

**COVID-19: UPDATE ON PROGRESS
TOWARD 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 AN UPDATE ON PROGRESS
TOWARD SAFELY GETTING BACK TO WORK AND BACK TO SCHOOL

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JUNE 30, 2020
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COVID-19: UPDATE ON PROGRESS TOWARD SAFELY GETTING BACK TO WORK AND BACK TO SCHOOL

Tuesday, June 30, 2020

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

The Committee met, pursuant to notice, at 10:05 a.m., in room G-50, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR ALEXANDER

The CHAIRMAN. 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 consulting with the Department of Health and Human Services and the Centers for Disease Control, individuals in the hearing room are seated 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.

The hearing may be watched online. An unedited recording will be available on our website, www.help.senate.gov.

All of our witnesses today are participating in person. We thank you for that. Some Senators are participating by videoconference.

Before I make my opening statement, I would like to say a word about masks. The Office of Attending Physician has advised us that we may remove our masks and talk into the microphone as long as we are 6 feet apart. So, that is why my mask is off right now, because I am 6 feet away from everybody else. But, like many other Senators, when I am walking the hallways or on the Senate floor, I am wearing a mask.

People wear masks because CDC has said, "Simple cloth coverings slow the spread of the virus and help people who may have the virus and do not know it from transmitting it to others."

Unfortunately, this simple lifesaving practice has become part of the political debate. It says this: If you are for Trump, you do not wear a mask. If you are against Trump, you do. That is why I have suggested that the President occasionally wear a mask, even

though in most cases it is not necessary for him to do so. The President has plenty of admirers. They would follow his lead. It would help end this political debate. The stakes are too high for this political debate about pro-Trump, anti-Trump masks to continue.

Around here, Senators and staff wear masks because we do not want to make each other sick. For example, I was exposed to COVID-19 by a pre-symptomatic staff member on my way to Dulles Airport and, as a result, had to self-quarantine for 2 weeks. The Senate physician told me that one reason I did not become infected was because the staff member was wearing a mask, and that, in the physician's word, greatly reduced the chances of an exposure.

It is also a pretty good way to make a statement. I like to wear my plaid mask. Dr. Fauci uses his mask to demonstrate his loyalty to the Washington Nationals. Senator Kaine is either a cowboy or a bandit. I am never sure which.

If you want college football to return this fall, here is what Coach Phillip Fulmer, our athletic director at the University of Tennessee says: "If you really, really want to see some football this fall, wear a mask." That might have more influence than anybody else in Tennessee.

The United States is in the midst of a very concerning rise in COVID-19 cases and hospitalizations in many states. The experts in front of us have told us that washing our hands, staying apart, and wearing a mask are three of the most important ways to contain the disease and slow the spread of the virus.

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

Now, Senator Murray and I will each have an opening statement, and then we will turn to our witnesses, who we thank for being with us today. Each will have 5 minutes. We would ask you to summarize your testimony in 5 minutes, and then the Senators will have a chance to ask 5-minute round of questions. We have full participation today, it looks like. It should be an interesting morning.

Among the casualties of this dangerous and very sneaky COVID-19 virus are the 75 million students who were sent home from school and college in March. Add to the casualties the teachers who were not prepared to teach remotely and the working parents who suddenly had children at home and who were not prepared to home school. Add the lost sports seasons and the once-in-a-lifetime graduation opportunities. Then there were unprecedented dilemmas for administrators and inadequate school budgets.

Being sent home from school does not rank with the sickness and the death that the virus has caused. The United States has over 2.5 million cases of the virus and over 125,000 deaths, according to Johns Hopkins. While states and communities continue to take action to keep people safe, nothing, though, was more disruptive to American life, and nothing would head it back toward normalcy more rapidly than for those 135,000 public and private schools and 6,000 colleges to reopen this fall.

Earlier this month, this Committee heard from college presidents and school leaders about their plans for safely reopening this fall.

This hearing is an opportunity for an update and to hear from the Nation's top health experts on how headmasters, principals, superintendents, chancellors, and college presidents can open their schools safely just a few weeks from now.

This Committee last heard from today's four witnesses on May the 12th, when three of the four were quarantined and most of the Senators were participating virtually. That was one of the first virtual Senate hearings in history, and surely the best watched. Every network carried the two-and-one-half hours of statements and questions and answers from Senators.

The question before the country today is not whether to go back to school or college, or childcare or work, but how to do it safely. Even though COVID-19 does not, in general, hurt young children and college age students nearly as much as older and more vulnerable Americans, there is some health risk. But, in my view, the greater risk is not going back to school.

Guidance for reopening schools from the American Academy of Pediatricians tells school administrators the following: "Our academy strongly believes that all policy considerations for the coming school year should start with a goal of having students physically present in school."

The Academy continues, "The importance of in-person learning is well documented."

There is already evidence of negative impacts on children because of school closures in the spring of 2020. Lengthy time away from school and associated interruption of supportive services often results in social isolation, making it difficult for schools to identify and address important learning deficits, as well as child and adolescent physical or sexual abuse, substance use, depression, and suicidal ideation. This, in turn, places children and adolescents at considerable risk of morbidity, and in some cases, mortality.

Beyond the educational impact and social impact of school closures, there has been substantial impact on food security and physical activity for children and families, says the American Academy of Pediatricians.

Dr. Lloyd Fisher, the incoming president of the Massachusetts Chapter of that Academy of Pediatricians, told reporters, "While for most children COVID-19 has not had the devastating and life-threatening physical health effects that have occurred in adults, the negative impact on their education, mental health, and social development has been substantial." Nothing can take the place of the daily face-to-face interaction our children experience when attending school in person, Dr. Fisher said.

Many American colleges, overall considered the best in the world, will be permanently damaged or even closed if they remain, in Brown University President Christina Paxson's words, ghost towns.

Mitch Daniels, the President of Purdue, wrote in a *Washington Post* op-ed, "Failure to take on the job of reopening would not only be anti-scientific, but also an unacceptable breach of duty."

Today, in addition to hearing more about the concerning rise in cases and hospitalizations in some states, I would like to ask our witnesses in their statements and answers to questions to put yourselves in the place of one of America's approximately 14,000 superintendents of school districts, or the principal or headmaster

of one of 135,000 schools, or as president or chancellor of one of 6,000 colleges, and help them answer the question of how to reopen schools and colleges safely.

Dr. Fauci, I hope that in your opening statement or answers to questions, you will suggest steps a superintendent might take to open schools safely. And, not only how to keep children safe, but to keep safe the adults—teachers, parents, grandparents—with whom they come in contact.

Dr. Hahn, will there be treatments or medicines this fall that will help speed the recovery from COVID-19 or reduce the possibility of death? I believe the fear of going back to school, or going anywhere these days, is in large part because of the fear of severe illness or even death. If that risk can be lessened by new treatments, it should increase confidence in going back to school.

I would also like to commend Dr. Hahn and the work the FDA did to get tests on the market quickly as possible to help understand the spread of the virus. Since then, FDA has worked out which tests have not worked as well as they should and taken steps to remove them from the market. That is what is supposed to happen in the urgency of a pandemic.

Admiral Giroir, at our last hearing, you said you expected there to be 40 to 50 million diagnostic tests available each month by September. Is that still true? And exactly how does a school district go about making sure it gets those tests and who pays for them? What are the prospects from the shark tank at the National Institutes of Health that there will be new, reliable, and inexpensive tests so we can have even more widespread testing?

Dr. Redfield, you are continuing to work on updated guidelines about going back to school and college safely. Are CDC employees going to be available in our states to help work with school districts to develop their plans? And what advice do you have about the arrival of the flu season this fall at the same time as COVID-19?

This is a lot to discuss, but there will be time during the next 2.5 hours to answer most of those questions.

Let me quickly highlight three areas that have come up in our four earlier hearings this month that I think need clarification.

First, on contact tracing. No doubt, contact tracing is crucially important. It identifies the people who might have been exposed so that people who do not—so that they do not in turn expose someone else.

According to an NPR report on June 18, states have already hired at least 37,000 contact tracers. State officials and Johns Hopkins Center for Health Security issued a report estimating the need for as many as 100,000 contact tracers.

Several reports suggested Congress appropriate money to pay for those tracers. The reality is Congress already has. On April 24th, Congress appropriated \$11 billion, which has been sent to states and tribes for the expenses of testing. That legislation explicitly said the money could be used for contact tracing. This is in addition to \$755 million from the first emergency appropriations legislation on March 6th that could be used for contact tracing, and that is in addition to the March 27 legislation in which Congress appropriated \$150 billion—I mean \$1.5 billion in the CARES Act for

states, territories, and tribes to use for COVID preparedness and response.

The CARES Act also included the \$150 billion to states, but a significant amount of that \$150 billion has not been spent, even though it is all designated for expenses related to COVID-19, which include contact tracing.

For example, Tennessee's Governor has told me he is reserving as much as \$1 billion of that so that he can determine what flexibility he has in spending the money.

Washington State has not spent as much as \$1.2 billion. Missouri State Treasury says they have not spent about \$1 billion.

According to the report by state health officials and Johns Hopkins, an average salary for a contact tracer would be a little more than \$35,000. This adds up to about \$3.5 billion for 100,000 contact tracers. So, the point is, Congress has already sent to states plenty of money to hire all the contact tracers that are needed.

Second, who pays for the testing? In the CARES Act, Congress voted to make all COVID-19 tests available to patients at no cost. This meant insurers would cover diagnostic tests, which detect whether a person is currently infected with the virus, and also antibody tests, which indicate whether a person has had COVID-19 in the past and now may have some protection in the future.

Guidance from the Labor Department, Treasury Department, and Centers for Medicare and Medicaid Services said last week that insurers are only required to pay for tests without patient cost sharing if a doctor orders it. I agree with that. But, given that the CDC specifically recommends doctors order tests in two situations—when a person has signs or symptoms of COVID-19 or recently had contact with someone known or suspected to have COVID-19—who pays for the testing at other times? I believe Congress will need to take action to further clarify who pays for the testing at other times.

For example, a school may want to do random testing. Perhaps it should make an arrangement with the state to pay for that. Or, perhaps Congress needs to provide more money to pay for that.

If an automaker wants to test all of its employees at the plant every 2 weeks, perhaps the automakers should pay for that. Or, perhaps the state would want to pay for that. That needs to be clarified.

Finally, flu shots. CDC has said more people need to get flu shots this fall so healthcare workers can better distinguish between COVID-19 and the flu. CDC says a priority is for all children over the age of 6 months to be vaccinated for the flu so they do not become sick and pass it to more vulnerable populations, who can have more severe consequences.

On January 24th, Senator Murray and I hosted our first bipartisan briefing on coronavirus at a time when there were only four cases in the United States. Since then, this Committee has had four more briefings. Today is our eighth hearing on coronavirus and U.S. preparedness.

Last week's hearing was about steps to take this year while our eye is on the ball to better prepare for the next pandemic. I have issued a white paper outlining five recommendations for Congress to prepare Americans for the next pandemic, and that paper has

received more than 350 substantive comments that are available to all Members of the Committee.

After all Senators have had a chance to ask their questions, I will conclude the hearing by asking our witnesses if they have two or three suggestions about steps Congress should take this year to deal with the next pandemic, most of which will also help with this one.

But, this hearing is about what happens now as administrators prepare to reopen schools and colleges. Experts underestimated this dangerous and sneaky virus, and there is still much we do not know about it.

But, we do know the basic steps to take to reopen schools and colleges in 2020, before there is a vaccine, and those are these: social distance, wear a mask, wash your hands, test, contact trace, and isolate those exposed or sick. And, hopefully, by the fall, there will be treatments to make the consequences of the disease less severe.

I look forward to hearing from our distinguished witnesses how school leaders and college presidents can safely reopen 135,000 schools and 6,000 colleges, and also learning the latest developments on testing and treatments that we can expect during the year 2020 before vaccines arrive.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. Thank you to all of our witnesses for joining us here today. And, of course, thank you to our staff for setting up the technology so we can hold this hearing safely.

I want to get to the point quickly, and I am going to be blunt about it. The COVID-19 response in our Country is still a disaster. One hundred and twenty-six thousand lives lost was once considered an estimate on the high end of the spectrum, but the year is just half way over and it is now a grim reality. We have lost more Americans to COVID-19 than we lose to the flu each year, than we lost to the opioid crisis last year, and more lives than we have lost in every American war except the Civil War and World War II.

Despite what President Trump claims, this pandemic is not fading. Far from it. Several states are seeing rapid, record-setting increases, and the Country just saw its largest single-day increase to date.

While this public health crisis rages across the Country, we have seen a leadership crisis raging in the White House. As the President proves time after time, he cares less about how this pandemic is impacting families and communities and more about how it makes him look.

Just consider his appalling, continued failure on testing. President Trump said anyone that wants a test can get a test. They still can't.

He said testing was overrated. It is not.

He said we prevailed on testing. We have not.

Now he is saying we should be doing fewer tests, and testing makes us look bad. Well, it clearly does not, and we clearly need to be doing more.

The most honest thing he has said about testing is that he does not take responsibility at all, and that is exactly the problem. It is why Congress actually took bipartisan action in the last COVID-19 response bill to require the Trump administration to submit a comprehensive, national testing plan. That is why I am still pushing for this Administration to include more details in that plan and take more steps to ramp up testing. Because we are still nowhere close to the testing and tracing capacity we need to safely reopen our Country, and ending support for Federal testing sites, while sitting on billions in testing funds Congress provided, is not going to get us there.

The ongoing struggle to get President Trump to take testing seriously should be a stark warning to Congress that, when it comes to vaccines, we cannot just leave this Administration to its own devices. We have to hold it accountable.

We know this pandemic will not end until we have a vaccine that is safe and effective, that can be widely produced and equitably distributed, and that is free and accessible to everyone, which is why we need a comprehensive, national vaccine plan from the Trump administration as soon as possible. Given the testing plan, which Congress only received after forcing the Administration's hand, was too little, too late, we need to take the opportunity we have right now to get a vaccine plan much earlier and avoid the missteps we have seen with testing.

I hope Republicans will work with me in a bipartisan way once again to require this Administration to put forward a plan. We need the Trump administration to show us how they will ensure a vaccine is safe and is effective. I am as eager as anyone for a vaccine. But this is not just about doing something fast; it is about doing it right. That is why we need to know the process for developing a vaccine is rigorous, it is inclusive, it is transparent, and it is science-driven.

But, in light of the hydroxychloroquine debacle and the removal of Dr. Bright from BARDA for questioning the Administration's efforts to promote that unproven treatment, we cannot take for granted this process will be free of political influence. We have to demand serious oversight.

In order to give the public full confidence that a vaccine is safe and effective, the Administration needs to commit now to being fully transparent about the standards a vaccine will be expected to meet and releasing the clinical trial data that FDA uses to evaluate safety and effectiveness.

We also need a plan detailing how to produce and distribute vaccines nationwide and make sure everyone can actually get them. We saw with testing how avoidable bottlenecks create damaging delays when the Federal Government refuses to step in and lead like it needs to do in a time of crisis. And, unfortunately, we saw how existing health disparities are exacerbated without a plan to overcome them as even the incomplete data we currently have shows Black, Latino, and Tribal communities have significantly less access to testing than White communities. This is an injustice that we must not repeat when it comes to vaccines.

We also need a plan to guarantee vaccines are free so that cost is not a barrier for patients. And, it is worth noting, we still need

to act to make COVID–19 treatment available at no cost, too. And the plan must address barriers, like vaccine hesitancy and misinformation, especially when one of the most prominent sources of misinformation so far has been the President of the United States.

While the discovery of an eventual vaccine may still be far off, these are issues we need the Administration to answer now. So, I hope Republicans will work with me to require the Administration to submit a comprehensive vaccine plan and address many of the other urgent issues stemming from this pandemic.

Our businesses, our workers, teachers, students, and families do not have what they need to safely return to work or school, period.

Our medical system, doctors, nurses, frontline workers continue to face unimaginable risk, stress, and fatigue. They need Congress to step up to help them continue to save lives.

Families need us to continue to ensure they have basic services and can keep food on their tables.

The House passed the HEROES Act 46 days ago to get more relief to frontline workers, to families, and businesses. It is well past time for Leader McConnell and Senate Republicans to sit down with fellow Democrats and get to work. There is no question our Country is still in crisis, and every day the Senate fails to take action is a day we allow it to get worse.

I also hope, Mr. Chairman, that we will be able to have another hearing on this crisis soon with Administration officials, whose testimony is long overdue—Secretary Azar, Secretary DeVos, and Secretary Scalia.

Thank you, Mr. Chairman. I look forward to our witnesses today, and testimony, and the questions that we have for them.

The CHAIRMAN. Thank you, Senator Murray.

We would ask each witness now to summarize his testimony in 5 minutes. I am pleased to welcome our witnesses. Each of you are making significant contributions to our Government's response to COVID–19, helping us go safely back to school, back to work. We are grateful for your service to our Country.

Our first witness is Dr. Anthony Fauci. He is director of the National Institute of Allergy and Infectious Diseases at the National Institute of Health. He has held this position since 1984. He has led the Agency's research related to HIV-AIDS, influenza, malaria, Ebola, and other infectious diseases. He has advised six presidents on domestic and global health issues. He is one of the principal architects of the Emergency Plan for AIDS Relief. In 2014, he was involved in treating Ebola patients at NIH and worked on vaccine trials for Ebola.

Next, Dr. Robert Redfield, director of the U.S. Center for Disease Control and Prevention, CDC. For more than 30 years, he has been involved with clinical research related to chronic human viral infections and infectious diseases, especially HIV. He was founding director of the Department of Retroviral Research within the U.S. Military's HIV Research Program and retired after 20 years of service with the U.S. Army Medical Corps.

Third, Admiral Brett Giroir. Admiral Giroir is the Assistant Secretary for Health at the U.S. Department of Health and Human Services. He oversees the development of the Department's public health policy recommendations. Specific to COVID–19 response,

Admiral Giroir has taken on testing and focused on increasing the number of tests we can do with existing technology. His Federal service includes directing the Defense Sciences Office of the Defense Advanced Research Projects Agency and a variety of other important responsibilities.

Finally, we will hear from Dr. Stephen Hahn. Dr. Hahn is commissioner of the U.S. Food and Drug Administration, the FDA. Before joining FDA, he held leadership positions as chief medical executive at the University of Texas MD Anderson Cancer Center and as chair of the Department of Radiation Oncology at the University of Pennsylvania. Early in his career, he was senior investigator at the National Cancer Institute at the National Institutes of Health. He has been commander of the U.S. Public Health Service Commission Corps in 2005.

We welcome our witnesses.

Dr. Fauci, welcome. Let us begin with you.

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, Members of the Committee. Thank you for giving me the opportunity to discuss briefly with you today the role of the National Institutes of Health in research addressing COVID-19. And, as you indicated, Mr. Chairman, I will, during the question period and alluding to in the presentation, address some of the issues regarding schools.

The NIAID NIH Strategic Plan for COVID Research involves four major components. The first is to improve the fundamental knowledge of understanding the biology of the virus and the immune response to the virus in order to better inform us in the development of diagnostics, therapeutics, and vaccines. Some of the work that has come out of that program right now informs very greatly how we will address vaccine development, particularly understanding the confirmation of the components of the virus that induce an appropriate immune response.

In addition, we will develop and are developing animal models. Apropos of what you mentioned about children in school, we have a program called HEROS, which is Human Epidemiology and Response to SARS coronavirus, which is determining the incidence and transmissibility among children—a very important issue when you talk about opening schools and the impact that might have. In addition, the development of diagnostics, point-of-care sensitive and specific diagnostics under the RADx Program, including the RADx-UP for underserved populations.

Third, to characterize and test therapeutics. You mentioned the importance of this as we open up schools. There are a number of programs very active that have already shown efficacy or not in some drugs, as well as a number of clinical trials that are ongoing. One in particular was the first randomized placebo-controlled trial showing that the drug Remdesivir diminishes by about 32 percent the time it takes to get to recovery in people with advanced disease, pulmonary involvement. In addition, we have another study combining this with an anti-inflammatory agent.

Next, we have vaccines. As several have mentioned, it is extremely important to have safe and effective vaccines available for everyone in this Country, as well as globally. In that regard, we put together, myself and some of my colleagues, and published in *Science Magazine* a few weeks ago what we call a Strategic Approach to Coronavirus-19 Vaccine Research and Development. It is not a comprehensive plan about every aspect of vaccine, but it is a strong plan regarding the research and development pathway. And, what we have done in this is that we have what is called a harmonized effect because we know there are many vaccines that are in trial now at various stages.

What we did, and the Federal Government, thanks to the generosity of the Congress, has put a considerable amount of money in order to harmonize the trials of multiple candidates from different companies so that we have common endpoints, common data and safety monitoring board, and common immunological parameters that are being funded and are being pursued.

In addition, there are a number of different platforms that are being pursued so that we do not have all our eggs in one basket. As you know, one of those is right now getting ready as we approach next month of going into Phase 3 trials, and others will be staggered along the way in the middle of the summer, end of the summer, early on.

There is no guarantee, and anyone who has been involved in vaccinology will tell you, that we will have a safe and effective vaccine, but we are cautiously optimistic looking at animal data and the early preliminary data that we will at least know the extent of efficacy sometime in the winter and early part of next year. Again, working with the companies and the investment made by this Congress, hopefully there will be doses available by the beginning of next year.

These are the things that we feel aspirationally hopeful about, and we will continue to pursue this.

I will stop there, Mr. Chairman, and be happy to answer questions later.

Thank you.

[The prepared statement of Doctors Fauci, Redfield, Giroir, and Hahn follow:]

PREPARED STATEMENT OF DOCTORS FAUCI, REDFIELD, GIROIR, HAHN

Introduction

Chairman Alexander, Ranking Member Murray and distinguished Members of this Committee. It is an honor to appear before you today to discuss the Department of Health and Human Services' ongoing response to the COVID-19 pandemic. We are grateful for this opportunity to address how each of our agencies and office are harnessing innovation to prevent, diagnose, and treat the novel coronavirus SARS-CoV-2.

COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID-19) by the World Health Organization (WHO), is caused by the SARS-CoV-2 virus. There are many types of human coronaviruses including some that commonly cause mild upper-respiratory tract illnesses. Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, coronaviruses that infect animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID-19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two

other examples of coronaviruses that originated in animals and then spread to people.

The Department of Health and Human Services (HHS) is working closely with all of our government partners in this response. We thank Congress for supporting our efforts through the passage of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020; the Families First Coronavirus Response Act; the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and the Paycheck Protection Program and Health Care Enhancement Act. These laws have provided additional resources, authorities, and flexibility. Within HHS, the Centers for Disease Control and Prevention (CDC), the National Institute of Allergy and Infectious Diseases (NIAID), the Assistant Secretary for Health, and the Food and Drug Administration (FDA), along with additional components not represented today, play critical roles in the response to this public health emergency as discussed below.

Centers for Disease Control and Prevention

CDC is America's health protection agency, and works 24/7 to save lives and protect America from health, safety and security threats, both abroad and in the United States. CDC has a key role in preparedness and response, and addressing infectious diseases like COVID-19 is central to our mission. CDC is building upon decades of experience and leadership in responding to prior infectious disease emergencies, including SARS, MERS, Ebola, Zika, and the H1N1 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, prevention, and laboratory capacity, to develop and provide the Nation with the science-backed information and analysis needed to address this public health emergency. CDC has developed and continues to update guidance for healthcare professionals and the public to encourage 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 collaborating to prepare the Nation's public health system and the private sector to disseminate rapidly a vaccine to the American people when one is available. Abroad, CDC is leveraging investments in global health security, pandemic influenza preparedness and public health infrastructures and capacities built through Presidential initiatives, including the President's Emergency Plan for AIDS Relief to support countries in mitigating and containing COVID-19. In addition, CDC has staff in over 60 countries, who work very closely with host governments. Since the beginning of the outbreak, they have been providing technical assistance, and now programmatic funding, to help countries mitigate the effects of COVID-19 and stop the disease from spreading. 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 regular situation reports, including input from our respiratory disease experts in the CDC Country Office in China, 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, reach out to our state and local partners, and deploy staff where needed to support state and local screening and investigation efforts. CDC is an integral part of the COVID-19 response and coordinates with other agencies through the Joint Coordination Center (JCC) led by Secretary Azar. Addressing COVID-19 is 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 June 22, 2020, CDC has announced or obligated \$12.1 billion in direct awards to jurisdictions across America from the funds provided by Congress, including \$10.25 billion from the Paycheck Protection Program and Health Care Enhancement Act.

CDC is providing direct technical assistance and support to STLT partners as they consider approaches to mitigate and contain COVID-19. CDC has deployed 149 teams at the request of state, tribal, local, and territorial partners to provide infection prevention and control consultation and epidemiological expertise in support of those on the front lines of this battle. 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 June, 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, including deploying over 1,500 individuals to over 100 locations across the United States. These support staff 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 working with and providing support to STLT partners as they develop plans to conduct contact tracing. Contact tracing is a core disease control strategy that involves case and contact investigation followed by the implementation of an intervention (for example, isolation and quarantine) that interrupts disease transmission. Case investigation and contact tracer staff have been employed as local and state health department personnel for decades to address other infectious diseases, and contact tracing is a key strategy for preventing further spread of COVID-19 as well as a key component of state plans to reopen. As of June 5, 2020, CDC has posted 12 different guidance documents including case investigation guidelines, checklists for developing a case investigation and contact tracing plan, digital contact tracing tools, and a Contact Tracing Communications Toolkit for Health Departments.

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 also is augmenting the existing National Healthcare Safety Network to monitor and analyze the capacity of the healthcare system daily—including hos-

pitals and nursing homes—so that Federal, state, and local officials can adjust their response and mitigation efforts as needed.

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 work with individual jurisdictions to address where there may be racial and ethnic disparities in morbidity and mortality. CDC is leveraging all available surveillance systems to monitor COVID-19 and protect vulnerable communities. CDC is using diverse systems to define a more complete picture of the outbreak, including race/ethnicity data and is working with communities of color to protect communities at risk. CDC has recently updated the COVID-19 Case Report Form (CRF) to allow for better collection of data on populations that have previously been under-represented in reporting. The initial CRF included questions for sex, age, race and ethnicity and whether the case is part of a recognized outbreak. The revised form includes additional variables for populations that may be at higher risk for severe illness (e.g., tribes) and risk factors (e.g. homelessness, disabilities, and other factors). States have improved the completeness of their CRF reporting in the past two months; in particular, the percentage of reports that include race/ethnicity data has increased from 18 percent in April to 43 percent in early June. While progress has been made, CDC will continue to work with states to improve completeness of the data. Additionally, new reporting requirements that accompanied more than \$10 billion in funding for states from the Paycheck Protection Program and Healthcare Enhancement Act require states to report race, ethnicity and other important demographic information with test results providing information on those impacted. Furthermore, race and ethnicity data for hospitalizations captured in CDC's COVIDNET has increased to more than 80 percent providing a much stronger picture of the different levels hospitalizations from COVID.

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 three 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. The test is currently not designed to test individuals who want to know if they have been previously infected with COVID-19.

During the week of March 30, CDC and public health partners began the first stage of antibody 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 use commercial or hospital clinical laboratory viral tests for COVID-19 that have been issued an Emergency Use Authorization (EUA) by FDA or are being offered as outlined in FDA's policy regarding COVID-19 tests or continue to coordinate testing through public health laboratories and work with their local and state health departments. Increasing testing capacity will allow clinicians to consider the medical necessity of COVID-19 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. Other considerations that may guide testing are epidemiologic factors such as known exposure to an individual who has tested positive for SARS-CoV-2, and the occurrence of local community transmission or transmission within a specific setting/facility (e.g., nursing homes) of COVID-19. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. 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.

CDC has developed a new laboratory test that checks for three viruses at the same time, two types of influenza viruses (A and B) and SARS-CoV-2, the virus that causes COVID-19. Testing for all three viruses simultaneously will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find co-infections of influenza and SARS-CoV-2, which is important for doctors to diagnose and treat people properly. CDC requested emergency use authorization (EUA) for this combined laboratory test from the U.S. Food and Drug Administration (FDA) on June 18, 2020. CDC expects that private sector laboratory test developers may be creating similar multiplex assays to meet clinician needs during influenza season. 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 a range of audiences, individuals and communities, including business, schools, and healthcare professionals. 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>.

CDC released consideration documents to help businesses and community organizations operate as safely as possible during the COVID-19 pandemic, including K-12 schools and universities. These documents complement other CDC resources, including interim guidance documents that are posted online and the decision tools that help communities make decisions about resuming and gradually scaling up operations. These decision tree tools quickly walk through some key questions that should be answered in preparation for phased opening of schools, businesses, mass transit, and other settings. These suggestions are updated as we learn more about COVID-19 and as state and local leaders continue to decide how to adjust mitigation strategies in their communities. School administrators and officials can consult with state and local health officials to determine how to put these considerations into place. In addition, schools may need to make adjustments to meet their unique needs and circumstances.

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. CDC offers a framework for providing non-COVID-19 clinical care that outlines key considerations for healthcare systems and health care providers. Key considerations include monitoring trends in local cases and deaths, consulting with state or local health depart-

ments for region-specific information and recommendations, following recommended infection control practices, screening all patients for COVID-19 symptoms and expanding services gradually.

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 grant recipients to help ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking.

While it remains unclear how long the pandemic will last, COVID-19 activity will likely continue for some time. It is also unclear what impact the ongoing COVID-19 pandemic will have on health care and public health systems during the upcoming influenza season. If there is COVID-19 and flu activity at the same time, this could place a tremendous burden on the health care system related to bed occupancy, laboratory testing needs, personal protective equipment and health care worker safety. In the context of likely ongoing COVID-19 activity, getting a flu vaccine is more important now than ever. Getting a flu vaccine will help keep you and your loved ones out of a doctor's offices and hospitals and help conserve scarce medical resources to care for COVID-19 patients.

CDC works with public health and clinical partners each year to increase the number of people who get the flu vaccine and eliminate barriers to vaccination. Ongoing COVID-19 activity may affect where and how flu vaccines are given. CDC is working with manufacturers to maximize flu vaccine supply and with providers and health departments to develop contingency plans so that people can be vaccinated in a safe environment.

In addition, on June 4, CDC awarded \$140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable state health departments to launch an initial scale up for influenza season, given the increased risk of COVID-19. Funds will, among other activities, begin to support staffing and preparedness early this summer and focus on ensuring flu coverage for these vulnerable populations. Due to the risk of COVID-19, the goal is to increase flu coverage for vulnerable populations during the 2020-21 flu season, ensure Americans are aware of the importance of getting vaccinated this flu season, and increase access to flu vaccines for uninsured, high-risk adults.

COVID-19 is the most significant public health challenge to face our Nation in more than a century. CDC is providing the American public with the information and assistance it needs to address COVID-19 head on. As we work together to fight COVID-19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease threats and to save lives.

National Institute of Allergy and Infectious Diseases

NIH is the HHS agency leading the research response to COVID-19 and the novel coronavirus that causes the disease, 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 emerging infectious diseases, 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 enhanced our fundamental understanding of coronaviruses in general and provides a strong foundation for our accelerated efforts to address the specific 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.

As part of a longstanding collaboration, the NIAID Vaccine Research Center worked 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. On May 18, 2020, Moderna announced encouraging interim findings from the Phase 1 clinical trial and, on May 29, 2020, a Phase 2 clinical trial was initiated to further study safety and the immune response to the experimental mRNA vaccine. NIAID and BARDA are working with Moderna to launch a Phase 3 clinical trial as early as July 2020, pending positive results from this Phase 2 trial. The Coalition for Epidemic Preparedness Innovations (CEPI) funded the manufacture of the vaccine candidate for the Phase 1 trial, and BARDA is supporting advanced development of the candidate.

Scientists at NIAID's Rocky Mountain Laboratories (RML) in Hamilton, Montana, are collaborating with University of Oxford researchers to develop a SARS-CoV-2 chimpanzee adenovirus-vectored vaccine candidate AZD1222, formerly known as ChAdOx1, now in a Phase 2/3 clinical trial supported by the University of Oxford. BARDA recently announced plans to support advanced development and production of AZD1222. 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 vaccine 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 patients who have been infected with SARS-CoV-2. On February 21, 2020, NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID-19 Treatment Trial (ACTT), to evaluate the safety and efficacy of therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of severe COVID-19 in hospitalized adults (ACTT-1). The adaptive design of this trial will enable the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib, which was recently added to the next iteration of the study (ACTT-2). An analysis of preliminary data from 1,063 patients enrolled in the ACTT-1 indicated that those who received remdesivir had a 32 percent faster time to recovery, a median of 11 days compared with 15 days for those who received placebo. Additionally, the analysis found that remdesivir may benefit survival, although the mortality data did not reach statistical significance. A mortality rate of 7.1 percent was observed for the group receiving remdesivir versus 11.9 percent for placebo. These initial findings were published on May 22, 2020, in the *New England Journal of Medicine*. NIAID is developing and testing other novel and repurposed therapies. A study to evaluate monoclonal antibodies (mAbs) in outpatients with mild-to-moderate COVID-19 is planned for launch in early July. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin (IVIg) and mAbs for treatment of COVID-19 in hospitalized adults.

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. Other Institutes and Centers across NIH also are working concurrently with partners in academia and industry to pursue the development and testing of mAbs, antiviral, and anti-thrombotic drugs for potential treatment of COVID-19. NIAID, NCI, NHLBI, NCATS, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the National Institute of Neurological Disorders and Stroke (NINDS) 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, DOD, the Department of Veterans Affairs, CDC, and FDA. NIAID has been asked to lead the effort of U.S. government-supported clinical trials for certain vaccine candidates and some therapeutic interventions that have been considered by ACTIV.

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 COVID-19 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. On May 12, 2020, in response to the preliminary analysis of ACTT-1, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID-19 in hospitalized patients with severe disease requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation. The guidelines are updated regularly as new evidence-based 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 is working to identify, support, and make innovative strategies for COVID-19 testing widely accessible, in collaboration with FDA, CDC, and BARDA. RADx is leveraging the Point-of-Care Technologies Research Network established by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) to allow for the 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-based 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 the developers of tests.

NCI is coordinating with FDA and NIAID to assess the sensitivity and specificity of certain SARS-CoV-2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV-2. NCI and NIAID also are working to establish a collaborative national network to increase national capacity for high-quality serological testing with return-of-results to subjects. In addition, they will conduct research to increase the understanding and application of those results and support related clinical efforts, including clinical trials of convalescent serum and the creation of registries of tested subjects for sero-protection studies.

NIAID, NCI, NCATS, and NIBIB also are partnering on a new study to investigate whether adults in the United States 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 incidence of infection in specific populations, including children and their household contacts, and aspects of the clinical course of infection, including incidents of thrombosis, strokes, 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 and evaluate whether unique immune responses may be associated with clinical disease trajectories; 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 help to identify individuals or groups at high risk.

In order to improve understanding of neurological consequences of SARS-CoV-2 and inform potential treatment strategies, NINDS is supporting development of a data base that would collect data on the prevalence and spectrum of neurological symptoms observed in patients with SARS-CoV-2 infection. NHLBI and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development are leading a trans-NIH effort, with participation from NIAID, to coordinate research into the multisystem inflammatory syndrome in children (MIS-C), an extremely serious inflammatory condition that has been associated with SARS-CoV-2 infection in children and adolescents.

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 and evaluating safe and effective COVID-19 vaccines and therapeutics, and sensitive, specific, and rapid point-of-care molecular diagnostic and serological tests. These efforts will improve our response to the current pandemic and bolster our preparedness for the next, inevitable emerging disease outbreak.

Office of the Assistant Secretary for Health

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 is now further magnified as states continue in their various stages 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 Administration has produced numerous documents that establish the strategy and specific tactics for testing in America. These include:

- White House: *Testing Blueprint Opening Up America Again*
- White House: *Addendum to the Testing Blueprint*
- HHS: *Report to Congress COVID-19 Strategic Testing Plan*
- CDC: *Priorities for Testing Patients with Suspected COVID-19 Infection*
- CMS: *Long Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities): CMS Flexibilities to Fight COVID-19*
- CMS: *Nursing Home Reopening Recommendations for State and Local Officials*

These will be followed soon with a number of additional guidance documents that apply the strategic principles to specific situations. In addition, the Administration is now reviewing testing plans from each state, territory, and major city public health unit, as a requirement of \$10.25 billion in cooperative agreement funding distributed by the CDC.

Currently, there are tests for the presence of the virus and tests 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; however, research is ongoing in determining if past infection confers immunity. Today I will focus mostly on widespread testing for the presence of the virus, which has represented the primary challenge the Nation has faced since the onset of the pandemic.

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. 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 ca-

pability and has a defined role because of its low throughput and relatively limited sensitivity especially early or late in the infection. 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 essential supplies and materials. 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, diversity, and quality of tests;
- Enhancing states' ability to collect specimens through novel "front ends" like drive-through community-based testing 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; and
- Enhancing reimbursement for tests to stimulate the private sector, and providing additional incentives for testing in nursing homes and vulnerable communities

Stage 1: Launch: Engaging the Emerging Crisis

In the early stages of the COVID-19 pandemic, the Centers for Disease Control and Prevention (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 24, 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 3, CDC submitted an emergency use authorization (EUA) request, and the Food and Drug Administration (FDA) issued an EUA on February 4, just 24 hours after receiving the complete package, enabling use of the CDC's COVID-19 diagnostic panel.

Understanding the importance of increased testing, the FDA engaged test developers from the beginning of the pandemic. Any developer, including labs, could introduce tests through the EUA process, as they had during previous emergencies; and FDA encouraged labs and commercial manufacturers to do so swiftly, engaging with more than 550 test developers since January who indicated their intent to submit requests for EUAs. In mid-January, the Biomedical Advanced Research and Development Authority (BARDA) within ASPR 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 the 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 voluntary 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 outbreaks. 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. As of June 25, 2020, FDA has issued more than 150 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, while providing enough oversight to assure patients can depend on the results of these tests.

Throughout the COVID-19 outbreak, the Administration has encouraged and worked collaboratively with diagnostic test manufacturers, commercial laboratories, public health 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 can provide 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 June 25th, our Nation has performed over 30 million tests, and now at a rate of between 400,000 and 500,000 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.

To expand capacity and scale without impinging on the traditional health care system like emergency rooms and urgent care clinics, HHS worked closely with FEMA, interagency, and 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. 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 318,000 individuals, and with an overall COVID-19 test positive rate of approximately 13.5 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 the FDA authorized use 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. Majority of the federally supported community based testing sites have been transitioned to be state led efforts and the few remaining sites will be transitioned in the weeks to come.

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 June 26, and with the assistance of the Federal Government, U.S. retailers have opened and are operating 624 testing sites in 48 states and the District of Columbia, and they have tested over 774,000 individuals. The Federal Government built 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 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 at least one thousand 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 addi-

tional supply types has led to a dramatic broadening of available supplies and reagents.

In May alone, working collaboratively with FEMA and utilizing their logistics, the Federal Government has procured and began to distribute to states—according to their needs and plans—over 12.8 million specimen collection swabs and more than 8.9 million tubes of transport media. To meet state needs, this procurement and distribution will continue in June and the following months, as necessary.

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 procured over 20 million swabs and tubes of transport media (or saline) in June. These supplies will be shipped out to states over the course of the next few months. ThermoFisher, which has more than 3,000 lab machines across the country, will be producing more than 10 million laboratory testing extraction and PCR kits per month, enabling states to complete millions of additional tests starting 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. Beginning in early May, Hologic began shipping several million test kits per month to labs across the Nation.

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, describe 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.

On May 24th, HHS delivered a COVID-19 strategic testing plan to Congress. This Plan is a direct outgrowth of the work done by the Laboratory Testing Task Force and Community Based Testing Task Force, both under the leadership of HHS and supported by FEMA personnel within the NRCC. It outlines how HHS increased domestic testing capacity across the United States and provides additional guidance and information about diagnostic technologies, platforms and inventory that states, territories and tribes can utilize to develop flexible, adaptable, and robust COVID-19 testing plans. This report fulfills a requirement of the Paycheck Protection Program and Health Care Enhancement Act, signed into law on April 24th. Furthermore, HHS recently distributed \$11 billion in support to states, territories, and tribes to support implementation of jurisdictional testing goals as well as a broad array of activities associated with testing, as indicated in the Paycheck Protection Program and Health Care Enhancement Act.

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. The Office of Minority Health issued a Notice of Funding Opportunity on May 1. On June 23rd, the HHS Office of Minority Health (OMH) announced the selection of the Morehouse School of Medicine as the awardee for a new \$40 million initiative to fight COVID-19 in racial and ethnic minority, rural and socially vulnerable communities. The Morehouse School of Medicine will enter into cooperative agreement with OMH to lead the initiative to coordinate a strategic network of national, state, territorial, tribal and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic. The three-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 minorities 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.

On June 4th, using authorities provided to the Secretary under the CARES Act, HHS released new mandatory laboratory data reporting guidance for COVID-19 testing. This guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform COVID-19 response efforts, including data on demographic information such as race, ethnicity, age and gender. This will help ensure that all groups have equitable access to testing, and will equip public health professionals with the data to determine accurately the burden of infection on vulnerable groups.

To further support testing efforts in underserved communities, in May the Health Resources and Services Administration (HRSA) awarded \$583 million to 1,385 health centers to support COVID-19 testing efforts. Health centers serve over 28 million patients in 12,000 service delivery sites across the Nation and in the territories. They provide care to 1 in 5 of those uninsured, 1 in 5 rural Americans, 1 in 3 individuals below the poverty line, more than 1.4 million homeless individuals, and nearly 1 million migrant agricultural workers. Health centers are uniquely situated in communities to serve those that are most vulnerable and 93 percent of these centers offer COVID-19 testing. As of June 26, health centers have reported testing nearly 1.3 million individuals in total and racial and/or ethnic minority patients represent 55 percent of those tested in the past week.

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 United States 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 4,532 officers as of June 24, 2020, 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 U.S. 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. At the end of March, the Navajo Nation requested CDC assistance to provide care amidst a surge of COVID-19 cases. Since that time, the Corps has deployed teams to support the response. The Corps has also deployed two teams, totaling more than 70 officers, to the Pennsylvania and the Florida State Health Departments to provide infection control, personal protective equipment (PPE) training, and consultation to long term care facilities.

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.

Food and Drug Administration

From the beginning of this 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. FDA stood up an internal cross-agency group that continues to ensure we are doing everything possible 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 the development and availability

of medical countermeasures to diagnose, treat, and prevent COVID-19, 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. 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

An important part of FDA's role concerns determining whether the tests developed for clinical use in the United States provide accurate and reliable results and to help provide timely access to such tests. In general, during an emergency, including this pandemic, FDA oversees the validity of tests developed by others through the Emergency Use Authorization (EUA) process. Every action FDA has taken regarding testing during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make tests available with a level of oversight to help ensure accurate tests are being deployed.

COVID-19 has created a demand for new tests that is unprecedented in both volume and urgency. 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 diagnosed U.S. cases of COVID-19, FDA proactively reached out to developers to encourage the development of tests and to offer assistance from the Agency to help facilitate development. To balance the urgent need to increase diagnostic testing capacity in the U.S. with the need to provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA has announced several policies to facilitate oversight. These include engaging in rolling reviews of EUA submissions, and authorizing tests that have the necessary data to support that the criteria for issuance are met. To date, we have authorized more than 150 EUAs for COVID-19 tests. 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. False positive or false negative results can contribute to the spread of COVID-19, so all tests used for COVID-19 should be validated before use. FDA's public health emergency policies do not change that. As with medical treatments, we want tests to be safe and accurate. FDA is monitoring imported test kit products and where appropriate detaining and examining them at the ports and border and is engaging in outreach when we become aware that test developers are making false or misleading claims about their tests. We are monitoring the market for fraudulent tests and are not issuing EUAs for tests that do not meet the EUA standards. FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk. FDA updates its website continually to make clear which tests have been authorized by the Agency, and which tests have not.

FDA has been working around the clock to (1) encourage and support test development for the U.S. market, working with over 500 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 nontraditional device manufacturers to support use of new swabs and other supplies that are needed in the United States; and (6) offer support to developers through a hotline and key resources, including FAQs that are updated regularly and serve 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 a current COVID-19 infection; however, they can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have overcome an infection in the past and may 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 for severely ill COVID-19 patients, which is a potential treatment currently being researched.

In March, FDA issued a policy providing regulatory flexibility for developers of certain serological tests to market or use their tests once they have performed the appropriate evaluation to determine that their tests are accurate and reliable, with-

out FDA authorization and as further recommended in the policy. The policy was intended to allow for early patient access and flexibility for developers, with appropriate transparency regarding the limitations of these tests. At the time FDA issued this policy, flexibility was important to allow for early use of antibody tests to begin to answer some of the critical population-level questions about the prevalence of COVID-19 infections in different communities, whether the presence of antibodies conveys immunity and, if so, for how long, while also encouraging test developers to seek an EUA, as many did. Answering these questions is critical for informing how best to use these tests, but we could not answer these questions without tests being available.

Once FDA had authorized more serology tests, we built on this policy by updating it on May 4th and again on May 11th to outline key expectations for antibody test developers, including that commercial manufacturers would 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 the policy, whichever was later. FDA also provided specific performance recommendations for 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 was not changed. Such laboratories perform their own validation and provided notification to FDA while following other recommendations with respect to labeling as described in the policy.

FDA has also introduced 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 that decide to seek FDA authorization. These templates can help facilitate the preparation and submission of an EUA request and can be used by interested developers. Also, 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.

We are continuing to provide updated information and educational materials to states and health care partners. When particular commercial manufacturers that are currently marketing serology tests under the May 4th and May 11th policy fail to submit an EUA within 10 business days of notification or policy publication (whichever is later), we have been removing those tests from our website notification list and are sharing this information publicly. We will also keep up our work to stop illicit tests from entering the U.S. and to keep fraudulent products off the market.

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, among other conditions outlined in the umbrella EUA, can be authorized under this umbrella EUA, streamlining the submission and review of these important tests.

FDA will continue to appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant. Importantly, we continue to work with developers of serological tests and are reviewing submitted EUA requests to authorize even more of these tests. 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 and Therapeutic Development

At this time, there is no FDA-approved vaccine to prevent being infected with COVID-19, nor are there any FDA-approved drug products to treat 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.

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 announced on March 31, 2020 the creation of an emergency review and development program for possible therapies for COVID-19: the Coronavirus Treatment Acceleration Program, or "CTAP". The Agency is supporting the program by reassigning staff and working continuously 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.

Further, FDA is partnering with the NIH in its 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.

There are a variety of therapeutic products 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 announced the positive results of the 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 potential 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. We are evaluating convalescent plasma in the context of clinical trials and facilitating a national expanded access program and emergency access for individual patients, as appropriate. A key to ensuring the availability of convalescent plasma to those in greatest need, as well as to supporting clinical development of convalescent plasma and hyperimmune globulin, has been by persuading fully recovered COVID-19 patients to donate plasma if they meet FDA's donor eligibility criteria. To that end, FDA continues to work with blood collectors to facilitate the collection of convalescent plasma, and to work with developers of these therapies to move forward with clinical evaluations. Thousands of COVID-19 patients have received investigational COVID-19 convalescent plasma under FDA's pathways for use of investigational products, including expanded access and clinical trials.

Medical Product Supply

FDA monitors and proactively adjusts 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, biological product, and device 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.

FDA understands the significant impact shortages can have on patient care and is doing everything within our authorities to help prevent and alleviate this impact. For example, 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 conditions explained in FDA guidance.

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. For example, the Agency quickly identified the need for making hand sanitizers available as demand spiked. FDA has published and updated three guidances to facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. As another example, the Agency granted an EUA to authorize use of propofol approved in the European Union, thus alleviating a shortage of this critical drug for COVID-19 patients who need to be on a ventilator.

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 reached out to over 1000 manufacturers since January and has helped facilitate an increase of the availability of PPE while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them. FDA has issued several EUAs to help make more respirators available to health care personnel and 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 ap-

proved 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 and masks and gowns. 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, where appropriate.

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.

FDA has worked steadily to support those manufacturing PPE, as well as those who are dealing with limited supplies and shortages, to provide alternatives when there are no other options available. This includes initiating biweekly virtual town hall meetings for those seeking and manufacturing respirators to ask questions and discuss challenges they are facing.

FDA's policies and active engagement with the medical product and healthcare community 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 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. We are monitoring these situations closely and identifying mitigation strategies.

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 and agricultural workers, industry, and consumers on how to stay safe, and help ensure the continuity of operations in the food and agriculture critical infrastructure sector during the pandemic and as retail establishments begin to reopen. FDA's Coordinated Outbreak Response and Evaluation team has been working throughout the pandemic, is fully staffed, and on-the-job looking for signs of foodborne illness outbreaks. 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. For example, in March, FDA found and detained *Salmonella*-contaminated tahini products at the port of entry; products that were already in U.S. distribution were recalled. Earlier this month FDA started investigating a multistate outbreak of *Cyclospora* illnesses potentially linked to store brand garden salads; three retailers have recalled the product.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from firms and individuals selling unproven products with false or misleading claims to prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil and criminal enforcement actions, where appropriate. For example, FDA has sent hundreds of abuse complaints to domain name registrars and internet marketplaces, which in most instances have voluntarily removed listings for products that fraudulently claim to diagnose, cure, mitigate, treat, or prevent COVID-19. The Agency also has sent more than 50 warning letters to sellers of such fraudulent products. Working with the Department of Justice, FDA has sought and obtained several preliminary injunctions that require defendants to halt the sale of fraudu-

lent products claiming to treat or prevent COVID-19, including one product that, when used as directed, is equivalent to industrial bleach.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining, reviewing, and sampling import entries, and refusing admission where appropriate. We protect the supply chain in two equally critical ways: first, we help ensure safe products are coming in and second, that illegal, dangerous and fraudulent products do not get into the country. As FDA import staff screen medical products entering our country, we also find and block the entry of fraudulent products that falsely claim to prevent, treat, mitigate, diagnose, or cure COVID-19. For example, in March, at the border, FDA intercepted fraudulent COVID-19 “treatment kits” that were falsely declared as “water treatment.” Import examination of these shipments found misbranded “kits” intended to treat SARS-CoV-2. This joint investigation, which included FDA’s Office of Criminal Investigations, led to an arrest in the UK by law enforcement partners there. In addition, in April, FDA intercepted a bulk shipment of hydroxychloroquine coming from China going to a physician in California. The physician was charged with smuggling hydroxychloroquine from China to make his own pills and concealed the shipment from CBP by misdeclaring it as yam extract. In May, FDA worked with U.S. Customs and Border Protection (CBP) to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before getting into U.S. commerce.

We are in close communication with our partners at U.S. CBP 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

HHS appreciates the support and interest of Congress in our work related to COVID-19. We look forward to continuing to work together as the Country continues to open safely again. Thank you for the invitation to testify today and we look forward to answering your questions.

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, Ranking Member Murray, and distinguished Members of the Committee. I want to thank you for the opportunity to testify before you today with my HHS colleagues.

The COVID-19 pandemic is the most significant global public health challenge that we have faced as a Nation in more than a century. In the United States, daily cases are increasing after an extended decline. We are seeing significant increases in the southeast and southwest regions of this Nation. The number of jurisdictions in upward trajectory has continued to increase. Now 29 of 55 jurisdictions fall into this category.

The evidence tells us that these cases are driven by many factors, to include increased testing, community transmission, and outbreaks in the settings, such as nursing homes and occupational settings. Hospitalizations now are going up in 12 states. And, as of this weekend, daily death now has increased in the State of Arizona.

CDC is closely monitoring these increases and have 48 teams with more than 140 staff currently deployed in 20 states and two territories. CDC is providing technical expertise to the health de-

partments in epidemiology, contact tracing, infection prevention and control, and communication.

Beyond providing this critical boots on the ground, CDC is working with your states and community in other ways. CDC is speaking with the states, tribal, local, and territorial health departments on a daily basis to develop strategies to stop COVID while reopening businesses and schools. The initial guidance for institutes of higher learning was shared in March, and the K through 12 setting was shared in February. Both these guidances have been updated since and over the past several months. As more information becomes available, we will continue to disseminate that more broadly.

CDC released consolidated recommendations for COVID testing, including interim testing guidelines for nursing homes, as well as testing options for high-density, critical infrastructure workplaces after a COVID case is identified.

Testing guidance for higher education and K through 12: the higher education should be posted today, and K through 12 later this week. These recommendations are consistent with previously published testing guidelines and are meant to supplement, not replace, the guidance of local jurisdictions.

CDC continues to advance science around the COVID-19 impact in certain populations and those who are at heightened risk for severe outcomes. Our most recent analysis of the United States case data from the pandemic, hospitalizations were six times higher and death 12 times higher among those with reportedly underlying conditions compared to those who did not have these conditions.

We have expanded the list of underlying conditions where the evidence is clear that they put people at higher risk of severe illness. These conditions include chronic kidney disease, COPD, having a weakened immune system from a solid organ transplant, obesity, serious heart disease, sickle cell disease, and Type 2 diabetes.

Our analysis also provides further evidence that racial and ethnic populations are disproportionately affected by this epidemic.

While data is the backbone of this response, containing the outbreak depends on four core interventions: readily available testing, comprehensive contact tracing, timely isolation of known cases, and quarantine to break the transmission.

We are not defenseless against this disease. We have powerful tools at our disposal—social distancing, wear a face cover in public, and be disciplined about the frequent hand washing.

It is critical that we all take the personal responsibility to slow the transmission of COVID-19 and embrace the universal use of face coverings. Specifically, I am addressing the younger members of our society, the Millennials, and the Generation Zs. I ask those that are listening to spread the word.

Before I close, I would like to speak briefly about how CDC is assisting the frontlines of our health departments to fight COVID. With your support, CDC has awarded \$12 billion to 64 jurisdictions. Data modernization is underway. Public health laboratories are building resilience. Number of contact tracers have grown 345 percent.

The disease impacts us all, and it is going to take all of us working together to stop it. Together, I believe we can achieve the possible.

Thank you, and I look forward to your questions.
 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. Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee, it is good to see all of you again.

First, I want to clarify my current role. On March 12th, Secretary Azar requested that I lead the coordination of COVID-19 testing efforts within the Department. To be clear, although I am assuming some of my traditional duties as the assistant secretary, I am maintaining my role of coordinating testing, including now the NIH RADx Diagnostics Program, along with Dr. Collins, to assure that innovations are immediately translated into practice.

In order to get back safely to work and school, the overarching, most critical, and essential action we must first accomplish is to control the virus, meaning rapidly extinguishing any outbreaks and minimizing community transmission. All of us are concerned about recent data from several states, indicating rising infections, and now an uptick in hospitalizations and deaths even as other states and the majority of counties are maintaining a low infection burden.

Knowing what we know now about asymptomatic transmission, and the fact that we are in a much better position today in terms of our mitigation strategies, PPE, and testing, we can reverse these concerning trends if we work together.

First, we must take personal responsibility and be disciplined about our own behavior. Maintain physical distancing. Wear a face covering whenever you cannot physically distance. Wash your hands. Stay at home if you feel sick. If you have been in close contact with someone infected or at a gathering without appropriate precautions, get tested. Shield the elderly and the vulnerable of any age. And, follow the guidelines for opening up America again. The criteria are very specific and are as relevant today as when we released them.

In addition, this week we are initiating surge testing in multiple communities of highest concern in coordination with state and local officials.

Now, back to schools and businesses. As Dr. Redfield stated, the CDC will release recommendations on K through 12, institutions of higher education, and general business reopening. These will include considerations for integrating testing, especially surveillance testing, into a comprehensive strategy.

As you asked me, Mr. Chairman, if you are a superintendent of a school system or a president of a university, No. 1, apply the CDC guidelines in consultation with your state and local public health officials so that testing is a part of your comprehensive plan, which should also include prevention and clear mechanisms to isolate positive students.

No. 2, assure your testing needs are incorporated into your state testing plans. As we outlined in the national testing strategy, each

state has developed and will continue to build upon a customized-to-state testing plan developed in full coordination with the Federal Government.

The next iteration, covering July to December, is due on July 10th. These state plans drive the allocation of certain scarce resources. For example, in May and June, the Federal Government has distributed nearly 26 million collection swabs and over 19 million tubes of transport media.

HHS also prioritizes allocation of certain key laboratory tests, like point-of-care tests, according to state-specific needs.

There are also strategies particularly relevant to surveillance testing, especially in universities and businesses. For example, pooling of samples, meaning combining two or more samples, and possibly up to 10, into a single test makes sense where the prevalence of infection is low, and such pooled surveillance testing can be conducted in a university research lab outside of a CLIA environment. But, if a pooled sample is positive for COVID, every individual in that pool would need to be tested through a health system.

I would like to close by recognizing my fellow officers in the United States Public Health Service Commission Corps, the uniformed service that I lead. Four thousand, five hundred, and thirty-six officers have deployed to support the pandemic response, exemplifying the care and compassion that all of us feel for those who have suffered during this pandemic. I thank each and every one of these officers and their families. And, on their behalf, sincerely thank all of you in Congress for supporting our training needs in establishment of a ready reserve corps to supplement our rank during inevitable future national emergencies.

Thank you for the opportunity to provide these remarks.

The CHAIRMAN. Thank you, Admiral Giroir.

Welcome, Dr. Hahn.

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

Dr. HAHN. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the HELP Committee. I appreciate very much the support that you all have provided for our efforts during this time of COVID-19.

FDA has a vital role in the Federal Government's response to the pandemic. One of our core missions is to advance the public health by helping to speed medical products that are safe and effective. We have provided appropriate regulatory flexibilities to assure that the American public has access to critical medical products and safe food, and confidence that our decisions are based on medicine and science.

Since the public health emergency was declared, FDA has issued more than 100 Emergency Use Authorizations for diagnostic tests, personal protective equipment, ventilators, other devices, and drug products. And, we have issued more than 50 guidance documents to ensure the continuity of healthcare in the food supply.

I am pleased to announce that today, FDA is taking action to aid the timely development of a safe and effective vaccine to prevent

COVID-19 by providing guidance for developers with recommendations on the data needed to facilitate manufacturing, clinical development, and approval. We recognize the urgent need to develop a safe and effective vaccine to prevent COVID-19, and we want to work collaboratively with industry, researchers, and other partners to accelerate these efforts.

While the FDA is committed to help expedite this work, we will not cut corners in our decisionmaking. And, we are making clear in our guidance what are the data that we need that should be submitted to meet our regulatory standards of approval. This is particularly important as we know that some people are skeptical of vaccine development efforts.

The FDA strongly encourages the inclusion of all—of diverse populations in all phases of clinical development, including populations most affected by COVID-19, and specifically racial and ethnic minorities, as well as adequate representation in late-phase trials of elderly individuals and those with medical comorbidities. We also have information in this guidance about including women who are pregnant, as well as for pediatric assessments of safety and effectiveness.

The American people should know that we have not lost sight of our responsibility to maintain our regulatory independence and ensure that our decisions related to all medical products, including COVID-19 vaccines, are based on sound science and the available data. This is a commitment that the American public can have confidence in and that I will continue to uphold personally.

While vaccine research is ongoing, rapid testing and therapeutic development can aid in the safe return to school, college, and the workplace. FDA is constantly evaluating new data we receive on testing so that we can promote the development of new and better tests, and remove tests that are not reliable from the market.

We have put into place an initiative to accelerate the development of treatments called the Coronavirus Treatment Acceleration Program, or CTAP. We have seen some of the consequences of that program, such as the authorization of Remdesivir and the recent information regarding other therapeutics that might be of benefit to patients with COVID-19.

We are working day and night to provide guidance to and review proposals from companies, scientists, and researchers, who are developing therapies for COVID-19.

We are now preparing for the next phase of addressing this evolving crisis. It is mission-critical that the Agency constantly evaluate whether our processes are maximal to promote and protect the public health, and therefore, we are beginning a comprehensive real time review and assessment of our actions to date to address the COVID-19 pandemic, and I am glad to answer questions about that review.

I want to thank the more than 17,000 FDA employees, who have been working night and day to help expedite medical products, but also to provide the necessary oversight with the appropriate science and data. We know that the virus remains with us. FDA is committed to doing the critical work that will get the Country to the point at which Americans judge it safe to return to work and school as quickly as possible. I am incredibly proud of the dedicated

women and men of the FDA, whose commitment to defeating this pandemic has been unwavering.

I can assure you the FDA will continue to provide leadership, expertise, guidance, and information as we continue to address this unprecedented challenge and fulfill our mission to protect and promote public health.

Thank you, and appreciate and look forward to your questions.

The CHAIRMAN. Thank you, Dr. Hahn. And thanks to each of our witnesses.

We will now begin a round of 5-minute questions. All the Senators are participating today—almost all—and so I would ask the Senators and the witnesses to try to keep each segment within 5 minutes.

Dr. Fauci, assume I am superintendent of one of 14,000 school districts. In our community, we understand that there are health risks for children going back to school, but we have concluded that the risks of—to their education, mental health, and social development is a greater risk if they don't go back to school.

What would your advice be to a school superintendent about what he or she should be thinking about as children go back to school in a few weeks to keep it safe?

Dr. FAUCI. Thank you for that question, Mr. Chairman. It is an important question, but I think we need to point out that it really will depend on the dynamics of the outbreak in the particular location where the school is. And one of the things we want to emphasize, and have been emphasizing, is to take a look at where you are in the particular area of the so-called opening America again. Are you at the gateway? Phase 1? Phase 2? Phase 3? The CDC has guidelines about the opening of schools at various stages of those checkpoints.

The basic, fundamental goal would be, as you possibly can, to get the children back to school and to use the public health efforts as a tool to help get children back to school.

Let me explain what I mean. In other words, if we adhere to guidelines of what we have heard in many of these presentations you just heard about—the physical distancing in the community, the use of masks, things like that—that will help to keep the level of infection in the community down, which will then make it easier to get the children back to school.

If you are in an area where you have a certain amount of infection dynamics, there are things that can creatively be done about modifying things like the school schedule—alternate days, morning versus evening, allowing under certain circumstances online, virtual lessons. Those are the kind of things that we need to consider.

But, also importantly, always make the goal that it is very important to get the children back to school for the unintended, negative consequences that occur when we keep them out of school.

The CHAIRMAN. Thank you, Dr. Fauci.

Dr. Redfield, one of the concerns would be that children, who have—who, generally speaking, have not been damaged nearly as much as adults, particularly elderly adults, by this virus might carry the virus to their teachers, administrators, or parents or grandparents at home.

It seems to me that the availability of treatments this fall, medicine for the environments that reduce the risk of sickness and death, could be very important in increasing confidence in going back to school. You mentioned some of those in your testimony. Are there others? What would the availability of treatments be this fall? And, specifically, what about so-called antibody cocktails of the kind that were developed for Ebola and approved by the FDA?

Dr. REDFIELD. Well, I think that would be a great question also for Dr. Fauci. I am going to make a small statement. He may want to add to it.

Clearly, we do have Remdesivir, as you mentioned. We have now evidence that steroids can improve therapy. And, as you mentioned, we have convalescent plasma, that Steve Hahn could comment on, that is using the antibodies from individuals that have gotten better from COVID, that are currently under evaluation and potentially be available.

The CHAIRMAN. I have just a minute, Dr. Redfield. Let me go to Dr. Hahn and let him answer that question, too. Thank you.

Dr. HAHN. As I mentioned, Remdesivir has been authorized based on its reduction in hospitalization days. The steroids were mentioned. Convalescent plasma, we have evaluated the safety through a large, expanded access program at the Mayo Clinic and it has been found to be safe in over 20,000 patients administered it. We are waiting for the safety data, and we will be passing those data along to BARDA, who is the sponsor of that program.

I think that antibody data will help us in terms of the development of monoclonal antibodies. We have a number of sponsors who have come in for monoclonal antibody studies. We are already well into that treatment. Monoclonal antibodies are synthetic antibodies that will provide—that the theory is will provide protection against the infection of the virus. And, we are hopeful that those studies by the late summer, early fall will provide us information about their effectiveness and safety. And as you—

The CHAIRMAN. You are optimistic that there will be more than one treatment available this fall for teachers, administrators, older adults?

Dr. HAHN. Yes, sir, I am optimistic.

The CHAIRMAN. Thank you very much.

Senator Murray.

Senator MURRAY. Thank you very much to all of our witnesses. We all very much appreciate your service and your work.

Dr. Fauci, last time you testified before this Committee, you warned us of needless suffering and death if states begin reopening too early. And just over a month later now, we are seeing a record number of cases. We do not have enough tests and we do not have enough contact tracers. And just yesterday, CDC's Dr. Schuchat said we have too much virus to control in the U.S., arguing, and I quote, "This is really the beginning."

Our strategy has not worked. I wanted to ask you, what do the Federal Government and the more than 30 states with rising case numbers need to do to reverse this trend?

Dr. FAUCI. Thank you very much for that question, Senator Murray. I am also quite concerned about what we are seeing evolve right now in several of the states. As you know, in four of the

states—in Florida, Texas, California, and Arizona—more than 50 percent of the new infections are in the those areas where we are seeing surges.

The things we need to do I think you alluded to in your question to me. We have to make sure that when states start to try and open again, they need to follow the guidelines that have been very carefully laid out with regard to checkpoints. What we have seen in several states are different iterations of that. Perhaps maybe in some, going too quickly and skipping over some of the checkpoints.

But, even in states in which the leadership in the form of the Governors and the mayors did it right with the right recommendations, what we saw visually in clips and in photographs of individuals in the community doing an all-or-none phenomenon, which is dangerous. And by all-or-none, I mean either be locked down or open up in a way where you see people at bars, not wearing masks, not avoiding crowds, not paying attention to physical distancing.

I think we need to emphasize the responsibility that we have both as individuals and as part of a societal effort to end the epidemic, that we all have to play a part in that.

I think if you look at the visuals, what we saw were a lot of people who maybe felt that because they think they are invulnerable—and we know many young people are not because they are getting serious disease—that therefore, their getting infected has nothing at all to do with anyone else when, in fact, it does. Because if a person gets infected, they may not be symptomatic, but they could pass it someone else, who passes it someone else, who then makes someone's grandmother or grandfather, sick uncle, or a leukemic child on chemotherapy get sick and die.

We have got to get that message out, that we are all in this together. And if we are going to contain this, we have to contain it together.

Senator MURRAY. Well, I assume that would mean that elected and community leaders need to model good public health behavior and wear a mask.

Dr. FAUCI. We recommend masks for everyone on the outside, anyone who comes into contact in a crowded area. You should avoid crowds where possible. And when you are outside and not have the capability of maintaining distance, you should wear a mask at all times.

Senator MURRAY. Thank you.

Dr. Redfield, last week Dr. Julie Gerberding, who served as the CDC director under President George W. Bush, testified to our Committee that if she were in charge, one of her top priorities would be the creation of a national vaccine plan that addresses the science, development, allocation, uptake, and monitoring of a vaccine, saying, "We know this is in our future, and we are not ready for it."

I could not agree more. And that plan has to detail how the Federal Government will scale up manufacturing, coordinate the supply chain so we avoid the missteps we saw with testing. It needs to combat misinformation and vaccine hesitancy, and make sure that vaccine distribution addresses health disparities, and a lot more.

Dr. Redfield, do you agree a plan like that is needed?

Dr. REDFIELD. Senator, I think it is very important that we have an integrated plan for this vaccine.

Senator MURRAY. When can we expect to see one?

Dr. REDFIELD. Well, I am going to ask Dr. Hahn if he would like to comment. I know recently they had a vaccine plan for—at least for the FDA's perspective. CDC is working on the issues that you said that I think are so important in building vaccine confidence—

Senator MURRAY. Well, can you tell me—

Dr. REDFIELD [continuing]. In this Country.

Senator MURRAY [continuing]. When the CDC will be giving us their plan since CDC would be writing the comprehensive plan?

Dr. REDFIELD. We are developing a plan as we speak. And again, depending—building on the efforts that we have to rebuild what I call vaccine confidence in this Country, which is really critical. And then on top of that, there will be a very defined plan for distribution of this vaccine, prioritization of this vaccine—

Senator MURRAY. But you cannot tell—

Dr. REDFIELD [continuing]. Monitoring for safety of this vaccine.

Senator MURRAY [continuing]. Us if it will be a couple weeks? A couple months? The end of the year? Do you have any estimate on when we will see that plan?

Dr. REDFIELD. Well, it is currently in development within the group, and, I would anticipate that we will see that plan in the near weeks ahead, Senator.

Senator MURRAY. Weeks, not days or months?

Dr. REDFIELD. In the weeks ahead. It is a collective effort that we are doing together within the concept of Operation Warp Speed. But, CDC has been working on this plan literally for probably the last 10 to 12 weeks.

Senator MURRAY. Well, Mr. Chairman, I would just say we need to see that plan. We need to know what it is. The American public needs to know what that is. Communities need to know what that is. So, I hope that we urge that plan to be public as soon as possible so we all know what to expect.

Dr. REDFIELD. Thank you, Senator.

The CHAIRMAN. Thank you, Senator Murray.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

After working on pandemic policy now for 17 years, I am reminded this morning, Tony Fauci has been doing it twice as long as I have, and most of you at the dais have been doing that, as well.

I urge my colleagues, pay attention to what each of these individuals say. Because some things are predictable up here. Congress is a full-fledged partner and funds things when there is an urgent need, a threat that is out there. And I know, Tony, you have seen over the years when there is not that threat out there, things get shelved, like platforms, that we could have developed and had better countermeasures today, platforms that then could address vaccines at a much faster pace than maybe what we are doing. But, we spend more time with the blame game than we do with focuses on how the future should look.

While all of us, Members of Congress and people within Government, wish that we could get back to normalcy, your agencies and Members of Congress are also charged with making sure that we map the future so the future generations have better protections than what we have, and that is why I applaud the Chairman for his white paper. And I would encourage every member of that dais to be brutally honest with us about where changes need to be made and where they don't need to be made.

Dr. Redfield, I think you would agree with me that testing and surveillance on this has not been the best performance by CDC. I do not want to dwell on where we have come up short. Share with these Members and myself, what can we expect over the next several months from CDC that will be different than what the past has looked like?

Dr. REDFIELD. Well, thank you, Senator, for your question. I think CDC will continue to work with the state, local, tribal, territory health departments to build their capacity.

I think we all know that for decades, there has been consistent underinvestment in public health in this Nation and the core capabilities to do that job. Data, data modernization, predictive data analysis, laboratory resilience, workforce—very appreciative for the emergency response fund that Congress provided—these are critical infrastructure issues that the reality are have been underinvested.

CDC is right now probably providing 50 to 70 percent of all public health funding to each state. We need to have a much more robust investment in these core capabilities.

What you are going to see, because of the Congress acting, CDC has provided now \$12 billion to the local, state, territorial, tribal health departments to begin to build that core capability that we would have liked to build over the last several decades so that there is enhanced testing.

It has been mentioned, it is complicated here because this virus is so asymptomatic for so many, so the traditional methods of diagnosis, contact tracing, isolation are going to be inhibited for many individuals, and that is going to require broader community-based surveillance strategies.

Those plans, as was mentioned by the Admiral, are—we have received them for June and July. We are working with the local jurisdictions. They are going to have them in middle July for the plans for the rest of the year. And we are going to be working side by side with them to continue to augment the public health capacity to respond to the COVID virus with basically enhanced surveillance and enhanced early diagnosis, contact tracing, isolation to begin to bring this outbreak under control.

Senator BARR. I hope some of that money will be used to upgrade the systems at CDC that are antiquated.

Dr. REDFIELD. Sir, I agree with you there. I mean, I think, as those of you know, when I was given the opportunity to do this job, very early on, within a month, I recognized that the core capabilities of our public health infrastructure is not there, particularly the one that I know you have been very supportive of—data, data modernization, predictive data analysis—and that is in progress. It cannot happen too soon.

We are appreciative of the support that Congress has given. And I do think it is fundamentally critical to bring our data system, and, as you know, the data personnel that we have, and we thank you for your efforts there. And as we need to hire those individuals strategically, we will continue to do that to make sure that the premier public health agency in this Country has the personnel and data systems that it does need.

But, I will say, the other big issue we have to correct is to make sure our public health—state, local, territorial and tribal—have that integrated health system of data.

Senator BURR. Dr. Hahn, I think you have used your authorities under PAHPRA at FDA in a very effective way, and the FDA has risen to the challenge during the public health emergency, cutting red tape and maintaining the Agency's gold standard for review of lifesaving medical products. You have specifically mentioned innovative trial—clinical trial designs and the use of real-world data as areas where the FDA has gained ground during the response to COVID. How do you plan to ensure that this progress is maintained long after the coronavirus response is over?

Dr. HAHN. Thank you, Senator Burr. Critical issues that you bring up. In addition, some of the things that we are doing on the review side to actually expedite review and work with innovators and developers, we will continue. Part of our review of our actions to date, so a mid-action review, will inform how we move forward.

No question, the fact that real-world evidence and modernization of our data systems are needed, particularly around supply chain and demand for medical products, but also on the review cycle and the innovative clinical design trials, as you just—as you mention.

Senator BURR. Thank you for that.

Mr. Chairman, I do hope that you or another member will allow Dr. Fauci at some point today to make any comments on the reports that there is a new swine flu that the Chinese have apparently identified and how that might affect us in the future in this Country.

The CHAIRMAN. Well, Dr. Fauci, why don't you do that now if you have anything to say about a swine flu.

Dr. FAUCI. The Chinese, over the last week or two, have identified a virus in the environment. It is not yet shown to be infecting humans, but it is exhibiting what we call re-assortment capabilities. In other words, when you get a brand new virus that turns out to be a pandemic virus, it is either due to mutations and/or the re-assortment or exchanges of genes.

They are seeing virus in swine, in pigs, now that have characteristics of the 2009 H1N1, of the original 1918, which many of our flu viruses have remnants of that in it, as well as segments from other hosts like swine. When they all mix up together and they contain some of the elements that might make them susceptible to being transmitted to humans, you always have the possibility that you might have another swine flu-type outbreak as we had in 2009.

It is something that still is in the stage of examination. It is not so-called an immediate threat where you are seeing infections, but it is something we need to keep our eye on, just the way we did in 2009 with the emergence of the swine flu. It is called G4, is the name of it.

The CHAIRMAN. Thank you.

Senator SANDERS.

Senator SANDERS. Thank you very much, Mr. Chairman. And let me thank all of our panelists for being here and for the great work that they are doing on this pandemic.

Let me ask a question that has just bothered me lately. All of you, and I think most Americans, understand how important social distancing is. We are told over and over again, and the Chairman told us at the beginning of this meeting, stay apart, at least 6 feet apart, if you can.

Just the other day, however, American Airlines announced that they were going to fill up all of their planes, and other airlines have done the same. So, you are going to have people going from New York to California, 5, 6 hours, sitting inches apart from each other. And then you have buses all over America where people are kind of packed in like sardines.

But, my question is, why hasn't the Government, whether it is the CDC or the Department of Transportation, issued guidelines prohibiting those violations of what we all know to be common-sense?

Who wants to—Dr. Fauci, you want to start on that one or—

Dr. FAUCI. Thank you, Senator. Well, I am not the CDC, but I would be happy to make a comment on that, and maybe Bob would, also. I mean, obviously, that is something that is of concern. I am not sure exactly what went into that decisionmaking. I would hope there would be something to mitigate against that because I know, as we have said and I continue to repeat it, that avoiding crowds, staying distant, and when in a situation like that, wear a mask. I think in the confines of an airplane, that becomes even more problematic.

Senator SANDERS. But generally, I agree—I understand the mask thing, but doesn't it sound a little bit silly and little bit in violation of everything you guys have been talking about to have people sitting next to each other for 5 or 6 hours in an airplane or crowded into a bus? And my question is, why hasn't, the President issues a lot of executive orders. Why haven't we stopped that type of activity and told the airlines and bus companies that is unhealthy?

Dr. REDFIELD. Senator, I appreciate your question, and I think it is a critical area. I can tell you that when they announced that the other day, obviously there was substantial disappointment with American Airlines. A number of the airlines had decided to keep the middle seat thing. I cannot say this is under critical review right now by us at CDC. We do not think it is the right message, as you pointed out. Again, we think it is really important in individuals that are in whether it is a bus or a train or a plane are social distancing to the degree that it is feasible and at least have a reliable face covering. So—

Senator SANDERS. Okay. Well, thank you, and I—I just hope very much that the CDC or the appropriate agency basically tells these companies that is unacceptable behavior. They are endangering the lives of the American people.

Let me go to another question. And I just have a few more questions and not a lot of time, so I would appreciate brief answers.

At the University of Washington, the Institute of Health there indicated that if 95 percent of the American people were to wear masks, we could save some 30,000 lives. A number of countries, including South Korea, France, Turkey, and Austria, have provided low-cost or free masks to all of their people—something that I believe in. Would you support an effort to greatly increase the production of high-quality masks in this Country and distribute them free of charge to every household in America?

Dr. FAUCI. Yes.

Senator SANDERS. Dr. Fauci, or anybody else wants to jump in on that?

Dr. FAUCI. Yes, of course. I think masks is—are extremely important, and we keep hammering home. And I think what you just mentioned is as important. There is no doubt that wearing masks protects you and gets you to be protected. So, it is people protecting each other. Anything that furthers the use of masks, whether it is giving out free masks or any other mechanism, I am thoroughly in favor of.

Dr. REDFIELD. I just want to echo that, Senator. In my opening statement, again, I called on an environment that we have universal masks. I think it is fundamentally—

Senator SANDERS. Good.

Dr. REDFIELD [continuing]. The most important thing we can do.

Senator SANDERS. That is great. But when you refer to “universal masks,” which I agree with you on, would you be supporting the increased production of high-quality masks and basically distributing free of charge to every household in America? Because I think that is going to save tens of thousands of lives. Would you agree?

Admiral GIROIR. Senator Sanders, this is Brett Giroir. Yes, sir. I agree that is very important because we need to support mask wearing.

I would also point out that Dr. Kadlec, the ASPR, has contracted for hundreds of millions of cloth face coverings to—that could be distributed around the Country, and those kinds of processes are being thought of. When I am not in uniform, I wear them. They are white. They work very effectively, and I think they are a great investment for the American people.

Senator SANDERS. Good. Thank you.

My very last question. It is an issue I have raised now for the last couple of months. All of us hope to God that a good, safe vaccine will be developed as soon as possible, but that vaccine may not mean anything to a lower income person who might not be able to afford it. I happen to believe that we should make these vaccines—and by the way, as you all know, Federal Government, our tax dollars, are going to the tune of billions of dollars into drug companies to help develop this vaccine. That is okay. But don't you—do you—would you agree with me that after that kind of investment, we should make sure that every American, every person in this Country, can get a vaccine regardless of their income?

Dr. FAUCI. Yes.

Senator SANDERS. Okay. Anybody else want to comment on that?

Admiral GIROIR. Yes, Senator. Agreed.

Dr. REDFIELD. Yes, Senator.

Dr. HAHN. Yes, Senator.

Senator SANDERS. Well, good. Thank you all very much.

The CHAIRMAN. Thank you, Senator Sanders.

Senator Paul.

Senator PAUL. Thank you.

Fatal Conceit is the concept that central planning with decision-making concentrated in a few hands can never fully grasp the millions of complex, individual interactions occurring simultaneously in the marketplace.

It is a fatal conceit to believe any one person or small group of people has the knowledge necessary to direct an economy or dictate public health behavior. I think Government health experts during this pandemic need to show caution in their prognostications.

It is important to realize that if society meekly submits to an expert and that expert is wrong, a great deal of harm may occur when we allow one man's policy or one group of small men and women to be foisted on an entire nation. Take, for example, Government experts who continue to call for schools and daycare to stay closed, or that recommend restrictions that make it impossible for a school to function. For a time, there may not have been enough information about coronavirus in children, but now there is. There are examples from all across the United States and the world that show that young children rarely spread the virus.

Let's start in Europe. Twenty-two countries have reopened their schools and have seen no discernible increases in cases. These graphs behind me show no surge when schools open. The red line is where the schools opened. There is data from Austria, Belgium, Denmark, France, Germany, Netherlands. No spike when schools are opened.

Contact tracing studies in China, Iceland, Britain, and the Netherlands failed to find a single case of child-to-adult infection.

Here at home, childcare for essential workers continued to be available in some states throughout the pandemic. Brown University researchers collected data on daycares that remained open during the pandemic. Over 25,000 kids in their study, found that only .16 percent got COVID. And when you look at the confirmed cases for staff, there was about 1 percent of more than 9,000 staff.

The YMCA also has put forward statistics. Forty thousand kids at 1,100 sites, there were no reports of coronavirus outbreaks or clusters.

Dr. Joshua Sharfstein of Johns Hopkins writes, "There is converging evidence that the coronavirus doesn't transmit among children like the flu," that it is a lower risk.

Just yesterday, the American Academy of Pediatrics says we have to get kids back in school. We want them physically present in school. They even cite mounting evidence that children are less likely to contract the virus.

Ultimately, this all comes down to the fatal conceit that central planners have enough knowledge somehow to tell a nation of 330 million people what they can and cannot do.

Perhaps our planners might think twice before they weigh in on every subject.

Perhaps our Government experts might hold their tongue before expressing the opinion whether we can play NFL football or major league baseball, not in October.

Perhaps our experts might think twice before telling the whole world that a COVID vaccine likely won't provide herd immunity.

We don't know. Why weigh in with these opinions that we have no knowledge of? These are forecasts that may well be wrong.

Perhaps our experts might consider the undue fear they are instilling in teachers who are now afraid to go back to work.

No one knows the answers to these questions. We should not presume that a group of experts somehow knows what is best for everyone.

Hayek had it right. Only decentralized power and decision-making based on millions of individualized situations can arrive at what risks and behaviors each individual should choose. That is what America was founded on, not a herd with a couple of people in Washington all telling us what to do and we, like sheep, blindly follow.

This all begs the question, when are we going to tell the people the truth, that it is okay to take their kids back to school?

Dr. Fauci, every day, virtually every day, we seem to hear from you things we cannot do, but when you are asked can we go back to school, I don't hear much certitude at all. I hear, well, maybe, it depends.

All of this body of evidence about schools around the world shows there is no surge. All of the evidence shows that it is rare. I mean, we have so politicized this and made it politically correct that the WHO releases that it is rare. And you have a scientist up there honestly giving her opinion. What happens to her? She is blackballed and her report that she refers to is taken off the website. When you go to that scientist's speech and you try to click on the link, the WHO has now streamed it from us because it said something that is not politically correct; that guess what, it is rare for kids to transmit this.

But, I hear nothing of that coming from you. All I hear, Dr. Fauci, is we can't do this, we can't do that, we can't play baseball. Well, even that is not based on the science. I mean, flu season peaks in February. We don't know that COVID is going to be like the flu season. It might, but we don't know that. But we wouldn't ban school in October. You might close some schools when they get the flu. We need to not be so presumptuous that we know everything.

But, my question to you is, can't you give us a little bit more on schools, that we can get back to school? That there is a great deal of evidence and that it is actually good—good evidence that kids are not transmitting this? It is rare and that kids are staying healthy and that yes, we can open our schools?

Dr. FAUCI. Mr. Chairman, do I have a little bit of time to—

The CHAIRMAN. I will give you a little. That was well over 5 minutes, but we will—

Dr. FAUCI. Thank you, Senator.

The CHAIRMAN. Go ahead and answer the—please answer the question.

Dr. FAUCI. Yes. So, very quickly, Senator Paul. I agree with a lot of what you say about, this idea about people having to put their opinions out without data. And sometimes, you have to make extrapolations because you are in a position where you need to at least give some sort of recommendation.

But if you were listening, and I think you were, to my opening statement and my response to one of the questions, I feel very strongly we need to do whatever we can to get the children back to school. So, I think we are in lock agreement with that.

The other thing that I would like to clarify very briefly is that I—when things get into press of what I supposedly said, I didn't say. I never said we can't play a certain sport. What happens is that people in the sport industry—they could either be people from players association, owners, people involved in the health of the players—ask me opinions regarding certain facts about the spread of the virus, what the dynamics are. I give it, and then it gets interpreted that I am saying you can't play this sport or you can't play that sport.

I agree with you. I am completely unqualified to tell you whether you can play a sport or not.

The only thing that I can do is, to the best of my ability, give you the facts and the evidence associated with what I know about this outbreak.

Thank you.

Senator PAUL. Thank you. We——

The CHAIRMAN. Senator Paul——

Senator PAUL [continuing]. Just need more optimism. There——

The CHAIRMAN. Thank you, Senator Paul.

Senator PAUL [continuing]. Is good news out there. We are——

The CHAIRMAN. We will now go to Senator Casey.

Senator PAUL [continuing]. Not getting it.

Senator CASEY. Mr. Chairman, thank you very much for the hearing, and I want to thank our witnesses for their public service.

Mr. Chairman, let me start with Dr. Hahn. Then I will move to Admiral Giroir.

Dr. Hahn, I wanted to ask you about vaccines. And as your testimony indicates, and as we have been discussing over time, as researchers work to develop vaccines to protect against COVID-19, it is important that the final FDA-approved products have the full confidence of the American people. A vaccine doesn't help if people don't choose to in fact be vaccinated.

My first question is, given that we have seen very high rates of both vaccine refusal, as well as skepticism, what role can the FDA play in the coming months to earn the public's trust that the COVID-19 vaccines are safe and effective? That is question No. 1, what role the FDA can play.

Then the second question is, what steps can you take as FDA commissioner to bolster public confidence?

Dr. HAHN. Thank you, Senator, for that question. I could not agree more that public confidence in vaccines is so important.

To your first question, we have an obligation to use all of our scientific knowledge, our regulatory framework, to ensure that any vaccine that comes before us, whether for authorization or approval, meets our stringent standards for safety and effectiveness.

One of the reasons that we issued that guidance that I mentioned in my opening statement was to provide regulatory clarity around what FDA expects with respect to those data. We want to see certain parts of those data so that we can demonstrate to the world, to the Nation, to the American people, that we are following our rigorous standards with respect to safety and efficacy.

The other thing that we have done is draw a very bright line between FDA and our regulatory independence and all the sponsors who are putting forth vaccine applications to us, and that includes Operation Warp Speed. So, we are providing technical assistance to those sponsors, but we are not part of the decisionmaking process, and we will maintain our regulatory independence. I will not prejudge. The Agency will not prejudge any decision with respect to this. We will use the science and the data.

With respect to what I can do personally, Senator, I commit to you that I will continue to be a voice emphasizing the regulatory independence. We have a number of communications in progress to communicate to the American people that the standards we are going to uphold are firm, they are rooted in science and data, and that they will ensure that we meet the usual high standards of FDA with respect to safety and efficacy.

Senator CASEY. Thanks very much, Doctor. I might submit a question for the record to Dr. Redfield, as well, but just so I can get my second question in to the Admiral.

Admiral, I want to ask you about testing and insurance coverage. Testing, as you know and as we have emphasized in these hearings, is so fundamental in order to prevent the spread of COVID-19. Congress, I think, acted upon that knowledge by mandating total coverage of COVID-19 diagnostic and antibody testing, both in the Families First bill, as well as the CARES Act. We made it clear that Americans should not have to pay a dime for COVID-19 testing, but we are hearing alarming reports of people not being tested often for one of two reasons: because they are under the impression they will have to pay for testing, and patients who have been tested are receiving surprise medical bills.

The Administration has issued guidance that appears to be in conflict with congressional intent and public health guidance, and so we have some confusion here. I would ask you, Admiral, can you assure the American people that the Department of Health and Human Services will fulfill the intent of both the Families First bill and the CARES Act and ensure that the American people will be provided wide access to COVID-19 tests without cost or limitation?

Admiral GIROIR. Thank you, Senator. And I want to thank all of you for emphasizing the importance of testing and eliminating any barriers that there could be.

I cannot speak for the Department. I certainly speak as the assistant secretary and as the testing person that we firmly believe and support the concept of no-cost testing. There should not be a disincentive in any single way to get the diagnostic test that you need to get tested during screening or the serology test as Congress intended. So, thank you for that. We do need to keep getting that message out. It is a very important one to have.

Senator CASEY. Thank you, Admiral. Thank you, Mr. Chairman.
The CHAIRMAN. Thank you, Senator Casey.

Senator Collins.

Senator COLLINS. Thank you very much, Mr. Chairman. And I want to thank all of our witnesses today for your dedication and hard work. It has really been important.

The Chairman raised a very important question about who pays for the testing when a person has no symptoms and no known exposure to the virus. And I would add another key question, and that is how are such tests even accessed?

These are critical questions for the reopening of schools and for the thousands of jobs in the tourism industry, upon which Maine's economy depends. In Maine, for a tourist to come and visit, that out-of-state visitor, one option is to show a recent negative COVID test. The problem is that when hotel owners in Maine surveyed testing sites in 10 states, they found that 90 percent of requests for a test for travel purposes were denied.

Now, this lack of access to tests is devastating for reopening Maine's tourism businesses. One innkeeper told me that last year in the month of June, she had an occupancy rate of 94 percent. This year, it was 6 percent, so you can imagine the impact on employment at that inn.

Given the impact on reopening schools and on jobs in the tourism and other industries, how is the Federal Government working with states to better match demand for testing with supply and to overcome these geographic variations? Admiral, I would direct that question to you.

Admiral GIROIR. Thank you, ma'am. I will try to be brief and not to take much of your time. But, we were very careful in our prioritization that we do prioritize persons without symptoms who are prioritized by health departments or clinicians for any reason, including public health monitoring, surveillance, or screening of other asymptomatic individuals according to state and local plans. So, that is a priority that if it is important for the state, those asymptomatic individuals can be screened.

The second issue, just again to be brief, is we work—we have worked individually with every single state to determine what their state testing needs are, how are they organizing in the context of the CDC, and we are supplying them with the supplies they need to meet that. So, every week, shipments of the basic supplies go to every single state according to their state testing plans. And we keep a little bit in reserve, right, because when there is an outbreak somewhere that we need to surge, we do have that. So, for example, the state testing goals for July are somewhere—across the Country are about 13.9 million tests is their first-line goals, and we will match those state by state.

Senator COLLINS. I hope that you will help us get that word out to testing sites in states from which—a lot of tourists usually come to Maine. That would be very helpful to us.

Dr. Fauci, let me turn to you. Earlier this month, higher education leaders in Maine issued a framework for safely returning to campuses this fall that recognizes the importance of testing and the need to include financially struggling institutions in partnerships in order to make sufficient testing protocols possible.

You, last week, spoke about the possibility of the development of pool testing strategies. And, as I understand this, this would allow more people to be tested using fewer resources.

The medical director of Stanford's clinical virology lab suggests that this makes particular sense in areas with low rates of COVID-19 where you would expect the large majority of tests to be negative. Could you expand on the possibility of expanding pool testing and tell us more about that?

Dr. FAUCI. Yes. Thank you for the question, Senator. What that really is, if you want to get a feel for the penetrance of infection in a community, rather than testing multiple, each individual person, which takes resources and time, what you do—and you can do a statistical analysis of—not losing sensitivity by pooling let us say 10 or 15 or five together.

You put all the tests together and you do one test. If that test is negative, then those 10 people are all negative. So, instead of utilizing 10 tests, you have utilized one test.

Then you get another batch of we will say 10 or so. And if you then find one is positive, then you go backtrack and figure out who that person is. And if you do the mathematical calculation, you can save a lot of time, a lot of resources, and use the testing for a variety of other things that you would need.

It is a really good tool. It can be used in any of a number of circumstances at the community level, or even in school if you wanted to do that. So, apropos of what you started your comment off with, it clearly can be extrapolated to that.

Senator COLLINS. Thank you so much. That sounds like an excellent technique for our schools to use.

The CHAIRMAN. Thank you, Senator Collins.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. I want to thank all of our witnesses today for joining us.

Like so many Members of this Committee, I am concerned about new outbreaks and increasing cases. Certainly, I have seen them in my home State of Wisconsin, and I know we are seeing that nationally.

Now, CDC and OSHA have issued recommended safety guidance for businesses, but this guidance is not enforceable. Many businesses are truly trying to do the right thing in protecting workers and customers and the public that interacts with those businesses.

We also had a previous discussion. I think Senator Sanders raised the issue of American Airlines filling up their planes, versus others that are still not trying to push to do so because of safety concerns.

We also had—I think it was Admiral Giroir pulled up the—what he called critical guidance. Please follow this critical guidance.

Dr. Redfield, should we be supporting businesses that have taken the steps to protect their workers and customers by fully implementing CDC's and OSHA's recommended safety guidance? Yes or no.

Dr. REDFIELD. Yes. We should be supporting those businesses.

Senator BALDWIN. Now, can you confirm, yes or no, that all businesses have adopted and implemented this guidance as they have opened up?

Dr. REDFIELD. I think, Senator, you know that, unfortunately, that has not been the case.

Senator BALDWIN. It is an uneven playing field, and it hurts businesses that are trying to do the right thing by voluntarily adopting CDC and OSHA safety guidelines because their competitors don't have to incur the same safety and health costs. And, if you believe that we should be supporting the good actors, then shouldn't we create a level playing field by issuing an emergency, temporary standard to require all business to adopt and comply with enforceable safety standards?

Dr. REDFIELD. I make two comments, Senator. First one, it is so important that we have tried to say is that this is a time that everyone in our Nation accept the responsibility that Dr. Fauci and I spoke about to recognize they have the fundamental responsibility not just to protect themselves, to protect others, by the social distance, face mask, and hand washing.

Second, again, is we look at the local jurisdictions, again, to see where, in fact, that enforceability would be, whether it is in the local health department, the state health department, or the Federal Health Department. I think, again, we see that the community can get behind that responsibility. Those businesses that support that responsibility may find, in fact, their business is better than those businesses that don't.

I can tell you that—

Senator BALDWIN. I want to interrupt you. I apologize, Dr. Redfield, but my time is limited. The panel right now is composed of people representing public health and public health institutions. OSHA is our lead Federal agency for protecting workers' safety and health. Have you had communication with the Department of Labor and OSHA about issuing mandatory, enforceable standards rather than this voluntary guidance?

Dr. REDFIELD. Secretary Scalia is a member of the task force, and he is in the discussions with us that the Vice President chairs. That specific topic—

Senator BALDWIN. The answer is yes?

Dr. REDFIELD [continuing]. We have not had a discussion directly, but we have had discussions in review of the guidance that we put to businesses, both critical infrastructure and non-critical infrastructure businesses, with OSHA.

Senator BALDWIN. I have limited time left, but I do want to say that the University of Wisconsin announced that they will be reopening for classes in the fall. They have released a plan called start—Smart Restart. It calls for about 2,000 tests per week on campus. They will need supplies to do this, including PPE, reagents, and swabs. At every hearing on COVID-19, we have heard about shortages of these supplies, and it is why I introduced the Medical Supply Transparency and Delivery Act to unlock the full authority of the Defense Production Act to increase production of critical supplies, the things that are needed to conduct widespread testing.

Admiral Giroir, can you describe how you are working to make sure that universities and others will have access to these supplies needed to conduct this testing in the fall?

Admiral GIROIR. Thank you so much, Senator. And I want to communicate this, and I am happy to work with any university. We coordinate what we give to the states through the state plan, so it is very important that universities coordinate through the states. And we supply those materials directly to a single point of contact in the state, who distributes them.

We have been through a lot, but we have a lot of swabs now, partially because of increased domestic production using the DPA. We are distributing about 20 million swabs per month. We are going to do a lot more than that.

Senator BALDWIN. What about reagents?

Admiral GIROIR. Reagents, we do not purchase centrally because the market is a little bit more mature, so we can trust with an allocation strategy that we allocate—we support the allocation to different states depending on their needs.

We have mapped every single machine in every single state, every single county, every single city, and unfortunately, there is not enough of one thing that everybody if they want that can get it. So, we really do a matching game to understand specific state needs. For example, in Alaska, it is very rural and there is varied limitations to what they have, so we need to make sure they get what they absolutely need, versus other states that can be a little bit more flexible. So, we do have this control——

Senator BALDWIN. With respect——

The CHAIRMAN. Senator Baldwin, I am afraid we are——

Admiral GIROIR. I am so sorry.

The CHAIRMAN [continuing]. Well over time. We have a large number of Senators who want to ask questions, so I would renew my——

Senator BALDWIN. Thank you, Mr. Chairman.

The CHAIRMAN [continuing]. Request that Senators and witnesses try to keep the questions and answers within 5 minutes.

Senator Cassidy.

Senator CASSIDY. Thank you, gentlemen, for all that you are doing.

I have a couple slides. Can you—can I ask for the staff to show the first two slides?

[Slides shown.]

Senator CASSIDY. Here it shows that we are doing poorly relative to the countries that are doing it best. And you can argue that Taiwan is much smaller than we, but Taipei is a very congested city. So, consider our cities just a collection of Taipeis, for example, than our Seoul, South Korea. It would suggest that what we are currently doing is less robust and less whatever adjective you want to use than the countries that are doing it best.

Could I have the next slide, please?

[Slide shown.]

Senator CASSIDY. This is developed out of a group by Harvard. And, just so I can put a plug in it, they will be speaking at a roundtable we have Thursday morning, and you can get details from my office if you wish.

But, kind of that interplay between collecting—doing the testing, tracing those, compiling your data, knowing where your hotspots

are, and then tracing. And everyone on this panel knows this is how it is done.

You mention that you are going to have a strategy that is coming out later on. It does beg the question, why has it been so long? And I am not accusing. I am just curious. But this has been developed—

You can take the slide down, please.

Knowing that you are going to develop this strategy, and kind of building upon what Senator Burr mentioned, what is the goal of the strategy? Is the goal of the strategy to achieve suppression? That is No. 1.

No. 2, what metrics will you use?

Knowing that CDC is the one who really gives guidance to state and local governments—I am hoping, Dr. Redfield, since I will direct this to you, that it won't be up to the states and locals to put this plan together; it will be the considerable intellectual fire power of the CDC that gives a pretty detailed—if you have this kind of community, this is what you do. If you have that kind of community, that is what you do. Because that is the kind of role that CDC is expected to play.

Dr. Redfield, any thoughts on this?

Dr. REDFIELD. Thank you very much, Senator. A very important question.

First—on your first slide, just as a quick comment, and I will try to be quick. I think it is really important because it does illustrate back to the comment that we tried to make of the importance of personal responsibility, to really practice the social distancing and—

Senator CASSIDY. That is a given, Dr. Redfield. I want to ask you just to go quickly because I have limited time. That is a given. But there has to be a testing aspect of this because people don't—you awaken people to their responsibility if they know they have been exposed. If they don't know they have been exposed, they tend to be more complacent. So, please focus upon the testing data and tracking aspect.

Dr. REDFIELD. Yes, Senator. Initially, obviously, the—it was early case identification, contact tracing, isolation. Obviously, testing and contact tracing without isolation has little value. The challenge has been when we learned in March that this virus is significantly asymptotically transmissible, and then, therefore, requiring alternative strategies.

The strategy that we are evaluating now is more of a community-led testing strategy where you go into a broader community and you actually test a wide number of individuals as opposed to—

Senator CASSIDY. But do you have—what metrics are you following? And is there a specific strategy that is going to be given to state and locals as to how to implement this? That is very high level. What we need is granularity. That is my question.

Dr. REDFIELD. Yes. We did the initial strategy, and as I said, we are currently evaluating this community test-led strategy in a number of communities now.

The metrics are simple. It is the percent cases that are positive. We were doing well there for a while. You know—

Senator CASSIDY. But now—again, sorry to interrupt. But, of course, if you take the entire city of New Orleans or Shreveport, you are going to have some that are hot spots and some that are really fairly safe. And, so, I guess I am pointing to the granularity. Should it be a census track? Should it be a hot spot—a building with multifamily housing, et cetera? So, I—

Dr. REDFIELD. You are exact—

Senator CASSIDY [continuing]. Guess I am just frustrated because when I speak to my state and locals, they are not getting that granularity from CDC. That seems to be where we get to where Seoul, South Korea is, and I have not yet heard that is kind of what we are doing.

Dr. REDFIELD. We are sharing right now at the county level the exact kinetics. We have about 130 counties in this Country out of the more than 5,000—more than 3,000 are having trouble. And, continuing to get that granularity—I think you have said it, Senator. It is critical. It has got to be a very local, focal response at the granular level. We are trying—

Senator CASSIDY. But, Dr. Redfield, do we have that granularity? We have been at this for 3 months. We have all these data systems. We know where the people live who are tested. You know, we have a federated system, which you alluded to earlier. Is the plan coming out tonight, this afternoon, going to implement that granularity?

I am over time, but if you would allow, Mr. Chairman, for an answer, then I will cease. I apologize for going over.

Dr. REDFIELD. My comment would be that is where we are going with that granularity. We appreciate some of the changes in reporting to CDC in terms of testing that Congress recently did. We are now looking at the granular level. We don't disagree with the premise behind you. It is that granular response to control those mini outbreaks, which is going to be fundamental to get this under control.

The CHAIRMAN. Thank you—

Senator CASSIDY. Thank you.

The CHAIRMAN [continuing]. Senator Cassidy.

Senator Murphy.

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

Mr. Chairman, if this were the policy of the United States of America, the recommendations and guidelines being given by our panelists today, we would likely not be in the situation we are with a virus back on the march, spreading at rapid rates throughout big parts of the Country.

The problem is our four panelists do not set the policy of the United States of America. The President of the United States does. And, so, while our panelists tell us about the importance of wearing masks, the President of the United States is re-Tweeting articles, for example, entitled “Mandatory Masks Aren't About Safety, They're About Social Control.” He re-Tweets people that are criticizing how folks look when they wear masks.

Though our panelists today are telling us about the effectiveness of social distancing, the President of the United States is holding rallies all across the Country, in which he deliberately prevents

people from distancing. His staff ripped signs off of chairs encouraging people to separate from each other.

The President's allies are out there on TV every day saying that wearing masks are dehumanizing. Somebody said the other day, a Member of the House, that viruses do what viruses do; the only way you are going to get immunity is to get exposed. These are the President's allies trying to curry favor with him.

We have these two parallel messaging operations, and I just think it is worth stipulating that everything we are hearing today is responsible. It is based on evidence.

But, the agencies represented here today have social media followings of about five million people. The President of the United States has a social media following of 82 million. And, so, you can understand why folks are confused out there. They hear the recommendations from Dr. Fauci and Dr. Redfield, but then they hear the President of the United States criticizing a reporter for wearing a mask because that reporter is being social—is being politically correct.

That is why we are in the position we are in today where you see large numbers of people not complying with recommendations because they are hearing something very different from the Chief Executive, and they are watching him behave in a manner and encourage behavior that is directly contrary to what we are being told today. And it just probably requires saying that out loud at this hearing.

Let me ask a few questions, Mr. Chairman, if I can, about global public health because we have not covered that here today.

Dr. Fauci, this virus got here really quickly, and what we learned is that while travel restrictions can help or give you time, they cannot fully prevent a disease from arriving here. And, so, even if we do turn the corner in the United States in a meaningful way, so long as this virus exists in large quantities outside of the United States, we are still vulnerable. Is that right?

Dr. FAUCI. That is correct, sir.

Senator MURPHY. Dr. Redfield, what is your understanding of why the United States has not joined the global vaccine effort? Why are we not in something like CEPI, an organization that is working with other nations to try to coordinate not only the development of the vaccine, but also the distribution of the vaccine?

Dr. REDFIELD. Well, I think the U.S. has obviously developed an aggressive, comprehensive program, but, Senator, it would not preclude being part of these international organizations, also, from my perspective.

Senator MURPHY. We have legislation pending right now before the Foreign Relations Committee that would put the United States into these global vaccine efforts. It just doesn't make a lot of sense to many of us on both sides of the aisle as to why the Trump administration has not joined.

Finally, Admiral, just maybe help us understand what our relationship with the WHO is today. Right around the time that the President declared that we were pulling out of the WHO—not just that we were not going to fund it, but his announcement was actually we were going to sever our relationship with the WHO—you were confirmed to a seat on the executive board. And, so, have you

been recalled from the WHO? Are you attending meetings? Are you participating? What are the details surrounding our withdrawal from the WHO? Which, by the way, is maybe one of the most dangerous things in my opinion that the Administration has done in the middle of a global pandemic. What is our status and what is your status as a confirmed member of that board?

Admiral GIROIR. Thank you, Senator, and I really do appreciate the confirmation.

I was confirmed on May 7th, and I did attend the executive board on May 22d. The executive board, it was virtual. I did participate and support our multilateral commitments. I have not been recalled. I have not been given any direction to recall myself in any way. There would be another executive board meeting probably in October.

I believe all of us on our public health standards still work with the WHO as a WHO partner. For example, we participated with the WHO on a global sickle cell meeting just 2 days ago.

We work—we certainly work from the public health aspects direction on the official—whether we are going to be a member or whether I am not going to go to the executive board, I have not gotten that direction yet.

Senator MURPHY. Okay. Thank you. The announcement was that we are terminating our relationship with the WHO, so probably some additional clarification would be helpful.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And, gentlemen, thank you for not only your testimony today, but all that you have been doing.

I think I have had conversations with each one of you about the Alaska-specific issues, most notably with regards to our seafood processing. This is the time of year where we typically welcome a million plus tourists, as well as many thousands that come up from the Lower 48 and other places to help with our seafood processing.

It has been a very anxious time, I think, for all of us in Alaska as we see outsiders coming in. We have seen obviously elevated cases of confirmed COVID. Our numbers, I think, are enviable when other states look at us to know that we are working about 500 active cases right now. About double that in terms of what we have seen throughout this whole pandemic.

But, again, we know, and you have stated, that we don't have resources that we can look to, to neighboring states. We are kind of on our own island there in terms of resourcing. So, what you have done to help facilitate, whether it is the plans with the seafood processors, the guidance, the ability to come in on an as-needed, if the situation so demands, we appreciate that.

We have seen the benefit of how these very rigorous plans have worked. An individual who comes up to work in a seafood processing facility is tested before they come to the state. They are tested when they get to the state. They are put in a 14-day quarantine. We have seen positive cases once people have arrived, but we have been able to do what the plan calls for, which is that contact trac-

ing and then isolation and keeping things to a minimum. So, I think it does demonstrate that these tough plans really can work.

They are expensive, though. If you are bringing in several hundred or perhaps a thousand workers and you have to put them up in a hotel for 14 days, with pay, when you have to provide for the health protocols, this is costly. I would ask for your input, and probably a question for the record, just in terms of which agencies can best help facilitate these seafood processors with not only implementation of this specific guidance, but how we can be dealing with the cost. We do receive some benefit from the discretionary funds provided to the states.

But, I think we would all recognize, like the meatpacking facilities, our seafood processors are an important and a critical industry, not only to Alaska, but to the Country, so we want to work to address that.

I do want to speak very quickly, though, to the public health infrastructure. I am told that in Alaska, as we are doing our contact tracing, it is still a paper copy Excel spreadsheet faxed to the epidemiology labs. This is how we are doing our tracing. I thought, well, maybe that is just Alaska, and I am told by Dr. Zink, who you have all had conversations with, that, well, this is actually going on in California, as well.

That, to me, is not a contact tracing system that works and is sufficient. So, I want to ask about not only your view of the sufficiency of contact tracing—and this is probably to you, Dr. Redfield.

But, then, Dr. Fauci, I want to ask you about the concern that we have with certain parts of the Country where you have public mistrust of vaccines in general. My fear is that we may get to the place where—we will get to that place where we have that successful vaccine, but we still have the concern from many, and a mistrust. And whether it is vaccine hesitation or vaccine confidence—I don't know what the buzz word is, but I am worried that we don't have a plan for how to deal with that.

First, contact tracing, and then the vaccine.

Dr. REDFIELD. Thank you very much, Senator. I think it is really important just to highlight what you said about the current state of data systems for public health in the United States, that they really are in need of aggressive modernization. And, again, thank Congress for the funding there. But, it is a substantial investment that needs to take place. There are a number of counties that are still doing this pen and pencil, as you commented, and we need to have a comprehensive, integrated public health data system that is not only able to do something that is in real time, but actually can be predictive. And it would be one of the great, I think, investments of our time to make that happen once and for all.

Senator MURKOWSKI. Agreed.

Dr. REDFIELD. That is really fundamental to be able to operationalize contact tracing, et cetera.

Contact tracing in this case, and I will be very quick, really does not have any value unless you can do it in real time. It doesn't help, like I just did with the airlines, where we had the people that were flying infected from Afghanistan and we didn't get the information until Day 14, Day 15, Day 16. It is irrelevant.

Again, we love the partnership to get an integrated public health data system, not just for CDC, but for all of our jurisdictions across the Nation, into one timely, integrated system.

Dr. FAUCI. Senator, thank you for the question about——

The CHAIRMAN. If you could be succinct, we are——

Dr. FAUCI. Yes.

The CHAIRMAN [continuing]. Well over time.

Dr. FAUCI. We will be quick. We have a community engagement program that is embedded within the sites where the vaccine trials will be done because we are thoroughly aware of what you are concerned about. And it is a reality—a lack of trust of authority, a lack of trust in Government, and a concern about vaccines in general.

We need to engage the community by boots on the ground and getting community—particularly those populations that have not always been treated fairly by the Government—minority populations, African Americans, Latinx, and Native Americans. And we have a program that is already operable right now to do that.

Thank you.

Senator MURKOWSKI. Thank you.

The CHAIRMAN. Thank you, Senator Murkowski.

Senator Warren.

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

Dr. Fauci, you came before the HELP Committee 7 weeks ago to discuss the Country's response to the COVID-19. And at the time, you told me that the U.S. did not “by any means have total control over this outbreak.” But, you also told me that we were “going in the right direction.”

Now, on the day you testified before the Committee—that was May 12th, 2020—there were about 21,000 new cases of coronavirus. Yesterday, there were about 40,000 new cases of coronavirus.

Dr. Fauci, do these numbers show that the Country is still moving “in the right direction” and that the coronavirus pandemic is under control?

Dr. FAUCI. Well, I think the numbers speak for themselves. Although we do have a number of parts of the Country that are doing well, I am very concerned about what is going on right now, particularly in the four states that are accounting for about 50 percent of the new infections, but the other vulnerable states.

I would have to say the numbers speak for themselves. I am very concerned and I am not satisfied with what is going on because we are going in the wrong direction if you look at the curves of the new cases. So, we have really got to do something about that, and we need to do it quickly. Short answer to——

Senator WARREN. So——

Dr. FAUCI [continuing]. Your question is that clearly we are not in total control right now.

Senator WARREN. Thank you. Thank you very much. You know, our case numbers are getting worse, and our death rates are going to get worse soon.

During this same period of time, some other countries around the world have controlled the virus. They are reporting fewer cases each day, and they are able to provide targeted testing and to keep it up so that they can tell what is happening and follow-up if there

is an outbreak. In other words, controlling the coronavirus can be done. But because of bad Federal leadership, we have not been able to do this here in the United States.

Dr. Fauci, the last time you were before this Committee, you told me that if the U.S. did not have “an adequate response” that the Country would “have the deleterious consequences of more infections and more deaths.” Now, I know that we have made some progress, but half measures won’t save lives.

Dr. Fauci, I am asking you to be very direct with all of us on this. If we don’t fully implement the widespread testing, contact tracing programs, and social distancing practices that everyone seems to agree that we need, can we expect these spikes in infection to keep happening in different places around the Country?

Dr. FAUCI. Thank you, Senator. I am always direct with you. And I will tell you in direct answer to your question that, if you look at what is going on and just look at some of the film clips that you have seen of people congregating, often without masks, of being in crowds and jumping over and avoiding and not paying attention to the guidelines that we very carefully put out, we are going to continue to be in a lot of trouble, and there is going to be a lot of hurt if that does not stop. And that gets back——

Senator WARREN. Okay. If——

Dr. FAUCI. No. I was——

Senator WARREN. If we don’t get our act together, more and more communities around the Country are going to see these dangerous surges——

Dr. FAUCI. Right.

Senator WARREN [continuing]. Of COVID-19. Dr. Fauci, back in March, you also said, “Looking at what we are seeing now,” you expected there to be between 100,000 and 200,000 coronavirus deaths and millions of infections in the U.S. So, let’s flash forward to late June. Here we are, at the end of June. We have already seen 126,000 deaths with infection rates rising rapidly.

Dr. Fauci, based on what you are seeing now, how many COVID-19 deaths and infections should America expect before this is all over?

Dr. FAUCI. I cannot make an accurate prediction, but it is going to be very disturbing—I will guarantee you that—because when you have an outbreak in one part of the Country, even though in other parts of the Country they are doing well, they are vulnerable. I made that point very clearly last week at a press conference. We cannot just focus on those areas that are having the surge. It puts the entire Country at risk.

We are now having 40-plus thousand new cases a day. I would not be surprised if we go up to 100,000 a day if this does not turn around, and, so, I am very concerned.

Senator WARREN. Can you make any kind of estimate on what we are looking at overall on the number of deaths before this is over? You made an estimate back in March, between 100,000 and 200,000——

Dr. FAUCI. Right.

Senator WARREN [continuing]. But we have a lot more information now, and we are already at 126,000 deaths.

Dr. FAUCI. Right. I can't make an estimation because that would have to be modeled out. Because when models are done—and that is where those original numbers came from, Senator. As I have said very often, models are as good as the assumptions that you put into the model, and those assumptions often change, depending upon what your response is. So, I would really be hesitant to give a number that will come back and either be contradicted and overblown or underblown.

But, I think it is important to tell you and the American public that I am very concerned because it could get very bad.

Senator WARREN. Alright. I appreciate that, Dr. Fauci.

The CHAIRMAN. Okay. We are——

Senator WARREN. We all want our economy——

The CHAIRMAN. We are well over time, Senator Warren.

Senator WARREN [continuing]. To recover.

I would just like the same time that my Republican colleagues got. Because I want to say——

The CHAIRMAN. Alright. Then your——

Senator WARREN [continuing]. That we want our economy——

The CHAIRMAN. Then your time is up. Senator Warren.

Senator WARREN [continuing]. To recover.

The CHAIRMAN. Senator Warren.

Senator WARREN. But we can't keep pretending——

The CHAIRMAN. Senator Warren, now, I am being just as——

Senator WARREN. I need to get the——

The CHAIRMAN [continuing]. Fair to you as I was——

Senator WARREN. Our Republican——

The CHAIRMAN [continuing]. To Senator Sanders and the others.

Senator WARREN [continuing]. Colleagues got a lot more time.

The CHAIRMAN. Senator Warren.

Senator WARREN. Mr. Chairman.

The CHAIRMAN. I always treat you fairly, and I would appreciate your respecting the Chairman's rules. If you would like to make a closing statement, go ahead and do it, but I don't appreciate your——

Senator WARREN. Thank you.

The CHAIRMAN [continuing]. Questioning my fairness in——

Senator WARREN. I appreciate that, Mr. Chairman.

The CHAIRMAN [continuing]. Presiding over the hearing.

Senator WARREN. I just was under the understanding——

The CHAIRMAN. Because I have been scrupulously fair.

Senator WARREN [continuing]. Based on what others had done that you were allowing more time since we had such important witnesses.

The CHAIRMAN. Well, when——

Senator WARREN. I appreciate——time.

The CHAIRMAN [continuing]. Are chairman, you can make that—you can make those decisions.

Senator WARREN. Thank you.

You know, I just want to make the point that we can't keep pretending this virus is getting better when it isn't. That is how we end up with messes like the situation in Texas. Racing to reopen too soon; then scrambling to close down before the hospitals get completely overwhelmed.

If we don't get our act together, this is our future, see-sawing back and forth between too few restrictions and then exploding cases and repeated shutdowns.

In this future, thousands more Americans will die and our economy will be brought to its knees. We have got to have a national strategy that makes testing available to every school, every business, every hospital, every church, anywhere that Americans come together.

We need to expand contact tracing, and we need leaders, starting with President Trump, who have enough backbone to face reality, distribute our resources, set our standards, and stick to them. Because if we don't, the result is going to be more economic wreckage and more death.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.

What I have tried to do in this hearing is to ask Senators to stay within 5 minutes and the answers within 5 minutes. And, if the answers go beyond that, I have tried to be respectful of that. But to—but I would ask Senators not to ask their questions into well past 5 minutes and then expect to make a speech at the end.

Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman, and I will certainly respect your time limits. I think we all should do that.

Frankly, as we were asking Dr. Fauci for an estimate of how many lives may be lost, I recall the first estimates were between one and 2.4 million lives, so I am certainly glad that we are not there.

Perhaps one of the reasons why we should be thankful for where we are now and force ourselves to have a serious conversation about continuing to flatten the curve is because the all-hands-on-deck approach is effective. We just need as much cooperation from as many people as conceivably possible in every state around the Country in order for us to see these numbers continue to make a dive in the right direction as opposed to spike in the wrong direction.

I think about the Operation Warp Speed, along with the crucial support from BARDA and other Federal agencies, public-private partnerships, and accelerating groundbreaking technologies that could eradicate COVID-19 and revolutionize, frankly, the vaccine development landscape. Because of these efforts by industry, academia, and Government working in concert, we could see a viable candidate or candidates in a matter of months for a vaccine.

Because of the growing number of large-scale manufacturing agreements with companies like Moderna, Pfizer, and J&J producing hundreds of millions of doses at risk, which means in advance, we are already working to address issues of access. And this is critical, especially for our most distressed communities.

That said, effective development and widespread access, while essential, are only part of the equation. If and when—and I feel optimistic that it is when and not if—we get a viable vaccine, we need to encourage folks to choose to get vaccinated.

I was really concerned when I saw a recent AP survey that showed that only 49 percent of American adults plan to get vaccinated once the COVID-19 vaccine came to market. A full 20 per-

cent said that they did not plan to get vaccinated, and one-third of Americans were not sure.

Given the public's recent and vital focus on health disparities, it is worth noting that among certain groups, these figures are even more alarming. Just 25 percent of Black Americans, 37 percent of Hispanic Americans plan to get vaccinated against the coronavirus.

My question to the full panel, what steps can we take at every level of Government and in the private sector with healthcare providers to ensure a proactive education campaign and outreach strategy on the importance of getting vaccinated, both for COVID-19 and, frankly, even more broadly?

Dr. FAUCI. I will take a shot at it first, Senator. As I mentioned in response to another question, that we have a community engagement program that actually operates out of Operation Warp Speed, the vaccine development program component of that.

Also, there needs to be engagement of people who the community trusts, particularly individuals who are noted sports figures or whomever. When we were involved, and continue to be involved, in community engagement with HIV, we used people in the community, boots on the ground, to go out who looked and lived and are like the people they are trying to engage. It is very critical, because I share with you the concern that we get to the hoop and we get through it of getting a safe and effective vaccine only to find that a substantial proportion of the population do not want to get vaccinated.

Of particular concern is that it is that proportion of the population that generally are the most vulnerable in the sense of the minority communities—African Americans, Latinx, Native Americans, who, in fact, because of underlying conditions, make it more likely that if they do get infected, they would have a poor outcome. So, it is extremely important to engage them at the local level.

Thank you.

Senator SCOTT. Thank you very much for your answer, Dr. Fauci.

Let me just close with my 40 seconds that I have left and respecting the time, and I hope that we continue to do so.

The pandemic has triggered a drop of 60 to 80 percent of immunization rates among children. And even now that states are reopening, we are not seeing the rebound in these rates as—that are necessary. This creates a real risk of secondary infections and disease outbreaks that are not on the general public's radar as we reckon with the chief crisis at hand.

I think it is incredibly important that we follow your strategy, Dr. Fauci, as it relates to engaging community leaders and perhaps people with notoriety to challenge us to get involved in taking the vaccines.

Thank you, Mr. Chairman. I apologize for being 4 seconds over my time.

The CHAIRMAN. Thank you, Senator Scott, for respecting the time. We have eight Senators remaining who have questions, and we should have time for all of them to have a chance to ask their questions.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman, and thank you to the witnesses.

Dr. Fauci, I saw an interview with you last week where you talked about a concern that there is too sizable a percentage of our population that sort of doesn't like science and scientists and advice from scientists. And I hear real emotion in your voice as you express concern about people gathering in large groups and without masks, and I gather that is the kind of anti-science concern that you were worrying about when you had that interview last week.

Dr. FAUCI. Yes. That is part of it, Senator, yes, because a disregard of recommendations that come from authorities only because it is a recommendation. I think the attitude of pushing back from authority and pushing back on scientific data is very concerning. We are in the middle of a catastrophic outbreak, and we really do need to be guided by scientific principles.

Senator KAINE. This could cause problems down the road if we get to a vaccine, but people don't want to get the vaccine, so we all have to message this pretty strongly.

Dr. Redfield, I want to thank you. I was going to ask you a question today that I have been asking over and over again: Why does the CDC's guidance for institutions of higher education not even mention the word testing?

But as soon as your testimony was done this morning, the CDC website changed and there are now guidelines for the institutes of higher education with fairly extensive recommendations and guidance, not mandates, about testing. I didn't have a chance to read them, but I saw them popped up on the CDC website, and I wanted to thank you for that.

Your testimony, Dr. Redfield, today in some of the written testimony talks about the fact that the public health system relies on timely and accurate data systems, but that we have underinvested in them and the crisis has "highlighted the need to continue efforts to modernize the public health systems."

Last year, I introduced a bill called the Saving Lives Through Better Data Act. It was with Senator Isakson and Senator King, and colleagues were helpful in this. We were able to get \$50 million in December in the appropriations deal, and then another \$500 million in the CARES Act. But, I would urge my colleagues to do even more because the request from our public health communities is significantly more sizable. I hope we might be able to get that into the next COVID package.

Dr. Fauci, this is a challenging question, challenging how to figure it out. The CDC last week said that a new group that we have to consider at risk is pregnant women and lactating women. The NIAID's Remdesivir testing and vaccine testing often does not include pregnant women, I think for some safety reasons. But, we would want to make sure that pregnant and lactating women have access to treatments and access to vaccines. So, how will we be trying to do research and testing so that women can safely access these—

Dr. FAUCI. Yes.

Senator KAINE [continuing]. Treatments or vaccines?

Dr. FAUCI. Yes. That is a great question. It applies also to children. So, what we are doing with the vaccine is you do a Phase 1 trial in normal, healthy adults—not pregnant, not children—and

you show initial safety. Then when you move into the Phase 2 and 3 studies, if you get even the slightest glimpse of efficacy and safety in that population, you go back and do a Phase 1 in pregnant and lactating women, as well as in children. And, if that is safe there, you bridge the data so that you could use the efficacy data that you already started to apply back to pregnant women.

Senator KAINE. I see.

Dr. FAUCI. That is how you do it.

Senator KAINE. Let me ask you this. At this point, is the Nation's goal with respect to coronavirus to mitigate it or suppress it?

Dr. FAUCI. Vaccines right now—are you talking about vaccines, sir?

Senator KAINE. No. I am just talking about what is our goal? Are we—

Dr. FAUCI. Yes.

Senator KAINE [continuing]. Trying to mitigate or are we trying to suppress?

Dr. FAUCI. It depends on where you are. There is containment and mitigation. So, if you have a level of virus that is low enough that you can adequately contain by the standard way of identification, isolation, contact tracing, particularly if you make sure you link the identification with isolation—because if you just do contact tracing without isolation, it is not going to work. When you get into a situation—

Senator KAINE. If I could, Dr. Fauci, because I don't want to go over time. I want to say just one thing about testing real quick.

Admiral Giroir, when you were here last, you said we would have capacity to do 40 to 50 million tests a month in September. That is about 1.3 to 1.7 million a day. On May 12th, we had done about 310,000. Yesterday, we did 560,000. Are we going to get to 1.3 to 1.7 million tests a day by September?

Admiral GIROIR. Thank you for asking that. We will absolutely have the capacity to do that. It is depending on the need. And, again, as you might expect, a few weeks ago, the need for testing was much less than it is now.

We had a good system that—it was actually very good that we were able to identify an increase in positivity very early. But, obviously, with the outbreaks we are having now, we need to massively surge testing in those areas.

We will have that capability across the board. Yes, we will have that, and that is assuming no pooling. When we start pooling these together, three, four tests, then you do the math. So, I am never going to be happy until we have more tests, that we never have to say the word test again, but we are going to be in reasonably good shape given those parameters.

Senator KAINE. Thanks, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman, and thank you to each of the panelists for the sacrifice and the effort that you have been making over these past several years—past several months, as well as years.

As you know, because we didn't know a great deal about this virus when it first came on the scene in America, we asked the

American people to basically shut down their lives. Cut back on flying, family reunions, funerals, church services, restaurants, bars, theaters. Everything got shut down.

Well, now it is end of June, and hopefully we have learned something about how this disease actually spreads, and the American people need to go back out. They are going to go back out, and they are going back out. We saw, for instance, at the Lake of the Ozarks, all these people and we said, oh, my goodness, this is going to be a major problem. But, my impression was because people were outside or who knows what other reason, it wasn't a major problem.

My question is this: Where is the risk greatest? How is it that it is spreading? Is it spreading indoors? Is it spreading more in restaurants and bars? Is it okay to be outdoors and perhaps not socially distance? Are family reunions okay?

Could you give us some guidance based on what hopefully we know as to where the risks are greatest? I know you keep saying social distance and masks, but, people are getting in airplanes, they are going to restaurants. Where is the risk greatest and where are we relatively safe? Can you help us through that? Family reunions? Can we get together with family reunions, outdoors? Is it safer outdoors than indoors?

Give us some guidance. Can you do that, Dr. Fauci and Dr. Redfield?

Dr. REDFIELD. Thank you, Senator. I think first and foremost, the most important thing in that assessment is knowing at the granular level what the kinetics of transmission are in that community. As I mentioned, we have 130 counties right now in the United States where we consider them "hot spots." We have many other areas where there is very limited transmission. So, first and foremost, it is knowing the—if you are in that area of active transmission.

Then second, it is knowing what you do when you are in that area of active transmission and what precautions one takes. I think these—

Senator ROMNEY. Got to be brief. You got to be brief, Doctor. I have only got 5 minutes.

Dr. REDFIELD. Alright. Well, I think those are the two things. I will say that there is just more and more data showing that the use of face coverings and masks are an effective way to prevent transmission in these gatherings. And I think we are just going to come back and tell you the most important thing, if you are within a community with limited transmission and you are wearing face masks, or if there is significant transmission and you are wearing face masks, and you practice the social distance and hand washing, that is the best thing, best recommendations, I can tell you.

Dr. FAUCI. Yes. In addition, Senator, outdoor better than indoor. Bars, really not good. Really not good. Congregation at a bar inside is bad news. We have really got to stop that right now when you have areas that are surging like we see right now.

But in answer to your question a little bit more granular, outdoor is always better than indoor. If you are outdoor, distance, as Bob said. Wear a mask if you can. But you can have some social interaction.

The one point I want to make very briefly is that we should not look at the public health endeavors as being an obstruction to opening up. We should look at it as a vehicle to opening up so that you don't want to just restrict everything because people are not going to tolerate that.

You can get outdoors. You can interact. Wear a mask. Try to avoid the close congregation of people. Wash your hands often. But don't just make it all or none. We have got to be able to get people to get out and enjoy themselves within the safe guidelines that we have. So, make public health work for you as opposed to against you.

Senator ROMNEY. I very much appreciate those responses. I think it would be extraordinarily helpful for all of us, as we are going about our lives, if there was data that indicated where people are getting infected. Were they in a bar? Were they in a restaurant? Were they outdoors at a pool?

I have heard reports that virtually nobody has been infected if they are outdoors. Is that true or not true?

We—given how long we have been at this, we have got to have more granular data so people know where there is greater risk. How many people, for instance, have been infected as a result of flying on airplanes? We have to know that. If we could publish that information for the American people, they will know where they can be safe and go back. Of course, continuing social distancing and wearing masks, but we need that data.

Finally, I will just ask one—an answer. Who is responsible for distributing the vaccine? What person or what agency determines how the vaccine, when it is available, will be distributed?

Dr. REDFIELD. Well, since—thank you, Senator. This is a central function of CDC where we really help with vaccine distribution throughout the Nation. Childhood vaccines—

Senator ROMNEY. That is—so that is the CDC. That is on your shoulders. Thank you.

Mr. Chairman, back to you.

The CHAIRMAN. Thank you very much, Senator Romney.

Senator HASSAN.

Senator HASSAN. Well, thank you, Mr. Chairman, and thank you to all the witnesses for being here and for the teams you lead. I know how hard everybody is working.

Dr. Redfield, I want to start with a question to you. Forty-three percent of the deaths in this Country have been in nursing homes or long-term care facilities. In my State of New Hampshire, 80 percent of our deaths are attributed to residents of nursing homes and long-term care facilities.

In mid-May, the White House urged states to complete COVID-19 testing on every nursing home worker and resident within 14 days. A month and a half later, that still has not happened.

CDC has since put out different guidance on nursing home testing, calling for a baseline test for residents and weekly testing for nursing home workers.

Given the widespread outbreaks within nursing homes and unique risks posed to residents, what is CDC doing to ensure that states carry out the recommendations for nursing home testing

issued by CDC on June 13th? And, how many states have met these guidelines so far?

Dr. REDFIELD. Thank you, Senator. We are working in close contact with CMS on that issue. As you say, we are not an enforcement agency. We make recommendations.

Senator HASSAN. But I am asking, and my time is short. I am asking what you are doing to keep track of compliance with guidelines. Forty-three percent death rate nationwide is huge, and people are looking to you all for granular guidance here. So, what are you doing to find out who is in compliance and who is not?

Dr. REDFIELD. I was trying to emphasize that we are working in partnership with CMS, which has that regulatory oversight. We are there to continue to reinforce the guidances you mentioned, which we think is critical. And we think we do have to get everyone screened in these nursing homes, and the employees every week.

Unfortunately, we still think that we need to keep visitors isolated from the homes right now, particularly in areas with high jurisdictions. But, the regulatory function of this is CMS, but we are really meeting with them daily to see what more we can do to try to ensure that there is greater compliance.

Senator HASSAN. I thank you for that. People are looking to the CDC for not only very clear and granular guidelines—and you have heard that all throughout the questioning—but particularly with nursing homes and long-term care facilities. There is a lot more work to be done, and we are still hearing that they are not getting usable personal protective equipment all the time, either.

Let me go to another question. And, Dr. Fauci, I will start with you. We have heard discussion already today about the difference in the effectiveness of measures taken, for instance, in Europe and the United States. This is a graph that shows the disparities between new confirmed cases per million residents over the previous 7 days to the United States, Europe, Canada, and Japan. The disparity is eye-popping.

[Slides shown.]

Senator HASSAN. Surveys suggest that mask-wearing in the United States occurs less frequently than in Europe. You and our witnesses have been very clear on the importance of mask-wearing in public places. Do you attribute the improvements in Europe to more widespread use of masks? Or are there also other specific Government policies or individual behavioral differences that you believe should be incorporated into our national strategy?

Dr. FAUCI. It certainly—masks play a role, but there are a number of other multifaceted things in each of those very disturbing graphs that you show.

Senator HASSAN. Yes.

Dr. FAUCI. One of the things that became clear, when we shut down as a Nation, in reality, only about 50 percent of the Nation shut down with regard to other things that were allowed.

In many of the European countries, 90, 95 percent of all activities were shut down. So, that is one of the reasons why you saw, particularly in Italy, which shut down to a much greater extent than we did, the cases came way down in a sharp curve downward and then stayed.

It is not only masks. It is the fact that the countries in Europe and the other countries you have there had a much more uniform response. We are a very heterogeneous Country, and we had a heterogeneous response, depending whether you are in the northeast, southern, west, or what have you.

There is a number of other factors, probably some that we still don't even understand.

Senator HASSAN. Well, thank you.

I am going to move onto just one other issue, and it is really just to urge Dr. Redfield and the CDC to issue additional guidance for schools, in particular on reopening. I understand that you are continuing to do that.

I appreciate that the CDC has released FAQ—frequently asked questions—documents on things like youth sports, which provide more concrete, useful information for families. And, I am hoping that you will do the same kind of FAQ documents for parents and teachers that directly address practical questions and concerns about school reopening plans. Simply like, what happens? What should a school do specifically if one or two positive cases come up in a classroom or in a teacher? What should parents and teachers expect school administrations to do?

We can follow-up with that. I appreciate the Chairman's indulgence.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman.

I have two sets of questions and would like for Dr. Fauci and Redfield to give about a minute each to the first.

I want to get the broad numbers. I think, Dr. Redfield, you might have been on record that you think there is 10 times as many cases out there as—and I know that is a guess. I would like to know because, if that is the case, all the sudden, the fatality rate goes from 5 percent down to five-tenths a percent; 20 times as many cases, of course, 2.5 down to .25.

What is your—start with you Dr. Redfield. How many cases do you think we actually have out there? And then, how many vaccinations in our herd immunity combinations, as a percentage of our total population, do we need to get to for this thing to be in the rearview mirror? So, we have a few big numbers to kind of relate to the journey ahead.

Dr. REDFIELD. Thank you very much, Senator. Quickly, we now know that this virus began to really spread in the United States in March. And between March and the end of May, we have been able to do antibody testing, and that is what allowed us to understand how many people were really infected. So, during that period, it was our best estimate about 10 to one, so we are probably talking over 20 million, 22 million Americans have been infected.

I don't want people to assume that is the same ratio now in June and July going forward because there is—

Senator BRAUN. You think it is more than that or less than that?

Dr. REDFIELD. No. I think it is going to be less because we are doing more and more testing. Okay? But, clearly, it gives us a good idea the extent of infection was more in March, April, and May.

Not two million individuals, but more closer to 20 million individuals.

Senator BRAUN. What is your opinion of how many individuals we need vaccinated and/or having herd immunity before this thing goes into the rearview mirror?

Dr. REDFIELD. Yes. Tony may comment on that, too. It has really got to be over 70 percent of the population—

Senator BRAUN. Okay.

Dr. REDFIELD [continuing]. Has got to be immune before we even see any impact of herd immunity.

Senator BRAUN. Dr. Fauci.

Dr. FAUCI. Yes. I totally agree. Given the transmissibility, which is highly efficient, you are going to need somewhere between 70 and 85 percent. I would say 70 at the lowest.

Senator BRAUN. Okay. Second set of questions would be on the issue of herd immunity. Because, of course, we have the—we don't know how long it is going to take to have an effective vaccine. And, I am guessing when you are talking about herd immunity, it has to actually confer immunity if you get it, and there might be some uncertain—let's assume you do get the immunity.

What is the—how do we go about—the approaches that we have used to this point, is herd immunity going to be something that you think will march through if we take the strategy of having a different approach for younger people that seem to have lower hospitalization rates and less significant consequences? Because I think—that is another thing we need to know because I think that is already going to be done by each individual in a way as they seize up their own personal risk. So, how much can we count on herd immunity?

Dr. REDFIELD. I can answer quickly and then turn it to Tony.

I think it is important to realize even now, we are probably looking at somewhere between five and 8 percent of the American public has experienced this virus. So, for me, herd immunity as a basic strategy, you are talking about a multi-year strategy. This is why it is so important that the alternative strategy is a biological countermeasure in the development of a vaccine.

Dr. FAUCI. One of the issues that might be complicating—I don't think it is going to be something that is going to be any kind of a show-stopper, but we have got to realize and, as Senator Paul said, we have to be humble and know there is a lot we don't know.

What we don't know is what the durability is. In other words, so, if you wound up getting herd immunity to 75, 80 percent, what we need to learn, and only time will teach us this, is how long this immunity lasts. Is it a year? Two? Three? Four? Or is it even less? Is it months? We don't know.

When we find out, then that will inform us as to whether or not if you get a vaccine, how often you need to boost it. So, we have to realize, we don't really know the answer to your question in any definitive way.

Senator BRAUN. At least that gives some clarity, some parameters to live within.

Senator Hassan stressed the point of protecting the most vulnerable. Because, to me, the one thing it looks like we could certainly do is to take that highest-risk group from the data we have already

got and build, in essence, an iron dome around them. That is the one thing that would seem to be the most important thing to do where you get certain results. And I think that has to be in place as we—the uncertainty of herd immunity, and when we get an effective vaccine, actually converge.

Dr. FAUCI. I might add, just—we always think about herd immunity with regard to natural infection and/or vaccination. But, when you want to talk about protecting the vulnerable, we want to see if some of the other programs that are more prophylactic treatment programs, like passive transfer of plasma, or monoclonal antibodies, or hyperimmune globulin. Those are some of the things that you can do to protect the vulnerable until we do get an effective vaccine.

Senator BRAUN. Thank you.

The CHAIRMAN. Thank you, Senator Braun.

Senator Smith.

Senator SMITH. Thank you, Chairman Alexander, Ranking Member Murray. It is good to see all of you today. And thank you again to our panelists.

We need robust surveillance and occupational testing if we are going to safely reopen our economy and our schools, our nursing homes and our group homes, to make sure that they are not a conduit for infection. And we are seeing this. A good example of this is in New York State, where employees in nursing homes are required to get a COVID-19 test twice a week.

Here is the problem if you are a worker. Who pays for that test? Is it my employer? Is it my private insurance, if I have insurance? Or, do I have to pay for it out of my pocket? So, I am thinking about that low-wage worker working in childcare or food processing or maybe a security, worker, or a janitor. And, the average cost of a test is somewhere in the neighborhood of 75 to \$150, though there are reports of people being charged over \$6,000 to be tested, assuming you can find a test.

This is my first question. Last week, Federal agencies posted guidance on this question, and the guidance said that health plans are not required to cover the full cost of tests for surveillance or occupational reasons. And, the Federal testing plan, which talks about the value of surveillance testing and occupational testing, is silent on this.

Let me ask you, Dr. Fauci, do you agree that we are going to be better able to contain the spread of COVID-19 and save lives if we have surveillance testing?

Dr. FAUCI. No doubt surveillance testing is going to be a very important part of the program to understand not only the current penetrance of the virus to society, but where it is going.

Short answer to your question is it is going to be very important in our public health measure.

Senator SMITH. Would not also the price of these tests or the ability to pay for these tests be a pretty significant barrier to having that surveillance happen?

Dr. FAUCI. I think common sense tells you that if people cannot pay for it, they are not going to do it. That is one of the reasons we have got to figure out how we can do it without having the stress of people who cannot afford it to be part of that process.

Senator SMITH. Of course, the worry, of course, is that this ability to pay for these surveillance tests or this kind of surveillance testing, that could really tend to exacerbate underlying inequities since a lot of frontline workers and essential workers, who don't have the privilege of working from home, are much more likely to be Black and Brown and indigenous people, people of color. Is that not right?

Dr. FAUCI. As in all cases that people who are economically not able to engage in some of the things that benefit others, they always, in general, get a short end of the stick on that, and that is what we have to be concerned about.

Senator SMITH. Right. Well, colleagues, I think this is a really important place where we have the potential to work together to make sure that, as we expand surveillance testing and occupational testing, as we look at our schools, our higher institutions of higher education coming back, that we have the ability to do this and that the ability to pay for that test is not a barrier.

I appreciate—Chairman Alexander, you mentioned this at the beginning, others of my colleagues have mentioned this, and I think this is a place where we could work together in a constructive way.

I want to ask a question specifically related to vaccines because there has been a lot of discussion about this, a lot of discussion about how we can make sure that people trust these vaccines, that they are safe, that they work, and that the long-term consequences, potential negative side effects, we understand those.

Let me just ask—maybe I will ask you again, Dr. Fauci. How do we trust a vaccine that has only had a short number of months potentially being tested in a human body?

Dr. FAUCI. There are a couple of ways to overcome that. First is that you have a large number of people in the trial. The trials that we are talking about now are going to have 30,000 people in the trial, and maybe even more in some of them. You can get a considerable amount of safety data.

But, then there is a process, after a vaccine maybe would show efficacy to do further studies following licensure, availability. I will let Dr. Hahn maybe comment on that more because that becomes something very much involved with the FDA's authority in making sure we do have safe vaccines. So, Steve?

Senator SMITH. Let me just—if I could maybe put a finer point on this question for you, Dr. Hahn. I mean, what if a manufacturer were to say that they could get a vaccine to market in January, but only if they were released from liability? What is the FDA policy on that? How would you resolve that question?

Dr. HAHN. Thank you, Senator. So, we would not get into the issue of liability for an individual sponsor. And, what we would do, and that is why we released the guidance this morning, is we would ensure that our normal regulatory approach and our standards for safety and efficacy are met. So, while we are all—

Senator SMITH. You would not release that manufacturer from liability?

Dr. HAHN. That is not an FDA authority that—

Senator SMITH. Okay.

Dr. HAHN [continuing]. We would use.

Senator SMITH. How do you guard against—

The CHAIRMAN. Senator Smith, we are running—

Senator SMITH [continuing]. The possibility—

The CHAIRMAN. We are running a little late. Go ahead with your question, but let's—the witnesses have to—

Senator SMITH. This should be—hopefully this will be an easy one. I mean, what I am worried about is that there is some sort of October surprise and that there is pressure put on the decision-makers here to announce the vaccine in October 2020.

Dr. Hahn, can you just tell us how we can have transparency so that people can trust that is not happening?

Dr. HAHN. Senator Smith, a very good question and really important and leads to the issue of public confidence. It is why we released our guidance today. We want to be clear about what the standards and the data that we will need to make a decision and what factors go into this decision. I want the American people to hear me when I say we will use the science and data from those trials, and we will ensure that our high levels of standards for safety and efficacy are met.

The CHAIRMAN. Thank you, Senator Smith.

Senator SMITH. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Loeffler.

Senator LOEFFLER. Good morning. Thank you all for being here. Sorry I cannot be there in person.

I wanted to ask, Dr. Redfield, can you outline what steps the CDC is taking to, look at, as we prepare for handling both the flu and COVID-19 season simultaneously this fall? I know the CDC recently developed a test that diagnoses both COVID-19 and the flu, but what other activities is the Agency engaged in? And, are there any novel approaches that you see in terms of implementing this? I would love to hear about the Agency's process for approaching the season this fall and your thoughts there.

Dr. REDFIELD. Thank you very much, Senator. I think it is really important to recognize that it is going to be difficult with the flu and COVID this fall.

First and foremost is to try to increase the American public's acceptance of flu vaccine. As you know, less than 50 percent accept it. We are working hard to begin to reach out, particularly to groups that have been under-represented, to try to build that confidence in vaccination.

We have worked with the manufacturers to see if they could boost the amount of vaccine that would be available. They have now increased their commitment to almost 189 million doses. CDC bought another 7.1 million doses. Normally, we buy about 500,000 to be able to be available to the states and local health departments for uninsured adults. We have—we increased that to 7.1 million doses.

We have augmented our commitment to the children's vaccine program, anticipating that there is going to be more children that will qualify in light of the unemployment.

Those are some of the areas that we have begun to prepare for.

Senator LOEFFLER. Thank you. And this question is for Dr. Hahn.

The pandemic has exposed our vulnerabilities in the medical supply chain, and obviously we have a reliance on imports from coun-

tries like China that can quickly pose a national security risk in the face of an outbreak of infectious disease. We need to come up with a strategy to boost our production here of pharmaceuticals and supplies.

I have introduced some legislation entitled the BEAT CHINA Act to offer incentives to companies that bring manufacturing back to the United States, but would like to hear from you, what additional steps can policymakers take to boost our capability to produce these supplies and pharmaceuticals domestically?

Dr. HAHN. Thank you, Senator Loeffler, and thank you for your leadership on this. I think one issue that we can all agree upon is the lack of redundancy in the supply chain and the dependency that we have seen during the COVID-19 pandemic has been a problem.

The Agency's primary focus has been on instilling redundancy in the supply chain, particularly of pharmaceuticals, by diversifying that supply chain and really looking for opportunities to encourage domestic manufacturing.

We, of course, on the regulatory side provide guidance, as well as regulations, around the manufacturing specifications to ensure quality of pharmaceuticals and other medical products. We will continue to do that, particularly in the advanced manufacturing space, in order to encourage domestic manufacturing.

We look forward very much to working with you and other Members of Congress to see how we can create the proper incentives to have that redundancy, and particularly to have as much domestic manufacturing as possible.

Senator LOEFFLER. Thank you, Dr. Hahn.

No further questions. I yield my time.

The CHAIRMAN. Thank you, Senator Loeffler.

Senator Jones.

Senator JONES. Thank you, Mr. Chairman. Thank you all for being here today. I really appreciate your testimony, your consistency over the last few months. It has got to be somewhat discouraging to all of you, as it is to us, to see these numbers.

I want to kind of focus a little bit on schools as we will start opening schools up in Alabama in August. And, let me give you a little chronology here.

The State of Alabama kind of began to open up its economy more in May, a little bit more toward the end of May, and then in—for Memorial Day, we saw the photographs and videos that Dr. Fauci referred to with everybody just having a big time over the Memorial Day holiday.

Now, at the end of June, we are at our highest levels. The last 14 days have shown over 10,000 cases, which is 28 percent of the cases that we have seen have occurred just in the last 14 days.

At the end of this week, we have the July 4th holiday coming up. And, we are going to see a delay in hospitalizations from right now. If we do the same thing on July 4th, we are going to have a huge problem at the end of July and early August when we start opening schools up.

Our state school superintendent this week said that it would cost about \$1.8 million for the average school system to do those things necessary to try to protect kids and the faculty. But, I heard Sen-

ator Paul in his comments and discussing a number of things to where you would get the impression that we could just open schools back up without spending any of that money.

My question, primarily to Dr. Fauci and Dr. Redfield, could you comment on some of the statistics and some things that you heard about children transmitting this disease and whether or not we need to spend some extra, additional moneys for our schools to do things like have extra PPE? To do things like hiring—potentially hiring additional health officers, temperature screenings, those kind of things? Are those going to be necessary, based on what I have heard from Senator Paul and what happened on his charts in other countries?

Dr. Fauci and Dr. Redfield?

Dr. FAUCI. I will quickly give it a shot and then hand it over to Dr. Redfield.

We don't know precisely. I think the data that was very interesting that Senator Paul showed about school openings and not seeing any real obvious surge in cases is important, but we don't really know exactly what the efficiency of spread is.

First of all, how many children get infected. That was the reason why in my opening statement I mentioned the study that we are doing at the NIH of 6,000 families, looking at children, what is the rate of their infection and how often did they infect their families. Because if it is true that the rate is down, we would know that they don't get seriously ill with hospitalizations when they get infected. But, if the rate of infection is down and they don't readily transmit to their parents and family members, that is going to be very important in the decisionmaking process of opening schools. Hopefully, we are going to find that out reasonably soon by this study that we are doing.

Bob.

Dr. REDFIELD. I would echo what Dr. Fauci said. CDC has a number of what we call household studies going on to try to get a better understanding of how does the virus get into a household, who brings it in, what happens with—when it is in the household, how does transmission vary depending on how the household responds in terms of social distancing, et cetera. So, there is information that we are gathering. I think—we don't know the impact that children have yet on the transmission cycle, so I think we should just acknowledge that.

The greater threat, obviously, is, again, the children to the vulnerable, but I think one can actually have social behavior that can prevent that. So, I think that would be just to emphasize. I think it is really important.

It has been said already that we move forward and work to reopening schools in a safe way. I think it is of note that CDC never really recommended closing schools. It sort of just happened, as you know. We can do targeted school closings if we have to in a particular region like we have done for other viral diseases.

But, I think we really need to move forward now and work to how to reopen these schools safely.

Senator JONES. Thank you. Admiral Giroir, just—I want to make sure you are—we are tuned in, and we have talked about it a little, about are we going to be able to make sure that we get vaccines

distributed in the most vulnerable of communities? Because that seems to be where so much is happening right now, in the rural south. And, are you making specific plans to make sure that we get that into the rural areas?

Admiral GIROIR. Thank you very much. So, we all work on parts of this problem, right? So, the CDC actually controls the distribution. But, what my office does, running the national vaccine program, does things like the Morehouse Grant that—the cooperative agreement that we announced last week. That really reaches into the rural, into the Hispanic, into African American, to really have the community, the people who are in that community, not only linked to services like testing, but to lay the groundwork for vaccine acceptance. Because we know that the burden of disease is fundamentally burdened on these individuals. So, these are the people, assuming the science works out, that we want to get vaccinated first.

Senator JONES. Alright. Great. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Jones.

We know the witnesses need to leave about 1. We are going to try to respect that.

Senator Rosen.

Senator ROSEN. Hold on. Can you hear me?

The CHAIRMAN. Yes, we can.

Senator ROSEN. Well, good morning. I will try to be as quick as I can, talking about antibodies this morning. Thank you Chairman Alexander, Ranking Member Murray, all of our witnesses, for being here today.

As our communities focus on how to safely get back to work and school, just like we are all talking about, we know we have to follow the science and adapt to new information to be sure that we are making timely, targeted, and thoughtful decisions to protect both lives and livelihoods.

Dr. Fauci, the last time you were here, we talked about the monoclonal antibody treatments, and I would just like to follow-up on that conversation if we could.

As we have learned more about the virus, how it functions, how it is different from other respiratory illnesses, what updates can you tell us about the development of preventative treatments that block the virus from attaching to the cells that it is targeting?

Dr. FAUCI. Thank you for the question, Senator. You mentioned monoclonal antibodies. Monoclonal antibodies are going into trials right now in a number of trials sponsored by a number of groups. Hopefully, within a reasonable period of time, we will get information as to whether or not that is effective both in the prevention, as well as in the treatment. Those antibodies are directed against a component of the virus that is—what is called the spike protein, and that protein is the one that binds to the now well-established receptor in your body for the virus, and that is the receptor called ACE2.

There are a number of other studies that are not necessarily antibody studies, but studies that have an effect on the virus itself and its initial replication.

In answer to a question that the Chairman mentioned just a bit ago is that there will be therapies that we will be giving some for treatment early on and others for prophylaxis. And, as—we hope, as we get into the fall and winter, we will have everything from small molecule treatments and prophylaxis to the kinds of antibodies that you are talking about.

There is a lot of activity going on to do that early in disease, both for prevention and for the treatment of early disease.

Senator ROSEN. I know that you have been doing a lot of serology testing and that individuals are presenting with antibodies. So, out of the five types of antibodies that people are most likely to have, which ones do most recovered patients—which ones do they show? And, if one of these specific antibodies are present, does that make a difference in if the patient can be re-infected or not? Are they effectively immune at least for some period of time? What kind of answers does this give us if you do have the presence of certain antibodies?

Dr. FAUCI. I am—I would like—I would love to give you a really precise, scientifically based answer, but the fact is, we don't know. Standard wise, when you get an acute infection, you get an IgM antibody. As you go off in time and develop a more mature immune response, it becomes an IgG. There are subclasses of IgGs, some more protective than others.

The thing we don't know, Senator, that we—we will know in time, but it is going to take time to know it, is what the relationship between the neutralizing antibody and binding antibodies that don't neutralize, what is the relationship between the titer and degree of protection, and what is the durability of protection.

We have seen some puzzling things. We have seen people recover from COVID infection and find out they don't have very high numbers of antibody. Could it be a cell mediated response that got them through the illness? And, some other individuals have very high levels, and we don't know how long those levels last.

We are getting there with regard to our knowledge, but it is going to take several more months to a year to really be able to definitively answer your question about the role of antibodies in protection following natural infection.

Senator ROSEN. Well, building upon that, I would like to ask this question then. We know that this virus affects—it is multi organ. It can affect your kidneys, your lungs, your heart, producing strokes, all kinds of things, your digestive system, your sense of smell. So, on the science that you are talking about and the antibodies, is the science of stopping the virus from causing harm the same regardless of which organ it attacks? And how do we help direct funding for the kind of research that you are going to need to look at this multi organ attack of this virus, if you will?

Dr. FAUCI. This is a very perplexing virus because it is a respiratory virus and it gets in through the respiratory tract. If the virus stays in the respiratory tract and doesn't go systemic to involve other organs, that is good news because you don't get very sick.

The other side of the coin is your antibody response is not as potent because when you get systemic involvement, invariably, you will have a more potent and robust immune response. So, many

people, and probably the people who are the asymptomatic carriers, they have a reasonable titer of virus in their nasopharynx, but the virus doesn't go any other place in their body.

People who get multi system disease that get triggered by the virus, those are the ones that, unfortunately, get more sick, but also the ones that make a more potent immune response.

Senator ROSEN. Thank you so much. I appreciate you all being here today.

The CHAIRMAN. Thank you, Senator Rosen. Very interesting questions.

Senator Murray, do you have closing remarks?

Senator MURRAY. I have one additional question, if I might, and then some closing remarks. I wanted to ask Admiral Giroir one question.

Admiral GIROIR. Yes, ma'am.

Senator MURRAY. Thank you. Despite some of the limited data, we do know that COVID-19 is infecting and killing Black, Latino, and Native American people at a much higher rate than White people. I wanted to ask you how HHS is going to adjust its response to reduce cases and deaths in communities of color. And, specifically, can you commit to redirect some of the \$14 billion that is in unspent funds Congress provided to address those disparities?

Admiral GIROIR. Let me answer the two parts of the question. First, as you know, and we really appreciate your support, we have tried to focus our testing into high social vulnerability communities. So, 70 percent of our over 600 pharmacy sites are in high SVI communities. That means racial and ethnic minorities, language disparities, socioeconomic.

FQHCs: We have made a major push that the federally qualified health centers that take care of one out of three of those in poverty, over 1,300 of those are now offering testing.

Of course, we are super excited about the award to Morehouse School of Medicine last week that has a large coalition to create a national infrastructure to reach minorities and underserved.

That is what we are really doing. And, my office, this is what we do on a daily basis, but even without a pandemic.

Your second question is, I don't commit the money. So, I certainly think we need continued investment in this area, continued significant investment in this area, that the \$40 million is a down payment on how we could best reach the underserved community, but you are going to have to talk to OMB about how the money is spent.

Senator MURRAY. Well, actually, HHS oversees that, so we will ask them. But, I think that is an important question. I will keep following up and tracking that.

Admiral GIROIR. Yes, ma'am.

Senator MURRAY. Thank you, Mr. Chairman.

I appreciate all of our witnesses taking the time to join us today to update our Committee on the course of this pandemic and all of our efforts to respond to it.

I hope we will continue to have an opportunity to hear from all of you, as well as other key Administration officials, about this because the absolute worst thing we could do right now is to pretend this crisis is over when it is painfully obvious that is not true. The

reality is that the losses in this pandemic so far are nearly unthinkable, and any further delays in our response is really unacceptable. We need to take—this President to take this crisis seriously and lead, and we need Congress to act.

I hope we can all get back to work as soon as possible. We need to support our families, our frontline workers, our businesses, our schools, our communities. We need to get testing where it needs to be. We need to make sure we are making progress toward a safe, effective, widely available vaccine, and we need to strengthen our ties with the global community rather than cut them.

There is a lot left to do, Mr. Chairman. I look forward to working with you on this.

The CHAIRMAN. Thank you, Senator Murray.

I know our witnesses have a meeting they need to go to, so I will abbreviate my remarks. But, one thing I want to ask you—perhaps you can each do it in a minute or less.

I put out a white paper in recognition of what some of you have said, which is that in between pandemics, we have found it difficult to do some of the things we need to do to prepare for the next pandemic. So, if there were one or two things that you thought we should try to do now in order to be prepared for the next pandemic, what would those one or two things be? Dr. Fauci?

Dr. FAUCI. One of the things that I would like to see is an appreciation on the part of our entire Nation of the importance of responding as a Nation as a whole and not have a situation where, when you have a challenge such as we have right now, we have very disparate responses. We have got to do it in a coordinated way because we are all in this together.

The other thing I would like to do now is to cement in our minds as we bridge to the future the fact that we cannot forget that what was thought to be unimaginable turned out to be the reality that we are facing right now. So, it relates to the kind of appreciation that outbreaks happen, and you have to deal with them in a very aggressive, proactive way.

The CHAIRMAN. Dr. Redfield.

Dr. REDFIELD. Thank you, Mr. Chairman. I think the most important thing that I could say is that when it comes to public health threats, our Nation needs to be over-prepared, not under-prepared.

As I mentioned before, decades of under-investment in the core capabilities of public health, data modernization, laboratory resilience, workforce, emergency response, I think is fundamental. We have really been hit with this simple virus, and I think at the end of the day, it is going to cost our Nation trillions of dollars.

I think that we have a moment in time where I think people are attuned, and I would say now is the time to make the necessary investment in our public health at the local, territorial, tribal, state, and Federal level so that this Nation finally has the public health system not only that it needs, but that it deserves.

The CHAIRMAN. Admiral Giroir.

Admiral GIROIR. Of course, I agree completely with my colleagues and we are all singing from the same hymnal here.

I will say three things. No. 1, data infrastructure is really important. When we came into this, we didn't know how many ventila-

tors were in use, how many tests were out there, were the tests positive or negative, who was being tested. I mean, the complete soup to nuts infrastructure that we need to make decisions. You need those data to make decisions and to allocate resources. And now that—we have built this on the fly, but we absolutely have to invest in that.

Second, I would say resiliency of the healthcare system. Yes, we need to attack COVID, but what happens to everything else? We have seen cancer screenings go down by 80 percent. Childhood immunizations plummet. Just about every other thing in the healthcare system was sacrificed for our COVID response. So, it is not just the pandemic response, but it is everything else we need to do.

The third thing I would say is we continue to have to focus on health disparities. If everyone was healthier in the Country, if we invested into those—to hypertension, diabetes, obesity, all the things that could bring the general health up, you would not see as horrible of outcomes as we have in any pandemic. So, working on health disparities that have been here for decades is, I think, critical to raise our general health and prepare us for whatever is going to hit us.

The CHAIRMAN. Dr. Hahn, you can have the last word.

Dr. HAHN. Thank you, Mr. Chairman. First of all, thank you for your leadership and your white paper. I think that is really important to put this conversation forward.

There are two things I want to emphasize. One is the data modernization, but from an FDA perspective. It is a very manual process to, No. 1, collect data on demand, and also, the supply chain. We need a very robust system to understand that.

We also need a robust, real world evidence approach so that when we make decisions in real time during an emergency—doctors do that all the time, agencies do that, particularly during public health emergencies—we have the appropriate data infrastructure to collect real world evidence and feedback into our decisions, and then revise those decisions as needed. Critically important for the Agency.

The second thing is linked, and that is to my previous comments that Senator Loeffler asked about. We absolutely need redundancy in the supply chain. We need redundancy in manufacturing. And, we need to emphasize the importance of domestic manufacturing.

Thank you.

The CHAIRMAN. Thank you, Dr. Hahn.

Well, the one thing this sneaky, dangerous virus has reminded us is that there will be another sneaky, dangerous virus one day. And, we know from experience that it may be easier to take the steps you have just described while our eye is on the ball rather than between pandemics because we get interested in other issues.

I am grateful to the witnesses for your time. I thank the Senators on both sides of the aisle for really careful, insightful, and courteous questioning.

The hearing record will remain open for 10 days. Members may submit additional information within that time if they would like. Thank you for being here. The Committee will stand adjourned.

ADDITIONAL MATERIAL

TESTIMONY OF DR. JOYCELYN ELDERS

15TH U.S. SURGEON GENERAL

CO-CHAIR AFRICAN AMERICAN HEALTH ALLIANCE

Good morning Chairman Alexander, Ranking Member Murray and Members of the Senate Committee on Health, Education, Labor, and Pensions. I am Dr. Joycelyn Elders the 15th Surgeon General of the United States. I am also co-chair of the African American Health Alliance a nonprofit organization working to help eliminate racial and ethnic health disparities and the social determinants thereof. We thank you for convening this special hearing on *COVID-19 Update on Progress Toward Safely Getting Back to Work and Back to School* as well as the hearing on *COVID-19 lessons learned to Prepare for the Next Pandemic, along with the many other coronavirus hearings held by this Committee.*

COVID-19 continues to take its deadly toll, especially across the Black community and other vulnerable populations. As the United States seeks to send workers back to work and children back to school, among the major missing factors to date remains: safe and effective treatment and vaccines, and an overall safe, effective and sustained public health response that includes ongoing robust reliable testing, contact tracing, care and treatment, and isolating. This is just basic responsible operating requirements for opening the workplace and schools.

In a whirlwind of disasters, Americans remain barraged by a worldwide pandemic of a new virus and medical unpreparedness; shortages of PPE, hospital space and medical personnel; government unpreparedness, economic recession and unemployment; huge numbers of hungry and homeless people; police brutality and systemic racism.

Our Nation's underbelly has been exposed in COVID-19, brutal policing, racism and income insecurity. People are taking to the world's streets to demand peace with justice and an end of racism. The world has awakened to discover that huge numbers of people are dissatisfied with disparities that are obvious in all areas of economics, social justice, education, housing, medicine and more. Black lives do matter.

It is crystal clear that the events of the past few weeks and months have revealed the awful truth about the impact made by racial, health and economic disparities in our country. Standing there naked in view of the world, we are humbled. However, being humble is not enough. We can see clearly how unfavorably we compare to other countries in the world, and they can see it, too. The people of the United States have not fared as well as other developed countries. Our nation's responses to the coronavirus pandemic including its disease rates are higher and our ability to mobilize resources, identify the presence of the virus, isolate and support people while they do, is miserably deficient.

Our Nation's infection rates and death numbers are higher than many other industrialized countries. While our Nation offers hope of a vaccine that remains out there on the horizon the immediate need is for safe, effective, lifesaving treatments that are accessible to all that need it. This must be coupled with an effective "Test-Trace-Treat-Isolate-Repeat" package. People across the Nation and around the world are asking how, when, where, why, and what went wrong in United State, that America has been bent so low? Especially with regard to coronavirus, it seems ridiculous, since America has the best doctors, nurses, medical teams, and research laboratories in the world. However, being the best professionals doesn't cover all our bases in providing the best health care for all our people. Because, all our people do not have access to this remarkable world of medicine that we have built.

Mr. Chairman, Ranking Member Murray and Members of the Committee surely you can understand my deep concerns regarding access to safe, effective and accessible treatments and vaccines to the Black community and other vulnerable communities. Even before COVID-19, our Nation's delivery system, for all its wonderful medical know-how, was and remains broken. And, doctors scarcely have a word in the way health is delivered to all our people. While doctors provide medical expertise, the organizational power is given over to others in the corporate and political world.

At least for 30 years, we have been "working" on eliminating healthcare disparities. When Healthy People 2000 came out in 1990, eliminating Disparities in Health Care was an objective. Then, it was an objective in Healthy People 2010; then it

was an objective in Healthy People 2020. In these 30 years, we have not made much of a dent in the actual disparities. The Affordable Care Act is helping and it must be protected and strengthened. Additionally, we must address the social determinants of health. Clearly, a person is only as healthy as the least healthy person.

Health care must be extended to everyone for public health to be good. Without it, the risk to opening America including its schools—is too risky. It is unsafe without the appropriate tools, resources, medical and mental health teams, PPE, safe and effective coronavirus treatments as well as access to safe, effective and affordable medications for pre-existing health conditions and more. The unintended negative consequences are real and must not be ignored. Instead, we must “test-trace-treat-isolate-repeat”.

The compounding coronavirus pandemic, the economic collapse, police brutality and systemic racism, individually and collectively take their toll. Again, while these epidemics are truly humbling, being humble is not a solution. As a Nation, we are at a dangerous low point in society and humanity. Know that when there is a vacuum, someone and/or something will fill it good or bad. We are all in this together: doctors, scientists, clergy, elected officials, frontline workers, the public and private sectors, and we the people. Equity is important to the well-being of every man, woman and child and to our Nation on every front.

Disparities must not only be addressed; they must be eliminated. COVID-19, racism, excessive policing and the economic disaster, continue to show us that we can no longer just re-arrange the deck chairs on the Titanic. We must conquer coronavirus, put an end to racism, reform our policing and healthcare system, and build a life sustaining economy for all. Among these, that includes developing a healthcare system that provides healthcare to all and eliminates disparities in health and health care.

Now, our Nation only has a sick-care system for all, with a healthcare system for some. The United States cannot stop at only healthcare access and delivery; we must also address all the disparities in the social determinants of health. They are the backbone on which to develop the most effective response. America has not wanted to spend the money investing in health care for all and public health. Now, America is reaping the negative consequences of her reluctance to invest in people. The United States will continue paying until our Nation invests in eliminating racial and ethnic disparities.

The compounding intersecting adverse outcomes come as no surprise. Either we will invest in people now or pay later. The Committee will recall the findings of the 2002 Institute of Medicine Report “Unequal Treatment” that urged the Nation to confront racial and ethnic disparities in health and healthcare. The African American Health Alliance strongly believes that if the recommendations of that report had been implemented the burden of coronavirus and other health disparities would not be so dire. Nevertheless, we are once again at the urgency of now and must effectively deal with this deadly novel coronavirus head-on.

While Coronavirus has been declared a National Emergency, the void is clear racial and ethnic health disparities elimination and racism elimination *have not*. Surely, the deadly extent of coronavirus in the Black community and the impact of the virus across communities of color demands that racial and ethnic health disparities elimination and racism elimination must be declared national emergencies, and effectively addressed as such. To that end, from lessons learned to the opening of places of work, schools, entertainment and more, the African American Health Alliance submits recommendations via my testimony to this distinguished Committee to help our Nation better address the COVID-19 epidemic.

It is against this collective backdrop that the African American Health Alliance urges implementation of the recommendations coupled with the accelerated development of safe, effective, accessible and affordable to all COVID-19 treatments and vaccines and the required wrap around services people need to benefit from them.

Recommendations Details and Justification:

The coronavirus pandemic requires a comprehensive response. Black lives do matter. Declare Racism a National Emergency: Declaration to provide for inclusion of racism elimination and prevention provisions in all policies, practices, and programs. This action systematically takes into account the adverse consequences of racism in policing and all social determinants impacting the quality of life. For all, the declaration limits and helps to prevent the harmful effects of racism across the lifespan. Black lives do matter.

The elimination and prevention of racism is vital to helping to ensure that all persons achieve their fullest potential, freedom and justice. Conduct racism impact assessments, elimination efforts including engaging state and local and community workgroups for the purpose of informing decisions that promote elimination thereof as well as those that prevent elimination. Racism's consequences and protests nationwide and worldwide against racism support this declaration. [Within, that is AAHA's recommendation for the declaration of "Racism" and the "Elimination of Racial and Ethnic Health Disparities" national emergencies.]

Disease Detection, Manage, Control and Monitor

Coronavirus Testing: Provide Testing, Contact Tracing, Isolate, Treat, Social Distance, Repeat: Remove barriers and provide accessible, robust rapid accurate and timely testing with accurate rapid results: priority testing must be targeted especially for those African Americans with chronic pre-existing health conditions that place them at increased risk for coronavirus deaths and disease. Lack of testing remains a major missed opportunity to help control the spread and reduce coronavirus cases and deaths, and for making informed decisions about re-opening. This requires testing of not just those with symptoms but also those without.

Provide both COVID-19 mobile testing labs along with mobile health units. This companion effort provides for continuity of care for pre-existing chronic health conditions. Together, they are absolutely essential especially in high-risk communities, pre-existing health condition, hot spot breakout areas, crowded public housing and frontline jobs/workplaces. Additionally, re-energize the DHHS health in public housing program. DPA: Robust test production, testing, contact tracing and isolation are essential to help control this deadly pandemic and treat and manage pre-existing health conditions.

Coronavirus test to also include the serology test. Negatives must continue precautions including social distancing and isolation. Effective contact tracing requires that tracers also include African Americans and others from communities of color. Coronavirus testing coupled with contact tracing, monitoring, identification, isolation, diagnosis and immediate coronavirus care, treatment and management coupled with ongoing testing and treatment for pre-existing health conditions is a must solution.

State and local health departments must be supported also to help do the contact tracing and follow-up that is necessary to be effective. Directly fund each state and territory to do contact tracing and robust testing. The CDC's respiratory surveillance system is not adequate to the task. States must demonstrate a system where data is collected from all populations indicating the ability to provide rapid diagnostic services to all residents and ongoing serologic monitoring the state's population including unserved and underserved areas (MUAs).

Responsible opening, care, treatment and control are them care. Do not open schools without testing. Without it, the approach is reckless. National robust testing requires releasing the full powers of the Defense Procurement Act; that act exists to help save lives; do it now.

Engage/ Command / Control /Preparedness / Emergency Response / Resilience Expert: We strongly urge you to work with retired General Russell Honore to develop a comprehensive Coronavirus Resilience National Strategy with emphasis on public health, the supply chain, economic security, vulnerable populations, cyber security, broad band and more including a build-back-better approach. General Honore has tremendous expertise that is needed to help improve the coronavirus response.

Extent of Need: Pre-existing Health Conditions

Pre-existing Health Conditions: Provide Healthcare Access for Care and Treatment: Expand and ensure access to care and treatment: include Medicaid expansion; allow Medicare enrollment at age 45, allow "special open ACA enrollment season now" and permit young adults to remain on their parents' health care plan to age 30. In addition, expand existing community health centers and continue to increase the number of new centers especially in unserved and underserved communities. There must also be mobile community health satellite centers with full or near full array of services. Coronavirus and chronic health conditions together require immediate, short and long-term care, treatment and follow-up.

Continuity of care is vital. Expansions in access to care and treatment with wrap around services is necessary to respond to both the coronavirus medical, mental health conditions and to chronic pre-existing health conditions that the virus further

complicates. Overall, make sure everyone has some form of affordable health care coverage with facilitated access to it, and that effective responds to their needs.

Concern abounds about rationing: care, treatment, medications and testing, including that for chronic pre-existing health conditions. Unserved and underserved communities need reliable connectivity technologies to effectively accommodate and benefit from telemedicine, tele-health, tele-mental health, tele-dental, and tele-nutrition to name a few. Stable reliable internet/broad band services are essential for health, home schooling, higher education, training in the trades and more.

These deficiencies adversely limit health, education and employment opportunities. In addition to care, treatment, and dire testing shortages, medication shortages are also on the rise. Addressing the overall twin conditions: *coronavirus* and *ongoing health needs* of people in public housing, nursing homes, prisons, assisted living, the homeless and similarly situated environments is paramount.

Data Collection Analysis and Reporting

Extent of the Coronavirus: Provide Data Collection, Analyses, Monitoring and Reporting: Racial and ethnic health disparities are well known to Federal, national, state, local leaders, officials and community gate-keepers and agencies. Data must be collected and documented at point of medical system and testing entry. Agencies must collect, analyze, monitor and publically report coronavirus racial and ethnic demographic data. Months into the coronavirus pandemic and national emergency race and ethnic data are insufficient to appropriately inform the medical, the Nation's and community's response to the deadly and highly contagious coronavirus.

The Department of Health and Human Services and its agencies must collect, compile, analyze, release, and report race and ethnic demographic data including but not limited to that on cases, deaths, location, zip code, outbreaks, hospitalizations, and testing. Data is extremely limited and seriously life-threatening-insufficient. National, state and local coronavirus reporting must be accurate, timely, complete and transparent. Additionally, data is an essential factor helping to identify where services and resources must be targeted and concentrated. Testing, care and treatment data help inform efforts to improve outcomes.

Workforce

Provide Hazardous Pay, Worker Protections and Whistle Blower Protections: Provide hazardous pay to coronavirus frontline workers, double existing pay/salary. Months into this deadly contagious coronavirus the shortages of staff, personal protective equipment and gear continue to place workers and their family at increasing risk for disease and death. The frontline workforce includes nurses and doctors, non-medical hospital staff; home health and nursing home workers; grocery store, postal, transportation, medical technicians, meat packing plant workers; the list goes on and on. Direct OSHA to update issue and monitor coronavirus worker protection guidelines. Provide whistle blower protections.

Coronavirus frontline and essential workers across all fields must be paid hazard pay, double current pay. Every day, they put their life on the line to serve the public ... facing the deadly coronavirus head-on without hazardous pay. Months into this deadly pandemic, despite dire working conditions, still the full powers of the DPA have not been released and that deficiency has now spilled over into the extreme deadly shortage of coronavirus tests. Essential materials, equipment, test and test material remain in short supply including medical equipment, cleaning supplies, gowns, gloves, masks and medications.

Care and Treatment

Establish Coronavirus Community Access Points: Because of the highly contagious nature of COVID-19, the fact that it may spread before the individual becomes symptomatic, the severity of its illness, and the fact that many individuals will be at risk of becoming infected for years to come, the health system must adopt modifications immediately to respond to medical, mental health, social determinant requirements and complications stemming from coronavirus in immediate, short-and long-term.

Without national testing and within it African American priority is testing, the coronavirus is more deadly for all. Community Access Points must be developed to provide unserved and underserved communities with sites which will be: highly accessible loci for services and for the provision of information regarding COVID-19; sites providing immediate testing and informing of virus status; care entry points

for those testing positive; and loci for isolating, counseling and contact tracing staff in the community. [Test-trace-treat-isolate-repeat.]

Access points must have separate waiting areas for patients and address (treat, manage and control) pre-existing chronic health conditions. These facilities must have: up to date laboratory test and equipment; access to the most up to date COVID-19 information provided by DHHS; ability to diagnose and quickly report COVID-19 status; a waiting room separate from non-COVID-19 patients; and ability to transport positive patients to an in-patient facility which serves symptomatic COVID-19 patients. Staffing team minimum requirements: a physician or nurse practitioner; nurse, technicians, counselor with social work training; and contact tracing staff. The unit/entity/facility should be located on the site of an established community health facility and operated by that facility collaborating with local or state health departments.

Establish Prison Coronavirus Systems: The Federal Bureau of Prisons must develop a coronavirus plan for each of its regions. Each plan must specify mechanisms for: identifying positive staff and inmates; separation of positive staff and inmates from the general population; isolation, contact tracing, and also ongoing identification of staff and inmates missed in the initial screening; and screening of all incoming staff and new inmates and separation of positives.

Collaborating with state health departments for contact tracing purposes: each region must designate a COVID-19 coordinator, preferably a physician. A COVID-19 counselor must be designated within the staff of each prison's clinical facility. This counselor must have direct communication with the regional coordinator. Regions must also designate a clinical facility for patients who must be hospitalized and specific systems for transportation to the facility and management of the hospitalized inmates.

State Grants: Make grants to each state to develop systems to manage COVID-19 within its prisons. Each plan must specify mechanisms for: identifying positive staff and inmates; separation of positive staff and inmates from the general population; contact tracing; and ongoing identification of staff and inmates missed in the initial screening; and screening of all incoming staff and new inmates and separation of positives. Collaborating with the state health department for contact tracing purposes:

States must designate a COVID-19 coordinator, preferably a physician, for its prison system. A COVID-19 counselor must be designated within the staff of each prison's clinical facility. This counselor must have direct communication with the state's coordinator. States must also designate a clinical facility for patients who must be hospitalized and specify specific systems for transportation to the facility and management of the hospitalized inmates. Oversight of these state systems must be shared by the Federal Bureau of Prisons and the Department of Health and Human Services. [Test-trace-treat-isolate-repeat.]

Small Businesses and Community Investment

Provide for Small Businesses: Continuing to struggle, African American businesses are among the hardest hit. Low cash and weaker banking connections threaten their existence as they compete for PPP against much larger businesses. The combination compounding crises income, pay checks, unemployment insurance, job instability, and others seriously threaten small businesses and their staff. The disadvantage conditions collide and escalate in the coronavirus national emergency requiring automatic triggers and path ways to help save families and businesses during this national emergency that is no fault of their own. They did not choose the deadly coronavirus health and financial crises.

Invest in Community Development: Increase investments in jobs (with living wages); quality education Pre-K through 12th grade; safe schools; meaningful employment training; job creation and placement; entrepreneurial opportunities; creation of avenues for innovation; grocery stores and transportation; business development, growth and sustainability; safe affordable housing; convenient access to quality affordable healthcare; safe communities; and affordable quality daycare.

These interlinking investments are absolutely essential for viable productive communities. Establish and make available to communities a team of Federal Government experts from Department of Justice, to Department of Education, DHHS to EPA, to Office of Preparedness and Response, to Department of Labor, SBA, DHS and others to work in partnership with local agencies, community leaders, business and others. Provide technical assistance focused on helping communities identify

and establish linkages and partnerships with business and industry. Fund at such sums as necessary.

Community Empowerment Zones: Provide community partnership grants to establish community empowerment zone programs in communities that disproportionately experience over-policing. Funding provided for Black communities that seek to improve economic, race relations, health, education, environment and policing to help reduce disparities, and other highly coronavirus vulnerable communities. Assist community in accessing Federal programs; to obtain and coordinate the efforts of governmental and private entities regarding the elimination of racial and ethnic justice disparities and over-policing crisis.

Communities to be served by the empowerment zone program are those that disproportionately experience over-policing and economic opportunity deserts. The community establishes an empowerment zone coordinating committee: determine priorities, establish measurable outcomes, obtain technical assistance and utilize but not limited to community and evidence-based strategies including goals, management, implementation, monitoring, assessment and evaluation. Submit to the Congress community empowerment zone reports. Fund at such sums as necessary.

Training and Education

Conflict Resolution Training: Include conflict resolution in the education curriculum Pre-K through 12. The techniques learned in conflict resolution training would be beneficial across the life span. They would be helpful in encounters with police and all other relationships. Fund at such sums as necessary.

Expand Academic Opportunity and Achievement: Have school systems, courts and police work with the community and academic institutions to implement mentorship programs focused on youth including troubled youth to provide them with insight and opportunity to better benefit from the powerful value of education and training beyond high school. Tie college and training scholarships to these programs, and help to ensure that free community college becomes a real accessible opportunity. This investment in the individual's and America's future helps to further innovation, entrepreneurial development, research, business, industry and technology advances on all fronts in all fields. Fund at such sums as necessary.

Provide Summer Enrichment and Afterschool Programs: After school and summers is the most unsupervised period of time facing latchkey children and teenagers. Effective programs must be implemented that provide that supervision ranging from summer jobs, to summer education and training, to sports and arts, to innovation and business, to enrichment programs and Junior Achievement. For young children, provide summer Pre-K. Overall, programs must also provide meals and transportation for those in need. Fund at such sums as necessary.

Establish National Teaching-Learning-Tutoring Corp: [Establish, Provide, Conduct, Monitor and Fine-tune as necessary] Provide students and parents the academic assistance needed to bring students up to grade level and beyond. This must be a joint goal. The portfolio must include but is not limited to materials, computers, technologies, skilled supplemental personnel and other resources needed. Students and parents must not be penalized for the education and stress crises created by the Pandemic. Additionally, establish a family support hotline professionally staffed to address family stress, mental and behavioral health control and management support.

Compile, train and provide techniques and exercises that parents and students need to help control and manage stress. Also, identify and provide parents and students the privacy tools needed to help keep online schooling and socializing safe. Remain mindful that our Nation's children and parents sudden thrust into full scale home schooling, online learning/educating has placed students at increased academic disadvantage and to successfully close the void they must be provided the necessary resources. Fund at such sums as necessary. Additionally, increased online use by the elderly also places them at increased online fraud. Fund at such sums as necessary.

Enhance Community Participation

State and Local Offices on Community Relations: Establish Offices on Community Relations to help communities empower themselves: make available technical expertise, linkages, and resources. Create and make available community relations improvement resource toolkits that communities can tailor to fit their needs.

Voting: The African American Health Alliance would be remiss to not *highlight voting*. Voting no matter what form or forms it takes must be protected, voter-

friendly and facilitated, and funded at such sums as necessary. Voter registration and rolls must also be respectively facilitated and protected. Every vote counts and must be counted. Also, as a Nation, we can and must improve the response to all aspects of the coronavirus national emergency. The response deficiencies are life threatening especially for Blacks. Clearly, everyone must be a part of the solution to the Nation's emergencies racism, policing, COVID and the economy.

In closing, Mr. Chairman, Ranking Member and Members of the Committee our collective purpose must hold us accountable to the reality that we are all in this together and we must do our part. As Dr. King's quote continues to remind us: "**We are caught in an inescapable network of mutuality, tied in a single garment of destiny. Whatever affects one directly, affects all indirectly.**"—*Martin Luther King Jr., Why We Can't Wait* The coronavirus pandemic requires a comprehensive response. The African American Health Alliance thanks you for this opportunity to provide testimony and recommendations. We deeply appreciate your ongoing leadership and support. **Black lives do matter.**

AAHA Board Members: Co-Chairs: M. Joycelyn Elders, MD, 15th U.S. Surgeon General and Lucille Perez, MD, President and CEO, The Cave Institute, Past President, National Medical Association; Members: Clive Callender, MD, Professor of Surgery, College of Medicine, Howard University, Howard University Hospital Transplant Center; Founder, National Minority Organ/Tissue Transplant Education Program; Fredette West, Director, African American Health Alliance; Rev. Fred Williams, President and CEO SYF Associates; Allan S. Noonan, MD, MPH, Founding Dean, School of Community Health and Policy, Morgan State University, Assistant Surgeon General (RET), U.S. Public Health Service Point of Contact: Fredette West.

[Whereupon, the hearing was adjourned at 1:11 p.m.]

