

COVID-19: AN UPDATE ON THE FEDERAL RESPONSE

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 THE FEDERAL RESPONSE

SEPTEMBER 23, 2020

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COVID-19: AN UPDATE ON THE FEDERAL RESPONSE

Wednesday, September 23, 2020

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

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

Present: Senators Alexander [presiding], Enzi, Burr, Paul, Collins, Cassidy, Murkowski, Romney, Braun, Loeffler, Murray, 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, I would like to welcome everyone and go through some administrative things. We have taken the advice of the Attending Physician, the Centers for Disease Control, Health and Human Services so we are all seated six feet apart. There is no room for the public in this arrangement, the press is operating by pool, although this can be watched by streaming or later in an unedited fashion. And our witnesses are all here in person. We welcome them. Some Senators are in person. Some are participating by video conference. I would like to say this about masks.

We have consulted with the Attending Physician. He says, since we are six feet apart, we can—we do not need to wear masks when we are here, although you are free to if you want to. I wear my mask when I am outside of this room, according to the recommendation of all four of the witnesses who are here today. I am grateful to the Rules Committee, Sergeant at Arms, the Press Gallery, the Architect of the Capitol, the Capitol Police, and Chung Shek and Evan Griffis for all their hard work to keep us online and safe.

Senator Murray and I will each have an opening statement. Then we will turn to our witnesses. We would like to ask you to summarize your remarks in 5 minutes. Then we will recognize each Senator for 5 minutes of questioning. We have full participation today so I expect a very good hearing. This will be the final hearing during my 6 years as Chairman of the Committee. Last week at our hearing, I thanked Senator Murray and her staff for their friendship and diligence and cooperation, without which our Com-

mittee would not have accomplished all the things we have been able to accomplish. This week, I would like also to thank the most senior Republican Member, Senator Mike Enzi, and all other 20 Senators on the Committee, both Democrat and Republican.

Senator Ted Kennedy used to say that our Committee had the broadest jurisdiction in the Senate. You only have to look around the room at a hearing and see that we also have the broadest range of views in the Senate and some of the ablest advocates of those views. But thanks to our Committee Members and to Senator Murray, most of our hearings have been bipartisan, which means we have agreed on a broad range of witnesses to present points of view. And while the questioning and the statements of Senators has been probing, there has always been a high level of courtesy, both to the witnesses and to the other Senators, which I am grateful for.

I believe this ability to work together during such a rancorous time is a big contributor to why we have been able to accomplish so much. The work of this Committee represents my view that, as far as the U.S. Senate goes, it is hard to get here, it is hard to stay here, and while you are here, you might as well try to accomplish something good for the country, which this Committee has done on numerous occasions. The Trump administration's program to develop and deploy a vaccine against COVID-19 is on track to be an unprecedented sprint to success. The program called Operation Warp Speed will save lives without cutting corners on safety and efficiency. The COVID-19 vaccine development process is likely to produce its first tens of millions of doses within 1 year.

The United States has never produced a vaccine that rapidly. When I was a child, I saw classmates in iron lungs. We waited 10 years for a polio vaccine to be—so we would not be afraid of polio. Many existing vaccines for other diseases that children take routinely before they go to school, like chicken pox and measles, have taken 10 years to develop. The secret to the success of this effort is that the Government, in partnership with private industry, is for the first time developing and manufacturing vaccines in parallel. Now, what that means is that Operation Warp Speed is manufacturing tens of millions of doses of the six vaccine candidates at the same time the clinical trials are ongoing and the Food and Drug Administration works to determine whether those vaccines are safe and effective. If the FDA does not approve the vaccine, it will not be distributed. So the risk is taxpayer money, not the safety and efficacy of the vaccine.

The Administration had set a stretch goal that once seemed impossible but now seems likely. The Administration hopes to have as many as 300 million doses of vaccines available to be deployed by mid-2021, according to an August 26 article by Operation Warp Speed program's principal adviser, Dr. Moncef Slowey, and vaccine expert, Dr. Matthew Hepburn, that was published in the *New England Journal of Medicine*. The authors also wrote, "no scientific enterprise could guarantee success by January 2021, but the strategic decisions and choices we have made, the support the Government has provided, the accomplishments to date make us optimistic that we will succeed in this unprecedented endeavor."

Mr. Paul Mango with the Department of Health and Human Services said recently in a meeting that if all goes well, it is possible that up to 700 million doses will have been manufactured by April of next year, 2021. The Department of Health and Human Services, Department of Defense, private sector, public health and medical professionals also are working together to lay the groundwork for deciding who gets the first doses, such as health care workers and certain high-risk populations, and how to get those doses to those individuals. The Centers for Disease Control has asked states to submit plans by the middle of October of this year, next month, to begin distribution. Now, there has been a lot of back and forth over exactly which date the first vaccine doses, which remember are already being manufactured and made ready for distribution, when will they be available for distribution to the public?

The answer, of course, is that the only people who know when a vaccine will be ready are the scientists at FDA who will review the science and the clinical trial data and determine whether the vaccine is safe and it works. Even Dr. Stephen Hahn, the Commissioner of the FDA who is testifying today, does not know when that date will be because the FDA will not approve a vaccine until three things happen. One, independent experts overseeing clinical trials determine there is enough data available to the FDA to make a decision. Two, after demonstrating safety and efficacy based on clinical trials, the vaccine manufacturer submits an application to the FDA. And then three, FDA experts conduct their review and make the final determination the vaccine is safe and that it works.

Now, as to treatments, the second unprecedented story of the United States response to COVID-19 is the development of treatments. There are five products authorized for emergency use today to help treat and manage COVID-19 symptoms, including Remdesivir, certain steroids, blood thinner, convalescent plasma. Operation Warp Speed officials are optimistic, they say, that more treatments will be identified or developed and in clinical trials this fall with potential for approval or authorization by the end of the year. The most promising appear to be monoclonal antibody cocktails, which have been used to prevent and treat other diseases like Ebola. Three companies are in clinical trials of antibody cocktails. Knowing there is some medicine that will help treat COVID-19 should greatly relieve the anxiety of Americans who want to go back to college, back to school, back to child care, back to work and out to eat.

Third, a third success story is the explosion of fast, cheap, reliable diagnostic tests. After initial missteps, our country lost several crucial weeks in distributing the diagnostic tests that would help to identify and isolate those who contracted the virus. But since then, an unprecedented effort of public and private research has created capacity this month for administering more than 90 million tests, about half of them rapid tests, according to Admiral Giroir, who is here today. Abbott Laboratories says that it is on track to produce 50 million of those tests—of its tests—50 million of its tests a month by October, which can produce a result in 15 minutes and cost \$5 a test.

The Government has purchased 150 million of Abbott's tests to help expand testing in places like schools and nursing homes, and

I am sure we will hear something about how that will be distributed today. Congress funded the so-called Shark Tank, or Rapid Acceleration of Diagnostics Initiative at NIH with the objective of developing and deploying tens of millions of new rapid diagnostic tests. Dr. Francis Collins, Director of NIH, has reported that combined, these new technologies have the potential to add at least 60 million new tests a month by December. Dr. Collins has told me, “this is not the end of the story. There are lots of additional technologies coming through the pipeline, many of which are rapid, inexpensive point of care and home based tests.”

Until vaccines and treatments are widely distributed, this explosion of many cheap, reliable, rapid diagnostic tests is our best weapon to build confidence among the American people that it is safe to go back to school, back to work and out to eat. There should be plenty of tests. In fact, there are now to do surveillance testing of those without symptoms in certain settings like colleges and child care centers. It is important to give credit to this Congress and this President for funding this unprecedented effort to develop and manufacture vaccines before they are all approved, knowing full well that one or all of them might fail with a considerable loss of money. Since March, Congress has appropriated more than \$47 billion for tests, treatments, and vaccines, a large amount that pales in size, though, to the \$3 trillion spent to try to ease the pain by shutting down the economy. And it is important to give credit to the previous Presidents and previous Congresses for the bipartisan work they have done over the last 20 years to make possible the remarkable successes I just described earlier.

Dr. Slowey, for example, told me that the Government today could not be manufacturing four of the vaccines that are currently being developed if Congress had not provided the Department of Health and Human Services with funding to make awards in 2012, 8 years ago, to build three manufacturing plants that would be on standby for the next epidemic. The decision to look ahead then to the next pandemic and some on this Committee, Senator Burr specifically, had a role in that. Dr. Slowey said that was visionary. On March 1, The New York Times reported that the United States is among the countries best prepared to prevent or manage such an epidemic, focused on COVID. Why would they say that on March the 1st? Well, let’s look at the NIH.

For five consecutive years, this Congress has significantly increased investment in the National Institutes of Health for Biomedical Research and NIH’s Infectious Clinical Research Consortium, which was established last year, was able rapidly to shift ongoing clinical trials and quickly enroll volunteers for COVID-19 trials and treatments and vaccines—or look at the FDA. Congress provided FDA with specific authorities beginning in 2004, 16 years ago, to review and issue emergency use authorizations for test, treatments, and vaccines to respond to public health emergencies. Dr. Hahn has used that authority. FDA has used that authority to authorize 250 tests and 5 treatments as quickly as possible, and also to remove tests and treatments when additional evidence showed they did not work as well as they should—or look at BARDA.

Congress established the Biomedical Advanced Research and Development Authority in 2006, 14 years ago, to help companies work with FDA to get safe and effective tests, treatments and vaccines out. BARDA was able to announce awards for potential COVID-19 treatment and vaccine candidates just over 1 month after the vaccine was first reported in China. As I said earlier, four of the first six vaccines are being manufactured in facilities built in 2012 for this purpose, for a future pandemic. And then there has been Federal support over the years for state, local and hospital preparedness, \$21 billion between 2002 and 2017. CDC has used existing programs to help states retrain workforces, expand lab capacity, planning for future pandemics from pandemics during the last several years. And even with supercomputing, these Congresses, the last few, have increased funding in the Department of Energy so that the United States is first in the world in supercomputing. They are in our national laboratories and they are being used to help develop treatments and vaccines.

I go through all of that to show that several Congresses and several Presidents have done things to help us get ready for this unprecedented sprint toward success in vaccines, treatments and tests. Now, finally, I would like for this Congress to be visionary as well. And while we are in the midst of this pandemic, to be ready, help get ready for the next one.

Former Senator Frist, the Majority Leader, testified before this Committee that the next pandemic is not a question of if, but when. Jared Diamond, the author of *Guns, Germs and Steel*, says the main thing that is different about this and this germ is the jet plane, that people can travel around the country and around the world and spread it. And so he concludes that the next pandemic could be next year. Congress should take stock now, while our attention is on the current crisis, of what we have learned during COVID-19 and address some of the problems we know we can solve just like previous Congresses and previous Presidents did.

Many of the witness that have appeared before this Committee have agreed we have three things to do. One, sustain onshore manufacturing of test, treatments, and vaccines. Two, create and sustain state stockpiles of supplies so they will be available in a public health emergency. And strengthen the strategic national stockpile. We have seen time and time again, attention spans are short. We must act now to stop the cycle of panic, neglect, panic.

I look forward to hearing from all of our witnesses today about how the Federal Government is continuing to respond and to help states respond, how soon we can expect more treatments and a vaccine for COVID-19, and what steps we can take now to prepare for the next pandemic. I will now recognize Senator Murray for her opening statement.

OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman. And thank you so much to our witnesses for joining us once again today. Before we begin, I do want to take a personal moment to acknowledge the passing of Justice Ginsburg, a friend, a role model,

and a woman who opened doors for all of us with her genius and her relentless pursuit of justice, freedom, and equality.

This appointment to our Nation's highest court could not be more pivotal, especially as we face down an historic public health crisis. We are in the middle of a pandemic that has cost more than 200,000 American lives on this administration's watch, has left nearly 7 million people across our country with new preexisting conditions and 5.4 million people without coverage, yet none of that has stopped Republicans from using every tool at their disposal, including the Supreme Court, to attack healthcare and protections for families across our country. I am not going to let anyone forget. Many of the same Republicans who are considering filling this vacancy with a nominee virtually guaranteed to tip the balance of the court against people's healthcare in the critical case coming up this year previously said in March 2016, the American people should have a voice in the selection of the next justice, and said many times over the past few years they support protections for pre-existing conditions.

The entire country is going to be hearing about what another Supreme Court nominee handpicked by President Trump would mean for their healthcare and their rights. Now to today's hearing. Back in January, I worked to help organize the first bipartisan briefings with the Administration officials about the COVID-19 threat. And I wrote to Secretary Azar shortly after asking what steps we were taking and specifically asking about our diagnostic testing capacity. At a hearing in February, I pressed him directly about issues with those tests and I asked him point blank if our Country was ready. Tragically, the clearest answer I got to that question did not come from the Trump administration. It came back from families in my home State of Washington, and it came as a resounding no. By March, I was hearing from people in my state who believed they had been exposed but could not get tested and who had been tested but were left waiting for results.

I was hearing from schools in my state, including my granddaughter's, that they were canceling classes and closing schools. And I was seeing nothing from the Trump administration to inspire confidence or to act with urgency. Let's be clear, we had a window to prepare for this and the Administration missed it. We had a pandemic playbook that warned against some of the very problems we were facing. They ignored it. We had a clear understanding of how dangerous this disease could be and they downplayed it. So much has changed since those early days of this crisis. Now, the number of people infected in our country has passed 6.5 million. The number of people killed passed 200,000. The number of people without a job and without health insurance has skyrocketed and businesses have been shuttered. Gatherings from weddings to birthdays to graduations to funerals have been delayed or canceled.

But one thing has not changed. President Trump is still putting politics ahead of public health. He is still downplaying this crisis and falsely claiming it will just go away or we are turning the final corner when the reality is cases and deaths are still alarmingly high. Testing and contact tracing are frustratingly inadequate. The health disparities in Black, Latino and Tribal communities and other communities of color face are still severe. And we need to

prepare for the upcoming flu season when experts warn us we could see another wave of cases. And yet, President Trump is still trying to sabotage the work of our scientists and public health experts for his own political ends.

As the leaders of health agencies on the frontline of our response to this pandemic, our witnesses have an important firsthand perspective on this interference. Dr. Hahn, the Food and Drug Administration has a critical role to play in evaluating the safety and efficacy of treatments, diagnostics and vaccines. The American people are counting on you to uphold sound, scientific principles and the work of agency specialists, scientists. So it is incredibly alarming that this administration has undermined public trust in the work of your agency by spreading conspiracies and pressuring the agency to ignore the science. Earlier this year, the Administration dangerously promoted hydroxychloroquine, an unproven treatment for COVID-19. But even more recently, the Administration pressured FDA to rush through an emergency use authorization for convalescent plasma therapy.

Last month, Secretary Azar reportedly overruled you directly and undermined FDA's authority when he loosened oversight of lab developed tests, a move that allows unreliable tests to flood the market. Then last week, Secretary Azar further undercut your agency by completely barring FDA from signing any new rules without his approval, an alarming power grab for a political appointee to make in the middle of a pandemic. Dr. Redfield, the Centers for Disease Control and Prevention plays a critical role, providing data and science based public health guidance that our families, public health professionals, researchers and health care providers rely on for life and death decisions. Yet the Trump administration has repeatedly and recklessly interfered with those efforts. We have seen the White House block and contradict critical guidance on reopening poor communities and returning to school. We have seen the President spread conspiracies about the death count and misinformation about masks. And the Trump administration officials have reportedly taken unprecedented steps to hijack the CDC's trusted voice and undermine its credibility.

The Administration ignored the objection of CDC scientists and posted guidance under CDC's name advising restricted access to testing, a move that was immediately criticized by public health experts and has since thankfully been reversed. Political appointees have demanded to oversee and manipulate the agency's morbidity and mortality weekly reports. And last week, you confirmed the Administration took hundreds of millions of dollars out of your budget for a feel good pandemic ad campaign spearheaded by a Trump official that believed CDC was part of a, "deep state conspiracy," in which CDC inexplicably has no role and which they have not even indicated will be reviewed by your agency to make sure it is based on facts and science.

If this weren't all bad enough, after your testimony before Congress last week, the President said you were, "confused," that you made a mistake and given incorrect information. All of this raises serious concerns about the agency's decision Monday to put out guidance with new information on how this virus is transmitted only to immediately reverse course and pull it down. And Dr.

Fauci, you have been a trusted voice on public health issues in this country for decades. Yet, the Trump administration officials have tried unsuccessfully to dictate talking points to you and undermine your credibility through opposition research. And in an Op-ed, the President himself even retweeted a message calling for you to be fired.

Any of these examples of political pressure would be alarming on their own, but together, they paint a clear pattern of interference that is downright terrifying. The Trump administration did not just start its political interference yesterday, and we are not going to expect them to cut it out tomorrow. So Congress has to make it stop. The President has made it painfully clear where he stands when it comes to picking between politics and science, politics and public health, politics and the safety of our country. Now, each of us has to do the same. Yesterday, Senator Schumer and I, along with over 30 of our Democratic colleagues, introduced the Science and Transparency over Politics Act. It will create a task force to conduct a thorough investigation into political interference in our public health agencies.

I do hope every Republican who has spoken out about how important it is we stick to the science will support that bill, because you cannot stand for science if you will not stand against political interference. I am also going to be asking our witnesses more about this as well because it is so critical that we know what political pressure they have been under and what is being done to resist it.

Finally, Mr. Chairman, as this may be our last hearing this Congress, I want to recognize again the work we have done together on this Committee in your time as Chairman. The list of major bipartisan bills we have gotten signed into law over the past few years, you know them, every Student Succeeds Act, 21st Century Cures Act, Opioid Crisis Response Act, Perkins CTE Reauthorization and more. The kind of bipartisan approach we used to get those bills passed is going to be critical if we are finally going to take the steps we need to take to address the pain of this pandemic, which is why the current state of discussions to pass more much needed relief is so frustrating. Republicans did not offer anything for months, and after they finally put forward a proposal, they did not even sit down with us to move toward common ground. Instead, they moved further away from us with their next proposal.

After all the success we have had on this Committee, I think we have shown by example that is just not how bipartisan negotiating works. So I am not done pushing for Republicans to come back to the table on a new COVID-19 package, put partisanship aside, put our families first and work together to respond to this pandemic with the kind of sweeping response that is so clearly needed. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray. We will now introduce our witnesses. We ask them to summarize their comments in 5 minutes each. Our first witness is Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the National Institute of Health. He has held this position since 1984, led the agency's research related to HIV, AIDS, Influenza, Malaria, Ebola and other infectious diseases.

Dr. Fauci has advised six Presidents on domestic and global health issues. He was one of the principal architects of the President's emergency plan for AIDS Relief.

Next, Dr. Robert Redfield. He is Director of the U.S. Centers for Disease Control and Prevention. For more than 30 years, he has been involved with clinical research related to chronic human viral infections and infectious diseases, especially HIV. He served as the Founding Director of the Department of Retroviral Research within the U.S. Military's HIV research program, retired after 20 years of service in U.S. Army Medical Corps.

Third witness, Admiral Brett Giroir. Admiral Giroir is the Assistant Secretary for Health in the U.S. Department of Health and Human Services. He oversees the Commission Corps of the United States Public Health Service and key public health programs. Specific to COVID-19, he has taken on testing and focused on increasing the number of tests that we can do with existing technology. His Federal service includes directing the Defense Services Office of the Defense Advanced Research Projects Agency, and several other important responsibilities.

Finally, we will hear from Dr. Steven Hahn, Commissioner of the U.S. Food and Drug Administration, the FDA. Before joining FDA, he held leadership roles as Chief Medical Executive at the University of Texas M.D. Anderson Cancer Center and is Chair of the Department of Radiation Oncology at the University of Pennsylvania. Early in his career, he was a senior investigator at the National Cancer Institute at NIH. Additionally, he held the rank of Commander in the U.S. Public Health Service Commission Corps. Welcome again to our witnesses. Dr. Fauci, let's 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. Mr. Chairman, Ranking Member Murray, Members of the Committee, thank you for giving me the opportunity to speak with you today briefly on the role of the National Institutes of Health research in addressing COVID-19. As I mentioned to this Committee in a prior hearing, the NIH and NIAID has a four part strategic plan for research to address COVID-19. The first is to improve the fundamental knowledge of the virus itself, viral biology, and the clinical manifestations resulting from infection.

We have continued to push the frontier of understanding this virus, particularly with regard to the conformational structure of the spike protein, which serves as the basis for all of the vaccines that are being pursued now, which I will get to in a moment. In addition, there have been a number of important clinical observations that we will be pursuing in the future. I bring to your attention the fact that a number of individuals who virologically have recovered from infection in fact have persistence measured in weeks to months of symptomatology that does not appear to be due to persistence of the virus. They are referred to as long haulers. They have fatigue, myalgia, fever and involvement of the neurological system, as well as cognitive abnormalities, such as the inability to concentrate.

In addition, we found to our dismay that a number of individuals who have completely recovered and apparently are asymptomatic, when they have sensitive imaging technologies such as magnetic resonance imaging or MRI, have found to have a disturbing number of individuals who have inflammation of the heart. These are the kind of things that tell us we must be humble and that we do not completely understand the nature of this illness. Next, with regard to diagnostics, we have the RADx program that is going to in the next several months, allow us to have a considerable number of point of care testing. Moving on to therapeutics, I mentioned to this Committee some time ago that the NIH put together an expert panel for treatment guidelines, which is a living document that reviews the literature, as well as the areas of expertise that are pre-publication to help clinicians throughout the world to address the clinical components of this outbreak.

I must tell you that as of last night, there have been 4.5 million views of these treatment guidelines so it clearly is helping people throughout the world. I want to mention two of the drugs that have actually now—be part of these guidelines. Remdesivir, which you have heard about, has been shown in a randomized placebo controlled trial to diminish the time to recovery in individuals who are hospitalized who have lung disease. In addition, dexamethasone, a commonly used steroid, has been shown in a randomized placebo controlled trial involving more than 6,000 individuals, has been shown to clearly and significantly reduce the 28 day mortality.

In addition, there are a number of other treatments, including antiviral convalescent plasma, which is still being tested in randomized controlled trials. And you mentioned appropriately and correctly that we feel optimistic about monoclonal antibodies, which are currently being tested in an outpatient setting, in an inpatient setting, family prophylaxis, which means when an individual in a given family gets infected. If you give monoclonal antibodies to the rest of the family, can you prevent the spread within the family unit? And finally, nursing home prophylaxis. As you mentioned, there are three companies involved in this.

Finally and importantly, the issue of vaccine. We have put together what is called a strategic approach to COVID vaccine development. As you mentioned, Mr. Chairman, there are six companies that the Federal Government is playing a role in either helping to develop, subsidizing or supporting the clinical trials. We are harmonizing the trials so that information from one can be applicable to another. Currently, there are three platform candidate vaccines that have entered into phase 3 trial. Very soon there will be a fourth. As I mentioned to this Committee, we feel cautiously optimistic that we will be able to have a safe and effective vaccine, although there is never a guarantee of that. Early studies in animals and in human, phase 1 and phase 2, indicate that individuals induce a response that is comparable to, if not better than natural infection.

As these trials go on, we predict that sometime by the end of this year, let's say November or December, we will know whether or not these are safe and effective. And as you mentioned, Mr. Chairman, right now, doses of this vaccine are being produced so that they will be ready to be distributed.

I will close with the comment that we feel strongly that if we have a combination of adherence to the public health measures together with a vaccine that will be distributed to people in this country and worldwide, we may be able to turn around this terrible pandemic that which we have been experiencing. Thank you, Mr. Chairman. Happy to answer questions later.

[Prepared statement of U.S. Department of Health and Human Services:]

PREPARED STATEMENT OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

Chairman Alexander, Ranking Member Murray and distinguished Members of 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 offices 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. Congress passed 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 Food and Drug Administration (FDA), and the Assistant Secretary for Health, 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 prevent illness, save lives and protect America from health, safety, and security threats. CDC has a key role in preparedness and response in the United States and abroad, and addressing infectious diseases like COVID-19 is central to our mission.

When there is an emerging pathogen like the SARS-CoV-2 virus, CDC expertise lies in our ability to study the new pathogen to understand how it is transmitted, and translate that knowledge into public health action. Since first learning of the cluster of cases in Wuhan, China, CDC has rapidly advanced the science around this new human pathogen, SARS-CoV-2. CDC has been both on the forefront of understanding this new disease and led the Nation's efforts to protect Americans from infection. Currently, over 6,700 CDC employees have been engaged in the agency's COVID-19 response, and over 1,200 of these staff have been deployed to nearly 200 different locations in the United States and abroad. CDC staff have conducted rapid investigations of outbreaks that identified highest-risk priority populations and settings. Understanding specific population-level vulnerabilities and how infections spread in various types of settings has been instrumental in the development of guidance that will help keep the American people healthy and allow critical infrastructure services to be provided safely. For example, after data emerged that contrary to expectation, SARS-CoV-2 could be transmitted by people without symptoms, CDC recommended that people wear masks around others who do not live in their households, especially in settings where it is difficult to maintain a distance

of six feet. There is increasing evidence that masks help prevent people who have COVID-19, including those without symptoms, from spreading SARS-CoV-2 to others.

The *Morbidity and Mortality Weekly Report* (MMWR), sometimes called the “voice of CDC,” has published more than 100 COVID-19 reports since the beginning of the pandemic, providing cutting-edge scientific articles that have been viewed by tens of millions of readers. These reports have provided the public, scientists, healthcare workers, and policymakers critical information about the virus, how it spreads, and the communities it has impacted. MMWR publications yielded the earliest descriptions of asymptomatic and pre-symptomatic transmission of the virus and elucidated the substantial risk of transmission at large gatherings, choir practices, and congregate living situations, including nursing homes, prisons and jails, meat processing plants, homeless shelters, and camps for children. They have described the disparate impact of COVID-19 in racial and ethnic minorities and identified the elevated risk of severe outcomes for older adults and people with underlying conditions. Finally, the MMWR has indicated what successful control of the virus looks like, through careful mitigation efforts in everyday high-risk settings such as hair salons and childcare centers. In short, MMWR’s rapid publication of the highest quality science has laid the foundation of what we know about COVID-19 and illuminated the way forward.

In addition to publishing our own scientific information on SARS-CoV-2 and COVID-19, CDC scientists are monitoring in real time the rapidly expanding scientific literature and have reviewed over 100,000 scientific papers thus far. This ensures that CDC responders are armed with the best information available. This comprehensive understanding of the emerging science base helps direct CDC’s scientific agenda and informs CDC guidance, and helps guide CDC’s direct support of clinicians and the public. Since January 20, 2020, CDC’s hotline for public inquiries has responded to nearly 500,000 calls and e-mails, including 32,000 from clinicians.

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 carry out research and share new knowledge related to this novel pathogen and its consequences. CDC provides guidance for healthcare professionals, essential workers, businesses, schools, and the public to encourage safer practices, improve health outcomes, and save lives. CDC works with partners to develop decision tools to assist STLT officials and other stakeholders with mitigation strategies. Importantly, CDC is preparing the Nation’s public health system and the private sector to disseminate a safe and effective vaccine when one is available. CDC is leveraging investments in global health security and pandemic influenza preparedness infrastructures in over 60 countries to mitigate the effects of COVID-19 and stop the disease from spreading.

As of September 20, 2020, there have been 6,748,935 COVID-19 cases reported and 198,754 deaths attributed to the virus in the United States. The latest data can be found on CDC’s website: <https://www.cdc.gov/covid-data-tracker/index.html>. The U.S. Government has taken unprecedented action to address the public health threat posed by this new coronavirus. CDC has substantial supplemental funding to help respond to this pandemic at home and abroad. This funding supports a federally guided, STLT government managed, and locally implemented response to COVID-19 in the United States.

With funds provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act and the CARES Act, CDC is providing jurisdictions with resources needed to detect, respond, and prevent the spread of SARS-CoV-2 and to inform community mitigation strategies.

CDC’s highest priority is to ensure that STLT public health programs have the resources they need to address the COVID-19 pandemic. These jurisdictions are best positioned to understand the unique situation of each community, including the status of their public health infrastructure and workforce and its needs for enhancement. CDC is supporting STLT partners who are working to identify cases; conduct contact tracing; implement containment measures and mitigate spread of the virus in the community. CDC is working alongside these health departments to improve surveillance and reporting and enhance testing capacity. Together, STLT and CDC teams are responding to COVID-19 outbreaks in high-risk settings and implementing best practices to control the spread of the virus.

As a public health agency and the Nation’s primary resource for STLT health departments on managing disease outbreaks, CDC provides guidance and support for the development and implementation of effective containment and community miti-

gation strategies. The goal is for all jurisdictions to have robust public health systems, which include a contact tracing infrastructure that meets their unique needs. As of September 2020, CDC has posted over 30 contact tracing 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. To support these activities, CDC has awarded \$12.1 billion to these entities in fiscal year 2020, including \$10.25 billion in funds executed on behalf of HHS to be used primarily to support each jurisdiction's testing goals (as outlined in state testing plans).

Testing Strategy

Beginning in April, the White House, and Federal partners including CDC, convened calls with all 50 states, Puerto Rico, and the District of Columbia to identify testing capacities and needs. Through these calls and other outreach efforts, CDC, under the leadership of the Office of the Assistant Secretary for Health (OASH), has worked with individual jurisdictions to identify needs, develop plans, and offer technical assistance to enhance testing capacity. From June 30 to July 17, following an initial review by CDC and OASH, the Association of Public Health Laboratories (APHL) reviewed individual state testing plans with a focus on achieving increased monthly testing targets. These discussions and plans for action emphasize the need to serve disproportionately affected populations and include focused efforts for long-term care facilities, federally qualified health centers, American Indian/Alaska Native serving health facilities, and urban health facilities, among others.

CDC is working with STLT health departments to support forward-looking testing strategies that ensure that populations at higher risk, such as persons of color, have adequate access to testing. For example, CDC worked with the Health Resources and Services Administration (HRSA) and federally Qualified Health Centers (FQHCs) to survey FQHCs and better understand the populations they are serving. Approximately 60 percent of responding FQHCs are in urban areas, where persons of Hispanic or Latino ethnicity were the largest proportion of individuals testing positive for SARS-CoV-2. This information allows STLT health departments to implement strategies to increase testing in FQHCs and provide them with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

CDC has developed a new multiplex 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, using a single sample collected from an individual. Testing for all three viruses will allow public health laboratories to continue surveillance for influenza while testing for SARS-CoV-2. 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. The FDA issued an Emergency Use Authorization (EUA) for this combined laboratory test on July 2, 2020, and CDC released these reagents for distribution to states' public health laboratories on August 5, 2020. As of August 17, 2020, 135 multiplex kits were shipped to more than 100 laboratories. Each kit provides approximately 500 tests. Adjusting for the controls, 135 kits provides approximately 67,000 tests. CDC has provided these kits to each state's or territory's main public health laboratory, as well as any regional or local laboratories that are approved to provide SARS-CoV-2 surge testing support. Importantly, multiplex assay technical information is publicly available on CDC's website so that commercial developers can use this information in developing proprietary tests. CDC also granted assay manufacturers a right of reference to the data submitted in its EUA request to FDA, allowing developers to use the data to streamline their efforts when requesting an EUA. CDC took these steps to catalyze the development and validation of assays that can detect and differentiate SARS-CoV-2 from influenza by the commercial sector.

In March 2020, CDC and public health partners began seroprevalence surveys of community transmission of SARS-CoV-2. Seroprevalence surveys help identify infections that might be missed due to lack of symptoms or testing not being performed. Serology studies can also help determine risk factors associated with SARS-CoV-2 infection, including transmission in health care settings, and inform guidance and mitigation strategies. For example, CDC has published the results from one of the seroprevalence studies that used remnants of samples collected during routine clinical care. This was done in conjunction with two commercial companies and results suggested that greater than 10 times more SARS-CoV-2 infections occurred than the number of reported COVID-19 cases. Another study on healthcare personnel who routinely cared for COVID-19 patients found that 6 percent had evidence of previous SARS-CoV-2 infection. This study identified two factors poten-

tially associated with SARS-CoV-2 infection among health care personnel: personal protective equipment (PPE) shortages and not wearing a mask while interacting with patients.

Data Collection, Analysis and Understanding of the Pandemic

CDC, in concert with HHS, continues to focus on data modernization efforts including expanding core data, informatics, and IT capacity; advancing interoperable systems and tools; strengthening and expanding collaboration with and support for partners and; coordinating data and IT investments and governance.

Accurate data are critical as we continue to assess the burden placed on the American healthcare system to inform reopening. CDC is leveraging all available surveillance systems, including influenza and viral respiratory disease systems, to monitor COVID-19 and protect disproportionately affected communities. These data collected by CDC help target critical COVID-19 interventions. In collaboration with STLT public health partners, CDC is committed to making data available to the public, while protecting individual privacy.

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. 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. Modernization efforts include support for the surveillance and data workforce, a key asset of the public health system. For example, CDC is working closely with our partners to help STLT health departments implement the Sara Alert system. Sara Alert is a standards-based, open source tool that automates the process of public health monitoring and reporting individuals exposed to, or infected with, COVID-19. To date, nine states and two territories, along with eight counties and one Tribal Council, have adopted the Sara Alert system. Almost 350,000 individuals have been monitored since April 8. During an average week, close to 80,000 individuals roll in and roll back off of monitoring through Sara Alert.

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 provide weekly estimates for age-specific hospitalization rates and describe characteristics of persons hospitalized with COVID-19 illness as well as predictors of those with more severe outcomes. CDC's existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and other long-term care facilities. NHSN also continues to collect data from hospitals across the United States to address healthcare-associated infections and fight against antibiotic resistance.

The COVID-19 Case Report Form includes variables such as race and ethnicity to enable identification of populations that may be at higher risk for severe illness and risk factors. Though states are not required to report demographic information in the Case Report Form, they have improved the completeness of their reporting. In particular, the percentage of reports that include race data has increased from 21 percent in April to 63 percent in mid-September, while the percentage of reports that include ethnicity data increased from 18 percent to 52 percent during the same time period. While progress has been made, CDC will continue to work with states, tribes, territories, and other health system partners to improve completeness of the data.

Health Disparities

COVID-19 has disproportionately impacted many racial and ethnic groups. CDC continuously looks to enhance our COVID-19 outreach and mitigation efforts for communities identified as highest risk. For example, CDC is supporting local activities in Black and African American, Hispanic/Latino, American Indian and Alaska Native, and Asian American, Pacific Islander, and Native Hawaiian communities to deliver COVID-19 prevention messages and community mitigation strategies. CDC recently released a COVID-19 Health Equity Strategy (www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html) that provides an evidence-based, comprehensive and coordinated framework for reducing COVID-19 disparities. The Strategy includes expanded plans for collecting and reporting timely, complete, representative, and relevant data on testing, incidence, vaccination, and severe outcomes among populations at highest risk. Additionally, CDC is working with existing program grantees, such as Racial and Ethnic Approaches to Community Health (REACH), and tribal grantees through a number of programs, to enhance outreach to populations at increased risk of complications from COVID-19. These

broad-based community engagements and strategies are working with the aim of ensuring equitable access to testing, health care, and future COVID-19 vaccines.

American Indian and Alaska Native communities are some of the most affected by COVID-19. As of August 2020, CDC has provided \$206.4 million to tribal nations, consortia, and organizations for responding to COVID-19 across tribal communities. This amount exceeds the minimum of \$165 million directed by Congress through the Coronavirus Preparedness and Response Supplemental Appropriations Act and the CARES Act. CDC is using a multifaceted approach, guided by data, to allocate COVID-19 funding to tribal communities, enabling broad access to COVID-19 resources through a variety of direct and indirect supports.

Children

We are learning more about how COVID-19 impacts children every day. Although children are less likely than adults to develop severe illness when infected with SARS-CoV-2, household studies and outbreak investigations confirm that children can transmit the virus and often have the same or higher viral loads in their nasopharynx compared with adults. Though the mortality rate is low for children aged 18 years and younger, COVID-19—associated hospitalization rates increased among this age group during the summer. From March 1, 2020 to July 25, 2020, one in three hospitalized children was admitted to an intensive care unit.

CDC is committed to providing schools, teachers, staff, parents, and caregivers with information and guidance to help keep our children as safe and healthy as possible as schools reopen. CDC has developed enhanced guidance based on the most recent science, including considerations for operating schools during COVID-19, considerations for Institutions of Higher Education regarding the appropriate use of testing, and a school decisionmaking tool for parents, guardians, and caregivers. These resources provide students, school administrators, and parents the information they need to guide decisionmaking and how to adapt to local conditions.

Vaccine Planning

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 a safe and effective COVID-19 vaccine once available. CDC is working closely with the Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts who develop recommendations on the use of vaccines to control disease in the United States. ACIP members have expertise in areas such as vaccinology, immunology, internal medicine, family medicine, virology, public health, infectious diseases, and/or preventive medicine, and one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. An August ACIP meeting focused on post-marketing vaccine safety surveillance, epidemiology of individuals at increased risk of COVID-19, and modeling allocation strategies of the initial COVID-19 vaccine supply. Any recommendations ACIP makes and CDC adopts for who should get COVID-19 vaccine and in what order will be grounded in guidance from the country's foremost experts on immunization science.

CDC is using its expertise in public health preparedness and response, along with its immunization infrastructure, to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring. On September 10, CDC and its Operation Warp Speed partners conducted a vaccine implementation tabletop exercise in Washington, DC. The exercise walked through end to end stages of vaccine implementation for different scenarios.

CDC is working closely with state, local and tribal health departments and community organizations to prepare a detailed yet flexible plan for vaccine distribution that will be informed by a prioritization framework recommended by ACIP and adopted by the CDC Director. These efforts include 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. State and local health departments have conducted pandemic vaccination planning with immunization and preparedness funding from CDC for over a decade. Updating these vaccination response plans for implementation of COVID-19 vaccines will build readiness for timely administration when a vaccine becomes available. During August 2020, CDC completed in-person and virtual site visits to assess needs as vaccine planning intensifies. Lessons learned during these site visits will inform CDC's provision of technical assistance to all jurisdictions to aid in the development of state-specific COVID-19 vaccination plans.

In addition, some state and local health departments utilized supplemental resources to build infrastructure that would address current COVID-19 response

needs and incorporated planning for future phases. One example is in Chicago, where the health department has developed the Chi COVID Coach app to communicate directly with Chicago's residents who may be COVID-19 positive. The forward-thinking app, built by private sector companies, can be adapted throughout the course of the pandemic. It now allows users to register to receive a vaccine once they become available.

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 and beyond. Circulation of SARS-CoV-2 and influenza virus at the same time could place a tremendous burden on the health care system. Therefore, getting a seasonal flu vaccine is especially important. It is important that Americans have confidence in all vaccines. CDC will leverage its immunization program to help maintain high coverage in routine childhood immunizations, to increase coverage for flu vaccinations, and prepare for a potential COVID-19 vaccine.

CDC works with public health and clinical partners each year to increase the number of people who get a flu vaccine and eliminate barriers to vaccination. Ongoing COVID-19 activity may affect where and how flu vaccines are given. On June 4, CDC awarded \$140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to launch a scale up for influenza season, given the increased risk of COVID-19. Funds are supporting staffing and preparedness with a focus on ensuring flu vaccine coverage for populations most at risk.

Conclusion

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 defeat COVID-19. 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, now and in the future.

National Institute of Allergy and Infectious Diseases

The National Institutes of Health (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 and Monoclonal Antibodies to Prevent SARS-CoV-2 Infection and/or COVID-19

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 recently established the COVID-19 Prevention Network (CoVPN) by leveraging four existing NIAID-funded clinical trials networks: the HIV Vaccine Trials Network (HVTN), the HIV Prevention Trials Network (HPTN), the Infectious Diseases Clinical Research Consortium (IDCRC), and the AIDS Clinical Trials Group (ACTG), in partnership with the Department of Defense (DOD). The CoVPN aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from SARS-CoV-2 infection and/or COVID-19. The CoVPN is a functional unit of "Operation Warp Speed" (OWS), a public-private partnership led by HHS to invest

in and coordinate the development, manufacture, and distribution of safe and effective COVID-19 vaccines, therapeutics, and diagnostics. The CoVPN is participating in harmonized protocols developed in collaboration with the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, vaccine manufacturers, and Biomedical Advanced Research and Development Authority (BARDA). The network is participating in numerous trials at more than 100 clinical trial sites across the United States and internationally. The CoVPN has developed an extensive community engagement framework to reach out to the diverse communities most affected by COVID-19; to understand their interest in, and concerns about, research participation; and to partner with them to ensure their input is reflected in study implementation.

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. On July 14, 2020, interim findings from the Phase 1 clinical trial were published in the *New England Journal of Medicine*. The investigational mRNA-1273 vaccine was generally well tolerated and induced robust neutralizing antibody responses in healthy adults in this interim analysis of data from the ongoing trial. This trial also enrolled older adults, and Moderna recently presented encouraging interim safety and immunogenicity data that suggested the immune responses in older adults were consistent with those reported in younger adults. On May 29, 2020, a Phase 2 clinical trial, sponsored by Moderna, was initiated to further study the safety and immune responses to the experimental mRNA vaccine. On July 8, 2020, Moderna announced that the Phase 2 trial was fully enrolled, with one cohort of younger adults and a separate cohort of older adults. NIAID and BARDA are working with Moderna on a Phase 3 clinical trial with the CoVPN that launched on July 27, 2020. The vaccine efficacy trial was the first to be initiated under OWS. 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.

On August 31, 2020, NIAID announced the launch of a Phase 3 clinical trial with AstraZeneca of the AZD1222 COVID-19 vaccine candidate, which uses a chimpanzee adenovirus-vectored vaccine approach developed by researchers at the University of Oxford in collaboration with scientists at NIAID's Rocky Mountain Laboratories in Hamilton, Montana. On September 8, 2020, AstraZeneca paused enrollment in this and other studies of its candidate vaccine to allow for the review of safety data following a serious adverse event in a single trial participant in the United Kingdom. This pause is consistent with standard practice for such events and is a sign that safeguards for volunteers are robust. The U.S. trial will resume when the independent Data and Safety Monitoring Board overseeing the trial and the FDA determine that it is safe to proceed. This event and subsequent review exemplify how OWS is working with industry partners to ensure the safety of COVID-19 vaccine candidates.

NIAID expects to announce the launch of an OWS-supported Phase 3 clinical trial with the CoVPN for the Janssen-developed Ad26-vectored vaccine candidate shortly. Along with the Pfizer-supported study of its mRNA vaccine candidate (developed with BioNTech), four candidate COVID-19 vaccines will have entered Phase 3 clinical trials in the United States. An OWS-supported Phase 3 study with the CoVPN for the Novavax, Inc., candidate vaccine, an adjuvanted recombinant protein vaccine, is expected to begin in October 2020.

The rigorous clinical testing required to establish vaccine safety and efficacy means that it might take some time for an FDA-licensed COVID-19 vaccine to be available to the general public, but there is growing optimism that one or more of these vaccine candidates will prove safe and effective by late 2020 or early 2021.

In addition to vaccine candidates, the CoVPN is evaluating monoclonal antibodies directed against SARS-CoV-2 as tools to prevent transmission and spread. On August 10, 2020, NIAID scientists, collaborating with Regeneron Pharmaceuticals, initiated a Phase 3 clinical trial to evaluate the investigational monoclonal antibody combination known as REGN-COV-2. The trial will enroll approximately 2,000 volunteers to determine whether REGN-COV-2 can prevent infection or disease symptoms in asymptomatic adults who are household contacts of persons with SARS-CoV-2 infection. In addition, NIAID scientists are collaborating with Eli Lilly and Company in conducting a Phase 3 clinical trial of the monoclonal antibody LY-

CoV555 to prevent SARS-CoV-2 infection in people at high risk of exposure due to living or working in skilled nursing or assisted living facilities.

Identifying Therapeutics to Treat COVID-19

Safe and effective therapeutics for COVID-19 are 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 investigational therapeutics for COVID-19, initially examining the antiviral drug remdesivir for treatment of severe COVID-19 in hospitalized adults (ACTT-1). An analysis of preliminary data from 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*. The adaptive design of ACTT has enabled the evaluation over time of additional promising therapies, such as the anti-inflammatory drug baricitinib. This drug was added to the second iteration of the study (ACTT-2); enrollment for ACTT-2 is now complete. On September 14, 2020, Eli Lilly and Company and Incyte announced the preliminary finding that ACTT-2 participants receiving baricitinib in combination with remdesivir showed a modest benefit in recovery time versus those treated with remdesivir alone. On August 5, 2020, NIAID launched a clinical trial to evaluate the use of interferon beta-1a, which is used to treat individuals with multiple sclerosis, in combination with remdesivir in the third iteration of the study (ACTT-3).

In addition to the prevention studies described above, monoclonal antibodies also are a promising approach for the *treatment* of COVID-19. On August 20, 2020, NIH and OWS convened a scientific summit to explore the current scientific evidence and future opportunities for monoclonal antibodies that neutralize SARS-CoV-2 as possible treatments for COVID-19. On August 4, 2020, as part of the ACTIV partnership and in collaboration with other NIH Institutes, NIAID launched two OWS-supported studies, ACTIV-2 and ACTIV-3, to evaluate the use of the monoclonal antibody LY-CoV555 to treat COVID-19 in outpatient and hospitalized settings, respectively. The ACTIV-2 and ACTIV-3 clinical trials utilize master protocols that allow for inclusion of additional investigational therapeutics as the trials continue. NIAID also is planning separate clinical trials to assess hyperimmune intravenous immunoglobulin for treatment of COVID-19 in both outpatients and hospitalized adults.

The National Heart, Lung, and Blood Institute (NHLBI) has established the Collaborating Network of Networks for Evaluating COVID-19 and Therapeutic Strategies (CONNECTS) to better understand the impact of COVID-19 on the heart, lungs, blood, and blood vessels, and to identify therapies that will slow or halt disease progression and speed recovery. CONNECTS will leverage existing NIH-funded clinical trial networks to conduct adaptive trials, in which researchers can test a variety of interventions simultaneously, easily share their data, and quickly identify the most promising treatments. CONNECTS also will bring together ongoing NIH-funded epidemiological cohort studies to examine the characteristics of individuals who do and do not develop SARS-CoV-2 infection and to help shed light on who is at risk for developing severe illness due to COVID-19. This knowledge will identify risk factors, inform strategies for primary and secondary prevention, and suggest biomarkers of infection and adverse outcomes. It also will inform us about the natural history and long-term consequences of the disease. Among the first trials to be conducted through CONNECTS, and as part of the ACTIV initiative, on September 10, 2020, NHLBI launched two adaptive Phase 3 clinical trials evaluating the safety and effectiveness of varying types of blood thinners (antithrombotics) to treat adults diagnosed with COVID-19. Researchers have noted that many patients who died from COVID-19 had formed blood clots throughout their bodies, including in their smallest blood vessels. This unusual clotting (thrombosis) has caused multiple health complications, from organ damage to heart attack and stroke. Collectively known as ACTIV-4 Antithrombotics, the trials will provide critical insights to help guide the care of patients with COVID-19, hoping to prevent life-threatening blood clots that occur in many COVID-19 patients. The trials will be conducted at more than 100 sites around the world; one trial focuses on hospitalized COVID-19 patients and the other focuses on outpatients. A third clinical trial to start later will focus on recovering patients discharged after hospitalization for moderate to severe COVID-19.

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, NHLBI, NCATS, the National Cancer Institute (NCI), 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 has established the COVID-19 Treatment Guidelines Panel, comprised of representatives of NIH and five other Federal agencies along with representatives of nine professional organizations, academic experts, and treating physicians including providers from high COVID-19 incidence areas, and community representatives. On April 21, 2020, the panel issued the initial iteration of the COVID-19 treatment guidelines for clinicians. The guidelines provide recommendations regarding specific treatments and address considerations for special populations, including pregnant women and children. Based on a randomized controlled trial of the antiviral drug remdesivir compared to placebo, the Panel updated these treatment guidelines to recommend remdesivir for the treatment of COVID-19 in hospitalized patients who require supplemental oxygen with the caveat that due to insufficient data, the panel could not recommend for or against the use of remdesivir for those patients who require oxygen delivery through a high-flow device, noninvasive, ventilation, invasive mechanical ventilation, or ECMO. On June 25, 2020, based on a preliminary analysis of the data from the *Randomised Evaluation of COVID-19 Therapy* (RECOVERY) study sponsored by the University of Oxford, the treatment guidelines were updated again to recommend the glucocorticoid dexamethasone for the treatment of COVID-19 in hospitalized patients with severe disease requiring supplemental oxygen, including those on high flow oxygen or mechanical ventilation. Recently the treatment guidelines were updated to emphasize that potentially effective treatments for COVID-19 not be withheld from pregnant women. The guidelines are updated regularly as new evidence emerges.

In addition, the Pediatric Trials Network, funded by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), has incorporated testing of 12 drugs in its ongoing clinical trials that may prove helpful specifically for treating children with COVID-19 and/or multisystem inflammatory syndrome in children (MIS-C).

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 drive the development of new products by fall 2020. This \$500 million initiative supports 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. To date, NIH has awarded more than \$370 million in Phase 2 contracts to 16 organizations for technology validation, clinical studies, scale-up, and manufacturing. These funds, combined with additional pending projects in the RADx pipeline, are projected to produce millions of new tests per day for a total of more than 6.5 million tests per day by the end of the year. 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.

The RADx Underserved Populations (RADx-UP) initiative will augment the reach and power of technologies developed and enhanced through RADx by identifying and addressing implementation factors that present barriers to testing and follow-up in vulnerable populations. On June 12, 2020, NIH announced four new funding opportunities for community-engaged projects within RADx-UP. The goal of this is to better understand factors that have led to a disproportionate burden of the pandemic on underserved and vulnerable populations so that interventions can be imple-

mented to decrease these disparities. Awards are expected to be made in late September or early October 2020.

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 establishment of registries of tested subjects for seroprotection studies.

NIAID, NCI, and NHLBI, along with scientists from CDC, BARDA, FDA and DOD, convened the COVID-19 Serology Studies workshop to bring together over 300 scientists and clinicians from the Federal Government, industry, and academia on May 7, 2020. Participants discussed the role of serology testing in understanding and responding to the COVID-19 public health crisis and explored strategies to address key scientific opportunities and knowledge gaps in this emerging field. On July 14, 2020, a report of the conclusions and recommendations from the workshop was published in the journal *Immunity*. The group recommended that additional research is needed to determine whether, and to what extent, a positive antibody test means a person may be protected from reinfection with SARS-CoV-2. Additional research also is needed to determine the duration of protection. They also emphasized that serology tests should not be used as a stand-alone tool to make decisions about personal safety related to SARS-CoV-2 exposure until additional information about SARS-CoV-2 immunity is available.

NIAID, NCI, NCATS, and NIBIB also are partnering on a 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. Public interest in participating was extremely robust and recruitment was significantly expanded by leveraging the NCATS Clinical and Translational Science Awards (CTSA) program. Enrollment is now complete. 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 a data base that is collecting data on the prevalence and spectrum of neurological symptoms observed in patients with SARS-CoV-2 infection. NHLBI and NICHD are leading a trans-NIH effort, with participation from NIAID, to coordinate research into MIS-C, an extremely serious inflammatory condition that has been associated with SARS-CoV-2 infection in children and adolescents. This centralized effort will permit data to be shared across studies to determine the spectrum of illness in children and predict the long-term consequences of infection.

To improve participation of minority communities in research on vaccines and therapeutics for COVID-19, NIH established the Community Engagement Alliance Against COVID-19 Disparities (CEAL) initiative led by NHLBI and the National Institute on Minority Health and Health Disparities. The initiative is bringing together community leaders to act as “champions” to share information with their communities about COVID-19 research, how to participate, and the importance of having diverse participants who represent all people in need of vaccines and treatments. NIH intramural and NIH-funded extramural researchers are helping to provide authoritative, expert information that champions can tailor to their communities. Together, these champions and researchers are leading CEAL research teams in African American, Hispanic or Latino, and Native American communities that are hardest hit by COVID-19 to provide timely, accurate information about COVID-19 prevention and treatment, and to ensure that COVID-19 clinical studies include appropriate representation of the racial and ethnic minority populations that have been disproportionately affected by the pandemic.

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 (Added 9/11)

Diagnostics and Testing

Testing is an essential component of the public health response to SARS-CoV-2 (the virus that causes COVID-19). It enables clinical decisionmaking, informs resource allocation and disease prevalence monitoring, and is necessary to minimize community and economic disruption through targeted infection prevention and control measures. The indications for viral testing depend on the stage of the pandemic and the extent of community spread. In general, testing is indicated for diagnosis of those who are symptomatic or asymptomatic, tracing of those in contact with those who are infected, screening of specific employees (for example nursing home staff), and surveillance testing of those who are asymptomatic to achieve infection control and/or other public health objectives.

Repeated testing of a majority of the U.S. population is not feasible at this time, nor necessary to ensure a safe return to work, school, and other activities. Rather, a targeted testing strategy that rapidly diagnoses those who are ill, protects the vulnerable, and identifies emerging outbreak areas—when combined with public health mitigation measures like mask wearing—is proven to reduce the spread and flatten the curve.

To date, the United States has realized over 95 million tests, at an average current rate of between 700,000–800,000 tests per day, with enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. In June, July, and August, states far surpassed their goals for testing. Specifically, state goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, states far exceeded their goals by conducting over 25 million tests. In August the Nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. Over the next several months, the Nation's testing capacity will continue to increase. We anticipate that supplies and reagents will be sufficient to conduct approximately 90 million tests in September. If pooling of specimens from different individuals occurs today even for a fraction of these tests, there is capacity to perform more than 100 million tests per month. Pooling allows for more people to be tested at once in a “batch”, using fewer testing resources. Turn-around time in providing test results continues to improve. Currently, 97 percent of American Clinical Laboratory Association tests ordered in the previous week received results within 3 days, and 99 percent received results within 5 days.

The role of the Federal Government is to set the overall testing strategy and requirements, provide technical guidance, secure the supply chain, scale scarce resources, enable innovation, and support state plans to achieve the overall national objectives as well as any specific state objectives. States, territories, and tribes are responsible for formulating and implementing testing plans that meet national objectives and additional goals for their state. The academic, commercial, and private sectors will continue to develop and produce technologies, supplies, and services to meet the needs of the states and the Nation at large.

The national strategy for testing was formally outlined in the *Testing Blueprint: Opening Up America Again*, and the *Addendum to the Testing Blueprint*. The immediate objectives of the strategy are to:

- Identify newly emergent outbreaks
- Support public health isolation and contact tracing
- Diagnose COVID-19 rapidly in hospitalized patients
- Protect the vulnerable
- Support safe reopening of schools and businesses
- Enable state testing plans

The national strategy for testing was further enumerated in the COVID-19 Strategic Testing Plan Report to Congress initially submitted to Congress on May 24th. On August 22nd, HHS submitted the first update to the Strategic Testing Plan. The report outlines how HHS increased domestic testing capacity across the United States and provides additional guidance and information about diagnostic tech-

nologies, platforms and inventory that states, territories and tribes can utilize to develop flexible, adaptable, and robust COVID-19 testing plans.

Identifying Newly Emergent Outbreaks

In addition to public health surveillance systems monitored by the CDC, the Nation is currently maintaining sufficient baseline testing for SARS-CoV-2 in order to detect early changes in percent positivity. At present, a minimum target of testing 2 percent of a state's population per month has been sufficient to detect early changes in percent positivity, and thus enable state and local officials—with the technical assistance of the Federal team—to implement mitigation steps rapidly to curb the emerging outbreak.

In order to ensure that states meet this 2 percent threshold to detect any threat of emergence in that state, the Federal Government will continue to:

- Assist states with the procurement of collection supplies to achieve a minimum of 2 percent population testing per month; and if possible, provide more supplies if needed to meet the approved state plan targets. To date, the Federal Government has procured and delivered 95 million swabs and 77 million tubes of media;
- Ensure sufficient supply of reagents to achieve testing goals in the context of point of care utilization and use of commercial referral labs;
- Prioritize states with outbreaks or potential outbreaks, if needed, and;
- Continue to expand the availability and use of point of care tests.

Support Public Health Isolation and Contact Tracing

A key function of testing is to support identification of SARS-CoV-2 of infected individuals, many of whom may be asymptomatic, in communities identified with outbreaks or emerging outbreaks. In response to “hotspot areas”, the Federal Government has set up surge testing to increase baseline testing 2X–5X for short periods of time. Surge testing sites have been implemented in Miami, FL; Jacksonville, FL; Edinburg, TX; Yuma County, AZ; Pima County, AZ; Coconino, AZ; Phoenix, AZ; Atlanta, GA; Birmingham, AL; Cochise County, AZ; Mohave County, AZ; Yavapai County, AZ; Baton Rouge, LA; New Orleans, LA; Bakersfield, CA; Houston, TX; Harris County, TX; Clark County, NV; and Honolulu, HI, and these 19 sites have conducted approximately 290,000 tests. Surge testing is a supportive adjunctive activity; it cannot substitute for disciplined adherence to mitigation measures including masking, hygiene, social distancing, avoidance of indoor crowded areas and crowds, and protection of the vulnerable. These mitigation techniques, when combined with selective surge testing, have proven highly effective in reversing recent community outbreaks.

In order to support public health isolation and contact tracing, and to reduce turnaround time, the Federal Government has:

- Provided massive surge testing to localities prioritized by the White House Coronavirus Taskforce, and agreed to by state and local officials;
- Augmented testing, both baseline and surge, for FQHCs and retail sites;
- Supported local testing efforts with surges of collection supplies and reagents;
- Worked collaboratively to validate and promote EUAs for pooling across all laboratory platforms;
- Worked collaboratively to validate and promote EUAs for new extraction methods to increase productivity;
- Invested in new testing technologies that improve sensitivity, specificity, and/or turnaround time, including new point-of-care tests, and;
- Provided point-of-care testing to all nursing homes in America.

Diagnose COVID-19 Rapidly in Hospitalized Patients

Because there are now treatments authorized by the FDA for hospitalized patients with COVID-19, including remdesivir, convalescent plasma, and steroids, it is critical to diagnose patients as soon as possible. Currently, large commercial labs are prioritizing inpatient samples to ensure diagnosis within 24–36 hours. Our best information also suggests that the great majority of individual hospitals are able to meet this timeframe for patients within their hospital systems.

Protect the Vulnerable

The elderly, particularly those in nursing homes, are much more likely to suffer serious consequences, including death, from COVID-19. In addition to the elderly, racial and ethnic minorities are also disproportionately affected.

To ensure that specimens are collected without overburdening the traditional health care system, and to ensure testing in the most vulnerable communities, in mid-March, the Federal Government established Community-Based Testing Sites (CBTS) in White House Task Force on Coronavirus-prioritized locations across the country based on CDC data. The CBTS model was developed for states, local public health agencies, healthcare systems, and commercial partners as they work together to stop the spread of COVID-19 in their communities, focusing initially on healthcare facility workers and first responders. The CBTS federally supported, state managed, locally executed model has been a profound success, testing approximately 400,000 individuals. For the initial 41 sites, CBTS 1.0, the Federal Government provided a Federal physician who ordered all of the COVID-19 tests, the Federal contracts for shipping the specimens, laboratory processing, patient notification, and logistics (to include supplies, personal protective equipment, and language translation services). The Federal Government also utilized U.S. Public Health Service personnel to provide data management, safety, and quality control checks at each site.

Building on the initial success of the CBTS model, the Federal Government next leveraged public-private partnerships with pharmacy and retail companies (CVS, Health Mart, Kroger, Rite Aid, Walgreens, and Walmart), also known as CBTS 2.0, to accelerate testing for more Americans in more communities across the country. The public-private partnership model operates on the federally supported, state managed model.

As the transition of CBTS federally run sites to state-run sites has been completed, the Federal Government has broadened its community testing support to a more sustainable model—specifically by continued support of retail and pharmacy partnerships in more than 800 locations in all 50 states and the District of Columbia, which collectively have conducted over 2 million tests to date. The Federal Government focused on communities with high social vulnerability using the CDC’s Social Vulnerability Index (SVI) as one of the main factors to select site locations. Approximately 65 percent are located in communities with moderate to high social vulnerability. The SVI measures the resilience of communities when confronted by external stressors along four main themes: socioeconomic status, household composition and disability, minority status, and housing type.

This pharmacy and retail partnership provides convenient access to COVID-19 testing, but it is also a bridge for retailers to implement new regulatory flexibilities and expanded reimbursement options HHS has provided through private insurance, Medicare, and Medicaid. This partnership also leverages the newly expanded authority given to pharmacists to order and administer COVID-19 testing; this effort is also known as CBTS 3.0. Now, CVS and Walmart have over 1,900 sites utilizing these new regulatory and reimbursement options with over 2 million tests performed.

HRSA supported health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care to medically underserved communities and vulnerable populations across the United States. Nationwide, nearly 1,400 HRSA-funded health center grantees operate approximately 13,000 sites, providing primary and preventive care to more than 28 million patients each year. Over 91 percent of health center patients are individuals or families living at or below 200 percent of the Federal Poverty Guidelines and nearly 63 percent are racial and/or ethnic minorities. Health centers are uniquely situated in communities to serve those that are most vulnerable and 97 percent of these centers offer COVID-19 testing. As of September 4, 2020, health centers have administered 3,690,098 COVID-19 tests (including 215,231 antibody detection tests), with over 49 percent of tests provided to racial and/or ethnic minority patients. Of these tests, 444,186 returned positive, and among racial and/or ethnic minorities, 59 percent tested positive.

To prevent further spread and deaths in nursing homes, CDC and the Centers for Medicare & Medicaid Services (CMS) recommended that nursing homes perform baseline testing of all residents and staff, followed by routine testing of residents and/or staff to reduce outbreaks, morbidity, and mortality, based on additional factors. CMS requires a regimen of staff and resident testing based on the degree of community spread.

To protect the vulnerable and to assist states in meeting these recommendations and requirements, on July 14, 2020, the Trump administration announced that HHS would embark on a one-time procurement of rapid point-of-care testing instruments and tests to be distributed to nursing homes using the Defense Production Act. Through this aggressive action, nursing homes will be able to augment their

current capacity for coronavirus testing, bolstering their response and helping to prevent the spread of SARS-CoV-2. This will facilitate baseline testing among nursing home residents and staff, and enable a pathway to conduct ongoing testing according to public health guidelines.

I am pleased to announce that all 13,850 initially eligible nursing homes have received one or more point-of-care (POC) instruments, and nearly 5 million tests. Following this initial distribution, we will facilitate nursing homes being able to reorder supplies via their normal commercial distribution channels. Additional billions of dollars in funding have been provided by HHS to support this effort.

Vulnerable populations in many underserved communities are suffering disproportionate health impacts resulting from COVID-19, including numbers of infections, hospitalizations, and deaths. As part of the HHS response to this crisis, on June 23, 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.

Morehouse School of Medicine has entered into a 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.

Support Safe Reopening of Schools and Businesses

While we must be prudent to protect those most vulnerable, we must also be mindful of the prolonged effects that school and business closures have on millions of children and parents. The efforts of the Federal Government to galvanize the testing infrastructure in the United States, and the efforts to reduce turnaround times, have provided communities with the resources they need to safely reopen schools and businesses.

Enable State Plans

To enable states to achieve the testing goals developed in coordination with the Federal Government, the Federal Government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The Federal Government then provided this information to states so they could better determine how to optimize their testing strategy. The Federal Government also purchased and allocated POC devices and over 2.3 million tests; developed, implemented, and facilitated community-based testing sites across the country; and provided significant guidance and technical assistance for state plans. The increase in the numbers of tests performed since early March is a direct reflection of these efforts.

States and territories have now submitted two iterations of their testing plans. These plans were developed in collaboration with Federal multidisciplinary experts through teleconferences and other meetings. Plans were reviewed by a multidisciplinary Federal team that included leadership from CDC, the Immediate Office of the Secretary, and the Office of the Assistant Secretary for Health.

The first iteration of the jurisdictional testing plans for May and June were released to the public on July 10, 2020, and are available for viewing on the following website: <https://www.hhs.gov/coronavirus/testing-plans/index.html>. The Federal team provided feedback to each state, and each state incorporated this feedback into detailed plans covering July through December. The state plans for July-December have been reviewed and scored and were released to the public on August 10, and are available for viewing on the following website: <https://www.hhs.gov/coronavirus/testing-plans/index.html>.

To ensure states meet their testing goals, the Federal Government procured FDA-authorized swabs and transport media, and is distributing these supplies to a single location in each state determined by the Governors' offices. Starting in May and through September 11, the Federal Government has distributed over 95 million swabs and more than 77 million tubes of transport media.

Moving forward, jurisdictions should use the \$10.25 billion provided to states, territories, and localities by the Federal Government to support the purchase of tests

and related supplies, personnel for contact tracing, and reporting infrastructure, etc., for their jurisdictions, as needed to fulfill their approved testing plans.

Other Initiatives

In order to capture feedback and foster communication between Federal officials and the private sector, HHS created the National Testing Implementation Forum (Forum). The Forum brings together representatives from key stakeholder groups to share information and provide input to Federal leaders about SARS-CoV-2 testing. Members of the Forum provide their perspectives on how HHS can best identify and address end-to-end testing supply chain issues across commercial, public health, academic, and other sectors and define optimal testing in various settings (diagnostic, screening, surveillance, others). Members also provide input to improve technical assistance across the Nation to prioritize testing among the vulnerable and underserved and create a sustainable diagnostics ecosystem that is sustainable and fully capable for future public health challenges. The first Forum meeting was held on July 30th and the principal topic of discussion was the testing supply chain. On August 13th the second meeting was held and surveillance and reopening strategies were discussed. The third forum, with the topic of engaging minority and underserved communities, was held on September 3rd.

On August 27th, the Administration announced that a \$760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 Ag Card point-of-care tests. This initiative will expand strategic testing in the United States. The Abbott BinaxNOW COVID-19 Ag Card, which recently received an EUA from the FDA, does not require instrumentation and will deliver COVID-19 test results in 15 minutes or less. This test uses nasal swabs and can be easily deployed in many settings across the country.

United States Public Health Service Commissioned Corps

Since the early stages of the COVID-19 pandemic, 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 53 officers on January 24, 2020 to 4,170 officers deployed as of September 8th, with many officers being deployed numerous times. 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, Michigan. 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 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, help ensure the safety, efficacy, and quality of FDA-regulated medical products, and provide the industries we regulate with 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 public 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

This pandemic has created a demand for new tests that is unprecedented in both volume and urgency. FDA's important role in testing includes determining whether the tests developed for use in the U.S. provide sufficiently accurate and reliable results and helping to provide timely access to such tests.

Even prior to any diagnosed U.S. cases of COVID-19, FDA proactively reached out to developers to encourage and facilitate the development of tests and to offer assistance from the Agency. FDA has been proactive and supportive of test development by all interested parties to speed development and quickly authorize tests that the science supports. The Agency has worked with over 500 developers since January and has been working around the clock to issue over 240 Emergency Use Authorizations (EUAs) for tests. The sheer volume and variety of available tests is a testament to FDA's support of innovative test design and our commitment to public health. From molecular diagnostic tests, to rapid antigen tests, to antibody tests, to tests run in clinical labs, to tests run in emergency rooms, pharmacies and nursing homes (point-of-care, or POC, tests), to samples self-collected at home, FDA has authorized a multitude of options. We have also been working with developers on tests that can be administered and delivered entirely outside of a lab or health care setting, such as in a patient's home.

In a public health emergency, obtaining an accurate test result is important not only for the individual patient, but for the public at large. Similarly, timely access to diagnostic tests is critically important. To best address these dual, and sometimes competing, needs, FDA has used its EUA authorities. EUAs permit the emergency use of a product, in this case a test, when FDA determines that certain criteria are met based on the totality of the scientific evidence available. The EUA process made it possible for molecular diagnostic tests to be developed, validated, and offered for clinical use within weeks rather than months or longer.

To balance the urgent need to increase diagnostic testing capacity in the United States with the need to provide adequate oversight to help ensure that patients can depend on the results of these tests, FDA announced several policies to facilitate oversight. FDA has engaged in rolling reviews of EUA submissions, authorized tests that had the necessary data to support that the criteria for issuance are met, and issued a policy for states that have the capacity and expertise to authorize tests for use within a laboratory in that state.

From the beginning of the pandemic, FDA also developed several EUA templates, which have helped to streamline the EUA submission process as well as provide helpful information to developers that can speed validation and authorization of new tests. FDA's EUA templates are intended to help developers provide appropriate validation data and other information to FDA, but alternative approaches can be used, and FDA would consider issuing EUAs for tests if the data show that the known and potential benefits outweigh the known and potential risks of the tests, among other considerations. FDA developed EUA templates for molecular diagnostic, serology, and antigen tests as well as for tests with at-home specimen collection. On July 29, 2020, FDA published a new template for at-home and over-the-counter diagnostic tests for use in non-lab settings, such as homes, offices, or schools, and that could be available without a prescription. This template helps continue to facilitate innovation in test development, and is intended to provide recommendations to help foster development of tests that are simple enough to use at home and could provide results within minutes. However, our recommendations are just that—recommendations. FDA is always open to alternative proposals from developers and will continue to consider those. More significant tradeoffs in test accuracy may be appropriate where the need for availability and fast results is not being met. Yet, even in those circumstances, steps can be taken to protect consumers, including strategies to increase accuracy. For example, strategies for serial testing with less sensitive diagnostic tests, such as 70 percent sensitivity, could be considered cumulatively rather than based on one-time testing. Any proposal for serial testing should generally include estimated manufacturing capabilities to ensure a sufficient supply of tests with which to conduct multiple tests per person. As with all EUA requests, the FDA will evaluate the totality of the evidence to determine whether the known and potential benefits outweigh the known and potential risks, among other considerations.

FDA provided regulatory flexibility to developers of tests due to the unprecedented nature of this public health emergency and the need to ensure timely patient access to COVID-19 tests. However, flexibility never meant we would allow fraud. Unfortunately, FDA continues to see unscrupulous actors marketing fraudulent test kits and using the pandemic as an opportunity to take advantage of Americans.

Some test developers have falsely claimed their tests are FDA-approved or authorized. Others have falsely claimed that their serology tests can diagnose COVID-19 or that they are authorized for at-home testing. FDA also became aware that a concerning number of commercial serology tests were performing poorly based on an independent evaluation by the NCI.

When we become aware of these issues, we have and will continue to take appropriate action against firms unlawfully marketing and selling their tests. FDA has and continues to issue Warning Letters and continues examining shipments of tests at ports of entry, the borders, and international mail centers, detaining and refusing fraudulent test kits.

To date, FDA has refused admission to more than 470 shipments of tests at the border, representing more than 460,000 tests overall, helping to prevent fraudulent tests from entering the country in the first place. FDA's actions have resulted in sellers of unapproved and unauthorized products removing false or misleading COVID-19 claims. FDA also has sent abuse complaints to online marketplaces and domain registrars for websites or listings that were offering to distribute fraudulent COVID-19 test kits for at-home testing. FDA has and will continue to take appropriate action against firms and individuals that place the public health at risk.

To further support efforts to ensure that patients and health care providers can depend on the results of COVID-19 tests, FDA has announced our participation in the COVID-19 Diagnostics Evidence Accelerator, a multi-stakeholder collaborative project to advance the development of diagnostics through the generation of real-world evidence. Organized by the Reagan-Udall Foundation for FDA in collaboration with Friends of Cancer Research, this initiative is designed to allow the community to analyze both diagnostic and clinical data in real time, which has the potential to contribute to the scientific evaluation of diagnostic tools and medical interventions for COVID-19.

Evidence generated by the Accelerator project is intended to be complementary to other studies that have been conducted or are underway as well as to provide actionable information about the prevalence of SARS-CoV-2 in specific populations and highlight individual risk factors for patients. This helps improve our understanding of the disease, allows us to tailor public health interventions and strategies to mitigate risks for individuals and communities, and will help to stop the spread of SARS-CoV-2.

In addition, FDA also continues to work with NIH, the CDC, and BARDA regarding the NCI's independent evaluation of certain commercial antibody tests for the U.S. Government, including antibody tests that are not the subject of an EUA or pre-EUA, as well as those that are under FDA review. Where appropriate, FDA is using NCI data to inform future decisionmaking, such as whether to authorize the test, engage the test developer for additional information to support its continued use, or take other action regarding tests that do not perform adequately, including removing them from our notification list and working with developers to stop distribution in the United States.

We are continuing to provide updated information and educational materials to states and health care partners. When commercial manufacturers that are currently marketing serology tests as outlined in FDA policy fail to submit an EUA within 10 business days of notification, we have been removing those tests from our website notification list and are sharing this information publicly.

In parallel with FDA's engagement with developers and monitoring the marketplace, FDA has: researched and mitigated shortages of test components, including identifying and sharing alternatives for components on FDA's website; arranged with DOD weekly airlifts of swabs to the United States; engaged nontraditional device manufacturers to support the manufacture of new swabs and other supplies that are needed in the United States; maintained public FAQs that are updated regularly; served as a clearinghouse for scientific information that the community may leverage to increase testing capacity; and operated a hotline (FDA continues to provide other means for industry to contact the FDA directly).

The availability of accurate tests has been a priority issue for public health authorities throughout the COVID-19 pandemic. However, it is important to note that the specific need for tests and the evidence available for different tests have evolved over time. At all stages of the pandemic, FDA has sought to provide regulatory clarity to innovators and adapt policies based on the latest available data. FDA will continue supporting any testing proposal where, among other criteria, the test benefits outweigh the risks based on sound science, and we continue to work with test developers and encourage those with novel testing ideas to reach out—by email, phone, or during our weekly test developer town hall meetings.

FDA will continue to appropriately balance assurances that tests are accurate and reliable with timely access to such tests as continually evolving circumstances and public health needs warrant. FDA continues to work closely with White House Coronavirus Task Force Members in examining the role testing will play as we look to reopen our country's schools, businesses, and public services.

Vaccine Development

At this time, there is no FDA-approved vaccine to prevent SARS-CoV-2 infection and/or COVID-19, and FDA is providing regulatory flexibility to help ensure the most efficient and timely development of safe and effective vaccines to prevent COVID-19. In this crisis, in which there is so much at stake, we are facilitating expedited vaccine development without sacrificing our standards for quality, safety, and effectiveness.

FDA is working closely with Federal partners, vaccine developers, researchers, and manufacturers to help expedite the development and availability of safe and effective vaccines to prevent infection with SARS-CoV-2 infections. Knowledge sharing is considered a key part of the scientific process and it could efficiently advance these efforts. We are utilizing all appropriate regulatory authorities and are providing rapid scientific and technical advice to sponsors and researchers to help expedite the development and availability of safe and effective COVID-19 vaccines.

On June 30, FDA took additional action to facilitate the development of safe and effective vaccines to prevent COVID-19 by providing guidance that includes recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, entitled *Development and Licensure of Vaccines to Prevent COVID-19*, reflects the advice and assistance FDA has been providing to companies, researchers and others, and describes the Agency's current recommendations regarding the data needed to facilitate the manufacturing, nonclinical and clinical development, and approval of COVID-19 vaccines.

The guidance provides an overview of key considerations to help manufacturers satisfy requirements for chemistry, manufacturing and controls, and nonclinical and clinical data needed for development and licensure to assess the safety and effectiveness of vaccines, and for post-licensure safety evaluation of COVID-19 vaccines. The guidance explains that, given our current understanding of SARS-CoV-2 immunology, the goal of development programs at this time should be to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.

In its interactions with vaccine developers, FDA provides sponsors with advice regarding the data needed to support the manufacturing, clinical development, and approval of vaccines, including such advice to those sponsors pursuing development of vaccines to prevent COVID-19. The size of clinical trials to evaluate the efficacy of COVID-19 vaccines will depend on a number of factors including the criteria for demonstrating safety, efficacy, and the incidence of COVID-19 in the population and areas where the trials are conducted. The guidance document conveys that FDA would expect that a COVID-19 vaccine would be at least 50 percent more effective than placebo in preventing COVID-19 or SARS-CoV-2 infection among the clinical trial participants. FDA anticipates that clinical trials to demonstrate vaccine efficacy would also be of sufficient size to provide an acceptable safety data base. However, further pre-licensure safety evaluation may be needed if safety concerns arise during clinical development.

While FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards. This is particularly important, as we know that some people are skeptical of efforts to develop a safe and effective COVID-19 vaccine. To help ensure an evaluation process that is as transparent as possible, and to help the public understand the FDA's process for evaluating the safety and effectiveness of new vaccines, FDA will convene a meeting of our Vaccines and Related Biological Products Advisory Committee on October 22, 2020, to address the general development of COVID-19 vaccines. We stand ready to rapidly schedule additional meetings of this Committee after submission to discuss Biologic License Applications or request for an Emergency Use Authorization for COVID-19 vaccines.

It is clear that manufacturing and fill finish capacity will need to be scaled up on U.S. soil in order to have a safe and effective vaccine widely available in a timely manner. FDA is committed to working with sponsors by providing timely regulatory advice and technical assistance regarding manufacturing to help support such scale-up activities, including sponsors who may be proceeding at risk to scale-up manufacturing while clinical trials are being completed.

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

Therapeutic Development

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 has supported 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 ACTIV partnership developed 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 key areas, such as in reducing lung inflammation and improving lung function in COVID-19 patients. All this work is beginning to pay off. For example, we saw positive results of the National Institute of Allergy and Infectious Diseases (NIAID) trial of remdesivir in patients with severe COVID-19. On May 1, 2020, FDA issued an EUA for remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. On August 28, 2020, FDA broadened the EUA for remdesivir to include all hospitalized patients for treatment of COVID-19, irrespective of their severity of disease.

Another potential approach for treatment is the use of antibody-rich products such as convalescent plasma and hyperimmune globulin. These investigational blood products are manufactured from plasma donated by people who have recovered from the SARS-CoV-2 virus, and such products are being studied to determine if they could shorten the length, or lessen the severity, of COVID-19. We are evaluating convalescent plasma in the context of traditional clinical trials, and on August 23, 2020, FDA issued an EUA for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients. This EUA followed FDA’s extensive review of the science and data generated over several months prior to the EUA. This data stemmed from efforts to facilitate expanded access to convalescent plasma for COVID-19 patients. Clinical trials to definitively demonstrate safety and efficacy of convalescent plasma remain ongoing.

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 to encourage 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 collection entities to facilitate the collection of convalescent plasma, and to work with developers of such 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.

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 (human and animal), biological product, and device manufacturing in a timely manner.

Drugs and Biological Products

In addition to our usual communication with drug manufacturers, we work 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 for outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or Federal facilities, regarding the compounding of certain drugs used to treat hospitalized patients with COVID-19 when approved drugs are not available. The Agency has also published guidance to help applicants and manufacturers provide FDA with timely and informative notifications about changes in the production of certain drugs and biological products and urging the submission of these notifications, which may assist in our efforts to prevent or mitigate shortages of such products.

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. The Agency quickly identified the need for making hand sanitizers available as demand spiked, while also continuing our mission to ensuring these products remain safe for consumer use by removing adulterated products from the market. FDA has published and continues to update three guidance documents designed to help facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. The agency has initiated several enforcement initiatives and import alerts to stop adulterated and subpotent hand sanitizer products from getting U.S. distribution channels through importation into the United States. The Agency has also issued three EUAs to authorize the emergency use of products currently authorized for marketing in the European Union, which has helped to alleviate shortages of some therapies that are essential for the care of critically ill COVID-19 patients.

Medical Devices

FDA continues doing everything in our authority to help increase the availability of PPE and other critical medical devices relied upon by patients and those on the front lines of the U.S. response. FDA has reached out to over 1,000 manufacturers since January and has helped facilitate an increase in the availability of these devices, while taking steps to ensure that patients and our health care workers on the front lines can depend upon these products to protect them.

One way FDA has helped to increase the supply of medical devices in the United States is by issuing EUAs. For PPE, FDA has issued EUAs to make more respirators available by authorizing certain existing supplies of PPE for healthcare personnel use that are not traditionally intended for use in health care settings, authorizing imported respirators that are demonstrated to meet comparable performance standards so that they can be used in health care settings, authorizing systems for decontamination of PPE so they can be reused as appropriate. The Agency has also issued EUAs for face masks (as source control to help stop the spread of the virus), surgical masks, face shields, and certain gowns and other apparel for use in health care settings in accordance with CDC recommendations (including but not limited to shoes and shoe covers, non-surgical isolation gowns, surgical helmets, and surgical caps). The need for PPE continues to outpace the available supply, but these EUAs have been critical to maximize available supply in the United States and help bolster manufacturing of new supply to support the COVID-19 response.

FDA has seen an unprecedented volume of EUA requests for medical devices—some of which have been for ventilators, infusion pumps, remote or wearable patient monitoring devices, and blood purification devices for which FDA has reviewed pre-market submissions but has never issued EUAs in prior emergencies. FDA has also seen EUA requests for novel medical products that it has never previously reviewed under any circumstances, such as decontamination systems for PPE.

Another way FDA has helped to support increasing the supply of PPE and other devices during the pandemic is through issuance of several guidance documents intended to help manufacturers develop new products more quickly and efficiently. These guidance documents are for PPE and other devices including facemasks (as source control to help stop the spread of the virus), surgical masks and respirators, gowns, other apparel and gloves, as well as guidance for sponsors requesting EUAs for decontamination systems and bioburden reduction systems for face masks and respirators. FDA has also published guidance documents for a wide variety of other medical devices, including ventilators and accessories, infusion pumps and accessories, remote ophthalmic assessment and monitoring devices, non-invasive remote monitoring devices used to support patient monitoring, imaging systems, and non-invasive fetal and maternal monitoring devices used to support patient monitoring.

In addition, FDA has provided conservation strategies intended to outline contingency and/or crisis circumstances when reuse, extended use, and preservation of cer-

tain devices may be necessary if supplies are short or unavailable. To date, FDA has published conservation strategies for gloves, masks and gowns.

In these ways, FDA has worked consistently to support those manufacturing PPE and other devices, as well as those who are dealing with limited supplies and shortages, to provide alternatives when other options are not available. This includes close collaboration with many non-traditional device manufacturers who have turned their operations to manufacturing PPE and other devices. FDA has worked interactively with manufacturers to continue increasing the supply of medical devices to meet continuing unmet needs all over the country. FDA also provided instructions for importers to facilitate the import entry process for PPE and other devices, to help expand access to these products. To further support these efforts, FDA initiated biweekly virtual town hall meetings for those seeking and manufacturing respirators and other PPE to ask questions and discuss challenges they are facing.

We are also in close communication with our partners at U.S. Customs and Border Protection (CBP) to proactively identify and mitigate any potential backlogs of lawfully marketed medical products for COVID-19. FDA participates in HHS Supply Chain Advisory Group meetings, providing regulatory support and subject matter expertise to respond to questions concerning medical products identified by HHS, to facilitate the lawful entry and use of imported medical products coordinated through HHS, and to inform medical product supply chain discussions.

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 further expand these authorities, consistent with the fiscal year 2021 Budget.

Inspections

Despite pausing onsite domestic and foreign routine surveillance inspections in March 2020 to safeguard the health and well-being of our staff, our investigators continued to conduct mission critical inspections both domestically and abroad and other activities to ensure FDA-regulated industries were meeting applicable FDA requirements. In July 2020, FDA resumed prioritized onsite domestic routine surveillance inspections. To arm our investigators with the most reliable and accurate information, the FDA developed a rating system to assist us in determining when and where it is safest to conduct prioritized domestic inspections. The COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data. We have also made the Advisory Level data available to our state partners who carry out inspections of FDA-regulated entities on the agency's behalf under contract. We will continue closely monitoring reopening criteria established at the Federal, state or county levels are planning to identify when and where to resume domestic inspections, investigations, sample collections and analyses, prioritizing these assignments based on risk and other factors. Similarly, we will use data to inform resumption of prioritized operations abroad as it becomes feasible and advisable to do so.

FDA has determined that, for the foreseeable future, prioritized domestic inspections will be pre-announced to FDA-regulated businesses. This will help ensure the safety of FDA investigators and firm employees, providing the safest possible environment to accomplish our regulatory activities, while also ensuring the appropriate staff are onsite to assist FDA staff with inspection activities.

Over the course of the COVID-19 pandemic we have had great success by using a number of tools as part of the agency's risk-based approach to ensuring safety. This includes denying entry of unsafe products offered for import into the United States, conducting physical examinations and/or product sampling at our borders, utilizing remote regulatory assessment tools to verify compliance with safety regulations, and continuing to work with Federal, state and local partners to monitor the medical product and food supply for indications of interruptions or shortages. As the COVID-19 pandemic continues, we will continue to adjust our processes and guidance as necessary to maintain the appropriate level of review to ensure the safety of consumer products, including hand sanitizer, diagnostic tests and more.

In response to ensuing travel restrictions due to the pandemic, FDA is utilizing its authority under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to request records in advance of or in lieu of drug inspections, and is also utilizing establishment inspection reports from capable foreign regulatory authorities under the Mutual Recognition Agreement (MRA). Both options help inform decisions related to drug approvals or addressing drug shortages.

Our Foreign Supplier Verification Program, or FSVP, remains a high priority for U.S. food imports and is critical to ensuring the safety of food received from foreign suppliers. In March of this year, we started using remote FSVP Assessment Protocols to conduct inspections and have found that these inspections have been effective and help ensure compliance with the new importer requirements under FSMA during the current pandemic.

Food Supply

FDA is working with Federal, state, and local partners as well as industry to help ensure a safe and adequate food supply for both people and animals. We 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 and initiating responses as needed. 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.

In July, FDA announced the New Era of Smarter Food Safety Blueprint outlining the Agency's plans over the next decade to create a more digital, traceable, and safer food system. The challenges that have arisen during the pandemic have made it clear that the actions called for in the blueprint will strengthen how we approach the safety and security of the food supply, not just in the normal course of events but especially in times of crisis.

Fraudulent Products

FDA exercises its regulatory authority to protect consumers from firms and individuals selling unapproved products with false or misleading claims that the products prevent, treat, mitigate, diagnose, or cure COVID-19, including by issuing warning letters and pursuing civil and criminal enforcement actions, where appropriate. In March 2020, FDA launched Operation Quack Hack, which leverages agency expertise and advanced analytics to protect consumers from fraudulent medical products including unproven cures, illegitimate test kits, and substandard or counterfeit respirators. FDA has sent thousands of abuse complaints to domain name registrars and internet marketplaces. The Agency also has sent more than 110 warning letters to sellers of fraudulent products. Working with the Department of Justice, FDA has sought and obtained preliminary injunctions that require defendants to halt the sale of fraudulent 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. For example, in March, at the border, FDA intercepted at the border 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 thereafter charged with mail fraud stemming from the allegations that he smuggled hydroxychloroquine from China to make his own pills and concealed the shipment from CBP by mis-declaring it as yam extract. In May, FDA

worked with CBP to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before getting into U.S. commerce.

More recently, FDA has taken steps to address hand sanitizer products that pose safety concerns, such as products that contain or may contain toxic chemicals like methanol or 1-propanol, or that do not meet the required alcohol levels. FDA has issued warnings to consumers not to use these hand sanitizers, and has taken steps to help ensure that these dangerous or subpotent products do not enter domestic commerce. FDA has coordinated with CBP to identify such products, and we have listed products made by more than 40 manufacturers on import alert.

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. Let's go to Dr. Redfield and then Admiral Giroir and then Dr. Hahn.

Dr. Redfield, welcome.

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

Dr. REDFIELD. Thank you, Chairman Alexander, Ranking Member Murray, and Members of the Committee. And I want to thank you for the opportunity to be here today. On behalf of the CDC, I also want to thank you for your continued support of our public health professionals and their lifesaving work that they are committed to 24/7. Over 6,700 CDC staff have been engaged in our agency's COVID-19 response so far, and more than 1,200 have been deployed to more than 200 locations, tribal nations in the United States and abroad. I know that you join me in expressing our collective deep gratitude to the women and men of CDC for their resilience, their dedication, and their service to our Nation.

Throughout this global pandemic, CDC has brought its science expertise to the frontlines, grounded in science and data, conducting rapid investigations of disease outbreaks that identify the highest risk populations and settings, and putting in place measures to prevent further spread of COVID-19. Understanding which populations are most at risk and how this virus spreads in various settings is critical in developing guidance and protecting the health of Americans. As you are aware, in the United States, we are approaching nearly 7 million cases and sadly over 200,000 deaths. Every death means that a loved one was lost. But there is some progress to report. Since the pandemic peaked in July 24th of this year, we have experienced nearly a 50 percent reduction in daily cases and a 32 percent reduction in deaths.

There has also been significant improvement in the mortality, particularly in the elderly. For example, during the peak of the epidemic, April 17th, 75 year old Americans had a mortality of about 46.8 per 100,000. And by the end of August, the numbers had significantly declined into about 10 per 100,000. These improvements, however, do not mean that we can let our guard down. Over last week, we had an average of over 40,000 cases and nearly 800 daily deaths. I do want to emphasize the shift in age in these case counts. The 18 to 25 year olds currently make up over 26 percent

of new infections in more than any other group. It is imperative that these young adults recognize that even though they are unlikely to get seriously ill from this virus, they are major contributors to the spread of COVID-19 in our country at this time.

In order to understand what proportion the population has been infected with COVID-19 and what proportion remains at risk, CDC is currently performing large scale serology testing across the United States. Preliminary results appear to show that most Americans have not been infected with the virus and are still vulnerable to the infection, serious illness, and death. We hope to be able to post the analysis of the first round of this study in the next several weeks. As I have stated before, the CDC encourages all Americans to embrace the powerful public health tools that we have right now, wear a mask, maintain social distance, practice routine hand washing with vigilance, be smart about crowds, and stay home when you are feeling sick. And as we move into the fall, I want to add one more critically important step, flu vaccination. Flu vaccination is safe. CDC encourages all Americans to embrace the flu vaccine with confidence for themselves, their families, their loved ones and their communities.

This year, CDC has purchased an additional 9.3 million doses of adult flu vaccine, as well as 18.5 million doses for children. This is a significant increase in previous years. When combined with the tools that I mentioned above, this could help our Nation avert a very difficult fall and lessen the burden on our health care system and save lives. To further strengthen our public health resilience, CDC awarded 140 million to 64 jurisdictions through the CDC existing Immunization Cooperative Agreements to begin to scale up staffing and preparedness for flu season.

We also developed a new multiplex laboratory diagnostic test. It is capable of measuring both Influenza A and Influenza B, as well as COVID 2 using a single specimen and a single assay. This test will help our public health professionals better identify infections with Influenza and COVID. I also am announcing today an additional \$200 million from the CARES Act, funding that will be used as a first step to help the jurisdictions complete their individual plans and implement their COVID—further COVID vaccination in follow-up to the playbook that we released last week.

CDC is an integral part of Operation Warp Speed. We are leveraging our expertise and immunization infrastructure to support and promote distribution, administration, and monitoring of the future COVID-19 vaccines. In coordination with Operation Warp Speed, CDC is working closely with state and local community organizations on their detailed, flexible plans for vaccine distribution. As I have emphasized in prior hearings, now is the time to commit to sustained investment in core capabilities of public health data, data analytics, laboratory resilience, workforce expansion, and rapid response capabilities.

Years of underinvestment in public health infrastructure have led to a system that has been sorely tested in this current pandemic. COVID-19 is the most significant public health challenge that our Nation has faced in more than a century. Now is the time to build not only the public health core capability that our Nation needs, but the capability that the people of our Nation deserve.

As we work together collectively to fight COVID-19 and the pandemic, CDC and all of the outstanding women and men of CDC remain strongly committed to our mission to protect all Americans from disease, threats, and to save lives. I want to thank you for your time 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, I am honored to update you on our Nation's efforts to combat COVID-19, with a specific focus on testing. Recommended public health practices like wearing a mask, avoiding crowds especially indoors, and washing your hands combined with smart testing is the formula to effectively slow the spread, flatten the curve and save lives. By providing county specific guidance to Governors on a weekly basis, expanding and managing supplies, providing the right test to the right person at the right time, and developing and equitably distributing safe and effective therapeutics, we are seeing promising results. Specifically since the post Memorial Day peaks in community spread, the number of new COVID cases is down, as Dr. Redfield just testified.

The number of people hospitalized with COVID-19 is down 54 percent. The number of people in an intensive care unit due to COVID is down 65 percent. And deaths associated are down 32 percent. But let me emphasize that to sustain these gains, we must continue our disciplined mitigation efforts, especially wearing masks when we can, physically distance, avoiding crowds particularly indoors, and increasing our screening and surveillance testing. Now, specifically regarding testing, the Nation has performed over 106 million tests for the virus causing COVID-19. On 10 separate days, we performed over 1 million tests per day. The Federal Government has purchased and delivered over 106 million swabs and 88 million tubes of media to states, tribes and Federal partners. Starting on April 7th, we have purchased and delivered to public health laboratories in every state and the Indian Health Service over 2.5 million Abbott ID Now point of care molecular tests to support outbreak control and rural testing.

We have implemented Federal surge testing sites in 20 different cities, helping to squelch emerging outbreaks, typically among asymptomatic young adults. We are now at an inflection point in testing. This month, we will have available on average 3 million tests per day, nearly half of which will be rapid point of care. We have been building toward this inflection point and I have previously testified to its coming several times over the past months. Now, let me discuss two specific testing initiatives. Protecting the elderly has been, is, and will continue to be a foremost priority for this administration.

On July 14th, we announced that every single eligible nursing home in America would receive a point of care instrument and testing supplies. We have delivered on this promise. All 13,850 eligible

nursing homes have now received a total of 13,985 instruments and over 4.9 million rapid point of care tests ahead of schedule. On August 27th, after months of planning and only 1 day after its FDA authorization, the Administration announced a \$760 million dollar contract with Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 point of care tests. This test is easy to perform, does not require an instrument, delivers test results in 15 minutes or less, and costs \$5. We have already deployed 65,000 of these tests in support of disaster operations in California, Oregon, Texas and Louisiana.

Last week we also shipped 974,000 tests to 7,600 nursing homes in areas of significant community transmission, 541,000 tests to over 5,500 assisted living facilities with a clear certificate of waiver, and 300,000 tests to the Indian Health Service. This week we will be shipping 249,000 tests to historically Black colleges and universities and 2.6 million tests to assisted living, nursing homes, home health, and hospices. In the coming weeks, we will begin shipping millions of tests per week in support of our teachers and our students to open and keep open our K through 12 schools.

Now, I would like to close by recognizing my fellow officers in the public health service, the uniformed service, which I have the honor of leading. 4,172 women and men have deployed 8,918 times in direct support of this pandemic on the Diamond Princess cruise ship in Japan, to our community-based testing sites, to FEMA and our task forces, and to nursing homes and field hospitals in the hardest hit communities.

I thank each and every one of these officers and their families, and on their behalf, thank all of you in Congress for supporting our training needs and the establishment of a ready reserve to supplement our ranks during inevitable future national emergencies. Thank you for the opportunity to provide these remarks.

The CHAIRMAN. Thank you, Admiral Giroir.

Dr. Hahn, welcome.

**STATEMENT OF STEPHEN HAHN, M.D., COMMISSIONER OF
FOOD AND DRUGS, UNITED STATES FOOD AND DRUG AD-
MINISTRATION, SILVER SPRING, MD**

Dr. HAHN. Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee. Over the past several months, I have had the honor to work shoulder to shoulder with FDA's career staff as we fought a historic pandemic that has altered the lives of every American. I am proud of all FDA employees and how they have measured up to this extraordinary challenge. The efforts of the FDA's expert workforce are critical to ensuring the safety and health of the American public at any time, but it is magnified during a public health emergency. Of course, our work on COVID-19 and non-COVID issues comes with unprecedented public scrutiny and sometimes criticism.

Any agency that has the broad responsibilities and far reaching impact of FDA, particularly involving issues of public health, cannot expect to do its job without inviting controversy and disagreement. But it is also essential that the criticism we get never shakes the underlying faith the public has and should have in FDA and our commitment to protecting the public health. I am confident in

the decisions that are being made related to COVID-19 and that will be made in the coming months as we continue to address the challenges of this pandemic. Now, I know there has been particular attention paid to a few of the decisions reached by FDA over the past several months. I want to assure you and emphasize that every one of the decisions we have reached has been made by career FDA scientists based on science and data, not politics. FDA represents science in action. Often we must make real time decisions based on ever evolving data concerning a previously unknown, highly contagious virus that we are still learning about.

Sometimes it is necessary to reverse decisions as new data emerge. This is inherent in the emergency use authorization process, otherwise known as EUA, and it is akin to how a doctor might approach a patient in an emergency situation, constantly updating a treatment plan as new data emerge. So in the interest of transparency, I would like to use this opportunity today to lay out the process we will use to review vaccines for COVID-19. When a vaccine sponsor reaches the conclusion that the data from its phase 3 clinical trials are adequate to submit to FDA, they will decide whether to apply for approval or emergency use authorization. This will be based upon the trial meeting prespecified success criteria that were established by that sponsor.

Now, this is really important. They should also be consistent with FDA recommendations regarding those criteria. FDA will receive that application or submission and our career scientists will review its safety and efficacy data, as well as manufacturing quality and consistency data. FDA made clear recommendations in our June 30 guidance regarding the safety and effectiveness of vaccines so that we can see that prior to the approval process. We will also work to provide additional information so that it is clear what we expect to see should a sponsor choose to submit an emergency use application—emergency use authorization application. As we have indicated previously, we plan on seeking advice from the Vaccines and Related Biologics Products Advisory Committee, comprised of independent members who have been screened for ethics conflicts.

The safety and effectiveness data and the committee's decision will be public, although we will need to adhere to confidentiality requirements. The public will have an opportunity to comment. The process will be transparent and independent. FDA career staff will then take the committee input into account as they make their decisions regarding the application or EUA request. Now, before we were to issue an EUA, if that were to happen, FDA would have to determine, among other things, that the statutory standard is met.

We expect that this would be demonstrated based on adequate manufacturing data to ensure a vaccine's quality and consistency, and data from at least one well-designed phase 3 clinical trial that demonstrates its safety and efficacy in a clear and compelling manner. Let me emphasize that again, data from at least one well-designed phase 3 clinical trial that demonstrates its safety and efficacy in a clear and compelling manner. FDA also expects that an EUA request would include a plan for active follow-up to monitor safety among individuals who receive the vaccine. In the end, FDA will not authorize or approve a vaccine that we would not feel comfortable giving to our families. On behalf of the 17,000 plus employ-

ees of the FDA, I want to make the following commitments today to the American public and this Committee.

FDA will not authorize or approve any COVID-19 vaccine before it has met the agency's rigorous expectations for safety and effectiveness. Decisions to authorize or approve any such vaccine or therapeutic will be made by the dedicated career staff at FDA through our thorough review processes, and science will guide our decisions. FDA will not permit any pressure from anyone to change that. I will fight for science, Mr. Chairman. I will fight for the integrity of the agency and I will put the interests of the American people before anything else. Thank you and I look forward to answering your questions.

The CHAIRMAN. Thank you, Dr. Hahn. We will now turn to questions from Senators. We have full participation today, so I would like to ask the Senators and witnesses to keep your exchanges within 5 minutes so all Senators will have a chance to participate. And for my 5 minutes, I would like to ask for the courtesy of short answers so I can ask all my questions. Dr. Hahn, let me go back to two things you said. Who makes decisions about safety and efficacy at the FDA? Do you do it, do career scientists do it, or does the White House do it?

Dr. HAHN. Career scientists at the FDA do it. We—that is very clear. I am briefed on all major medical product decisions. Overruling a center's decision is a very rare event. I have expressed on multiple occasions my intention and have done during this COVID-19 to make sure that those decisions are made by career scientists in the centers.

The CHAIRMAN. You referred to this, but once FDA approves a vaccine, and as we have said today we are going to have tens of millions of doses ready, none can be distributed until FDA approves it. Will you be willing to take that vaccine for you and for your family?

Dr. HAHN. Absolutely, yes, Senator—Mr. Chairman. I have the complete and absolute faith in the expertise of the scientists who are terrific at FDA. If they were to make a determination a vaccine would be safe and effective, I would do that and I would encourage my family to take the vaccine.

The CHAIRMAN. Dr. Fauci, you have been around since the Reagan years. You have seen lots of diseases, pandemics, and lots of responses to it. Is the Administration cutting corners in safety and efficacy in its effort to produce vaccines and treatments rapidly?

Dr. FAUCI. Not at all, Mr. Chairman. In fact, the rapidity of where we are right now is a reflection of the technological advances in vaccine platform technology, as well as the risks that were taken financially so that we will have doses available when the decision is made by the FDA as to the safety and efficacy, as you have heard from Dr. Hahn. So there is no cutting corners.

The CHAIRMAN. We are risking the taxpayers' money, but we are not risking safety and efficacy. Is it your testimony?

Dr. FAUCI. Yes, it is. That is absolutely correct.

The CHAIRMAN. Now, millions of students are going back to thousands of colleges and there are inevitably outbreaks of COVID-19, Dr. Fauci. Is the smart thing for college administrators to do is to

send those college students home when the outbreaks occur on campus?

Dr. FAUCI. Absolutely not, Mr. Chairman. They should be able to accommodate the students in a facility, maybe a separate dorm or a separate floor, so they do not spread among the student body, but do not send them home to their community because of the likelihood of then re-seeding infection in the community.

The CHAIRMAN. Dr. Fauci, I have listened to your testimony for the last several months. Some people say that your message is that you want to lockdown the country in order to stop the spread of the vaccine. Is that accurate?

Dr. FAUCI. That is completely inaccurate, Mr. Chairman. I have said multiple times we do not need to shut down. If we follow carefully and prudently the recommendations and the guidelines for opening America again, I believe we can do that safely and still accomplish the goal of opening the economy again.

The CHAIRMAN. Dr. Fauci, some people said it was political to ask the states to get ready to distribute the vaccine in October. Is that true or false?

Dr. FAUCI. That is false. The reason that was done is because we want to make sure that when a decision is made, that we will be ready to distribute the vaccine.

The CHAIRMAN. Dr. Redfield, the British Ambassador told me yesterday the Government studies in the United Kingdom said that based on serology testing, that 5 to 25 percent of their country's population, depending on the location, has been exposed to COVID-19. What does—what about the American population? How many of us have been infected by COVID-19?

Dr. REDFIELD. Thank you, Mr. Chairman. CDC is in the process of a very large sequential study across the entire United States measuring serology. As I mentioned, the preliminary results in the first round show that a majority of our Nation, more than 90 percent of the population, remains susceptible. It varies in different geographic parts from states that have less than 1 percent. With evidence of previous infections, some that have more than 15, 20 and one as high as 24 percent. We will have that finalized and probably published in the next week or so, but it does show that a majority of Americans are still susceptible to this virus.

The CHAIRMAN. Just so I understand, you are saying that based on the preliminary indications from your serological testing and studies, that as many as 90 percent of Americans are still—still have not had the virus yet?

Dr. REDFIELD. Yes, sir.

The CHAIRMAN. Thank you, Dr. Redfield.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. Dr. Redfield, we know that a lot of patients avoid getting a necessary test or a treatment because of cost. And I have been pushing to make sure insurers have to cover COVID treatment at no cost to patients as we fight this deadly disease. Meanwhile, President Trump, as we all know, is fighting at the Supreme Court to overturn the Affordable Care Act, which would leave 23 million more people without health insurance and allow insurers to once again discriminate against

people with preexisting conditions, leading to higher costs. COVID-19 actually—could become a preexisting condition.

Dr. Redfield, let me just ask you straight out, will increasing the number of uninsured by tens of millions and increasing costs for the 133 million people with a preexisting condition make it easier or harder to contain this pandemic?

Dr. REDFIELD. Thank you, Senator, for the question. Clearly, access to timely healthcare is critically important in terms of public health. And in terms of this pandemic, it is also true access to timely and effective health care remains an important public health measure.

Senator MURRAY. I would take that—case is overturned, that this is going to make it a lot harder to control this pandemic. Dr. Redfield, we have got to understand what happened with CDC's testing guidance for asymptomatic people exposed to COVID-19. I am relieved that CDC reversed course on Friday, but I am concerned about why CDC put out guidance that contradicted the widespread views of the medical and public health community, was not drafted by CDC scientists and did not undergo CDC strict scientific review process. Dr. Redfield, how is it a document published on CDC's website was not drafted by CDC scientists nor underwent the agency's strict scientific review process?

Dr. REDFIELD. Senator, the original testing guidelines of August 26 had full engagement of individuals at CDC, but it was a cooperative document that included the Assistant Secretary as well as the coronavirus task force. I will say the intent of that document, as I mentioned before and I tried to clarify in my statement on August 27th, was never to limit testing, never to limit testing of asymptomatic individuals.

The attempt was to reengage the medical and public health community as part of testing so that there was a public health action that happens as a consequence of every test. It became progressively apparent that the guidelines were not interpreted in the manner in which we had intended them to be interpreted and that is what led me to realize we had to put out a clarification to make it explicitly clear that we believe very much that asymptomatic transmission is an important part of the transmission cycle of this virus. Those individuals, when they have been exposed, should, in fact be tested—

Senator MURRAY. I appreciate that answer. I do not hear you answering the question. But let me ask Dr. Giroir. You said in an interview that coordinated editing of the guidance—that you coordinated, editing of the guidance. The American Medical Association, the Infectious Disease Society of America, and state health departments recommend testing for asymptomatic people. I want to ask you, on what scientific basis did members of the task force take a different position? Scientific evidence.

Admiral GIROIR. Thank you, Senator Murray. I want to reiterate what Dr. Redfield said is that the original guidance that was published by the CDC with the approval of Dr. Redfield and the senior scientist, did not, unequivocally it did not recommend against testing asymptomatic individuals.

In fact, there were multiple sentences that said it is important to test asymptomatic individuals, but in certain circumstances, it

is important to do that within the context of public health or medical supervision. That is all it said. It was widely misinterpreted. It was widely misrepresented. And Dr. Redfield told the reason, we have done FDA guidance, clear guidance, and I issued a prep back declaration to——

Senator MURRAY. Okay. I just have a few seconds, on Friday, CDC quietly updates another guidance identifying aerosols as common route of transmission of the virus that causes COVID-19. Yet on Monday, CDC reversed course. Dr. Redfield, you told me the earlier guidance had been posted in error, but especially given the Trump administration's track record, the reversal raises significant red flags. So here is my question to you. If I want the best guidance on the latest science so I can protect myself and my family, can I trust CDC's website to give me that information?

Dr. REDFIELD. Yes. I am going to say again that my agency and myself, we are committed to data and science and to give the American public the best public health recommendations we can based on that data and science, and be open, if necessary, if the data and science changes, to modify that guidance based on that new data. But we are committed to data and science, and that will be the grounding of how we make these recommendations.

Senator MURRAY. Mr. Chairman, I am out of time, but I am concerned that the American public needs to be able to trust the decisions that are made and what is posted on that website needs to be trusted.

The CHAIRMAN. Thank you, Senator Murray.

Senator Enzi.

Senator ENZI. Thank you, Mr. Chairman, for continuing to hold these regular hearings so that we and the American public can check on the Federal efforts to fight the Coronavirus. I know it can be hard for our witnesses to find the time to testify, since they are all working very hard to respond to the pandemic, but I appreciate them being here and their information. I am glad to see that we are making progress in planning how we distribute a safe and effective vaccine when it is ready.

I am optimistic and pleased that there are all these efforts going forward. I hope we are thinking through how to ensure access, though, to rural areas. One of the things that I am asked about that people have heard that some of the vaccines—this is a question for Dr. Redfield. Some of the vaccines in phase 3 testing, evidently need to be stored at extremely cold temperatures. That is even by Wyoming standards. And that would be potentially as low as -94 degrees Fahrenheit.

Hospitals and nursing homes, pharmacies, doctors' offices might all be places where Americans go to get their shots. However, they do not have the specialized freezers that would be necessary to store the vaccine, especially in rural areas. So very few of those out—is there another solution or how can we ensure sufficient freezer and storage capacity or so there is access to the vaccine and it isn't just limited to major cities?

Dr. REDFIELD. Thank you very much, Senator. Again, there is a total commitment to work that this vaccine is distributed in an equitable and fair way across our Nation. The funding I announced today that we will get out to the individual states to be able to

really begin to operationalize their plans on the playbook is critical, and each jurisdictions going to have to address those issues, particularly as you looked at the importance of cold change and how they are going to maintain that. Clearly, we have—this is not something that we do not routinely do. I mentioned before, CDC routinely administers and distributes over 80 million vaccine doses a year through our routine work.

We are going to build on that. Obviously, the ability to bring all the pharmacies in is a really important step. But these micro plans that your state, the State of Wyoming will do, will identify what are the gaps that are there. And over the next four, six to eight weeks, we are going to need to figure out strategies that are going to fill those gaps to ensure that there is a proper cold storage for the vaccine distribution throughout this Nation in an equitable way. We are committed to making sure that happens.

Senator ENZI. Dr. Hahn, do you have any comment on that?

Dr. HAHN. Well, FDA's role, Senator Enzi, in this is to ensure that the controls around manufacturing and storage are followed. If, in fact a vaccine is authorized or approved that requires such cold storage as you mentioned, we will provide technical assistance and we will work with CDC to ensure that happens.

Senator ENZI. Thank you. Director Redfield, do you anticipate that once the Food and Drug Administration approves the vaccine, that the Centers—you kind of touched on this, the Centers for Disease Control and Prevention will have to work with the states to develop new, more detailed vaccine distribution plans or will the work the states are doing in advance suffice?

Dr. REDFIELD. Senator, it is very important, and I want to stress this is why it is so important, the playbook we put out last week and the funding we announced today, that we get these plans executed. We wanted to see the plans completed by October 16th so we can interact, share best practices of other states to try to get these plans as rock solid as possible. I am confident there will be some things that weren't thought of that will have to be dealt with as they come upon us.

But it is my expectation that each of the plans—we have done the micro planning now in Minnesota and North Dakota, California, Florida and Philadelphia over the summer just to get a sense on the complexity of it. Now we are looking for each of the four jurisdictions to complete that by October 16th. And it is our hope that is going to really lay out the individual plan to get this vaccine equally distributed in that jurisdiction, recognizing that there will be things that come up that we are going to have to work together to deal with as we see them. But hopefully we will be 95 percent of the way there based on the planning between now and October 16th.

Senator ENZI. Thank you, Mr. Chairman and Ranking Member.

The CHAIRMAN. Thank you, Senator Enzi.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much. I want to thank our witnesses for appearing and for their work. This week, we have announced to the world that we have reached the 200,000 grim milestone of deaths in America from COVID-19. That number translates in Pennsylvania into 8,000 deaths. So as we are thinking

about those—all those we have lost, we now have to consider the possibility that COVID-19 could be and likely will be considered a preexisting condition.

Just as the Affordable Care Act would be struck down by the Supreme Court in early November, at least the arguments starting then, and at the same time, we have got to consider the ravages of this disease, the COVID-19 disease in the context of nursing homes. I released yesterday with Senator Wyden a report, I will just hold up the cover of it, but the headline on the report, the Cost of Inaction, Eleven Deaths An Hour—11 deaths an hour.

That means that in the months of July and August of this year, 11 nursing home residents died from COVID-19 every hour. In total, when you look at the total number from the beginning of the pandemic, more than 78,000 residents and workers in long-term care facilities have died of COVID-19. And unfortunately, the Trump administration has no effective strategy, no effective plan in place to reduce this number, either or to reduce the death number or the case number in long-term care settings. This is an American tragedy. There is no excuse for these numbers just to keep going up. We should not allow the next couple of months to transpire and have the number of nursing home deaths or the nursing home case number go up again. That is not the America we should be.

Now, the majority in the Senate could be doing something about this. The majority in the Senate has been obsessed with confirmation votes. All kinds of confirmation votes, all summer long. And we did a defense bill as well. But mostly, almost all of our votes were on confirmations. Now, the Senate majority is obsessed with getting a confirmation vote on a Supreme Court Justice.

I just have one question for the majority, when will the Senate Republicans and the Trump administration become obsessed, yes, obsessed with reducing nursing home deaths? Now, let me get to our witnesses. I want to ask a question that Dr. Hahn was already kind enough to answer, which is about the vaccine and his response to that in terms of his own family, his own person. One of the most important challenges we face in developing and then distributing and administering a safe and effective vaccine is public confidence.

As a way to demonstrate faith in the integrity of both the approval process and to assure the American public that vaccines are safe, I would ask the other three members of our panel if they will commit to receiving the COVID-19 vaccine in public view once one becomes available and is authorized or approved by FDA. Starting with Dr. Fauci.

Dr. FAUCI. Thank you for the question, Senator Casey. Yes, I have said that in the past that if a vaccine that is shown to be, and proven to be, and authorized by the FDA to be safe and effective, I certainly would take that vaccine and I would recommend to my family that they take that vaccine. Yes.

Senator CASEY. Thank you.

Admiral GIROIR. I have every confidence in the FDA process to provide us a safe and effective vaccine. I would have no hesitancy to take that vaccine. I would have no hesitancy to recommend my family. But I think the question is a little bit inappropriate. People need to read that vaccine. They need to understand, have a discus-

sion with their physicians or providers before you ask anyone to commit to that. But I just want to tell you, I have complete confidence in the FDA process.

Senator CASEY. Dr. Redfield.

Dr. REDFIELD. Yes, Senator Casey. Yes, absolutely. As I would with my wife, children, 11 grandchildren, I would recommend it to all of them. And of course, myself, I would take it. I have total confidence in the FDA, in the process of getting us a safe—if they give an EUA, then I am confident it will be a safe vaccine and I am ready to take it.

Senator CASEY. Dr. Redfield, I have a question for you on state immunization information systems in light of the vaccine program interim playbook. Just have one question before my time expires. How many jurisdictions immunization information systems need all the standards set forth in the playbook today?

Dr. REDFIELD. Senator, I would have to get back to you to be able to answer that specifically. And I will say that we are building on, as I mentioned, the system that we regularly use in these 64 jurisdictions to distribute 80 million vaccine doses a year. In addition, there will be additional information capacity that will be put in to where there are new points of service where that technology currently does not exist. But I will have my team put together a comprehensive answer for that question for you.

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

The CHAIRMAN. Thank you, Senator Casey.

Senator Burr.

Senator BURR. Mr. Chairman, thank you very much. Welcome to all of our witnesses and our thanks to your agency and the many workers who work on this. And let me say to Senator Casey, answering his question, the majority has been focused on pandemics since 2002 when we first started passing legislation to create in many ways the architecture that we fall under today and the protocols that allow Dr. Hahn, Dr. Fauci, Dr. Redfield, Admiral Giroir to do, in fact, what they are doing.

We thank you for that. Dr. Hahn, have we made up new protocols for the review of a COVID vaccine, or are we simply following the protocols that we have used for every vaccine that every Member of this Committee, every Member of Congress and the American people have always seen as the gold standard?

Dr. HAHN. Well, with respect to our approval or authorization of medical products, FDA does represent the gold standard. Now, the statutory definition for an EUA or authorization is different, of course, than it is for an approval. But we are following those criteria. With respect to our performance during COVID-19, I want to give you a few examples, because in fact you are correct. FDA does represent the gold standard. Our scientists are incredible. They have done really remarkable work here. And one of the major things that distinguishes us from other regulatory agencies around the world is that we actually look at the primary data. We do not just look at a paper. We just do not look at a press release. We look at the primary data.

Our scientists analyze that data, and then we draw conclusions from that data. We did that with remdesivir. We did that with convalescent plasma. We are doing that with tests. And so those are

the sort of things that FDA does that I believe represent the gold standard and allow us to have great confidence in the decisions that our career scientists are making.

Senator BURR. Dr. Hahn, would it be appropriate to say that the clinical trials, phase 3 clinical trials that are currently going on, now four, manufacture, I think the fourth one was announced this morning, are the most expansive and diverse trials that we have seen in recent memory just simply because they are global trials and typically we have not picked up that international data until post approval in many cases and reviewed it?

Dr. HAHN. Senator Burr, it is correct to say that they are among the most diverse and expansive trials. I think that is a reasonable way to put this. We were very clear in our June 30 guidance about what we needed to see with respect to efficacy. A floor, not a ceiling, a floor of 50 percent, which led to the power calculations in these trials, and therefore 30,000 plus volunteers in each of these trials.

If you think about the number of trials that are ongoing and plus the studies that were done before in phase 1 and phase 2, a great, if you will, number of people who would have received these vaccines, which will give us the data we need to see in order to make the determination. So these have been very robust. The private sector has responded, the Government has responded, and I think it has been a great effort to get these trials together.

Senator BURR. Dr. Hahn, you talked about the steps that an applicant would go through and how it would be their decision as to whether they applied for emergency use authorization or for approval. The one thing I did not hear you mentioned, and I think you just left it out, is the Data Safety Monitoring Board, DSMB, which actually looks at the data prior to the application coming to the FDA. Is that in fact correct and is that another safety step?

Dr. HAHN. Senator Burr, exactly. It is another check and balance, if you will, in addition to the others. So let me just explain that, if you will, sir. When a sponsor, someone that is developing a vaccine, a company performs a phase 3 clinical trial, there is something called a Data Safety Monitoring Board. That is an independent board and they have set check-ins to look at the data. Now, when they meet, they can make a couple of determinations. No. 1, if there are significant safety issues, they could stop the trial because of safety issues.

No. 2, they could do what is called a futility analysis, meaning that continuing that trial won't do any good because there is not a statistical probability that it will reach the primary endpoint, that it will be successful. And then, of course, they could have met the prespecified criteria around effectiveness in the case of the vaccines, prevention of infection.

That would be another criteria that would be used to say, Okay, the data are mature, give it to the company, and then the company can put that into an application to us.

Senator BURR. Thank you. Dr. Fauci, I want to turn to you just real quick, because the Moderna vaccine works off of a technology platform that you actually created at NIAID. Are you confident of the process that is going on at the FDA that will, in fact, review the application of clinical data from that platform? And as an add

on to that, would you also answer from Members of Congress for the husband and wife that come to us and say, my husband got COVID and I, the wife, did not get it. How with a highly transmissible infection like this can two people live together and one be positive and one never get positive? If there is an answer, I would love to be able to know.

Dr. FAUCI. Yes, I mean, that happens all the time with infections, Senator, that although a virus can be highly transmissible, there is a great degree of variability of a person's natural resistance to a particular type of an infection. So although a highly transmissible virus usually has an attack rate that is high, we see all the time individuals who are exposed to someone with an infection who do not get the infection.

If you look at the population as a whole, you see the kinds of things that we are seeing as this pandemic evolves, that it is highly contagious. We had the same situation where you had HIV, where individuals were living with the person who had sex on a regular basis with someone with HIV, and they never got infected, whereas another person could have sex one time with a person with HIV and get infected. That is the nature of the variability of susceptibility to infection among individuals. So it is entirely conceivable.

Senator BURR. Your confidence in the FDA review and the technology platform?

The CHAIRMAN. We are running well over time.

Dr. FAUCI. Yes, absolutely. The answer is yes, I am quite confident in the FDA's ability to review that technology and to determine safety and efficacy based on the data of the trial.

Senator BURR. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burr.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman. Dr. Redfield, in April, the CDC staff conducted an investigation into a COVID-19 outbreak at a meatpacking plant in South Dakota. Following the investigation, your staff sent a report to the state that is South Dakota's Department of Health that included strong safety recommendations the CDC determined were necessary to stem the transmission of COVID-19 at the plant. That report was dated April 21st of this year.

Last night, it was reported that your office intervened and ordered that the safety recommendations be watered down. The next version of that memo dated the following day or April 22nd, essentially adds the words, if feasible, to those strong safety protocols over and over again throughout the document, telling the plant essentially that these recommendations were voluntary or optional. Workers continue to work shoulder to shoulder at that plant, and the plant ignored the safety guidelines. To date, at least 1,200 workers from that very plant have been infected with COVID-19 virus, 34 have been hospitalized, and 4 have died.

I will also note that in that same time period in April, on Tuesday, April 24—or 28 excuse me, that is when President Trump issued his Executive Order basically naming meat packing as an essential industry and meat packing workers as essential workers.

I would like to enter the two documents I referred to, the April 21st and April 22d safety recommendations concerning these meat

packing plant. If that is Okay, Mr. Chairman, I would like unanimous consent to do so.

The CHAIRMAN. Without objection.

[The information referred to can be found on page 75 and 90.]

Senator BALDWIN. I think I heard somebody indicate that I got unanimous consent. Dr. Redfield, why did your office demand that these recommendations be watered down?

Dr. REDFIELD. Thank you very much, Senator. I would not characterize it the way that you did. What I would say is that the field teams that we had that were in on the Smithfield plant investigation that you are referring to had a report that they did in the field and they shared it with the local South Dakota health department. One of the critical things that needed to be stressed in that report was the CDC is not a regulatory authority. These were, in fact, recommendations.

The Department of Labor and OSHA have regulatory oversight, and their report can direct that regulatory oversight. Our report was recommendations from an Epi-Aid, and so as that document was reviewed, we wanted to make clarification, then make sure people understood ours was a recommendation and not a regulatory requirement.

Senator BALDWIN. Okay. Thank you. And I will note that OSHA and the Department of Labor have failed to issue anything that voluntary guidance, as has CDC. There are no pandemic emergency standards in place for workplaces in the U.S., even though they have had eight months to work on this. But that is not your responsibility. Did your office have any contact with Smithfield Foods or the U.S. Department of Agriculture or the White House concerning specifically this memo before it was edited?

Dr. REDFIELD. No, not at that time. There is a multi-interagency discussions between Labor, Agriculture and ourselves on a variety of the issues and intersect, but in that regard, again, it was—the purpose was to stress clarity that we were not a regulatory agency. These were recommendations.

Senator BALDWIN. Well, given that, I would ask you to consider changing the meat packing guidance, you could simply say we are not a regulatory agency, but these are the safety protocols that we would recommend and not have if feasible, if feasible, if feasible. It makes it sound like these are not particularly important. You can do it great, if you can't—you can say these are our safety recommendations without it being construed as an OSHA standard. And I would ask, will you change that meat packing guidance in light of the death toll and harm?

Dr. REDFIELD. I appreciate your comments, Senator.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Paul.

Senator PAUL. Initially, Government officials were honest enough to admit that the goal of mitigation efforts, a.k.a. lockdown, was to flatten the curve. But the area under the curve, the total deaths from the virus would likely be the same. In other words, the lockdown was to mitigate the spike in viral deaths so our hospitals would not be overwhelmed. But the same amount of people would likely die with or without the lockdown. The media, and frankly Government officials, seem to have forgotten this important caveat.

Flattening the curve morphed into a belief that we could change the course of the pandemic with an economic lockdown. This is unfortunate and has led to the protracted lockdown recession we are currently mired in. It is important that we examine the data, learn from the data and try to avoid the manmade aspect of this calamity in the future. To those who argue that the lockdown flattened the curve in New York and New Jersey, the evidence argues otherwise. New York and New Jersey wound up with the sharpest spike or highest death rate in the world at over 1,700 per million.

In contrast, Sweden had a relatively softer touch, few mandates and mostly voluntary guidelines. Sweden's death rate ended up about a third that of New York and New Jersey. Some might argue that Sweden and New York, New Jersey are different populations, perhaps, but even the average death rate for the U.S. is now greater than Sweden. In fact, the U.S. death rate is quite comparable to less developed parts of the world where social distancing is virtually impossible, such as Brazil, Bolivia and Ecuador. Which brings us to an important question, is man really capable of altering the course of an infectious disease to crowd control?

The statistics argue a resounding, no. The evidence argues that mitigation efforts have failed to flatten the curve, that most countries, regardless of public health policy, suffered a significant spike in deaths and then a gradual decline. Now some will argue, what about Hong Kong, Taiwan, South Korea, Japan, each which have had extraordinarily low death rates? Hong Kong, Taiwan and South Korea certainly enforced strict quarantine and contact tracing rules in the U.S. but Japan's rules were largely voluntary since their prime minister lacks the legal powers to enforce a lockdown.

One explanation for the low death rate in much of Asia is that the population may have a higher degree of exposure to Coronavirus colds and therefore have more preexisting, cross reactive immunity. If scientists were interested, there is a fascinating field of inquiry looking at susceptibility of COVID-19, an assessment of whether people not have preexisting immunity to similar coronaviruses. In fact, preexisting cross reactive immunity to Coronavirus may explain why we have so many people that have very little symptoms or are asymptomatic.

While there are still many things we need to learn about this pandemic, it is important that we, the people, not simply acquiesce to authoritarian mandates on our behavior without first making the nanny state prove their hypothesis. As for now, what we do know is that New York and New Jersey and Connecticut and Rhode Island still allow the highest death rates in the world. We also know that Sweden, who enforced few mandates, ended up with a death rate of one third of New York and New Jersey.

We also know that the overall death rate for the U.S. now is essentially equivalent to that of South America, where social distancing and mitigation efforts are virtually impossible. Dr. Fauci, today you said you are not for economic lockdown down, yet your mitigation recommendations from dating to baseball to restaurants to movie theaters have led to this economic lockdown.

Do you have any second thoughts about your mitigation recommendations considering the evidence that despite all of the things we have done in the U.S., our death rate is essentially worse

than Sweden, equivalent to the less developed world that is unable to do any of the things that you have been promoting? Do you have any second thoughts? Are you willing to look at the data that countries that did very little actually have a lower death rate to the United States?

Dr. FAUCI. Senator, I would be happy at a different time to sit down and go over detail. You have said a lot of different things. You have compared us to Sweden. And there are a lot of differences. And you said, well, there are a lot of differences between Sweden, but compare Sweden's death rate to other comparable Scandinavian countries. It is worse. So I do not think it is appropriate to compare Sweden with us. Yes, we have—I think in the beginning, we have done things based on the knowledge we had at the time.

Hopefully, and I am and my colleagues are humble enough and modest enough to realize that as new data comes, you make different recommendations, but I do not regret saying that the only way we could have really stopped the explosion of infection was by essentially, I would not say shutting down—I mean essentially having the physical separation and the kinds of recommendations that we have made.

Senator PAUL. You have been a big fan of Cuomo and the shut down in New York. You have lauded New York for their policy. New York had the highest death rate in the world. How can we possibly be jumping up and down and saying, oh, Governor Cuomo did a great job. He had the worst death rate in the world.

Dr. FAUCI. No, you misconstrued that, Senator. And you have done that repetitively in the past. They got hit very badly. They have made some mistakes. Right now, if you look at what is going on right now, the things that are going on in New York to get their test positivity 1 percent or less is because they are looking at the guidelines that we have put together from the task force of the four or five things of masks, social distancing, outdoors more than indoors, avoiding crowds and washing hands.

Senator PAUL. Or they have developed enough community immunity that they are no longer having the pandemic because they have enough immunity in New York City to actually stop it.

Dr. FAUCI. I challenge that, Senator. Please, sir, I would like to be able to do this because this happens with Senator Rand all the time. You were not listening to what the Director of the CDC said, that in New York it is about 22 percent. If you believe 22 percent is herd immunity, I believe you are alone in that.

Senator PAUL. There is also the preexisting immunity of those who have cross reactivity, which is about a third of the public in many estimates and studies, which would actually get you to about two thirds.

Dr. FAUCI. I would like to talk to you about that also because there was a study that recently came out that preexisting immunity to Coronavirus or that of a common cold do not cross react with the COVID-19.

The CHAIRMAN. Thank you, Senator Paul.

Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. I will stay with you, Dr. Fauci. Apologies for not giving you a break.

There was a study that got some attention regarding Big Ten in PAC 10 athletes that found that 15 percent of them who had COVID-19, whether or not they showed symptoms, had evidence of myocarditis, inflammation and damage to the heart muscle. What are the long term effects for someone with myocarditis? What is the current understanding of the possible more general long term effects of somebody who has had COVID and recovered? And are these effects observable in asymptomatic COVID-19 patients?

Dr. FAUCI. Yes. Senator, thank you for that question. I actually had mentioned that in my opening comments, but thank you for giving me the opportunity to expand on that. That is really quite puzzling because the individuals that was—there were two studies. There was one study, not in athletes, and then there was the study that you mentioned, in athletes.

The study in the non-athletes were individuals who had recovered from COVID-19 and had various degrees of involvement, to moderate disease, to disease that would require intervention medically. And by doing MRIs, they found that about 60 to 70 percent of them had indication of inflammatory disease in the heart. Interestingly, they were relatively asymptomatic. So I think we need to be careful and just watch what happens, because one of the possibilities that could develop is that, A, it could clear up and they have no problem for the rest of their lives. The other things that they could wind up when you have inflammation, you could have scarring. That could lead to a arrhythmias later on, or that could lead to cardiomyopathy. I have to tell you, I do not know what it would be, but it is something we really need to keep our eye on.

Senator MURPHY. Insurance companies tend to err on the side of caution. And so what we believe is that because of this uncertainty, because of this potential for long term health effects, that any diagnosis of COVID, whether you are symptomatic or not, will become a preexisting condition and that it is likely probable that insurance companies, if they are allowed to discriminate against people with preexisting conditions, as will happen if the Supreme Court justice is put on the court and the ACA is invalidated, we will see rates skyrocket for anybody who has had COVID.

I think that is something we all need to talk about over the course of the next few weeks. Dr. Redfield, admiral, I want to come back to this question of the guidance on testing. I think this is really important because, we have to take the President at his word. He announced that he had instructed his advisers to, “slow the testing down, please.” When folks suggested he was kidding, he was asked by reporters, are you kidding? And he said, I do not kid. Let me just tell you. Let me make it clear. So the President made it clear he wants less testing.

It never did not seem coincidental to us that this strange guidance came out in August that recommended significantly less testing. And yet that is not what you are testifying to today. You are both saying that, in fact, that August guidance did not recommend less testing. And all you were doing with this third set of guidance in 30 days was to clarify. But where in the August guidance does it tell people that they should get a test if they are asymptomatic but in close contact?

Where in that guidance does it actually tell them that they should proactively see a health care provider if they have been in contact? Because I have read it 20 times and I do not see anywhere in this guidance that it tells people they should get a test. I do not see anywhere in this guidance where it tells them that they should go see a doctor. It reads, you do not necessarily need a test unless you are a vulnerable individual or you are a health care provider or your local health officials recommend you take one. That does not say you should go to the doctor.

That just says if you have been recommended to get a test, you should. So it stands to reason that when folks read this, that they will be under the impression that they should not get a test which seems to comport with the directions of the President, slow the testing down, please. Where in this guidance that you issued in August does it tell people that they should get a test or they should proactively see a doctor?

Dr. REDFIELD. Thank you very much, Senator. And as I have said before, I take the position that more tests will actually lead to less cases, particularly if it fully engages public health action. And when I issued the clarification on August 27th, again, I said that we are placing emphasis on symptomatic illness issues and also, as you said, individuals with significant exposure of vulnerable populations, critical infrastructure workers, health care workers, and those individuals who may be asymptomatic when prioritized by a medical or public health official.

The reason that this came from a public health perspective, we were seeing individuals drive up, get a test and then go on to work. There was not a public health action associated with testing. So we calculated that this would help bring a public health action to testing.

Senator MURPHY. But notably, you do not tell people in this guidance that they should go see a doctor.

Dr. REDFIELD. When—I said when we clarified the day after, I put very clearly what the clarification was about the emphasis in the final category with those individuals who are asymptomatic when prioritized by a medical or public health individual. And again, the intent was for testing to drive an action that was for a public health objective. It was clear, through a variety of different reasons when we found that some individuals were not even doing testing for contacts, the individuals with significant exposure, we then put the further clarification.

I had thought that the August 27th clarification statement that I put out would carry the football over the goal line. It did not. But I can tell you there was no intent to this guidance to decrease testing. On the contrary, the intent was to link testing and to drive a public health action. And again, the manner in which it was interpreted by a number of individuals was such that it did not accomplish that goal.

Senator MURPHY. I think I am over my time. This has just been dizzying, dizzying for public health professionals. They are just awaiting the next correction. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy. In my effort to be fair to everybody, we are running over the 5-minutes pretty well. So we have about 14 Senators remaining who would like to ask

questions so I would ask their colleagues to keep that in mind, please, with the 5-minute rule.

Senator COLLINS.

Let me begin my questions today by thanking each of you for your hard work, your professionalism, and your integrity. I do not think you get the appreciation that each of you deserves. Admiral, the American people clearly need to have confidence that all our Federal health agencies will abide by their gold standard, rigorous protocols and preserve scientific integrity. And we have heard this morning just such strong assurances. Nevertheless, just last week, Secretary Azar barred the Nation's health agencies from signing new rules themselves regarding medicines or medical devices as they normally would do.

Such a major change at this critical time could delay progress and cause the American people to doubt whether the proper protocols are being followed. Could you explain why these changes are taking place and whether they could affect new medical countermeasures for COVID-19?

Admiral GIROIR. Thank you for that, Senator. I have spoken to several people in the immediate office of the Secretary. And as I understand it, and I do absolutely believe it, that this was an administrative decision by the Secretary because rulemaking authority in an agency that has 90,000 people gets disseminated broadly and widely and he wanted to make sure that whatever rules were proposed by FDA or other rulemaking organizations had review and scientific integrity.

I do not believe that this will interrupt the process. You have my commitment to make sure that I will provide the best public health advice to the Secretary on all these matters. I do not believe it will make a difference. And these can be redistributed back out. This was an administrative process, as I understand it, to bring them back in, to gain control so that there aren't hundreds of different ways to make rules during this very important time. And perhaps Dr. Hahn, as a rulemaking agency, might have a comment on that as well.

Senator COLLINS. I have a different question for Dr. Hahn that I want to make sure I get to. Let me just say that while I appreciate your assurances, if everything is going to have to flow up to the Secretary, it seems inevitable that it is going to create delays and doubts, and neither of those are helpful as we deal with this pandemic. Dr. Hahn, I want to bring up with you an issue that we have discussed many times, and that is the fact that so many of our active pharmaceutical ingredients for medicines for the American market are manufactured overseas.

In fact, 72 percent of the facilities are located overseas in countries like China and India. India put an export ban on some 26 APIs. We know that China hoarded PPE that our country needed. So my question to you is, are we making any progress in ensuring that the APIs that may be critical in therapeutics for treating people with the Coronavirus or in the ultimate vaccine are manufactured right here in the United States and not in China or India or somewhere else?

Dr. HAHN. Thank you, Senator Collins. You bring up an incredibly important topic and one that I think has been very much high-

lighted during the pandemic. We have seen situations where the lack of redundancy in our supply chain, the lack of domestic manufacturing has led to shortages here at home. So we have been very active and I believe we are making progress with respect to what we are calling advanced manufacturing.

Now Senator Collins, we have spoken about this many times and the issue of making sure that we have this redundancy through advanced manufacturing is important. It is something that FDA has been involved with for years. With respect to the issue of medications, for example, and PPE, I know that the White House task force has been particularly focused through FEMA and now HHS on making sure that we buildup our domestic capacity, particularly around PPE.

Yes, those are in progress. It remains a top priority for the Food and Drug Administration. Our role in this will be to help to create whatever regulatory path that we can so that we can facilitate advanced manufacturing that is domestic.

Senator COLLINS. Thank you very much.

The CHAIRMAN. Thank you, Senator Collins.

Senator Warren.

Senator WARREN. Thank you, Mr. Chairman. Vaccines are our best chance to end this pandemic but Americans are not going to take a vaccine if they do not trust the Federal officials who are promoting it. If Federal officials stand to gain financially from certain COVID vaccines and not from others, then Americans might reasonably worry that the vaccine was pushed for personal profit and not because it was best for our health.

I have a question for all of our witnesses, and I think you can answer with just a simple yes or no. Dr. Fauci, do you hold direct financial investments like stocks in any of the companies that are developing COVID-19 vaccines?

Dr. FAUCI. No.

Senator WARREN. Thank you. What about you, Dr. Redfield?

Dr. REDFIELD. No, Senator.

Senator WARREN. Alright. Dr. Hahn?

Dr. HAHN. No, Senator Warren.

Senator WARREN. Admiral Giroir?

Admiral GIROIR. No, Senator Warren.

Senator WARREN. Okay, thank you. So none of you stands to get richer if any particular drug company gets money from the Government. And I am not surprised by your answers because Federal ethics law prevents you from owning stocks like that. Public health, not money, guides to your work for the American people, and that is exactly how it should be.

Dr. Hahn, the FDA is responsible for deciding whether a COVID-19 vaccine is safe. In your opinion, if the FDA officials making these decisions had financial conflicts, would that increase or decrease people's confidence in a COVID-19 vaccine?

Dr. HAHN. Senator, I am not aware of anyone at FDA that has a conflict related to vaccines who is involved in that decision-making process so it would be difficult for me to speculate on that since we have very rigorous standards in place. We have monthly review, particularly of senior officials. We have regular training. And we have a culture at FDA which looks at the issue of self-de-

clared as well as Office of Government Ethics Review of all conflicts. So one thing I would like to say to you, Senator, if anyone is aware of anyone at FDA who has a conflict related these, I would personally want to know because we will address that right way.

Senator WARREN. Well, I very much appreciate this, because what you are saying is that financial conflicts are a real problem in the drug and vaccine development process. But here is the problem we have got. Dr. Monsef Slowey, the man that President Trump selected as the Government's "vaccine czar" is a former drug company executive.

The Trump administration used a loophole in Federal ethics law to hire him to keep his conflicts from the public. Now, he reportedly owns about \$10 million of stock in GlaxoSmithKline Drug Company that is working on a Coronavirus vaccine. And according to documents released yesterday by the House, he may own stock in Lonza Group, which is a company working with Moderna, another pharmaceutical company that is trying to make this vaccine. Why does this matter? Well, Operation Warp Speed, the Federal vaccine project that Dr. Slowey heads up has invested billions, that is billions of dollars in the companies that Dr. Slowey hold stock in.

Dr. Hahn, you and other FDA officials involved in the COVID-19 vaccine must comply with conflict of interest laws. You have just told me how seriously you take that. So can you explain to me why Dr. Slowey should get to play by a different set of rules?

Dr. HAHN. Senator Warren, I can't explain the situation. I do not have any knowledge of what you describe. What I can tell you is that we have established a very bright line between Operation Warp Speed and FDA. We do not participate in their decisions. We provide technical assistance, just as we would for any sponsor.

Senator WARREN. With all due respect, Dr. Hahn, you just told me that financial conflicts of interest basically undermined the public's trust in a vaccine and Dr. Slowey has conflicts of interest. So to boost the public's confidence, shouldn't he eliminate these conflicts?

Dr. HAHN. Senator Warren, I am not aware of the conflicts you are describing. And so I can't comment—

Senator WARREN. Let me put it this way, hypothetically, if these conflicts exist, and we will only know if they exist if he makes a full disclosure, but there is much evidence that they exist—if these conflicts exist, should he resign?

Dr. HAHN. In a hypothetical situation that you are describing, again, I can't prejudge because I do not know the facts. But I do take very seriously the issue of conflicts of interest and how that might affect public perception.

Senator WARREN. Well, let me put it this way, Congress should strengthen the Federal ethics laws to root out this kind of corruption. It should pass the Corona Virus Oversight Recovery Ethics Act, which is a bill that I introduced in order to prohibit conflicts of interest in the Federal COVID-19 response. And the first person to be fired should be Dr. Slowey. The American people deserve to know that COVID-19 vaccine decisions are based on science and not on personal greed and Congress should pass my bill today. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Warren.
Senator Cassidy.

Senator CASSIDY. Thank you, Mr. Chairman. I was distracted when Senator Burr was given his answer, but he may have replied to Senator Casey. It is as if Senator Casey did not hear Admiral Giroir's testimony, when he said, what is the Administration doing to prevent deaths in nursing homes and we just heard how many resources were being deployed to nursing homes.

I just want to, in case Burr was not able to raise that, I just want to emphasize that. Second, coming in on previous testimony, Baldwin and Redfield. Dr. Redfield, I thought you answered Senator Baldwin's question very well, and I will say my office has called OSHA as regards to guidelines for people who are, for businesses in terms of how to conduct themselves and OSHA said that they are deferring to CDC. That is not CDC's fault.

Mr. Chairman, I would just recommend we have a hearing with OSHA to kind of straighten that out, because I thought that is a good point. Dr. Giroir, it is my understanding that the Administration is granting authority to pharmacies to immunize those between ages 3 and 18. Because of the crisis, we have had a kind of slowdown in those children. They are missing their vaccines that they should get. Is there going to be a requirement that they put these vaccine records in the state's immunization registry?

Admiral GIROIR. Yes, sir.

Senator CASSIDY. What about Federal facilities such as DOD, V.A., Indian Health Service, etcetera? Will they likewise be required to enter their data into the state's immunization registry?

Admiral GIROIR. Sir, I actually do not know about DOD. I just do not know that specific. I know that for the pharmacists, of course, and anyone in the civilian population, they are required. That was a part of the Prep Act declaration and my guidance about that.

Senator CASSIDY. Just the suggestion, the DOD should be required, because obviously many of them will be separating from the military and it may be a condition of employment by a health care facility that someone be vaccinated. It would be nice to have that documented as opposed to someone just, stating that they had been. Just to point that out.

Admiral GIROIR. Yes, sir. I wasn't commenting on whether it is good or bad. I just did not know the regulation for DOD. Would be very happy to look that up and bring it back, sir.

Senator CASSIDY. Oh, yes. And I am not fussing about it. I am just kind of pointing that up. Now, Dr. Redfield, maybe Dr. Giroir, I understand that the vaccine can be given without cost to the patient, but there is a concern by the provider that they would be compensated for all their costs associated with administering the vaccine. So in the guidance coming out that Americans will not have to pay, but is there still going to be compensation for the provider who is administering the immunization?

Admiral GIROIR. Thank you, Senator. And let me speak generally that, of course, we would assume that there are costs for the provider. These are going to be tens or hundreds of millions of vaccines. There are details to be worked out but the Administration is committed to assuring that no patient has out-of-pocket ex-

penses, whether it is for the vaccine itself or for the administration of that vaccine.

Senator CASSIDY. Got you. Dr. Hahn, the vaccine may only have 50 percent efficacy. I think that is the FDA's minimum as to considering whether a vaccine is effective, is that it is efficacious at least 50 percent of the time. Presumably, the level of antibody response would be a marker as to whether or not somebody has had a response.

My question is, for those folks who are at higher risk, think the emergency room nurse, the tech or the clerk admitting people to the E.R., will antibodies serology be required after the vaccine is given? And do we have enough antibodies serologic tests, which were not sufficiently accurate nor sufficiently available, in order to conduct this?

Dr. HAHN. Senator, thanks for the question. For the first several trials, when they mature, we will not yet have data that bridges between a clinical outcome, which is the, of course, primary endpoint we have required for showing its effectiveness. That is the prevention of COVID-19 illness and the development of antibodies. So it is unlikely in that situation, although again I can't prejudge the data, that we would have a requirement there. Again, the data will point us in that direction. For subsequent trials, if in fact there are bridging data or from the initial trials there is bridging data, one could imagine a situation where that could occur. But again, we do not know that because we have not seen the data yet, sir.

Senator CASSIDY. Thank you all for your brief answers. I yield back.

The CHAIRMAN. Thank you, Senator Cassidy.
Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman. And I want to just say a word to you, Senator Alexander, how much I am going to miss you as the Chairman of this Committee. I have learned a lot from you about how to be a good Senator, both from working with you, but also from observing you. And I am going to miss your friendship and I am going to miss your leadership. I also just want to acknowledge what it means to have 200,000 people in this country who are no longer with us. My wife and I have four friends who died of Coronavirus. We have each had Coronavirus so I guess we have preexisting conditions now and hopefully some antibodies that might do something.

I agree with the Chairman. His opening comments said that as of March 1, The New York Times said and others did to Johns Hopkins that the U.S. was the best prepared of any Nation to deal with this. And I believe that. And yet I think the management, beginning with our preparation and the resources we have as a country, the management of this crisis has been one of the worst failures of domestic governance in the history of this country. And do not believe me. I mean, I am just a U.S. Senator, but when people who are staffers on the task force are resigning and saying the same thing, I think we have got to pay attention to that.

I am also mindful of the fact that during this crisis, not for a second has this administration stopped its concerted four year effort to take health insurance away from millions and millions of people. I can only imagine how much worse this would be in Virginia if

400,000 people did not have Medicaid expansion, but many are hoping to see what it will be like if we take health insurance away from millions of people so we may have the opportunity to see that.

One of the reasons I think this has been handled so badly is not because of the dedication of wonderful professionals. I think we have some wonderful professionals who are very dedicated, but I think it goes back to communication. I was a mayor and Governor. I dealt with a lot of crises, weather crises, hurricanes, mass shootings at Virginia Tech when I was Governor, H1N1 when I was Governor. None were at the scale of this.

But one thing I learned from dealing with crises is communication. Clear communication to people who are worried is absolutely critical. And that is where we have fallen down on the job with a President who has preached hydroxychloroquine or bleach or disinfectant. The day that the Administration laid out guidelines for states on reopening, my Governor, who is a doctor, said those are good guidelines, I am going to follow them. The next morning the President tweeted out a tweet against them, liberate Virginia against this tyrannical Governor who is following my advice. And we have seen so many other examples of poor communication or mixed messages. And that has really confused the public.

Dr. Fauci, just this week, a key communications staffer at the NIH had to resign when he was outed as somebody who was in a conspiracy laden website trashing you, trashing other public health professionals, trashing your advice about mask wearing, suggesting that this was just a hoax or an invented crises. My four dead friends would say it was not an invented crisis.

Dr. Redfield, I was very, very concerned when the CDC changed its website this week about how the virus is transmitted. I would like to ask that a slide be put up. This is going to be very hard to read and so I will sort of bring it to your attention, but the CDC I believe on the 18th of September put up new guidance based on just the ongoing analysis of this crisis about what we could do to protect ourselves and how the virus is transmitted but then almost immediately reversed it. What about the September 18th version that is on that screen was incorrect?

Dr. REDFIELD. Thank you, Senator. I think what I tried to comment before that this was a first draft document—

Senator KAINE. No, and I heard that so I don't want to ask that question. What about it was incorrect?

Dr. REDFIELD. It is looking at the balance of the component that aerosolized transmission plays compared to droplet transmission.

Senator KAINE. Let me read you two examples. The version that posted on the 18th. People who are infected but do not show symptoms can spread the virus to others. Clear, unequivocal. But you changed it back to some people without symptoms may be able to spread the virus. Now is that phrase, people who are infected but do not show symptoms can spread the virus to others, is that inaccurate?

Dr. REDFIELD. Let me just set the stage here. The document that it was reverted to was the original cleared document. It was not a changed document.

Senator KAINE. I understand that but back to my question. Is it accurate to say people who are infected but do not show symptoms can spread the virus?

Dr. REDFIELD. Absolutely they can.

Senator KAINE. That is accurate, isn't it?

Dr. REDFIELD. Absolutely.

Senator KAINE. The document further said there is growing evidence that droplets and airborne particles can remain suspended in the air and be breathed in by others and travel distances beyond six feet, for example, during choir practice, in restaurants or in fitness classes. Is that statement accurate?

Dr. REDFIELD. There is definitely evidence of that, sir.

Senator KAINE. There is no inaccuracy in this statement?

Dr. REDFIELD. There is definitely evidence of that.

Senator KAINE. But that was removed in the changed document and it went back to its original form, which did not—

Dr. REDFIELD. I just want to highlight that it is not that anything was removed—

Senator KAINE. Well, it is not on the website right now, correct?

Dr. REDFIELD. Technically, the cleared document that went through the proper channels is what was put up. I can say that all these decisions about the aerosolize document were made by career staff individuals far below my level as the Director. When they saw this non-scientifically cleared document go up—

Senator KAINE. Well, I am over my time. I understand. But the point I am trying to make is we need to communicate clearly. When you put up a document at the CDC that you have just testified is accurate and then it is changed to suggest that the risk is more minimal by someone for some reason, it contributes to the massive confusion that is so troubling to scientists and so troubling to people. And then that leads to, well, gosh, is the vaccine going to be safe?

Dr. REDFIELD. And again, I just want to stress for the American public and for everyone here that document that went up was a draft. It had not been technically reviewed by CDC. It reverted to the document that was taken and reviewed. There is going to be a technically reviewed document on this issue coming on the website but the one that was posted on Friday was not technically reviewed, and as a consequence, the career scientists at CDC took it down, put up the technically reviewed document until the new technology to review document can be posted.

Senator KAINE. But you testified that the one was taken down was accurate and that was the point that I wanted to make. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Mr. Chairman. And gentlemen, I want to echo Senator Collins's comment and her thanks and appreciation. I share that. I know that there is plenty to argue and quibble about and whether or not communication has been clear or not clear. I think we do owe that to the American public. But I also know that the work that you and those that are part of your team is hard, hard, arduous work and you have definitely been put to the task.

I appreciate the work that you do. I want to direct my questions to you, Dr. Redfield. And first, thank you for CDC's effort to help our state and local public health departments. Recently, we had a CDC team deployed to Anchorage to assist us there with an outbreak of COVID that we had seen within our homeless population. And you have been—you were quick when asked, and we greatly appreciate that assistance.

I want to speak about—I want to ask you about the interim guidance, the interim guidelines that states are considering as they are drafting these plans to be submitted for mid-October. And it goes to Senator Kaine's comments about the communication and the need for additional clarity that I am hearing from my state, specifically in the allocation, the first allocation of the vaccine in terms of the jurisdictions and who is to receive that. It states, but, for instance, the tribal health system is that its own jurisdiction for purposes of allocation.

When we talk about critical populations, it is my understanding that the first phase is going to be allocated based on targeting these critical populations. Well, in Alaska, we have got about one quarter of our population Alaska Native that could be determined to be 18 percent, determined to be critical population. And then further to additional guidance on what qualifies as a health care worker.

In our state, our community health aides are some of those front-line workers. Can you help me with further clarification for purposes of the state's plan on guidance with allocation and defining critical populations?

Dr. REDFIELD. Thank you, Senator. Obviously critical questions. I will say at this moment in time, the definitive answers in terms of the allocation process have not been completed. I do take Senator Kaine's and your comments to heart how important it is that when that is completed, that it is communicated in an effective way. That we are currently going to see the plans, as you know, from each of the states, how they would propose to allocate. The prioritization of how this vaccine will be distributed will depend on which vaccine and what the data says.

But that decision, ultimately, the recommendation will be the advisory committee of immunization practices that will give that recommendation once they know what vaccine they are recommending it for. But I will reiterate the comments from this hearing back to Operation Warp Speed, as that allocation decision is made, that it is communicated effectively.

Senator MURKOWSKI. That allocation decision, can you confirm that it is the CDC that is responsible for determining that allocation?

Dr. REDFIELD. The allocation will be, the decision will be made by the Operation Warp Speed is what I would believe—what will happen, though, is that the ACIP, which is an advisory group to me as the Director of CDC, will recommend the prioritization of who should be vaccinated.

As you said, should it first be all the individuals that are vulnerable in nursing homes? Should it be health care workers? If so, what kind of health care workers? Should it be Native Americans,

African Americans, Hispanics, a greater risk? I can't get ahead of the ACIP—

Senator MURKOWSKI. Let me interrupt to ask just one more question of you here. I have got the direction that you are going with the definitions there in terms of critical workers. We have talked before about the public health IT infrastructure. I think we recognize that certainly in a state like mine, it has been pretty tough when you are faxing, literally faxing the results of your COVID tests.

It is not just Alaska, the State of California, it is a mess out there. What is the Administration's plan to ensure that states have the support that they need for the requirements on reporting for this new vaccine? Because we are concerned in our state that we are not prepared for the level of reporting that will be required. We do not mind the reporting, but we are not—we do not have the infrastructure, if you will, right now on health IT—.

Dr. REDFIELD. Yes, that is going to be a very important part of the plan that each of the states' jurisdictions, the 64 make. In addition, there is plans within the Operation Warp Speed to augment IT capacity where there are gaps. But again, in order to see that, we are going to see the states' plans. I did release \$200 million today for the states to begin to develop those plans and really identify those gaps that they have so then hopefully there will be further resources to begin to fill those gaps, because it is going to be very important that we do have the reporting for the monitoring and safety of these vaccines, as well as to make sure that we can distribute this vaccine in an effective way equitably to the American public.

The CHAIRMAN. Thanks, Senator Murkowski.
Senator Hassan.

Senator HASSAN. Let's see if I can get that on. Thank you. Thank you, Mr. Chairman. I want to thank Chairman Alexander and Ranking Member Murray for holding this hearing. I know he stepped out to vote, but I want to thank the Chairman for his service and his example as a Committee Chairman. And I want to thank our witnesses for being here today. And I want to especially thank you all for wearing your masks, even though your six feet apart, because there has even been some confusion in this body about what the best practices were inside with others, so thank you for the example you are setting.

I am concerned that Americans are losing confidence in the Federal Government's COVID-19 vaccine review process. An ABC poll from this past weekend found that 69 percent of Americans will not have confidence in the President vouching for a vaccine. And we have seen other data reflecting that lack of confidence in vaccine approval process. FDA and CDC have existing vaccine review processes that are considered the gold standard by public health experts all around the globe. We have to make sure that these proven review processes take place in a transparent way, free from political influence.

Let me start with a question to you, Dr. Hahn. There is widespread concern about the independence of FDA's COVID-19 vaccine review process, in large part due to your own actions and inaccurate statements over the past several months.

Last week, you received a letter from more than 90 physician groups, doctors and public health experts asking you to ensure that any vaccine approvals or authorizations are based on facts and science and free from political influence. And Mr. Chairman, I would like to enter this letter into the record, without objection.

The CHAIRMAN. Without objection.

Senator HASSAN. Thank you. Dr. Hahn, I appreciate the work that the FDA has done to draft new guidance for vaccine products seeking emergency use authorization. I look forward to reading that document. I would like to ask a couple of clarifying hit questions based on what you have outlined earlier in your testimony. In addition to the general meetings scheduled for October, will the guidance require that FDA's Vaccines and Related Biological Products Advisory Committee hold meetings, review clinical trial data, and release their findings to the public for each vaccine candidate?

Dr. HAHN. Senator Hassan, we are committed absolutely to having meetings that will be scheduled, we will be flexible about those, of the Vaccine Advisory Committee. And as I mentioned in my remarks, they will be transparent. The clinical data and summary that we provide the Committee will be transparent and known, and it will be public.

Senator HASSAN. Right. What I am asking for is will you do it for each of the vaccine products?

Dr. HAHN. Yes, Senator.

Senator HASSAN. Will the findings be made public before the FDA approves or authorizes any vaccine product?

Dr. HAHN. It will be a public process. The vote, the discussion, and the recommendations will be public and we will incorporate those and then make our decision.

Senator HASSAN. Alright. So it will happen before?

Dr. HAHN. Yes, ma'am.

Senator HASSAN. Okay. Now to Dr. Redfield, my office has heard from clinicians across the country about the importance that they place on CDC recommendations when determining whether they are comfortable giving a vaccine to their patients. I talked with a long serving and practicing pediatrician in New Hampshire yesterday, and one of her concerns is how will they know about what dosages to use for children, for instance.

Will CDC's advisory committee on immunization practices meet publicly, review data, and issue public recommendations, again, for each COVID-19 vaccine before it enters the market so health care providers are confident giving these vaccines to their patients?

Dr. REDFIELD. It is very important that the advisory committee accusation practice will conduct their deliberations in public. The only caveat is when there is national security interests, which should not be the case here, or if there is proprietary information on the commercial side. But you should anticipate this will be a public discussion.

Senator HASSAN. I am going to ask you for the same commitments I asked Dr. Hahn. Each product?

Dr. REDFIELD. Each product.

Senator HASSAN. Before the approval, it will be made public or the recommendations will be made public before the approval?

Dr. REDFIELD. The ACIP will make those recommendations after the FDA recommends an EUA or BLA. Then they will deliberate how the vaccine should be used in the United States and that will happen in public.

Senator HASSAN. Before they are distributed?

Dr. REDFIELD. Before it is recommended to be used for the American public.

Senator HASSAN. Thank you. Dr. Fauci, do you believe that the existing FDA and CDC advisory committees should conduct an independent, transparent, evidence based review of safety and efficacy data for each vaccine product seeking approval or emergency authorization? And could those independent meetings help improve public confidence? We have heard commitments about them. I just would love your comments about it.

Dr. FAUCI. Yes, I agree, Senator, with Dr. Hahn, that is a process that occurs and they do have an independent look at that and they are advisory to the FDA. The FDA makes the ultimate decision but what they do will be public. And I as I have said myself, not only do you have a very qualified advisory committee in VRBPA, but you also have the entire scientific community that is going to be scrutinizing this because it will be made public. And for that reason, I have confidence in the process.

Senator HASSAN. Well, I thank you. And I thank you, Mr. Chairman. Senator Murkowski and I have legislation that would ensure that the processes that you have committed to will be followed. And I look forward to working with you on that. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman. And thanks to the members of this panel for the work that you have done to help safeguard as many Americans as possible from this terrible infection. Dr. Hahn, you surely speak with the pharmaceutical companies and get a sense of what progress they are making on their clinical trials. When do you believe that you will receive the first application? Is this something that is going to come in the next couple of weeks? Are you getting any indication it might be a couple of months? What kind of timeline are you anticipating before you will receive your first application?

Dr. HAHN. Senator Romney, thanks for the question. I honestly do not know when we will receive our first application. As I mentioned earlier—

Senator ROMNEY. Of course not. Of course not. You would not know. But you are speaking with them. Are they getting close to the results from the 30,000? Are they just getting going? Is this—have there been any applications that have been sent to the DSMB? So is it getting close or is it going to be, a month or two from now?

Dr. HAHN. Senator, I cannot speak to confidential commercial information that we have. From the publicly available data, the enrollment is going as expected in these clinical trials, and in the case of one, has exceeded where they expected to be with respect to the 30,000. When they submit an application, it will be dependent upon when events occur in this trial, including or involving pre-

vention of infection. When those events occur, and at prespecified time by the DSMB, that is when the first judgment will be made about the maturity of the data. And I can't prejudge that. I do not know.

Senator ROMNEY. I know you can't predict, but you are getting an indication as to whether they are receiving those things or not. And have any applications been received by the DSMB at this point?

Dr. HAHN. I do not know the answer to that, sir.

Senator ROMNEY. Well, they would not let you know that whether they received an application?

Dr. HAHN. The—you mean the sponsor, sir?

Senator ROMNEY. No, the DSMB.

Dr. HAHN. No, I do not know the answer to that question, sir.

Senator ROMNEY. Okay, let's say that tomorrow morning the application is received, how long typically is the process inside the FDA to go from the time you receive an application until you make a determination of yes, let it go ahead?

Dr. HAHN. Typically that process can take weeks, sometimes months. It really depends upon the complexity of the data and the dataset that we are looking at. We have not made a commitment to the timeline, per say, because we have not seen the data and we do not know the complexity of the data or the amount of data that will come our way. What I can tell you, sir, is we do feel the urgency of the moment. We do take very much—very seriously our responsibility to protect American lives. And we will not delay, but we will not cut corners in our process.

Senator ROMNEY. Okay. Dr. Fauci, I think everybody is very, very pleased with the fact that our Government has proceeded with manufacturing vaccines, even though we do not know whether they are going to work or not. And that is something we will be able to have vaccines to the American people as soon as possible.

If the FDA were to approve an application let's say on November 1st, how long would it take for the American people to get vaccinated? Maybe I will change that to say, what proportion of our population, if it were approved on November 1st, what proportion of our population would be able to be vaccinated, let's say, by the end of the year? That is a two-month period.

I do not know whether these manufacturing facilities are producing 100 million vaccines right now or 5 million or 10 million. So is this something that would really just go to a small subset of the population or could we possibly inoculate the great majority?

Dr. FAUCI. Well, good question, Senator. The fact is that the production as it is rolling out, and when you hear the numbers, that is the totality of all of the companies, so that in November you will probably be, maybe 50 million doses available, by December, maybe another 100 plus million. And then when you get into January, February, by the time you get to April, they will be a total of about 700 million.

If you are talking about who is going to get vaccinated in December or November, it is not going to be a large proportion of the population. It will be, according to what we were discussing before, namely those who are, according to the Advisory Committee on Immunization Practices, getting the priority. Likely it will be health

care providers and likely will be those who are vulnerable with underlying conditions.

I can't say that for certain, but if anything is the past prologue and that likely will be the case. But we are not going to have all of the doses available, for example, by the end of December. They will be rolling in as the months go by and by the time you get to maybe the third or fourth month of the 2021, then you will have doses for everyone.

Senator ROMNEY. Thank you.

The CHAIRMAN. Senator Romney, thank you.

Senator Smith.

Senator SMITH. I want to thank Ranking Member Murray and Chairman Alexander, if you are back for your final hearing, I understand. It is really incredible. Dr. Redman I wanted to—Dr. Redfield, pardon me. I wanted to follow-up on something you have said. You have said that you thought that the vaccine—that when you have a vaccine, that it would be distributed broadly by the second quarter or the third quarter of next year. And you also said that you thought that masks were the most effective tool that we had to stem the spread of the virus. So you still think that is true, right? You stand by that?

Dr. REDFIELD. Thank you, Senator, for the opportunity. When it comes to the question about masks, first I want to say I have total confidence in the importance of vaccines. And ultimately, it is going to be the vaccines that are going to get us back to the way of life as we get an effective vaccine. What I was trying to comment, as Senator Kaine alluded to, if the vaccine only induces an immune response in half the people, then it is conceptual that half the people may not get protection from the vaccine. And what really I was trying to say maybe was just to re-emphasize how important this mask is. We have this right now and it will protect the American public.

The second question you asked was that Dr. Fauci was very clear in using the term doses and we should have, if projected, about 700 million doses by April, late March. And that should be enough to vaccinate 350 million people because you require two doses. When I was alluding to late second quarter, early third quarter, I was alluding to how long I felt it would take to get those 700 million doses into the American public and complete the vaccine process.

I can defer to Dr. Fauci for his opinion, but I think that is going to take us April, May, June, possibly July, to get the entire American public completely vaccinated. But we will have the 700 million doses based on projection by late March, early April.

Senator SMITH. I appreciated that and I appreciated that you were pointing out, as we have this sort of in some way the sort of this political campaign against masks that masks are going to continue to be important, contact tracing, and testing will continue to be important as we go forward. And I appreciate that what you were saying, actually. My question is, Dr. Redfield, did you get any political pushback for saying what you said?

Dr. REDFIELD. I stand by trying to present the data and the science as I see it, and I will continue to do that.

Senator SMITH. But did you get any political pushback from political folks within the Administration for what you said?

Dr. REDFIELD. Again, I am going to just stay with my comment that I will continue to present science and data as I see it. And it is not going to be modulated by whether individuals really appreciate what I say or do not appreciate what I say.

Senator SMITH. Didn't the President say that he called you to complain to you about what you said?

Dr. REDFIELD. Again, I am not going to comment on my conversations with the President.

Senator SMITH. Alright. Well, that is—I think that this is the thing that worries, I think, so many Americans. But let me ask about something else. To the panelists, Senator Cassidy and I are working on a bipartisan bill which is called the Suppress COVID-19 Act, which would invest in testing and contact tracing and what we need to do to suppress this virus. And it would do this by empowering states to work together through interstate compacts to accomplish this.

Mr. Chairman, I would like to enter into the record bipartisan Op-ed that Senator Cassidy and I wrote with Dr. Daniel Allen that appeared in The Washington Post for the record, if I could.

The CHAIRMAN. Without objection.

Senator SMITH. Dr. Fauci, will we still need COVID-19 diagnostic testing and contact tracing even after we have a vaccine and even after that vaccine is available to the public?

Dr. FAUCI. Thank you, Senator, for that question. The answer is absolutely, because a vaccine, depending upon the degree of efficacy and depending, as Dr. Redfield just mentioned, depending on the people who ultimately decide they want to get the vaccine, you are still going to have vulnerable people in the United States, which would require not only testing, contact tracing, but an implementation of the public health measures that we have been talking about all along.

The vaccine availability will go a giant step to controlling the infection, but you are not going to completely eradicate or eliminate it, particularly if you have a vaccine that is even moderately effective, 75 percent. If you do not have a vaccine that is 98 percent effective and everybody takes it, you are still going to have vulnerable people in the population.

The presence of those vulnerable people will require the implementation of public health practices, including testing, identification, isolation and contact tracing.

Senator SMITH. Continuing to wear masks and practice good social distancing and other public health strategies that we that we know work to keep us safe.

Dr. FAUCI. Absolutely.

Senator SMITH. Great. Thank you, Mr. Chairman. I am out of time.

The CHAIRMAN. Thank you, Senator Smith.

Senator Braun.

Senator BRAUN. Thank you, Mr. Chairman. Yesterday, we reached a sad milestone. We have recorded over 200,000 COVID related deaths in the U.S. I want to go back to the beginning to look at where we started and where we are now. I think it is important for the American people to understand and remember what the context was. When this outbreak began, where we are now, and

that the President called on the American people to come together by shutting down the country for 45 days to avoid the catastrophic models calling for millions of deaths by August 1st.

On March 16th, President Trump issued guidelines for Governors calling for a partial shutdown of 15 days to slow the spread. By March 29, it was clear the President, again, followed the advice of the task force and called for an additional 30 days of shutdown to slow the spread of COVID-19. Dr. Fauci, I have several questions for you, and a yes or no is fine unless you want to elaborate further.

Then one final question for Dr. Hahn. During those critical days in March, was it your recommendation and that of the task force for President Trump to issue the guidelines to shut the country down for 45 days?

Dr. FAUCI. Yes. I would not use the word shut the country down. It was to implement separation, avoiding contact, all the kinds of things we did in the recommendation. The short answer to your question is yes.

Senator BRAUN. Thank you. Let's look at the chart over here. This was used by Dr. Birx at the task force briefing on March 31st. We can all see what Dr. Birx called the giant blue mountain that predicted over 2 million deaths without mitigation efforts. And the stippled foothill that shows a range of 100,000 to 240,000 deaths if we took the drastic actions to put the mitigation into effect, which did require some shutting down the country.

Did you and Dr. Birx explain at March 31st briefing that initial projections from the health experts showed that if we did not act, the death tolls by August 1st could exceed a couple of million?

Dr. FAUCI. Yes, that is what we presented based on a model, sir. It is a model.

Senator BRAUN. Sure. And was the goal of the national mitigation effort to bring the projected death tolls down from over 2 million to the range of 100,000 to 140,000?

Dr. FAUCI. Yes, with an exception, because as I mentioned at a press conference associated with that, I said the model would say it would go down but I do not think we should be accepting that. That we could likely do much better. If I could just have 20 seconds more, I will explain it, because if we had done the kinds of things uniformly and consistently throughout the country of the recommendations of the gateway, phase 1, phase 2, phase 3, what would have happened is that we would have had less than that.

We know that some states did a good job. Some states did not so good a job. Some states tried to do a good job, but people did not listen. We saw pictures of people congregating at bars with no masks. So even though the models said that likely would be the number of deaths, I and my colleagues always said we should strive very hard to not reach that number if we did the public health measures that we were talking about, masks, physical separation, etcetera.

Senator BRAUN. Outside of that qualification, which I think it is admirable to try to always best what you think might be the case, do you think the actions of the American people and the actions of President Trump and the task force at least hit where you were hoping, notwithstanding the qualification that you made?

Dr. FAUCI. Yes. What we did show and we know the data, and that is very important because it helps us to look ahead, that the kinds of things that were put into effect, the mitigation going from the control as well as mitigation, we believe have saved a lot of lives.

Senator BRAUN. Would you agree that the task force and the President took the outbreak very seriously from the beginning, taking unprecedented action, saving millions of American lives as a result?

Dr. FAUCI. Yes. I mean, obviously, I think one of the first things that we had said and discussed before was the shutting off of travel, for example, from China. And then second, after that, we did it at a time, for example, when we were getting cases from Europe, which actually seeded the northeastern part of a country, particularly the New York metropolitan area.

Senator BRAUN. I think the importance of that is understated in terms of those early decisions, what impact they did have. As we can see from this chart poster, quick Google search will reveal that the President and the task force told the American people on March 31st millions could die if we did not follow the White House guidelines. If we did everything optimally, then we would be where we are today.

If we want to ask the American people to continue to take the virus seriously and keep making sacrifices in their daily lives until we have a vaccine, then do you think the media, politicians and scientists like you need to do a better job reminding the American people about the blue mountain warning of millions dead and how their collective actions will continue to save lives?

Dr. FAUCI. Yes, Senator. In fact, virtually every time I am in public and given the opportunity to talk about this, I continue to stress the four or five things that if we all did and we did it consistently, we would not only prevent the surges that we have seen, but we would also get those surges down, as we are seeing in different parts of the country now where cases are starting to come down.

Some of the areas of the country that are doing it well are seeing a good control and others are not. I think we need uniformity throughout the country of a consistent adherence to the public health practices that we talk about.

The CHAIRMAN. Thank you, Senator Braun.

Senator Jones.

Senator JONES. Alright—

The CHAIRMAN. We will fix it.

Senator JONES. Okay. Thank you, Mr. Chairman, and thank you for having this hearing, but also thank you for your service on this Committee. I want to thank all of our witnesses for being here today again. We always appreciate you being here. I want to first comment something that Senator Kaine said. I think he was referring to Dr. Redfield's testimony about the importance of timely and effective health care, the ability to get health care. And Senator Kaine noted, he would not know what 400,000 Virginians would have done had they not had the benefit of Medicaid expansion.

I can tell you, Senator, unfortunately, I have got to almost the same number in Alabama, 400,000 who did not have that benefit

at all because Alabama refused to expand Medicaid. And I still can not get folks to seem to understand the importance of giving states like Alabama that opportunity with Federal incentives again. But that is for another day. I would like to—I think it is pretty clear, gentlemen, that one of the concerns a lot of people have on both sides of the aisle is this mixed message going back and forth, and it is really difficult.

Since the very beginning of this, I have tried to tell people in Alabama, listen to the health care folks, do not listen to politicians, listen to the health care folks. Every week at the beginning in April, I had a Facebook live with media that we broadcast. Dr. Fauci was gracious enough to join me for one of those which I really appreciated. But it has gotten more difficult, I am sure you can see. And it has gotten more difficult as we approach the election.

Dr. Hahn, the President at one point said in a news conference that the FDA wanted to limit the use of the convalescent plasma until after the election and he tweeted that there was a deep state within the FDA that is making it difficult for drug companies to get people involved in order to test vaccines. And his chief of staff said that the President wanted to make the FDA feel the heat, which I am not sure exactly what that meant. But, Dr. Hahn, you said that you have every confidence in the scientists and staff at FDA. And I appreciate that. And I do, too, by the way. Is there some kind of deep state that you have seen in the FDA that is in any way trying to do anything other than quickly get a vaccine, get therapeutics to the American public?

Dr. HAHN. Senator, I will answer your question this way. I have 100 percent confidence in the outstanding scientists, doctors, nurses, pharmacists at FDA who have remarkably stood up during this pandemic to help expedite getting medical products to the American people. I have complete confidence in their decisions and I have complete confidence in the actions that have been taken today.

Senator JONES. That confidence is based on following the science, not any political pressure. And that is what we are expecting with a vaccine of approval.

Dr. HAHN. Yes, sir. And I have said that several times today, and I appreciate the opportunity to say it again. Our career scientists for any medical products and particularly vaccines will follow the science and data and our rigorous standards and it won't be politics that make any part of that decision, sir.

Senator JONES. Great. Dr. Redfield, a similar question with you. You said in your testimony that you—and all of you have in one way or another continued, every time we have talked, every time you have been here, you have continued to tell the people wear mask, social distance, wash your hands.

Dr. Redfield, you said today you have added a fourth, be smart about crowds, but yet we see time and time again in political gatherings and to not be partisan here in public protest, peaceful protests, folks aren't doing that. They are not doing that. And in fact, some are being encouraged not to wear masks, not to do anything. What is the public to do when you have got public officials and others that are giving a different message from what you guys are doing?

Everybody has been pretty consistent. But we have got clear messages coming from the President and folks on both sides of the aisle, in my opinion, that it is okay under the circumstances if you want to ignore those guidelines. We do not know whether those people are washing their hands or not, but we know that most of them are not wearing a mask and not social distancing, and they are certainly not being smart about crowds. What do we do? How do we get the information to our people?

Dr. REDFIELD. Thank you very much, Senator. Again, we have to just keep stressing what I have said before that we want all Americans, all Americans to embrace wearing a face mask, be smart about social distancing and crowds, wash their hands, and obviously, I have confidence in the flu vaccine. If we all wore a mask and we were smart about social distancing, as Dr. Fauci alluded to, this outbreak would really start to come under control. This simple, simple decision—but unfortunately, it is not something that 75 percent of us can do and we are going to get the results we want.

This is something that we all have to do to get the results we want. And we will continue to stress that. I want to add, how disappointed I have been personally when people at HHS made comments that they felt that there was a deep state down at CDC. I will tell you, these are dedicated men and women that are confronting the greatest public health crisis of our time, working 24/7, over 6,700 of them involved in the outbreak itself, 1,200 deploying, and it is offensive to me when I hear this type of comment.

I think in my 21 years, 22 years in the military, you never knew people's political perspective. I would say that is the same about the men and women at CDC. They are dedicated to protect the public health of this Nation. And I know that you all appreciate that. I would obviously, people do not understand the ability to suck energy out of people that are working 24/7 when they get unfairly criticized or unfairly characterized. And really, that is the real harm in all of this.

Senator JONES. Thank you. Thank you very, very much for that. I completely agree. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Jones.

Senator Rosen.

Senator ROSEN. Thank you, Mr. Chairman. And again, I want to thank everybody on the panel for just everything you and your teams are doing to save us from this pandemic, move us forward with therapeutics and vaccines and back to our regular lives. But, my office has heard from a number of our local health departments in recent weeks about the challenges that they continue to face, not only in addressing COVID-19, but appearing to combat COVID alongside the seasonal flu, which is just about to begin.

As we enter flu season, we are again faced with that preventable public health crisis. But this time we can avoid catastrophe by adequately supporting our medical officials on the ground with the resources they need. Dr. John Novak, who leads the Washoe County District Court of Health in Northern Nevada recently explained the critical need to address both flu and COVID prevention, saying the flu vaccine this year is very COVID related since they are both respiratory diseases. Initial symptoms extremely close in pattern. The

flu season fast upon us is extremely important to reduce the number of flu patients that need the same overtaxed medical care.

Dr. Fauci, could you just please explain, if you will, the importance to keep current planning of flu shots and our COVID response. And maybe we should be providing things at the same rate before we get a vaccine or something like that, individuals at the same location drive up. How are we going to do that?

Dr. FAUCI. Yes. Well, thank you for the question, Senator. First of all, I want to just emphasize what your health officials already have mentioned to you, the importance of getting an influenza vaccine, because what we do not want is two conflated respiratory infections at the same time as we enter into the fall and the winter. We want to get as many people vaccinated with the flu vaccine as possible.

The logistics of how you can get them done together, I do not think I can comment on that right now. Perhaps Dr. Redfield can. But one of the things I do want to mention, because we have seen that in Australia as well as South Africa and Argentina, is that if we continue to do what each of us have been saying regarding the kinds of preventive measures of mask wearing, social distancing, avoiding crowds, washing hands, etcetera, if we do that as we get into the fall in the winter for the purpose of COVID-19, it is likely to have a positive impact on the infection rate of influenza because our colleagues in the southern hemisphere, particularly in Australia, have found because of that, they have had a very, very low, mild influenza season.

If we could combine the vaccination as much as we possibly can with influenza, together with the public health measures, hopefully we can have a very, very low level of flu that would not then complicate what will clearly be a challenge in the winter with COVID-19. Thank you.

Admiral GIROIR. Senator, I am sorry—.

Senator ROSEN. I appreciate that. I want to—I just have a minute left. I want to ask about some interesting research, and any of you can take this if you know about it. I have been seeing some information come out recently about the Bradykinin peptide and how it is overactive it causes inflammation that could be part of the reason that COVID 90 causes this fluid buildup in the lungs. Anybody could take this. And we have been talking about that research. And is that really going to be helpful? I know that there are drugs out there to help reduce this kind of—well I am not sure if it is inflammation, but attack this kind of response. Maybe someone wants to take that question and is that a good possibility for treatment?

Dr. FAUCI. Yes. Real quickly, there are a number of interventions to block and blunt the overactive inflammatory response, which is relevant as you get into advanced disease. Dexamethasone, which I mentioned in my opening comments, is a commonly used steroid which blocks inflammation. There are a variety of other trials that are either ongoing or being prepared to look at blocking a variety of other inflammatory indicators, such as cytokines, IL-6 and a variety of others.

These are things that are being actively pursued. There is no evidence thus far, except for the dexamethasone evidence, that by

blocking inflammation you can actually help people with advanced disease and actually decrease mortality. So it is one of those things that are involved in blocking inflammation.

Senator ROSEN. Thank you, I appreciate that. And I appreciate everything that you are doing. I look forward to speaking to you again and hopefully going to continue to get positive news. Thank you.

The CHAIRMAN. Thank you, Senator Rosen. We will go to Senator Murray now for her closing questions or remarks and if Senator Loeffler returns from voting in time, we will go to her next and then we will close the hearing.

Senator Murray.

Senator MURRAY. Well, Mr. Chairman, thank you. I will submit my additional questions for the record. I would like to thank all of our witnesses for joining us today. And Senator Alexander, you announced earlier that this would be the last hearing of the HELP Committee that you Chair and I just want to start by saying, it has been a pleasure to work with you to lead this Committee over the past several years and through many critical challenges for our country. From working to address the opioid crisis, supporting medical innovation, replacing No Child Left Behind, there is a lot we have gone through.

We have been able to do a lot of that by listening to each other, and most importantly, listening to the people in our states about what they need. So I just want to say, I think that I speak for every one on my side of the aisle when I say I am very proud of the work we have been able to do together with you on the other side of the dais. And this may be our last hearing, but just know I appreciate all you have done and will continue to do. I want you to know I am going to continue to follow our response to this pandemic very closely. I will continue pressing for answers, including on issues like whether our meat packing plants have accurate information, as Senator Baldwin raised earlier, given what has happened in my state and others. We need answers on that.

I am also going to continue demanding a full comprehensive plan to finally get testing where it needs to be and fully prepared to make sure we develop, manufacture, distribute and administer a safe, effective and trusted vaccine. I am going to continue to push back against every effort from this President to interfere in our response and put politics over science and public health. I will continue to call out misinformation or lies or conspiracies and work to make sure we are communicating clear, science based facts to people in this country.

I am going to urge our Republicans to come back to the table and negotiate in earnest so we can finally pass the kind of sweeping relief our communities really need. Despite President Trump's careless claims that we are rounding the final turn or that this disease affects virtually nobody, we know the painful reality is that this crisis has tragically killed over 200,000 Americans already and that it is far from over. So our work to respond to it cannot be over either. Thank you, Mr. Chairman. Thank you for the time.

The CHAIRMAN. Thank you, Senator Murray, and thanks for your kind remarks and I expressed, again today, how much I appreciate our friendship, your diligence, and your leadership, which has been

absolutely crucial to the considerable results that have come out of this Committee, especially over the last six years. So thank you very much for that.

Senator Loeffler.

Senator LOEFFLER. Thank you, Mr. Chairman. And I want to start by thanking each of you here today. I want to thank you and your workforces for the tremendous work, the effort that has been done to combat this virus. Dr. Redfield, this question is for you. I wanted to touch on the subject that I feel has been overlooked as we continue to confront the pandemic. That issue is mental health, particularly in younger populations and the frontline.

Yesterday, I had the opportunity to be briefed by Dr. Deborah Houry. She is the Director of the National Center for Injury Prevention and Control and also one of your colleagues at the CDC. And we spoke on the rising mental health issues due to the pandemic and particularly suicidal ideation. We spoke about the importance of comprehensive community level outreach programs to prevent this issue from growing worse. The CDC is funding several different programs that are aimed at this goal and the CDC's comprehensive suicide Prevention Program is currently funding nine grant recipients in different states to a COVID suicide prevention funded project in Georgia, in my state, that is being run through your Department of Public Health.

The question for you is, what more can we do on the Federal level to shine a light on this issue and make sure that these communities have the resources they need to have comprehensive outreach and to ensure that we are not turning a blind eye to the critical issue of mental health that so many are facing due to this pandemic? Thank you.

Dr. REDFIELD. Thank you very much, Senator. It is a very, very important issue, and I am glad Dr. Houry had the opportunity to brief you. On one of our recent survey, it was surprising that over 30 percent of Americans are feeling anxiety and depression as part of the COVID experience. And we have seen, sadly, an uptick, particularly in adults in suicide.

One of the reasons I was so aggressive in reminding the American public that the public health interest of K through 12 is best served by getting kids back to face to face learning. Many people may not realize that over 7 million children get their mental health services in the context of schools. We also, unfortunately, I have seen an increase in substance abuse and drug use disorder that has been associated with this COVID situation, some of which has been driven by the lack of availability of medical appointments when the health industry basically pulled back to help manage people that had chronic pain syndrome or were recovering from drug use disorder.

It is a very important issue. I think we do have to keep it—we did start, you have probably seen it on TV, how right now initiative to let people know that it is not stigmatizing to say that you are not doing well, that you are depressed or you are suicidal. These are medical conditions, like I have argued about on drug use disorder. These are not behavioral issues. These are medical conditions. They need to be treated as medical conditions. And, I think

it is one of the collateral damages that we saw as part of the COVID pandemic.

Senator LOEFFLER. Thank you. I will yield my time.

The CHAIRMAN. Thank you, Senator Loeffler. We will wrap up the hearing now. I have just three or four questions about the vaccine, which I will start with Dr. Fauci, but any of the others who want to answer it—pretty simple questions, but it may be important for the American people. One is, and I have had people say this to me, Dr. Fauci, if I take a shot to get the vaccine, does that give me COVID?

Dr. FAUCI. Absolutely not. That would be impossible.

The CHAIRMAN. That would be impossible?

Dr. FAUCI. Yes, sir.

The CHAIRMAN. One of the risks of a vaccine shot is not getting COVID?

Dr. FAUCI. That is correct. That risk does not exist.

The CHAIRMAN. Will the vaccine for COVID, will it likely be more like the polio vaccine or the flu vaccine? By that, I mean if you take the polio vaccine, you assume you will never get polio. If you take the flu vaccine each year, it is sort of a guess about whether the vaccination really will be effective. And I think it also helps speed the cure, if you do get sick, but it may not be more than 50 percent effective. So is it more like the polio vaccine or the flu vaccine or do we know that yet?

Dr. FAUCI. We do not know that yet, Mr. Chairman. And that is one of the things that we will learn. Polio is a highly, highly effective vaccine that gives long lasting protection. What we do not know yet is how effective the COVID-19 vaccine will be nor do we know the durability of the protection, how long it will last. We will find out the answer to those questions through the clinical trials and the follow-up of the clinical trials.

The CHAIRMAN. Will the vaccine be free when it is distributed and administered to Americans?

Dr. FAUCI. We have been assured that, in fact, the American public will not have to pay for the vaccine. We have been told that at the level of the task force.

The CHAIRMAN. When we are talking about vaccines, are we—most of the six vaccines, we are anticipating that you would have to take two shots about 4 weeks apart. And then the effectiveness of the vaccine might be 2 weeks after that, or is that wrong?

Dr. FAUCI. It varies from candidate to candidate. For example, the Moderna and the Pfizer, which are out there now, are two shots, a prime and a boost. One is the boost at 28 days. One is a boost at 21 days. Whereas the J and J, or Johnson is a single shot.

The CHAIRMAN. Well, I want to thank all four of you for what many of the Senators said today, which is extraordinarily able and dedicated service to our country. And what I have heard today is that we are in an unprecedented sprint toward success in terms of first vaccines. The polio vaccine took more than 10 years. Other vaccines we are familiar with took a long time. But what the Administration is telling us is that we likely will have a vaccine approved within a year from the time it was first developed.

We know that we will have tens of millions of doses of a total of six vaccines ready for distribution once it is approved. We have

also heard that we have five treatments, that if you get COVID-19, there are five medicines for it and that there are more coming, likely. And the most promising may be the so-called antibody cocktails that were used so effectively with Ebola. And we have also heard that despite a bumpy start with a diagnostic test at CDC at the beginning of the year, that we have had an explosion of quick diagnostic tests. And the Administration, for example, has bought up 150 million of the Abbott tests, which is \$5, 15 minutes, more specific results.

We will begin to distribute those to schools or is beginning to distribute those to schools, colleges, and to states, and that Dr. Collins Shark Tank at NIH is producing even more. Dr. Hahn, when I ask him who makes the decisions. Dr. Hahn, the scientists at FDA or the White House? He said the scientists at FDA in terms of safety and efficiency, and all of you have said that you would take the test or the vaccine when is produced and recommend it to your families, although Admiral Giroir said, it is wise—you should talk to your doctor before you take any type of shot, I assume. But they said they had great confidence in the FDA.

We have also heard, and I think this is most important, Dr. Fauci, as did all of you say, but Fauci has been involved with these things since 1984, the Reagan years or even before. Are we cutting corners on safety and efficiency? And he said no. And the risk we are taking is to the taxpayers because of the new way we are doing things. We could lose a lot of money if these vaccines are not approved. But I think the Congress and the President decided that was well worth it if it saves lives by having a vaccine ready in a year rather than two, three, four years.

Finally, I asked whether it was a good idea, having been a college president, to send home the students who get sick with COVID if an outbreak comes out, as it is on many college campuses. And Dr. Fauci said, no, that is not the right way to do it. The right way to do it is to manage your campus in such a way that you can isolate the sick students. Send them home and they will just infect grandma, grandpa, everybody else in the community.

It has been a very useful and effective hearing. It was widely carried on live on television for a couple of hours so the American people had a chance to see the Administration's top health experts, answer tough questions from Democrats and Republicans, and give straightforward answers. I thank you for your service and I thank you for today's hearing.

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

ADDITIONAL MATERIAL



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control
and Prevention (CDC)**Memorandum**

Date: April 21, 2020

From: Michael Grant, CDC National Institute for Occupational Safety and Health
Colin Basler, CDC National Center for Emerging Zoonotic Infectious Diseases
Jessica Jacobs, CDC Laboratory Leadership Service Officer
Erin Kennedy, CDC Center for Global Health
John Osburn, South Dakota Department of Health
Jonathan Steinberg, CDC Epidemic Intelligence Officer, South Dakota Department of Health
Suzanne Tomasi, CDC National Institute for Occupational Safety and Health

To: Joshua Clayton, South Dakota Department of Health

Copy: Russ Dokken, Smithfield Foods
Scott Reed, Smithfield Foods
Mark Wiggs, Smithfield Foods
B.J. Motley, President, UFCW Local 304A Union

Subject: Strategies to reduce COVID-19 transmission at the Smithfield Foods Sioux Falls Pork Plant

Background

The South Dakota Department of Health requested an Epi Aid for assistance in developing strategies to help reduce SARS-CoV-2 infections among Smithfield Foods Sioux Falls pork processing plant employees. SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). A team from the Centers for Disease Control and Prevention (CDC) traveled to Sioux Falls, South Dakota for an Epi Aid on April 14, 2020. The CDC team included veterinary epidemiologists, an Epidemic Intelligence Service Officer, an industrial hygienist, and a Laboratory Leadership Service Fellow. One component of this effort was to visit the Smithfield Foods pork processing plant to evaluate existing health and safety controls and provide recommendations for improvement. This memorandum provides observations and recommendations based on our visits to the plant on April 16 and 17, 2020 and conversations with plant management and the United Food and Commercial Workers Union (UFCW) local president.

No slaughtering or further production work were taking place in the plant while we were on site. The first case among employees was detected on March 24, 2020. Smithfield Foods announced that the process to halt production began on April 1, 2020. The plant informed us that all processing activities were completed on April 14, 2020 and that the plant would be shut down indefinitely while Smithfield continued extensive sanitation and modification efforts in the plant. The few employees we observed in the plant during our walkthroughs were performing maintenance and distribution center tasks. We

toured the plant and observed workstations from the pens where the swine are delivered through the distribution center, where product is shipped out of the plant. We also observed the route that employees take from the parking lots through the symptom screening tents and into the facility. Additionally, we observed administrative areas, the occupational health clinic and quarantine room, and the common areas (e.g., break rooms, cafeterias, locker rooms) shared by employees.

Our team was unable to identify important demographic information about this workforce, limiting our ability to understand the diversity of the employees. However, plant management reported that there were approximately 40 different languages spoken by employees in the plant and that English, Spanish, Kunama, Swahili, Nepali, Tigrinya, Amharic, French, Oromo, Vietnamese are the top 10 languages. We were also unable to obtain information about the workstations of confirmed positive cases. This type of information could provide a better understanding of what workplace factors may have contributed to the spread of COVID-19 among employees. Key demographic and workstation information was requested from the company to help answer some of these questions in the future. Additional recommendations and findings may be provided upon receipt of demographic and workstation information.

Observations and Discussion

Employee Screening

Employees were screened before entering the plant prior to their shift. The company had set up two screening locations, one on either side of the plant. Visual markers were added every six feet to decrease crowding while employees approached and moved through the screening tents. The screening consisted of walking past a thermal imaging system for body temperature measurement and self-reported symptom checks. Screening was conducted by a contracted health care professional who informed the employee of their temperature and asked whether the employee had a cough or shortness of breath.

We were informed that if an employee had a fever ($>99.8^{\circ}$) or reported experiencing symptoms, the employee underwent secondary screening by a contracted nurse. Additionally, we learned that the screening process also looked for visible signs of symptoms as employees were screened. Secondary screening consisted of a temperature check with an infrared thermometer and a more in-depth evaluation of symptoms. We understand that if an employee was found to have a fever or symptoms consistent with COVID-19, they were given an informational packet (in English) and instructed to return home. Employees were provided two weeks of paid sick leave (40 hours pay per week) when sent home and were asked to call a hotline operated by a local health system for guidance regarding next steps.

Plant management informed us that they had identified a department of the plant (Pork Conversion) with a high density of positive cases. The whole department was placed on two weeks paid sick leave. We also learned that efforts had been taken to adjust schedules to facilitate distancing of employees working in essential operations (e.g., wastewater treatment). Additionally, we learned of a “responsibility bonus” of \$500 being offered to employees who did not miss time (e.g., were not late or sick) during the time period of April 1 through May 1, 2020. The company informed us that COVID-19-related absence will not impact the receipt of the bonus.

Increasing Distance Between Employees During Work and Breaks

Plant screening tents had posters on the wall to remind employees to maintain a social distance of 6 feet during the screen process. In all lunchrooms and break areas that we observed, dividers had been placed on tables to remind employees to maintain a physical barrier between each other. Some tables had been marked “off-limits” by tape. Additional tables were placed in one hallway (the “flag hallway”) to decrease the density of employees inside the nearby cafeteria. Some outdoor picnic tables had been moved to facilitate social distancing, although other outdoor tables were less than 6 feet apart.

In at least one department (Ground Seasoned Pork), line speed had been reduced to accommodate fewer employees on the line due to social distancing efforts and workforce availability constraints (i.e., illness amongst employees). Plant management had identified and installed approximately 800 plexiglass barriers in locations where distancing was not possible (e.g., production lines). Plant management reported that, on some production lines prior to shutting down the plant, employees on opposite sides of the line alternated workstations to maintain distancing. On other lines, barriers had been hung in an attempt to separate employees. Management reported that the barriers were made of plexiglass. Among the few employees that were present in the plant during our walk throughs, we observed several who were congregating less than 6 feet apart when away from their workstations.

Supplementary Infection Control Measures

We saw hand sanitizer dispensers located in limited locations throughout the plant, notably at the entrances to the building and within cafeterias and break rooms. Plant management indicated that more hand sanitizer dispensers will be added as COVID-19 prevention measures. We learned of plans to increase the number of dispensers to 3500 (i.e., roughly one dispenser station per employee). The hand sanitizing dispensers were all manually operated (i.e., not touchless). Limited handwashing stations were available in locker rooms and in some production areas of the plant. We learned from the union that there were approximately 30 employees in a locker room at any given time. Some handwashing stations were touchless, but the majority were not. Management also indicated they were developing a plan to have people assigned to enforce hand sanitizing for every employee in the plant every 30 minutes. However, the plant had not yet finalized the rollout plans for this effort.

Additional staff have been assigned to clean and sanitize commonly touched surfaces more frequently, such as handrails, doors and door handles, and lunch tables. Time clocks in the plant were touchless for plant employees, and the plant informed us of plans to install over 100 additional time clocks to decrease bottlenecks.

Use of Facemasks and Other Face Coverings

Plant management informed us of plans to institute a universal facemask requirement for all employees in accordance with CDC recommendations for critical infrastructure employees and the public. We learned that plant management will provide a facemask with moldable nosepiece to all employees before entering the plant each day. We learned that they have a plan to provide additional facemasks to employees throughout the day if facemasks become wet or soiled. We also learned that face shields will be provided to all non-administrative employees moving forward. These face shields will be affixed to

the hard hat. We observed some employees still working at the plant either not wearing facemasks or wearing them incorrectly (e.g., wearing them over the mouth but not the nose). Plant management indicated that they had estimated the number of facemasks and face shields that would be required for a 30-day supply for the plant running at full capacity. Plant management was also conducting informal experiments with both commercial and home-remedy-style anti-fogging products (e.g., shaving cream) for the face shields.

Educating Employees on COVID-19 Risks, Prevention, and Company Policies

There were informational flyers with pictures representing COVID-19 symptoms of fever, cough, and shortness of breath on the walls of the screening areas, but not at the screening table itself. Throughout the plant, informational flyers were posted on walls encouraging employees to practice social distancing, keep their mouth and nose covered, regularly wash their hands, and report symptoms to occupational health. Some flyers were translated into multiple languages and there were some that included pictograms. Most flyers were approximately 9" x 11" but were not positioned at eye level. Many flyers had densely packed words and limited pictograms. There were video loops on display in cafeterias and break rooms, but we did not observe any COVID-19-related educational information. The plant had recently implemented a new messaging strategy using an application called "Beekeeper" that allowed management to mass-communicate with employees in a language of their choice. We learned from the union that they also have the ability to send mass communications to their members. The union also reported the ability to translate messaging for members and identified key plant employees who served as translators when needed. Although plant management stated that many of their employees used smart phones, it was unclear how widely the app was being used among employees at the time of our visits. The plant also utilized a text messaging alert system that could send COVID-19 related messages to employees. Management expressed that communicating messages to their diverse staff presented challenges due to the number of languages spoken.

Pending Activities Reportedly Planned by the Company

1. Developing and finalizing standard operating procedures for new infection prevention and control measures, especially related to supplementary disinfection of high-touch areas.
2. Increasing engagement with the Beekeeper application. We were informed that approximately 1,400 employees have signed on to receive text messages from this system.
3. Completing installation of plexiglass barriers in close contact workstations.
4. Increasing the number of hand sanitizer dispensers in the plant to 3,500 (i.e., roughly 1 per employee).
5. Installing over 100 additional time clocks to prevent bottlenecks.
6. Promoting increased adoption of mass communication methods to communicate COVID-19 prevention and informational messages to employees. We learned that they are planning to start this process during the plant closure.
7. Having designated staff walk around lines to provide hand sanitization to line employees every 30 minutes.
8. Relaxing sick leave policies related to COVID-19. Eliminating premiums, copays, and waiting periods for COVID-19 testing.

Conclusions

The company implemented several controls at the plant to help reduce and mitigate the spread of coronavirus between employees while in the plant and is in the process of implementing additional strategies as discussed above. Additional recommendations are provided below to help both management, employees, the union, the South Dakota Department of Health, and strategic community partners to limit virus transmission in the plant. Consult with the United States Department of Agriculture (USDA) staff at the plant to determine if proposed controls are acceptable with regards to food safety and sanitation.

Recommendations

The following actions are recommended to ensure that existing and future control efforts are effective in preventing the spread of COVID-19 between employees while they are at work. With ongoing community transmission, COVID-19 cases among staff will likely continue to be identified. A combination of control measures with ongoing education and training will be useful in reducing or eliminating transmission in the workplace. These recommendations are intended for this specific Smithfield plant, but broader interim recommendations for meat and poultry processing industries are in development. Management, along with the safety committee and employee representative/union representative at the plant, and in direct collaboration with the South Dakota Department of Health and strategic community partners should develop an implementation plan for these and any other interventions to reduce the spread of COVID-19 to be rolled out in the workplace.

Hierarchy of Controls

The following recommendations should be implemented according to the hierarchy of controls. [Hierarchy of controls](#) is an approach to hazard intervention that starts with the controls perceived to be most effective and moves down to those considered least effective. In most cases, the preferred approach is to eliminate a hazard or exposures, install engineering controls, and implement appropriate sanitation and cleaning to shield or reduce employees exposure to the hazard. Until such controls are in place, or if they are not adequately effective or feasible, administrative measures and personal protective equipment (PPE) may be needed.

Social Distancing, Screening, and Sick Leave

In addition to [everyday steps to prevent COVID-19](#), keeping space between individuals ([social distancing](#)) is one of the best strategies to avoid being exposed to the virus and slowing its spread. Barriers are one method to physically separate employees in areas of the plant (including work areas and other areas such as break rooms, parking lots, hallways and corridors, entrance/exit areas, and locker rooms). Other practices such as use of visual cues at six-foot intervals (e.g., floor markings, signs) can be used to encourage physical distancing. Follow CDC Interim Guidance – “[Implementing Safety Practices for Critical Infrastructure Employees Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19](#)” for best practices regarding screening and sick leave. Until the broader interim recommendations for meat and poultry processing industries are completed, many strategies for social distancing, screening, and sick leave can be utilized from CDC’s [Interim Guidance](#)

[for Businesses and Employers to Plan and Respond to COVID-19](#). Some specific recommendations that the plant can follow include the following considerations:

- Consider the following actions to physically separate employees (at least 6 feet, where possible) and reduce employee density in non-work areas of the facilities, such as cafeteria, break rooms, equipment dispensing stations, locker rooms, smoking areas, entrance/exit areas, and other areas where employees may congregate (e.g., the box shop):
 - Adding more visual cues at six-foot intervals (e.g., floor markings, signs, traffic cones) in the cafeterias, knife and gear acquisition areas, and other areas where lines may form. Additional areas where visual cues may be implemented include:
 - Areas where knives, uniforms, and PPE are checked out. Consider methods to increase the physical distance between employees picking up equipment and ensure contactless interactions between employees as much as possible.
 - The tattoo stations in the pig barn to maintain at least 6 feet between the truck door (and the truck drivers offloading swine) and the employee that is tattooing swine.
 - Areas around the sinks in the locker rooms.
 - Areas where employees punch in and out for the day.
 - Outside the front of the building where employees may congregate waiting for rides.
 - Cafeterias and break rooms (e.g., around food lines, vending machines, cash registers).
 - The bridge and main staircases used by employees to enter the plant.
 - Outdoor common areas.
 - Expanding distance between tables in the 3rd floor flag hallway – remove some tables to facilitate more space between the chairs of adjacent tables.
 - Reducing the number of tables in the 6th floor cafeteria to reduce crowding.
 - Changing the orientation of table dividers in the 3rd floor cafeteria to promote one employee per side of the table.
 - Spreading out the shelving that is used for storage of lunch boxes in the cafeteria so there is some distance between each set of shelves. Place markings on the shelves to encourage employees to keep their personal items separate. Place visual cues of six feet so that people do not come into close contact when retrieving their personal items.
 - Increasing the flexibility around shift start times and break times to decrease the number of employees in locker rooms or break areas at one time.
 - Identifying alternative locker locations (e.g., converting currently unused spaces into temporary locker areas).
 - Installing portable or temporary bathroom and handwashing facilities could be utilized near the temporary locker rooms (or in general) to ease the density of employees in bathrooms during break and lunch times.
 - Staggering employees along line workstations so that employees are not working directly across from each other. Changes in production practices (e.g., line speed reductions) may be necessary in order to maintain appropriate distancing among employees.

- Altering additional workstations to minimize close contact among employees by adding plexiglass, stainless steel, or durable polycarbonate barriers between workstations. Barriers should be used in combination with (and not replace) other social distancing, hand hygiene, and personal protective equipment efforts outlined in these recommendations.
 - Staggering shifts, start times, and break times as much as feasible to decrease number of employees in locker rooms, break areas, and cafeterias at one time.
 - Setting up break and lunch areas outdoors to reduce the density of employees in existing breakrooms and cafeterias and encourage employees to spend their breaks in locations with air movement and space for social distancing. For example, tents could be set up and have the capability of being heated to encourage use of the outdoor space in inclement weather. Other facilities have implemented similar controls and are incentivizing outdoor breaks and lunches. Consider including portable or temporary bathroom and handwashing facilities as a part of this setup.
 - Adding additional touchless clock in/out stations throughout the plant to reduce crowding and congregating at these areas.
 - Adjusting the physical layout and the maximum class size for trainings. Consider moving training online, by video, or other methods to increase distance between employees while receiving training and orientation.
 - Increasing the space between outdoor tables to at least six feet to reduce the density in spaces where employees or truck drivers may congregate.
 - Making unidirectional paths through facility, where possible, including stairs, hallways, and cafeterias. This will ensure less contact in narrow hallways, stairs, and break areas.
 - Limiting the number of employees in the cafeteria serving and payment area at one time.
 - Encouraging employees, drivers, and contractors to maintain distancing in indoor and outdoor common areas.
 - Assigning an individual to monitor the social distancing efforts in communal spaces (e.g., break rooms, cafeterias, locker rooms).
- Source Control and Hygiene
 - Face coverings are generally recommended as an addition to social distancing. They are especially important for source control. Cloth face coverings keep the person wearing one from spreading respiratory droplets when talking, sneezing, or coughing; is also referred to as “source control.” The face covering is meant to protect other people in case employees are infected but not symptomatic.
 - All employees should wear the face covering being used by the company to cover their nose and mouth in all areas of the plant (including break areas and locker rooms). Some specific recommendations that the plant can follow include the following considerations:
 - Continuing with the plan to mandate all employees wear a face covering and a face shield anytime they are at work. The face shield is being used in this plant to supplement the use of the face covering.

- Employees should wear the supplied facial covering to cover their nose and mouth – this may prevent people who do not know they have the virus from transmitting it to others.
 - The facial covering should allow for breathing without restriction, not be touched after putting on to prevent transferring infected materials and be discarded and replaced when dirty or wet.
 - Management and supervisors will be essential for continued training and encouragement of employees to follow these guidelines.
 - Having replacement face masks available in case an employee's face mask becomes wet or soiled.
 - If possible, distribution should be contactless, while still allowing for control of the number of face masks distributed. For example, consider placing face masks on a table and having employees step forward one at a time while another employee oversees the process.
 - The employee distributing face masks should be following appropriate social distancing and wearing appropriate PPE (gloves) and facial covering.
 - Providing face coverings to truck drivers when they check in at the office. Consider asking drivers about symptoms or screening them when they arrive to the plant.
 - Encouraging or requiring contractors and FSIS inspectors to follow face covering and face shield use recommendations. Work with the appropriate partners to discuss how to roll this out among contractors and FSIS employees.
- Face shields are not acceptable substitutions for eye protection (such as safety glasses) that are used for impact protection. If needed, face shields should be used in addition to the eye protection, not as a replacement for jobs requiring eye protection, as identified by the plant's OSHA PPE hazard assessment ([29 CFR 1910.132](#)).
- Consider the following actions to improve the existing screening policies and processes:
 - Screening all individuals entering the plant (e.g., employees, management, contractors, FSIS inspectors).
 - Adjusting the orientation of the screening tent exit so that employees exiting the screening tent do not exit into the path of employees who are leaving the facility.
 - Identifying off site housing for employees who have tested positive for COVID-19 and live in a household where they do not have the ability to self-isolate from other household members, especially individuals who are at high-risk for developing severe illness or other critical infrastructure employees.
 - Specifically ask employees about recent history of fever in addition to the symptoms (e.g., cough and shortness of breath) and the objective measurement of temperature.
 - Temperatures should be measured individually using a temporal, tympanic, or oral thermometer with a probe cover.
 - If continuing to use thermal imaging systems, procure FDA-approved system(s) and use in accordance with the manufacturer specifications.

- If such a system cannot be procured, use the existing thermal imaging system in accordance with all manufacturer specifications and FDA guidance. Ensure that it is set up in such a way to accommodate the height variation of all individuals being screened.
- Including large pictograms in the screening process to increase non-verbal communication.
- Instructing employees to report to supervisors if they get sick during work shift.
- Continuing to send ill employees [home immediately](#) if they become ill during the day. Employees who are ill should stay home, and not work or be allowed in the workplace. Surfaces in their workspace should be [cleaned and disinfected](#). Continue to work with your state and local public health authorities in using CDC guidance in identification and follow up of contacts of ill persons.
- Translating the secondary screening packet into other languages commonly spoken in the plant to improve communication with employees. Additional steps to improve communication may include:
 - Having the screener point to large pictures of symptoms for employees whose primary language is not English.
 - Adding CDC guidance: “[What to do if you are sick](#)” to the informational packet provided to employees being sent home after screening. There are multiple languages available on the CDC website.
- Consider the following actions to improve the existing sick leave policies and practices:
 - Ensuring that sick leave policies are flexible and consistent with public health guidance and that employees are aware of and understand these policies.
 - Adjusting any incentive programs such that employees are not penalized for taking sick leave related to COVID-19.
 - Maintaining flexible policies that permit employees to stay home to care for a sick family member or take care of children due to school and childcare closures. Additional flexibilities might include giving advances on future sick leave and allowing employees to donate sick leave to each other.
 - Discontinuing any policies requiring a positive COVID-19 test result or a healthcare provider’s note for employees who are sick to validate their illness, qualify for sick leave, or to return to work. Healthcare provider offices and medical facilities may be extremely busy and not able to provide such documentation in a timely manner.
 - Reviewing human resources policies to make sure that policies and practices are consistent with public health recommendations and are consistent with existing state and federal workplace laws (for more information on employer responsibilities, visit the [Department of Labor’s](#) and the [Equal Employment Opportunity Commission’s](#) websites).
 - Connecting employees to employee assistance program (EAP) resources (if available) and community resources as needed. Employees may need additional social, behavioral, and other services, for example, to cope with the death of a loved one.

- Continuing to evaluate and augment the return to work plan. Employees with COVID-19 who have stayed home (home isolated) should not return to work until the [criteria to discontinue home isolation](#) are met, in consultation with healthcare providers and state and local health departments.

Hand Hygiene and Sanitation

[Hand hygiene](#) and sanitation (infection prevention and control) are other important tools to avoid being exposed to the virus and slowing its spread. Follow the [CDC recommendations for cleaning and disinfection during the COVID-19 response](#). Monitor these recommendations for updates. Cleaning and disinfection of surfaces and objects that are frequently touched, especially in common areas, several times per day is an important component to control the spread of COVID-19. Until the broader interim recommendations for meat and poultry processing industries are completed, many strategies for hand hygiene can be utilized from CDC's [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#). Some specific recommendations that the plant can follow include the following considerations:

- Encouraging frequent handwashing with soap and water for at least 20 seconds. Use hand sanitizer with at least 60% alcohol if soap and water are not available.
- Increasing access to hand washing and hand sanitizing stations throughout the facility.
 - Continue with the plan to put hand sanitizer at every table in the break hallway (or periodically along the hallway).
 - Focusing on adding stations before and after high touch surfaces (e.g., bottoms and tops of stairwells, doffing areas, entrance and exit points for break areas and lunchrooms).
 - Ensure hand sanitizing stations are located immediately before employees take anything out of a bin (e.g., frocks, gloves, silverware in the lunch room).
 - Increasing the number of hand sinks available, especially in locker rooms.
- Installing no-touch sinks, soap dispensers, sanitizer dispensers, and paper towel dispensers (preferred over hand dryers) wherever possible – make everything as touch free as possible.
- Encouraging employees to perform hand hygiene when coming off the line for break, lunch, or end of shift. Utilize the current plan for roaming sanitizing employees to coordinate these actions.
- Emphasize proper hand hygiene after gloves are removed and before and after facial coverings are donned or doffed. Installation of hand hygiene stations, training, and routine monitoring will encourage compliance.
- Adding portable or temporary bathroom and handwashing facilities near any temporary locker room areas or break areas.

- Continuing to frequently disinfect high-touch areas in food production areas with products meeting [EPA's criteria for use against SARS-CoV-2](#), the virus that causes COVID-19, and approved under the facility's sanitation standard operating procedures.
 - If EPA-registered disinfectants are not available, diluted household bleach solutions (final concentration at least 1000 ppm sodium hypochlorite), or alcohol solutions with at least [70% alcohol](#), can be used. Additional guidance on cleaning and disinfecting non-food production areas of your facility can be found on the [CDC website](#).
- Continuing to conduct targeted and more frequent cleaning of high-touch areas of shared spaces (e.g., time clocks, bathroom fixtures, break room tables and chairs, locker rooms, vending machines, railings, door handles, handles from ceiling, plug attachments and orange door cords hanging from ceiling). Follow [CDC guidance for disinfection](#). Some additional recommendations to improve the existing efforts include:
 - Sanitizing break areas between breaks, between shifts, and between groups of employees using these areas.
 - Developing sanitization guidelines for administrative areas of the plant.
 - Developing a standard operating procedure for environmental sanitization that includes a list of areas considered high-touch, frequency of disinfection, what product to use, training requirements, and required personal protective equipment. Comply with the Occupational Safety and Health Administration (OSHA) PPE ([29 CFR 1910.132, 1910.138](#)) and Hazard Communication ([29 CFR 1910.1200](#)) Standards.
 - Disinfectants should be applied according to the [label instructions](#).
 - Coordinate disinfectant product use with United States Department of Agriculture (USDA) if used in food production areas.
 - For other high-touch areas (outside of food production areas), such as door handles, bathroom surfaces, railings, and tables, use products that meet [EPA's criteria for use against SARS-CoV-2](#).
- Replacing any plexiglass barrier if it becomes damaged (e.g., cracks cannot be sanitized effectively) to be consistent with USDA Food Safety and Inspection Service (FSIS) [Sanitation Performance Standards Compliance Guide](#) that requires inspected establishments to build their facilities and maintain it in a sanitary manner.
- Continuing to disinfect tools between use when used by multiple employees.
- Performing enhanced cleaning and disinfection after persons with suspected or confirmed COVID-19 have been in the plant
 - If a sick Employee is suspected or confirmed to have COVID-19, follow the [CDC cleaning and disinfection recommendations](#).
- Ensuring that contracted cleaning services are meeting the guidelines listed above.

- Developing a protocol for sanitizing hard hats and face shields at the end of the shift.
- Developing a protocol for how employees can safely store their hardhats while going on break without bringing them into the shared areas (e.g., break rooms, locker rooms, cafeterias).

Training and Communication

When developing training and communication materials, the plant should use current, correct messaging from a trusted source. Follow the CDC [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#) for general information related to training and communication for employees. Training should be reinforced by the use of signage (preferably infographics) placed in strategic locations. Graphics and suggested messages are [available from CDC](#) for use on social media profiles and web pages. [Print resources](#) are also available from CDC. [Communication guidance](#) exists for three phases: before a COVID-19 outbreak occurs, during a COVID-19 outbreak, and after a COVID-19 outbreak. It is important to maintain ongoing communication and message coordination with plant preparedness workgroup members, partners, stakeholders, news media, and other channels to ensure consistent messaging. If technical terminology and concepts must be used in training or communications, definitions and examples should be included to help improve understanding. Communications should be early, empathetic, accurate, and effective. Early communication of COVID-19 information helps limit misinformation and rumors that could contribute to confusion and fear. Empathetic communication conveys concern and reassurance, empowers people, and reduces emotional turmoil. Accurate communication provides the facts about a situation and what is being done to resolve it. Effective communication helps build understanding and guide the response to COVID-19 and complying with public health recommendations. Some specific recommendations that the plant can follow include the following considerations:

- Continuing to provide COVID-19 informational signage throughout the plant.
- Enlarging and simplifying signage. Remove as much outdated signage as possible or relocate historical signs to a more appropriate viewing area (e.g., visitors center).
- Using more pictures/pictograms and adding more languages to increase the percentage of the workforce that engages with signs and messaging.
- Adding additional signage in cafeterias, locker rooms, and break areas to remind employees about hand hygiene, social distancing, and PPE.
- Ensuring signage is at eye level and can be easily seen by the employees.
- Installing additional video monitors throughout the plant to deliver messaging throughout the day.
- Developing or providing existing training and messaging (in multiple languages) for social distancing, hand hygiene, donning, doffing, and sanitizing PPE, and messaging about what to do

if you are sick. Consider alternatives to traditional in-person trainings for delivery of this information (e.g., videos). Develop a method to verify employee understanding and participation in these strategies.

- Provide the training materials in multiple languages, whenever possible. Be aware of potential concerns (e.g., comfort, anxiety) that employees may have around wearing face coverings at work.
 - Use a mass distribution method for transmission of training (e.g., the Beekeeper application to which the employees already have access).
 - Partner with community organizations to distribute messaging to employees.
 - Include use of facial coverings, hand hygiene, and social distancing messaging on the televisions in the cafeteria on a continuous loop.
 - Include messaging about social distancing and hand washing guidelines over the speakers in the flag hallway during breaks and lunch.
 - Work with the South Dakota Department of Health and other partners to develop specific messaging that address the communication needs of the employees of Smithfield Foods.
- Providing training to employees, supervisors, and management whenever changes are implemented in the workplace. Refresher trainings should be provided on a regular basis.
- Utilizing current down time to “pre” train employees about what changes to policies and practices are occurring in the plant before they come back to work.
- Adopting simplified messaging for staff. For example, the “top three things to protect yourself from COVID-19 at work: Social Distancing, Hand Hygiene, and PPE.”
- Empowering employees to provide corrective guidance to other employees about improperly worn PPE.
- Encouraging employees to download and utilize the Beekeeper application and sign up for other mass-communication methods available to the plant.
- Deploying training through the Beekeeper application and other mass-communication methods. Use read receipt functions to gauge participation and engagement. Consider ways to incentivize employee utilization of these trainings.
- Following the [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#) to provide more education around steps employees can take to protect themselves at work and at home. The guidance includes the following suggestions for communications with employees:
 - Employees can [take steps to protect themselves](#) at work and at home. Older people and people with serious chronic medical conditions are at [higher risk for complications](#).
 - Follow the policies and procedures of your employer related to illness, cleaning and disinfecting, and work meetings and travel.

- Stay home if you are sick, except to get medical care. Learn [what to do if you are sick](#).
- Inform your supervisor if you have a sick family member at home with COVID-19. Learn what to do [if someone in your house is sick](#).
- Wash your hands often with soap and water for at least 20 seconds. Use hand sanitizer with at least 60% alcohol if soap and water are not available.
- Avoid touching your eyes, nose, and mouth with unwashed hands.
- Cover your mouth and nose with a tissue when you cough or sneeze or use the inside of your elbow. Throw used tissues in the trash and immediately wash hands with soap and water for at least 20 seconds. If soap and water are not available, use hand sanitizer containing at least 60% alcohol. Learn more about [coughing and sneezing](#) etiquette on the CDC website.
- Clean and disinfect frequently touched objects and surfaces such as workstations, keyboards, telephones, handrails, and doorknobs. Dirty surfaces can be cleaned with soap and water prior to disinfection. To disinfect, use [products that meet EPA's criteria for use against SARS-CoV-2](#), the cause of COVID-19, and are appropriate for the surface.
- Avoid using other employees' phones, desks, offices, or other work tools and equipment, when possible. If necessary, clean and disinfect them before and after use.
- Practice social distancing by avoiding [large gatherings](#) and maintaining distance (approximately 6 feet or 2 meters) from others when possible.

Personal Protective Equipment (PPE)

Workers should continue to wear PPE required for the job tasks being performed.

- Provide appropriate PPE for specific jobs and ensure it is used by all workers as needed
 - Use videos or in-person visual demonstrations of proper PPE donning and doffing procedures. (Maintain social distancing during these demonstrations.)
 - Emphasize that care must be taken when putting on and taking off PPE to ensure that the worker or the item does not become contaminated.
 - PPE should be: (1) disposed; or (2) properly disinfected and stored in a clean location when not in use.
 - PPE worn at the facility should not be taken home.
- Consider the use of face shields or other types of PPE that may serve as both PPE and source control
 - If helmets are being used, use face shields designed to attach to helmets
 - Face shields can provide additional protection from both potential process-related splashes and potential person-to-person droplet spread
 - Safety glasses may fog up when used in combination with masks or cloth face coverings
 - Face shields can help minimize contamination of masks and cloth face coverings
 - If used, face shields should be cleaned and decontaminated after each shift and when not in use should be kept in a clean location at the work facility

- Stress hand hygiene before and after handling all PPE

The US Government is developing additional guidance for meat and poultry processing facilities to prevent and mitigate the spread of SARS-CoV-2 between employees while at work. Please review this guidance when it becomes available and institute recommended controls in your plant. Consult with USDA to determine if proposed controls are acceptable with regards to food safety and sanitation. Continue communicating and working with the South Dakota Department of Health, strategic community partners, and union leadership.

End of Memo



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control
and Prevention (CDC)**Memorandum**

Date: April 22, 2020

From: Michael Grant, CDC National Institute for Occupational Safety and Health
Colin Basler, CDC National Center for Emerging Zoonotic Infectious Diseases
Jesica Jacobs, CDC Laboratory Leadership Service Officer
Erin Kennedy, CDC Center for Global Health
John Osburn, South Dakota Department of Health
Jonathan Steinberg, CDC Epidemic Intelligence Officer, South Dakota Department of Health
Suzanne Tomasi, CDC National Institute for Occupational Safety and Health

To: Joshua Clayton, South Dakota Department of Health

Copy: Russ Dokken, Smithfield Foods
Scott Reed, Smithfield Foods
Mark Wiggs, Smithfield Foods
B.J. Motley, President, UFCW Local 304A Union

Subject: Strategies to reduce COVID-19 transmission at the Smithfield Foods Sioux Falls Pork Plant

Background

The South Dakota Department of Health requested an Epi Aid for assistance in developing strategies to help reduce SARS-CoV-2 infections among Smithfield Foods Sioux Falls pork processing plant employees. SARS-CoV-2 is the virus that causes coronavirus disease 2019 (COVID-19). A team from the Centers for Disease Control and Prevention (CDC) traveled to Sioux Falls, South Dakota for an Epi Aid on April 14, 2020. The CDC team included veterinary epidemiologists, an Epidemic Intelligence Service Officer, an industrial hygienist, and a Laboratory Leadership Service Officer. One component of this effort was to visit the Smithfield Foods pork processing plant to evaluate existing health and safety controls and provide recommendations for improvement. This memorandum provides observations and recommendations based on our visits to the plant on April 16 and 17, 2020 and conversations with plant management and the United Food and Commercial Workers Union (UFCW) local president. The recommendations in this memorandum are steps that Smithfield Foods may want to consider implementing to address the conditions we identified at the plant. These recommendations are discretionary and not required or mandated by CDC.

No harvesting or further production work were taking place in the plant while we were on site. The first case among employees was detected on March 24, 2020. Smithfield Foods announced that the process to halt production began on April 11, 2020. The plant informed us that all processing activities were

completed on April 14, 2020 and that the plant would be shut down indefinitely while Smithfield Foods continued extensive sanitation and modification efforts in the plant. The few employees we observed in the plant during our walkthroughs were performing maintenance and distribution center tasks. We toured the plant and observed workstations from the pens where the swine are delivered through the distribution center, where product is shipped out of the plant. We also observed the route that employees take from the parking lots through the symptom screening tents and into the facility. Additionally, we observed administrative areas, the occupational health clinic and quarantine room, and the common areas (e.g., break rooms, cafeterias, locker rooms) shared by employees.

Our team was unable to identify important demographic information about this workforce, limiting our ability to understand the diversity of the employees. However, plant management reported that there were approximately 40 different languages spoken by employees in the plant and that English, Spanish, Kunama, Swahili, Nepali, Tigrinya, Amharic, French, Oromo, and Vietnamese are the top 10 languages. We were also unable to obtain information about the workstations of confirmed positive cases. This type of information could provide a better understanding of what workplace factors may have contributed to the spread of COVID-19 among employees. Key demographic and workstation information was requested from the company to help answer some of these questions in the future. Additional recommendations and findings may be provided upon receipt of demographic and workstation information.

Observations and Discussion

Employee Screening

Employees were screened before entering the plant prior to their shift. The company had set up two screening locations, one on either side of the plant. Visual markers were added every six feet to decrease crowding while employees approached and moved through the screening tents. The screening consisted of walking past a thermal imaging system for body temperature measurement and self-reported symptom checks. Screening was conducted by a contracted health care professional who informed the employee of their temperature and asked whether the employee had a cough or shortness of breath.

We were informed that if an employee had a fever ($>99.8^{\circ}\text{F}$) or reported experiencing symptoms, the employee underwent secondary screening by a contracted nurse. Additionally, we learned that the screening process also looked for visible signs of symptoms as employees were screened. Secondary screening consisted of a temperature check with an infrared thermometer and a more in-depth evaluation of symptoms. We understand that if an employee was found to have a fever or symptoms consistent with COVID-19, they were given an informational packet (in English) and instructed to return home. Employees were provided two weeks of paid sick leave (40 hours pay per week) when sent home and were asked to call a hotline operated by a local health system for guidance regarding next steps.

Plant management informed us that they had identified a department of the plant (Pork Conversion) with a high density of positive cases. The whole department was placed on two weeks paid sick leave. We also learned that efforts had been taken to adjust schedules to facilitate distancing of employees working in essential operations (e.g., wastewater treatment). Additionally, we learned of a “responsibility bonus”

of \$500 being offered to employees who did not miss time (e.g., were not late or sick) during the time period of April 1, 2020 through May 1, 2020. The company informed us that COVID-19-related absence will not impact the receipt of the bonus.

Increasing Distance Between Employees During Work and Breaks

Plant screening tents had posters on the wall to remind employees to maintain a social distance of 6 feet during the screen process. In all lunchrooms and break areas that we observed, dividers had been placed on tables to remind employees to maintain a physical barrier between each other. Some tables had been marked “off-limits” by tape. Additional tables were placed in one hallway (the “flag hallway”) to decrease the density of employees inside the nearby cafeteria. Some outdoor picnic tables had been moved to facilitate social distancing, although other outdoor tables were less than 6 feet apart.

In at least one department (Ground Seasoned Pork), line speed had been reduced to accommodate fewer employees on the line due to social distancing efforts and workforce availability constraints (i.e., illness amongst employees). Plant management had identified and installed approximately 800 plexiglass barriers in locations where distancing was not possible (e.g., production lines). Plant management reported that, on some production lines prior to shutting down the plant, employees on opposite sides of the line alternated workstations to maintain distancing. On other lines, barriers had been hung in an attempt to separate employees. Management reported that the barriers were made of plexiglass. Among the few employees that were present in the plant during our walk throughs, we observed several who were congregating less than 6 feet apart when away from their workstations.

Supplementary Infection Control Measures

We saw hand sanitizer dispensers located in limited locations throughout the plant, notably at the entrances to the building and within cafeterias and break rooms. Plant management indicated that more hand sanitizer dispensers will be added as COVID-19 prevention measures. We learned of plans to increase the number of dispensers to 3500 (i.e., roughly one dispenser station per employee). The hand sanitizing dispensers were all manually operated (i.e., not touchless). Limited handwashing stations were available in locker rooms and in some production areas of the plant. The union shared its observation that there were approximately 30 employees in a locker room at any given time. Some handwashing stations were touchless, but the majority were not. Management also indicated they were developing a plan to have people assigned to remind employees about hand sanitizing every 30 minutes. However, the plant had not yet finalized the rollout plans for this effort.

Additional staff have been assigned to clean and sanitize commonly touched surfaces more frequently, such as handrails, doors and door handles, and lunch tables. Time clocks in the plant were touchless for plant employees, and the plant informed us of plans to install over 100 additional time clocks to decrease bottlenecks.

Use of Facemasks and Other Face Coverings

Plant management informed us of plans to institute a universal facemask requirement for all employees in accordance with CDC recommendations for critical infrastructure employees and the public. We

learned that plant management will provide a facemask with moldable nosepiece to all employees before entering the plant each day. We learned that they have a plan to provide additional facemasks to employees throughout the day if facemasks become wet or soiled. We also learned that face shields will be provided to all non-administrative employees moving forward. These face shields will be affixed to the hard hat. We observed some employees still working at the plant either not wearing facemasks or wearing them incorrectly (e.g., wearing them over the mouth but not the nose). Plant management indicated that they had estimated the number of facemasks and face shields that would be required for a 30-day supply for the plant running at full capacity. Plant management was also conducting informal experiments with both commercial and home-remedy-style anti-fogging products (e.g., shaving cream) for the face shields.

Educating Employees on COVID-19 Risks, Prevention, and Company Policies

There were informational flyers with pictures representing COVID-19 symptoms of fever, cough, and shortness of breath on the walls of the screening areas, but not at the screening table itself. Throughout the plant, informational flyers were posted on walls encouraging employees to practice social distancing, keep their mouth and nose covered, regularly wash their hands, and report symptoms to occupational health. Some flyers were translated into multiple languages and there were some that included pictograms. Most flyers were approximately 9" x 11" but were not positioned at eye level. Many flyers had densely packed words and limited pictograms. There were video loops on display in cafeterias and break rooms, but we did not observe any COVID-19-related educational information. The plant had recently implemented a new messaging strategy using an application called "Beekeeper" that allowed management to mass-communicate with employees in a language of their choice. We learned from the union that they also have the ability to send mass communications to their members. The union also reported the ability to translate messaging for members and identified key plant employees who served as translators when needed. Although plant management stated that many of their employees used smart phones, it was unclear how widely the app was being used among employees at the time of our visits. The plant also utilized a text messaging alert system that could send COVID-19 related messages to employees. Management expressed that communicating messages to their diverse staff presented challenges due to the number of languages spoken.

Pending Activities Reportedly Planned by the Company

1. Developing and finalizing standard operating procedures for new infection prevention and control measures, especially related to supplementary disinfection of high-touch areas.
2. Increasing engagement with the Beekeeper application. We were informed that approximately 1,400 employees have signed on to receive text messages from this system.
3. Completing installation of plexiglass barriers in close contact workstations.
4. Increasing the number of hand sanitizer dispensers in the plant to 3,500 (i.e., roughly 1 per employee).
5. Installing over 100 additional time clocks to prevent bottlenecks.
6. Promoting increased adoption of mass communication methods to communicate COVID-19 prevention and informational messages to employees. We learned that they are planning to start this process during the plant closure.

7. Having designated staff walk around lines to provide hand sanitization to line employees every 30 minutes.
8. Relaxing sick leave policies related to COVID-19. Eliminating premiums, copays, and waiting periods for COVID-19 testing.

Conclusions

The company implemented several controls at the plant to help reduce and mitigate the spread of coronavirus between employees while in the plant and is in the process of implementing additional strategies as discussed above. Additional recommendations are provided below to help management, employees, the union, the South Dakota Department of Health, and strategic community partners to potentially limit virus transmission in the plant. The following recommendations are steps that the plant may want to consider implementing to address the conditions we have identified at the plant. These recommendations are discretionary and are not required or mandated by CDC. Consult with the United States Department of Agriculture (USDA) staff at the plant to determine if proposed controls are acceptable with regards to food safety and sanitation.

Recommendations

The following actions are recommended -to reduce the spread of COVID-19 between employees while they are at work. With ongoing community transmission, COVID-19 cases among staff will likely continue to be identified. A combination of control measures with ongoing education and training will be useful in reducing or eliminating transmission in the workplace. These recommendations are intended for this specific Smithfield plant, but broader interim recommendations for meat and poultry processing industries are in development. It is recommended that management, the safety committee/union representative at the facility, the South Dakota Department of Health, and strategic community partners work together to implement recommendations and plans at the facility to further reduce the spread of COVID-19.

Hierarchy of Controls

The following recommendations should be implemented according to the hierarchy of controls, wherever feasible. [Hierarchy of controls](#) is an approach to hazard intervention that starts with the controls perceived to be most effective and moves down to those considered least effective. In most cases, the preferred approach is to eliminate a hazard or exposures, install engineering controls, and implement appropriate sanitation and cleaning to shield or reduce employee's exposure to the hazard. Until such controls are in place, or if they are not adequately effective or feasible, administrative measures and personal protective equipment (PPE) may be needed.

Social Distancing, Screening, and Sick Leave

In addition to [everyday steps to prevent COVID-19](#), keeping space between individuals ([social distancing](#)) is one of the best strategies to avoid being exposed to the virus and slowing its spread. Barriers are one method to physically separate employees in areas of the plant (including work areas and other areas such as break rooms, parking lots, hallways and corridors, entrance/exit areas, and locker rooms). Other practices such as use of visual cues at six-foot intervals (e.g., floor markings, signs) can

be used to encourage physical distancing. Follow CDC Interim Guidance – [“Implementing Safety Practices for Critical Infrastructure Employees Who May Have Had Exposure to a Person with Suspected or Confirmed COVID-19”](#) for best practices regarding screening and sick leave. Until the broader interim recommendations for meat and poultry processing industries are completed, many strategies for social distancing, screening, and sick leave can be utilized from CDC’s [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#). Some specific recommendations that the plant can follow include the following considerations:

- Consider the following actions to physically separate employees (at least 6 feet, where possible) and reduce employee density in non-work areas of the facilities, such as cafeteria, break rooms, equipment dispensing stations, locker rooms, smoking areas, entrance/exit areas, and other areas where employees may congregate (e.g., the box shop):
 - Adding more visual cues at six-foot intervals (e.g., floor markings, signs, traffic cones) in the cafeterias, knife and gear acquisition areas, and other areas where lines may form. Additional areas where visual cues may be implemented include:
 - Areas where knives, uniforms, and PPE are checked out. Consider methods to increase the physical distance between employees picking up equipment and ensure contactless interactions between employees as much as possible.
 - The tattoo stations in the pig barn to maintain at least 6 feet between the truck door (and the truck drivers offloading swine) and the employee that is tattooing swine.
 - Areas around the sinks in the locker rooms.
 - Areas where employees punch in and out for the day.
 - Outside the front of the building where employees may congregate waiting for rides.
 - Cafeterias and break rooms (e.g., around food lines, vending machines, cash registers).
 - The bridge and main staircases used by employees to enter the plant.
 - Outdoor common areas.
 - Expanding distance between tables in the 3rd floor flag hallway – remove some tables to facilitate more space between the chairs of adjacent tables.
 - Reducing the number of tables in the 6th floor cafeteria to reduce crowding.
 - Changing the orientation of table dividers in the 3rd floor cafeteria to promote one employee per side of the table.
 - Spreading out the shelving that is used for storage of lunch boxes in the cafeteria so there is some distance between each set of shelves. Place markings on the shelves to encourage employees to keep their personal items separate. Place visual cues of six feet so that people do not come into close contact when retrieving their personal items.
 - Increasing the flexibility around shift start times and break times to decrease the number of employees in locker rooms or break areas at one time.
 - Identifying alternative locker locations (e.g., converting currently unused spaces into temporary locker areas).

- Installing portable or temporary bathroom and handwashing facilities could be utilized near the temporary locker rooms (or in general) to ease the density of employees in bathrooms during break and lunch times.
 - Staggering employees along line workstations so that employees are not working directly across from each other. Changes in production practices (e.g., line speed reductions) may be necessary in order to maintain appropriate distancing among employees.
 - Altering additional workstations to minimize close contact among employees by adding plexiglass, stainless steel, or durable polycarbonate barriers between workstations. Barriers should be used in combination with (and not replace) other social distancing, hand hygiene, and personal protective equipment efforts outlined in these recommendations, wherever feasible.
 - Staggering shifts, start times, and break times as much as feasible to decrease number of employees in locker rooms, break areas, and cafeterias at one time.
 - Setting up break and lunch areas outdoors to reduce the density of employees in existing breakrooms and cafeterias and encourage employees to spend their breaks in locations with air movement and space for social distancing. For example, tents could be set up and have the capability of being heated to encourage use of the outdoor space in inclement weather. Other facilities have implemented similar controls and are incentivizing outdoor breaks and lunches. Consider including portable or temporary bathroom and handwashing facilities as a part of this setup.
 - Adding additional touchless clock in/out stations throughout the plant to reduce crowding and congregating at these areas.
 - Adjusting the physical layout and the maximum class size for trainings. Consider moving training online, by video, or other methods to increase distance between employees while receiving training and orientation.
 - Increasing the space between outdoor tables to at least six feet to reduce the density in spaces where employees or truck drivers may congregate.
 - Making unidirectional paths through facility, where possible, including stairs, hallways, and cafeterias. This will reduce contact in narrow hallways, stairs, and break areas.
 - Limiting the number of employees in the cafeteria serving and payment area at one time.
 - Encouraging employees, drivers, and contractors to maintain distancing in indoor and outdoor common areas.
 - Assigning an individual to monitor the social distancing efforts in communal spaces (e.g., break rooms, cafeterias, locker rooms).
- Consider the following actions to improve source control and hygiene:
 - Face coverings are generally recommended as an addition to social distancing. They are especially important for source control. Cloth face coverings keep the person wearing one from spreading respiratory droplets when talking, sneezing, or coughing; is also referred to as “source control.” The face covering is meant to protect other people in case employees are infected but not symptomatic.

- If feasible, all employees should wear the face covering being used by the company to cover their nose and mouth in all areas of the plant (including break areas and locker rooms). Some specific recommendations that the plant can follow include the following considerations:
 - Continuing with the plan for all employees wear a face covering and a face shield anytime they are at work. The face shield is being used in this plant to supplement the use of the face covering.
 - Employees should wear the supplied facial covering to cover their nose and mouth if possible – this may prevent people who do not know they have the virus from transmitting it to others.
 - The facial covering should allow for breathing without restriction, not be touched after putting on to prevent transferring infected materials and be discarded and replaced when dirty or wet, if possible.
 - Management and supervisors will be essential for continued training and encouragement of employees to follow these guidelines.
 - Having replacement face masks available in case an employee's face mask becomes wet or soiled.
 - If possible, distribution should be contactless, while still allowing for control of the number of face masks distributed, if possible. For example, consider placing face masks on a table and having employees step forward one at a time while another employee oversees the process.
 - The employee distributing face masks should be following appropriate social distancing and wearing appropriate PPE (gloves) and facial covering, if possible.
 - Providing face coverings to truck drivers when they check in at the office. Consider asking drivers about symptoms or screening them when they arrive to the plant.
 - Encouraging or requiring contractors and FSIS inspectors to follow face covering and face shield use recommendations. Work with the appropriate partners to discuss how to roll this out among contractors and FSIS employees.
- Face shields are not acceptable substitutions for eye protection (such as safety glasses) that are used for impact protection. If needed and feasible, face shields should be used in addition to the eye protection, not as a replacement for jobs requiring eye protection, as identified by the plant's OSHA PPE hazard assessment ([29 CFR 1910.132](#)).
- Consider the following actions to improve the existing screening policies and processes:
 - Screening all individuals entering the plant (e.g., employees, management, contractors, FSIS inspectors).
 - Adjusting the orientation of the screening tent exit so that employees exiting the screening tent do not exit into the path of employees who are leaving the facility.
 - Identifying off site housing for employees who have tested positive for COVID-19 and live in a household where they do not have the ability to self-isolate from other household

members, especially individuals who are at high-risk for developing severe illness or other critical infrastructure employees.

- If possible, specifically ask employees about recent history of fever in addition to the symptoms (e.g., cough and shortness of breath) and the objective measurement of temperature.
 - Temperatures should be measured individually using a temporal, tympanic, or oral thermometer with a probe cover.
 - If continuing to use thermal imaging systems, procure FDA-approved system(s) and use in accordance with the manufacturer specifications.
 - If such a system cannot be procured, use the existing thermal imaging system in accordance with all manufacturer specifications and FDA guidance. If feasible, ensure that it is set up in such a way to accommodate the height variation of all individuals being screened.
- Including large pictograms in the screening process to increase non-verbal communication.
- Instructing employees to report to supervisors if they get sick during work shift.
- Continuing to send ill employees [home immediately](#) if they become ill during the day. Employees who are ill should stay home, if possible, and not work or be allowed in the workplace. Surfaces in their workspace should be [cleaned and disinfected](#). Continue to work with your state and local public health authorities in using CDC guidance in identification and follow up of contacts of ill persons.
- Translating the secondary screening packet into other languages commonly spoken in the plant to improve communication with employees. Additional steps to improve communication may include:
 - Having the screener point to large pictures of symptoms for employees whose primary language is not English.
 - Adding CDC guidance: “[What to do if you are sick](#)” to the informational packet provided to employees being sent home after screening. There are multiple languages available on the CDC website.
- Consider the following actions to improve the existing sick leave policies and practices:
 - Ensuring that sick leave policies are flexible and consistent with public health guidance and that employees are aware of and understand these policies.
 - Adjusting any incentive programs such that employees are not penalized for taking sick leave related to COVID-19.
 - Maintaining flexible policies that permit employees to stay home to care for a sick family member or take care of children due to school and childcare closures. Additional flexibilities might include giving advances on future sick leave and allowing employees to donate sick leave to each other.
 - Discontinuing any policies requiring a positive COVID-19 test result or a healthcare provider’s note for employees who are sick to validate their illness, qualify for sick leave,

or to return to work. Healthcare provider offices and medical facilities may be extremely busy and not able to provide such documentation in a timely manner.

- Reviewing human resources policies to make sure that policies and practices are consistent with public health recommendations and are consistent with existing state and federal workplace laws (for more information on employer responsibilities, visit the [Department of Labor's](#) and the [Equal Employment Opportunity Commission's](#) websites).
- Connecting employees to employee assistance program (EAP) resources (if available) and community resources as needed. Employees may need additional social, behavioral, and other services, for example, to cope with the death of a loved one.
- Continuing to evaluate and augment the return to work plan. Employees with COVID-19 who have stayed home (home isolated) should not return to work until the [criteria to discontinue home isolation](#) are met, in consultation with healthcare providers and state and local health departments.

Hand Hygiene and Sanitation

[Hand hygiene](#) and sanitation (infection prevention and control) are other important tools to avoid being exposed to the virus and slowing its spread. Follow the [CDC recommendations for cleaning and disinfection during the COVID-19 response](#). Monitor these recommendations for updates. Cleaning and disinfection of surfaces and objects that are frequently touched, especially in common areas, several times per day is an important component to control the spread of COVID-19. Until the broader interim recommendations for meat and poultry processing industries are completed, many strategies for hand hygiene can be utilized from CDC's [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#). Some specific recommendations that the plant can follow include the following considerations:

- Encouraging frequent handwashing with soap and water for at least 20 seconds. Use hand sanitizer with at least 60% alcohol if soap and water are not available.
- Increasing access to hand washing and hand sanitizing stations throughout the facility.
 - Continue with the plan to put hand sanitizer at every table in the break hallway (or periodically along the hallway).
 - Focusing on adding stations before and after high touch surfaces (e.g., bottoms and tops of stairwells, doffing areas, entrance and exit points for break areas and lunchrooms).
 - Wherever feasible, ensure hand sanitizing stations are located immediately before employees take anything out of a bin (e.g., frocks, gloves, silverware in the lunch room).
 - Increasing the number of hand sinks available, especially in locker rooms.
- Installing no-touch sinks, soap dispensers, sanitizer dispensers, and paper towel dispensers (preferred over hand dryers) wherever possible – make everything as touch free as possible.
- Encouraging employees to perform hand hygiene when coming off the line for break, lunch, or end of shift. Utilize the current plan for roaming sanitizing employees to coordinate these actions.

- Emphasize proper hand hygiene after gloves are removed and before and after facial coverings are donned or doffed. Installation of hand hygiene stations, training, and routine monitoring will encourage compliance.
- Adding portable or temporary bathroom and handwashing facilities near any temporary locker room areas or break areas.
- Continuing to frequently disinfect high-touch areas in food production areas with products meeting [EPA's criteria for use against SARS-CoV-2](#), the virus that causes COVID-19, and approved under the facility's sanitation standard operating procedures.
 - If EPA-registered disinfectants are not available, diluted household bleach solutions (final concentration at least 1000 ppm sodium hypochlorite), or alcohol solutions with at least [70% alcohol](#), can be used. Additional guidance on cleaning and disinfecting non-food production areas of your facility can be found on the [CDC website](#).
- Continuing to conduct targeted and more frequent cleaning of high-touch areas of shared spaces (e.g., time clocks, bathroom fixtures, break room tables and chairs, locker rooms, vending machines, railings, door handles, handles from ceiling, plug attachments and orange door cords hanging from ceiling). Follow [CDC guidance for disinfection](#). Some additional recommendations to improve the existing efforts include:
 - Sanitizing break areas between breaks, between shifts, and between groups of employees using these areas.
 - Developing sanitization guidelines for administrative areas of the plant.
 - Developing a standard operating procedure for environmental sanitization that includes a list of areas considered high-touch, frequency of disinfection, what product to use, training requirements, and required personal protective equipment. Comply with the Occupational Safety and Health Administration (OSHA) PPE ([29 CFR 1910.132, 1910.138](#)) and Hazard Communication ([29 CFR 1910.1200](#)) Standards.
 - Disinfectants should be applied according to the [label instructions](#).
 - Coordinate disinfectant product use with United States Department of Agriculture (USDA) if used in food production areas.
 - For other high-touch areas (outside of food production areas), such as door handles, bathroom surfaces, railings, and tables, use products that meet [EPA's criteria for use against SARS-CoV-2](#).
- Replacing any plexiglass barrier if it becomes damaged (e.g., cracks cannot be sanitized effectively) to be consistent with USDA Food Safety and Inspection Service (FSIS) [Sanitation Performance Standards Compliance Guide](#) that requires inspected establishments to build their facilities and maintain it in a sanitary manner.
- Continuing to disinfect tools between use when used by multiple employees.

- Performing enhanced cleaning and disinfection after persons with suspected or confirmed COVID-19 have been in the plant
 - If a sick Employee is suspected or confirmed to have COVID-19, follow the [CDC cleaning and disinfection recommendations](#).
- Ensuring that contracted cleaning services are meeting the guidelines listed above.
- Developing a protocol for sanitizing hard hats and face shields at the end of the shift.
- Developing a protocol for how employees can safely store their hardhats while going on break without bringing them into the shared areas (e.g., break rooms, locker rooms, cafeterias).

Training and Communication

When developing training and communication materials, the plant should use current, correct messaging from a trusted source. Follow the CDC [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#) for general information related to training and communication for employees. Training should be reinforced by the use of signage (preferably infographics) placed in strategic locations, wherever possible. Graphics and suggested messages are [available from CDC](#) for use on social media profiles and web pages. [Print resources](#) are also available from CDC. [Communication guidance](#) exists for three phases: before a COVID-19 outbreak occurs, during a COVID-19 outbreak, and after a COVID-19 outbreak. It is important to maintain ongoing communication and message coordination with plant preparedness workgroup members, partners, stakeholders, news media, and other channels to ensure consistent messaging, wherever possible. If technical terminology and concepts are used in training or communications, definitions and examples should be included to help improve understanding, wherever possible. Early communication of COVID-19 information helps limit misinformation and rumors that could contribute to confusion and fear. Empathetic communication conveys concern and reassurance, empowers people, and reduces emotional turmoil. Accurate communication provides the facts about a situation and what is being done to resolve it. Effective communication helps build understanding and guide the response to COVID-19 and complying with public health recommendations. Some specific recommendations that the plant can follow include the following considerations:

- Continuing to provide COVID-19 informational signage throughout the plant.
- Enlarging and simplifying signage. Remove as much outdated signage as possible or relocate historical signs to a more appropriate viewing area (e.g., visitors center).
- Using more pictures/pictograms and adding more languages to increase the percentage of the workforce that engages with signs and messaging.
- Adding additional signage in cafeterias, locker rooms, and break areas to remind employees about hand hygiene, social distancing, and PPE.

- Ensuring signage is at eye level and can be easily seen by the employees.
- Installing additional video monitors throughout the plant to deliver messaging throughout the day.
- Developing or providing existing training and messaging (in multiple languages) for social distancing, hand hygiene, donning, doffing, and sanitizing PPE, and messaging about what to do if you are sick. Consider alternatives to traditional in-person trainings for delivery of this information (e.g., videos). Develop a method to verify employee understanding and participation in these strategies.
 - Provide the training materials in multiple languages, whenever possible. Be aware of potential concerns (e.g., comfort, anxiety) that employees may have around wearing face coverings at work.
 - Use a mass distribution method for transmission of training (e.g., the Beekeeper application to which the employees already have access).
 - Partner with community organizations to distribute messaging to employees.
 - Include use of facial coverings, hand hygiene, and social distancing messaging on the televisions in the cafeteria on a continuous loop.
 - Include messaging about social distancing and hand washing guidelines over the speakers in the flag hallway during breaks and lunch.
 - Work with the South Dakota Department of Health and other partners to develop specific messaging that address the communication needs of the employees of Smithfield Foods.
- Providing training to employees, supervisors, and management whenever changes are implemented in the workplace. Refresher trainings should be provided on a regular basis.
- Utilizing current down time to “pre” train employees about what changes to policies and practices are occurring in the plant before they come back to work.
- Adopting simplified messaging for staff. For example, the “top three things to protect yourself from COVID-19 at work: Social Distancing, Hand Hygiene, and PPE.”
- Empowering employees to provide corrective guidance to other employees about improperly worn PPE.
- Encouraging employees to download and utilize the Beekeeper application and sign up for other mass-communication methods available to the plant.
- Deploying training through the Beekeeper application and other mass-communication methods. Use read receipt functions to gauge participation and engagement. Consider ways to incentivize employee utilization of these trainings.

- Following the [Interim Guidance for Businesses and Employers to Plan and Respond to COVID-19](#) to provide more education around steps employees can take to protect themselves at work and at home. The guidance includes the following suggestions for communications with employees:
 - Employees can [take steps to protect themselves](#) at work and at home. Older people and people with serious chronic medical conditions are at [higher risk for complications](#).
 - Follow the policies and procedures of your employer related to illness, cleaning and disinfecting, and work meetings and travel.
 - Stay home if you are sick, except to get medical care. Learn [what to do if you are sick](#).
 - Inform your supervisor if you have a sick family member at home with COVID-19. Learn what to do [if someone in your house is sick](#).
 - Wash your hands often with soap and water for at least 20 seconds. Use hand sanitizer with at least 60% alcohol if soap and water are not available.
 - Avoid touching your eyes, nose, and mouth with unwashed hands.
 - Cover your mouth and nose with a tissue when you cough or sneeze or use the inside of your elbow. Throw used tissues in the trash and immediately wash hands with soap and water for at least 20 seconds. If soap and water are not available, use hand sanitizer containing at least 60% alcohol. Learn more about [coughing and sneezing](#) etiquette on the CDC website.
 - Clean and disinfect frequently touched objects and surfaces such as workstations, keyboards, telephones, handrails, and doorknobs. Dirty surfaces can be cleaned with soap and water prior to disinfection. To disinfect, use [products that meet EPA's criteria for use against SARS-CoV-2](#), the cause of COVID-19, and are appropriate for the surface.
 - Avoid using other employees' phones, desks, offices, or other work tools and equipment, when possible. If necessary, clean and disinfect them before and after use.
 - Practice social distancing by avoiding [large gatherings](#) and maintaining distance (approximately 6 feet or 2 meters) from others when possible.

Personal Protective Equipment (PPE)

Workers should continue to wear PPE required for the job tasks being performed.

- Provide appropriate PPE for specific jobs and ensure it is used by all workers as needed:
 - Use videos or in-person visual demonstrations of proper PPE donning and doffing procedures. (Maintain social distancing during these demonstrations.)
 - Emphasize that care must be taken when putting on and taking off PPE to ensure that the worker or the item does not become contaminated.
 - PPE should be: (1) disposed; or (2) properly disinfected and stored in a clean location when not in use.
 - PPE worn at the facility should not be taken home.
- Consider the use of face shields or other types of PPE that may serve as both PPE and source control:
 - If helmets are being used, use face shields designed to attach to helmets

- Face shields can provide additional protection from both potential process-related splashes and potential person-to-person droplet spread
 - Safety glasses may fog up when used in combination with masks or cloth face coverings
 - Face shields can help minimize contamination of masks and cloth face coverings
 - If used, face shields should be cleaned and decontaminated after each shift and when not in use should be kept in a clean location at the work facility
- Stress hand hygiene before and after handling all PPE.

The US Government is developing additional guidance for meat and poultry processing facilities to prevent and mitigate the spread of SARS-CoV-2 between employees while at work. Please review this guidance when it becomes available and institute recommended controls in your plant, where feasible. Consult with USDA to determine if proposed controls are acceptable with regards to food safety and sanitation. Continue communicating and working with the South Dakota Department of Health, strategic community partners, and union leadership.

End of Memo

Congress of the United States
Washington, D.C. 20515

October 5, 2020

The Honorable Eugene Scalia
Secretary
U.S. Department of Labor
200 Constitution Ave NW
Washington DC 20210

Dear Secretary Scalia:

We are writing regarding the involvement of the Department of Labor (DOL) with the Centers for Disease Control and Prevention's (CDC) site visit memorandum and recommendations to the Smithfield Foods Sioux Falls Pork Plant (Smithfield) during April 2020.

As you may know, in response to a major COVID-19 outbreak at Smithfield, the South Dakota Department of Health (SD-DOH) requested CDC assistance in the form of an Epi-Aid in order to develop recommendations to reduce transmission of COVID-19 among the plant's workers. The CDC and the National Institute for Occupational Safety and Health (NIOSH) conducted several in-person visits to Smithfield in April of this year, and on April 22, 2020, the CDC issued a site visit memorandum and recommendations to Smithfield to help reduce COVID-19 infections among its employees.¹ After it came to our attention that CDC issued a Version 1 of this document before issuing Version 2 on April 22, 2020, Representative Adams requested—and NIOSH recently provided—a copy of Version 1.² The date on Version 1 was April 21, 2020, one day before Version 2 was issued.

According to NIOSH's responses to the Committee on Education and Labor's requests, Version 1 was cleared internally by two task forces within the CDC team before CDC subsequently replaced it with Version 2.³ A comparison of the two versions shows several differences, including phrases like "if feasible," "consider," and "if possible" that appear to weaken the recommendations.

CDC Director Redfield has informed Senator Baldwin that his office was in contact with DOL about the Smithfield outbreak during the time that CDC was working on their site visit memorandum. In order to better understand the reasons and process behind the changes from Version 1 and Version 2, and DOL's role in those changes, please provide the following answers and information:

1. Copies of all emails, attachments, and other communications between DOL and CDC or the Department of Agriculture (USDA) regarding any version of the site visit

¹ Strategies to reduce COVID-19 transmission at the Smithfield Foods Sioux Falls Pork Plant, CDC (April 22, 2020).

² Strategies to reduce COVID-19 transmission at the Smithfield Foods Sioux Falls Pork Plant, CDC (April 21, 2020).

³ NIOSH responses to Questions for the Record, *Examining the Federal Government's Actions to Protect Workers from COVID-19*, Committee on Education and Labor Workforce Protections Subcommittee Hearing (May 28, 2020).

The Hon. Eugene Scalia
October 5, 2020
Page 2


- memorandum, including but not limited to emails, memos or phone conversations concerning the April 20 summary or pre-clearance draft of the site visit memorandum.
2. Copies of all emails, attachments, and other communications between Smithfield, its representatives, or any other entity acting on behalf of Smithfield and DOL regarding this site visit memorandum, including but not limited to emails, memos or phone conversations concerning the April 20 summary or pre-clearance draft of the site visit memorandum.
 3. Copies of any reports, notes, summaries, or other descriptions of the in-person visits received or reviewed by DOL concerning the visit that CDC and NIOSH conducted at Smithfield on April 16 and 17.
 4. A list of all the versions of this site visit memorandum or any summaries that were received or reviewed by DOL, including but not limited to the pre-clearance draft that was sent to the South Dakota Department of Health on April 20, Version 1, Version 2, and any other drafts.
 5. Copies of all emails, attachments, and other verbal and written communications between DOL and any other federal agency or the South Dakota Department of Health regarding any version of this site visit memorandum.

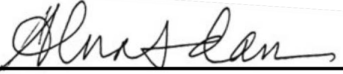
Please provide the requested information by October 19, 2020.


If you have any questions, please contact Cathy Yu at (202) 225-9721 or cathy.yu@mail.house.gov. Please direct all official correspondence to the Committee's Clerk, Mariah Mowbray, at Mariah.Mowbray@mail.house.gov.


Thank you for your prompt attention to this matter, and we look forward to your response.

Sincerely,


ROBERT C. "BOBBY" SCOTT
Chairman
Committee on Education and Labor


ALMA S. ADAMS, PH.D.
Chair
Subcommittee on Workforce Protections


PATTY MURRAY
Ranking Member
Committee on Health, Education, Labor and Pensions


TAMMY BALDWIN
Ranking Member
Subcommittee on Employment and Workplace Safety

TAMMY BALDWIN
WISCONSIN

United States Senate
WASHINGTON, DC 20510

COMMITTEES:
APPROPRIATIONS
COMMERCE
HEALTH, EDUCATION,
LABOR, AND PENSIONS

October 15, 2020

The Honorable Lamar Alexander
Chairman
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510

The Honorable Susan Collins
Chairman
Subcommittee on Employment and Workplace Safety
U.S. Senate
Washington, DC 20510

Dear Chairman Alexander, Ranking Member Murray, and Chairman Susan Collins:

I write to request a hearing with Centers for Disease Control and Prevention (CDC) Director Dr. Robert Redfield, Department of Agriculture (USDA) Secretary Sonny Perdue, and Department of Labor (DOL) Secretary Eugene Scalia regarding the Administration's effort to address COVID-19 outbreaks at our nation's meatpacking facilities.

As of this writing, 215,476 Americans have been killed by COVID-19. Of those, thousands worked in the meatpacking industry and at least 45,425 meat packing workers have tested positive, including many in Wisconsin. The Senate Health, Education, Labor and Pensions (HELP) Committee has held numerous hearings to better understand the impact of this virus, and the role that our federal agencies play in research, prevention, treatment, and preparation for future pandemics. We are now more than seven months into this fight, and we have yet to hold a hearing about the impact of this virus on workers. This is unacceptable, especially given the recent reporting and revelations regarding industry efforts to influence public health recommendations made by the CDC.¹

¹ <https://www.argusleader.com/story/news/2020/10/02/smithfield-foods-cdc-report-covid-19-outbreak-watered-down/3593620001/>

On September 23rd, the HELP Committee held a hearing with members of the Coronavirus Task Force, including CDC Director Dr. Redfield. I directed my questions to Dr. Redfield and asked him about CDC guidance for a Smithfield meatpacking facility in Sioux Falls, South Dakota. Specifically, I asked if he had contact with the USDA, Smithfield, or the White House regarding a watered-down CDC report written to address a COVID-19 outbreak at the facility. In response, Dr. Redfield stated that he did not have any contact with these entities.² However, following the hearing, I was made aware of conversations between CDC staff and congressional committee staff, confirming conversations between Secretary Perdue and Dr. Redfield on April 22nd, the same date the CDC report was edited and re-released. In a subsequent conversation, Dr. Redfield confirmed to me that he did in fact have conversations with Secretary Perdue, as well as conversations with DOL. Dr. Redfield defended the changes made to the report as edits to reflect that CDC is not a regulatory agency.

Recent reporting indicates that Dr. Redfield had an additional and previously undisclosed conversation about the CDC guidance for the Smithfield facility in question. A recent article in the New York Times reports that Dr. Redfield, at the direction of members of the White House Coronavirus Task Force, including its chair Vice President Pence, altered the CDC report. Specifically, the article describes how the Vice President's Chief of Staff Marc Short, "directed Dr. Redfield, the C.D.C. director, to soften the language of the report sent to the company, reducing the agency's recommendations to suggestions" and that, "Dr. Redfield dictated changes to the report to his staff in Atlanta from the vestibule outside Mr. Pence's office."

The New York Times story continues, "Not long after Dr. Redfield dictated changes to the report to his staff in Atlanta from the vestibule outside Mr. Pence's office, he confided to one of Mr. Pence's aides at the time, Olivia Troye that he felt that he was in an impossible position. 'My scientists are telling me what I need to do,' he said, according to Ms. Troye, who worked on the task force for Mr. Pence. But, he added, 'I want to make sure the vice president is happy.' From then on, a former senior health official recalled, Dr. Redfield would tell colleagues that the C.D.C. was not a regulatory agency, reflecting Mr. Short's view of the limits of its authority."³

Dr. Redfield was not truthful when he came before the HELP Committee on September 23rd. Now there is evidence that he did not mention an important conversation he had with the Vice President's Chief of Staff when he spoke with me in a follow-up conversation we had after the hearing. There is a pattern of dishonesty and a failure to tell the truth from the CDC Director and the Committee should hold a hearing to allow the truth to be shared with the American people.

In addition, the CDC is first and foremost a public health agency. Their focus and priority should always be public health. I am extremely concerned that the effort from CDC to change their recommendations represent not a regulatory clarification, but an effort to improve the public perception of meatpacking companies that did not want to be implicated or viewed as

² <https://www.help.senate.gov/hearings/covid-19-an-update-on-the-federal-response>

³ <https://www.nytimes.com/2020/10/08/us/politics/pence-coronavirus-task-force.html?action=click&module=Spotlight&pgtype=Homepage>

endangering workers. Evidence suggests that the call to Dr. Redfield, made by Secretary Perdue, was made at the behest of industry. And instead of putting public health first, Dr. Redfield cast it aside. The Committee should hear from Secretary Perdue so we can learn the extent to which USDA and Smithfield recommended changes to the CDC report.

Throughout this pandemic, I have called on the Administration to protect the health and safety of Americans, including our nation's workers. This work must be driven by the scientific expertise of career officials at the CDC, and it must be enforced by the federal agency that is charged with regulating businesses on behalf of worker safety. DOL has shirked its responsibilities time and again, allowing industry to both call the shots and the government officials it views as their champions. As members of the HELP Committee, we deserve to understand what Secretary Scalia and his staff discussed with CDC regarding the report and why it has failed to put forth enforceable safety standards for workers in response to the COVID-19 pandemic. In the midst of a pandemic, we must let public health lead the way. That means the expertise of the scientists and professionals at the CDC. Efforts to undermine public health at the request of industry are unacceptable. Misinformation presented to members of congress is equally egregious. The work of this committee is more important now than ever.

Sincerely,

A handwritten signature in blue ink that reads "Tammy Baldwin". The signature is fluid and cursive, with the first name "Tammy" and last name "Baldwin" clearly distinguishable.

Tammy Baldwin
United States Senator

CC: The Honorable Susan Collins

Chair, Subcommittee on Employment and Workplace Safety
Committee on Health, Education, Labor and Pensions
U.S. Senate
Washington, DC 20510



The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Developing Safe and Effective Covid Vaccines — Operation Warp Speed's Strategy and Approach

Moncef Slaoui, Ph.D., and Matthew Hepburn, M.D.

Announced on May 15, Operation Warp Speed (OWS) — a partnership of the Department of Health and Human Services (HHS), the Department of Defense (DOD), and the private sector

— aims to accelerate control of the Covid-19 pandemic by advancing development, manufacturing, and distribution of vaccines, therapeutics, and diagnostics. OWS is providing support to promising candidates and enabling the expeditious, parallel execution of the necessary steps toward approval or authorization of safe products by the Food and Drug Administration (FDA).

The partnership grew out of an acknowledged need to fundamentally restructure the way the U.S. government typically supports product development and vaccine distribution. The initiative was premised on setting a “stretch goal” — one that initially seemed impossible but that is becoming increasingly achievable.

The concept of an integrated structure for Covid-19 countermeasure research and development across the U.S. government was based on experience with Zika and the Zika Leadership Group led by the National Institutes of Health (NIH) and the assistant secretary for preparedness and response (ASPR). One of us (M.S.) serves as OWS chief advisor. We are drawing on expertise from the NIH, ASPR, the Centers for Disease Control and Prevention (CDC), the Biomedical Advanced Research and Development Authority (BARDA), and the DOD, including the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense and the Defense Advanced Research Projects Agency. OWS

has engaged experts in all critical aspects of medical countermeasure research, development, manufacturing, and distribution to work in close coordination.

The initiative set ambitious objectives: to deliver tens of millions of doses of a SARS-CoV-2 vaccine — with demonstrated safety and efficacy, and approved or authorized by the FDA for use in the U.S. population — beginning at the end of 2020 and to have as many as 300 million doses of such vaccines available and deployed by mid-2021. The pace and scope of such a vaccine effort are unprecedented. The 2014 West African Ebola virus epidemic spurred rapid vaccine development, but though preclinical data existed before the outbreak, a period of 12 months was required to progress from phase 1 first-in-human trials to phase 3 efficacy trials. OWS aims to compress this time frame even further. SARS-CoV-2 vaccine devel-

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opment began in January, phase 1 clinical studies in March, and the first phase 3 trials in July. Our objectives are based on advances in vaccine platform technology, improved understanding of safe and efficacious vaccine design, and similarities between the SARS-CoV-1 and SARS-CoV-2 disease mechanisms.

OVS's role is to enable, accelerate, harmonize, and advise the companies developing the selected vaccines. The companies will execute the clinical or process development and manufacturing plans, while OVS leverages the full capacity of the U.S. government to ensure that no technical, logistic, or financial hurdles hinder vaccine development or deployment.

OVS selected vaccine candidates on the basis of four criteria. We required candidates to have robust preclinical data or early-stage clinical trial data supporting their potential for clinical safety and efficacy. Candidates had to have the potential, with our acceleration support, to enter large phase 3 field efficacy trials this summer or fall (July to November 2020) and, assuming continued active transmission of the virus, to deliver efficacy outcomes by the end of 2020 or the first half of 2021. Candidates had to be based on vaccine-platform technologies permitting fast and effective manufacturing, and their developers had to demonstrate the industrial process scalability, yields, and consistency necessary to reliably produce more than 100 million doses by mid-2021. Finally, candidates had to use one of four vaccine-platform technologies that we believe are the most likely to yield a safe and effective vaccine against Covid-19:

the mRNA platform, the replication-defective live-vector platform, the recombinant-subunit-adjuvanted protein platform, or the attenuated replicating live-vector platform.

OVS's strategy relies on a few key principles. First, we sought to build a diverse project portfolio that includes two vaccine candidates based on each of the four platform technologies. Such diversification mitigates the risk of failure due to safety, efficacy, industrial manufacturability, or scheduling factors and may permit selection of the best vaccine platform for each subpopulation at risk for contracting or transmitting Covid-19, including older adults, frontline and essential workers, young adults, and pediatric populations. In addition, advancing eight vaccines in parallel will increase the chances of delivering 300 million doses in the first half of 2021.

Second, we must accelerate vaccine program development without compromising safety, efficacy, or product quality. Clinical development, process development, and manufacturing scale-up can be substantially accelerated by running all streams, fully resourced, in parallel. Doing so requires taking on substantial financial risk, as compared with the conventional sequential development approach. OVS will maximize the size of phase 3 trials (30,000 to 50,000 participants each) and optimize trial-site location by consulting daily epidemiologic and disease-forecasting models to ensure the fastest path to an efficacy readout. Such large trials also increase the safety data set for each candidate vaccine.

With heavy up-front investment, companies can conduct clinical

operations and site preparation for these phase 3 efficacy trials even as they file their Investigational New Drug application (IND) for their phase 1 studies, thereby ensuring immediate initiation of phase 3 when they get a green light from the FDA. To permit appropriate comparisons among the vaccine candidates and to optimize vaccine utilization after approval by the FDA, the phase 3 trial end points and assay readouts have been harmonized through a collaborative effort involving the National Institute of Allergy and Infectious Diseases (NIAID), the Coronavirus Prevention Network, OVS, and the sponsor companies.

Finally, OVS is supporting the companies financially and technically to commence process development and scale up manufacturing while their vaccines are in preclinical or very early clinical stages. To ensure that industrial processes are set, running, and validated for FDA inspection when phase 3 trials end, OVS is also supporting facility building or refurbishing, equipment fitting, staff hiring and training, raw-material sourcing, technology transfer and validation, bulk product processing into vials, and acquisition of ample vials, syringes, and needles for each vaccine candidate. We aim to have stockpiled, at OVS's expense, a few tens of millions of vaccine doses that could be swiftly deployed once FDA approval is obtained.

This strategy aims to accelerate vaccine development without curtailing the critical steps required by sound science and regulatory standards. The FDA recently reissued guidance and standards that will be used to assess each vaccine for a Biologics License

Application (BLA). Alternatively, the agency could decide to issue an Emergency Use Authorization to permit vaccine administration before all BLA procedures are completed.

Of the eight vaccines in OWS's portfolio, six have been announced and partnerships executed with the companies: Moderna and Pfizer/BioNTech (both mRNA), AstraZeneca and Janssen (both replication-defective live-vector), and Novavax and Sanofi/GSK (both recombinant-subunit-adjuvanted protein). These candidates cover three of the four platform technologies and are currently in clinical trials. The remaining two candidates will enter trials soon.

Moderna developed its RNA vaccine in collaboration with the NIAID, began its phase 1 trial in March, recently published encouraging safety and immunogenicity data,¹ and entered phase 3 on July 27. Pfizer and BioNTech's RNA vaccine also produced encouraging phase 1 results² and started its phase 3 trial on July 27. The ChAdOx replication-defective live-vector vaccine developed by AstraZeneca and Oxford University is in phase 3 trials in the United Kingdom, Brazil, and South Africa, and it should enter U.S. phase 3 trials in August.³ The Janssen Ad26 Covid-19 replication-defective live-vector vaccine has demonstrated excellent protection in nonhuman primate models and began its U.S. phase 1 trial

on July 27; it should be in phase 3 trials in mid-September. Novavax completed a phase 1 trial of its recombinant-subunit-adjuvanted protein vaccine in Australia and should enter phase 3 trials in the United States by the end of September.⁴ Sanofi/GSK is completing preclinical development steps and plans to commence a phase 1 trial in early September and to be well into phase 3 by year's end.⁵

On the process-development front, the RNA vaccines are already being manufactured at scale. The other candidates are well advanced in their scale-up development, and manufacturing sites are being refurbished.

While development and manufacturing proceed, the HHS–DOD partnership is laying the groundwork for vaccine distribution, subpopulation prioritization, financing, and logistic support. We are working with bioethicists and experts from the NIH, the CDC, BARDA, and the Centers for Medicare and Medicaid Services to address these critical issues. We will receive recommendations from the CDC Advisory Committee on Immunization Practices, and we are working to ensure that the most vulnerable and at-risk persons will receive vaccine doses once they are ready. Prioritization will also depend on the relative performance of each vaccine and its suitability for particular populations. Because some technologies have limited previous data on safety in hu-

mans, the long-term safety of these vaccines will be carefully assessed using pharmacovigilance surveillance strategies.

No scientific enterprise could guarantee success by January 2021, but the strategic decisions and choices we've made, the support the government has provided, and the accomplishments to date make us optimistic that we will succeed in this unprecedented endeavor.

Disclosure forms provided by the authors are available at NEJM.org.

From Operation Warp Speed, Department of Health and Human Services, Washington, DC.

This article was published on August 26, 2020, at NEJM.org.

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Perspective

Bridging the Gap at Warp Speed — Delivering Options for Preventing and Treating Covid-19

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Operation Warp Speed (OWS), an effort of the U.S. Department of Health and Human Services and the Department of Defense in partnership with the private sector, is providing

financial investment, scientific support, regulatory expertise, and logistic assistance to deliver vaccines, therapeutics, and diagnostics for SARS-CoV-2 to the American public as quickly as possible. Much attention has been directed to OWS's goal of delivering substantial quantities of safe and effective vaccines by early 2021. But the initiative also aims to combat Covid-19 by improving the use of existing therapies and providing additional treatment options. We hope in this way to ameliorate the pandemic as we wait for the U.S. population to be fully immunized.

Effective therapeutics could reduce disease severity and hospitalization rates, shorten hospital stays, and reduce mortality, lightening the burden on patients, fam-

ilies, and the health care system. If therapeutics are used for prophylaxis in at-risk populations, they could also prevent disease and reduce the spread of SARS-CoV-2.

We have used three criteria to select candidate therapeutics to support: timeliness, robust science, and ability to manufacture quickly at scale. First, OWS therapeutics must be in the clinic by early fall at the latest, with the potential for approval or Emergency Use Authorization (EUA) by the end of 2020. Although challenging, this time frame permits repurposed drugs — those already approved by the Food and Drug Administration (FDA) or in human trials for other indications — to be rapidly evaluated for Covid-19 and further developed if

clinical activity is detected. In addition, new antibody therapies for SARS-CoV-2 have been discovered and developed very quickly, thanks to advances in technology and extensive clinical experience with this drug class.

Second, sound science is essential. Researchers are constantly evaluating potential therapeutics. Government agencies such as the National Institutes of Health (NIH), the Biomedical Advanced Research and Development Authority (BARDA), and the Defense Advanced Research Projects Agency (DARPA); the NIH's Accelerating Covid-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership¹; and the OWS team are all seeking candidates that show promise in vitro and in animal models and early-stage clinical trials. When scientific evaluation predicts a reasonable probability of success, OWS investment and resources can be marshaled rap-

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idly to accelerate development and manufacturing.

Third, we seek manufacturability at scale within the desired time frame. With assistance, production of hundreds of thousands of doses should be achievable during 2020.

An infectious disease arsenal requires tools for targeting the virus itself and for treating disease symptoms and complications. OWS is considering the gamut of clinical needs, from preexposure prophylaxis through the convalescent period. Many candidates are being evaluated using master protocols developed by the ACTIV program, which permit efficacy comparisons among therapies, spare patients by using shared control groups, and can accommodate various types of interventions.

Therapeutics that attack the virus are the most straightforward to identify and develop and thus account for the majority of our efforts. Within this group, there are two primary mechanisms: providing passive immunity and inhibiting viral replication.

Antibody therapy, usually defined by the ability to neutralize the virus *in vitro*, has provided passive immunity in some viral infections. Antibody-based therapies include convalescent plasma, hyperimmune globulin, and monoclonal antibodies. For many infectious diseases, treatment with plasma isolated from convalescent patients has been a pragmatic early countermeasure, but it has limitations: it is usually most effective early in infection, must be sourced from donors during a relatively narrow period, requires blood-type matching, and does not scale to large populations. Hyperimmune globulin manufactured from convalescent plasma, by con-

trast, can be made to have a standard activity level per dose, does not require blood-type matching, and can often be concentrated for intramuscular delivery — a significant advantage over intravenous plasma delivery.

Highly potent, neutralizing monoclonal antibodies (mAbs) can be derived from patients who have recovered from Covid-19 using one of several well-established isolation platform technologies. Antibodies can then be manufactured at scale to enable multiple intervention points: preventing infection, treating early illness in outpatients, or treating later-stage disease in inpatients. These antibodies have the advantages of being highly characterized, exhibiting consistent levels of neutralizing activity, and being manufacturable at very large scale.

Early investment by DARPA in antibody discovery platforms has enabled rapid response capabilities: highly potent neutralizing mAbs were isolated, characterized, and moved to phase 1 safety testing within 90 days after sample receipt. With additional investment, regulatory expertise, and logistic assistance, we plan to support manufacturing of the most potent mAb products at (financial) risk so that if clinical studies succeed, hundreds of thousands of doses could be deployed this fall and winter.

As for inhibiting viral replication, small-molecule antivirals can take years to identify and develop. To meet our aggressive deadlines, we've focused on antivirals developed for other pathogens, such as remdesivir, which was developed for Ebola but may be effective against SARS-CoV-2. Antivirals whose safety profiles are already known can enter phase 2 and 3 clinical trials soon after demon-

strating activity against SARS-CoV-2 *in vitro* and in animal models.

To optimize assessment of these antiviral strategies, two phase 2–3 master protocols — ACTIV-2 (outpatients) and ACTIV-3 (inpatients) — have been established, in addition to company-sponsored studies. Neutralizing mAbs will also be tested as prophylaxis in high-risk cohorts, such as residents and caregivers at long-term care facilities, employees at meat-packing plants where infection has been detected, or households with confirmed Covid-19 cases.

We are also pursuing candidates that target major causes of illness and death from Covid-19. Although much remains unknown about SARS-CoV-2, we know that complications of severe Covid-19 include hyperinflammation with potential cytokine release syndrome and thrombotic events including stroke, venous thromboembolism, and thrombotic microangiopathy. Attempts to modulate host immune responses, however, walk a fine line between interfering with host defenses and curbing hyperinflammation. OWS is tracking studies of immunomodulators in patients with Covid-19. If and when we detect positive signals, OWS will move to accelerate clinical development and invest at risk in manufacturing as appropriate.

In addition, in collaboration with OWS, the NIH will implement the ACTIV-1 trial of immunomodulators,² and the OWS-supported ACTIV-4 trial will test anticoagulation regimens at different points in disease.

Several therapeutic products are advancing with OWS support. In April 2020, the FDA and clinical partners announced an Ex-

panded Access Protocol for the administration of convalescent plasma. OWS, in conjunction with the NIH, is supporting rapid execution of randomized clinical trials in inpatients and outpatients to evaluate the effectiveness of convalescent plasma. Early analysis of outcomes suggests clinical benefit from passive transfer of immunity — indeed, the FDA recently granted an EUA for convalescent plasma — and validates our prioritization of antibody products.

One such antibody product is hyperimmune globulin from SAB Biotherapeutics, derived from genetically altered cows that produce human IgG. Cows were immunized with the SARS-CoV-2 spike protein to generate a polyclonal antibody response that has high neutralizing activity against the virus. A phase 1 clinical safety study of the processed hyperimmune globulin from these cows began in August, and evaluation in the ACTIV-2 master protocol is anticipated. OWS is investing at risk to scale up production from this herd of cows so that tens of thousands of doses could be manufactured this year.

Our portfolio includes three mAb development programs originating at the NIH, BARDA, and DARPA and in the private sector. Two candidate antibodies are being evaluated for treatment in ambulatory and hospitalized patients and for prophylaxis in high-risk populations. A phase 3 prophylaxis trial for a third mAb product is expected to begin in September.

On July 6, OWS announced support for taking the first candidate therapeutic through commercial manufacturing — a mAb cocktail made by Regeneron. This product is in phase 2 trials for prophylaxis and inpatient and outpatient treatment. If a trial demonstrates success, Regeneron estimates that this \$450 million investment could produce 70,000 to 300,000 treatment doses (depending on dose), with initial doses ready over the next 3 months.

A mAb product discovered by AbCellera Biologics and developed by Eli Lilly is currently in ACTIV-2 and ACTIV-3 trials, and a Lilly-sponsored prophylaxis study in nursing home residents and caretakers is ongoing. A combination of two mAbs developed by AstraZeneca (licensed from Vanderbilt University) and engineered to have an extended half-life could be particularly useful for prophylaxis; it will be tested in nursing homes, meat-packing plants, and other settings starting in October.

We are also evaluating small-molecule antivirals, including a nucleoside analogue, EIDD-2801 (MK-4482), developed in a collaboration between Ridgeback Biotherapeutics and Merck, as a potential inhibitor of SARS-CoV-2 replication. It's now in phase 2 trials in outpatients and inpatients. Finally, three immunomodulators and three anticoagulants have been selected for testing in ACTIV-1 and ACTIV-4 trials, respectively, to assess potential efficacy in inpatients.

Predicting drug performance in a new disease is difficult. Many candidates may fail to demonstrate efficacy or have safety problems. It's necessary, however, to take a financial risk early to scale up manufacturing in order to have drug supplies on hand if the results are positive. If we wait for clinical trial readouts before initiating large-scale manufacturing, developing an adequate supply could take months or years.

Developing a vaccine by January 2021 will represent remarkably speedy scientific progress. But with therapeutics, we may be able to make inroads against the virus before we can fully deploy a vaccine. With mounting death tolls, increasing case burdens, and public confusion, we face an enormous task. We are taking essential steps toward bringing therapies to the American public as soon as possible.

Disclosure forms provided by the authors are available at NEJM.org.

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QUESTIONS AND ANSWERS

RESPONSES BY DR. ANTHONY FAUCI, TO QUESTIONS OF SENATOR MURRAY, SENATOR SANDERS, SENATOR COLLINS, SENATOR WARREN, SENATOR KAINE, AND SENATOR ROSEN.

SENATOR MURRAY

Question 1.

Dr. Fauci, I'm glad FDA issued official guidance on the emergency authorization of vaccines, as I have urged, but there are still a lot of pieces missing when it comes to the kind of comprehensive national vaccines plan I have pushed for—including when it comes to research. You and other experts have made clear the importance of greater enrollment of people of color, particularly due to the disproportionate impact of COVID-19 on Black, Latinx, and Tribal communities. However, these communities remain underrepresented in ongoing trials and in the online registry of volunteers for NIH's own COVID-19 Prevention Network. We must ensure communities who are suffering the most from this pandemic are included and equitably represented in clinical trials to ensure we have a comprehensive understanding of how well vaccines will work.

(a) Now that certain manufacturers are releasing their study protocols for COVID-19 vaccine trials, what specific goals has NIH outlined to ensure diversity in clinical trial enrollment and participation?

Answer 1 (a). Ensuring a diverse group of study volunteers is a major focus of recruitment and community engagement activities for clinical trials of investigational COVID-19 vaccines coordinated and overseen by the National Institute of Allergy and Infectious Diseases (NIAID) and Operation Warp Speed (OWS) team members. NIAID recognizes that increasing the diversity of study participants in clinical trials is needed to build public trust and ensure equitable access to a safe and effective vaccine to prevent COVID-19, when one becomes available.

To demonstrate that COVID-19 vaccine candidates protect individuals in communities disproportionately affected by SARS-CoV-2 infection, NIAID is specifically seeking to recruit an ethnically and racially diverse study population. NIAID is capitalizing on long-term investments in clinical research sites, many of which serve diverse populations, to enhance trial participation of communities of color through the COVID-19 Prevention Network (CoVPN). The CoVPN has developed an extensive community engagement framework to reach out to diverse groups of potential research volunteers and explain the specific details involved in participating in clinical studies evaluating COVID-19 vaccine candidates. NIAID also is applying novel real-time data tracking tools and outbreak data analytics to inform trial design, site selection, and recruitment of at-risk individuals. Throughout the clinical trials process, NIAID will continue to engage with communities who have been disproportionately affected by the COVID-19 pandemic.

Question 2.

Dr. Fauci, our country recently surpassed an extremely grim milestone: over 210,000 deaths due to COVID-19. This heartbreaking statistic is directly linked to the failure of this Administration to take the pandemic seriously, especially when compared to the rest of the world.

(a) Do you believe this indescribable death toll could have been avoided? If so, what specific Federal actions could have prevented the staggering number of deaths due to COVID-19 in the United States?

Answer 2 (a). The ongoing spread of SARS-CoV-2 is affected by multiple complex and interrelated factors and considerations. It is impossible to determine what effect different actions earlier in the pandemic may have had on the current case counts. I believe it is important that we, as a Nation, continue to follow the advice of the Centers for Disease Control and Prevention (CDC), including taking measures such as physical distancing, mask wearing, and washing hands in order to mitigate the spread of SARS-CoV-2 as much as possible. I will continue to provide expert medical and scientific advice to the White House Coronavirus Task Force. In addition, I am committed to leading NIAID in conducting and supporting research to better understand SARS-CoV-2 and to develop safe and effective medical countermeasures against the virus.

SENATOR SANDERS

Question 1.

It is clear that there is a commitment to bring a safe and effective COVID-19 vaccine to market as soon as possible. It also is clear that there is a commitment across agencies to work together not only to try to increase diversity in ongoing clinical trials, but to educate the public about the importance of getting vaccinated, especially with flu season upon us. Do you commit to leveraging your expertise and influence to ensure that a COVID-19 vaccine is available at no cost to every person in the U.S.?

Answer 1. As a public health official in the Administration, I am charged with supporting the Federal response to infectious disease threats on behalf of the American people. I will continue to provide expert medical and scientific advice to the White House Coronavirus Task Force. In addition, I am committed to leading the National Institute of Allergy and Infectious Diseases (NIAID) in conducting and supporting research to better understand SARS-CoV-2 and to develop safe and effective medical countermeasures against the virus.

The Administration has stated it is committed to providing free or low-cost, safe, and effective COVID-19 countermeasures to the American people as quickly as possible. Any COVID-19 vaccine or therapeutic doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. As is customary with government-purchased vaccines, healthcare professionals could charge for the cost of administering the vaccine. Information on health care provider reimbursement for vaccine administration for the uninsured is available here: <https://www.hrsa.gov/CovidUninsuredClaim>.

Question 2.

In addition to making sure that a future COVID-19 vaccine is free to every person in the country at the point of service, it is critical that health providers and states can afford to purchase the vaccine in bulk and distribute it to the public and, in particular, to vulnerable populations such as seniors and those who are living in rural areas.

- (a) What specific plans does the Federal Government have to directly purchase the COVID-19 vaccine and distribute it to the public, or to help health providers and states purchase the vaccine for distribution?

Answer 2 (a). In order to facilitate the distribution of free or low-cost, safe, and effective COVID-19 vaccines to the American people as quickly as possible, the Administration has made purchasing arrangements with manufacturers receiving Phase 3 clinical trial support through Operation Warp Speed (OWS). The Administration has committed to providing any vaccine purchased with U.S. taxpayer dollars to the American people at no cost and has partnered with AstraZeneca to make at least 300 million COVID-19 vaccine doses available to the Federal Government. Similar partnerships were formed with Novavax (100 million doses), Pfizer (100 million doses), Sanofi and GlaxoSmithKline (GSK; 100 million doses), Johnson & Johnson (Janssen; 100 million doses), and Moderna (100 million doses).

The Department of Health and Human Services (HHS) and Department of Defense have released the Administration's COVID-19 Vaccine Distribution Strategy, which provides a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to the COVID-19 pandemic within their respective jurisdictions (<https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html>). In addition, at the request of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), the National Academies of Sciences, Engineering, and Medicine formed a committee to produce a consensus study to assist policymakers in the U.S. and global health communities in planning for equitable allocation of vaccines against COVID-19. The National Academies Committee on Equitable Allocation of Vaccine for the Novel Coronavirus has since released the *Framework for Equitable Allocation of COVID-19 Vaccine* (<https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus>).

NIAID defers to the CDC and the HHS Assistant Secretary for Health to provide additional information on COVID-19 vaccine purchasing and distribution arrangements.

Question 3.

It is well documented that African Americans, Indigenous Peoples, and other racial and ethnic minorities have experienced harm and trauma when participating—both voluntarily and involuntarily—in medical research. These populations are also most at-risk for contracting COVID-19 and experiencing more severe outcomes from the disease. As history has taught us, vaccines are only effective in eventually eradicating a particular disease when there is widespread use. A lack of trust, however, can stall efforts to defeat a pandemic. Please provide specific details about the steps you are taking, and have already taken, to build public trust—especially among the most vulnerable and often hard-to-reach populations, including low-income individuals, people who live in rural communities, older individuals, and racial and ethnic minorities—so that when a safe and effective vaccine is available, it is successfully adopted?

Answer 3. NIAID recognizes that an important component of building public trust and ensuring equitable access to a safe and effective COVID-19 vaccine, when one becomes available, is the inclusion of a diverse group of participants in clinical trials. To determine if COVID-19 vaccine candidates protect individuals in the communities disproportionately affected by SARS-CoV-2 infection, NIAID is specifically seeking to recruit an ethnically and racially diverse study population. NIAID and NIH leadership have engaged directly with the congressional Asian Pacific American Caucus, the congressional Black Caucus, the congressional Hispanic Caucus, and the congressional Native American Caucus to discuss the importance of including communities of color in each of the OWS-supported Phase 3 clinical trials of COVID-19 candidates. In addition, NIAID and NIH leadership have conducted a wide range of outreach efforts through social media, television, and radio appearances to engage with community leaders, artists, faith-based organizations, and athletes on the topic of vaccine safety and the importance of having a diverse group of participants in ongoing clinical trials.

NIAID also is capitalizing on long-term investments in clinical research sites, many of which serve diverse populations, to enhance trial participation of communities of color through the COVID-19 Prevention Network (CoVPN). The CoVPN has developed an extensive community engagement framework to reach out to diverse groups of potential research volunteers and explain the specific details involved in participating in clinical studies evaluating COVID-19 vaccine candidates. In addition, NIAID is applying novel real-time data tracking tools and outbreak data analytics to inform trial design, site selection, and recruitment of at-risk individuals. Throughout the clinical trials process, NIAID will continue to engage with communities who have been disproportionately affected by COVID-19.

Question 4.

It is clear that this pandemic is far from over. However, even as COVID-19 infections spread among our government officials, misinformation continues to spread regarding the severity of COVID-19 and the steps we all need to take to limit the spread of the virus.

- (a) What are your recommendations for how our government leaders can ensure the American people are receiving consistent, accurate, and science-based information about COVID-19?
- (b) Given the rampant misinformation that has been spread by the President and some in the Administration since this hearing, what steps are you taking now to minimize the negative impact of this misinformation so that the public has accurate, reliable and credible information from which to base their decisions on regarding (1) consistently wearing masks; (2) giving COVID-19 the serious consideration that it deserves; and (3) ultimately taking the forthcoming vaccine when it comes to market?

Answer 4 (a)–4 (b). As a public health official in the Administration, I am charged with supporting the Federal response to infectious disease threats on behalf of the American people. I will continue to provide expert medical and scientific advice to the White House Coronavirus Task Force. In addition, I remain committed to leading NIAID in conducting and supporting research to better understand SARS-CoV-2 and to develop safe and effective medical countermeasures against the virus. NIAID also will continue to facilitate public availability of NIH-supported research via publication in peer-reviewed scientific journals and NIH press releases.

The dissemination of accurate information to the public is a crucial aspect of the response to the COVID-19 pandemic. Public education campaigns have been a significant part of the Administration's continuing efforts to promote and explain the importance of developing COVID-19 countermeasures and public safety measures to

individuals and their communities. Once a candidate vaccine to prevent COVID-19 is authorized for emergency use or approved for use by the U.S. Food and Drug Administration, OWS and its partners including CDC will continue to engage individual communities through public communication and outreach campaigns to provide information about the vaccine and how to access it as plans for vaccine distribution are finalized.

In addition, the NIAID-supported CoVPN, a functional unit of OWS, includes an extensive community engagement framework to reach out to the diverse communities most affected by COVID-19 to better understand their interest in, and concerns about, participation in clinical research and to partner with them to ensure their input is reflected in study design and implementation. This engagement also may lead to increased uptake of a safe and effective COVID-19 vaccine by individuals in these communities once it becomes available.

SENATOR COLLINS

Question 1.

Dr. Fauci, can you discuss any goals set by Operation Warp Speed to include older adults in vaccine trials and why proper representation in trials is so important? To what extent have older adults been included in the clinical trials for COVID-19 therapies?

Answer 1. The development and availability of a safe and effective COVID-19 vaccine would be an invaluable tool in our efforts to end the COVID-19 pandemic. As older adults have been shown to be particularly vulnerable to this disease, the National Institute of Allergy and Infectious Diseases (NIAID) has supported the evaluation of promising vaccine candidates in this demographic group. NIAID, in collaboration with Moderna, expanded the Phase 1 clinical trial of the mRNA-1273 vaccine candidate to include adults age 56 and older in April 2020. Interim results from this Phase 1 study suggested the immune responses in older adults were consistent with those reported previously in younger adults. Older adults also are included in all Operation Warp Speed (OWS)-supported Phase 3 clinical trials of investigational COVID-19 vaccine candidates. The results of these studies will provide valuable data about the efficacy of vaccination in older adults and will be used to assess the need for adjuvants or other strategies that could be used to boost the immune response in older populations.

The U.S. Food and Drug Administration (FDA) also strongly encourages enrollment of all people—including older adults—in clinical trials to test COVID-19 vaccine candidates, as outlined in the recommendations in the FDA's Development and Licensure of Vaccines to Prevent COVID-19 guidance. This FDA guidance can be found at the following web link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>. Studies involving older adults supported by the National Institutes of Health (NIH) are following the FDA's guidance. NIH will work to support vaccine developers as they expand clinical trials of vaccine candidates into older populations.

NIAID also is supporting the development of prophylactic treatments such as monoclonal antibodies that could be used to protect individuals who are at increased risk of disease, need immediate protection, or do not mount an effective immune response to a vaccine. Older adults are participating in ongoing NIAID-supported clinical trials of monoclonal antibodies to prevent or treat COVID-19. NIH-supported clinical trials evaluating other therapeutic approaches to COVID-19, such as antivirals, immune modulators, and antithrombotics, also continue to enroll older individuals.

SENATOR WARREN

Question 1.

Long Term Health Effects of COVID-19 There is evidence of patients continuing to feel the effects of COVID-19 well after they are discharged from hospitals or beyond the average known time of recovery, and some may face long-term health problems long after the pandemic is over. It is critical that the Federal Government conduct appropriate research and collect and disseminate appropriate data about the potential chronic health impacts of COVID-19—and do so without muzzling public health officials and medical professionals—in order to adequately inform decisions about reopening schools and businesses and assess the ongoing risks of the pandemic. As NIH continues to conduct and coordinate research efforts, it is critical that it collect, analyze, and disseminate data on the long-term impacts and severity of the disease, conduct research to understand the risks, and appropriately inform policymakers, the public and medical professionals of them. To help us understand

how the CDC is researching, monitoring, and evaluating the chronic long-term health impacts of COVID-19, we request answers to the following questions:

- (a) How is the NIH evaluating the long-term health risks of COVID-19 for the millions of Americans that will survive the disease?
- (b) How are NIH and its partner Federal agencies conducting long-term surveillance or other research on survivors of COVID-19, including those who presented with nonsevere symptoms and those who presented with severe symptoms?
- (c) Please provide a list of studies that NIH is currently undertaking or funding to understand the non-mortality related impacts of the disease, and, if publicly available, the findings or preliminary findings from these studies.
- (d) How is NIH collaborating with other Federal agencies regarding studies into the morbidity and long-term impacts of COVID-19?
- (e) What additional resources or authorities are needed from Congress to ensure that the agencies can effectively conduct this type of research?

Answers 1 (a)–1 (e). The National Institute of Allergy and Infectious Diseases (NIAID) is the lead Institute at the National Institutes of Health (NIH) responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID-19. NIAID is supporting a broad portfolio of research to understand the incidence and prevalence of SARS-CoV-2, the virus that causes COVID-19; characterize the clinical course of COVID-19 and identify predictors of disease severity; characterize immunologic responses to SARS-CoV-2 infection; and understand SARS-CoV-2 transmission mechanisms. We continue to learn more about the duration and manifestations of the disease as additional data are collected from patients who recover from COVID-19 or who transition from acute to post-acute phases of the disease.

NIAID is leveraging existing research networks and working with Institutes, Centers, and Offices across NIH, as well as with our partners in the Federal Government, industry, and academia, to expand surveillance of outcomes in patients across all ages, genders, co-morbid conditions, and acute disease experience. These studies can inform our understanding of the long-term health effects of COVID-19 and the development of relevant prevention and treatment interventions or strategies. A current list of research on post-acute COVID-19 syndromes conducted and supported by NIAID is below:

- NIAID intramural scientists have initiated the Longitudinal Study of COVID-19 Sequelae and Immunity to better understand any long-term medical problems that people who have recovered from acute SARS-CoV-2 infection might have, and whether they develop an immune response to SARS-CoV-2 that provides protection against reinfection.
- NIAID intramural scientists have extended their SARS-CoV2 Pandemic Serosurvey to include longitudinal serological testing. This study, in collaboration with the National Institute of Biomedical Imaging and Bioengineering, and with additional support from the National Center for Advancing Translational Sciences and the National Cancer Institute, is open for recruitment and follows participants over time to evaluate the durability of immunity and further explore correlates of protection. The study aims to enroll 15,000 participants.
- The NIAID International Network for Strategic Initiatives in Global HIV Trials has initiated a prospective observational cohort study of 10,000 outpatients with COVID-19 to determine the incidence of hospitalization or death over a 28-day period after an initial outpatient visit.
- Investigators in the NIAID-supported Human Immunology Project Consortium, in collaboration with researchers in the Asthma and Allergic Diseases Cooperative Research Centers and other NIAID-supported investigators, established the Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC). IMPACC aims to determine how integrated immunological measures correspond to, or may even predict, the clinical severity of COVID-19. The researchers are collecting detailed clinical data along with blood and respiratory samples from approximately 1,000 hospitalized COVID-19 patients of diverse race and ethnicity at approximately 20 hospitals across the country. Patients will be followed throughout their hospitalization and for up to one-year post hospital discharge to assess several measures of both functional and immunologic recovery.

- NIAID is supporting the Corona infectious virus epidemiology team (CIVET), which will leverage the previously established North American AIDS Cohort Collaboration on Research and Design to bring together epidemiologists, statisticians, and data scientists to analyze extremely large clinical data bases (i.e., millions of patients) to better understand the clinical epidemiology of SARS-CoV-2. Due to its large size and access to complete medical records in some medical systems, the CIVET will be able to evaluate the natural history and treatment history of SARS-CoV-2 in hospitalized and non-hospitalized patients and adjust for the impact of underlying medical conditions. To date, the CIVET has more than 200,000 persons with a history of COVID-19 illness in their data base. This will enable assessments of post-acute COVID syndrome in patients across the lifespan, demographic characteristics, and initial disease presentations.
- NIAID funds the Big Data Driven Clinical Informatics & Surveillance (BDD-CIS) project, which will develop a de-identified linked data base system that will collate data on both COVID-19 patients and health care workers treating COVID-19 patients in South Carolina. This data base will be used to examine the natural history of SARS-CoV-2 including transmission dynamics, disease progression, and geospatial visualization of infected individuals. The data base, used in conjunction with machine learning algorithms, also may help to identify important predictors of short-and long-term clinical outcomes, including for multisystem inflammatory syndrome in children (MIS-C) and post-acute COVID-19 syndrome in the study population.
- NIAID funds investigators at the South Texas Veterans Health Care System, a part of the Department of Veterans Affairs, to assess patients with SARS-CoV-2 infection. This study is assessing the immune response to the virus and developing an index to predict clinical outcomes of these patients. This study has enrolled more than 500 patients and will continue to follow them for long-term complications.
- NIAID is participating in a trans-NIH effort, led by the National Heart, Lung, and Blood Institute and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, to research MIS-C, an extremely serious inflammatory condition that has been associated with SARS-CoV-2 infection in children and adolescents. A collaboration between investigators from two NIAID supported networks, the Autoimmunity Centers of Excellence and the Clinical Trials in Organ Transplantation in Children, have developed an observational cohort study known as the Pediatric Research Immune Network on SARS-CoV-2 and MIS-C to assess 6 and 12 month clinical outcomes and immunological responses after infection with SARS-CoV-2 in children with and without MIS-C.
- NIAID Intramural scientists are developing a study with Children's National Medical Center for long-term follow-up of 1,000 children with SARS-CoV-2 infection ranging from those who are asymptomatic to those with severe manifestations. This research will provide critically needed data on SARS-CoV-2 infection in children including demographics and disease presentation, duration, and outcome, as well as identify factors associated with protection and disease severity.
- The NIAID Division of Clinical Research, in collaboration with the Partnership for Research on Vaccines and Infectious Diseases in Liberia, has initiated an observational, prospective cohort study of individuals testing positive for SARS-CoV-2, and controls who test negative, with enrollment over a two-year period and follow-up for 3 years after enrollment.
- NIAID funds the CHASING COVID Cohort study, which prospectively enrolled more than 7,000 participants between March 28th and April 20th from across the United States, including Puerto Rico and Guam. Participants performed a dried blood spot test for SARS-CoV-2 antibodies in early summer and a second test is planned for fall 2020. Subsequent interviews intend to collect data on long-term symptoms of SARS-CoV-2. The cohort represents a geographically and socio-demographically diverse sample of the adult U.S. population: 23 percent of participants were 60 years or older at enrollment; 24 percent are Black or Hispanic; and 52 percent are men. At least 24 percent of participants are frontline

workers, either in healthcare or other essential employment sectors such as police, first responders, food services, or transportation.

The studies listed above are designed to answer specific critical research questions about SARS-CoV-2 and COVID-19 and will contribute to general knowledge on the long-term effects of SARS-CoV-2 infection. These studies are ongoing and have not yet reported results. NIAID will continue to facilitate public availability of the results of this NIAID-supported research as it becomes available through publication of data in peer-reviewed scientific journals and NIH press releases. NIAID, in collaboration with several NIH Institutes and Centers, also is planning a workshop on post-acute COVID-19. The goal of this meeting is to characterize post-acute COVID-19 and identify key knowledge gaps.

NIAID is using the \$1.5 billion in supplemental appropriations provided by the Congress to aggressively accelerate and broaden research activities to address the COVID-19 pandemic and expedite the development of medical countermeasures. This investment will allow us to better understand virus biology, pathogenesis, and natural history, as well as to develop diagnostics, vaccines, and therapeutics.

SENATOR Kaine

Question 1.

Dr. Fauci, what is the domestic and global public health benefit to not collaborating with other nations through the COVAX Facility? Why shouldn't we participate?

Answer 1. Vaccine development activities undertaken by COVAX, the vaccine-focused program of the Access to COVID-19 Tools Accelerator (ACT Accelerator) initiative, are complementary to vaccine development activities supported by the National Institutes of Health (NIH) and the Department of Health and Human Services. NIH and other U.S. experts provide advice and guidance on numerous planning, coordination, and oversight entities associated with the ACT Accelerator initiative, and NIH participates in regular coordination calls with World Health Organization (WHO)-affiliated scientific leadership to facilitate scientific cooperation and to help avoid duplication of effort. Under the leadership of the White House Office of Science and Technology Policy, NIH also participates in regular SARS-CoV-2 research coordination calls with senior science advisors from approximately 20 countries.

The NIH, along with the Foundation for the NIH, also has launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) international public-private partnership to speed the development and clinical evaluation of COVID-19 vaccine and therapeutic candidates. The ACTIV partnership has brought 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. ACTIV is coordinating clinical trials in order to maximize trial capacity and expedite COVID-19 clinical trials. This includes the development of harmonized master protocols for adaptive trials of multiple COVID-19 candidate vaccines. The NIH has taken steps to ensure the ACTIV partnership is closely interconnected and complementary with other COVID-19 efforts, including those led by the U.S. Food and Drug Administration and the Biomedical Advanced Research and Development Authority's Medical Countermeasures Task Force, in addition to international initiatives.

NIH also is supporting Phase 3 clinical trials of COVID-19 candidate vaccines through Operation Warp Speed (OWS), the Administration's national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. OWS aims to have initial doses of a safe and effective vaccine available for Americans by January 2021. Activities supported by ACTIV and OWS will help inform ACT Accelerator efforts, including the support of the shared U.S. Government and COVAX goal of developing safe and effective vaccines for COVID-19. NIH will continue to engage with international partners through bilateral, multilateral, and regional efforts; to coordinate SARS-CoV-2 research; and to expeditiously advance the development and testing of candidate vaccines and other medical countermeasures that will urgently address the clinical and public health response to the COVID-19 pandemic.

SENATOR ROSEN

Question 1.

With regards to effective prevention, it is clear that wearing a mask, social distancing, and washing our hands are all critical. Dr. Fauci, I've heard that there

may be some confusion among the public about the effectiveness of a face shield instead of a face mask. I'm sure many Americans have seen employees in stores and restaurants wear a shield instead of a mask, thinking it offers the same protection. Can you please address this?

Answer 1. At the present time, there are no definitive data to determine whether face shields provide any benefit as source control to protect others from the spray of respiratory particles that can transmit SARS-CoV-2. However, it is reasonable to assume that wearing face shields may provide additional protection for the wearer along with the use of face coverings. The Centers for Disease Control and Prevention (CDC) does not recommend using face shields as a substitute for masks. For CDC's latest information on masks, please visit <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html>.

Question 2.

Dr. Fauci, when news about an approved vaccine comes out, many families may assume the vaccine is available for their whole family. Can you please discuss what needs to be clearly communicated regarding the populations included in trials, and who a vaccine might initially be approved for? Considering the lack of children in current studies, can you please discuss the best practice for including children and youth in clinical trials for COVID-19 and when it would be appropriate to include them? What recommendations do you have for COVID-19 vaccines that are found safe and effective in healthy adults to then transition to trials that include children, and how would age differences be addressed? What about underlying health conditions? Considering what we are learning about how children can spread the virus, along with at least 3,240 school-aged children in our country being hospitalized so far due to COVID-19, it is so important that we have a clear path forward for a vaccine that is safe, effective, and tailored for our pediatric population. Can you also please address similar concerns for pregnant and lactating women, and what scientific guidelines should be followed to ensure both safety and efficacy for this population as well?

Answer 2. The National Institute of Allergy and Infectious Diseases (NIAID) recognizes the importance of analyzing the safety and efficacy of candidate vaccines and other prevention interventions in pediatric patients as well as in pregnant and lactating women. These studies, which generally occur once safety and efficacy have been well-established in healthy adult populations, are essential to ensuring equitable access to medical countermeasures in these important populations. As the National Institutes of Health (NIH) responds to the current COVID-19 pandemic, scientists leading the development of medical countermeasures against COVID-19 are working closely with pharmaceutical companies, manufacturers, and biotechnology firms to ensure that special populations are being considered for inclusion in upcoming clinical studies.

NIAID currently is discussing plans to assess COVID-19 vaccine candidates in studies that will include both pregnant women and pediatric participants. NIAID also is evaluating the natural history of COVID-19 disease in children, including research on 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. These studies, and others performed in collaboration with current vaccine manufacturers, will provide important new insights into both the short- and long-term effects of COVID-19 on pregnant women and pediatric patients. In addition, the results of these studies may further inform the inclusion of pregnant women and children in clinical trials for candidate vaccines, as well as other candidate preventive strategies and therapeutics.

The U.S. Food and Drug Administration (FDA) also strongly encourages enrollment of all people—including racial and ethnic minorities, older adults, pregnant women, women of childbearing age, and, as appropriate, children—in clinical trials to test COVID-19 vaccine candidates, as outlined in the recommendations in the FDA's *Development and Licensure of Vaccines to Prevent COVID-19* guidance. This FDA guidance can be found at the following web link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>. NIH-supported studies involving special populations are following the FDA's guidance. NIH will work to support vaccine developers as they expand clinical trials of vaccine candidates into additional groups, including children and pregnant women.

Question 3.

As you know, our Tribal communities have been especially hard hit by the COVID-19 pandemic. According to the CDC, they are around three and a half times more likely to contract this virus and are also at a high risk for severe outcomes.

In Nevada, we have over 27 Tribal Nations, Bands and Colonies, with more than 32,000 members. Ninetyseven percent of our Tribes are rural and are spread across over a million acres of land.

(a) Given that our Tribal communities are especially vulnerable to COVID-19, are all too often populations with high rates of comorbidities such as diabetes, and frequently live in very rural areas, what else should the Federal Government be doing to address the immediate health needs of these communities, and what steps should be taken to ensure robust Federal support for COVID-19 vaccine distribution to be done in an equitable, effective, and culturally competent manner? What lessons were learned from the H1N1 response so we can improve upon past efforts?

Answer 3 (a). In order to support the equitable distribution of a safe and effective COVID-19 vaccine, the NIH and CDC requested a consensus study from the National Academies of Sciences, Engineering, and Medicine (NASEM) to assist policymakers in the U.S. and global health communities in planning for equitable allocation of vaccines against COVID-19. The National Academies Committee on Equitable Allocation of Vaccine for the Novel Coronavirus has since released the *Framework for Equitable Allocation of COVID-19 Vaccine* (<https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus>).

In addition to the NASEM study, the Department of Health and Human Services and Department of Defense have released the Administration's COVID-19 Vaccine Distribution Strategy, which provides a strategic distribution overview along with an interim playbook for tribal, state, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to the COVID-19 pandemic within their respective jurisdictions (<https://www.hhs.gov/about/news/2020/09/16/trump-administration-releases-covid-19-vaccine-distribution-strategy.html>).

The CDC will support COVID-19 vaccine distribution, drawing on planning experience with five states and local jurisdictions. CDC also will utilize their years of experience with past outbreaks, including H1N1 influenza, as they plan and work with state and local public health partners. We understand that CDC's responses to questions for the record from this hearing include additional information on vaccine distribution efforts and efforts to respond to immediate health needs in these communities.

RESPONSES BY DR. ROBERT REDFIELD, TO QUESTIONS OF SENATOR SANDERS, SENATOR TAMMY BALDWIN, SENATOR WARREN, SENATOR KAINE, SENATOR SMITH, AND SENATOR ROSEN.

SENATOR SANDERS

Question 1.

It is clear that there is a commitment to bring a safe and effective COVID-19 vaccine to market as soon as possible. It also is clear that there is a commitment across agencies to work together not only to try to increase diversity in ongoing clinical trials, but to educate the public about the importance of getting vaccinated, especially with flu season upon us. Will you use your expertise and influence to ensure that a COVID-19 vaccine is available at no cost to every person in the U.S.?

Answer 1. COVID-19 vaccine will be provided at no cost to enrolled vaccine providers and at no cost to the public. The Administration has stated it is committed to providing free or low-cost, safe, and effective COVID-19 countermeasures to the American people as quickly as possible. Any COVID-19 vaccine or therapeutic doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. As is customary with government-purchased vaccines, healthcare professionals could charge for the cost of administering the vaccine. Information on health care provider reimbursement for vaccine administration for the uninsured is available here: <https://www.hrsa.gov/CovidUninsuredClaim>.

Question 2.

In addition to making sure that a future COVID-19 vaccine is free to every person in the country at the point of service, it is critical that health providers and states can afford to purchase the vaccine in bulk and distribute it to the public and, in particular, to vulnerable populations such as seniors and those who are living in rural areas.

- (a) What specific plans does the Federal Government have to directly purchase the COVID-19 vaccine and distribute it to the public, or to help health providers and states purchase the vaccine for distribution?

Answer 2 (a). As stated above, COVID-19 vaccine will be provided at no cost to enrolled vaccine providers and at no cost to the public. In addition, as of October 22, more than \$500 million has been invested in the COVID-19 vaccination effort to support distribution, vaccine safety and effectiveness, and investment in tracking systems. On June 4, 2020, CDC awarded \$140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable state health departments to enhance their immunization programs, including launch an initial scale-up for influenza season, given the increased risk of COVID-19. On September 23, 2020, CDC also awarded \$200 million to 64 jurisdictions through the existing Immunizations and Vaccines for Children cooperative agreement. These funds, along with the previous support CDC has provided, will help states plan for and implement COVID-19 vaccination services. In addition, CDC invested \$180 million in a centralized depot for distribution of 200 million refrigerated vaccine doses and \$21 million in vaccine safety surveillance ramp up.

Question 3.

As you know, there were recently mixed messages from the CDC regarding the airborne transmission of the novel coronavirus. This caused a great deal of confusion among many people and may have contributed to the public's general lack of trust in our public health agencies. In fact, according to a recent Kaiser Family Foundation survey taken before the latest miscommunication, 54 percent of people surveyed said that they "would not get vaccinated" if one was available before the November election. And, this lack of confidence in a vaccine cuts across the political field, with 46 percent of Democrats, and a full six in ten (60 percent) Republicans reporting that they would not get vaccinated.

- (a) What concrete steps are being taken now, as the research continues to move forward, to ensure accurate, consistent, and scientifically reviewed messaging about COVID-19, including the severity of the disease, how the virus is transmitted and how people can protect themselves and each other? Specifically, how are you measuring and evaluating the impact of these efforts?

Answer 3 (a). CDC continues to provide the American public with the information and assistance it needs to address COVID-19 head on. Our guidance and recommendations are based on the best available science and data and undergo a rigorous review and clearance process. 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.

COVID-19 is thought to spread mainly through close contact from person to person, including between people who are physically near each other (within about 6 feet). People who are infected but do not show symptoms can also spread the virus to others. Some infections can be spread by exposure to virus in small droplets and particles that can linger in the air for minutes to hours. This kind of spread is referred to as airborne transmission. These viruses may be able to infect people who are further than 6 feet away from the person who is infected or after that person has left the space. There is evidence that under certain conditions, people with COVID-19 seem to have infected others who were more than 6 feet away. These transmissions occurred within enclosed spaces that had inadequate ventilation. Sometimes the infected person was breathing heavily, for example while singing or exercising. Under these circumstances, scientists believe that the amount of infectious smaller droplets and particles produced by the people with COVID-19 became concentrated enough to spread the virus to other people. However, available data indicate that it is much more common for the virus to spread through close contact with a person who has COVID-19 than through airborne transmission (<https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html>).

Question 4.

It is clear that this pandemic is far from over. However, even as COVID-19 infections spread among our government officials, misinformation continues to spread regarding the severity of COVID-19 and the steps we all need to take to limit the spread of the virus.

- (a) What are your recommendations for how our government leaders can ensure the American people are receiving consistent, accurate, and science-based information about COVID-19?

Answer 4 (a). CDC is providing the American public with the information and assistance it needs to address COVID-19 head on and continues to issue guidance and recommendations (<https://www.cdc.gov/coronavirus/2019-ncov/index.html>) based on the best available science and data. 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. CDC resources also emphasize the importance of state, tribal, local, and territorial public health recommendations that help meet the unique needs and circumstances of local situations, and the importance of individual jurisdictions having the authority and local awareness needed to protect their communities.

(b) Given the rampant misinformation that has been spread by the President and some in the Administration since this hearing, what steps are you taking now to minimize the negative impact of this misinformation so that the public has accurate, reliable and credible information from which to base their decisions on regarding (1) consistently wearing masks; (2) giving COVID-19 the serious consideration that it deserves; and (3) ultimately taking the forthcoming vaccine when it comes to market?

Answer 4 (b). CDC is providing the American public with the information and assistance it needs to address COVID-19 head on and continues to issue guidance and recommendations based on the best available science and data. 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.

On April 3, 2020, the White House Coronavirus Task Force and CDC recommended that persons wear a cloth face covering in public to slow the spread of COVID-19. A CDC report (https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e3.htm?s_cid=mm6928e3-w) analyzing data from an internet survey found that, after the initial recommendation was released, high rates of cloth face covering use were reported in the United States. The rate of cloth face covering use increased from about 62 percent of adults in April to more than 76 percent in May. The increase was driven largely by a significant jump in mask use by white, non-Hispanic adults, from 54 percent to 75 percent. Approval among Black, non-Hispanic adults went up from 74 percent to 82 percent, and remained stable among Hispanic/Latino adults at 76 percent and 77 percent. There was also a large increase in mask use among respondents in the Midwest, from 44 percent to 74 percent. Approval was greatest in the Northeast, going from 77 percent to 87 percent.

Understanding public confidence in any and all vaccines is necessary for promoting high vaccine uptake, and CDC is adapting its strategic framework, *Vaccinate with Confidence* (<https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html>), to strengthen public trust in COVID-19 vaccines. The framework emphasizes three key priorities: reinforcing communication to the public about the vaccine's rollout and its safety and benefits, empowering healthcare providers to communicate effectively with patients about the vaccine, and engaging with individuals and communities. Building confidence is inherent to all our work and CDC will continue to build upon the investments of our immunization program as we prepare both the Nation's public health system and the private sector to disseminate a safe and effective COVID-19 vaccine. As COVID-19 vaccine developments continue, CDC is working with Operation Warp Speed (OWS) to ensure community groups, physicians, and the general public receive the most up to date guidance and data on available prevention measures that can help reduce COVID-19 infection and spread. Adapting from approaches used with similar past threats, CDC will work with its public health partners to deliver resources on COVID-19 vaccine that assists physicians with proper vaccine administration and enhances public confidence in COVID-19 vaccine uptake.

Question 5.

It is well documented that African Americans, Indigenous Peoples, and other racial and ethnic minorities have experienced harm and trauma when participating—both voluntarily and involuntarily—in medical research. These populations are also most at-risk for contracting COVID-19 and experiencing more severe outcomes from the disease. As history has taught us, vaccines are only effective in eventually eradicating a particular disease when there is widespread use. A lack of trust, however, can stall efforts to defeat a pandemic. Please provide specific details about the steps you are taking, and have already taken, to build public trust—especially among the most vulnerable and often hard-to-reach populations, including low-income individuals, people who live in rural communities, older individuals, and racial and ethnic minorities—so that when a safe and effective vaccine is available, it is successfully adopted?

Answer 5. Understanding public confidence in any and all vaccines is necessary for promoting high vaccine uptake, and CDC is adapting its strategic framework, *Vaccinate with Confidence* (<https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html>), to strengthen public trust in COVID-19 vaccines. The framework emphasizes three key priorities: reinforcing communication to the public about the vaccine's rollout and its safety and benefits, empowering healthcare providers to communicate effectively with patients about the vaccine and engaging with individuals and communities. Building confidence is inherent to all our work and CDC will continue to build upon the investments of our immunization program as we prepare both the Nation's public health system and the private sector to disseminate a safe and effective COVID-19 vaccine. As COVID-19 vaccine developments continue, CDC is working with OWS to ensure community groups, physicians, and the general public receive the most up to date guidance and data on available prevention measures that can help reduce COVID-19 infection and spread. Adapting from approaches used with similar past threats, CDC will work with its public health partners to deliver resources on COVID-19 vaccine that assist physicians with proper vaccine administration and enhances public confidence in COVID-19 vaccine uptake.

CDC is enhancing communications efforts to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities, and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic/Latino communities realizing that these groups have lower rates of influenza vaccination, yet higher risk for COVID-19 complications.

CDC will also be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. In addition, CDC will be consulting individually with 15 national leaders in the field of health disparities, health equity, and social determinants of health to develop strategies to address racial and ethnic disparities in adult immunization.

CDC is testing influenza vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

CDC also is committed to ensuring rural populations can access the vaccine. We have decades of experience working with public health partners addressing the needs of hard to reach populations. We will work with communities, government, and other local partners to identify the best places and times to reach this population and utilize strategic distribution points via community health centers, schools, workplaces, mobile clinics, and pharmacies. Our immunization programs have built a strong public health immunization infrastructure, including through the provision of a safety net for those with no health insurance and through response to outbreaks of vaccine preventable diseases and other urgent public health issues.

In July, CDC released a Health Equity Strategy (www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html) that provides an evidence-based, comprehensive, and coordinated framework for reducing COVID-19 disparities. The strategy includes building on plans for collecting and reporting timely, complete, and representative data on testing, incidence, vaccination, and severe outcomes among populations at highest risk.

SENATOR BALDWIN

Question 1.

Dr. Redfield you have said numerous times that your agency is not a regulatory agency. Do you think an Emergency Temporary Standard (ETS), enforced by the Occupational Safety and Health Administration, requiring workplaces to implement comprehensive infectious disease exposure control plans, could help protect workers, and the general public from exposure to COVID-19?

Answer 1. CDC defers to the Occupational Safety and Health Administration.

Question 2.

As you know, between April 16-17, an Epidemiologic Assistance (Epi Aid) team consisting of CDC and NIOSH staff was sent to investigate the COVID outbreak at the South Dakota Smithfield meatpacking plant at the request of the South Dakota (SD) Health Dept. On April 21 CDC and NIOSH staff cleared a report summarizing that Epi-Aid team's findings and safety recommendations and that report was then

sent to the SD Health Dept. on April 21. On April 22, the CDC asked the SD Department of Health to retract that report. On April 22, the South Dakota Department of Health received an edited report that included language weakening the original safety recommendations by adding the phrases “if feasible” and “if possible”.

(a) How did you become aware that there were concerns with the language included in the original report sent on April 21 to the SD Health Department?

Answer 2 (a). On April 20, 2020, CDC provided a pre-clearance version of its draft site visit memo to the South Dakota Department of Health. This is consistent with CDC’s practice of partnering with state health departments in this kind of Epi-Aid. On April 20, 2020, the CDC team received an e-mail from an executive vice president with Smithfield Foods indicating that they had received a copy of the recommendations from the Governor’s office and wished to discuss the draft. On April 21, 2020, the USDA requested a call to understand the recommendations and clarification on whether the recommendations were binding. Given the public health implications and the engagement from USDA, the CDC Director was made aware.

(b) Who asked you to change or edit that report language, and why did you change it?

Answer 2 (b). CDC issues evidence-based guidance and recommendations, which are cleared through the U.S. Government interagency policy process. All CDC interim guidance for workplaces regarding COVID-19 is reviewed and updated based on three key inputs: stakeholder feedback, what is learned from our field teams, and the evolving science around COVID-19. When CDC staff conduct site visits, a memo describing observations and recommendations is written and provided to the requesting organization, typically the health department. It is important to note that CDC does not have enforcement authority and thus, CDC-developed memos and recommendations are advisory, not regulatory, in nature.

The South Dakota Department of Health requested assistance to develop strategies to help reduce infections from SARS-CoV-2, the virus that causes COVID-19, among Smithfield Foods Sioux Falls pork processing plant employees. The CDC team traveled to Sioux Falls, South Dakota on April 14, 2020. One component of this effort was to visit the Smithfield Foods pork processing plant to evaluate existing health and safety controls and provide recommendations for improvement.

On April 21, 2020, CDC issued a cleared memo to the South Dakota Department of Health. On April 22, 2020, CDC updated the memo to clarify that the CDC recommendations are non-binding. CDC recalled the April 21 cleared memo, and the final cleared memo, *Strategies to Reduce COVID-19 Transmission at the Smithfield Sioux Falls Pork Plan*, was issued on April 22, 2020. CDC, in partnership with the South Dakota Department of Health, provided Smithfield Foods and United Food and Commercial Workers Local 304A Union recommendations that can be used to help management, employees, the union, the South Dakota Department of Health, and community stakeholders limit the potential spread of COVID-19 in the plant.

CDC and the Occupational Safety and Health Administration (OSHA) then released the joint guidance on April 26, 2020, *Meat and Poultry Processing Workers and Employers: Interim Guidance from CDC and OSHA* (www.cdc.gov/coronavirus/2019-ncov/community/organizations/meat-poultry-processing-workers-employers.html). Information from the Sioux Falls plant evaluation was considered in the development of the CDC/OSHA guidance document, as was information gained from CDC assistance (also occurring at that time) to other meat and poultry facilities and health departments around the country. Subsequent to the date of the hearing, this guidance was most recently updated on November 12, 2020.

(c) In your role as Director of the CDC, do you normally review the wording of Epi-Aids? If not, why was did this particular Epi Aid warrant your attention?

Answer 2 (c). While the CDC Director does not typically get involved in editing reports from Epi-Aids, the CDC Director was provided with frequent updates from both investigations because of the rapidly evolving information and public health implications. Based on feedback from USDA about potential for a significant impact on the food supply chain, the Director reviewed the language in the Epi-Aid.

(d) Did you review the Epi Aid done for the JBS facility in Colorado before it was sent out? If not, why?

Answer 2 (d). The JBS facility in Colorado and the Smithfield facility in South Dakota were the first and second, respectively, COVID-19 Epi-Aids in meatpacking

and poultry facilities conducted by CDC. The CDC Director was provided with frequent updates from both investigations because of the rapidly evolving information and public health implications. The CDC Director wanted to make clear that CDC is not a regulatory agency and therefore does not have the authority to enforce recommendations.

- (e) The Epi Aid done for the JBS facility in Colorado didn't include language like "if feasible" "if possible" preceding the safety recommendations. What differed in process from the Colorado JBS Epi Aid to the Smithfield Epi Aid?

Answer 2 (e). The JBS and Smithfield field investigations were conducted very early in the pandemic response. The development and clearance processes for the reports from the site visits was still evolving. As those processes were formalized, along with the publication of the guidance for meat processing, the reports became more standardized. While CDC/NCEZID has a history of conducting food-borne investigations and CDC/NIOSH has experience in workplace health hazard evaluations, these site visits were a new activity that required merging the experiences of both of those functions. That meant that CDC had to create protocols for how these site visits would be run and what the final site-visit reports should include.

SENATOR WARREN

POLITICAL INTERFERENCE AT CDC

Question 1.

Numerous public reports have revealed that political appointees at HHS and the White House have repeatedly interfered with, undermined, and even overruled career experts at the CDC. In August, guidance reportedly developed by HHS and the White House Coronavirus Task Force was published to the CDC's website—reportedly without approval from the CDC—recommending that asymptomatic individuals do not need to be tested, even after exposure to someone with COVID-19. This guidance contradicted clear advice from career CDC officials and other public health experts. Further, according to public reports, political appointees at HHS have sought to review, alter, and delay the CDC's Morbidity and Mortality Weekly Reports (MMWR), which provide the latest information and recommendations on public health threats, including COVID-19. This interference, which reportedly began in May, also appears to have occurred in other CDC reports. In order to better understand the extent of political interference at CDC, we request answer to the following questions:

- (a) What impact has political interference had on the work of public health experts at CDC, including career officials, and COVID-19 response efforts?

Answer 1 (a). The COVID-19 pandemic is the most significant public health challenge to face our Nation and the world in more than a century. Approaches to the pandemic must be coordinated across the U.S. Government to keep pace with the needs of the American people and the world. CDC, along with the Food and Drug Administration (FDA), Assistant Secretary for Preparedness and Response (ASPR), Federal Emergency Management Agency (FEMA), Department of State, US Agency for International Development (USAID), and the White House Coronavirus Task Force, and others, is an integral part of that. CDC works hand-in-hand with our colleagues throughout the Administration to ensure a coordinated approach that leverages each agency's strengths.

- (b) Has all public guidance issued on the CDC's website or otherwise attributed to the CDC—including guidance pertaining to testing for the virus that causes COVID-19 and re-opening schools for in person learning—been developed and approved by CDC personnel and gone through the standard CDC scientific review process?

Answer 1 (b). The requested information could be considered deliberative, pre-decisional, or otherwise implicate other executive branch privacy equities and cannot be produced at this time.

- (c) How has the editorial and publication process for MMWRs changed from years past, and to what extent have political appointees attempted to alter or delay MMWRs? What has been the impact of these interventions on the timing and content of MMWR reports?

Answer 1 (c). COVID-19 reports published in CDC's *Morbidity and Mortality Weekly Report* (MMWR) follow a rigorous scientific review and clearance process

from the inception of a manuscript to the final publication. Scientific review and clearance for COVID-19 reports mirrors the same process for standard non-COVID-19 reports published in MMWR, with additional steps added to include CDC's COVID-19 emergency response structure and to obtain concurrence from CDC's Director Dr. Robert Redfield and the White House Coronavirus Task Force Coordinator Dr. Deborah Birx to publish. The concurrence requirement started in late spring 2020, and neither Dr. Redfield nor Dr. Birx has ever withheld concurrence for a COVID-19 MMWR report.

The MMWR, sometimes called the “voice of CDC,” has published more than 100 COVID-19 reports since the beginning of the pandemic, providing cutting-edge scientific articles that have been viewed by tens of millions of readers. These reports have provided the public, scientists, healthcare workers, and policymakers critical information about the virus, how it spreads, and the communities it has impacted. MMWR publications yielded the earliest descriptions of asymptomatic and pre-symptomatic transmission of the virus and elucidated the substantial risk of transmission at large gatherings, choir practices, and congregate living situations, including nursing homes, prisons and jails, meat processing plants, homeless shelters, and camps for children. They have described the disparate impact of COVID-19 in racial and ethnic minorities and identified the elevated risk of severe outcomes for older adults and people with underlying conditions. Finally, the MMWR has indicated what successful control of the virus can look like, through careful mitigation efforts in everyday high-risk settings such as hair salons and childcare centers. In short, MMWR's rapid publication of the highest quality science has laid the foundation of what we know about COVID-19 and illuminated the way forward.

CDC declined to make any suggested change to MMWRs that was inconsistent with the best available science.

(d) What role, if any, have entities outside of HHS—including the White House, the Office of Management and Budget, or the Office of Science and Technology Policy—played in developing, revising, and issuing guidance, reports, or policy changes at CDC?

Answer 1 (d). The COVID-19 pandemic is the most significant public health challenge to face our Nation and the world in more than a century. Approaches to the pandemic must be coordinated across the U.S. Government to keep pace with the needs of the American people and the world. CDC, along with FDA, ASPR, FEMA, Department of State, USAID, and the White House Coronavirus Task Force, and others, is an integral part of the pandemic response. CDC works hand-in-hand with our colleagues through the Administration to ensure a coordinated approach that leverages each agency's strengths.

LONG TERM HEALTH EFFECTS OF COVID-19

Question 2.

There is evidence of patients continuing to feel the effects of COVID-19 well after they are discharged from hospitals or beyond the average known time of recovery, and some may face long-term health problems long after the pandemic is over. It is critical that the Federal Government conduct appropriate research and collect and disseminate appropriate data about the potential chronic health impacts of COVID-19—and do so without muzzling public health officials and medical professionals—in order to adequately inform decisions about reopening schools and businesses and assess the ongoing risks of the pandemic. As CDC continues to conduct and coordinate research efforts, it is critical that it collect, analyze, and disseminate data on the long-term impacts and severity of the disease, conduct research to understand the risks, we are learning that many organs besides the lungs are affected by COVID-19 and there are many ways the infection can affect someone's health. CDC will continue to assess and provide updates as new data emerge.

(a) How is the CDC evaluating the long-term health risks of COVID-19 for the millions of Americans that will survive the disease?

Answer 2 (a). CDC is actively working to learn more about the whole range of short-and long-term health effects associated with COVID-19. As the pandemic unfolds, we are learning that many organs besides the lungs are affected by COVID-19 and there are many ways the infection can affect someone's health. CDC will continue to assess and provide updates as new data emerge.

CDC is funding several cohort studies to assess long-term consequences and sequelae of COVID-19. For example:

CDC is funding a cohort study designed to follow 3,600 patients with COVID-19 and 1,200 matched controls from 8 different sites across the United States that will allow comparison of long-term sequelae (consequences) in comparison to a control subgroup who test negative. Complications of COVID-19 will be assessed using health record data and validated survey instruments, for 18 months after infection. Participants will include vulnerable populations such as race/ethnic minorities, individuals from low income communities, and those with pre-existing underlying conditions.

CDC is also funding a large cohort study that is designed to integrate syndromic, serologic, and health record data for 65,000 participants with or without infection, to be followed for 6 months to 1 year. This will enable assessment of health outcomes including for patients who report symptoms and seroconvert but do not receive clinical care for the initial illness.

Among inpatients with COVID-19 in Louisiana, a cohort study is underway with plans to enroll 400–500 participants. An additional cohort of approximately 400 individuals who had tested positive for COVID-19 from outpatient settings will be enrolled. A subgroup of 100–200 participants is to be followed up for 1 year to assess clinical outcomes and ability to perform usual activities.

Additionally, CDC is funding a study that will enroll patients with COVID-19 and their household contacts. Clinical sequelae will be assessed up to 1 year after infection, including neurocognitive outcomes of infection in a subgroup of participants. This study will focus on American Indian populations.

Each of the above studies will examine race and ethnicity trends to better understand high risk populations.

(b) How are these risks being factored into CDC actions and recommendations alongside the mortality risks of the disease? Specifically, how does the CDC evaluate and assess these risks with regard to reopening schools, businesses, and the economy?

Answer 2 (b). Very little is known at this time about long-term sequelae for children and adolescents, which makes it even more critical to do everything we can to prevent the spread of the virus within this population. CDC recommendations are based on the best available science and CDC will adjust interventions and guidance as more information becomes available.

CDC has been working with both health departments and education partners and stakeholders since the beginning of the COVID-19 pandemic to provide helpful and actionable information to schools, parents and caregivers, and the public based on local situations. Recognizing that schools are an important part of the infrastructure of communities and play a critical role in supporting the whole child, CDC has established a dedicated team to prioritize and develop additional guidance and resources for communities, schools, and institutions of higher education; these are based on the best available science to protect the health, safety, and well-being of students, teachers, other school staff, families, and communities. CDC is conducting surveys of parents and educators to identify key information needs and inform development of resources. CDC is also conducting behavioral and epidemiologic research to fill information gaps and is updating guidance as new information becomes available.

Further, CDC has provided information and resources for employers (<https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>) as they consider how best to decrease the spread of COVID-19 and lower the impact in the workplace. This should include activities to prevent and reduce transmission among employees, maintain healthy business operations, and maintain a healthy work environment.

(c) How is the CDC working with other Federal agencies conducting long-term surveillance or other research on survivors of COVID-19, including those who presented with non-severe symptoms and those who presented with severe symptoms? How is this information being transmitted to and used by other Federal agencies?

Answer 2 (c). See response to part a.

(d) What data are CDC and its partner agencies collecting from patients, health care providers, and other sources, and how are the agencies using this data to understand and inform long-term risk assessments?

Answer 2 (d). CDC uses several different surveillance systems to gather information to provide as complete a picture as possible to inform our public health re-

sponse. CDC has been working quickly with states, counties, cities, territories, tribes, and other partners to improve data collection and reporting and continues to make progress to ensure key data are available to identify those most affected by this pandemic.

Various laws, regulations, and policies in public health jurisdictions require healthcare providers, hospitals, laboratories, and others to provide information on reportable conditions to public health authorities. COVID-19 is a mandatory reportable condition in all U.S. states, several territorial health departments, and local health departments. These entities voluntarily send case reports to CDC through the National Notifiable Diseases Surveillance System (NNDSS) to help monitor and mitigate the adverse effects of this pandemic. On June 4, 2020, HHS announced new guidance that specifies additional data that must be reported to HHS by laboratories submitting COVID-19 test results, including race, ethnicity, and sex. The guidance, COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act section 18115 (www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf), which took effect August 1, 2020, standardizes reporting to give public health officials access to comprehensive and nearly real-time data to inform decisionmaking and public health action in their response to COVID-19.

CDC's existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and other long-term care facilities. NHSN also continues to collect data from hospitals across the U.S. to address healthcare-associated infections and fight against antibiotic resistance.

CDC's population-based COVID-NET system monitors COVID-19-associated hospitalizations that have a confirmed positive test in more than 250 acute care hospitals in 99 counties in 14 states. Data gathered are used to estimate age-specific hospitalization rates on a weekly basis and describe characteristics of persons hospitalized with COVID-19 illness.

CDC is also currently working with a few Institutes of Higher Education (IHEs) to rapidly gather data on mitigation measures employed and the occurrence of COVID-19 to increase understanding of the best practices for reducing or preventing COVID-19 transmission. CDC is also developing a list of core variables, including key demographic information, that IHEs could collect. This approach of defining core variables for this setting can facilitate aggregating data across multiple states; CDC will issue a data call to our partners in state, tribal, and territorial health departments to request submission of de-identified IHE data to summarize data across states and provide a national picture. This is similar to the approach CDC has used to rapidly gather information on COVID-19 transmission in other settings, such as high-density worksites. CDC is also monitoring school outbreaks and school closures using publicly available information.

In addition, CDC continues to work with state, tribal, local, and territorial health departments and healthcare systems to collect data on the number of COVID-19 cases, hospitalizations, and deaths, which is used to better direct resources to address target populations. CDC also supports partnerships among researchers, professional groups, community groups, tribal medicine leaders, and community members to share culturally tailored information which allows for messaging to be more applicable to specific groups. Additionally, CDC continues to publish and update COVID-19 guidance that is designed for specific target populations including occupational, racial and ethnic, and regional populations.

(e) How is the CDC collaborating with state, local, Tribal, and territorial public health officials, universities, and other governments and international organizations to research and understand the long-term impacts of COVID-19?

Answer 2 (e). CDC works closely with state, local, and territorial health departments and Tribal leaders through regular engagement between these groups and subject matter experts supporting the agency's response to COVID-19. CDC works with partners to respond to COVID-19 in the areas of community health, workplace safety and health, and epidemiology and data analysis. CDC provides both direct support through the physical deployment of staff to state, tribal, local and territorial jurisdictions and virtual support by providing teams to assist jurisdictions remotely from Atlanta. CDC is working with health departments to research critical questions, including:

1. How well are prevention and control strategies performing (feasibility, implementation, effectiveness) in schools, congregate settings, and critical infrastructure settings?

2. What are the health impacts of infection with special consideration for long-term sequelae, pediatric populations, and persons with co-morbidities?
3. How do antigen assays perform relative to presence of transmissible virus, including in asymptomatic individuals?

CDC is working with Institutes of Higher Education to understand the impact of COVID-19, and the mitigation strategies put into place to address it, on students. A survey has been created and is being shared with colleges and universities who express an interest in better understanding the impacts on their students. This survey addresses personal experiences with COVID-19, social support, school experiences during COVID-19, changes to daily routines, relationships with family and friends, other protective factors like school connectedness, mental health, use of health services, academic performance, and substance use.

- (f) What additional resources or authorities are needed from Congress to ensure that the CDC can effectively conduct this type of research?

Answer 2 (f). The COVID-19 pandemic put a spotlight on the needs and disparities in the public health infrastructure across the country. CDC's mission depends on a strong public health system with robust core capabilities like data and analytics, laboratory capacity, a top-tier workforce, rapid response capabilities, and a broad global footprint to stop disease at its source. The Administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19. The investments supported with COVID-19 Supplemental funds will help improve public health infrastructure at all levels across the country.

- (g) On July 14, 2020, HHS announced changes to hospital reporting protocols, under which data on COVID-19 in hospitals will now be reported directly to an HHS contractor rather than to CDC.⁷ Will this change affect CDC's ability to obtain and analyze data on the medium-and long-term health risks from COVID-19?

Answer 2 (g). As the department leading the Federal pandemic response, HHS recognized it needed a central way to make data collected by various operating divisions, including CDC, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration (HRSA), accessible in real-time to first responders at the Federal, state, and local levels. The HHS Protect ecosystem allows HHS to create a single portal with over 3.5 billion data elements across 200 different data sets in real time to drive HHS's response to the COVID-19 pandemic. HHS reports HHS Protect data publicly on *HealthData.gov* and the HHS Protect Data Hub (available at: <https://protect-public.hhs.gov/>). Following the change in systems, CDC staff revised data analysis methods to make necessary adjustments for the change in variables reported within the two systems and differences in how the systems were constructed.

While hospital capacity and patient impact data are no longer collected by the CDC, the surveillance systems for cases, mortality, nursing homes, studies, and clinical data continue to be led by CDC, including population-based surveillance data on hospitalization through COVID-NET. The joint analysis of all this data remains within the domain of the CDC and the other Federal agencies in the COVID-19 response. NHSN continues to collect COVID-19 data from nursing homes and long-term care facilities, leveraging authority from CMS to require reporting from 100 percent of CMS-certified nursing homes across the country. NHSN continues its efforts around data collection from hospitals across the U.S. for the fight against healthcare-associated infections and antibiotic resistance. The U.S. healthcare system relies on NHSN to track healthcare-associated infections, improve patient safety, and fulfill Federal and state reporting requirements to track and improve patient safety related to healthcare-associated infections, antibiotic-resistant infections, and antibiotic use. Though CDC does not directly collect COVID-19 hospital capacity and patient impact data, CDC staff have access to it in HHS Protect.

NURSING HOMES AND LONG TERM CARE FACILITIES

Question 3.

The COVID-19 pandemic has had a deadly impact on nursing homes and other long-term care facilities, with disproportionately negative consequences borne by residents of color. On July 15, 2020, my colleagues and I sent a letter to the CDC and the Centers for Medicare and Medicaid Services urging you to fully inform the national response to this crisis by expanding COVID-19 data collection for nursing home residents and staff to include race, ethnicity, sex, age, primary language and

disability status. Specifically, we urged you to follow the data collection standards set by the Office of Minority Health at the Department of Health and Human Services, and add questions about race, ethnicity, sex, age, primary language, and disability status to the COVID-19 nursing home data collection under 42 CFR §483.80(g); publicly release this demographic information aggregated at the state and Federal level; and devise reliable methods to collect this information retroactively.

(a) What specific steps has CDC taken to collect demographic data from residents living in nursing homes who test positive for COVID-19?

Answer 3 (a). Long-term care facilities (LTCF) report COVID-19 data through CDC's National Healthcare Safety Network (NHSN). CDC released the COVID-19 Point-of-Care Testing module for LTCF in NHSN on October 15, 2020. This module includes data fields for race and ethnicity for facilities to report testing results from nursing homes and other long-term care facilities. Initially the HHS decision made on October 15, 2020 required CMS-certified LTCFs to report antigen testing data in NHSN; however, that decision has been updated to recommend CMS-certified LTCFs report antigen testing as of December 22, 2020. CDC is working with CMS to communicate the CDC-and CMS-preferred pathway for reporting POC SARS-CoV-2 testing data, including antigen testing data, through NHSN.

Additionally, CDC is examining methods for developing internal estimates of COVID-19 burden in long-term care facilities by race and ethnicity, such as incorporating demographic data from CMS; however, these will not be as accurate as comprehensive data reporting.

(b) What specific steps has CDC taken to collect demographic data and other information pertaining to COVID-19 cases and deaths in other congregate settings, including intermediate care facilities and psychiatric hospitals?

Answer 3 (b). CDC is committed to making COVID-19 case surveillance data available for public use to inform the public health and research communities while meeting our legal and ethical responsibilities to protect privacy. The most recent public use case surveillance data can be found at: <https://data.cdc.gov/Case-Surveillance/COVID-19-Case-Surveillance-Public-Use-Data/vbim-akqf>. This site provides a download link to access a de-identified dataset of COVID-19 case surveillance records that includes 11 different data fields (when available), including sex, age group, race and ethnicity, presence of an underlying condition, hospitalization, ICU admission, and death.

In addition to case-based reporting, CDC uses two other primary sources of data to report on race and ethnicity information: The Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET) and the National Vital Statistics System (NVSS). COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19 hospitalizations in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, and UT) and provides weekly updates on rates of hospitalization as well as data on the race and ethnicity, underlying medical conditions, gender, and age of hospitalized patients (<https://gis.cdc.gov/grasp/COVIDNet/COVID19-5.html>). COVID-NET draws from a carefully selected group and covers approximately 10 percent of the U.S. population (about 32 million people) to create a nationally representative sample of the U.S. population from which we can extrapolate broader information about hospitalizations.

NVSS reports provisional counts of deaths related to COVID-19 based on death certificate data, which includes race and ethnicity. This information is collected by the National Center for Health Statistics (NCHS) from state vital statistics offices for all deaths occurring in the United States. Current estimates indicate that at least 75 percent of certificates are complete within eight weeks of when the death occurred.

NCHS is releasing provisional aggregate public-use data sets with counts of COVID-19 deaths through the NVSS daily (<https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Week-Ending-D/r8kw-7aab>) and more detailed demographic and geographic aggregate public use data on a weekly basis (www.cdc.gov/nchs/nvss/vsrr/covid-weekly/index.htm). Public-use micro data files for annual (complete) mortality data from NVSS are provided for all causes of death in a year when the data for that year are finalized. NVSS COVID-19 mortality data for 2020 are provisional and cannot be finalized until 2021, so NCHS is unable to produce a complete public-use micro data file containing individual-level death records on COVID-19 mortality until the data are finalized.

(c) In what way has CDC coordinated with state and local health departments to improve data collection of COVID-19 cases, particularly concerning the collection of demographic information, including race, ethnicity, sex, age and disability status?

Answer 3 (c). Clear and accurate demographic data allow for more precise determinations of the burden of infection and illness severity on populations who are at high risk for poor outcomes from COVID-19. CDC has been working quickly with states, counties, cities, territories, tribes, and other partners to improve data collection and reporting and continues to make progress to ensure key data are available to identify those most affected by this pandemic. CDC uses several different surveillance systems to gather information to provide as complete a picture as possible to inform our public health response, including case-based reporting, laboratory testing data, the Coronavirus Disease 2019 (COVID-19)-Associated Hospitalization Surveillance Network (COVID-NET), and the National Vital Statistics System (NVSS).

Case-Based Reporting

Various laws, regulations, and policies in jurisdictions require healthcare providers, hospitals, laboratories, and others to provide information on reportable conditions to public health authorities. COVID-19 is a mandatory reportable condition in all U.S. states, several territorial health departments, and local health departments and these entities voluntarily send case reports to CDC through the National Notifiable Diseases Surveillance System (www.cdc.gov/nndss) to help monitor and mitigate the adverse effects of this pandemic. Case-based reporting uses standardized case definitions and defined demographic and clinical variables. However, while case report forms for notifiable diseases are required by state law, completion of demographic data, including race/ethnicity, is voluntary; there is no mandate requiring that healthcare providers or health departments fill out all data fields, including race/ethnicity, in the case report form.

As of October 13, 2020, CDC has received a total of 5,832,737 case report forms (inclusive of about 75 percent of all cases). Among these case reports, 48 percent contain race and ethnicity data. Overall, from April 2 to October 13, there was an improvement in completeness of race and ethnicity in the case reports, from 21 percent to 65 percent for race and from 18 percent to 54 percent for ethnicity. However, this improvement has slowed since late June. In August, CDC recommended that states focus case notifications to CDC on a core set of data elements in order to improve the completeness of reporting on this core set, which includes race and ethnicity but does not include disability. CDC expects to see continued improved in demographic reporting in the future, including for race and ethnicity.

In fiscal year 2020, CDC began a multi-year effort to modernize the public health data system. This work will help enhance the capabilities of state and local health departments and improve data collection to inform decisionmaking related to COVID-19 and future public health emergencies. Among the priority investments in CDC's public health data modernization initiative is an effort to scale up electronic case reporting—that is, digitally automating the provision of COVID-19 case reports from electronic health records to public health without placing extra burden on healthcare workers. This electronic reporting provides more consistently complete data than manual reporting so public health can have a comprehensive view of the pandemic's impact in near real-time. It is part of a broader effort to automate all mandated disease reporting to state and local jurisdictions.

Laboratory Testing Data

On June 4, 2020, HHS announced new guidance that specifies additional data that must be reported to HHS by laboratories submitting COVID-19 test results, including demographic data, such as sex, race, and ethnicity. The guidance, *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* (www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf), which took effect August 1, 2020, standardizes reporting to give public health officials access to comprehensive and nearly real-time data to inform decisionmaking and public health action in their response to COVID-19. As of October 11, 2020, de-identified individual-level data from 45 jurisdictions had been included in the COVID-19 electronic lab reporting (CELR) testing reporting dataset. Both race and ethnicity were identified in only about 18 percent of reported tests in the 45 jurisdictions, and race/ethnicity completion was over 40 percent in seven jurisdictions. CDC continues to work with laboratories to improve completion of race and ethnicity data. Disability data are not included in laboratory reports.

NHSN LTCF COVID-19 Module

CDC's NHSN LTCF COVID-19 module Point-of-Care Testing form released October 15, 2020 includes required data fields for race and ethnicity when facilities report testing results from nursing homes and other long-term care facilities. CDC provided support to LTCFs as they began providing resident-level data and has been working with LTCFs to update their security access levels to provide case level data. Around two-thirds of LTCFs now meet these higher-security criteria. CDC is working with CMS, health departments, and other public health partners to promote use of the NHSN LTCF COVID-19 module to meet CMS reporting requirements for testing conducted by CMS-certified LTC facilities.

COVID-NET

COVID-NET conducts population-based surveillance for laboratory-confirmed COVID-19 hospitalizations in 14 states (CA, CO, CT, GA, IA, MD, MI, MN, NM, NY, OH, OR, TN, and UT) and provides weekly updates on rates of hospitalization as well as data on the race and ethnicity, underlying medical conditions, gender and age of hospitalized patients (<https://gis.cdc.gov/grasp/COVIDNet/COVID19-5.html>). COVID-NET draws from a carefully selected group and covers approximately 10 percent of the U.S. population, approximately 32 million people to create a nationally representative sample of the U.S. population from which we can extrapolate broader information about hospitalizations. Completeness of race and ethnicity data in COVID-NET is 95 percent as of October 3, 2020. Conclusions about persons with a disability cannot be drawn from COVID-NET data because they are based on retrospective chart review and do not include a comprehensive list of all ICD-10 codes from each hospitalization.

NVSS

NVSS reports provisional counts of deaths related to COVID-19 based on death certificate data, which includes race and ethnicity information. This information is collected by the National Center for Health Statistics from state vital statistics offices for all deaths occurring in the U.S. These provisional counts are based on death certificates that contain COVID-19 as a cause of death and are over 99 percent complete for race and ethnicity data. NVSS does not include data collection items on disability.

- (d) What plans have been developed to perform reliable retroactive reporting of COVID-19 data to the beginning of the public health emergency on January 31, 2020, including demographic variables such as race, ethnicity, sex, age, primary language, and disability status, in nursing homes and other settings?

Answer 3 (d). CDC has provided guidance to nursing homes and other LTCFs on how to submit retrospective data in the NHSN. In addition, CDC has worked with health departments, LTC organizations, and other public health partners to promote reporting of COVID-19 data from the beginning of the public health emergency period. Facilities can enter these data any time during the response. Thus, CDC continues to provide technical support to those LTCFs that are reporting retrospective data to NHSN. The purpose of the CDC collecting retrospective data is to gain a comprehensive understanding about the impact of COVID-19 on nursing homes using a systematic reporting mechanism and standard data definitions. Standard data definitions enable more fair comparisons across facilities and states. CDC plans to review these data to perform facility-level trend analysis to better track the burden of COVID-19 cases.

- (e) In what ways has CDC utilized COVID-19 data to inform treatment and prevention strategies in nursing homes and other congregate settings?

Answer 3 (e). CDC utilizes COVID-19 data to inform and develop guidance and technical assistance resources to assist nursing homes and public health authorities with COVID-19 prevention and response activities. For example, CDC has developed and published guidance to help nursing homes implement effective strategies for testing residents and staff in response to outbreaks, as well as cohorting residents with confirmed COVID-19 infections in designated COVID-19 care units. Similarly, CDC developed a COVID-19 Infection Control Assessment and Response (ICAR) tool to help nursing homes and other long-term care facilities take steps to assess and improve their preparedness for responding to COVID-19. As new evidence accumulates, CDC will continue to adjust its COVID-19 infection prevention and control guidance for nursing homes and other long-term care facilities. Based on data and lessons learned during the COVID-19 response, CDC is also working with CMS to identify structural changes and practices to improve nursing home infection prevention and control program development, management, and monitoring.

CDC and CMS also use the NHSN LTCF COVID-19 module data to generate weekly summaries and lists that are shared with state survey agencies, health departments, and CDC-funded state healthcare-associated infection and antibiotic resistance (HAI-AR) programs to help them identify long term care facilities with new or growing outbreaks to better focus and support state and local investigation and control efforts. This includes information provided to state survey agencies to identify facilities for focused infection control surveys. CDC also uses these data to identify states with worrisome trends and to engage health department HAI-AR programs to alert them and identify areas where assistance is needed.

CDC has outlined a range of specific mitigation strategies (<https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html>) for people and communities to consider to slow the spread of COVID-19 by level of mitigation required. Such strategies include promotion of healthy behaviors (e.g., social distance, masks, hand hygiene), maintaining healthy environments (e.g., cleaning and disinfecting, modifying layouts, ventilation, closing communal spaces), and maintaining healthy operations (e.g., by staggering scheduling, cohorting), and preparing for when someone gets sick. Factors to consider for determining mitigation strategies include the epidemiology of COVID-19 in the community and community characteristics (such as size and population density, congregate settings in the community, healthcare capacity, and public health capacity). Levels of mitigation needed, stratified by level of community transmission and community characteristics, are described on CDC's website (<https://www.cdc.gov/coronavirus/2019-ncov/community/community-mitigation.html>). CDC has provided specific considerations for schools and childcare settings, correctional settings, community-based organizations, and communities of faith to provide additional information on factors more commonly encountered in those settings.

(f) In what ways has CDC or its partner agencies utilized COVID-19 data to direct resources such as funding and personal protective equipment to the facilities most in need?

Answer 3 (f). Because no single system can capture all parameters of the pandemic, CDC has implemented multiple, complementary surveillance systems. For example, CDC's National Healthcare Safety Network (NHSN) is collecting COVID-19 data from nursing homes since long-term care residents (and the staff who care for them) are often at high risk for infection, serious illness, and death from COVID-19. NHSN provided the first national lens into the burden of disease in nursing homes and its impact on staffing and supplies, including personal protective equipment (PPE) and ventilator use. CDC uses these COVID-19 data to work with CMS, other Federal agencies such as ASPR and FEMA, and state and local health departments to take action to address PPE, testing, staffing, and other supply shortages. Other key COVID-19 data systems include case-based reporting through the National Notifiable Diseases Surveillance System (NNDSS), laboratory-based surveillance, and syndromic-surveillance data reported through the National Syndromic Surveillance Program (NSSP). Additional systems, such as COVID-Net, provide rich, publicly available information for meeting secondary objectives. CDC continues to explore emerging and experimental surveillance platforms with a critical eye toward proven utility.

To address PPE shortages due to the COVID-19 pandemic and help healthcare facilities optimize the use of PPE and other equipment during this time, CDC has also developed tools and guidance documents which can be found the CDC website. For example, CDC has developed a Personal Protective Equipment (PPE) Burn Rate Calculator, which healthcare facilities can use to plan and optimize the use of PPE in response to COVID-19. In addition, CDC's optimization strategies and guidance for PPE offer healthcare facilities a continuum of options when PPE supplies are stressed, running low, or exhausted.

(g) When will CDC collect and publicly release COVID-19 demographic information aggregated at the state and Federal level for residents in nursing homes and other congregate settings?

Answer 3 (g). CDC's National Healthcare Safety Network (NHSN) is the Nation's system for healthcare facilities and the government to track and take actions to address healthcare-associated and antibiotic-resistant infections. The experts use the data to help healthcare facilities and health departments take action and have an impact on care. It dramatically improves patient outcomes and stops the spread of infections.

Begun in 2005, NHSN is used by almost every hospital in the Nation (66,200), more than 7,500 dialysis facilities, and about 3,000 nursing homes—over 25,000 fa-

cilities in total. Since its pivot to meet the needs of the COVID-19 response, an additional 12,000 nursing homes now use NHSN—bringing the total number of healthcare facilities that use NHSN to approximately 37,000.

Beginning in April, all 615,400 CMS-certified nursing homes began reporting COVID-19 case and facility staffing and supply data to NHSN. NHSN was able to provide the first national lens into the burden of disease in nursing homes. NHSN continues to collect COVID-19 data from nursing homes and long-term care facilities. These NHSN nursing home data are key for transparency and are publicly reported on CMS's webpage. On October 15, CDC's NHSN LTCF COVID-19 module Point-of-Care Testing form was released that includes required data fields for race and ethnicity when facilities report testing results from nursing homes and other long-term care facilities. CDC is working with CMS, health departments, and other public health partners to promote use of the NHSN LTCF COVID-19 module to meet CMS reporting requirements for testing conducted by CMS-certified LTC facilities. As more data becomes available, CDC will analyze this data to provide additional estimates of the burden in nursing homes, including by race and ethnicity.

(h) To what extent can Medicare claims be used to analyze the demographics and other characteristics of COVID-19 patients in nursing homes and other congregate settings?

Answer 3 (h). As mentioned previously, CDC is discussing methods for developing internal estimates of COVID-19 burden in long term care facilities by race and ethnicity, including the use of Medicare claims and facility demographic data. However, these will not be as accurate as comprehensive data reporting. As reporting of nursing home COVID-19 testing data expands, CDC will reassess possible methods for developing aggregate estimates of burden based on race and ethnicity.

SENATOR Kaine

Question 1.

What is the domestic and global public health benefit to not collaborating with other nations through the COVAX Facility? Why shouldn't we participate?

Answer 1. The United States does not plan to procure vaccine doses for domestic use through participation in the COVAX facility. CDC is supporting efforts to ensure that high risk populations in every country—including health care workers, older adults, and persons with chronic illnesses—have access to safe and effective COVID-19 vaccines.

Question 2.

Dr. Redfield, should the U.S. vaccine candidates prove viable and this Administration decides to hoard surplus doses domestically while other countries go without, isn't it true that Americans would still be susceptible to imported cases as the world reopens?

Answer 2. CDC's global efforts focus on enabling countries to prevent, detect, and respond to infectious disease outbreaks and other public health threats within their borders. Building partner countries' core public health capabilities so they can stop disease transmission at the source is the most effective way to protect Americans from COVID-19 and other infectious disease threats.

Question 3.

Dr. Redfield, do you believe that at a minimum the U.S. should pledge surplus doses of any successful federally funded vaccine to international efforts like COVAX to ensure a strategic, fair, and rational allocation of vaccines to the rest of the world?

Answer 3. CDC does not plan to procure vaccines for use internationally. Building on CDC's longstanding global immunization efforts focused on polio, measles, influenza, and other priorities, CDC is using COVID-19 funding to provide technical assistance and help ensure that select low-and middle-income countries are ready and able to deploy and evaluate COVID-19 vaccines when they become available.

Question 4.

Dr. Redfield, what steps is CDC taking to ensure that appropriated funds for public health data modernization from fiscal year 2020 and the CARES Act goes toward the critical long-term modernization that our public health systems require? Please provide an update on how funds have been spent and what plans have been made to allocate the remainder of appropriated funds.

Answer 4. Congress has supported CDC's data modernization initiative, including \$50 million in CDC's fiscal year 2020 appropriation and \$500 million in the

Coronavirus Aid, Relief, and Economic Security (CARES) Act, which will support efforts to modernize the Nation's public health data capabilities. These investments will help CDC enhance the capabilities of state and local health departments so they can marshal fast, targeted responses to disease outbreaks; enhance syndromic surveillance to serve as a national early warning system of emerging health threats; and build out laboratory data exchange to enhance rapid and accurate transmission of critical laboratory information, among other improvements. The vision is a real-time, interoperable networked health data system capable of moving faster than the health threats we combat, and we are moving toward that goal.

The investment in data surveillance and analytics will modernize public health data systems across the U.S. at all levels of government. By modernizing public health data systems, CDC will be better equipped to identify, track, and respond to emerging health threats, diseases, and pandemics. Rather than discrete, one-off projects or a narrow focus on individual capacities, CDC has looked at the entire surveillance and data ecosystem and identified the areas most in need of investment and modernization. The initiative will focus on three core parts of the public health data landscape:

1. *Data Sharing Across the Public Health Ecosystem*: Automate data collection and support multidirectional data flows among state, territorial, local, and tribal public health jurisdictions and CDC.
2. *Enhancing CDC Services and Systems for Ongoing Data Modernization*: Adopt enterprise-wide infrastructure and services that enable data linking, sharing, analysis, and visualization.
3. *New Standards and Approaches for Public Health Reporting*: Conduct real-world testing of new standards for accessing data in electronic health records and assess the policy implications of these new approaches.

CDC and its state and local health partners have made important strides in ensuring the Nation's public health surveillance infrastructure is up to the demands of this moment.

Question 5.

Dr. Redfield, what was the role of the CDC versus the White House and the Department of Homeland Security in drafting the March 20 order providing for expulsions of asylum-seekers and unaccompanied children at the border, as well as its April and May extensions? What less restrictive alternatives were considered and why were they rejected?

Answer 5. CDC cannot respond because the subject is an issue of ongoing litigation.

Question 6.

Dr. Redfield, a recent CNN article cited CDC officials stating that the White House asked CDC to conduct research about migration in light of COVID-19, and the team conducting this research raised concerns about the political, rather than public health, motivations of the research with you. Did you elevate those concerns within the Department, including to Secretary Azar? If so, what response did you get?

Answer 6. The COVID-19 pandemic is the most significant public health challenge to face our Nation and the world in more than a century. Approaches to the pandemic must be coordinated across the U.S. Government to keep pace with the needs of the American people and the world. CDC, along with FDA, ASPR, FEMA, Department of State, USAID, and the White House Coronavirus Task Force, and others, is an integral part of that. CDC works hand-in-hand with our colleagues throughout the Administration to ensure a coordinated approach that leverages each agency's authorities and strength.

Question 7.

Dr. Redfield, Acting Customs and Border Protection (CBP) Director Mark Morgan publicly stated last week that the CDC order shutting down asylum may extend after COVID-19 eases, saying "it's not going to go back to the way it was pre-COVID overnight." Why is the Acting CBP Director making such a statement about an order ostensibly issued by CDC? What is the role of the CDC in determining whether the order will be extended, versus DHS and/or CBP?

Answer 7. CDC defers to CBP regarding any statements made by CBP officials. The Order Suspending the Right To Introduce Certain Persons From Countries Where a Quarantinable Communicable Disease Exists (<https://www.cdc.gov/coronavirus/2019-ncov/order-suspending-introduction-certain-persons.html>) was issued pursuant to public health authorities under Title 42 of the United States

Code delegated to CDC. As stated in the Order itself, it remains effective until the CDC Director determines that the danger of further introduction of COVID-19 into the United States has ceased to be a serious danger to the public health, and continuation of this Order is no longer necessary to protect public health. The Order is subject to review by CDC every 30 days and may be extended, modified, or terminated at any time as needed to protect public health.

Question 8.

DHS is allegedly expelling children under Title 42 because of the risk of these children bringing Covid-19 into the country. However, children are returned to home countries if they test negative for Covid-19, thus undermining the stated reason for denying them entry. On what grounds do you justify expulsion of children who test negative? If children test negative for Covid-19 why aren't they being transferred to ORR?

Answer 8. CDC cannot respond because the subject is an issue of ongoing litigation.

SENATOR SMITH

Question 1.

COVID-19 vaccine should be free for all Americans, no matter their insurance status, once it is available.

(a) If I'm an uninsured adult or an adult on Medicaid, will my vaccine be free? Will it depend on where I go to get my vaccine? b. Does Congress need act to make sure people in these situations don't pay anything?

Answer 1 (a). COVID-19 vaccines and ancillary supplies will be procured and distributed by the Federal Government at no cost to enrolled COVID-19 vaccination providers and no cost to the public.

Question 2.

Are you and the Centers for Disease Control and Prevention (CDC) working with Admiral Brett Giroir so that testing is readily available while a vaccine is being distributed? Please provide specific details and plans on these efforts.

Answer 2. CDC is providing resources to communities to enhance and expand testing and epidemiologic activities to control the spread of COVID-19 (<https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/funding-update.pdf>). The Paycheck Protection Program and Health Care Enhancement Act provided \$11 billion to HHS to support testing for COVID-19/SARS-CoV-2. CDC provided \$10.25 billion to 64 state, territorial, and local jurisdictions through the existing Epidemiology and Laboratory Capacity (ELC) cooperative agreement. In coordination with HHS/OASH, the funding will support testing, case investigation, and contact tracing.

SENATOR ROSEN

Question 1.

As you know, our Tribal communities have been especially hard hit by the COVID-19 pandemic. According to the CDC, they are around three and a half times more likely to contract this virus and are also at a high risk for severe outcomes. In Nevada, we have over 27 Tribal Nations, Bands and Colonies, with more than 32,000 members. Ninetyseven percent of our Tribes are rural and are spread across over a million acres of land.

(a) Given that our Tribal communities are especially vulnerable to COVID-19, are all too often populations with high rates of comorbidities such as diabetes, and frequently live in very rural areas, what else should the Federal Government be doing to address the immediate health needs of these communities, and what steps should be taken to ensure robust Federal support for COVID-19 vaccine distribution to be done in an equitable, effective, and culturally competent manner? What lessons were learned from the H1N1 response so we can improve upon past efforts?

Answer 1 (a). CDC's COVID-19 Tribal Support Section (TSS) is working closely with tribal nations, state and local public health officials, and other Federal agencies to implement a comprehensive public health response to the COVID-19 pandemic. TSS provides technical assistance, training, tools, and field support to tribes and tribal-serving organizations to assist them in addressing COVID-19 (www.cdc.gov/coronavirus/2019-ncov/community/tribal/index.html). Areas of technical assistance include data collection and analysis, incident command structure,

increasing access to safe water, community mitigation, and contact tracing. As of October 15, 2020, TSS has completed 30 deployments in tribal communities to provide onsite technical assistance and support, has six active teams deployed and is actively planning to deploy teams to 8 tribes and tribal organizations. Technical assistance for each tribe is tailored to their respective situations, needs, and priorities.

In September 2020, CDC published the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations (<https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim—Playbook.pdf>), a document for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their jurisdictions. The document covers specific areas of COVID-19 vaccination program planning and implementation and provide key guidance documents and links to resources to assist those efforts. The playbook also recommends that jurisdictions review their 2009 H1N1 pandemic vaccination response plans and lessons learned. After-action reports and improvement plans from that time provide an opportunity for jurisdictions to build on prior strengths and determine any gaps that may need to be addressed. CDC's COVID-19 Response Vaccine Task Force (VTF) continues to review plans, standard operating procedures (SOPs), and reports from the 2009 H1N1 response to incorporate lessons learned into COVID-19 vaccination planning.

The Indian Health Service COVID-19 Pandemic Vaccine Plan (<https://www.ihs.gov/coronavirus/vaccine>) further details how the Indian Health Service (IHS) health care system will prepare for and operationalize vaccine distribution for IHS Direct, Tribal, and Urban Indian Health Programs. CDC is working directly with IHS on vaccination planning. It is important that jurisdictions include tribal leaders and tribal organizations in their planning efforts.

CDC has a strong vaccine delivery infrastructure connecting public health departments, health care providers, community groups, pharmacists/chain drug stores, and others that can be used to efficiently reach the population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

CDC is enhancing communications efforts to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities, and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic/Latino communities as these groups have lower rates of influenza vaccination, but higher risk for COVID complications. CDC is testing influenza vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination. CDC has expanded outreach to populations at high-risk of severe COVID-19 by working with new and existing partners, including leveraging existing partnerships with National Association of Community Health Centers (NACHC) and state and local immunization programs to distribute 9.3 million supplemental influenza vaccine doses to those seeking care at community health centers.

Using resources appropriated through the Coronavirus Aid, Relief, and Economic Security Act, CDC provided its immunization awardees \$140 million in supplemental funding to support and enhance their immunization programs.

In addition, CDC has been working with influenza vaccine manufacturers to maximize influenza vaccine supply; CDC is projecting this will increase available doses to 194–198 million this season, about 12 percent more than last year. CDC is also increasing the length of the vaccination season through the duration of flu season, into spring 2021. CDC also purchased an additional 2 million pediatric doses and 9.3 million adult doses to enhance influenza vaccine coverage in under-vaccinated communities. This includes optimizing the use of federally procured vaccine through promotion of influenza vaccination within the Vaccine for Children (VFC) program and expanding partnerships to increase vaccine utilization by community health centers.

CDC is providing increased support and resources for immunization programs and partners, including disseminating guidance for safe immunization services, encouraging vaccination where it is most convenient to maximize vaccine uptake, and developing and disseminating guidance for planning vaccination clinics held at satellite, temporary, or offsite locations.

Question 2.

Dr. Redfield, I've heard from Tribes in Nevada that they are especially concerned about the eventual vaccine distribution process. Given that so many of our Tribal communities are located in rural areas, how is CDC currently ensuring timely and

targeted relief, and how will it equitably deliver COVID-19 vaccines to these communities? Does CDC plan to ship vaccine and ancillary supplies directly to Indian Health Service facilities or directly to Tribes themselves? Additionally, many Tribes lack the financial resources to help their members if there are costs associated with vaccine distribution. How will CDC and other Federal agencies work to ensure there is no cost sharing for Tribal communities to receive vaccines? What else do you need from Congress to ensure we do not leave our Tribal communities behind?

Answer 2. CDC is currently working with the Indian Health Service (IHS), state, territorial, and local public health programs to ensure that tribal communities located within their boundaries have full visibility of COVID-19 vaccine supply and vaccination activities. Tribal subject matter experts at CDC are integrated in the review process for COVID-19 vaccination plans submitted by States and Federal Entities to ensure plans incorporate considerations for vaccine implementation in tribal populations efficiently and equitably.

Tribal Nations are required to decide on their preferences for vaccine allocation—that is, for health facilities serving the communities to either receive vaccine through the state or through the IHS. Tribal Consultation calls occurred in September to review these options. Tribal Nations were asked to assess existing immunization program operations to determine how this can be leveraged for the COVID-19 strategy and communicate the decision to IHS and states. This process will require strong collaboration and close communications between tribal populations, urban Indian organizations, IHS, and the jurisdiction.

While IHS may provide vaccination services to the populations they serve, plans are currently in development regarding vaccine distribution to tribal health facilities, including urban facilities, that are not officially connected to IHS. Those facilities will have the option to work through IHS or work through their jurisdiction to receive vaccine. It is also critical that jurisdictions reach out to any non-federally recognized tribes in their area to ensure they have access to vaccination services, since these groups will likely not be served by IHS. One way tribal communities can ensure close coordination with their jurisdictions is to include a representative or liaison in the Vaccine Task Force or equivalent coordination entity within the jurisdictions COVID-19 response framework.

COVID-19 vaccines and ancillary supplies will be procured and distributed by the Federal Government at no cost to enrolled COVID-19 vaccination providers.

RESPONSES BY ADMIRAL BRETT GIROIR, TO QUESTIONS OF SENATOR SANDERS, SENATOR COLLINS, SENATOR WARREN, SENATOR MURKOWSKI, SENATOR SMITH, AND SENATOR ROSEN.

SENATOR SANDERS

Question 1.

It is clear that there is a commitment to bring a safe and effective COVID-19 vaccine to market as soon as possible. It also is clear that there is a commitment across agencies to work together not only to try to increase diversity in ongoing clinical trials, but to educate the public about the importance of getting vaccinated, especially with flu season upon us. Will you use your expertise and influence to ensure that a COVID-19 vaccine is available at no cost to every person in the U.S.?

Answer 1. The Administration has stated it is committed to providing free or low-cost, safe, and effective COVID-19 countermeasures to the American people as quickly as possible. Any COVID-19 vaccine or therapeutic doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. As is customary with government-purchased vaccines, healthcare professionals could charge for the cost of administering the vaccine. Information on health care provider reimbursement for vaccine administration for the uninsured is available here: <https://www.hrsa.gov/CovidUninsuredClaim>.

Question 2.

In addition to making sure that a future COVID-19 vaccine is free to every person in the country at the point of service, it is critical that health providers and states can afford to purchase the vaccine in bulk and distribute it to the public and, in particular, to vulnerable populations such as seniors and those who are living in rural areas.

- (a) What specific plans does the Federal Government have to directly purchase the COVID-19 vaccine and distribute it to the public, or to help health providers and states purchase the vaccine for distribution?

Answer 2 (a). Ensuring that high risk and vulnerable populations receive the vaccine is of paramount importance. Operation Warp Speed and its private partners are developing a plan for delivering a safe and effective product to Americans as quickly and reliably as possible. Experts from HHS are leading vaccine development, while experts from the Department of Defense are partnering with the Centers for Disease Control and Prevention (CDC) and other parts of HHS to coordinate distribution and administration of vaccines. On September 16, 2020 HHS *released documents* developed by HHS in coordination with DoD, that provide a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their respective jurisdictions. The CDC can provide more information on vaccine distribution as needed.

Question 3.

As you know, there were recently mixed messages from the CDC regarding the airborne transmission of the novel coronavirus. This caused a great deal of confusion among many people and may have contributed to the public's general lack of trust in our public health agencies. In fact, according to a recent Kaiser Family Foundation survey taken before the latest miscommunication, 54 percent of people surveyed said that they "would not get vaccinated" if one was available before the November election. And, this lack of confidence in a vaccine cuts across the political field, with 46 percent of Democrats, and a full six in ten (60 percent) Republicans reporting that they would not get vaccinated.

- (a) What concrete steps are being taken now, as the research continues to move forward, to ensure accurate, consistent, and scientifically reviewed messaging about COVID-19, including the severity of the disease, how the virus is transmitted and how people can protect themselves and each other? Specifically, how are you measuring and evaluating the impact of these efforts?

Answer 3 (a). Presenting accurate and consistent information to the American people is essential. Ensuring that the American people are equipped with the most up to date and scientifically accurate information is of the utmost importance. As more is discovered about this virus and as research continues to move forward, we will continue to provide the public with that information in an accurate and appropriate method so people can continue to make informed decisions on how best to protect themselves and those around.

SENATOR COLLINS

Question 1.

Rapid instrumented molecular point-of-care testing has played an important role in combatting the spread of the COVID-19 virus because they yield results in minutes rather than hours or days. They can also be deployed in settings that enable more convenient patient access to testing. Currently, there is a significant gap in Medicare reimbursement for rapid instrumented molecular point-of-care tests compared with lab-based PCR tests. I understand that this inequity has created a disincentive for health care providers to offer these tests, and I encourage CMS to look at making reimbursement more equitable for these tests to ensure that providers choose the test system that best suits the needs of their patients. Dr. Giroir, how does the Administration plan to address this issue?

Answer 1. Point of care testing is an essential part of our testing strategy and continues to expand in its use throughout the country. These testing modalities are a very important tool in our testing plan and we will work with our colleagues across the Federal Government to ensure that the issues you have raised are addressed. Ensuring access to point of care testing and promoting that access through equitable reimbursement will continue to be explored with the appropriate agencies.

SENATOR WARREN

POLITICAL INTERFERENCE AT HHS

Question 1.

Numerous public reports have revealed that political appointees at HHS and the White House have repeatedly interfered with, undermined, and even overruled career experts at the scientific agencies within HHS, including the CDC and FDA. In August, HHS Secretary Azar reportedly overruled FDA when he revoked the agency's ability to regulate lab-developed diagnostic tests, including COVID-19 tests, potentially undermining the accuracy of the results that patients receive from these

tests. That same month, guidance reportedly developed by HHS and the White House Coronavirus Task Force was published to the CDC's website—reportedly without approval from the CDC—recommending that asymptomatic individuals do not need to be tested, even after exposure to someone with COVID-19. This guidance contradicted clear advice from career CDC officials and other public health experts. At least one public health expert—Rick Bright, the former Director of the Biomedical Advanced Research and Development Authority—has alleged that he was retaliated against for emphasizing the threat of COVID-19 and resisting political pressure in making certain purchases or approvals pushed by White House and other Administration officials.³ In order to better understand the extent of political interference at HHS, we request answer to the following questions:

- (a) What is the extent of political interference at CDC, FDA, and other key public health agencies involved in the response to COVID-19?
- (b) What impact has political interference had on the work of public health experts at HHS, including career officials at its operating divisions, and COVID-19 response efforts?
- (c) Have all applicable laws, rules, regulations, and policies—including the requirements of HHS's, CDC's, and FDA's scientific integrity and communications policies—been followed in the development and issuance of public guidance, reports, or policy changes?
- (d) What role, if any, have entities outside of HHS—including the White House, the Office of Management and Budget, or the Office of Science and Technology Policy—played in developing, revising, and issuing guidance, reports, or policy changes at CDC or FDA?

Answers 1 (a)–1 (d). All response efforts across the Federal Government have been conducted in the best interest of the American people and all of these efforts have been guided by data and grounded in science. Through the entire response, all laws, rules, regulations, and policies have been followed and scientific integrity is supreme in all public communications. There have been no instances of political influences on any actions taken, all actions that have been taken have been based in the most up to date data and science.

SENATOR MURKOWSKI

COVID-19 TESTING SUPPLY ISSUES:

Question 1.

First, I'd like to thank the administration, and particularly you Admiral Giroir for all of the support you have provided in getting testing supplies to Alaska, this support has been critical in making sure the unique needs of hyper-rural areas are *taken into account*. However, I am concerned about what a declining focus from HHS on the distribution of testing supplies, as the private industry capacity increases, could mean for states like Alaska. I have been pleased to see the growth in testing capacity across the United States, and understand that, as the private supply has increased, states are being told to go through traditional private industry channels to access supplies, rather than working through HHS. I'm concerned what this might mean for small, rural states, many of whom are still experiencing high levels of COVID19 transmission. I have been told that larger states are able to put in bulk orders to private industry, and that officials in smaller states such as Alaska are concerned that their orders will not be prioritized going forward. We saw this early on in the outbreak, where states with lower numbers or limited industry presence struggled to get supplies from manufacturers, and the help of the administration was critical in getting supplies to these communities.

- (a) Can you reassure me that the administration will continue to support the distribution of testing supplies to rural areas? What advice do you have for smaller states without large industry presence worried about being left behind?

Answer 1 (a). The Federal Government will continue to help all states procure the materials and supplies they need to conduct testing and meet the goals laid out in each state testing plan. In addition, the Federal Government *announced* on September 28, 2020 and began distributing Abbott BinaxNOW tests to states.

Subsequent to the date of the hearing, on October 13, HHS in collaboration with the Department of Defense (DOD) awarded a \$481 million to Cue Health, Inc. to expand U.S. production capacity for a cartridge-based point-of-care COVID-19 molecular test that produces results in about 20 minutes.

HHS has launched a pilot program with five states to use portable, cartridge-based COVID-19 molecular test kits that provide rapid results. The pilot program will assess how to best integrate diagnostic technology developed by Cue Health, Inc., into strategies for disease surveillance and infection control in institutions such as nursing homes.

During the week of November 9, HHS distributed 27,000 test kits, which include the Cue Sample Wand (nasal swabs) and the Cue COVID-19 Test Cartridges, and 600 Cue Health Monitoring Systems (Cartridge Readers) as follows: 4,500 test kits and 100 cartridge readers each to Florida, Louisiana, New Jersey, and Texas, and 9,000 test kits and 200 cartridge readers to Alaska. Alaska received a greater quantity of components due to the remote nature of access.

MILITARY VACCINE DISTRIBUTION ISSUES:

Question 1.

Admiral Giroir, in the guidance issued by the administration regarding a COVID-19 vaccine and its distribution, military members were not identified as a critical population for the vaccine. This is despite that the Department of Defense and military hospitals having assisted in the development of the vaccine.

- (a) How will military members and their families will be prioritized due to the transit nature of military members with travel, deployments and moves?
- (b) Additionally, how will the military work with state and local health departments in coordination on distributing a COVID-19 vaccine?

Answers 1 (a)–1 (b). Ensuring that high risk, vulnerable, and critical populations receive the vaccine is of paramount importance. Operation Warp Speed and their private partners are developing a plan for delivering a safe and effective product to Americans as quickly and reliably as possible. Experts from HHs are leading vaccine development, while experts from the Department of Defense are partnering with the CDC and other parts of HHS to coordinate distribution and administration of vaccines. On September 16, 2020 HHS released documents developed by HHS in coordination with DoD, that provide a strategic distribution overview along with an interim playbook for state, tribal, territorial, and local public health programs and their partners on how to plan and operationalize a vaccination response to COVID-19 within their respective jurisdictions.

DOD would be in the best position to provide additional information on their plans for vaccine distribution.

SENATOR SMITH

Question 1.

The New York Times recently reported that Americans are receiving surprise medical bills for their COVID-19 tests and related office visits. However, Congress worked in the coronavirus relief packages to make sure Americans would not have to pay for their COVID-19 tests or associated office visits.

- (a) Why are Americans getting charged for COVID-19 tests?
- (b) Should Americans get charged for these tests?
- (c) Should Congress act to stop these testing charges?

Answer 1 (a)–1 (c). HHS is working to ensure that testing is available across the country and has provided funding to states and tribes through the CDC, IHS and to health centers across the country to ensure that testing is affordable or at no cost to Americans. HHS Office of Inspector General will continue to investigate any instances of fraud or abuse. OASH defers to CMS for further inquiries.

Question 2.

Are you working with the Centers for Disease Control and Prevention (CDC) so that testing is readily available while a vaccine is being distributed? Please provide specific details and plans on these efforts.

Answer 2. Yes, I am working with the CDC constantly to ensure that our efforts are complementary. Testing remains a critical component to the response efforts. Testing will continue and the amount of testing available to the American public will continue to increase as we have seen throughout this pandemic. Since March 2020, testing in the United States has increased over 30,000 percent. As more testing technologies are developed and the investments in the supply chain continue to provide more materials, the testing capacity of the United States will continue to

increase. Subsequent to the date of the hearing, as of December 1, the United States is conducting an average of over 1 million tests a day. As of December 17, 2020, over 94 percent of COVID-19 tests results are received within 3 days.

Question 3.

You have previously acknowledged the need to expand testing to asymptomatic individuals since they are known to spread the virus.

- (a) Do you still believe that we should test asymptomatic individuals to suppress COVID-19?
- (b) How many COVID-19 tests are we running per day?
- (c) What is our daily testing capacity?
- (d) If we are not running at capacity, what is impacting our ability to do so?
- (e) Should Congress act to increase daily testing capacity?

Answers 1 (a)–1 (e). As previously stated, testing of asymptomatic individuals is important and CDC guidance (<https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html#who-should-get-tested>) enumerates when this is recommended. Subsequent to the date of the hearing, as of December 1, on average, we are conducting over 1 million tests per day, our daily testing capacity is constantly increasing as new technologies, and other testing modalities are introduced. As of December 17, 2020, over 94 percent of COVID-19 tests results are received within 3 days. Testing capacity does exceed the number of tests conducted each day and we will continue to encourage testing as indicated by CDC guidance.

SENATOR ROSEN

Question 1.

Admiral Giroir, doctors and nurses across the country continue to report issues with still not having enough PPE. There is a lack of transparency regarding how much is being produced, and where. We need a stronger Federal response, and we needed it yesterday. What steps do you recommend to ensure that every front-line worker has exactly what they need to stay safe as they care for the critical needs of this country?

Answer 1. Specific to the current COVID-19 response, as of August 18, 2020, and in coordination with interagency partners including the Department of Defense and the Department of Homeland Security, the Strategic National Stockpile (SNS) has provided more than 18.5 thousand tons of personal protective equipment (PPE) and other medical material to support States to aid in medical response as well as the Federal repatriation effort to bring American citizens back from abroad. Since the start of the pandemic, orders have been placed for approximately 800 million N95 respirators and face masks for delivery to the SNS. HHS has leveraged and utilized actions under the Defense Production Act (DPA). Title I of the DPA allows the President, among other authorities, to require businesses and corporations to prioritize and accept government contracts for materials and services. HHS has exercised Title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the places of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventilators, are in high demand. A priority rating has at times proved necessary to provide the requested quantities and qualities of these health resources within a specified time period or delivery date. These rated orders are filled first when there are both commercial demands and government demands for the same product, or component(s) of a product. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed. HHS is working with DoD to expand domestic manufacturing capacity. The partnership between DoD and HHS, which allowed SNS to tap into DoD's contracting resources and experience with industrial based expansion projects, was critical for the success of the U.S. Government's efforts to expand domestic production capacity of medical supplies during the COVID-19 pandemic. More information about distribution of PPE and investments to support these efforts can be provided by HHS ASPR.

Question 2.

As you know, our Tribal communities have been especially hard hit by the COVID-19 pandemic. According to the CDC, they are around three and a half times more likely to contract this virus and are also at a high risk for severe outcomes. In Nevada, we have over 27 Tribal Nations, Bands and Colonies, with more than

32,000 members. Ninety 7 percent of our Tribes are rural and are spread across over a million acres of land.

(a) Given that our Tribal communities are especially vulnerable to COVID-19, are all too often populations with high rates of comorbidities such as diabetes, and frequently live in very rural areas, what else should the Federal Government be doing to address the immediate health needs of these communities, and what steps should be taken to ensure robust Federal support for COVID-19 vaccine distribution to be done in an equitable, effective, and culturally competent manner? What lessons were learned from the H1N1 response so we can improve upon past efforts?

Answer 2 (a). The CDC can provide additional information in regards to Tribal communities and the distribution of a COVID-19 vaccine. The Indian Health Service (IHS) continues to support an all-of-government COVID-19 response that is locally executed, tribally and state managed, and federally supported. The IHS has a robust system-wide testing strategy that is aligned with the strategy laid out by the White House Coronavirus Task Force. The IHS seeks to continue to maintain a per capita testing rate (by IHS user population) that exceeds the US all races rate AND to maintain positivity of <10 percent. As part of the HHS response to this crisis, on June 23, 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 a 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. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information, which is culturally competent, on resources to help fight the pandemic to those who need it most.

RESPONSES BY DR. STEPHEN HAHN, TO QUESTIONS OF SENATOR MURRAY, SENATOR SANDERS, SENATOR BURR, SENATOR WARREN, AND SENATOR KAINE.

SENATOR MURRAY

Question 1.

Dr. Hahn, just in the last few weeks, Secretary Azar tried repeatedly to undermine the FDA and its public health mission: first, declaring that FDA could not regulate laboratory developed tests, abruptly overruling precedent during a pandemic without any apparent public health justification, and second, stripping the agency's authority to issue any new rules without his sign off.

(a) You said nothing after Secretary Azar stripped FDA of its ability to regulate tests in the middle of a pandemic. What concrete actions will you take the next time Secretary Azar interferes with FDA's ability to protect the public health?

Answer 1 (a). FDA's role is to make independent, science-based decisions and base its review decisions on legal and scientific standards with the overriding objective to help with the development of safe and effective medical products for American patients. FDA review decisions will continue to be based on the statutory requirements and available scientific data.

(b) On October 6, FDA published guidance containing criteria the agency intends to apply in considering whether to issue an emergency use authorization (EUA) for a COVID-19 vaccine. The criteria set forth in the guidance are more rigorous than the legal standard for issuance of an EUA. The same day FDA published the guidance, President Trump tagged you in a tweet in which he asserted that the guidance makes it more difficult for FDA to "speed up vaccines for approval before Election Day" and is "another political hit job." What specific steps will you take if Secretary Azar or the White House attempts to interfere with FDA scientists' review of a COVID-19 vaccine for emergency use or approval?

Answer 1 (b). We ate the data with only the public health in mind. If FDA approves or authorizes a vaccine it will do so when we have determined that it meets the applicable legal standards (set forth in statute for both licensure and authorization) for efficacy and is safe enough to give to our own families.

We at FDA do not permit politics to enter into our scientific decisions. FDA will remain data driven in making public health decisions. On behalf of FDA's 18,000 career employees, we want to reassure the American public about this commitment. It is important that the American people continue to have confidence in the FDA and the decisions we make. Our strength comes in part from the fact that we are a science based, science focused agency, and that we base our decisions only on the best available science.

SENATOR SANDERS

Question 1.

It is clear that there is a commitment to bring a safe and effective COVID-19 vaccine to market as soon as possible. It also is clear that there is a commitment across agencies to work together not only to try to increase diversity in ongoing clinical trials, but to educate the public about the importance of getting vaccinated, especially with flu season upon us. Will you use your expertise and influence to ensure that a COVID-19 vaccine is available at no cost to every person in the U.S.?

Answer 1. FDA's regulatory functions and role in reviewing and authorizing or approving vaccines are distinct from the other HHS operating divisions responsible for determining vaccine accessibility. The following response has been provided by other components of the Department of Health and Human Services (HHS).

On September 16, 2020, HHS and Department of Defense released the Trump administration's detailed strategy to deliver safe and effective COVID-19 vaccine doses to the American people as quickly and reliably as possible through Operation Warp Speed.

In accordance with the plan, the Federal Government is procuring hundreds of millions of doses of vaccines, and has contracted with McKesson Corporation for purposes of vaccine distribution, such that vaccine providers will not be charged for the distribution of the COVID-19 vaccine and recipients will not be charged for its cost. Various plans, supported by the CARES Act and the Families First Coronavirus Response Act, are under development with the objective of ensuring no one will be charged any out-of-pocket costs for the administration of the vaccine either. The objective is to ensure no one desiring vaccination will face an economic barrier to receiving one. Section 3203 of the CARES Act (P.L. 116-136) requires health insurance issuers and plans to cover any Advisory Committee on Immunization Practices (ACIP)-recommended COVID-19 preventive service, including vaccines, without cost-sharing within 15 days of such recommendation to the CDC. Once an authorized or licensed COVID-19 vaccine is recommended by ACIP, and the recommendation is adopted by the CDC Director, required coverage for vaccines as preventative services for Medicaid Early and Periodic Screening, Diagnostic and Treatment beneficiaries and the Affordable Care Act provisions for most private insurance coverage and for the Medicaid expansion populations will also apply.

As part of efforts to make administration sites easily accessible, the vaccination program will make maximum use of all healthcare professionals licensed to administer vaccines, including allied health professionals such as pharmacists. HHS is also committed to ensuring that rural populations can receive the vaccine, and has decades of experience working with public health partners addressing the needs of hard-to-reach populations. CDC will work with local communities, governments, and other partners to identify the best places and times to reach this population and utilize strategic distribution points via community health centers, schools, workplaces, mobile clinics, and pharmacies.

Question 2.

In addition to making sure that a future COVID-19 vaccine is free to every person in the country at the point of service, it is critical that health providers and states can afford to purchase the vaccine in bulk and distribute it to the public and, in particular, to vulnerable populations such as seniors and those who are living in rural areas.

- (a) What specific plans does the Federal Government have to directly purchase the COVID-19 vaccine and distribute it to the public, or to help health providers and states purchase the vaccine for distribution?

Answer 2 (a). Please see the response to #1 above.

Question 3.

It is well documented that African Americans, Indigenous Peoples, and other racial and ethnic minorities have experienced harm and trauma when participating—both voluntarily and involuntarily—in medical research. These populations are also

most at-risk for contracting COVID-19 and experiencing more severe outcomes from the disease. As history has taught us, vaccines are only effective in eventually eradicating a particular disease when there is widespread use. A lack of trust, however, can stall efforts to defeat a pandemic. Please provide specific details about the steps you are taking, and have already taken, to build public trust—especially among the most vulnerable and often hard-to-reach populations, including low-income individuals, people who live in rural communities, older individuals, and racial and ethnic minorities—so that when a safe and effective vaccine is available, it is successfully adopted?

Answer 3. CDC contributed to this response (first seven paragraphs), followed by FDA's response to address the question.

Understanding public confidence in any and all vaccines is necessary for promoting high vaccine uptake, and CDC is adapting its strategic framework, *Vaccinate with Confidence* (<https://www.cdc.gov/vaccines/partners/vaccinate-with-confidence.html>), to strengthen public trust in COVID-19 vaccines. The framework emphasizes three key priorities: reinforcing communication to the public about the vaccine's rollout and its safety and benefits, empowering healthcare providers to communicate effectively with patients about the vaccine, and engaging with individuals and communities.

Building confidence is inherent to all our work, and CDC will continue to build upon the investments of our immunization program as we prepare both the Nation's public health system and the private sector to disseminate a safe and effective COVID-19 vaccine. As COVID-19 vaccine developments continue, CDC is working with Operation Warp Speed (OWS) to ensure community groups, physicians, and the general public receive the most up to date guidance and data on available prevention measures that can help reduce COVID-19 infection and spread. Adapting from approaches used with similar past threats, CDC will work with its public health partners to deliver resources on COVID-19 vaccine that assist physicians with proper vaccine administration and enhances public confidence in COVID-19 vaccine uptake.

CDC is enhancing communications efforts to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities, and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic/Latino communities realizing that these groups have lower rates of influenza vaccination, yet higher risk for COVID complications.

CDC will also be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination coverage among underserved priority populations. In addition, CDC will be consulting individually with 15 national leaders in the field of health disparities, health equity, and social determinants of health to develop strategies to address racial and ethnic disparities in adult immunization.

CDC is testing influenza vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination.

CDC also is committed to ensuring that rural populations, including tribes, can access the vaccine. We have decades of experience working with public health partners addressing the needs of hard to reach populations. We will work with communities, government, and other local partners to identify the best places and times to reach this population and utilize strategic distribution points via community health centers, schools, workplaces, mobile clinics, and pharmacies. Our immunization programs have built a strong public health immunization infrastructure, including through the provision of a safety net for those with no health insurance and through response to outbreaks of vaccine preventable diseases and other urgent public health issues.

In July, CDC released a Health Equity Strategy (www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html) that provides an evidence-based, comprehensive, and coordinated framework for reducing COVID-19 disparities. The strategy includes building on plans for collecting and reporting timely, complete, and representative data on testing, incidence, vaccination, and severe outcomes among populations at highest risk.

At FDA, we recognize that certain populations are more vulnerable to COVID-19 and that there may be unique challenges to building vaccine confidence in racial and ethnic minority and other diverse communities, for example. We also recognize that transparency around FDA's decisionmaking with respect to COVID-19 vaccines

is likely to affect public confidence in these vaccines, and vaccines to prevent other infectious diseases that follow. FDA remains committed to principles of transparency, consistent with our statutory authority and regulations.

To help ensure an evaluation process that is as transparent as possible, and to help the public understand FDA's process for evaluating the safety and effectiveness of new vaccines, FDA has issued guidance related to the Development and Licensure of Vaccines to Prevent COVID-19 (June 2020) and Emergency Use Authorizations for Vaccines to Prevent COVID-19 (October 2020). In addition to outlining our expectations for vaccine sponsors, we also hope the agency's guidance on COVID-19 vaccines helps the public understand our science-based decisionmaking process that assures vaccine quality, safety and efficacy for any vaccine that is authorized or approved. Additionally, FDA convened a meeting of our Vaccines and Related Biological Products Advisory Committee (VRBPAC) on October 22, 2020, to address the general development of COVID-19 vaccines. The VRBPAC consists of a panel of outside independent technical experts from various scientific disciplines that provides input on scientific data and its public health significance in a public forum. We stand ready to promptly schedule additional meetings of VRBPAC to discuss specific vaccine candidates prior to the approval of a Biologic License Application or issuance of an Emergency Use Authorization for a COVID-19 vaccine.

FDA's Office of Minority Health and Health Equity (OMHHE) has also continued to support efforts to advance racial and ethnic minority representation in clinical trials. FDA OMHHE has increased amplification of clinical trial diversity messages, provided tailored FDA COVID-19 communications to racial and ethnic minority stakeholders, and held a listening session with diverse stakeholders to learn more about the gaps in communication with and needs of racial and ethnic minority communities and to share information on FDA's COVID-19 activities.

FDA OMHHE has also increased outreach by disseminating COVID-19 health education materials for consumers in multiple languages. The agency's official COVID-19 webpage: including the *FDA COVID-19 Frequently Asked Questions*¹ has been translated into Spanish. FDA has also created a COVID-19 Multilingual Resources webpage that features a growing collection of educational materials in Spanish, Simplified Chinese, Korean, Vietnamese, and Tagalog, among other languages.

To further enhance outreach and dissemination, FDA launched a COVID-19 Bilingual (English/Spanish) Social Media Toolkit that features consumer friendly messages and culturally appropriate graphics.

FDA has also engaged in considerable outreach with different stakeholder groups to help enhance understanding about the agency's science-based and objective regulatory review process for vaccines. As part of these efforts, FDA's Center for Biologics Evaluation and Research has provided a grant to the Reagan-Udall Foundation for the FDA to assist us in better understand the communication and perception barriers that lead so many Americans to feel hesitant about receiving a COVID-19 vaccine, when available, specifically perceptions related to FDA's role in vaccine review and authorization and approval. A key part of this effort has been a series of listening sessions to gather insight from different communities, as concerns may be specific to those communities' context and history. Listening sessions are prioritized for racial and ethnic minority and other diverse communities, the socio-economically disadvantaged, and essential personnel who may be in greater danger of being exposed to SARS-CoV-2, such as those working in retail and health care settings. The information gained from these sessions will help to inform FDA, build public confidence in COVID-19 vaccine development for the U.S. population, and contribute to adequate COVID-19 vaccine uptake once one or more such vaccines are available. More details regarding the Reagan-Udall Foundation COVID-19 Vaccine Confidence Project can be found on FDA's website.²

SENATOR BURR

Question 1.

The FDA has started the process of a mid-action review of the agency's activities and efficiencies gained during the COVID-19 pandemic. Please provide additional information on the FDA's processes and practices during the COVID-19 pandemic to—

¹ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions>.

² Reagan-Udall Foundation COVID-19 Vaccine Confidence Project: <https://www.fda.gov/media/142838/download>.

Answer 1. FDA remains focused on our public health mission of protecting the health and safety of the American people. The agency has provided regulatory flexibilities and issued temporary policies to help accelerate access to critical medical products, help ensure food safety and address public health issues. FDA's COVID-19 Pandemic Recovery and Preparedness Plan (PREPP) initiative is driven by the agency's commitment to continuous improvement to further its public health mission. PREPP is intended to facilitate learning and adaptation across the Agency as appropriate. The initiative is aimed to support real-time adjustments as needed and will inform recommendations to improve policies and processes as necessary to strengthen the agency's public health impact for future crisis preparedness. The initiative is continuing and ongoing.

A. Accelerate the drafting and publication of guidance documents;

FDA is committed to providing timely recommendations, regulatory advice, guidance, and technical assistance on an agency-wide basis on issues related to COVID-19, including to clarify our policies to support response efforts to this emergency. In accordance with FDA's good guidance practices regulation (GGPs), to facilitate issuance of agency recommendations and policies related to the COVID-19 public health emergency, in March 2020, FDA announced procedures for making available FDA guidance documents related to the COVID-19 public health emergency. In light of the need to act quickly and efficiently respond to the COVID-19 public health emergency, FDA has implemented immediately in effect COVID-19-related guidance documents where prior public participation would not be feasible or appropriate. Although FDA has implemented COVID-19-related guidance documents without prior comment, in accordance with GGPs, the agency solicits comments, will review all comments received, and will revise the guidance documents as appropriate. Each guidance specifies the docket number(s) to which comments can be submitted. These procedures were published in the Federal Register on March 25, 2020, 85 Fed. Reg. 16949.

FDA has issued³ more than 60 COVID-19 related guidance documents and has revised COVID-19 related guidance documents to provide updated policies, transparency, and regulatory flexibility to address the vital medical products and public health issues facing the American public during this pandemic. These guidance documents provide clarity on diagnostics, personal protective equipment, other medical devices, treatment with investigational convalescent plasma, conduct of clinical trials of medical products, blood donor deferrals, hand sanitizer, food safety and supply, telemedicine and other topics.

B. Enhance the communications between FDA review staff and sponsors (or potential sponsors) of medical products for COVID-19;

In response to the urgent nature of the pandemic, in April 2020 FDA launched a new program called the Coronavirus Treatment Acceleration Program (CTAP) to move new treatments to patients as soon as possible, while at the same time finding out whether they are helpful or harmful. CTAP aims to enable the FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to leverage cross-agency scientific resources and expertise to bear on COVID-19 therapeutic development and review. FDA realized there would be a need for early and frequent discussions between the agency and potential sponsors, thus CTAP was also designed to allow inquiries from researchers and developers to be triaged by a team of experienced clinical reviewers, other scientific reviewers, policy experts, and regulatory project management staff to help with proposals, provide additional information, and to quickly direct the proposal to the appropriate organization unit for review.

When CTAP was initially launched, 72 clinical trials of potential therapies for COVID-19 were underway with FDA oversight. As of September 30, 2020, there are more than 550 drug development programs in planning stages, more than 350 clinical trials have been reviewed to determine that an Investigational New Drug (IND) trial is safe to proceed, and five COVID-19 treatments received authorization for emergency use. These numbers are updated monthly and made available to the public at: <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap>.

³ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

C. Expedite the regulatory decisionmaking processes at the agency;

As a critical threshold matter, FDA remains steadfast in its commitment to protect and promote the health and well-being of the American public, and to base regulatory decisions in support of our public health mission on sound science and adequate data. FDA is dedicated to addressing emerging public health issues and promoting innovation while ensuring safety of the products regulated by the agency. In addition to COVID-19 related guidance documents and CTAP, as described in (A) and (B) above, pursuant to section 564 of the FD&C Act, the HHS Secretary has issued Emergency Use Authorization Declarations,⁴ allowing FDA to issue Emergency Use Authorizations (EUA), as outlined in the declarations, for (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an emergency unapproved use of an approved drug, approved or cleared device, or licensed biological product. To issue an EUA, FDA must determine, among other things, that the product may be effective for its intended use and that its known and potential benefits outweigh its known and potential risks. As legally required, FDA periodically reviews the circumstances and continued appropriateness of an EUA, including review of emerging data. If warranted by the data, FDA may revoke or revise an EUA. Subsequent to the date of the hearing, as of October 14, 2020, FDA has six EUAs for therapeutics to treat COVID-19 and serious conditions caused by COVID-19.⁵

Given the unprecedented demand for diagnostic tests, PPE, and other devices, FDA has authorized over 475 devices for emergency use to respond to the current health crisis. The number of device EUAs for COVID-19 dwarfs the total number of device EUAs issued for other public health emergencies. At the same time, the volume of “traditional,” non-COVID-19 submissions (e.g., PMAs, 510(k)’s, de novo request, etc.) received has not changed, resulting in over 10,000 COVID and non-COVID submissions received by CDRH since January 1, 2020.

D. Utilize real world evidence and real world data to generate data to support and accelerate the development and review of products to treat, prevent, or diagnose COVID-19;

Given the large global population infected with COVID-19, the availability of digital health data holds promise to inform product development for the disease. For example, understanding the natural history of COVID-19 can inform clinical trial design. In addition, as many of the drugs being used for COVID-19 are already on the market, approved for use for other conditions, real world evidence (RWE) has the potential to generate hypotheses for future study.

FDA has been an active participant in the COVID-19 Evidence Accelerator, which brings together experts in RWE to answer key questions about COVID-19, including questions related to natural history and the use of therapeutics, to inform further research. The COVID-19 Evidence Accelerator is run by the Reagan-Udall Foundation and Friends of Cancer Research. This collaborative activity focuses on understanding the data, developing consensus around best practices and methodologies and determining which questions such data can most appropriately answer.

In addition, real world data (RWD) may also be collected as part of clinical trials as these trials are capturing clinical endpoints that are recorded during clinical practice, such as discharge from the hospital.

The sharing of data on COVID cases across the globe has also led to insights into risk factors, unusual presentations, and unexpected outcomes for patients infected with this novel respiratory pathogen.

E. Utilize decentralized clinical trials and alternative clinical trial designs to support marketing applications; and

With respect to decentralized clinical trials, recognizing that COVID-19 would disrupt traditional trial operations due to self-isolation, site closures, and travel limitations, among others, FDA promptly issued guidance to as-

⁴ <https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration>; <https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>; <https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>.

⁵ <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

sist sponsors conducting clinical trials during the COVID-19 public health emergency in meeting their regulatory requirements. See FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic.⁶ This guidance was issued on March 18, 2020 and has been updated multiple times, most recently on September 21, 2020. FDA has added 25 questions and answers, many in response to the over 500 inquiries to the mailbox *Clinicaltrialconduct-COVID19@fda.hhs.gov* that FDA set up with the issuance of the first guidance to assist the clinical trial community. The topics addressed by the guidance include use of technology and local providers and facilities in ways that can help decentralize the conduct of clinical trials. In April, a survey of pharmaceutical companies, research participants, investigators and academia done by the Clinical Trials Transformation Initiative, a public-private partnership supported by FDA, reported that 85 percent transitioned to using virtual visits in one or more clinical trials.⁷

F. Exercise available authorities to conduct remote or virtual assessments and inspections and document-based inspections

In March 2020, FDA postponed onsite domestic and foreign routine surveillance inspections due to concerns around the pandemic, although FDA investigators have continued to conduct mission-critical inspections both domestically and abroad, along with other activities, to ensure FDA-regulated industries are meeting applicable FDA requirements. In July, we resumed prioritized domestic surveillance inspections. To help ensure FDA-regulated industries are meeting applicable FDA requirements, FDA's Office of Regulatory Affairs (ORA) is also using FDA's authority under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to request records in advance or in lieu of inspections of establishments that manufacture drugs. ORA is, where appropriate, relying on inspection reports by European regulatory authorities as specified in an agreement between the European Union and FDA. With regard to imported products, FDA is expanding the use of other tools and approaches to help ensure the quality of medical products, including using its statutory authority to refuse admission if a product does not appear to meet applicable FDA standards based on records requested directly from manufacturing facilities, reviewing the compliance histories of facilities information, information shared by trusted foreign regulatory partners through mutual recognition and confidentiality agreements, and physical examinations of products arriving at U.S. borders or product sampling and testing before release into commerce. In furtherance of FDA's commitment to learning from our experiences during this public health emergency, we are evaluating how we can optimize the agency's inspection program, including studying how we might incorporate new technologies and tools to support our inspections.

SENATOR WARREN

TRANSPARENCY IN VACCINE REVIEW PROCESS

Question 1.

Full transparency throughout the review and authorization process for COVID-19 vaccines is essential to countering real or perceived politicization and building public confidence in any approved vaccine. Due to the speed of the vaccine development process, consistent political pressure on FDA from Trump administration officials, and longstanding mistrust of the medical establishment in communities of color, there is currently significant public skepticism about an eventual COVID-19 vaccine. A recent poll found that only 49 percent of American adults plan to accept a coronavirus vaccine, with 20 percent not planning to be vaccinated and 31 percent unsure. A poll from the Kaiser Family Foundation found that 62 percent of Americans are worried that "the political pressure from the Trump administration will lead the FDA to rush to approve a coronavirus vaccine without making sure that it is safe and effective." In order to understand how the FDA is addressing these concerns, my colleagues and I wrote to you on September 14, 2020, requesting answers to the following questions:

⁶ <http://ucms-internet.fda.gov/media/136238/download>.

⁷ <https://www.ctti-clinicaltrials.org/briefing-room/webinars/adapting-clinical-trials-during-covid-19-solutions-switching-remote-and->

(a) Will all meetings of the Vaccine and Related Biological Products Advisory Committee (VRBPAC) to discuss COVID-19 vaccine products, as well as documents reviewed during these meetings, be open to the public?

Answer 1 (a). An open session of FDA's VRBPAC will be convened prior to the issuance of any EUA for a COVID-19 vaccine, to publicly discuss whether the available safety and effectiveness data support issuance of an EUA or a license for the specific vaccine under review. Such discussions, which will be specific to the particular vaccine that is the subject of the EUA request or Biologics License Application (BLA) submission, will be separate from, and in addition to, any general discussion by the VRBPAC regarding the development, authorization, and/or licensure of vaccines to prevent COVID-19. A VRBPAC meeting may also include a closed session, if it is deemed necessary, to discuss proprietary manufacturing information.

FDA intends to provide briefing materials to the VRBPAC members as far in advance of any scheduled meeting as practicable and intends to post a publicly available version of the briefing materials on the FDA webpage no later than two full business days before the day the advisory committee meeting is scheduled to occur.

FDA recommends that, in order to facilitate discussion by the VRBPAC, an EUA request or BLA submission be accompanied by briefing materials summarizing data to support the safety and effectiveness of the vaccine and that the sponsor submissions be fully releasable to the public to be considered at the open session of the VRBPAC. In addition, if requested by FDA, separate briefing materials addressing proprietary manufacturing information for the vaccine should be provided for a closed session. The purpose of any closed session would be limited to the review and discussion of manufacturing information that is considered confidential commercial or trade secret information exempt from public disclosure.

(b) What steps has the FDA taken to prevent political interference in the agenda or discussions at the October 22 meeting of the VRBPAC, in light of its timing shortly before the Presidential election?

Answer 1 (b). Commissioner Hahn and Secretary Azar have repeatedly noted that the evaluation process to determine the safety and effectiveness of a vaccine will not be politicized, and that FDA's professional career staff will be making the required legal and scientific decisions.

(c) Will data generated by COVID-19 vaccine clinical trials be made available to the public? What steps will the FDA take to ensure that enough data are made available to allow the public to evaluate the outcome of the clinical trials, including data used to inform a decision to issue an EUA, while protecting participant privacy?

Answer 1 (c). As noted above, FDA intends to convene an open session of our Vaccines and Related Biological Products Advisory Committee prior to the issuance of any EUA, or approval of a BLA, for a COVID-19 vaccine, to discuss whether the available safety and effectiveness data support issuance of an EUA or approval of a BLA for the specific vaccine under review. As part of this process, sponsors and FDA provide to the Advisory Committee members briefing materials that summarize the data to support the safety and effectiveness of the vaccine under discussion; these briefing materials are made publicly available on FDA's webpage at least 2 days prior to the meeting. FDA's guidance titled "Advisory Committee Meetings—Preparation and Public Availability of Information Given to Advisory Committee Members," recommends that sponsors provide fully releasable briefing materials to facilitate a timely and thorough discussion during the Advisory Committee meeting.

Outside of the Advisory Committee process, there are limits on what FDA can disclose. We are aware that several sponsors have disclosed protocols for their phase 3 trials, and we encourage sponsors to be as transparent as possible during the development and review process.

(d) Will the FDA require public disclosure of the design details of Phase 3 clinical trials for a COVID-19 vaccine, including the procedure for ongoing monitoring of severe side effects and the criteria under which the trial would be ended early?

Answer 1 (d). FDA is encouraging companies to provide maximal transparency into their clinical trial programs. FDA intends to be as transparent as possible, consistent with applicable laws and regulations about what FDA can disclose about pending applications and EUA requests.

(e) How will the FDA assess safety and efficacy for groups with limited participation in early stage clinical trials, including pediatric patients and pregnant people?

Answer 1 (e). With respect to vaccines, FDA supports the inclusion of pregnant women in clinical development programs for vaccines against emerging infectious diseases, including vaccines to prevent COVID-19. Studying such vaccines in pregnant women is important to obtain data pertaining to the safety and effectiveness of use during pregnancy, including data on safety outcomes in infants whose mothers received such vaccines during pregnancy. The Agency is engaging with vaccine manufacturers in planning for the inclusion of pregnant women in pre-licensure clinical trials with COVID-19 vaccine candidates.

Before clinical trials in pregnant women proceed, it is important that adequate nonclinical studies, including reproductive and development toxicity studies in animal models, are conducted, and that safety and immunogenicity data for the vaccine are available from early Phase 1 and 2 clinical studies conducted in nonpregnant individuals. In this regard, FDA has published guidance for industry titled, "Considerations for Developmental Toxicity Studies for Preventive and Therapeutic Vaccines for Infectious Disease Indications," which sets forth recommendations for assessing the developmental toxicity potential of preventive vaccines for infectious diseases for females of childbearing potential and pregnant women. In addition, in 2015, to facilitate pre-licensure studies in pregnant women, FDA convened its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to solicit the input of independent, external experts on the evaluation of investigational vaccines intended for use during pregnancy to prevent diseases in newborn infants. The VRBPAC's input on evaluating safety outcomes in pregnant women and their newborns is broadly relevant to the evaluation of preventive vaccines used during pregnancy, whether intended to protect the mother or the infant.

It is important for developers of COVID-19 vaccines to plan for pediatric assessments of safety and effectiveness, and to ensure compliance with the Pediatric Research Equity Act (PREA). The epidemiology and pathogenesis of COVID-19, and the safety and effectiveness of COVID-19 vaccines, may be different in children compared with adults. In order to ensure compliance with 21 CFR Part 50 Subpart D (Additional safeguards for children in clinical investigations), vaccine developers should discuss with FDA, the considerations on the prospect of direct benefit and acceptable risk to support initiation of pediatric studies, and the appropriate design and endpoints for pediatric studies, in the context of their specific vaccine development programs.

FDA supports the appropriate inclusion of pregnant women in clinical trials for development of therapeutics to treat emerging infectious diseases, including COVID-19. FDA has been working with sponsors during the COVID-19 pandemic to encourage enrollment of pregnant women in COVID-19 treatment trials and is also working to provide treatment to pregnant women through individual patient emergency use investigational new drug applications (INDs) when necessary. FDA has also recently published draft guidance, *Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials*, which describes appropriate circumstances for the enrollment of pregnant women in clinical trials.

FDA has recently published several draft guidances related to therapeutics development during pregnancy and lactation, including: *Post-approval Pregnancy Safety Studies*, *Draft Guidance for Industry: Clinical Lactation Studies: Considerations for Study Design*, *Draft Guidance for Industry: and Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs*, *Draft Guidance for Industry*.

FDA is also involved in broader efforts to increase the availability of high-quality data to support the safe use of drugs, biological products, and vaccines during pregnancy and lactation. FDA's Office of Women's Health (OWH) serves as the Agency lead to the Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC).

(f) What steps has the FDA taken to involve representatives of communities of color, people with disabilities, older Americans, and other groups at elevated risk from COVID-19 in the review process for vaccines?

Answer 1 (f). Amongst other recommendations on developing a safe and effective vaccine, FDA strongly encourages the inclusion of diverse populations in all phases of vaccine clinical development, including populations most affected by COVID-19, specifically racial and ethnic minorities, to help to ensure that vaccines are safe and effective for the indicated populations. Late phase clinical development in adults

should also include adequate representation of elderly individuals and individuals with medical comorbidities to evaluate vaccine safety and effectiveness.

In addition, FDA's Office of Minority Health and Health Equity (OMHHE) has continued to advance racial and ethnic minority participation in clinical trials through a variety of culturally and linguistically competent strategies and resources, including an ongoing campaign to raise awareness on the need for racial and ethnic minority populations to participate in clinical trials. The campaign includes: educational materials in multiple languages that highlight the value of clinical trial participation; public service announcements and social media outreach that encourage different groups to participate; a dedicated webpage with various resources including a communications toolkit; engaging different communities and health professionals to raise awareness about the need for diverse participation; and developing close collaborations across government, academia, and industry to educate consumers about the importance of diverse participation in clinical trials.

FDA has developed policy strategies to support diverse participation in clinical trials, including the collection and reporting of race and ethnicity data, through the issuance of guidance documents, such as Collection of Race and Ethnicity Data in Clinical Trials, Guidance for Industry and Food and Drug Administration Staff.⁸

Hydroxychloroquine in Nursing Homes

Question 2.

Nursing homes continue to be at the epicenter of the spread of COVID-19 in the United States. Recent reports from state inspection officials have revealed that in more than one such facility, residents were treated with hydroxychloroquine without their consent or without approval from state officials. As the agency charged with protecting the public health by ensuring the "safety, efficacy and security" of pharmaceutical products, my colleagues and I wrote to you on September 8, 2020 to request information on what the Food and Drug Administration (FDA) is doing to track adverse events associated with the use of hydroxychloroquine in this population:

(a) Has FDA imposed additional post market surveillance requirements on the manufacturers of hydroxychloroquine? If so, please describe these requirements.

Answer 2 (a). FDA has not imposed additional post-market surveillance requirements for hydroxychloroquine (HCQ) as FDA regulations require post-marketing surveillance and reporting for applicants of approved drugs. Under 21 CFR 314.80, applicants are required to promptly review all adverse experience information obtained or otherwise received by the applicant and submit to FDA post-marketing safety reports either as soon as possible (but no later than 15 days after receipt) if the adverse experience is serious and unexpected or, if not, through periodic adverse drug experience reports. Each sponsor with an approved application must also develop written procedures for the surveillance, receipt, evaluation, and reporting of post-marketing adverse drug experiences to FDA. In addition, through the MedWatch system, FDA has made it easy for healthcare professionals and patients to report adverse events directly to the FDA.

Finally, sponsors of clinical trials using hydroxychloroquine must also report to FDA any serious and unexpected adverse events that occur during the clinical investigation and that might be related to the drug within seven to 15 days, depending upon the seriousness of the event.

(b) What steps has the FDA taken to monitor the use of hydroxychloroquine both before and since the revocation of the EUA? Please describe the steps that have been taken, including whether such steps include monitoring use outside of hospital or clinical trial settings.

Answer 2 (b). As discussed above, FDA has regulations to ensure that important safety information is reported by sponsors when using a drug in an FDA regulated clinical investigation and in commercial use. FDA reviewers analyze this safety information on an ongoing basis to identify new or worsening safety issues with the product.

In addition, FDA's EUA for hydroxychloroquine sulfate and chloroquine phosphate included requirements for tracking adverse events through the duration of the EUA. Specifically, the letter of authorization for hydroxychloroquine required, as a condi-

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>.

tion of the EUA, that health care providers be informed through a Fact Sheet of their obligation to report to FDA all serious adverse events and all medication errors associated with the use of the authorized products. The Fact Sheets for health care providers for hydroxychloroquine and chloroquine outlined information on reporting adverse events to the MedWatch system: submitting a MedWatch form on FDA's website² or using Form FDA 3500 (health professional) and mailing it to FDA or submitting it by fax (1-800-FDA-0178). Additionally, the Fact Sheets for hydroxychloroquine and chloroquine required health care providers to provide patients, prior to treatment, information about reporting side effects to MedWatch or FDA.

As part of its efforts to monitor the drug supply during COVID-19, beginning in April 2020, FDA began monitoring certain medications, including hydroxychloroquine, that were expected to see a surge in increased utilization during COVID-19. FDA continues to measure utilization of hydroxychloroquine and other medications potentially used in the treatment of COVID-19 and other conditions across inpatient and outpatient settings of care.

(c) Has FDA taken steps to track the use of hydroxychloroquine among seniors (adults age 65 or older) for treatment or prevention of COVID-19? If so, please describe the steps that have been taken.

Answer 2 (c). FDA is not aware of any data source that comprehensively tracks the use of drugs linked to specific indications at a national level, particularly for inpatient or long-term care settings. Indeed, even when FDA uses the Sentinel system to explore safety information about a particular drug, it is often difficult to determine if a drug is being used for its FDA approved indication or for a non-approved indication at the physician's discretion; relationship of the use of a drug and an indication are based on temporal associations of available data. FDA does, however, continue to monitor all safety data that is submitted pursuant to FDA's regulatory requirements, and will take appropriate action, if necessary, to protect the public.

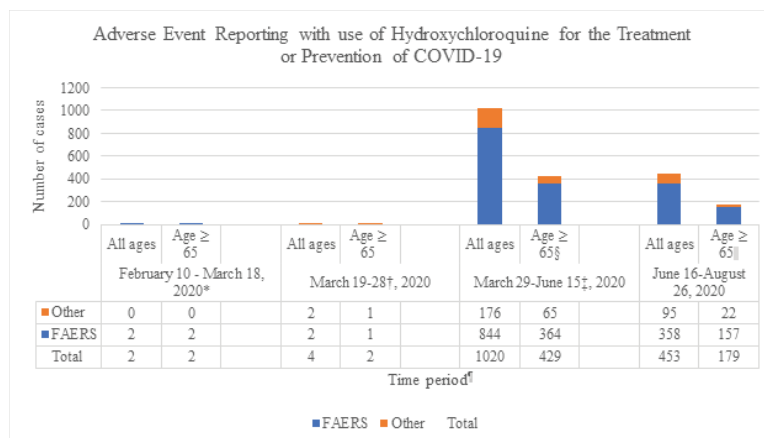
As part of a comprehensive assessment of cardiovascular (CV) adverse events reported to the Agency associated with the use of HCQ, FDA assessed utilization patterns for HCQ in the Medicare population. Although this analysis was not conducted to track the use of HCQ in seniors, it was one of many analyses conducted to assess patterns of concurrent use of HCQ and azithromycin to inform reports of CV events associated with HCQ and azithromycin based on data from MedWatch and other sources.

In this study, approximately 2,000 or fewer Medicare beneficiaries, weekly, had a new HCQ prescription between January 2019 and the week ending March 1, 2020. The weekly number of patients with a new HCQ prescription increased to approximately 2,500 patients in the week ending March 8, 2020, and to more than 14,000 patients during the week ending March 15, 2020. Although this analysis did not include age-specific strata, the Medicare population is comprised of approximately 85 percent seniors aged 65 years and older and 15 percent individuals with a qualifying disability.

Additionally, based on data obtained from other proprietary data bases, total weekly estimates of prescriptions dispensed for hydroxychloroquine from U.S. outpatient pharmacies across any indication and patient age increased from an estimated 115,000 prescriptions dispensed during the week ending February 7, 2020, to a peak of 300,000 prescriptions dispensed in the week ending March 20, 2020. By the week ending May 29, 2020, prescriptions decreased to an estimated 127,000 prescriptions dispensed, a 58 percent decrease from the peak in March.

(d) How many adverse event reports has FDA received regarding hydroxychloroquine since (a) President Trump's March 19 announcement, (b) FDA's issuance of the EUA, and (c) FDA's revocation of the EUA? How many of those reports are associated with seniors?

Answer 2 (d). Figure 1 below shows the number of cases reporting adverse events with the use of hydroxychloroquine for the treatment or prevention of COVID-19 for each requested time period. Data for each time period is represented by two columns. The first column represents the number of cases for all ages and the second column represents only those cases associated with patients 65 years of age and older. Cases in both columns are further categorized into the report source, the FDA Adverse Event Reporting System (FAERS) data base, and other data sources (i.e., medical literature, National Poison Data System (NPDS), and other safety reports).



*FDA/CDER started adverse event case review for all COVID-19 treatments on February 10, 2020. The first hydroxychloroquine case was received March 17, 2020.

†FDA issued an EUA for the use of hydroxychloroquine for treatment of COVID-19 on March 28, 2020.

‡FDA revoked the EUA for the use of hydroxychloroquine for treatment of COVID-19 on June 15, 2020.

§We identified 429 cases with age ≥ 65, though of the total 1020 cases identified in this time period, we note age was unknown or not reported in 62 cases.

||We identified 179 cases with age ≥ 65, though of the total 453 cases identified in this time period, we note age was unknown or not reported in 36 cases and reported only as “60s” in 3 cases.

¶Note that the length of time in each time period is not equal but rather corresponds to the requested time periods.

It should be noted that FAERS does not contain all adverse events occurring with a product and does not collect information about the total number of persons exposed to that product, therefore, FAERS data cannot be used to quantify a risk estimate or calculate the incidence of an adverse event. Given these limitations, it is difficult to interpret and draw conclusions based only on changes in the number of FAERS reports submitted to the FDA. Accordingly, FDA does not focus solely on the number of adverse event reports; rather, we also rely on the quality and scope of information in these reports when assessing adverse events. FAERS data by themselves cannot be used to fully characterize the safety profile of the drug or biologic. Additionally, because FDA reviewers have conducted a hands-on analysis of each report, they have removed duplicate reports, and in some cases, reclassified the adverse event terms for individual cases after reviewing the narrative details, the numbers provided in Figure 1 may differ from the number of the reports that may be obtained from the FAERS public dashboard.

(e) Is FDA conducting additional analysis of the adverse event reports linked to hydroxychloroquine? If so, please describe the analyses being conducted.

Answer 2 (e). In response to the COVID-19 pandemic, FDA has been conducting ongoing surveillance of postmarketing safety data for drug products—including hydroxychloroquine—used in the prevention or treatment of COVID-19 from FAERS, as well as several other data sources for the purpose of identifying newly emerging safety concerns.

(f) Has FDA received any complaints regarding the use of hydroxychloroquine in nursing homes or other congregate care facilities? If so, please provide those complaints.

Answer 2 (f). FDA has not received any complaints regarding the use of hydroxychloroquine in nursing homes.

(g) Has FDA issued any warning letters to nursing homes or other congregate care facilities regarding the use of hydroxychloroquine? If so, please provide those letters.

Answer 2 (g). FDA has not issued any warning letters to nursing homes or other congregate care centers regarding hydroxychloroquine. However, on April 24, 2020, FDA issued a drug safety communication to our stakeholders, including healthcare professionals, alerting the public about reports of serious heart rhythm problems in patients with COVID-19 being treated with HCQ and CQ, often in combination with azithromycin. As such, FDA warned that use of these drugs to treat COVID-19 should be limited to a clinical trial or for treating hospitalized patients under the now revoked EUA for CQ and HCQ. FDA has made it clear in its communications around the revocation of the EUA for CQ and HCQ that FDA does not recommend HCQ or CQ for COVID-19 outside of a clinical trial and has described the risks associated with the use of HCQ and CQ. FDA updated its safety communication on July 1, 2020, to provide a summary of the safety issues associated with HCQ and CQ to treat hospitalized patients, including reports of serious heart rhythm problems, kidney problems and liver failure.

Communication About Changes to EUAs

Question 3.

Transparency about the known and potential risks and benefits of drugs, devices, and biological products authorized under EUAs is critical to protecting public health. However, notification about such risks and benefits are of little use if they are not clearly communicated to health care practitioners and other first responders. With supply chains continuing to experience instability and first responders continuing to face shortages of PPE, Massachusetts health care workers are relying on the FDA to safeguard their health. To better understand how the FDA communicates changes to health care practitioners and the public, I wrote to you on August 24, 2020 to request answers to the following questions:

- (a) Please describe steps the FDA takes to inform any entity that is using a product authorized under an EUA of any modifications or revocations of the EUA, either directly or by imposing conditions on the product manufacturers and importers.

Answer 3 (a). If an EUA is revised or revoked, the Agency communicates to healthcare providers, patients, and the public at large through a variety of mechanisms, as noted above. This includes through stakeholder calls, updates to our EUA webpage, news releases, virtual webinars and town halls, meetings with stakeholder groups, and other communications to help ensure those impacted are aware of these important developments. Many examples can be found on FDA's website.

FDA makes available the most recent EUA documents for issued EUAs (i.e., Letter of Authorization, authorized labeling) on its website. FDA also maintains an archive of revoked EUAs for public reference on its website.

- (aa) Please describe steps the FDA takes to inform any entity that is using a product authorized under an EUA of preliminary data that suggests a change in the known and potential benefits and risks associated with the use of the product that has not yet resulted in modification or revocation of the EUA.

Answer 3 (aa). If FDA identifies an urgent safety signal that warrants public communication before the Agency is able to update the relevant EUA documents, FDA will communicate such information through the various mechanisms the Agency ordinarily employs for other products, such as safety communications, Letters to Health Care Providers, and consumer updates.

As noted, FDA maintains strong communication with all impacted stakeholders, including those who are using EUAs during public health emergencies, and regularly publishes information about new data and issues that we are seeing with EUAs, as well as communicating when we make updates to EUAs and revoke them.

- (b) Please describe how the FDA enforces compliance with modifications or revocations of an EUA, including any consequences for continued distribution or use after a product is no longer authorized.

Answer 3 (b). FDA exercises its inspectional authority to monitor manufacturing facilities and verify that required modifications are implemented and that unauthorized modifications are not made to medical products authorized through an EUA. FDA also monitors the marketplace. The Agency has and will continue to exercise its authorities to address products marketed in violation of the FD&C Act, including issuing Warning Letters, detaining and refusing products at the border, and asking

firms to change claims or remove language that falsely indicates that products are FDA approved or authorized, among other things.

(c) Please describe the role of health care workers and patient advocates in collecting and evaluating information about the safety and effectiveness of products authorized under an EUA, and how their perspectives are considered in decisions about whether to modify or revoke an EUA.

Answer 3 (c). Health care workers on our front lines and patient advocates play a critical role in providing information to the Agency about the safety and effectiveness of products authorized under EUAs. We also rely on these stakeholders to convey information and Agency updates broadly to their networks so that as many people as possible are aware when FDA makes communicates about EUAs. This is particularly critical if there are safety issues and adverse events. For this reason, depending on the facts and circumstances of the product, FDA publishes fact sheets for health care providers, patients, and healthcare facilities (HCFs) regarding use of cleared, approved, and authorized COVID-19 products (including tests, ventilators, respirators, personal protective equipment, and therapeutics) that outline information about the product and how to report adverse events. FDA encourages patients and may, depending on the product, require health care providers to report adverse events and other issues with authorized products to the Agency. This helps inform our continued evaluation of these products so we can take action to update or revoke EUAs when appropriate. Information received from these voluntary or required reports, in addition to other data sources, are important to FDA's continued efforts to protect patients.

SENATOR KAINE

Question 1.

Dr. Hahn, I am very troubled to see that your agency still has not updated the relevant regulations to reflect the new minimum age of sale for tobacco products, even though bipartisan legislation I authored required FDA to put this rule out no later than 180 days post-enactment of our bill—by June 17th, 2020. Given that youth e-cigarette use is still occurring at dangerously high rates, and the increased risk of COVID-19 to youth who use e-cigarettes, can you explain why the FDA has yet to follow through on its statutory obligation and provide a timeline for when we can expect the final rule?

Answer 1. In December 2019, the President signed legislation raising the Federal minimum age for sale of tobacco products from 18 to 21 years. This legislation was effective immediately upon signing. FDA inspections to determine retailer compliance now include the use of 16-to 20-year-olds (prior to T21, FDA used 16-and 17-year-old underage purchasers). FDA appreciates the importance of updating its regulations to conform with this statutory change and the rule is currently pending with OIRA for regulatory review.

Question 2.

Dr. Hahn, if the U.S. participated in the COVAX Facility, in addition to pursuing our own agreements with vaccine manufacturers as we have been doing, wouldn't we be increasing our odds of getting some of the first safe and effective doses of a COVID-19 vaccine to Americans as soon as possible? Why wouldn't we want to do that?

Answer 2. FDA's regulatory functions and role in reviewing and authorizing or approving vaccines are distinct from the other operating divisions responsible for determining vaccine distribution. The following response has been provided by other components of the Department of Health and Human Services.

The COVID-19 pandemic has demonstrated once again that infectious diseases do not respect borders and threaten local, regional, and global economies. Recognizing the critical role that medical countermeasures play in controlling and ending a public health emergency, especially in a pandemic, the USG remains committed to working closely with partners overseas to mitigate the impact of this devastating pandemic. Operation Warp Speed (OWS) has prioritized the research, rapid development, and manufacture of safe and effective, FDA-licensed vaccines, and teamed up with multiple pharmaceutical companies to potentially produce multiple safe and effective vaccines. As vaccine development and approval progresses, the United States will continue to demonstrate strong leadership in global health security and is developing policies to address the international distribution of surplus doses of authorized or licensed vaccines that are procured or reserved by the United States, once our domestic needs are satisfied. In distributing any vaccine, consideration will have to be given to the specific characteristics of the authorized or licensed products, in-

cluding the populations for which the products are most appropriate and product transport, storage, and administration requirements.

[Whereupon, at 1:03 p.m., the hearing was adjourned.]

