to complete millions of additional tests in May. In mid-March, the FDA issued an EUA for Hologic's Panther COVID–19 test, which runs on more than 600 lab machines across the United States. Hologic will be shipping several million test kits to labs across the Nation starting in early May.

The Administration will continue to work hand in hand with Governors to support testing plans and rapid response programs. The Opening Up America Again guidelines, provided by the Administration, describes roles and responsibilities as well as elements of the robust testing plans and rapid response programs called for in the President's Guidelines.

The Laboratory Testing Task Force is providing technical assistance to all 50 states, tribes and territories through calls with every State public health team to discuss their testing goals and the best mechanisms to achieve them. The Federal Government is assisting states to develop testing plans, supplying resources to help meet these testing plans, and deploying teams to states that need additional subject matter expertise.

Because of the Administration's success in rapidly scaling up of the testing ecosystem, states will be fully equipped to conduct more COVID–19 tests per capita each month than most countries have tested cumulatively to this date.

The Federal Government will continue to support Americans by providing expedited regulatory approvals for tests and equipment as necessary and appropriate, updating guidance for administering diagnostic testing, and catalyzing technological and scientific innovation. The process of reopening the United States will be one that is federally supported, state-led and locally executed.

We recognize that vulnerable populations in many underserved communities are among the highest risk of suffering devastating health and economic impacts of COVID–19. We issued a Notice of Funding Opportunity on May 1. The 3-year initiative will include the development and coordination of a strategic and structured network of national, State, territorial, and local public and community based organizations that will help mitigate the impact of COVID–19 on racial and ethnic minority as well as rural and socially vulnerable communities across the Nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most.

United States Public Health Service Commissioned Corps

Since the early stages of the COVID–19 outbreak, the Corps has been an indispensable asset leveraged to address the public health needs of the Nation in response to this crisis. The Corps is one of the eight uniformed services of the U.S. and the only uniformed service committed to protecting, promoting, and advancing the health and safety of the Nation. Corps officers serve throughout the Nation in

communities that are most in need by providing essential healthcare services to underserved and vulnerable populations.

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 38 officers on February 1, 2020 to more than 3,200 officers today with many of them undertaking multiple or consecutive deployments. Corps officers have been deployed across our Country and internationally to assist with the outbreak response, to support the return of American citizens, to assist in the management of hospitalized United States citizens with COVID–19 abroad, and to support clinical trials related to COVID–19. Corps officers provided critical assistance to community-based testing sites throughout the Nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID–19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a "cavalry" to support healthcare systems under stress in states across the country. COVID–19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City; and to the TCF Center in Detroit. The Corps is also preparing to send teams to the Navajo Nation to provide care amidst a surge of COVID–19 cases.

The United States Public Health Service Commissioned Corps stands ready and willing to respond to the public health needs of our Country and to provide essential healthcare services.

The CHAIRMAN. Thank you, Admiral Giroir.

Now Dr. Stephen Hahn, our fourth and final witness.

STATEMENT OF STEPHEN HAHN, M.D., COMMISSIONER OF FOOD AND DRUGS, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. HAHN. Chairman Alexander, Ranking Member Murray, and Members of the Committee, thank you for inviting me to participate in this hearing today.

I first want to start by thanking the American people for their incredible efforts at mitigation and extend my condolences to those who have lost loved ones.

From day one of this pandemic, the 18,000 FDA employees, who are just incredible scientists, doctors, and nurses, have taken an active role in the all-of-government response to this pandemic.

FDA has worked to facilitate the development of medical countermeasures to diagnose, treat, and prevent COVID–19. We have worked closely with laboratories, manufacturers, academia, product developers, our Federal partners, and companies—companies that don't even make medical products but want to pitch in, for example, by making hand sanitizer, personal protective equipment, and ventilators.

Every decision we have made has been driven by data, with the goal of protecting the health of the American people. In a public health emergency, however, our responses balance the urgent need to make medical products available with the provision of a level of oversight that helps ensure the safety and effectiveness of those medical products.

I would like to take a few minutes to tell you what FDA is doing to help the country at this point, in which, Americans safe to return to work and to school.

It starts with testing, as others have mentioned. FDA has worked with more than 500 developers who have, or said they will be submitting, Emergency Use Authorization requests for COVID–19 tests. This includes some newer technologies that not—that

heretofore have not been used as part of diagnostic tests in response to a pandemic.

We have issued 92 individual Emergency Use Authorizations for test kit manufacturers and laboratories, and we have been informed by more than 250 laboratories they have begun testing under the regulatory flexibilities we outlined in March.

We are conducting rolling reviews of EUA submissions so that we can quickly authorize tests which the data support. In a public health emergency, the accuracy of diagnostic tests is important, not only for the individual patient, but for the patient at large, republic at large. FDA is helping to ensure the availability of tests that are providing accurate answers.

We are also monitoring the market base for fraudulent tests and are taking appropriate action to protect the public health, and we are working to provide more clarity about which tests have been reviewed and authorized by FDA and which have not.

Serologic tests will play a role in our recovery. Unlike diagnostic tests, which detect the presence of the virus, serologic tests measure the amount of antibodies or protein present in the blood when the body is responding to an infection like COVID–19. These tests can help identify individuals who can overcome an infection and who have developed an immune response. We will continue working with labs, manufacturers, and across the Government to find a balance between the assurance that an antibody test is accurate, and timely access to such tests.

Of course, the way we will eventually beat this virus is with a vaccine, and FDA is working closely with our Federal partners, including the NIH, test—I mean, vaccine developers, manufacturers, and experts across the globe. We intend to use our regulatory flexibility to help ensure the most efficient development of a safe and effective vaccine to prevent COVID–19.

Until a preventative vaccine is approved, however, we need medical products to bridge the gap. FDA has been working for several months to facilitate the development and availability of therapeutics as expeditiously as possible, and we have created an emergency program for this acceleration called the Coronavirus Treatment Acceleration Program, or CTAP. We have reassigned staff to work with urgency to review requests from companies, scientists, doctors, who are developing therapies, and we are using every available authority and regulatory flexibility that is appropriate to facilitate the development of safe and effective products to treat COVID–19.

A variety of therapeutic areas are being evaluated, as mentioned by Dr. Fauci and others, including antiviral drugs and immunotherapies, as well as convalescent plasma, hyperimmune globulin, and monoclonal antibodies.

As Dr. Fauci also mentioned, we recently announced the positive results of the NIAID trial of Remdesivir and issued an EUA for the treatment of hospitalized patients with COVID–19. Two other promising treatments that I mentioned are the antibody-rich products, convalescent plasma and hyperimmune globulin, and I am certainly willing to go into more detail if Members of this Committee have questions about this.

But, we are working very aggressively and closely with stakeholders to facilitate the development of monoclonal antibodies, which, if shown to be safe and effective, could act as a bridge therapy to the development of a vaccine. We recognize that developing vaccines and therapies need to go hand in hand with ensuring that there will be sufficient supplies for our companies—for our Country, so we are also working with manufacturers to make sure that this supply chain is robust.

Mr. Chairman, Ranking Member, and Members of the Committee, please know that in FDA you have a dedicated team of some of the Nation's finest scientists, healthcare providers, and public health professionals. We are guided by science and data, and we will not let up until we facilitate the development of products that our Nation needs to get back to work. I look forward to your questions.

PREPARED STATEMENT OF STEPHEN HAHN

From day one of this emerging public health emergency, FDA has taken an active leadership role in the all-of-government response to the COVID–19 pandemic, inspired by the resiliency of the American people and our great innovators. Long before the first domestic case was reported, FDA stood up an internal cross-agency group that continues to ensure we are doing all we can to protect the American public, helps ensure the safety and quality of FDA-regulated products and provides the industries we regulate the tools and flexibility to do the same. Work has focused on facilitating medical countermeasures to diagnose, treat and prevent the disease, and surveilling the medical product and food supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary to protect the health of Americans. This work is a key component of the Federal Government's efforts to address this pandemic and reopen the economy so Americans can get back to work and school.

Diagnostic Testing

In an emergency, FDA oversees the validity of tests developed by others through the Emergency Use Authorization (EUA) process. Every action FDA has taken during this public health emergency to address the COVID–19 pandemic has balanced the urgent need to make tests available with providing a level of oversight that helps to ensure accurate tests are being deployed.

COVID–19 has created a demand for new tests that is unprecedented in both volume and urgency. As with other emergencies, FDA has been extremely proactive and supportive of diagnostic test development by all comers—laboratories, and large and small commercial manufacturers. Even prior to any U.S. cases of COVID–19, FDA proactively reached out to developers to encourage the development of tests and to see what the Agency could do to facilitate development. In its COVID–19 Testing Guidance, FDA has provided flexibility to encourage innovation and help speed development of COVID–19 tests. FDA is engaging in rolling reviews of EUA submissions and is quickly authorizing tests that the science and data support. As outlined in the guidance, certain laboratories and commercial manufacturers are developing their own diagnostic tests and, once validated, are beginning to use them while they prepare an EUA submission for FDA review. In addition, under our policies, states that have the capacity and expertise to do so have been authorizing tests for use within a laboratory in that state.

In a public health emergency, getting an accurate test is important not only for the individual patient, but for the public at large. All tests should be validated before use because it is critical that these tests work. FDA's policies do not change that. False positive and false negative results can contribute to the spread of COVID–19. As with medical treatments, we want tests to be safe and, in the case of diagnostics, accurate. FDA plays an important role helping to ensure we are getting accurate answers. We are monitoring the market for fraudulent and harmful tests. FDA has and will continue to take appropriate action against firms that place the public health at risk and follow-up with bad actors. There are several cases where developers of tests have updated or changed claims at FDA's urging.

FDA is working on several fronts to provide more clarity about which tests have been reviewed and authorized by FDA and which have not. FDA has been posting

on its website the tests for which it has received a notification as outlined in its COVID–19 testing policies.

FDA has been working around the clock to 1) encourage and support test development for the U.S. market, working with over 470 developers since January; 2) issue EUAs for diagnostic tests, including those for home self-collections; 3) research and mitigate shortages of test components, including identifying and sharing scientifically acceptable alternatives for components on FDA's website; 4) arrange with the Department of Defense weekly airlifts of swabs to the United States; 5) engage non-traditional device manufacturers to support use of new swabs and other supplies that are needed in the United States; 6) offer support to all developers through a 24-hour hotline and key resources, including FAQs, that it updates regularly as it serves as a clearinghouse for scientific information that helps everyone increase testing capacity.

Serological Testing

Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like the virus that causes COVID–19. Such a test detects the body's immune response to an infection. These tests do not diagnose COVID–19; however, we believe these tests can play a critical role in the fight against COVID–19 by helping healthcare professionals to identify individuals who may have overcome an infection in the past and have developed an immune response. These tests may also aid in identifying individuals with antibodies to the virus that causes COVID–19 so they may donate convalescent plasma as a possible treatment, which requires more data and research to determine if this is a safe and effective treatment for COVID–19, but may help those who are seriously ill from COVID–19.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serological tests that begin to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable, without FDA authorization, and as further outlined in the policy. The policy is intended to allow for early patient access and flexibility for developers, with appropriate transparency regarding the limitations of these tests. On May 4th , FDA took important steps to build on this policy by updating it to outline key expectations for antibody test developers: 1) commercial manufacturers will submit EUA requests, with their validation data, within 10 business days from the date they notified FDA of their validation testing or from the publication date of this policy, whichever is later, and 2) FDA has provided specific performance threshold recommendations for all serology test developers. The policy for laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing, regarding their developing and performing their own serology tests, has not changed. They continue to perform their own validation and provide notification to FDA, and should follow the other recommendations with respect to labeling as described in the policy. In addition to these updates, we are introducing a more streamlined process to support EUA submissions and review. Two voluntary EUA templates for antibody tests have been made available—one for commercial manufacturers and one for CLIA certified high-complexity labs who decide to seek FDA authorization. These templates will facilitate the preparation and submission of an EUA request and can be used by an interested developer. And as we do for diagnostic tests, we are happy to work with developers of serology tests on other approaches if they do not want to use one of the templates.

In addition, FDA issued an umbrella EUA for certain antibody tests that undergo a validation evaluation at NCI, or another government agency designated by FDA. Tests that FDA confirms meet the performance and labeling criteria outlined in the EUA may be added under the umbrella EUA, streamlining the submission and review of these important tests.

We are continuing to provide updated information and educational materials to states and health care partners. If particular commercial manufacturers that are currently marketing serology tests under the policy fail to submit an EUA within 10 business days of notification or policy publication (whichever is later), we intend to share this information publicly and take appropriate action as needed. We will also keep up our work to stop illicit tests from entering the U.S., and to keep fraudulent products off the market.

FDA will continue to take steps to balance assurances appropriately that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. To date, FDA has issued numerous EUAs for serological tests, issued an "umbrella" EUA for certain serological tests, and is working with hundreds of developers on pre-EUAs.

Importantly, we are working with developers and other partners to evaluate the validity of serological tests, and are working to authorize even more of these tests under EUAs. I continue to work closely with my fellow Coronavirus Task Force members in examining the role testing will play as we look to reopen our Country's schools, businesses, and public services.

Vaccine Development and Treatment Interventions

At this time there is no FDA-approved vaccine to prevent being infected with COVID–19. FDA is working closely with Federal partners, vaccine developers, researchers, manufacturers, and experts across the globe to help expedite the development and availability of vaccines and drugs to prevent or treat COVID–19 infections. FDA intends to use regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID–19.

FDA is partnering with the NIH in their efforts to develop a national strategy for a coordinated research response to the pandemic. The Accelerating COVID–19 Therapeutic Interventions and Vaccines, or ACTIV, partnership is developing a framework for prioritizing vaccine and drug candidates, streamlining related clinical trials, coordinating regulatory processes, and leveraging assets among all partners to rapidly respond to COVID–19 and future pandemics.

Therapeutic Development

At this time there are no FDA-approved drug products to treat COVID–19. Since the beginning of the COVID–19 pandemic, FDA has been working tirelessly to facilitate the development and availability of therapeutics for use by patients, physicians, and health systems as expeditiously and safely as possible. FDA recently announced the creation of an emergency review and development program for possible therapies for COVID–19: the Coronavirus Treatment Acceleration Program, or "CTAP". The Agency has been supporting the program by reassigning staff and working day and night to review requests from companies, scientists, and doctors who are working to develop therapies. Under CTAP, FDA is using every available authority and regulatory flexibility to facilitate the development of safe and effective products to treat patients with COVID–19.

There are a variety of therapeutic areas being evaluated, including antiviral drugs and immunotherapies, that may be helpful in reducing lung inflammation and improving lung function in COVID–19 patients. All this work is beginning to pay off, and we have recently announced the positive results of the recent NIAID trial of Remdesivir in patients with severe COVID–19. On May 1, FDA issued an EUA for Remdesivir for the treatment of suspected or laboratory-confirmed COVID–19 in adults and children hospitalized with severe disease.

Another promising approach for treatment is the use of antibody-rich products such as convalescent plasma and hyperimmune globulin. These blood products are manufactured from plasma donated by people who have recovered from the virus and such products are being studied to determine if they could shorten the length, or lessen the severity, of the illness. It is important that we evaluate convalescent plasma in the context of clinical trials as well as facilitate emergency access for individual patients, as appropriate. As this work moves forward, the key to ensuring the availability of convalescent plasma to those in greatest need, as well as to support clinical development of convalescent plasma and hyperimmune globulin, is getting fully recovered COVID–19 patients to donate plasma if they meet FDA's donor eligibility criteria. To that end, FDA is working with blood collectors to facilitate the collection of convalescent plasma, and working with developers of these therapies to move forward with clinical evaluations.

Medical Product Supply

FDA has been monitoring and proactively adjusting to the worldwide demand and supply chain disruptions for medical products caused by the COVID–19 pandemic. We are working closely with manufacturers to help ensure they continue to notify the Agency of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner. In addition to our usual communication with drug manufacturers, we are working closely with healthcare and pharmacy systems, hospitals, providers, and others on the frontlines of COVID–19 patient care to identify current or emerging regional shortages of critical care drugs used to treat COVID–19.

We issued temporary policies under which outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or Federal facilities can compound certain drugs used to treat patients with COVID–19 under particular condi-

tions explained in FDA guidance. FDA understands the significant impact shortages can have on patient care and is doing everything within its authority to help prevent and alleviate this impact. In addition, when we identify a shortage, we react swiftly to mitigate the impact to U.S. patients and health care professionals, and quickly share that information with the public.

We are working to increase the supply of personal protective equipment (PPE) and other critical devices that patients and those on the front lines of the U.S. response rely upon. FDA has issued three EUAs to help make more respirators available to health care personnel and help ease burdens on the health care system. These allow for the emergency use of NIOSH-approved respirators in health care settings for healthcare personnel and the importation of non-NIOSH approved respirators that meet certain specified criteria, as set forth in the various EUAs. FDA has also issued several guidances to provide flexibility for those manufacturing PPE for the COVID–19 response, and we have published conservation strategies for gloves, gowns, and masks. To support these efforts further, FDA has issued several EUAs for devices used to decontaminate respirators for reuse by health care workers in hospital settings.

FDA has also issued guidances for several other critical devices including ventilators, clinical electronic thermometers, and imaging systems, as well as remote digital pathology and remote monitoring devices intended to help facilitate remote care that puts patients and health care providers at less risk for exposure to COVID–19.

Taken together, FDA's policies and engagement have helped to accelerate patient access to critical devices. FDA appreciates Congress including provisions in the CARES Act for additional device shortages authority during or in advance of a declared public health emergency, and looks forward to continuing to work with Members of Congress to expand further these authorities, consistent with the fiscal year 2021 Budget so that we can address shortages in other situations as well.

Food Supply

FDA is working with our Federal, State, and local partners as well as industry to help ensure a safe and adequate food supply for both people and animals. I want to reassure you there is no evidence of food or food packaging being associated with transmission of COVID–19. Although food product production and manufacturing in the United States remains strong, resilient, and is for the most part dispersed throughout the United States, some components are under stress.

There has been a significant shift in where consumers are buying food, because of the pandemic. We have taken steps to provide temporary guidance to provide flexibility in packaging and labeling requirements to help industry divert products manufactured for food service and institutional use to retail grocery stores.

FDA recognizes that the food supply chain is dependent on the safety of the Nation's food and agricultural workforce. Along with our Federal partners, we have provided best practices for food workers, industry, and consumers on how to stay safe, keep food safe, and ensure the continuity of operations in the food and agriculture critical infrastructure sector during the pandemic.

FDA continues to monitor closely the overall safety of the Nation's food supply. Importantly, we continue to work with CDC, the U.S. Department of Agriculture, and our State and local partners to protect consumers from foods contaminated with pathogens such as listeria, salmonella and E. coli. FDA's Coordinated Outbreak Response and Evaluation team has remained at work during the pandemic, is fully staffed, and on-the-job looking for signs of foodborne illness outbreaks.

Fraudulent Products

FDA is exercising its regulatory authority to protect consumers from firms selling unproven products with false or misleading claims, including by issuing warning letters and pursing enforcement actions such as injunctions, against firms and individuals that violate the law. For example, we are actively monitoring for firms selling fraudulent and unproven products with claims to prevent, treat, mitigate, diagnose, or cure COVID–19.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining and reviewing import entries, and refusing admission where appropriate. We are in close communication with our partners at U.S. Customs and Border Protection to proactively identify and mitigate any potential backlogs. FDA participates in FEMA Supply Chain Task Force meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by FEMA, to facilitate the lawful entry and use of imported medical products coordinated through FEMA, and to inform medical product supply chain discussions.

Conclusion

Thank you for the opportunity to be here to provide an update on the activities of HHS in responding to COVID–19 and to answer any questions.

The CHAIRMAN. Thank you, Dr. Hahn. And, thanks to all four of you for your expertise, for your dedication to our Country, and your hard work.

We will now begin a round of 5-minute questions from each Senator on the Committee, alternating between Republicans and Democrats. Each Senator has—if you are on videoconference, you have a little time clock at the bottom, and I would ask you to try to stay within 5 minutes for your questions and answers.

I will start. I have a question for Dr. Fauci and then Admiral Giroir.

Doctor, let us look down the road 3 months. There will be about 5,000 campuses across the country trying to welcome 20 million college students, 100,000 public schools welcoming 50 million students. What would you say to the chancellor of the University of Tennessee Knoxville or the president—or the principal of a public school about how to persuade parents and students to return to school in August? Let us start with treatments and vaccines first, Dr. Fauci. And if you could save about half of my 5 minutes for Admiral Giroir for testing, I would appreciate it.

Dr. FAUCI. Thank you very much, Mr. Chairman. Well, I would be very realistic with the chancellor and tell him that what we are thinking in terms——

The CHAIRMAN. It is a her in this case, sir.

Dr. FAUCI. Oh, Okay. I would tell her—I am sorry, sir—that in this case, that the idea of having treatments available, or a vaccine, to facilitate the reentry of students into the fall term would be something that would be a bit of a bridge too far.

As I mentioned, the drug that has shown some degree of efficacy was modest, and it was in hospitalized patients; not yet, or maybe ever, to be used either yet as prophylaxis or treatment. So, if the issue is that the young individuals who would be going back to school would like to have some comfort in that there is a treatment, probably the thing that would be closest to utilization then would likely be passive transfer of convalescent serum.

But, we are really not talking about necessarily treating a student who gets ill, but how the student will feel safe in going back to school. If this were a situation where we had a vaccine, that would really be the end of that issue in a positive way. But, as I mentioned in my opening remarks, even at the top speed we are going, we don't see a vaccine playing in the ability of individuals to get back to school this term. What they really want is to know if they are safe, and that is the question that has to do with what we discussed earlier about testing.

I am about halfway through the remarks. I would like to just pass the baton to Admiral Giroir, who would address the question of the availability of testing and what role that might play in returning to school. Thank you, sir.

The CHAIRMAN. Well, thank you, Doctor. Thank you, Dr. Fauci.

Admiral Giroir, you said that while we are doing about 10 million tests this month that we might be as high as 40 or 50 million

by September, in a month, which is a significant increase. So, if I am chancellor of the University of Tennessee, could I develop a strategy where I would say to all of my students, we have, for example, an antigen test, which is quick and easy? We want everybody on campus to come by and take it once before you begin school? That will at least let everybody know that on that day, we have isolated anybody who is positive, and then we can continue to monitor. Is that strategy possible in August and September?

Admiral GIROIR. Thank you, Mr. Chairman, and I may reserve 20 seconds for Dr. Redfield, as well.

The strategy that is going to be employed really depends heavily on what is the community spread at that time. If there is almost no community spread, your strategy will be different. If there is high community spread, it will also be different.

But yes, technically, we will have the ability and your chancellor will have the ability. We expect there to be 25 to 30 million point-of-care tests per month available. It is certainly possible to test all of the students.

Or, it is much more likely that there would be a surveillance strategy done where you may test some of the students at different times to give an assurance that there is no circulation. That would be done in conjunction with the CDC and the local health department.

There is also strategies that are still needing to be validated, but of pooling samples. We know in some experimental labs, as many as 10 or 20 samples can be pooled, so essentially one test could test 20 students.

Finally, there are some experimental approaches that look interesting, if not promising, that, for example, waste water from an entire dorm or an entire segment of a campus could be tested to determine whether there is coronavirus in that sewage, the waste water. So, there are other strategies being developed.

I would like to at least give 20 seconds to Dr. Redfield, who really will be working on the strategy of how to employ the tests given different community spread.

The CHAIRMAN. Dr. Redfield.

Dr. REDFIELD. Yes, just some quick comments, sir. I mean, first, I think it is really important to evaluate critically the role of changes in social distancing on college campuses and schools in the situation, not to forget the importance of what we have learned.

Clearly, also developing a progressive program for wellness education, making sure people understand when they are symptomatic, they need to seek evaluation.

I think that you are going to have to look at the role of testing. I think there is going to be an important role of testing in these circumstances, and I think it will be individualized based on where these different schools are, where they—how much infection is in an area.

The CHAIRMAN. I am going to wrap it up there so I can set a good example for the other Senators with their 5 minutes.

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman, and thank you to all of our witnesses.

Dr. Fauci, you have warned of needless suffering and death if we push to reopen too soon, but the President has actually been sending the opposite message. I want to ask you today, what is the most important message you have for communities and states that are reopening, even as our public health experts make it clear it is too soon? Tell us what the consequences are.

Dr. FAUCI. Thank you very much for that question, Senator Murray. As I have said many times publicly, what we have worked out is a guideline framework of how we safely open America again. And, there are several checkpoints in that, with a gateway first of showing, depending on the dynamics of an outbreak in a particular region, state, city, or area, that would really determine the speed and the pace with which one does reenter or reopen.

My word has been, and I have been very consistent in this, that I get concerned if you have a situation with the dynamics of an outbreak in an area of such that you are not seeing that gradual, over 14-day decrease that would allow you to go to Phase 1. And then, if you pass the checkpoints of Phase 1, go to Phase 2 and Phase 3.

What I have expressed then, and again, is my concern that if some areas, cities, states, or what have you, jump over those various checkpoints and prematurely open up without having the capability of being able to respond effectively and efficiently, my concern is that we will start to see little spikes that might turn into outbreaks. So, therefore, I have been being very clear in my message to try to the best extent possible to go by the guidelines, which have been very well thought out and very well delineated.

Senator MURRAY. If a community or a state or a region does not go by those guidelines and reopens, the consequences could be pretty dire, correct?

Dr. FAUCI. The consequences could be really serious, particularly—and this is something that I think we also should pay attention to, that states, even if they are doing it at an appropriate pace, which many of them are and will, namely a pace that is commensurate with the dynamics of the outbreak, that they have in place already the capability that, when there will be cases, there is no doubt, even under the best of circumstances, when you pull back on mitigation, you will see some cases appear. It is the ability and the capability of responding to those cases with good identification, isolation, and contact tracing will determine whether you can continue to go forward as you try to reopen America.

It is not only doing it at the appropriate time with the appropriate constraints, but having in place the capability of responding when the inevitable return of infections occur.

Senator MURRAY. Well, thank you for that. And, it is very clear, in order to do that, we need knowledge, which is about testing. And, for months, this administration's approach to testing has really been plagued by unrealized goals and disregard for systemic problems within that supply chain. And, last week, an average of just 250,000 tests per day were performed in the United States. That is a small fraction of what we need. And yesterday, President Trump had the gall to declare the U.S. had "prevailed" on testing in a press conference that was filled with misinformation and distortions.

Dr. Giroir, public health experts do not think the U.S. has prevailed. I am glad you finally committed that states, including my home State of Washington, will receive enough tests to meet their goals for May and June, but this administration has had a record of giving us broken promises that more tests and supplies are coming and they don't. And we know, by the way, that testing is going to—needs will persist long past June, long past.

I wanted to ask you today, will the administration's forthcoming strategic plan that is now required under the COVID package that was just passed and signed into law, will that strategic plan on testing include specific numeric targets for testing capacity, supply chain capacity, and projection of shortages?

Admiral GIROIR. Thank you for that question and statement, Senator Murray. Yes, we are—as I have stated, we continue to have a work in progress as we build the testing capacity. We have established the targets with the states of over 12 million tests over the next 4 weeks. We think those targets are going to be good in May and June. But, as Dr. Fauci said, we really have to be evidence based. We expect those targets to go up as we progressively open, as communities go through Phase 1 and then into Phase 2. And, certainly those numbers will need to go up significantly again in the fall when we potentially have influenza circulating with COVID.

Yes, there will be targets. The targets will need to change based on the evidence that we see, but we are highly committed to securing the supply chain. We have worked daily with every manufacturer, and I am just pleased we are in May and June able to get ahead of the states so that we can supply them what they need so they have those assurances.

Senator MURRAY. Well, so my——

Admiral GIROIR. There is not going to be any doubts about that.

Senator MURRAY. My question to you is, when you put out that specific plan that you are required to do, we will see numbers that you are going to tell us that you will reach, targeted for testing and supply chain capacity and projections, and so forth? Instead of just saying we hope to have a million this week, next week, so you will give us the specific targets, correct?

Admiral GIROIR. We know specifically—I will say yes, ma'am, we know the specific—we know the specific amounts of tests we have. Over the summer, we are I think——

Senator MURRAY. Not have; how many we need.

Admiral GIROIR. Yes, ma'am. We develop the needs statements by working with the states individually, with epidemiologists, with the CDC, so that overall, in May, we will be testing about 3.9 percent of the overall U.S. population.

Senator MURRAY. Okay. But what I am telling you——

The CHAIRMAN. Well over time, Senator Murray.

Senator MURRAY [continuing]. Not how many we have, but how many we will need. Not just for May, but in the coming months so that we can be prepared to have them.

Admiral GIROIR. Yes, ma'am. And, not to be repetitive, but we need to be evidence and data driven because what we may see in May or June will drive differences in the amount of test goals we have. So, we really just need to be very humble about this. We

need to look at the data. We know that the testing needs will go up over May and June as we progressively open, and we will do our best to predict that. But, you have to understand, we have to see what the data and the evidence show at that time.

Senator MURRAY. Okay. I appreciate that. Mr. Chairman, again, what our strategic plan requires is what is the goal; not how many we have, but how many we need, and that is what we will be looking for. Thank you.

The CHAIRMAN. Thank you, Senator Murray.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman, and I particularly appreciated your opening statement where you had a very succinct list of preparations we need to learn from this pandemic for the next one. Not only should we be working on this and preparing, but we need to look at the future, too. And I think we have learned a lot. We are fighting a virus at the same time that scientists are learning about it.

We need to be nimble. We also need to be sure that we are prepared for a second wave of outbreaks that could coincide with the start of the flu season, potentially stressing our healthcare system even more than it already has been.

Admiral Giroir, I thank you for your comments. I think they have been comforting, about what has been done and what can be done. I agree with Senator Murray that we need to have some specific goals. As an accountant, that is always one of the things that I am looking for.

For questions, Dr. Hahn, our understanding of the clinical picture of COVID–19 continues to evolve. What first looked like a respiratory illness now seems much more comprehensive, potentially affecting the heart, the brain, the kidneys, and other organs. How does this evolving picture impact the ability to evaluate the appropriate clinical or surrogate endpoints for review of vaccines and treatment?

Dr. HAHN. Thank you, Senator, for that question. The evolving clinical picture, and obviously the way this is manifesting around the country clinically, does in fact inform the endpoints that we will work with developers of therapies on so that we can get the absolute, most efficient, but also the most accurate information and appropriate endpoints to make the necessary authorizations and approvals.

We have set up this program called the Coronavirus Treatment Acceleration Program where our top scientists and clinicians have been at the table consulting with our colleagues at NIH and CDC to actually address those questions—what are the appropriate endpoints?

I will give you an example. We do know that in some circumstances, patients who have had severe COVID disease have developed thrombotic or clotting-type episodes, and so we prioritize review of agents that we think might be beneficial. And, obviously, the clinical endpoints for those trials will be different than an agent that is an antiviral, like Remdesivir, where, as Dr. Fauci mentioned, we are looking at time to recovery.

We want to adapt it to the clinical circumstance, as well as to the type of therapy that is put before us.

Senator ENZI. Thank you. Another question to Dr. Hahn. We have made a lot of progress in vaccine development already. BARDA has identified that domestic manufacturing of needles and syringes, there is a significant gap in pandemic preparedness. What has HHS done in advance of a potential national vaccination campaign to ensure that we have sufficient capacity to administer a vaccine?

Dr. HAHN. Senator Enzi, thank you for that question. This is a really important point because, as you mentioned, it is not just about the vaccine, or hopefully vaccines, that are developed. It is all about—it is also about the supplies that are needed, as well as an operational plan for administering the vaccine.

This is an all-of-government approach. There is a program that has been set up called Operation Warp Speed that includes Dr. Collins, Dr. Fauci, his colleagues at NIH, the Department of Defense, as well as other members of HHS and FDA. Dr. Peter Marks from our Center for Biological Evaluation and Research has been helping coordinate that and is working very closely with Dr. Fauci and his team.

We have created what is called a Gantt chart to look forward, what are the necessary supply chain issues, syringes, needles, et cetera, depending on the various vaccines that are being developed, how many times they have to administer it, and the route of administration. So, we have been leaning in on this supply chain to ensure that when a vaccine is ready to go, we will have the necessary supplies to actually administer it and operationalize the vaccination.

Senator ENZI. Thank you. I have a couple more questions. But again, the clock is not visible there, so I suspect I have used up my time. I will submit those in writing.

The CHAIRMAN. Thank you, Senator Enzi.

Senator Sanders.

Senator SANDERS. Thank you very much, Mr. Chairman, and let me thank all of the panelists for the hard work they are doing and for being with us today.

It is sad to say that we have a President of the United States, the leader of our Country, who, from day one, downplayed the dangers facing this country from the pandemic; who told us that the crisis would be over in a few months; that we did not have to worry; who fired those members of the government who wanted to act aggressively; and, among other things, at a time when we need international cooperation, cut funding for the World Health Organization.

Let me also say that I think we understand that facts are terribly important. Not everybody—that we don't fully understand all of the ramifications of the COVID–19 epidemic. But, let me ask Dr. Fauci a few questions, if I might.

First off, the official statistic, Dr. Fauci, is that 80,000 Americans have died from the pandemic. There are some epidemiologists who suggest the number may be 50 percent higher than that. What do you think?

Dr. FAUCI. I am not sure, Senator Sanders, if it is going to be 50 percent higher. But, most of us feel that the number of deaths are likely higher than that number because, given the situation,

particularly in New York City when they were really strapped with a very serious challenge to their healthcare system, that there may have been people who died at home who did have COVID, who were not counted as COVID, because they never really got to the hospital.

A direct answer to your question, I think you are correct that the number is likely higher. I don't know exactly what——

Senator SANDERS. Right.

Dr. FAUCI [continuing]. Percent higher, but almost certainly, it is higher.

Senator SANDERS. Dr. Fauci, let me ask you this. In the terrible pandemic of 1918, the virus exploded in the fall. It came back with a vengeance. Are we fearful that if we don't get our act together, as bad as the situation is now, it could become worse in the fall or winter?

Dr. FAUCI. Senator, thank you for that question. It is a frequently asked question, and I think that a possibility does exist. However—and the reason I say that is that when you talk about will this virus just disappear—and as I have said publicly many times, that is just not going to happen because it is such a highly transmissible virus. And, even if we get better control over the summer months, it is likely that there will be virus somewhere in this—on this planet that will eventually get back to us.

My approach toward the possibility of a rebound and a second wave in the fall is that, A, it is entirely conceivable and possible that it would happen. But, B, I would hope that between now and then, given the capability of doing the testing that you have heard from Admiral Giroir, and the ability of us to stock up on personal protective equipment, and the workforce that the CDC under Dr. Redfield will be putting forth to be able to identify, isolate, and contact trace, I hope that if we do have the threat of a second wave, we will be able to deal with it very effectively to prevent it from becoming an outbreak not only worse than now, but much, much less.

Senator SANDERS. Okay. Let me ask—we have heard a lot of this question about vaccines. Obviously, everybody in Congress and in this country wants a vaccine. We want it as quickly as possible, as effective as possible. Let me ask the honorable FDA commissioner.

Sir, if, God willing, a vaccine is developed and if we are able to produce it as quickly as we all hope we can, I would imagine that vaccine would be distributed to all people free of charge; or make sure at least that everybody in America who needs that vaccine will get it, regardless of their income. Is that a fair assumption?

Dr. HAHN. Senator, I certainly hope so. FDA is very committed to making sure that all populations in the United States, including those most vulnerable, are included in the clinical trials, and very much——

Senator SANDERS. That is not what I am asking. What I am asking is, if and when the vaccine comes, it won't do somebody any good if they don't get it. And, if they have to pay a sum of money for it in order to profit the drug companies, that will not be helpful. Are you guaranteeing the American people today that vaccine will be available to all people regardless of their income?

Dr. HAHN. Sir, the payment of vaccines is a not a responsibility of FDA, but I am glad to take this back to the task force. I share your concern that this needs to be made available to every American.

Senator SANDERS. Does anybody else want to comment on that?

Mr. Giroir, do you think we should make that vaccine, when hopefully it is created, available to all, regardless of income? Or, do you think that poor people and working people should be last in line for the vaccine?

Admiral GIROIR. I am sorry, Senator. Were you asking me——

Senator SANDERS. Yes, I was, sir. Yes, I was.

Admiral GIROIR. No. I—my office is one of the offices committed to serving the underserved, and we need to be absolutely certain that if a vaccine or an effective therapeutic or preventative is available, that it reaches all segments of society, regardless of their ability to pay, or any other social determinants of health that there may be.

Senator SANDERS. Good. So, what you are telling the American people today, that regardless of income, every American will be able to gain access to that vaccine when it comes?

Admiral GIROIR. They should gain access to it. I don't control——

Senator SANDERS. Well, you represent—you represent an administration that makes that decision.

Admiral GIROIR. I will certainly advocate that everyone is able to receive the vaccine, regardless of income or any other circumstance.

Senator SANDERS. Let me just——

The CHAIRMAN. Senator Sanders.

Senator SANDERS. I am sorry. Alright. Thank you, Mr. Chairman.

The CHAIRMAN. Those are important questions. I don't want to cut Senators off, but—and it is hard to see the time clock. But if we could stay as close as possible to 5 minutes, then all Senators can get their questions in. Thank you Senator Sanders.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman, and thank our witnesses today for what you have done for the people in this country and their safety, and people around the globe.

Let me ask you, Dr. Fauci, because you have been in the task force and at a majority of the press conferences. Has anybody in this administration ever asked you or any member to take the foot off the gas in trying to find a cure or any type of countermeasure?

Dr. FAUCI. No, Senator, not at all. As a matter of fact, we at NIH, as you know, have been right from the very beginning, put our foot right on that accelerator in every aspect, including the development of vaccines and therapeutics. And as I described in my opening statement, we actually started that in January, literally days after the virus was known and its sequence was published. So, no, I have never been told by anyone to hold back on the development of any countermeasure or any basic, including the research project that we have been involved in.

Senator BURR. Thank you, Dr. Fauci.

This question is for Dr. Redfield. Dr. Redfield, we have authorized in this Committee and appropriated out of Congress multiple times over the last few decades money for biosurveillance, and you

talked about it. In the past 4 years, from Fiscal Year 2016 to Fiscal Year 2020, it has been $23 million a year, and with the CARES Act, it is over $1 billion in biosurveillance. We have seen the private sector go out and use data available to track the progress and spread of coronavirus around the world. Why has CDC not contracted with private sector technology companies to try to use their tools for biosurveillance?

Dr. REDFIELD. Senator, thank you for the question. This is a critical issue, as you know, and also comes into one of the core capabilities I talked about, data analytics and data modernization, which we are appreciative of the additional funding Congress has given.

I can tell you that this is under critical review now, and we do have contracts with some of the private sector groups now to try to make the type of availability of data that we have seen with Florida available in all of our jurisdictions across the country and in the process of making that happen.

Senator BURR. Dr. Redfield, in April of last year—June of last year, we reauthorized the Pandemic and All-Hazards legislation, which authorized at that time 30 new billets, 30 new employees, at CDC, specifically in surveillance. Now, I asked Dr. Schuchat in March how many of those 30 had been filled. She said zero. As of mid-April, zero of those 30 billets had been filled. How many of those 30 employees that this Committee authorized CDC to bring on for biosurveillance have been filled today?

Dr. REDFIELD. Sir, again, thank you for the question. I know our staffs have been in discussion since Dr. Schuchat's testimony, and I know we are in the process of continuing to try to figure out how to move that forward, sir. I can get back to you on it as I discuss what progress has been made since we had that discussion post her hearing with you when you brought that to light.

Senator BURR. Well, I brought it to light the 1st of March, and now we are in mid-May. So, I am hopeful that we won't just talk about surveillance; we will actually execute it and will focus the unbelievable amounts of money that we have provided for you, that they will show some benefit to the American people.

Dr. Fauci, let me come back to you. This is one of the fastest development timelines we have ever seen for vaccines, and the American people, and hopefully people around the world, will be the beneficiary of what you find and the eventual licensure of that product. What are the biggest unknowns with this particular virus that can affect the development process? And, Dr. Hahn, if you have anything to add after that to this, please do.

Dr. Fauci.

Dr. FAUCI. Thank you very much, Senator Burr. Well, there are a couple of things that I think are inherent in all vaccine development.

First of all, there is no guarantee that the vaccine is actually going to be effective. As you well know, because we have discussed this many times in the past, that you can have everything you think that is in place and you don't induce the kind of immune response that turns out to be protective and durably protective. So, one—the big unknown is, it will be effective. Given the way the

body responds to viruses of this type, I am cautiously optimistic that we will, with one of the candidates, get an efficacy signal.

The other thing that is an unknown that is of concern, but we will be able to get around that by doing the tests properly, is that, do you get an enhancement effect? Namely, there have been a number of vaccines, two in particular, Dengue and respiratory syncytial virus, when the vaccine induces a suboptimal response, and when a person gets exposed, they actually have an enhanced pathogenesis of the disease, which is always worrisome. So, we want to make sure that does not happen.

Those are the two major unknowns. Putting all those things together, Senator Burr, I still feel cautiously optimistic that we will have a candidate that will give some degree of efficacy, hopefully a percentage enough that will induce the kind of herd immunity that would give a protection to the population at whole.

Senator BURR. Dr. Hahn, anything to add to that?

Dr. HAHN. Yes, sir. Thank you for the question. The obstacles from a regulatory point of view I think are being met by the approaches being taken out of HHS and led by Peter Marks. That is, a common, preclinical development pathway so that we can appropriately assess one vaccine against the other, and then a master protocol that allows for a common control group and an assessment of very common endpoints. That will let us be as efficient as possible for the development of vaccine.

We will evaluate approximately 10 candidates pre-clinically and then in the Phase 1 and Phase 2 studies, and then take four to five into Phase 3 studies in this HHS effort.

I think those are the obstacles that can be broken down to speed the development, but also allow us to ensure safety and effectiveness.

Senator BURR. Mr. Chairman, yesterday, the State of North Carolina started to publicize the recovered numbers, those individuals who had coronavirus but have recovered. It is my hope that nationally, we will start reporting the recovered numbers. I think that is important for the American people to hear. I yield back.

The CHAIRMAN. Thank you, Senator Burr.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you for the hearing, as well as Ranking Member Murray.

Mr. Chairman, I wanted to start today with a question regarding nursing homes. In particular, across the state like ours, we have had, as you might know, a high number of cases in Pennsylvania. At last count, over 57,000 cases. The number of deaths have gone above 3,700 and, of course, a lot of those deaths are in nursing homes. We are told that nationally, more than one-third, as high as 35 percent, of all deaths, have been in nursing homes, either the death of a resident of a nursing home or a worker. So, I want to start today with a question for Dr. Redfield.

Doctor, when we consider this challenge in our long-term care facilities, when we look at the number of deaths in nursing homes, I think a lot of families want basic transparency. That is one of the reasons why Senator Wyden and I sent you a letter dated April the 2d. It was directed to you, as well as the administrator of the Centers for Medicare and Medicaid Services, Seema Verma.

In that letter, we asked for basic information about what the administration was doing to track the outbreaks in nursing homes, to provide information, basic information, to families and residents, the families of residents in nursing homes, certainly to the workers, as well as to the community and public health professionals.

Now, it took you over—about a month to respond to that. But, in your response, you didn't give us any information about the timeline. These families need this information. And, now we are told by the CMS administrator, after pressing her as Senator Wyden and I did, that this information may not be available until the end of May.

I need to hear from you today, why has there been a delay, a 3-month delay, in basic information that families and people within a community need about the outbreaks in nursing homes, the number of cases, what is happening in nursing homes? Tell us when we are going to see that information.

Dr. REDFIELD. Well, thank you very much, Senator, and you have highlighted one of the great tragedies that we have all experienced together. Clearly, the long-term care facilities have been particularly hard hit by this pandemic.

Several things. I know that, again, the CMS, who has oversight, several things have been done, and I can get back to you in terms of where they are at in terms of activation. But, clearly, all nursing homes now are required to report cases in either their individuals that are patients there or staff to the CDC.

Second, I know that Dr. Verma and I have put a policy in place at all nursing homes that required that they notify the members of that nursing home of the existence of COVID in that nursing home, including family members. In—verify in terms of when that is, if that is operational as of today or last week, but I will get back to you with that.

One of the most important—we have decided, as we talk about key in reopening, as Tony mentioned, we need—symptomatic cases. We need to be able to do the contact tracing.

But, the other thing that we really need to do is to do surveillance because this virus does appear to have a high propensity for asymptomatic infection, which means the traditional ways of identifying cases is going to be blunted. And, so, we are developing a national surveillance system, and first and most important in that is to do comprehensive surveillance in all the nursing homes in the United States. CDC will be doing that in partnership with the state and local and territorial health departments. I think HRSA is going to have the responsibility to do it within the inner city clinics that are selected, and the Indian Health Service for the Indian Health Service clinics.

But, this is critical, that we get in front of this and do comprehensive surveillance of everybody in these nursing homes.

We have also done, aggressive outreach in all of them in enhancing infection control procedures, et cetera. CDC has been out to help these nursing homes with that and to the guidance, along with the—but, I will get back to you in terms of the time. I am pretty confident they are already—it is already operational, but I need to double check just to make sure because I know Seema has announced it. They are all reporting to the CDC now any infection

in workers or patients, and that they are required now to notify other members in the nursing home, as well as family members, when COVID is one of those places.

Senator CASEY. Mr. Chairman, I just have one question for Dr. Fauci.

Doctor, I wanted to ask you, in your testimony earlier in response to a question by Senator Murray, you outlined a basic concern you have with regard to states reopening. Can you restate that for us?

Dr. FAUCI. Yes. Thank you, Senator Casey. Yes. My concern is that if states or cities or regions, in their attempt, understandable, to get back to some form of normality, disregard to a greater or lesser degree the checkpoints that we put in our guidelines about when it is safe to proceed in pulling back on mitigation. Because I feel if that occurs, there is a real risk that you will trigger an outbreak that you might not be able to control, which, in fact, paradoxically, will set you back, not only leading to some suffering and death that could be avoided, but could even set you back on the road to trying to get economic recovery because it would almost turn the clock back rather than going forward. That is my major concern, Senator.

Senator CASEY. Thank you, Doctor. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Casey.

Senator Paul.

Senator PAUL. Dr. Fauci, scientists have shown that rhesus monkeys that are infected with COVID–19 cannot be re-infected.

Several studies have also shown that plasma from recently infected coronavirus patients neutralizes the virus in lab experiments. In addition, infusion of convalescent plasma is based on the idea that recovering coronavirus patients are developing immunity and that it can be beneficial as donating.

Studies show that the recovering COVID–19 patients from the asymptomatic to the very sick are showing significant antibody response.

Studies show that SARS and MERS, also coronaviruses, induce immunity for at least 2 to 3 years, and yet the media continues to report that we have no evidence that patients who survive coronavirus have immunity. I think actually the truth is the opposite. We have no evidence that survivors of coronavirus don't have immunity, and a great deal of evidence to suggest that they do.

The question of immunity is linked to health policy and that workers who have gained immunity can be a strong part of our economic recovery. The silver lining to so many infections in the meat processing industry is that a large portion of these workers now have immunity. Those workers should be reassured that they likely won't get it again instead of being alarmed by media reports that there is no evidence of immunity.

You have stated publicly that you would bet it all that survivors of coronavirus have some form of immunity. Can you help set the record straight that the scientific record as it is being accumulated is supportive that infection with coronavirus likely leads to some form of immunity?

Dr. Fauci.

Dr. FAUCI. Thank you for the question, Senator Paul. Yes, you are correct that I have said that, given what we know about the recovery from viruses, such as coronaviruses in general, or even any infectious disease with very few exceptions, that when you have antibody present, it very likely indicates a degree of protection.

I think it is in the semantics of how this is expressed. When you say, has it been formally proven by long-term, natural history studies, which is the only way that you can prove, one, is it protective—which I said and would repeat is likely that it is—but also, what is the degree or titer of antibody that gives you that critical level of protection, and what is the durability?

As I have often said, and I again repeat, you can make a reasonable assumption that it would be protective, but natural history studies over a period of months to years would then tell you definitively if that is the case.

Senator PAUL. I think that is important because—in all likelihood is a good way of putting it. The vast majority of these people have immunity, instead of saying there is no evidence. You know, the WHO kind of fed into this by saying no evidence of immunity. And, in reality, there is every evidence stacking up. In fact, a lot of the different studies have shown that it is very unlikely that you get it again in the short term.

With regard to going back to school, one thing that was left out of that discussion is mortality. I mean, shouldn't we at least be discussing what the mortality of children is? This is for Dr. Fauci, as well.

You know, the mortality between zero and 18 in the New York data approaches zero. It is not going to be absolutely zero, but it almost approaches zero.

Between 18 and 45, the mortality in New York was 10 out of 100,000.

Really, we do need to be thinking about that. We need to observe with an open mind what went on in Sweden where the kids kept going to school. The mortality per capita in Sweden is actually less than France, less than Italy, less than Spain, less than Belgium, less than the Netherlands, about the same as Switzerland.

But, basically, I don't think there is anybody arguing that what happened in Sweden is an unacceptable result. I think people are intrigued by it, and we should be. I don't think any of us are certain when we do all of these modelings. There have been more people wrong with modeling than right. We are opening up a lot of economies around the U.S., and I hope that people who are predicting doom and gloom and saying, oh, we can't do this, there is going to be a surge, will admit that they were wrong if there is not a surge because I think that is what is going to happen.

In rural states—we never really reached any sort of pandemic levels in Kentucky and other states. We have less deaths in Kentucky than we have in an average flu season. That is not to say this is not deadly. But really, outside of New England, we have had a relatively benign course for this virus nationwide.

I think the one-size-fits-all that we are going have a national strategy and nobody is going to go to school is kind of ridiculous. We really ought to be doing it school district by school district, and

the power needs to be disbursed because people make wrong predictions. And really, the history of this when we look back will be of wrong prediction after wrong prediction after wrong prediction, starting with Ferguson in England.

I think we ought to have a little bit of humility in our belief that we know what is best for the economy. And, as much as I respect you, Dr. Fauci, I don't think you are the end-all. I don't think you are the one person that gets to make a decision. We can listen to your advice, but there are people on the other side saying there is not going to be surge and that we can safely open the economy.

The facts will bear this out, that if we keep kids out of school for another year, what is going to happen is the poor and underprivileged kids who don't have a parent that is able to teach them at home are not going to learn for a full year.

I think we ought to look at the Swedish model, and we ought to look at letting our kids get back to school. I think it is a huge mistake if we don't open the schools in the fall. Thank you.

Dr. FAUCI. Mr. Chairman, could I respond to that even though there are only 32 seconds left?

The CHAIRMAN. Yes. And you might make it clear whether or not you suggested that we shouldn't go back to school in the fall.

Dr. FAUCI. Well, first of all, Senator Paul, thank you for your comments. I have never made myself out to be the end-all and only voice in this. I am a scientist, a physician, and public health official. I give advice according to the best scientific evidence. There are a number of other people who come into that and give advice that are more related to the things that you spoke about, about the need to get the country back open again and economically. I don't give advice about economic things. I don't give advice about anything other than public health. So, I wanted to respond to that.

The second thing is that you used the word 'we should be humble' about what we don't know. I think that falls under the fact that we don't know everything about this virus and we really better be very careful, particularly when it comes to children. Because the more and more we learn, we are seeing things about what this virus can do that we didn't see from the studies in China or in Europe. For example, right now, children presenting with COVID–16—with COVID–19 who actually have a very strange inflammatory syndrome, very similar to Kawasaki Syndrome. I think we better be careful if we are not cavalier in thinking that children are completely immune of the deleterious effects.

Again, you are right in the numbers that children, in general, do much, much better than adults and the elderly and particularly those with underlying conditions. But, I am very careful, and hopefully humble, in knowing that I don't know everything about this disease, and that is why I am very reserved in making broad predictions. Thank you.

The CHAIRMAN. Thank you, Senator Paul.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman and Ranking Member Murray and our witnesses.

I want to try to cover a lot of territory in my 5 minutes, so I would certainly be appreciative of concise answers.

But, I want to start with Dr. Redfield. Dr. Redfield, do you think that the current testing protocols at the White House presents a model for other essential workplaces?

Dr. REDFIELD. I am sorry, Senator. You broke up at the beginning of your question. If you could just say it again. I am sorry.

Senator BALDWIN. Yes. Dr. Redfield, do you think that the testing protocols currently in place in the White House present a model for other essential workplaces?

Dr. REDFIELD. Well, I think—thank you for the question. I think one of the important things you bring up is the essential worker guidance that CDC put out. And I think it was originally modeled, obviously, on healthcare workers where there were significant healthcare shortages and individuals that were exposed——

Senator BALDWIN [continuing]. Workplaces. I am asking you if you think that the White House protocols for testing are a model for other essential workplaces.

Dr. REDFIELD. I would just say that I think each workplace has to define their own approach as to how to operationalize our——

Senator BALDWIN. You already had some considerable comment on the fact that OSHA has not stood up an enforceable, mandatory emergency temporary standard for workers in all sorts of work settings. But that aside, would you say that the PPE rules and protocols in effect right now in the White House are a model for other essential workplaces?

Dr. REDFIELD. We would—my own view would go back to the guidelines that CDC has put out about essential workplaces for people. If they are an essential workforce, that they go in public, they maintain 6 feet distancing and they wear face coverings.

Senator BALDWIN. Okay. Admiral Giroir, you have testified about how far you have come with regard to testing assessments. I want to ask you if you believe that we already have a national testing strategy today that spans from the nationwide testing needs assessment to the nationwide testing supply assessment, and a strategy to fill that gap to procure domestically what we need in terms of bridging that gap with testing platforms, swabs, specimen collection media and reagents, and the PPE needed to conduct those tests.

Admiral GIROIR. Thank you for that. We do have a strategy that spans us at least to the fall and beyond. As I mentioned, we are working individually with every state, and I think Senator Paul is correct that Kentucky, Wyoming or New Jersey, Rhode Island are different. There are vastly different testing needs. The East Coast will have multiples of testing versus other states, and we are working those individually.

Senator BALDWIN. So——

Admiral GIROIR. Yes.

Senator BALDWIN. I know you testified earlier that not only are you working with the states, but you are working with every lab in every state——

Admiral GIROIR. Correct.

Senator BALDWIN [continuing]. Trying to increase capacity. What about working with those who would be the—those who would need testing to, say, reopen their school, their university, their business? Each of them have identified what they think are their testing

needs based on, guidance, not mandatory, enforceable rules. But, are you in contact at that level? Does your dashboard have visibility at that lowest level, or are you mostly in contact with the states and with the labs?

Admiral GIROIR. Over the last few months, we have done a lot of the individual work at nursing homes, at meat packing plants, and other—I mean, really down to the very granular level.

Senator BALDWIN. Okay.

Admiral GIROIR. Where we are right now, however, is we are really working with the state leadership, with the public health lab, the state epidemiologist, the SHOs, the state health officials, because they really need to understand what their sum is going to be in their state.

Senator BALDWIN. Okay. Thank you.

Admiral GIROIR. Then the funding, we are asking very specifically, in the CDC funding, for specific plans for schools, nursing homes, underserved, et cetera.

Senator BALDWIN. Thank you. I have two more points that I am going to make. I don't have time for questions.

One is about the transparency of that needs assessment. Can the public see it? Can the states see it? Can the HELP Committee Members see it? Is it publicly available?

Second, the delivery of this supply is a critical issue, and it seems to me that the logistics for getting this out, whether it is PPE, testing, or medical equipment, is still extremely fragmented, leading to price gouging and many other inefficiencies. We need to stand up the full power of the Defense Production Act.

Admiral GIROIR. Would you like me to comment on that, ma'am? I am sorry.

Senator BALDWIN. I am happy to have you comment with the indulgence of the Chairman. We have gone over time and——

The CHAIRMAN. Why don't you try to give a succinct answer to the Senator, please, Admiral Giroir.

Admiral GIROIR. Yes, ma'am, and yes, sir. Particularly for things like swabs and media, there is still a very, I would say, non-mature industry within the country, and that is why we have made the decision to procure that all centrally through December and then distribute that to the states. Because there are just too many small companies, too many—too many variables to control without a really heavy Federal hand. That is just an example of where we really moved into that and used the DPA for swabs to help support American industry.

In more mature aspects of the industry, like some of the large test producers, we feel that by helping direct them to make sure that the states get what they need in the right distribution, that we are not procuring them directly by us. But again, we are going to be very evidence and data driven as we move on.

Thank you, sir.

The CHAIRMAN. Thank you very much, Senator Baldwin.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Let me begin by first thanking each of our witnesses today for their expertise, their dedication, and their hard work.

Dr. Redfield, I want to start with you. I am hearing from dentists all over the State of Maine that the fact that they cannot practice in our state, despite following very strict infection control protocols, is causing growing health problems.

Dentists tell me that teeth with cavities that could have been filled are now going to need root canals. Teeth that could have been treated with root canals are now going to require extractions. People with oral cancers cannot get the treatment, the cleanings, that they need before beginning their treatment.

Dental health is clearly so important, and Maine State officials, as well as our dentists, are seeking assistance in reaching the right decisions. Forty-seven other states either have reopened dental practices or have a day set for them to reopen.

My question to you is this. If dentists are following the American Dental Association guidelines, if they are instituting strict protective measures for their patients, their staffs, their hygienists, themselves, and if they are closely examining and seeing a decline in the number of COVID–19 infections in their county, are these reasonable factors for states to consider in reopening the practice of dentistry?

Dr. REDFIELD. Yes, Senator. Thank you for the question. You know, we have been interacting and talking with dentists and working with the state and local public health officials to update our guidelines on reopening a variety of medical services, as you know. And I think you raise a very important point, and I would not disagree with what you said about looking at the American Dental Association, as well as the reality of the outbreak in the area. But, we are in the process of updating those guidelines, and they will include direct guidelines for dental practices.

Senator COLLINS. Thank you very much, Doctor.

Dr. Giroir and Dr. Hahn, recently there has been a significant demand for Remdesivir, I may be mispronouncing it, which transitioned to receiving an Emergency Use Authorization.

Last week, Maine's two largest hospital systems contacted me with questions about how this therapeutic will be allocated going forward. HHS finally released a statement on Saturday about allocations going to states; interestingly, not directly to hospitals. But, once again, the decision making behind these allocations is very unclear.

HHS and the Assistant Secretary for Preparedness and Response say that each state is expected to receive an allocation, but no timetable has been provided. Beyond those who are being treated with this drug at Maine Medical Center through a clinical trial, I am concerned that hospitalized patients in Maine will have little or no ability to be treated with this promising therapeutic for the foreseeable future.

As this and more therapeutics, and ultimately a vaccine, come onto the marketplace, how can these allocation and distribution issues be resolved so that patient care is not delayed and so that it does not depend on which state you live in whether or not you are going to get access to these treatments and ultimately a vaccine?

Dr. HAHN. Senator Collins, this—oh, go ahead, Admiral Giroir.

Admiral GIROIR. Go ahead. Go ahead, Commissioner.

Dr. HAHN. Senator Collins, I think we completely agree with you that this has to be an evidence based approach getting the medical therapeutics, vaccines, Remdesivir, whichever it happens to be, to the people in need. I think we can all agree upon the fact that we learned a lot of lessons from the Remdesivir situation. And, of course, as you mentioned, that is being led by HHS and ASPR.

What you see in the most recent announcement is that what the task force did was provide guidance to HHS regarding where the most significant outbreak of hospitalizations, outbreak occurred and where those hospitalized patients were. This represented about one-quarter of the supply of drug that we have, and more will be allocated according to methodology that gets the drug to where those hospitalized patients are.

I think valuable lessons can be learned and will be learned with respect to other therapies, and to vaccines in particular, and we must incorporate those into our operational plans moving forward.

Senator COLLINS. Thank you, Doctor.

Admiral, do you have anything to add? I am over time. Sorry. Thank you. If you have anything to add, if you would do so for the record.

Admiral GIROIR. No, ma'am. No, ma'am. I agree with the commissioner. It is absolutely critical that it is evidence based, based on the people who could benefit from it, and also fair and just throughout our Country.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you to you and Senator Murray for convening this. Thank you to all the witnesses for your service.

This is obviously an exceptional hearing today in that three of our witnesses are in quarantine. So, I just want to start by asking a pretty simple yes or no question that I think I know the answer to.

Dr. Fauci, Dr. Hahn, and Dr. Redfield, I am correct that all of you are drawing a salary, as you should, during your period of quarantine. Is that correct?

Dr. FAUCI. Senator, let me start off. I think we better be careful about the issue of quarantine. We are essential workers as part of the essential infrastructure, and we are, when needed, which is often, do our duties in our respective places at the White House. I was at the White House yesterday, and I will likely even—perhaps even be there today, and in my office at the NIH. So, it is not really strictly speaking a quarantine as we know it, but it is performing our duties as critical workers. And I would be happy to have my colleagues also respond to that.

Dr. HAHN. Senator Murphy, this is Steve Hahn. I agree with Dr. Fauci. And yes, I am drawing a salary, and I have continued to work during my quarantine. And, as an essential worker, will participate in meetings face to face when that attendance is considered critical.

Senator MURPHY. My point here—listen, you all should draw a salary while you are taking precautionary steps because of the contacts you have made. My point is that quarantine is relatively easy

for people like you and me. We can still work and get paid. We can telework.

But, there are millions of other Americans who work jobs that cannot be performed from home, or are paid by the hour. And, it is just remarkable to me that this administration has not yet developed a mechanism for states to implement and pay for a quarantine system that will work for all Americans. Your plan to reopen America requires states develop that plan, and yet my state has no clue how to implement and pay for that system without help from the Federal Government, which leads me to my second question.

Dr. Fauci and Dr. Redfield, you have made news today by warning us appropriately of the dangers of states opening too early. But, as Senator Murray mentioned, this is infuriating to many of us because it comes hours after the President declared that we have prevailed over coronavirus, which I am just going to tell you is going to make it much harder on state leaders to keep social distancing restrictions in place. It comes days after the President called on citizens to liberate their states from social distancing orders.

I think you are all noble public servants, but I worry that you are trying to have it both ways. You say the states shouldn't open too early, but then you don't give us the resources to succeed. You work for a President who is, frankly, undermining our efforts to comply with the guidance that you have given us, and then the guidance that you have provided is criminally vague.

I want to ask my last question on this topic. Obviously, the plan to reopen America was meant to be followed by more detailed, nuanced guidance. Right? What does a downward trajectory mean? What happens if the trajectory is downward in some settings but upward in others? What happens if you reopen and then there is a spike in one location or another setting? And, of course, you knew this because you developed this guidance, this additional guidance, that is site-specific, that, frankly, is helpful. Some of this is on the CDC website, but some of it is not, and we need it. My state needs it. We don't have all of the experts that you have, and so we rely on you.

Reporting suggests, Dr. Redfield, that this guidance that was developed by you and other experts was shelved by the administration, that it was withheld from states and the public because of a decision made by the White House. So, my specific question is, why didn't this plan get released? And, if it is just being reviewed, when is it going to be released? Because states are reopening right now, and we need this additional guidance to make those decisions.

Dr. REDFIELD. Senator, I appreciate your question. Clearly, we have generated a series of guidances, as you know. And, as this outbreak response has evolved from a CDC to an all-of-government response, as we work through the guidances, a number of them go for interagency review and interagency input to make sure that these guidances are more broadly applicable for different parts of our society.

The guidances that you have talked about have gone through that interagency review. There are comments that have come back to CDC, and I anticipate they will go back up into the task force for final review.

Senator MURPHY. But we are reopening in Connecticut in 5 days, in 10 days. I mean, this guidance isn't going to be useful to us in 2 weeks. So, is it this week? Is it next week? When are we going to get this expertise from the Federal Government?

Dr. REDFIELD. The other thing I will just say is that the CDC stands by to be of technical assistance to your state and any state upon any request. I do anticipate this broader guidance, though, to be posted on the CDC website soon.

Senator MURPHY. Soon.

Dr. REDFIELD. I can't tell you soon, but I can tell you your state can reach out to CDC and we will give guidance directly to anyone in your state on any circumstance that your state desires guidance from.

Senator MURPHY. Soon isn't terribly helpful.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Cassidy.

Senator CASSIDY. Okay. Gentlemen, thank you very much for your service, and I will have a set of questions. So, if your questions can be brief, I appreciate your answers to be brief.

Dr. Hahn, in your testimony, you mentioned that the testing for the populations in the vaccine trials now includes older Americans. I guess my question, though, is what about children? Does it include children? Does it also include the obese, the diabetic, the immunocompromised, those who are at risk of having a less—a non-response or a mitigated response to vaccination? Can you comment on that, please?

Dr. HAHN. Yes, sir. Thank you, Senator Cassidy. When the Phase 2, Phase 3 trials are in place, they will include our most vulnerable populations, including the individuals that you describe. We are working very closely——

Senator CASSIDY. If I can interrupt. Phase 2——

Dr. HAHN. Yes, sir.

Senator CASSIDY [continuing]. Would normally check for safety. You would not have to do a separate Phase 2 in the patient who was younger? Do you follow what I'm saying? Or can you just assume the safety data from the adults applies to that of the children?

Dr. HAHN. Sir, no, we would also want to assess safety, sir, as well, in children.

Senator CASSIDY. The current Phase 2 trials, do they include children?

Dr. HAHN. They are in Phase 1 studies right now, sir.

Senator CASSIDY. Well, I thought Dr. Fauci said we had a Phase 2 going on.

Dr. HAHN. Well, I think it is about to start for the Moderna vaccine.

Dr. FAUCI. No.

Dr. HAHN. Perhaps, Dr. Fauci, you can answer that.

Dr. FAUCI. Yes. I—no, Senator Cassidy. No. I did not say a Phase 2. As I said, we are in a second dose of the Phase 1, and we will proceed when we finish the Phase 1 to go into Phase 2.

Senator CASSIDY. If this—so, I think I am hearing that children will be included Phase 2 trials?

Dr. HAHN. That is a—so, that is under discussion between FDA and NIH at this time, sir, because we do realize that it is important——

Senator CASSIDY. Sounds right.

Dr. HAHN [continuing]. For us to understand what this is in children.

Dr. Redfield, to build back upon what Senator Murphy said, the published guidelines for schools, school opening, obviously, you are about to modify. But, I notice as I read through them, there is nothing about testing. So, we speak about testing, targeted testing and how we use testing, but the guidelines for the school systems has nothing about how to integrate testing. Will these be in those guidelines that are being released?

Dr. REDFIELD. Senator, thanks for the question. Clearly, there is going to need to be, as has already been stated, an integration of a testing strategy. That is going to be different for different school settings, as well as different jurisdictions, where there is—setting, and that is going to have to be integrated into each of those. There is general overarching guidelines. And, then, as I say, I do think the testing strategy, which is important, is—including the surveillance strategy, needs to be an individualized——

Senator CASSIDY. Now, let me comment on that, Dr. Redfield.

Dr. REDFIELD [continuing]. Guidelines.

Senator CASSIDY. Dr. Redfield, in all due respect, I think children, whether you are rural, frontier, suburban, or urban, is the one setting in which there is a remarkable commonality. And I will echo what Senator Murphy said. The resources that the Federal Government has greatly exceeds all but the most sophisticated, the populous, wealthy state. And even then, it exceeds it by some extent.

I do think it would be good to have, okay, in a primary school setting, this is best practices, or these are three options and choose between one of these three. To say to each school district or each private or parochial or independent school, work with your state board of health, figure it out, seems a wasted effort. I say that because children play such a role in both protection of disease, the spread of disease, et cetera.

Your thoughts on that? Because it really seems that is the one setting where you can have, not cookie cutter, but certainly a pattern which can be followed.

Dr. REDFIELD. Senator, I must have been misunderstood. When I was talking about differences, I was thinking of the difference between an elementary school, a high school, a college in terms of how we—a trade school. There may be differences in how you integrate a testing strategy. But, I do think having a testing strategy with different options for people to evaluate based on different principles will be important in terms of guidance.

Senator CASSIDY. Dr. Fauci, you persuasively argue that the risk of reopening prematurely is great. But, I think the frustration, if I think of children in particular, the risk-benefit ratio of a child being at home, potentially away from enhanced nutrition, without the parent able to work because the school provides daycare, without the monitoring that sometimes occurs for incidences such as child abuse, but perhaps most importantly for all children, the op-

portunity cost of a brain, which is forming, not having access to the information that will help that brain form optimally.

Now, has there been any sort of kind of risk-benefit ratio for the child? Yes, they are at risk for Kawasaki's, but there are particular risks for missing out on a year of education, particularly for those from less than rich backgrounds.

I guess I am very concerned about that tension. What are your thoughts on that?

Dr. FAUCI. No. You make a very good point, Senator Cassidy. There are obviously very difficult of the unintended consequences of trying to do something that broadly is important for the public health and the risk of having a return or a resurgence of an outbreak, and the unintended, deleterious consequences of having children out of school. We fully appreciate that. I don't have an easy answer to that. I just don't. We just have to see on a step-by-step basis as we get into the period of time of the fall about reopening the schools exactly where we will be at the dynamics of the outbreak.

I might point out something that I think has been alluded to throughout some of the questions. We have a very large country, and the dynamics of the outbreak are different in different regions of the country. So, I would imagine that situations regarding school would be very different in one region versus another, so that it is not going to be universally or homogenous. And I don't have a good explanation or solution for the problem of what happens when you close schools and it triggers a cascade of events and could have some complicated circumstances.

Senator CASSIDY. Mr. Chairman, I will close by asking the permission of the Chairman to submit for the record an article that just came out in the *Journal of Pediatric Nursing*, Children are at Risk from COVID–19.

The CHAIRMAN. It is so ordered and it will be included. Thank you, Senator Cassidy.

[The information referred to was not submitted for the Record.]

The CHAIRMAN. Senator Warren.

Senator WARREN. Thank you, Mr. Chairman, and thank you to our witnesses for being here today. I hope everybody is staying safe and healthy.

In the past 16 weeks, over 1.3 million Americans have been infected with coronavirus. We now know that about 80,000 people have died, and 33 million people are out of work.

Dr. Fauci, you have advised six presidents. You have battled deadly viruses for your entire career. So, I would just like to hear your honest opinion. Do we have the coronavirus contained?

Dr. FAUCI. Senator, thank you for the question. Right now, it depends on what you mean by containment. If you think that we have it completely under control, we don't. I mean, if you look at the dynamics of the outbreak, we are seeing a diminution of hospitalizations and infections in some places, such as in New York City, which has plateaued and started to come down, New Orleans, but in other parts of the country, we are seeing spikes.

When you look at the dynamics of new cases, even though some are coming down, the curve looks flat with some slight coming down. So, I think we are going in the right direction, but the right

direction does not mean we have, by any means, total control of this outbreak.

Senator WARREN. Right direction. As I understand it, we have about 25,000 new infections a day and over 2,000 deaths a day. I think those are the right numbers. And some are estimating we could be at 200,000 new cases a day by June. Is that right, Dr. Fauci?

Dr. FAUCI. I don't—I don't foresee that as 200,000 new cases by June. I am hoping, in looking at the dynamics of things starting to flatten off and come down, that we will be much, much better than that, Senator. I mean, I think——

Senator WARREN. Just so I understand, we are right now at 2,000 new infections a day and—25,000 new infections a day and 2,000 deaths a day.

Dr. FAUCI. Right.

Senator WARREN. That is where we are right now?

Dr. FAUCI. Right.

Senator WARREN. Is that——

Dr. FAUCI. Yes.

Senator WARREN. Let me just ask. We know that it is possible to get this virus under better control. Other countries have done it, like South Korea. But, we are now 3 months into this pandemic and basically we have continued to set records for the number of people who are diagnosed and the number of people who die.

Dr. Fauci, you recently said that a second wave of coronavirus in the fall was "inevitable," but that if America "puts in place all of the countermeasures that you need to address this, we should do reasonably well." And the countermeasures you identified were things like continued social distancing, significantly more testing, widespread contact tracing. You also said that if America doesn't do what it takes, and this is your quote, "We could be in for a bad fall and a bad winter."

Right now we are about 16 weeks away from Labor Day. That is about the same length of time since the virus was first detected here in the U.S. Do we have enough robust countermeasures in place that we don't have to worry about a bad fall and winter?

Dr. FAUCI. Right now, the projection, as you have heard from Admiral Giroir, with regard to testing and other elements that will be needed to respond, the projection is that by the time we get to the end of the summer and early fall, that we will have that in place. That is the projection that I get from——

Senator WARREN. We don't have it in place now, but we are projecting that we will have it in place.

Let me just ask the other side of this. If we don't do better on testing, on contact tracing, and on social distancing, will deaths from coronavirus necessarily increase?

Dr. FAUCI. Of course. If you do not do an adequate response, we will have the deleterious consequence of more infections and more deaths, and that is the reason why—you quoted me, Senator, quite correctly, everything you said, and I will stand by that.

If we do not respond in an adequate way, when the fall comes, given that it is without a doubt that there will be infections that will be in the community, then we run the risk of having a resurgence. I would hope by that point in time in the fall that we have

more than enough to respond adequately. But, if we don't, there will be problems.

Senator WARREN. I appreciate your hope, and I wish we could tell the American people that the Federal Government has this pandemic under control, but we can't. In fact, you have said that the virus is not under control in the U.S. We haven't yet taken the measures necessary to prevent a second wave of death. And, we all know that the people who are going to be most affected are going to be seniors, essential workers, the people who are out on the front lines.

The President needs to stop pretending that if he just ignores bad news, it will go away. It won't. The time for magical thinking is over here. President Trump must acknowledge that the Federal response has been insufficient and that more people are dying as a result. We are running out of time to save lives, and we need to act now.

Thank you, Dr. Fauci, for all you are doing. We appreciate it, but the urgency of the moment could not be clearer.

Thank you.

The CHAIRMAN. Thank you, Senator Warren.

Senator Roberts.

Senator ROBERTS. Thank you very much, Mr. Chairman, and thanks to all the witnesses. You all are like the Fab 4. I guess there it a Fab 5 back in the day. But, we are shining the light of truth into darkness, with individual flashlights, for sure. Thank you, Mr. Chairman, for emphasizing that we have to be bipartisan in this approach or we are not going to get anywhere, and that obviously is in the eyes of the beholder.

I am happy to say that we have a great relationship with Governor Kelly, who happens to be a Democrat and obviously I am a Republican, and her emergency management team is spot on. Dr. Lee Norman is doing an outstanding job. This morning I talked to Lee. The situation in Kansas is not very good. I am reading here, "Kansas Receives 7,000 New COVID Tests for Counties With Food Processing Facilities."

You see this mural behind me. That is a stagecoach coming into Dodge and opposed to getting out of Dodge. That city is my hometown, and we are the hot spot in regards to Kansas, mainly because of two packing plants. We have five. That is 26 percent of the cattle market. At any rate, Kansas is going through a tough time, and it—we shouldn't be worrying about the safety of the food, but the food supply chain, I think nationwide, is under a great deal of stress. We see that in dairy. We see that in poultry. We see that in pork. They are euthanizing pigs, and obviously the livestock industry.

Sonny Perdue at the Department of Agriculture has stepped up, so has the President, declaring that these packing plants are a national asset. We have progress—Dodge City, when we first started out, had five tests. Five. That is between four and six. Five. It is not 50 million as we hoped to receive that has been said by one of the witnesses.

The reason I am really harping on all of the problems we are having in agriculture, on top of the fact that the relationship with China is such that even the first breakthrough with regards to

trade to China seems to be on hold now, and that is another price depressant. And this is going on 5 or 6 years where our prices have been below the cost of production.

End result, our consumers are really figuring out that food doesn't come from grocery stores, and I am very worried that the harm to the food value chain is very real, not to mention the financial situation that our farmers, ranchers, and our growers all face.

Now, having said all that, I want to ask. Admiral Giroir, you have spoken about the importance of having diversity in kinds of tests that are available. Of the five packing plants we have in Kansas, if we could get a rapid test and we could get it as we hopefully ask for it because of the hot spots that are developing not only in Kansas, but also doing great harm for the food value chain, that would be absolutely wonderful. Would you speak to that, sir?

Admiral GIROIR. Yes. Thank you, Senator. Both Dr. Redfield and I have been very actively involved in getting strategies for the industry, particularly in Kansas. We are supplying very heavily the public health labs with rapid diagnostics, as well as surging them to areas like that. The one tradeoff, however, is that the rapid—the "rapid" point-of-care diagnostics are very slow. So, each machine can only do four per hour, and that is very, very slow.

It is a mix of testing that you need at these kinds of situations. On sort of the high-throughput tests that are available at a major lab, a Quest lab right there in Kansas, as well as a mix of the rapid testing, and that is what we are supplying in order to provide a comprehensive, holistic solution. And, I believe CDC is on the ground, as well, in Kansas supporting that.

Senator ROBERTS. I appreciate that. If you are only doing four an hour, that is not a rapid test. Maybe it is a rapid, slow test. I am not quite sure how you define that.

But, I, for one, think that, as we reopen—and by the way, Governor Kelly started the opening process the 1st of this month. Then it is May 18, and then we go to June, and then the hope is we open up.

But, we do have contingency plans that, if that doesn't work as aptly described by Dr. Fauci, I think we will be alright. But, this is going to be a tough go. I have to tell you that, in terms of agriculture, we are not in good shape.

I appreciate everybody and the job that you are doing. I will stand beside you when you are taking the boos and behind you when you are taking bows.

The CHAIRMAN. Thank you, Senator Roberts.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman, to the Committee leadership, and witnesses for calling this important hearing.

The last time Dr. Fauci and Hahn were before us was March 3. I have a slide that I want to put up that shows what has happened in America since then.

The chart, which is here, compares the experience of the United States and South Korea on three dates.

On January 21, both nations experienced their first case of COVID–19. At that time, the unemployment rates in both countries were essentially identical.

On March 3, when the witnesses were last here, South Korea had experienced 28 COVID–19 deaths and the U.S. had experienced 9. Again, the economies of both nations as measured by the unemployment rates were nearly identical.

But, now the story changes. As of yesterday, more than 81,000 Americans have died, and the U.S. economy has experienced job losses not seen since the Great Depression. Meanwhile, the economy of South Korea has not changed dramatically at all, and the death toll is now at 256.

South Korea is smaller than the United States, one-sixth of our population. But, even if you bulk up the death toll to reflect the difference, the per capita death toll in the U.S. is more than 45 times the rate in South Korea. And, healthcare carnage here is causing a near depression, while South Korea has protected its economy by managing correctly.

I could have done this chart with other nations. The U.S. has the seventh highest per capita death rate in the world. Our death rate is off the charts higher than that in India, Australia, New Zealand, Japan, and Mexico. It is nearly three times the death rate in Germany; twice as high as Canada's rate.

The question is, Why? If we want to open up our economy and schools, we have to learn the lessons of nations that have managed this well.

Here are some things that don't explain the difference:

Our hospitals are as good or better than those in South Korea.

Our healthcare providers, heroes, are as good or better than those in South Korea.

Our research capacity is as good or better than that in South Korea.

We have more resources than South Korea. Our GDP is 12 times South Korea's, and our per capita income is 50 percent higher.

To Dr. Fauci, the death roll in the United States, the death rate in the United States, especially when compared with other nations, is unacceptable, isn't it?

Dr. FAUCI. Sorry, sir. Yes, of course. I mean, a death rate that high is something that in any manner or form in my mind is unacceptable.

Senator KAINE. Dr. Fauci, the experience of other nations shows that the U.S. death rate is not only unacceptable, but it is unnecessary. Isn't that correct?

Dr. FAUCI. I don't know if we can say that, Senator.

Senator KAINE. But would you say that the U.S. has to do better?

Dr. FAUCI. Of course. You always have to do better. I mean, as a physician and——

Senator KAINE. The experience of South Korea shows that how a nation manages the healthcare crisis has a huge impact also on its economic condition. Isn't that the case?

Dr. FAUCI. That is the case, sir. I understand where you are going with this, but I have to tell you, there is a big difference between South Korea and the United States——

Senator KAINE. Let—and——

Dr. FAUCI [continuing]. In the outbreak.

Senator KAINE. Let me get to that. I want to get to factors that do explain the difference since we know it is not resources or our health providers.

First is testing. South Korea began aggressive testing much earlier than the U.S. Now, in the fifth month of the pandemic, we have surpassed South Korea in per capita testing, but in the critical month of March, South Korea was testing its population at a rate of 40 times the testing in the U.S.

Admiral Giroir, Dr. Giroir, has set out the standard for us. When we get to September, he says the United States needs to do 40 to 50 million tests a month to be safe. That equates to about 1.3 million to 1.7 million tests a day. Yesterday, we did 395,000 tests. We have a long way to go.

A second factor is contract—contact tracing. South Korea embraced a rigorous contact tracing program right from the beginning. The United States still has not engaged in a national contact tracing program. Isn't that right? Would that be Dr. Fauci or Dr. Redfield?

Dr. FAUCI. I think that question would best be directed to the CDC and not the NIH.

Dr. REDFIELD. When the outbreak started, sir, we had an aggressive contact tracing program, but unfortunately, as cases rose, it went beyond the capacity and then we went to mitigation. So, we lost the containment edge clearly before that.

Senator KAINE. That was key to the economy, as well, because South Korea did testing, contact tracing, protect, serve, isolate the sick, and then they didn't have to do the shutdowns, which helped their economy.

Social distancing is a third factor. We have talked about it.

But finally, the last one, healthcare systems. Would you agree with me that it helps keep people safer, even from serious conditions or death from COVID–19, if they have access to healthcare?

Dr. FAUCI. Yes, of course.

Senator KAINE. Of course that is the case. In South Korea, 97 percent of the population have health insurance. In the United States before COVID–19, millions did not have it and lacked access to healthcare. The massive job losses in the last months threaten to take health insurance away from millions more. And, President Trump is doing all he can to dismantle the Affordable Care Act, which would take health insurance away from tens of millions more. Let us learn the lessons from those who are doing this right.

Thank you, Mr. Chairman. I yield back.

The CHAIRMAN. Thank you.

Admiral GIROIR. Can I make a clarification, please, Mr. Chairman? This is Brett Giroir.

I just wanted to clarify that I did project that we will have the ability to perform 40 to 50 million tests per month in that timeframe, but I said if needed at that time. I am not making a proclamation. We have to really understand what—where the epidemic is, what the community spread is, before we can estimate the number of tests that are needed. I was simply stating the fact that our combination of testing capabilities will be at that level even barring new input from the NIH.

The CHAIRMAN. Thank you very much, Senator Kaine.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And, gentlemen, thank you for being here this morning virtually, but also for all you have been doing for these many, many months.

Alaska is doing okay right now from a numbers perspective, and quite honestly, we want to keep it that way because we know we have exceptionally vulnerable populations. We know we have a geography that is challenging. We know that we have facilities that are very limited.

Last hearing, we had an opportunity to hear from Dr. Collins, and he shared where they are with the RADx, and also spoke to RADx-UP, which was very interesting, about what we can be doing in rural areas, but focusing on hot spots. And, as I reminded him, we don't want to be a hot spot in Alaska, so every effort that we make to keep the virus out of Alaska is—are lives that are saved.

I educated him on the community of Cordova, that it is just getting ready to open its Copper River salmon fishery in 2 days, and was able to share that they had one worker tested positive as he was coming in from the Lower 48 to come to work. The good news on that is that all of the protocols that we had put in place seemed to be working: the quarantine, the isolation, not only for that individual, but for others that he had come in contact, were secured.

I want to recognize the assistance that we have received from the administration. Dr. Eastman is in the state at this moment, the chief medical officer for the Department of Homeland Security, going out to rural communities to really better understand our vulnerabilities, going to some of our fishing communities to, again, understand how we can successfully prosecute our fisheries when you have to bring workers in from the outside. We thank you for the assistance with regards to additional testing capacity.

I have been in contact with our chief medical officer of the state this morning, and the mayor of Cordova, just better understanding, again, do we have the tests that we need? What do we need on the ground? And, one of the things that I would like to have clarified, and this is probably to you, Dr. Giroir, because you have been so helpful in kind of shining the light on what we need to be doing in these rural areas.

But so much of the focus has been on hot spots and responding to the hot spots, but how do you keep those rural, remote, small communities from becoming the hot spots in the first place? Are we doing enough? And, right now, the strategy has been we just lock it off. The travel restrictions that are in place are apparently working, but they are also devastating our economy, whether it is tourism, whether it is our resource industries, or whether it is the potential for our fisheries.

Admiral, if you might speak to that aspect of it, and then I have a very important question as it relates to contract—contact tracing that I would like to direct to either Admiral Giroir or Dr. Redfield.

Admiral GIROIR. Thank you, Senator. And, as you know, you have an outstanding state health officer in Dr. Anne Zink.

Senator MURKOWSKI. We do.

Admiral GIROIR. I have had the privilege of working with her, and you have a very good protocol in trying to keep Alaska safe by isolation over a period of time when you come in.

As you know, we also work with the state to meet your very challenging testing requirements because you can't really, send labs out a thousand miles away. So, we put a real customized mix of point-of-care and also the Cepheid machines—I think we sent nine or 10 new to Alaska—and about 50,000 tests, which is about four times than you have done to date collectively in order to provide that support. So, again, I do think there is a comprehensive strategy that you do have.

But, again, the mitigation, to the degree that you can given the circumstances: the face masks, the hand washing, the hygiene. We understand fully the challenges, particularly in the fishing environment and the remote. But all of these have to come together—the testing, the tracing, the mitigation, the hygiene factors—to try to keep your community safe.

We really understand culturally that many of your communities were almost annihilated in the 1918 influenza pandemic, so—and that memory is still very sharp and very hurtful to many of the citizens, so we want to do our best to assure them that we are giving them all the protection we can.

Senator MURKOWSKI. Admiral, let me turn to Dr. Redfield because this relates to contact tracing.

I think this is a very, very key part of how we move forward into getting people back to work, getting people back to school. Right now, we have about 100 people that are involved in contact tracing in Alaska. That is clearly not sufficient. There has been talk about a national strategy, but I think we recognize that we have teams in place, whether it is AmeriCorps or whether it is Peace Corps or whether it is our Public Health Corps.

What more do we need to be doing to make sure that once you have been tested positive, then what happens after that? Who else needs to be brought into this? And I am not convinced that we are focusing enough on that aspect of how we move to reopening if we have not done the contact tracing.

Dr. REDFIELD. Thank you very much, Senator. I want to just reemphasize what you said. I think contact tracing capabilities is critical. It is going to be the difference from succeeding in containing this outbreak from once again causing wide-scale community transmission, or not. We are positioned, as you know, to deploy, redeploy, the number of CDC—over 500 CDC individuals. We have another over—about 650 that we are trying to put in through our foundation.

But most importantly, we are trying to work with your health department. With the resources that we have been able to give because of Congress. Also, as you mentioned, with these other agencies, with Lab Corp—I mean with AmeriCorps, with the Census Bureau, to work together and have the state develop their contact tracing capacity. Some states have reallocated state workers. Some states have reallocated National Guard while they begin to do this.

But, I agree with you, and I said it is going to be a significant effort to build the contact tracing capacity that we need in this Nation. It will be state by state, but it is going to need to be augmented. Probably in your state, from what you just said, and increase five to tenfold, and we are there to work with the states to

help them get that accomplished. That needs to get in place before September.

The CHAIRMAN. We need to move on to the next question.

Senator MURKOWSKI. Thank you.

The CHAIRMAN. Thank you, Senator Murkowski. I don't want to cut any Senator off, but we have eight more Senators who have 5-minute rounds and it is 12:30, so I would like to request that the Senators and the witnesses, succinct questions and try to stay within 5 minutes would be appreciated.

Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chairman. Thank you and the Ranking Member for having this hearing, and thank you to our witnesses today. And, please pass our thanks along to all of the hardworking women and men in your agencies, who I know have been working virtually around the clock to try to improve our response and keep Americans safe. And, Mr. Chairman, I hope you and all the witnesses are healthy and safe today, as is everybody on your team.

I wanted to start by echoing the comments my colleagues have made about needing leadership from the CDC and our public health experts on how we are going to use facts and evidence as guidance so that our schools and our daycares and our businesses have the information they need to create safe and sustainable plans to reopen. And, of course, that means, too, that our testing capacity not only has to be enough, but it has to be flexible enough to meet our needs.

The key distinction between South Korea and the United States is not how many tests per capita over a certain amount of time we have done, but the fact that at the onset of this pandemic, South Korea was much more able to do a lot more tests per capita than we were. And then, follow that with all the other measures you have talked about. So, that—we continue to need to identify the need, and then build our capacity toward the need, not the other way around.

I wanted to start with a question to you, Dr. Fauci. First of all, thank you for your work and your expertise. I wanted to talk about nursing homes for a minute. In New Hampshire and across the country, a huge number of the deaths from COVID–19 that we are seeing have been in nursing homes. We all know people who have lost a friend or a family member in nursing homes, and the grief compounded by the fact that people couldn't be at their loved ones' bedside if they died.

Yesterday, Dr. Birx said that all one million nursing home residents should be tested within the next two weeks, as well as all nursing home staff.

Dr. Fauci, as a short-term goal, that makes sense to me, but after that, what will the ongoing Federal recommendations look like? How frequently do we need to test patients and staff on a continuing basis, and what other measures will be necessary to keep our loved ones in these facilities safe?

Dr. FAUCI. Thank you for that question, Senator Hassan. The general plan, as you mentioned, that was recommended by Dr. Birx, is a sound plan, as you said, in the immediate. The question is in the long range. We will have to have infection control capabili-

ties in nursing homes that are really pristine and really unassailable. We have to do the kinds of surveillances and have to have the capability of when you identify someone, you get them out of that particular environment so that they don't spread the infection throughout.

General testing for all I think is a good start. But, when you look where you are going to go in the future, there has to be a considerable degree of surveillance capability.

Senator HASSAN. Thank you, Doctor. The White House is now requiring all staff to wear masks, and anyone in regular contact with the President to be tested daily. Do you think nursing homes should implement those same measures to help make sure that our seniors can get the same level of protection?

Dr. FAUCI. I think there should be a certain—a system in place for the optimal protection of people in nursing homes, and that would be not necessarily testing every person, every day. That is one approach that might not be practical when you think of all the nursing homes in the country. But very strict regulations and guidelines about who is allowed to go into the nursing home. And the staff, I believe, needs to be monitored very carefully with intermittent testing to make sure that we don't have introduction into the nursing home of infected individuals. I am not sure you can practically do testing every day. That, I don't think would be feasible. But something that is much more aggressive than has been done in the past, I believe, should be done.

Senator HASSAN. Well, thank you. I have one last question for Dr. Fauci and Dr. Redfield. I would also just say that if we are able to get masks to everybody in the White House, I hope we can get masks to every nursing home employee who needs it.

Dr. Fauci and Dr. Redfield, the U.S. needs to be preparing now to ensure that we have capacity to manufacture and administer vaccines, something you have both touched on, both for an eventual COVID–19 vaccine, as well as other illnesses, such as the flu. The failure to ramp up production of testing and personal protective equipment early on during this crisis made things worse here. Those mistakes cannot be repeated when it comes to vaccine production and distribution. We are already seeing reports that some children are not receiving routine immunizations as it becomes more difficult to access in-person care.

Dr. Fauci, what steps should we take now to ensure that we have sufficient manufacturing and distribution capacity for a COVID–19 vaccine without putting at risk our capacity to manufacture and distribute other important products, such as the flu or measles vaccine? And my follow-up question to Dr. Redfield would be, What efforts are underway at CDC to ensure that all routine vaccines are accessible during the COVID–19 public health emergency?

Dr. FAUCI. Yes. Thank you for that question, Senator Hassan. I will answer it as quickly as possible.

I alluded to this in my introductory remarks when I was talking about vaccines for COVID–19. And, what we said, that as we do the testing on these vaccines, we are going to make production at risk, which means we will start putting hundreds of millions of dollars of Federal Government money into the development and production of vaccine doses before we even know it works so that when

we do—and I hope we will and I have cautious optimism that we will—ultimately get an effective and safe vaccine, that we will have doses available to everybody who needs it in the United States, and even contribute to the—what is the needs globally because we are partnering with a number of other countries.

The other part of your question about making sure that when we get into a situation like the so-called shutdown that we might be in now that we make sure that children get the vaccinations that they need. That would be an unintended consequence of shutting down, as we are right now. It is a very good point, and we want to make sure we don't fall behind on that, also. Thank you.

Senator HASSAN. Thank you very much. And I will take my answer from Dr. Redfield offline. Thank you so much for allowing me to go, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman, and to the panel. Thank you all for being here virtually. Without any question, we find ourselves in a situation that we wish we were not. And I am very thankful for folks like Dr. Birx, Dr. Fauci, and many others for your dedication 24/7. Without any question, our Nation is safer because of your hard work.

I am going to direct my questions toward Dr. Fauci. Really one specific question, Dr. Fauci. I am thinking about the reopening of America, and specifically the reopening of South Carolina.

I am taking into consideration the fact that South Carolina, I think, overall, our cases are moving in the right direction. We have a little less than 8,000 cases; unfortunately, 350 deaths. Our hospital capacity is actually better now than it was when the pandemic started. Our ability to isolate hot spots and mitigate the spread of the virus is, I think, where it needs to be.

With that in mind, I flew into Washington from South Carolina yesterday. We had plans to test additionally 220,000 more residents by the end of this month, focusing on at-risk populations. By the end of this month, we will have tested 100 percent, 100 percent, of nursing home residents and the staff that takes care of them.

And, after increasing our contact tracing workforce 20 fold in a matter of weeks, our state's health department announced yesterday that we are going to increase it by an additional 1,400 contact tracers.

We have built, and we continue to build, the tools necessary to better detect and isolate cases, to map their exposure, and to prevent substantial spikes moving forward. Most importantly, our healthcare system, thanks in part to flexibilities from this administration, has the beds and the equipment necessary to address the most serious cases when they arise.

Now, with these tools in hand, we have begun to reopen. To be clear, we continue to scale up testing and to make—to take measures to protect the most vulnerable, and the data points are increasingly clear. For older Americans and for those with chronic conditions, like diabetes and high blood pressure, this virus remains a threat—a dangerous threat.

A recent report suggests that in New York, roughly 90 percent of the fatalities had underlying issues. Two-thirds of fatalities were 70 years or older; 95 percent over the age of 50.

In South Carolina, the median age of patients who have died from the virus, 76.5. Nearly two-thirds of fatalities have been patients older than 71; and nearly 90 percent were over the age of 60; and roughly 98 percent in South Carolina are over the age of 50. Contrast that with those age 20 and younger where we have seen no deaths. Fewer than 1 percent of deaths in my state have been under the age of 40. Every single death is a tragedy, every single one, and we mourn with our family members who have lost their loved ones. We are taking every measure to protect our older South Carolinians, as well as those with underlying conditions.

When we set out to flatten the curve by taking aggressive, unprecedented measures, like staying-at-home orders and mass small business closures, we did not set out with the goal of preventing 100 percent of fatalities. That would be unrealistic. It is impossible. And we did not set out to keep quarantines in place until we found a safe and effective vaccine. That would take too long.

Dr. Redfield, your agency put out a helpful graphic showing two curves. One, which spiked quickly and peaked high, reflected daily cases without protective measures. The other, flatter curve, show cases with those measures in place. And the whole point, which the graphic illustrated, was to make sure that we did not exceed hospital capacity. So, while I respect the need for caution, we are too often presented with a false dichotomy: either saving our economy or saving lives.

We have seen the goalposts around flattening the curve move, and I think that is unfortunate. Because at the same time we are doing that, businesses have collapsed, mental and physical health have declined, deaths and despair escalate, educational outcomes nosedive, as we wait in our living rooms, praying for some good news around therapies and around vaccines. We set out to flatten the curve, and I think we have done a pretty good job with that. We need to do better and we will do better.

My question, Dr. Fauci, is, as we start the process of moving toward reopening South Carolina, what else would you suggest that we could do to protect our most vulnerable populations?

Dr. FAUCI. Thank you, Senator Scott. You gave a really very eloquent description of what I think is one of—would be a model way, the way you approach this. I mean, you have put things in place that I think would optimize your capability of reopening. And as—I was thinking as you were speaking, I almost want to clone that and make sure other people hear about that and see what you have been doing.

The issue of your direct question to me about the vulnerable populations is that, as we have said in our guidelines—and it looks like you were ready to progress carefully because you have put into place a very good system—that the vulnerables, the elderly and those with underlying conditions, should be those who at the very last lifting of mitigations, should be those who are left in a situation where they might be in danger of getting infected. In other words, protect them right up until the very end of the relaxation of your mitigation.

Because, as you said very correctly, those are the individuals that are the most vulnerable for the morbidity and the mortality. So, those individuals, particularly I might say, sir, those in the minority group, the African American and Hispanics, who, for a variety of situations that are the social determinants of health, have a greater likelihood of not only getting infected, but of also having the underlying conditions that would make their risk for a higher degree of morbidity and mortality higher.

It looks like you are doing things very, very well, and I would encourage you to continue and to follow the guidelines as you get closer to normalizing your state.

Thank you.

Senator SCOTT. Thank you, Dr. Fauci, and I will just simply close with this since I am out of time. Thank you for the many conversations that you and I have had about those vulnerable populations to include minorities, as well as our senior citizens. I will say that, without any question, when you look at nursing homes, that it is typically African Americans, Hispanics, are the certified nursing assistants who are providing care for the elderly population. So, your focus on those two very vulnerable groups is much appreciated, and thank you for your expertise.

The CHAIRMAN. Thank you, Senator Scott.

Senator Smith.

Senator SMITH. Thank you so much, Chairman Alexander and Ranking Member Murray. And thanks to all of you for being here today and for your service.

Dr. Fauci, I have to say, you are in the unenviable position of being a person that so many Americans and Minnesotans trust to give us the straight scoop and tell us what is really happening. You are about the facts and not about the politics, and that is a really good thing.

I have to start by asking you a question that I think a lot of Americans want to know, which is, how are you doing? How are you holding up? You have—it has been an unbelievable effort.

Dr. FAUCI. I am doing fine, Senator. Thank you very much for asking. This is such an important problem. It transcends all of us individually and has to be working as a team, and I enjoy very much working with your Senators and the Governors because it is at the local level that we are going to make this thing work. So, I am fine. I appreciate your concern.

Senator SMITH. Well, a lot of people are thinking about you and are grateful for your service, as we are for all of you.

We are gathered today to think about what we need to do to reopen our economy, and I think first about what is happening in my home State of Minnesota, where agriculture is such an important part of how our state works. It is a part of our history and our culture.

Pork processors right now are looking at the reality of euthanizing thousands of hogs a day because there is no place to process them because of what is happening in the processing plants. The working people, who do the hard work in those processing plants, are getting sick.

Here is one story. This is one worker—the Star Tribune wrote about this—named Jomari de Jesus. She is an asylum seeker and

a mom who works for a contractor that does the cleaning in the processing plants, and she works for $14 an hour, 7 hours a day, 5 days a week, and her job is to sanitize the machines that process the meat into ground meat.

She started feeling sick on April 11th, but she kept going to work. And, on April 21st, when one of her coworkers fainted, she told her supervisor that she felt sick. And, so, she was told to go home, but that if she didn't show any signs of illness, she should come back.

She went to the doctor and she paid $115 to get a test and found out a few days later that she was COVID positive, and she is still at home. She is still—she is not getting paid, and she doesn't have health insurance.

Nearly 2 weeks ago, President Trump deployed the Defense Production Act to keep these processing plants open, but the USDA gave really limited guidance about what would be safe for those workers. It said, for example, in response to testing, which has been such a big part of what we have been talking about today, they said—this is a quote. "Facilities should consider the appropriate role of testing and workplace contact tracing of COVID–19 positive workers in a worksite risk assessment."

Dr. Fauci, as we think about how we move forward, we all want to open up the economy, what guidance would you give us in a situation like this here in Minnesota?

Dr. FAUCI. Well, I can give you my commonsense guidance, although this is not the area of my expertise. It is more in others.

But, it would seem that if you want to keep things like packing plants open, that you have really got to provide the optimum degree of protection for the workers involved, the ability to allow them to go to work safely; and if and when individuals get infected, to immediately be able to get them out and give them the proper care.

I would think when you are calling upon people to perform essential services, you really have almost a moral responsibility to make sure they are well taken care of and well protected. And again, that is not an official proclamation. That is just me speaking as a physician and as a human being.

Senator SMITH. Well, thank you, Dr. Fauci. And I think that you speak as a human being, but you also speak as the chief epidemiologist of our Country and the person that we all trust.

This is the point that I want to make and drive home with everybody, which is this is the kind of guidance that we should be getting and following. And then, this is the kind of—these are the tools that we have got to have in our Country if we are going to reopen our economy, as we all want to do. And, this—we move forward with reopening our economy, and yet we still have circumstances like we have in these processing plants and in other places around the state. We are going to be—we are going to be right back where we started, and—except even in a worse place, as I think you have pointed out, Dr. Fauci.

Dr. FAUCI. Thank you, Senator. And again, it really does relate to one of the questions that one of your colleague Senators asked me before and one of the things that I keep emphasizing. And I will just repeat it again because it is important, that when you are in

the process of opening up and pulling back on mitigation, you really must have in place the capability of responding when you do have the inevitable upticks in cases. That will absolutely occur. It is how we deal with it and how successful we are in putting the clamps on it that will prevent us from getting the kind of rebound that, not only from the standpoint of illness and death would be something that is unacceptable, but it would set us back in our progress toward reopening the country.

Senator SMITH. Thank you.

The CHAIRMAN. Thank you very much, Senator Smith.

Senator Romney.

Senator ROMNEY [continuing]. this hearing and the participants in it.

Admiral Giroir, I am going to take off where Senator Hassan spoke. I understand that politicians are going to frame data in a way that is most positive politically. Of course, they don't expect that from admirals. But, yesterday you celebrated that we had done more tests and more tests per capita even than South Korea, but you ignored the fact that they accomplished theirs at the beginning of the outbreak, while we treaded water during February and March. And, as a result, by March 6th, the U.S. had completed just 2,000 tests, whereas South Korea had conducted more than 140,000 tests. So, partially as a result of that, they have 256 deaths, and we have almost 80,000 deaths.

I find our testing record nothing to celebrate whatsoever. The fact is, their test numbers are going down, down, down, down now because they don't have the kind of outbreak we have. Ours are going up, up, up as they have to. I think that is an important lesson for us as we think about the future.

On a separate topic, my impression is that, with regards to vaccines, that—where I am critical of what we have done on testing, on vaccines, we have done a pretty darn good job of moving ahead pretty aggressively. And yet, the President said the other day that President Obama is responsible for our lack of a vaccine.

Dr. Fauci, is President Obama, or by extension, President Trump, did they do something that made the likelihood of creating a vaccine less likely? Are either President Trump or President Obama responsible for the fact that we don't have a vaccine now, or in delaying it in some way?

Dr. FAUCI. No. No, Senator, not at all. Certainly President Obama, nor President Trump, are responsible for our not having a vaccine. We moved, as you said—because I described it in my opening statement—rather rapidly. No one has ever gone from knowing what the virus was to a Phase 1 trial as fast as we have done. So, I don't think that is something that one should say anybody is responsible for doing anything wrong on that. I think that is right. That is the correct way to do it.

Senator ROMNEY. Thank you. That was my impression. I was surprised by the comment, but that was my impression.

Dr. Redfield, Senator Sinema and I wrote a letter to you expressing our dismay at the lack of real-time data at the CDC. I am talking about granular, demographic, hospitalization, treatment data. How is it possible in this day and age that the CDC has never established such a real-time system with accurate data? And what

can Congress do to rectify that so we never have to look at something like this again?

Dr. REDFIELD. There we go. I am sorry. Senator, thanks for the question. I think you hit one of the—important they are. The first one I focus on is data modernization, data analytics, and predictive data analysis.

Clearly, Congress has come forward in providing funding for data modernization, and we are in the process of implementing it. The reality is there is an archaic system, a non-integrated public health system. Each public health department has their own systems. The Nation needs a modern, highly capable data analytics system that can do predictive analysis. I think it is one of the many shortcomings that had been identified as we went through this outbreak, and I couldn't agree with you more. It is time to get that corrected.

Senator ROMNEY. Thank you. Please help guide us as to what we need to do to make sure that happens. And I presume it is not build it ourselves, but work with companies that have that capacity and use that capacity in our favor.

Dr. Fauci, one last thing, which relates to the virus, and I know I am asking you the impossible question. But, we are all hoping for a vaccine, obviously. It is the objective of our administration to get it as soon as they can. And, from what I can tell, they are pulling out all the stops to do exactly that.

Given our history with vaccine creation for other coronaviruses, how likely is it? I mean, is it extremely likely we are going to get a vaccine within a year or two? Is it just more likely than not? Or, is it kind of a long shot?

Dr. FAUCI. It is definitely not a long shot, Senator Romney. I would think that it is more likely than not that we will because this is a virus that induces an immune response, that people recover. The overwhelming majority of people recover from this virus, although there is good morbidity and mortality at a level in certain populations. The very fact that the body is capable of spontaneously clearing the virus tells me that, at least from a conceptual standpoint, we can stimulate the body with a vaccine that would induce a similar response. So, although there is no guarantee, I think it clearly, much more likely than not, that somewhere within that timeframe, we will get a vaccine for this virus.

Senator ROMNEY. Thank you. Mr. Chairman, I yield.

The CHAIRMAN. Thank you, Senator Romney.

I want to thank the witnesses for their patience. We have four more Senators, and we would like to give them a chance to ask their questions.

Senator Jones.

Senator JONES. Thank you very, very much, Mr. Chairman, and thanks to all our witnesses for your being here virtually, and also for your incredible service during this time.

I want to follow-up real quick with an additional statistic that Senator Romney talked about with regard to South Korea, and that is the fact that we are a Nation that has about six times the population of South Korea, but yet we have about 310 times the number of deaths from this pandemic. So, I think we have to be very care-

ful in making comparisons around the world, comparing the United States to other countries.

Dr. Redfield, I want to follow-up just a little bit with what Senator Murkowski and I think Senator Kaine talked a little bit about, contact tracing and where we are going. I understand that you are working with states to try to develop plans for reopening. The testing is important. The contact tracing is important. But, using that data, as well, is also going to be important in terms of the quarantine plans that Senator Murphy talked about. Childcare facilities to have—allow people to put their kids in a facility while they are still—go back to work. All of those issues, including maybe even facilities like vacant hotels or motels that may be used for self-isolation.

How is this plan being developed within the CDC? Are those plans going to be individualized by state? Will we, as a Member of Congress, be—have access to those plans? And how are states going to pay for these? I say that because my state is already using the money that we have already given them as a wish list. I mean, they are talking about building a few hundred million dollar statehouse as opposed to developing the test and doing the contact tracing.

I would like for you just to drill down a little bit on how these plans are going to develop, what access we will have to have those plans and be able to see them.

Dr. REDFIELD. Thank you very much, Senator. This is obviously, as I said before, this is a critical component of us taking this time now to get prepared for next fall and winter and building that comprehensive contact tracing capacity. We are working individually with the leadership of the state health departments, the local health departments, territorial and tribal, to try to let them get us to understand what they think their capacity needs are. And, those discussions have already happened. As Admiral Giroir said, there has been a variety of Federal agencies together on testing and contact tracing.

CDC is in position that we have reprogrammed our individuals that we have across the country, over 500, begin to help each of these states. We have augmented that with some additional personnel that we are bringing onboard state by state through our foundation. We have put about $106 billion of the money that Congress has appropriated into the states so they can begin to start thinking about whether they want to hire—contact tracing capability. And, then, of course, it was mentioned that we are—well, other government programs, like AmeriCorps, Peace Corps so that each group is going to construct their contact tracing piece to what they think their needs are. And I do think it is going to be similar to what we heard from the Senator from South Carolina. These are significant increases. He said he increased 20 fold, and then they are going to increase again.

But the point you brought up is also critically important. And we found that as we already struggled through the repatriation of different Americans from around the country, where we had to put many of these in quarantine, as you know, ended up using military bases because many of the state and local health departments really have not developed that system. Where do they put somebody

who should be in isolation who is homeless? How do you develop those systems? So, this has to be part of it, too. Is it—there a certain capacity that is intrinsic? Or, is it hotels, as you mentioned?

I think the point that was made by one of the other Senators is so important about individuals that—particularly like the meatpacking individual that has to go home and self-isolate, but maybe they don't have the ability to go home and self-isolate because they live in a multi-generation house with about 12 other people.

There needs to be mechanisms to be brought in to have an effective way to identify cases, identify contacts, and then do the appropriate public health measure, and that these have to be comprehensive. It is going to be developed one jurisdiction at a time.

I see no reason why these are not transparent documents as they get completed. And, it really is a tribute to what the congressional support that you all have given so far. As I said, $1.6 billion got into the states for them to begin to do this, in addition of the resources that we have gotten.

But, it is fundamental. People underestimate how important it is that we have a highly functional, comprehensive, aggressive contact tracing programs so that the next—for this outbreak, we still contain them. We don't have to switch to mitigation.

Senator JONES. Alright. Thank you, Dr. Redfield. I appreciate it. It sounds to me like we have still got a lot of work to do. So, thank you.

The CHAIRMAN. Thank you very much, Senator Jones.

Senator Braun.

Senator BRAUN. Thank you, Chairman. There has been so much discussion about testing in general. Listening to Senator Romney earlier; I think Senator Kaine mentioned it; everybody has.

Dr. Hahn, if you remember when we first met, I said, Is the FDA going to be more entrepreneurial? Is the FDA going to kind of not be as stodgy? Talking then about how we fix the healthcare system in general. Now this has brought it into clear focus.

I have a timeline that I am going to submit for the record that shows from January 24th through March 5th. And I want to emphasize what Senator Burr asked earlier, has the administration ever put an impediment in front of trying to get to testing?

And, Dr. Hahn, this will end up in a question in a moment. But, there was a span of time, from January 24th through March 5th, that I hope the American public looks at. It gets back to what is wrong with our healthcare system in general. Early testing, from what I am seeing, was created by the fact that the CDC said it was going to do its own test. The South Korean test that gets cited so often was not going to be looked at; we had to do our own. I know the FDA worked with the CDC.

But the long and short of all of this is that for nearly a month, this was in that bureaucratic swirl. The FDA prevented private and academic development of tests for weeks. The CDC denied access to functioning tests, as I cited, in South Korea. This created, through all the red tape and bureaucracy, to where we had to come up with a one-size-fits all approach due to the uncertainty of the virus, and we are stuck with that now. I don't want to dwell on that necessarily because I think those are mistakes that we have

made. I am tired of having it heard that it is the administration's fault.

Dr. Hahn, I would like to ask you this question in that spirit of what we talked about during your nomination process. Here going forward, will we shed some of that stodginess? Will we look to get therapeutics and vaccines through the system in a quicker method? Because I fear if we don't, and if we treat through bureaucracy how we did the early period of testing, we can belabor this into the distant future. And, at that point, there is going to be not only the carnage from the disease itself, but from the economy to deal with.

I would like your comment on that 1-month stretch, what accountability the FDA and the CDC have, and then whether it looks better in terms of moving more quickly into the future.

Dr. HAHN. Thank you, Senator Braun, for the question. Our timeline of that period demonstrates that we began working with test developers beyond CDC on January 24th and had double digit number of test developers working with us. One of the issues that we identified was in fact availability of the virus and other supplies to actually get that test development done in a timely fashion.

Senator, I completely agree with you that this is an opportunity for us to take a look and determine how we can do things better, and I think that is a really important thing for all of us to do, and certainly the FDA, I can promise you, will do that.

Looking forward, sir, I can commit to you that we will look at every one of our regulatory authorities. We have done so during this outbreak. We have provided significant flexibility and have tried to provide the right balance between regulatory flexibility and enabling of the great test developers and therapeutic developers in this country with the need to ensure that our gold standard of safety and efficacy is in place.

We have leaned in with manufacturers. We have learned a lot from them, as well as the other stakeholders, and we will continue to learn. And we will, I commit to you, sir, implement the changes that are necessary to make sure that we can act in a more nimble way but still protect the safety and efficacy of medical products.

Senator BRAUN. Thank you.

Dr. Fauci, taking a page from your anti-AIDs playbook that implemented a formal, clearly defined treatment review pathway, can we do that for COVID–19 in a similar parallel track that you put into place back then in the 1990's? In fact, I have a bill called the Promising Pathways Act that is based upon that protocol you put into place. Can we do that to more quickly get through to therapeutics and vaccines here with COVID–19?

Dr. FAUCI. Well, it is a different story, but some similarities if you are referring to the parallel track that I put into place back in the late 1980's, which was when there was no availability of drugs at all for HIV. And when we were testing drugs within a protocol, that we would make it available outside of the protocol in what has ultimately turned out to be compassionate use.

What we did is we didn't want to interfere with the integrity of the protocol to determine in a controlled way what was safe and what was effective, but there was a dire need for some sort of accessibility to those drugs outside of a clinical trial for those who might even have some chance of having it. And, in fact, that was

really in many respects the birth of the really firm concept of compassionate use.

And, in fact, there is a version of that, which I will hand over to Commissioner Hahn, that is, when you have expanded access and Emergency Use Authorizations for drugs that have not yet been fully proven in a clinical trial. So, there is somewhat of an analogy and similarity between what I did in the 1980's and what is actually being done by the FDA now.

Steve, if you might want to comment on that?

Dr. HAHN. I think that is right, Dr. Fauci. The Emergency Use Authorization process by statute allows us to have flexibility and assess the risk-benefit ratio in a public health emergency, and we have done that on the therapeutic side in three separate occasions and continue to look at those requests as they come in.

The CHAIRMAN. Thank you very much.

Senator BRAUN. Thank you.

The CHAIRMAN. Thank you, Senator Braun.

Senator Rosen.

Senator ROSEN. Here I am. Thank you, Mr. Chairman, for bringing this hearing. And I want to thank the dedicated doctors today for their lifetime of work and study and passion. We are a grateful Nation for all of your lifelong commitment in fighting disease. And not just the United States, but around the world.

As I talk to Nevadans about safely reopening the economy, one question that frequently comes up is, so, when are we going to have a vaccine like everyone has talked about? In Nevada, travel and tourism, of course, the lifeblood for us, and the jobs associated with those industries, can only fully come back if we know it is safe to travel and visit or work in our hotels, casinos, restaurants, and attractions.

Ultimately, to make this happen, we have to build confidence in our visitors that it is safe. We need a vaccine, and that research is extremely important. However, understanding that this takes time to develop and ensure both safety and efficacy, I would like to hear more about what research is happening regarding preventative medication research that could be helpful in the timeframe before a vaccine, and especially before one is widely available. So, I would like to ask if this could be part of a path in helping us begin to reopen our economy safely and bring visitors not only back to Nevada, but across our Country.

Dr. Fauci, what research is currently happening to identify potential monoclonal antibody preventative treatments or other therapeutics? If the right antibody is identified or can be identified, could this be used as a preventative medication to block COVID–19 virus from latching onto those host cells, much like the treatments for rheumatoid arthritis, severe asthma, or other diseases? And second, would preventative medication options like this help complement the effectiveness of a vaccine once it is available?

Dr. FAUCI. Yes. So, thank you for that question, Senator Rosen. That is an excellent question. And, in all of the therapeutic interventions that we are developing, and you mentioned several of them, they could be direct antivirals along the line of Remdesivir, but that is just one of a number of possibilities since there are several viral targets in a replication cycle.

Using convalescent plasma in a preventive modality, as well as monoclonal antibodies in a preventive modality, are in fact all feasible and will be pursued in parallel with the development of a vaccine. The model of using drugs and other interventions that are effective for treatment is really a great success story in the issue with HIV-AIDS because many of the interventions that were developed for the full treatment of an infected person are exquisitely effective in preventing infection of HIV.

That is the kind of model that we work out in parallel with treatment for disease. It is using treatment as prevention. I believe that will be a part of our effort at the same time as we are putting a full court press on trying to get a vaccine. So, it is an excellent question. Very relevant.

Senator ROSEN. I know I have a short time left, so I am just going to kind of abbreviate this.

The second most important question that I get, not just from our first responders and people worried about work, but generally, what does the next generation of PPE need to look like for all of us as we go about our lives? Not just as workers. Depending on your work, you may need something stronger, more specific, but as all of us—as we want to go out and shop or out to eat or whatever those things are, get on an airplane. Should masks be made of a certain material? Gloves? Are handkerchiefs effective? Can you talk about PPE for the general public?

Dr. FAUCI. Well, the best PPE for the general public, if possible, right now is to maintain the physical and social distancing. But, as we have said, and I think all of us would agree, there are certain circumstances in which it is beyond your control when you need to do necessary things, like go to the drug store and get your medication, go to the grocery store and get your food, that in fact you need some supplementation to just physical distancing.

That is the reason why some time ago, the recommendation was made—I believe it was Dr. Redfield at the CDC who first said that—about getting some sort of a covering. We don't want to call it a mask because back then we were concerned we would be taking masks away from the healthcare providers. But, some sort of mask-like facial covering, I think for the time being, should be a very regular part of how we prevent the spread of infection. And, in fact, the more and more as you go outside right here where I am sitting in Washington, DC, you can see many people out there with masks on, which gives me some degree of comfort that people are taking this very seriously.

Senator ROSEN. Thank you.

The CHAIRMAN. Thank you, Senator Rosen.

Senator Loeffler.

Senator LOEFFLER. Thank you all for being here and for your service.

Admiral Giroir, before I start my questions, I want to recognize your new role as the U.S. Representative to the World Health Organization. Mitigating a resurgence of this pandemic will take global cooperation. In order to do that, we need accountability and transparency at the WHO. This organization was established to ensure the timely flow of accurate, unbiased information on global health emergencies, just as this. Reforms must be made in order

to restore the trust that we need here. I hope you will work with our allies to push for these reforms.

This question—I have two questions. The first one is for Dr. Redfield. And, Dr. Redfield, Georgians are wondering how we got here today. Fourteen hundred deaths, one-third of Georgia's workforce out of work. I am incredibly concerned about the cover-up and the misinformation coming from China and their efforts to suppress lifesaving information at the outset of this outbreak.

As we can sit—as we continue to reopen our economy safely, we have to take steps to ensure that another outbreak cannot take hold of the world in this way. I understand CDC has worked with the Chinese CDC on global health security for decades. Can you comment on the level and the timing of the information that you received and relied upon from your Chinese counterparts as this virus emerged?

Dr. REDFIELD. Well, thank you very much, Senator, and I want to echo how important global health security is as a national security priority for this Nation. We are going to need to be able to be able to respond to that as long as we are a Nation.

CDC has had relationships with different countries from around the world. We have offices in over 45 countries right now, people in over 60, and one of those happens to be China, where we have a U.S. CDC that is with the Chinese CDC. And we have worked together for decades, particularly on influenza and emergent infectious diseases, and that has been a very productive, collaborative, scientific interaction.

When this original outbreak of pneumonia of unknown etiology came from the original seafood market, there were obviously discussions with U.S. personnel in Beijing, with the Chinese CDC. I personally had discussions as early—I think CDC did as early as January 2d, and myself, January 3d with my counterpart to discuss this. So, at a scientific level, we had very good interactions. I think, that is different than the broader Chinese government level.

Senator LOEFFLER. Thank you, Dr. Redfield. I have a final question for each of our great witnesses today, and it is one that my constituents often ask me.

The mainstream media, and indeed some of my colleagues in the Senate, seem to want to paint each of your relationships with our President during this wartime effort as confrontational and lacking consensus. Can you categorically say here to the American people today whether this is true or untrue?

From your testimony today, I have seen a very coordinated effort to address this with the administration to combat this pandemic. Can you give me a sense of whether this characterization—what the characterization is—whether it is true or untrue? Thank you. And I ask Dr. Fauci to answer that first.

Dr. FAUCI. Yes. No, there is certainly not a confrontational relationship between me and the President. As I mentioned many times, I give advice and opinion based on evidence-based scientific information. He hears that. He respects it. He gets opinions from a variety of other people. But, in no way in my experience over the last several months has there been any confrontational relationship between us.

Senator LOEFFLER. Thank you. Dr. Redfield, Dr. Hahn.

Dr. REDFIELD. Again, I would echo what Dr. Fauci said, that we are there to give our best public health advice, and that is what we do, and it is grounded in data and science. And I have always felt free to give the best public health advice that I think needs to be given at the time, and it has always been done in a very professional——

Dr. HAHN. Senator Loeffler, this is Steve Hahn. I do not have a confrontational relationship, have not had a confrontational relationship with the President. He asks questions. I have given him my honest answers rooted in data and science, and he has listened respectfully to those, incorporating that into his decision making.

Admiral GIROIR. I have nothing else but to echo my colleagues. We work very closely together, all the scientists, all the physicians, of course Ambassador Birx, other scientists within our group. We have a very productive working relationship with each other and also with the President and Vice President. It would not be confrontational, and I certainly feel that we have the ability to honestly state our opinions and recommendations, and that has been that way since the beginning.

The CHAIRMAN. Thank you, Senator Loeffler.

Senator Murray, do you have closing comments?

Senator MURRAY. I do, and if it is alright, I have a couple of—two quick questions.

The CHAIRMAN. Sure.

Senator MURRAY. Well, thank you.

You know, Dr. Fauci, while President Trump claimed otherwise, there is no question that an essential part of reopening our economy safely is successfully developing and distributing a vaccine for COVID–19. We need to plan now to deploy a vaccine once it is proven safe and effective, but it is absolutely crucial this planning process, from the clinical trial to distribution and administration, recognizes and addresses racial and ethnic disparities in our healthcare system that, as we all know, for too long have been overlooked and unacknowledged in this country. And we have to ensure equitable access to this vaccine for everyone.

Dr. Fauci, let me start with you. What steps is NIH taking to make sure that clinical trials for COVID–19 vaccines and therapeutics account for racial and ethnic disparities?

Dr. FAUCI. Yes. Thank you very much. That is a very relevant question, Senator Murray. And, in fact, the design of our clinical trials and the sites that we have chosen in our clinical trial network is going to be very representative of being able to get minority populations and populations at most risk to be part of the trial so that we know during the trial what the relative efficacy, as well as potential adverse events. It is something we started back in the days of HIV when we tried to get good demographic representation, and we are going to do that with these trials. Thank you.

Senator MURRAY. Thank you. And Dr. Hahn, tell me what steps the FDA is taking now to make sure the United States is prepared to produce a sufficient number of vaccines, including the necessary manufacture and supply chain capacity, for supplies like vials and stoppers and syringes.

Dr. HAHN. Thank you, Senator. This is an effort that started as a partnership with the vaccine developers and the NIH in their efforts.

One of the most important things, ma'am, has been the data transparency, sharing of data, both with the agency, NIH, and with the manufacturers so we can understand what the capacities are; what the needs are from the supply chain; and then how to actually share that so that if one manufacturer's vaccine does not go forward, we can use the capacity of that manufacturer for another manufacturer's vaccine.

I am very happy to report that the work of Dr. Marks and Dr. Fauci has led to that sort of effort. We have developed, as I mentioned before, this Gantt chart that describes all the steps that go forward with vaccination, including those supplies you described. It is somewhat complicated, ma'am, in that we may very well have hopefully five to seven different candidate vaccines that may need different supplies associated with them. But, we have been up front identifying those supplies, where they are available, and then working with the manufacturers to make sure that they are available.

Senator MURRAY. Okay. Thank you. Thank you very much. And, Mr. Chairman, thank you, and thank you to all of our witnesses for joining us today.

It is really clear to me that we have more work to do before we can safely get back to work and school and some semblance of normal life in our Country.

We still need testing to be fast, free, and everywhere. And we need the White House to lay out a detailed, national plan to make that happen.

We still need adequate personal protective equipment, both for our healthcare workers and for workers at our businesses and at schools when the time comes.

We still need guidance from our experts so our communities have the information that they need to reopen schools and businesses safely, confidentially—confidently, and complete—competently; and so public health workers and healthcare providers have the information they need to keep their patients and communities safe.

While experts have been clear that the day we can safely reopen may be a ways off, there is plenty for us to do in the meantime, both to plan ahead—for example, to make sure that once we have a safe and effective vaccine, we can produce and distribute it to everyone quickly, equitably, and at no cost.

To address the immediate challenges. For example, making sure there are appropriate mental health resources for everyone who is coping with the challenges that are prevented—presented by this virus. From the stress of physical isolation, loss of income, to the trauma and anxiety of patients and workers who have been on the front lines.

I am going to keep pressing Congress and the White House to provide the action and the leadership that our communities need.

And, I hope, Mr. Chairman, that we will continue to have the opportunities like this to hear directly from the experts and ask pressing questions about how to get our Country through this crisis. It has clearly got a lot further to go, a lot more to do.

And, so, I hope that as our efforts continue, we will be able to bring any of you back, our witnesses, for another hearing soon.

Again, thank you to all of you for joining us today.

The CHAIRMAN. Thank you, Senator Murray.

I have a clarification question and a couple of quick comments, and then we will thank the witnesses and wind up our hearing.

My clarification is, I want to make sure I did not create some confusion by the way I asked the question about going back to school. I asked Dr. Fauci first about treatments and vaccines, and doctor—and Admiral Giroir second about testing.

What I thought I heard was that Dr. Fauci said that vaccines are coming as fast as they ever have, but it will be later in the year at least—at the earliest before we see that; but there are some treatments that have—that are modest, but are promising—there could be more; but that doesn't mean you should not go back to school. That would be more for a testing strategy. Am I right, Dr. Fauci? You didn't say you shouldn't go back to school because we won't have——

Dr. FAUCI. No.

The CHAIRMAN [continuing]. a vaccine by the fall?

Dr. FAUCI. No. Absolutely not, Mr. Chairman. What I was referring to is that going back to school would be more in the realm of knowing the landscape of infection with regard to testing. And, as Admiral Giroir said, it would depend on the dynamics of the outbreak in the region where the school is. But I did not mean to imply at all any relationship between the availability of a vaccine and treatment and our ability to go back to school. You are quite correct.

The CHAIRMAN. Thank you. And what I heard from Admiral Giroir was that you are ramping up current technologies. You are hopeful for Dr. Collins' Shark Tank and the National Institutes of Health. But, in any event, you would expect to have the capacity in the fall of 40 to 50 million tests a month, and that ought to be adequate for the principal of a middle school, or even the chancellor of a campus, to design a testing strategy that could provide, for example, an antigen quick test to screen all the students in the school if necessary. Is that correct?

Admiral GIROIR. Yes, sir, Mr. Chairman. And again, we want to make as many tests available as absolutely possible. What I said is, what I feel comfortable with, knowing the production schedules, being in the position of being able to work with the FDA and CDC, that we should have 40 to 50—we will have 40 to 50 million tests available per month that need to be deployed in a smart, strategic way, depending on the dynamics, in that area and in that region.

Still, having testing even widely does not nullify the need that we are going to have to change our practices in terms of sanitation, personal cleanliness, distancing, face masks, things like that, given what the dynamics could be.

The CHAIRMAN. Well, thank you for those comments, because given the—given that number of tests that will be available in, say, 3 months, or as we ramp up to that number 3 months from now, that should give every principal, every chancellor of every college campus—and again, we have about 5,000 campuses and 100,000 schools—some reassurance that testing, as well as the common-

sense hygiene practices you talked about, could be used to develop a strategy for reopening school for school in August.

And, then, two quick comments. One is, Senator Murray talked about the national plan, which was in the legislation that we all voted for. There is a little bit of a push and tug between what is national and what is Federal, what Washington should do and what the states should do.

I have always thought it is a mistake to say Federal equals national. In other words, COVID–19 is clearly a national problem, but that does not mean the Federal Government is supposed to do everything.

For example, in testing. The law actually requires states to tell you, Admiral Giroir, what their plans are, what their needs are. And, then, you said that during the month of May, you had a series of state plans that identified 12.5 million tests, and you thought you could help meet that.

On the other hand, you have also noticed inefficiency in the marketplace for some supplies, so the Federal Government is buying those and allocating them to the states.

We don't want to get in a situation where Admiral Giroir is telling all the states what to do. Governor Lee in Tennessee does not really want you to tell him what to do. He wants to tell you what he is doing and let you comment on it. I don't think Governor Cuomo wants President Trump telling him what to do. So, a push and tug between what Washington does and what the states do.

I think we have a testing, contact tracing, isolating national strategy and plan led by the Governors, designed by the Federal Government, as a national effort. And then the national effort, clearly, is to do the research for the treatments and the vaccines, and what we have heard today is that is coming along on a faster track than we have ever seen before.

Finally, I want to reiterate, I thought this was a very helpful hearing. I thank the Senators for their questions. I think anybody who took the time to watch would be impressed by the diversity of opinion and the honest answers we got from four really remarkable experts who are in the midst of this every day.

I want to reemphasize what I said earlier, that I intend to make sure that we focus. Senator Murray suggested we need to have more hearings. I agree with her.

And, as we deal with this pandemic, we need to make sure we are ready for the next one. What can we learn about faster treatments and vaccines for the next one? What can we learn about the stockpile, what ought to be in it, who ought to manage it for the next one? Or, what can we learn? Can we learn anything about having hospital beds so we don't have to shut down hospitals and bankrupt them and push patients out in order to create beds for sick people from the pandemic? What about states and hospitals that sell off their PPE in between pandemics?

How do we keep our focus in between pandemics when we are—have so many important things to be worried about in this country? How do we make sure that we, in Congress, sustain and fund all the things that we need to do? And, I want to make sure that we do that this year. I mean, our collective memory is short. So, while

we are all worried about this, we need to not only deal with this crisis, but get ready for the next one.

I thank the witnesses for their extra time. I hope they get a sense that our job, we see, is to create an environment in which you can succeed. Because if you succeed, our Country succeeds, which is what we desperately want.

The hearing record will remain open for 10 days. Members may submit additional information for the record within that time if they would like. Thanks to everyone for being here today.

The hearing is adjourned.

ADDITIONAL MATERIAL

FOOD & BEVERAGE ISSUE ALLIANCE

Hearing on COVID–19: Safely Getting Back to Work and Back to School

The Food and Beverage Issue Alliance (FBIA) represents fifty-eight allied U.S. based Food and Beverage Trade Associations. FBIA, through collaboration with regulatory authorities, ensures that any regulations and guidance are justified by verifiable, peer reviewed, published science that is accessible through an open and transparent process and enhance consumer understanding. In addition, FBIA works to ensure regulation implementation timelines are reasonable, achievable and economically feasible for both small and large food and beverage manufacturers. Find out more about FBIA and its members at *www.feedingUS.org*.

Critical Infrastructure Access to Testing

In March, the food and agriculture, consumer packaged goods (CPG) and retail industries respectfully requested that—as testing capabilities expand—the food and agriculture, CPG manufacturing and retail operations have prioritized access to testing in those situations where it helps protect workers. The current inconsistencies in testing approaches from State to State and between localities have resulted in the need to downscale or shut down operations altogether.

Since their initial request, the number of food operations that have closed due to illness within their worker communities has increased, and at the same time, testing has become more accessible. Now more than ever, it is critical to keep the Food and Agriculture sector, CPG and retail industries operations functional to feed American families. **What work is the agency doing to prioritize the testing resources for these sectors directly behind healthcare and first responders?**

State and Local Re-opening Testing Requirements

State and local health officials throughout the country are asking for 100 percent testing prior to allowing businesses to reopen. **While testing has become more accessible, but is still not readily available, do you believe that this is an appropriate request?**

Access to Personal Protective Equipment

In March, the Food and Agriculture industries, including retailers, requested prioritization for PPE directly behind the healthcare sector and first responders. It is vitally important to protect these essential workers as businesses strive to stay operational, produce food and to keep grocery store shelves stocked for American families. **What is being done to assist these sectors in securing needed supplies?**

Thank you for considering our questions. If you need any additional information, please contact me at *mgoscinski@namanow.org*.

[Whereupon, at 1:30 p.m., the hearing was adjourned.]

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