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AN EMERGING DISEASE THREAT: HOW THE U.S. IS RESPONDING TO COVID–19, THE NOVEL CORONAVIRUS

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SIXTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING AN EMERGING DISEASE THREAT, FOCUSING ON HOW THE UNITED STATES IS RESPONDING TO COVID-19, THE NOVEL CORONAVIRUS

MARCH 3, 2020

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C O N T E N T S

STATEMENTS

TUESDAY, MARCH 3, 2020

AN EMERGING DISEASE THREAT: HOW THE U.S. IS RESPONDING TO COVID–19, THE NOVEL CORONAVIRUS

Tuesday, March 3, 2020

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

The Committee met, pursuant to notice, at 10:03 a.m., in room 430, Dirksen Senate Office Building, Hon. Lamar Alexander, Chairman of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR ALEXANDER

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

I have one goal today, and that is accurate information, accurate information that can help Americans understand what they should do about the coronavirus, and accurate information to help Members of Congress decide what else we ought to be doing about the coronavirus.

Around the world, the spread of the novel coronavirus is alarming, with nearly 90,000 cases in 65 countries and 3,000 deaths, according to the World Health Organization.

But most people in the United States are at low risk.

Here is what the New York Times said on its front page 2 days ago on Sunday in describing the situation in our country. "Much about the coronavirus remains unclear, and it is far from certain that the outbreak will reach severe proportions in the United States or affect many regions at once. With its top-notch scientists, modern hospitals and sprawling public health infrastructure, most experts agree, the United States is among the countries best prepared to prevent or manage such an epidemic." That's from the front page of the New York Times 2 days ago in describing where we are in our country.

Today in our country, while there are 90,000 cases around the world, there are about 100 cases in the United States, maybe a few more, and about half of those contracted the disease overseas and have been brought back here to be quarantined and monitored. There have been six deaths in the United States.

In addition to the human suffering the virus is causing, it is disrupting the global economy.

According to our trade representative, more than 20 percent of everything we import is from China—medicines, car parts, cell phones, televisions.

China has shut down factories and locked down 16 cities where 760 million people live. Now think about that for a moment; 760 million people is more than twice as many people as live in the United States, and they've been locked down in China as China tries to grapple with this.

In the short term this could disrupt American companies' ability to buy and transport goods and materials. In the long term, the production of these materials could shift, and there would be implications on jobs and prices there.

The first goal of the hearing is to provide the American people with accurate information.

Today's witnesses are respected professionals who have a lot of experience in what we're talking about today and who know what they are doing, and I want to take a moment to emphasize their backgrounds.

Dr. Anne Schuchat, she spent 30 years at the Centers for Disease Control and Prevention. She is the Principal Deputy Director there. Her work has been with these kinds of epidemics through Democratic and Republican presidents and health emergencies, including the 2001 anthrax attack, the 2003 SARS outbreak, and the 2009 flu pandemic.

Dr. Anthony Fauci. Dr. Fauci has held his position as the Chief of Infectious Diseases at the National Institutes of Health since President Reagan's time. So he's worked for Presidents Reagan, H.W. Bush, Clinton, Bush, Obama, and now President Trump. He led the agency's response to HIV/AIDS in the 1980's and 1990's and the emergence of the West Nile virus in 1999, SARS in 2003, and the Ebola outbreaks in Africa in 2014 and 2018. For these professionals, this is not their first rodeo.

Third, 14 years ago, led by Senator Burr of this Committee, Congress created the position of Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. Dr. Robert Kadlec was working for Senator Burr at the time. He helped draft the bill. He now holds the position that was reauthorized by Senator Casey and Senator Burr not long ago. Dr. Kadlec had previous work assisting the FBI and the United States Air Force in biological threats.

Finally, Dr. Stephen Hahn is the newest to the Federal Government of these respected professionals, but he's had plenty of experience before becoming Commissioner of the U.S. Food and Drug Administration, the FDA. Most recently he was Chief Executive of the University of Texas' MD Anderson Cancer Center, a large organization with 21,000 employees.

The reason I go through that is because if we're looking for accurate information, these four ought to be able to provide it.

Now, in addition to getting accurate information for the American people, we want it ourselves to know what else we should be doing to limit the damage of the coronavirus to the American people and the American economy.

Before we talk about what else needs to be done, I want to briefly summarize what we have already done.

Let's start with Congress. It's not the first public health threat we have faced. There are some Senators and staff members who are here today who were here 20 years ago when the anthrax attack occurred; in 2003, SARS, another coronavirus similar to the one we are seeing today; the 2009 flu pandemic killed an estimated 151,000 to 575,000 people worldwide; and then there was the Ebola outbreak in 2014 and 2018.

Following the anthrax attacks in the Bush administration, Congress created Project BioShield in 2004 to develop and stockpile new treatments and vaccines.

After the SARS attack in 2006, also in the Bush administration, Congress passed the Pandemic and All-Hazards Preparedness Act. That guides the Federal Government in how it prepares for and responds to public health emergencies. It gave the Department of Health and Human Services the authority, for example, to prioritize funding for the development of vaccines and treatments for infectious diseases, and improved the Public Health Emergency Fund.

The Senate, as I said earlier, passed the most recent update of the pandemic law led by Senator Burr and Senator Casey.

Senator Blunt and Senator Murray, in their work on the Appropriations Committee, fund public health preparedness programs.

We all know that presidents and their budgets, and this includes all the presidents that I know about, sometimes underfund these programs. But last year, Congress provided more than $4.5 billion for public health and preparedness programs.

When a crisis occurs, we often need money quickly. That's why Congress has created two funds, the Public Health Emergency Fund and the Infectious Disease Rapid Response Fund.

For example, Secretary Azar has already used $105 million from the Rapid Response Fund, and using authority Congress has given him, he is transferring $136 million from other programs in his department to respond to the coronavirus. And the Trump administration has requested an additional $2.5 billion. Others in Congress have made suggestions, and we're likely to vote on that in the Senate this week.

In addition to what Congress has done to get ready for pandemics like this, both Democratic and Republican presidents over the last 20 years have used their executive authority during public health emergencies.

President Obama sent the military to West Africa during the Ebola outbreak. President Bush sent CDC experts around the world to investigate and respond to the SARS epidemic. President Trump similarly appointed a task force on January 29. He put the Vice President in charge. He moved Ambassador Birx from the State Department, who has had years of experience dealing with infectious diseases, to be a principal deputy leading that effort.

On January 31st, at a time when there were only six confirmed cases in the United States, the Administration, for the first time in 50 years, announced they would quarantine Americans who have been exposed to the virus while in China and impose travel

restrictions on foreign nationals who have traveled to China in the last 14 days.

At the same time, the State Department warned Americans not to travel to China, and the CDC recommends Americans reconsider cruises in Asia. A couple of days ago the State Department added Italy and South Korea to the countries that Americans should reconsider traveling in.

Under the authority of the Immigration and Nationality Act, the Administration said foreign nationals who have traveled to China in the last 14 days can't enter the United States. On Saturday, the President updated this to include travelers from Iran. Dr. Fauci, who is testifying today, has said that if we had not taken these steps, we would have had many more cases right now.

A third example of executive action is developing a test to diagnose the coronavirus. The FDA authorized that on February 4th. It has been made available to 46 labs in 38 states and Washington, DC.

Two days ago the FDA authorized a new test developed in New York. It is working with 65 other private-sector developers, including academic medical centers and commercial labs, to increase the availability of these tests.

Fourth, Dr. Fauci has said that we're developing a vaccine for coronavirus more rapidly than we have ever developed any other vaccine, and drug manufacturers met with the President yesterday to see if vaccines and other treatments could be made available more rapidly.

Finally, scientists at our national laboratories—Oak Ridge, Argonne, and Livermore—are using their super-computing and imaging capacity to try to understand this virus better.

Of course, in addition to the impact on us in our individual lives, there's the impact on the global economy. The trade representative says about 20 percent of what we import comes from China. As people get sick and can't go to work, that slows down what's sent here and has an impact across the board. Thirteen percent of the facilities that make active ingredients for drugs are in China, according to the FDA. Some people have said that 80 percent of the ingredients for drugs are produced in China. We should evaluate that figure carefully. It appears to be based on a 1998 report that may not have a source.

But I have discussed with a number of Senators how we can inquire into whether we should explore the dependence we now have on other countries, not just China, for medicines and health supplies. Most businesses in the United States that need supplies have more than one source for what they do. Perhaps we need to take another look at that.

It's not just medicines that are affected. In Tennessee we have Eastman Chemical. They have nine manufacturing plants. The CEO said the recent Phase 1 China trade deal caused orders to go up in his company, but the coronavirus problems in China have caused them to go down, and that has an effect on jobs in Tennessee, just as it does jobs in other places.

Today's hearing is an opportunity to listen carefully to four respected professionals who have decades of experience and are the right people to give the American people and Members of Congress

accurate information about the coronavirus, both what individuals can do and what else the Federal Government needs to do to respond.

We are going to finish by noon today so that Dr. Schuchat and Dr. Fauci can join the Vice President in briefing Senators at our respective lunches.

Senator Murray.

OPENING STATEMENT OF SENATOR MURRAY

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

Thank you to all of our witnesses today. I just want to say at the top that I'm really grateful to all the women and men out there who are working now to keep our country safe, and I hope you pass it along to all of your teams as well.

Mr. Chairman, this is really a frightening time. At least six people in my home State have already died from the virus. I am told we should expect more. We expect the number of infections to continue to grow, and the people across my State, and I'm sure across the Nation, are really scared. I'm hearing from people who are sick, who want to get tested, are not being told where to go. I'm hearing that even when people do get tested, and it's very few so far, the results are taking way longer to get back to them.

The Administration has had months to prepare for this, and it is unacceptable that people in my state and nationwide can't even get an answer as to whether or not they are infected.

To put it simply, if someone at the White House or in this Administration is actually in charge of responding to the coronavirus, it would be news to anybody in my state, and I've been on the phone with all of our local officials for days now.

This is unacceptable. We are now seeing community transmission of this virus. Families deserve to know, and fast, when testing will actually be ready to scale up; what they, the families, should be doing; and most importantly, what we are doing. And unfortunately, I have to say that while I am profoundly grateful for the work public health officials are doing, I'm very frustrated at the steps the President has taken, from repeatedly contradicting experts' advice to downplaying the seriousness of this threat, and to appointing a politician to lead the response.

I'm really glad today, Mr. Chairman, that we have the opportunity to hear today directly from the experts and get answers to the questions that I am hearing at home that I know people want answered, and one of those is when are we going to scale up this testing, especially now that we are beginning to see community transmission in the United States? After all, it's only after a long, frustrating delay that we are finally able to start testing patients for this disease at State labs across this country, and the last few days seem to confirm what experts have been warning, that this is likely to continue spreading.

We now have more than 100 cases of coronavirus that have been tested in this country, including repatriated cases. While there's a lot we are still learning, there are a few things that are abundantly clear about how we need to respond.

First of all, we do need to be listening to the experts and making sure facts and science drive our response. In particular, the public

needs to be able to trust the information they are hearing from experts, and the Federal Government is in no way influenced by political considerations or ideology, and that the policies being put in place are based on evidence about how to keep our families safe, not fear or prejudice.

I was very heartened to hear your assurances, Dr. Fauci, that contrary to reporting, you have not been muzzled by the Administration. It is essential that continue to be the case. We cannot have an effective response without accurate information and transparency from the Administration, and I will continue to be very focused on this.

Secondly, we've got to provide adequate resources to meet the needs of our Federal, state, and local health officials, because we know resources that come through programs like CDC's Public Health Emergency Preparedness Program are absolutely critical, but also were never envisioned to be sufficient to respond to a threat like this. So we have a lot more to do.

Congress, as you know, is now working on a bipartisan emergency supplemental funding agreement that will reimburse our State and local public health officials for costs they've already incurred combating coronavirus and provide additional resources to our communities. It will guarantee resources are available to respond to outbreak hotspots. It will support development of vaccines and therapeutics to prevent and treat this virus, and invest in public and global health programs to keep us prepared to respond to future emergencies.

I do want to thank and recognize all the Democrats and Republicans who came together to work quickly on this package, and I urge the Senate to pass it very quickly. I'm very glad we're working on that agreement that goes well beyond President Trump's inadequate request for $1.25 billion in new funding, and I really again urge the Senate to take this up as soon as the House does get it passed and get it to our local communities who are dealing with this.

I am also very encouraged by this Committee's strong bipartisan record in responding to public health emergencies as well. Just last year, this Committee strengthened and reauthorized the law underpinning so many of the Federal efforts and resources we are seeing employed today.

especially want to thank you, Mr. Chairman, for our work together, Senator Casey and Burr for their efforts on that.

Third, we have got to be sure we aren't just responding to the latest developments but staying ahead of this crisis by planning ahead, because this is not likely going to end anytime soon. We are already seeing some of the challenges that will come next, like the strain this will put on our healthcare system. We're seeing that in Washington State.

We need to make sure our hospitals have the capacity to address this virus without overwhelming their ability to provide other care that people need.

We need to make sure that those healthcare workers caring for coronavirus patients are safe from infections themselves, including by making sure we have a sufficient supply of protective equipment.

We need to manage our Nation's drug and medical device supply, especially considering we expect demand for some supplies, and are already seeing that, to skyrocket; and how many drugs and devices are manufactured in countries where an outbreak could interrupt production, something that we again are already seeing.

We also need to give adequate attention to our public health education. In an age where disinformation has been weaponized and falsehoods and rumors gain traction, as we all know, faster than ever, we can't let conspiracies stoke panic or spur ugly discrimination or spread dangerous misinformation or undermine our public health experts. We need to actively take steps to prevent and respond to bullying and harassment that is motivated by stereotypes and fear.

We also have to account now for the ways that some of the harmful healthcare policies have undermined our ability to respond to public health threats. Our uninsured rate is going up again, for the first time in years. Junk plans, which are not required to cover diagnostic tests or vaccines, are expanding. And those actions make it much harder for people to get the care they need to keep this crisis under control.

We have to make sure that everyone who needs it has access to diagnostic testing going forward. And while a vaccine is still likely over a year away, we need to make sure cost is not a barrier for that as well.

But it's not just our healthcare system we need to be considering as we work to stay ahead of this disease. Communities and families right now are facing difficult decisions. What measures should our schools take to keep our students safe? What can parents do? When should schools close? Employers and workers in my state, and I'm sure others, are facing similar questions about whether their employees should go to work or whether they should stay home. I will be pressing Secretary DeVos more later this week about how her department is helping to prepare for these issues, and I've written to Secretary Scalia about this as well.

As is so often the case, this public health threat will have hidden and higher costs for those who are low-wage workers who don't have affordable child care, who don't have health insurance, and who are experiencing homelessness. In my home State, people are being told to stay home for 2 weeks if they are sick. There aren't tests, so they can't get tested. Guess who can't stay home? If you don't have child care, if you're a low-wage worker, if you don't have sick leave. When those people's basic needs are not met, they cannot make choices to protect themselves, which means they can't make choices that best protect others too, because one person getting sick has repercussions for all of those around them.

Situations like this remind us that we are all a community in a very real sense. We all have a stake in one another's well-being. So when we talk about the impacts of this health threat, I want to be clear this is not just about changes in the stock market, but we also need to develop plans responsive to the day-to-day experience families actually have, and that is something I plan to raise today and will keep raising.

I look forward today to hearing from all of our witnesses about how we can best prepare our communities, and I will continue to

work with all of you and our health officials to keep families in my state and across the country informed about what they should be doing, what we are doing, and to keep them safe. And I'll keep pushing to make sure that as this situation continues to develop, we keep listening to the experts, providing our health officials the resources they need, and planning for the long term.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murray, and thank you for your cooperation, which is typical of the way you work in dealing with this issue.

Senator Murray and I have hosted four briefings for Senators, several briefings for staff. At Senator Burr's suggestion, we had one of our Senate briefings in a classified setting so Senators could be sure there weren't any secrets, that what we were saying in private is the same thing we're saying in public, and nothing came up in that meeting that we aren't able to say in public. And I agree with her that we should listen to our four professional, respected experts who are here today.

Each one will have 5 minutes to give his or her testimony. Then we'll go to a round of questions.

I gave each of them a pretty good introduction earlier, so I'll shorten it here, except to say Dr. Schuchat is the Principal Deputy Director for the Centers for Disease Control and Prevention. And she's had a variety of roles dealing with responses to SARS, to anthrax, to pandemic influenza over the last 30 years.

Dr. Tony Fauci is the top person at the National Institutes of Health in infectious diseases. He's held his position since 1984. He's worked with six presidents and led the Institute's efforts on HIV/AIDS, influenza, malaria, Ebola, and other infectious diseases.

Dr. Robert Kadlec is Assistant Secretary for Preparedness and Response at the Department of Health and Human Services. As I mentioned earlier, he spent time as Career Officer and Physician in the Air Force, Special Assistant to President George W. Bush. Working with Senator Burr, he helped write the legislation that makes our country better prepared for pandemics.

Finally, Dr. Stephen Hahn, who is the Commissioner of the U.S. Food and Drug Administration. He was formerly the Chief Executive at the University of Texas MD Anderson Cancer Center in Houston.

All of you are not getting much sleep these days. We thank you for your willingness to serve the American people in the way that you do, and we look forward to your testimony.

Dr. Schuchat.

STATEMENT OF DR. ANNE SCHUCHAT, PRINCIPAL DEPUTY DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. SCHUCHAT. Thank you so much, Chairman Alexander, Ranking Member Murray, and Members of the Committee.

CDC's role in this whole-of-government, whole-of-society response is built on decades of our infectious disease experience in pandemic influenza and other emergency preparedness planning. Our response is dependent on support from core public health capabilities

at CDC and at a network of dedicated, front-line public health workers at the state and local level living in your communities.

Two months into this response to a novel virus, CDC has learned a lot. We have acted nimbly in the United States and around the world, but we do so with humility about the work ahead. There are many things that each of us can do as individuals, businesses, communities, and organizations, and we're thrilled to see the website posted behind the Senators.

CDC is responding with the following strategy. Our goal has been to slow the spread of this virus through a multi-layered, aggressive containment, and, as needed, mitigation effort. We're using evidence-based public health interventions that have included early case recognition, isolation, and contact tracing. We've issued travel advisories and dealt with targeted travel restrictions, as well as the use of quarantine for individuals returning from transmission hot zones, including through funneling of flights from Hubei Province and mainland China to 11 airports. We've worked with the CBP to get data to ensure that appropriate follow-up could happen through the state and local public health departments, and we've supported the quarantine of repatriated Americans from Hubei Province and from the Diamond Princess cruise ship.

We've been working with the World Health Organization and ministries of health around the world, underscoring our leadership in global public health and the power of our investments in international influenza surveillance and global health security. More than 1,500 staff at the Centers for Disease Control and Prevention have been responding to this outbreak.

The situation today is evolving and dynamic. In just 2 months, this outbreak has grown from a cluster of pneumonia in China in one city to affecting over 70 countries and territories around the world, with more than 90,000 cases and about 3,000 deaths. We are now in the United States seeing, in addition to the very small number of travel-associated cases or close contacts, we are seeing community transmission in a few areas and a tragic outbreak in a healthcare facility or long-term care facility in Washington State.

Our hearts go out to the people affected by this virus directly or indirectly, and to everyone who is working so hard to counter it.

There are steps each of us can take. I want to recognize that people are concerned about this. As always, our number-one priority is the health and safety of the American people, and we appreciate that Americans are taking this threat seriously and continuing to seek information about how they can prepare.

While the immediate risk to the general American public remains low, and the U.S. Government is doing everything we can to keep it low, risk varies by exposure, and some areas of the country are now experiencing community spread.

State and local jurisdictions where community spread of the virus is occurring are intensely investigating and assessing potential community interventions. CDC has got staff on the ground in Washington and California and elsewhere to provide technical assistance. Our role in these types of community measures is to develop principles and tools based on our updated pandemic planning playbook and based on what we've learned from other areas that

have been experiencing the outbreak, including in Singapore, where they have done a very good job of managing it.

A key planning principle is to protect the most vulnerable. I trust you as senior leaders in your communities to help us with our mission to provide clear information to you and your constituents by urging people to get the facts from CDC.gov, which you can see up there, and I want to say that I look forward to answering your questions.

[The prepared statement of Dr. Schuchat follows:]

PREPARED STATEMENT OF ANNE SCHUCHAT

In late December 2019, Chinese authorities announced a cluster of pneumonia cases of unknown etiology centered on a local seafood market in Wuhan, China, with an estimated case onset in early December. CDC immediately began monitoring the outbreak, and within days – by January 7, 2020 – had established a Center-led Incident Management Structure. On January 21, 2020, CDC transitioned to an Agency-wide response based out of its Emergency Operations Center. This allows CDC to provide increased operational support to meet the outbreak's evolving challenges and provides strengthened functional continuity to meet the long-term commitment needed to curb the outbreak.

CDC is assisting ministries of health in countries in every region of the globe with their most urgent and immediate needs to prevent, detect, and respond to the COVID–19 outbreak.

CDC's most expert and practiced infectious disease and public health experts are dedicated to this response 24/7 to protect the American people. CDC is a disease preparedness and response agency, and this work is fundamental to our mission both domestically and internationally. The Agency's approach to COVID–19 is built upon decades of experience with prior infectious disease emergencies including responses to SARS, MERS, and Ebola, and to pandemic influenza.

To mitigate the impact of COVID–19 within the United States, CDC is working alongside Federal, state, local, tribal, and territorial partners, as well as public health partners. This public health response is multi-layered and includes aggressive containment and mitigation activities with an objective to detect and minimize introductions of this virus in the United States so as to reduce its spread and impact. It is impossible to catch every single traveler returning from an affected country with this virus – given the nature of this virus and how it's spreading. Our goal continues to be slowing the introduction of the virus into the United States as we work to prepare our communities for more cases and possible sustained spread.

To accomplish this, CDC is also working with multiple countries, in collaboration with U.S. Agency for International Development (USAID) and other federal agencies and WHO to support ministries of health around the globe to prepare and respond to the outbreak. For example, the U.S. Government is helping to support countries to implement recommendations provided by WHO related to the identification of people who might have this new infection, diagnosis and care of patients, and tracking of the outbreak. CDC staff are also starting to work together with interagency colleagues in those countries to conduct investigations that will help inform response efforts going forward.

The Agency is using its existing epidemiologic, laboratory, and clinical expertise to gain a more comprehensive understanding of COVID–19. CDC is leveraging prior programmatic investments in domestic and global public health capacity and preparedness to strengthen the Agency's response to COVID–19. Thus far, this response has been built largely on the foundation of our seasonal and pandemic influenza program's infrastructure. The ongoing response to COVID–19 also demonstrates CDC's continued commitment to strengthen global health security. CDC has been engaged in global health security work for over seven decades. Thanks to investments in Global Health Security, the U.S. Government's work has helped partner countries build and improve their public health system capacity. This global effort strengthens the world's ability to prevent, detect, and respond to infectious diseases like this new coronavirus.

This outbreak also underscores the need for the United States to continue to play a leadership role on the global stage, and to strengthen global capacity to stop disease threats at their sources, before they spread. Furthermore, the outbreak demonstrates the importance of continued investment in our nation's public health infrastructure. Despite years of progress in domestic disease prevention and response,

efforts to help modernize our federal, state, and local capability and health systems that are crucial to responding to and understanding unprecedented threats continue.

The U.S. Government has taken unprecedented steps to prevent the spread of this virus and to protect the American people and the global community from this new threat and allow State, local, territorial, and private partners time to prepare for any necessary response and mitigation activities. Since February 2, 2020, pursuant to arrival restrictions imposed by the Department of Homeland Security, flights carrying persons who have recently traveled from or were otherwise present within mainland China or other affected countries have been funneled to designated U.S. airports with CDC quarantine stations. At these airports, passengers are subject to enhanced illness screening and self-monitoring with public health supervision up to 14 days from the time the passenger departs the affected country. This enhanced entry screening serves two critical purposes. The first is to detect illness and rapidly respond to symptomatic people entering the country. The second purpose is to educate travelers about the virus and what to do if they develop symptoms.

These measures are part of a layered approach which includes our other core public health efforts, including aggressively tracking COVID–19 around the globe, building laboratory capacity, and preparing the national healthcare system for community spread. These core capabilities and expertise are essential to CDC's comprehensive approach to addressing this outbreak.

While CDC believes that the immediate risk of this new virus to the American public is low, CDC is preparing the nation's healthcare system to respond to identification of individual cases and potential person-to-person transmission of COVID–19 in the community, at the same time ensuring the safety of its patients and workers. CDC has developed guidance on appropriate care and infection control for patients with COVID–19 and is engaging regularly with clinical and hospital associations to confirm that its guidance is helpful and responsive to the needs of the healthcare system.

Furthermore, understanding the current constraints of the global supply of personal protective equipment (PPE), CDC is working with industry and the U.S. health system to comprehend possible effects on facilities' abilities to procure the needed levels of PPE, and to provide strategies to optimize the supply of PPE.

Effective disease surveillance enables countries to quickly detect outbreaks and continuously monitor for new and reemerging health threats. CDC continues to monitor the COVID–19 situation around the world.

CDC has begun working with domestic public health laboratories that conduct community-based influenza-like illness surveillance and leveraging our existing influenza and viral respiratory surveillance systems so that we may begin testing people with flu-like symptoms for the SARS–COV–2 virus. HHS is developing plans to expand this effort.

This collaboration with domestic public health labs is another layer of our response that will help us detect if this virus is spreading in a community. All of our efforts now are to prevent the sustained spread of this virus in our communities, but we need to be prepared for the possibility that it will spread. Results from this surveillance could necessitate changing our response strategy.

CDC has issued guidance for people at high risk of exposure to the virus, including flight crews, recent travelers to China, and healthcare workers. Through its extensive Health Alert Network, CDC shared guidance for clinical care for healthcare professionals and state and local health departments. Health departments, in consultation with healthcare providers, can evaluate patients and determine whether someone may have the illness and should be subjected to additional diagnostic testing.

CDC has a demonstrated record of innovative science and evidence-based decision-making, and an experienced and expert workforce that is working 24/7 to combat this public health emergency. The COVID–19 outbreak is evolving rapidly, and the U.S. Government is constantly making adjustments to respond to the changing nature of this public health emergency. Our goal continues to be slowing the introduction of the virus into the United States and preparing our communities for more cases and possible sustained spread. While leaning forward aggressively with the hope that we will be able to prevent community spread, CDC remains vigilant in confronting the challenges presented by this new coronavirus.

The CHAIRMAN. Thank you, Dr. Schuchat.

Dr. Fauci, welcome.

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

Dr. FAUCI. Thank you very much, Mr. Chairman, Ranking Member Murray, Members of the Committee. I appreciate the opportunity to spend a few minutes talking to you about one of the aspects of the all-government response to this emerging outbreak, and that is in the realm of what we call interventions both with regard to therapy, namely treatment of a person who is already infected, and the other is in the area of vaccines or prevention of infection for those who are not infected.

It's important to point out that the timelines for each of these are fundamentally different, and I'd like to just take a moment to kind of explain why, when you talk about and the American public and the global public understandably want to know how quickly we can get interventions to them. So let's start off first with therapy.

As we know from the data that have come out predominantly from China, if you look at the now 90,000 people who have been infected and the number of deaths that have occurred, about 80 percent of individuals who get infected do really quite well without any specific intervention. Namely, they spontaneously recover. However, about 15 to up to 20 percent of individuals, usually those who are elderly and in risk groups, wind up getting serious disease requiring supportive care. That could be oxygen, that could be intensive care, that could be intubation or even more dramatic interventions.

We want desperately to have a therapy for these individuals. There are a number of candidate therapies that literally as I speak to you today are being tested in randomized control trials. One of these is called remdesivir, which was developed by the Gilead Company. It is being tested in a large trial in China, and it is also being tested here in the United States in an NIH-sponsored trial in collaboration with Gilead. We should know within a period of a few months, several months, whether or not this particular drug works. If it does, the implementation of that would be almost immediate.

Now, I can't guarantee that it will work, or other drugs which are in the pipeline a little bit behind them. But the timetable for treatment is different than the timetable for a vaccine, and that's why I want to see if we can clear up any misunderstandings that are sometimes out there.

Right now, the technology that we have has allowed us to go from the time the sequence of the virus was put in a public data base to the time we actually stick a candidate into the arm of someone, has gone down to literally be the fastest that we have ever done. I expect that at least one of those candidates—and it's not the only one—will likely go into clinical trials in a Phase 1 study within about 2 months, or maybe even 6 weeks. That would be a record. However, that is not a vaccine, because it would take about 3 months or more to show that it is safe. And then if you show that it's safe, you've got to put it into what's called a Phase 2 trial to show that it works. And the reason is there are medical, ethical, and other considerations. We'd be giving this to normal people to prevent infection, so you must be sure of the edict of med-

icine: First, do no harm. So we need to make sure it's safe, and we need to make sure it works.

That entire process will take at least a year or a year-and-a-half. So when we hear talk about a vaccine is going to be ready in a couple of months, it won't be ready for being deployed. It's going to take a while. So we're going to have a multi-step process. We have the public health measures that you've heard about from Dr. Schuchat. You'll hear about it from Dr. Hahn and Dr. Kadlec.

But the issue is, in addition to those public health measures, interventions are going to be critical. So we hope that we'll be able to get good news to you and that we'll be able to say in the next X number of months that we have candidates, but there will be no guarantee of that, and the only way to know that will be to do the kind of clinical testings that I'm talking about.

Hopefully we'll have the opportunity to update you on a regular basis about where we are with that. Thank you.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY FAUCI

The National Institutes of Health (NIH) is the HHS agency leading the research response to the global health emergency of COVID–19. Within the NIH, the National Institute of Allergy and Infectious Diseases (NIAID) is responsible for conducting and supporting research on emerging and re-emerging infectious diseases, including COVID–19.

NIAID is well-positioned to respond rapidly to infectious disease threats as they emerge by leveraging fundamental basic research efforts; a domestic and international research infrastructure that can be quickly mobilized; and collaborative and highly productive partnerships with industry. NIAID provides preclinical research resources to scientists in academia and private industry throughout the world to advance translational research for emerging and re-emerging infectious diseases. These research resources are designed to bridge gaps in the product development pipeline, thereby lowering the scientific, technical, and financial risks incurred by industry and incentivizing companies to partner in the development of effective countermeasures including diagnostics, therapeutics, and vaccines.

NIAID also supports the Infectious Diseases Clinical Research Consortium, which includes a network of Vaccine and Treatment Evaluation Units (VTEUs). The VTEUs conduct clinical trials to investigate promising therapeutic and vaccine candidates when public health needs arise. NIAID collaborates with other Federal agencies, including through the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), to help advance progress against newly emerging public health threats. In addition, partnerships with academia, the biotechnology and pharmaceutical industries, domestic and international researchers, and organizations such as the World Health Organization (WHO) are integral to these efforts.

NIAID has a longstanding commitment to coronavirus research, including extensive efforts to combat two other serious diseases caused by coronaviruses: SARS and MERS. This research has improved our fundamental understanding of coronaviruses and provides a strong foundation for our efforts to address the challenge of SARS–CoV–2, the novel coronavirus that causes COVID–19. NIAID has responded to the newly emerging COVID–19 outbreak by expanding our portfolio of basic research on coronaviruses. NIAID scientists have rapidly identified the human receptor used by SARS–CoV–2 to enter human cells. In addition, NIAID investigators and their collaborators recently identified the atomic structure of the spike protein, an important SARS–CoV–2 surface protein that is a key target for the development of vaccines and therapeutics. NIAID scientists also are evaluating the stability of SARS–CoV–2 on various ordinary surfaces and in aerosols to better understand the potential for viral spread throughout the community.

NIAID-supported researchers are assessing the risk of emergence of bat coronaviruses in China, including the characterization of bat viruses and surveys of people who live in high-risk communities for evidence of bat coronavirus infection. Such research is necessary to better understand this emerging infection and to investigate optimal ways to diagnose, treat, and prevent COVID–19.

The NIAID Centers of Excellence for Influenza Research and Surveillance (CEIRS), which conduct influenza risk assessments in multiple sites throughout the

world particularly in Asia, have responded rapidly to the COVID–19 outbreak. CEIRS researchers at the University of Hong Kong are evaluating the epidemiology, transmission dynamics, and severity of COVID–19. These scientists also have performed environmental sampling of the Wuhan market where the first COVID–19 cases were reported.

NIAID is working with CEIRS collaborators and the CDC to obtain additional virus and biological samples from patients to further advance research efforts on COVID–19. Recently, the NIAID-funded BEI Resources Repository made samples of SARS–CoV–2 available for distribution to domestic and international researchers at Biosafety Level 3 laboratories. In addition, CEIRS researchers and other NIAID-supported scientists are developing reagents, assays, and animal models that can be used to evaluate promising therapeutics and vaccines. These research resources also will be shared with the domestic and international scientific community as soon as they become available.

On February 6, 2020, NIAID issued a Notice of Special Interest regarding the Availability of Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus. This notice encourages existing NIAID grantees to apply for supplements for research project grants focused on the natural history, pathogenicity, and transmission of the virus, as well as projects to develop medical countermeasures and suitable animal models for preclinical testing of COVID- 19 vaccines and therapeutics.

NIAID has responded to public health concerns about COVID–19 by increasing ongoing coronavirus research efforts to accelerate the development of interventions that could help control current and future outbreaks of COVID–19. These activities build on prior NIAID research addressing other coronaviruses, such as those that cause SARS and MERS.

The CDC has developed a real-time Reverse Transcription-Polymerase Chain Reaction (rRT–PCR) test that can detect COVID–19 using respiratory samples from clinical specimens. NIAID is accelerating efforts to develop additional diagnostic tests for COVID–19, and NIAID-supported investigators are developing PCR-based assays for SARS–CoV–2 to facilitate preclinical studies and aid in the development of medical countermeasures. NIAID scientists also are developing reagents for an enzyme-linked immunosorbent assay for SARS- CoV–2. CEIRS researchers at the University of Hong Kong have developed a separate RT–PCR test and made their protocol publicly available through the WHO. These NIAID-supported investigators also have distributed assay reagents to 12 countries to facilitate the diagnosis of COVID–19.

NIAID is pursuing the development of antivirals and monoclonal antibodies for potential use against SARS–CoV–2. NIAID has launched a multicenter, randomized controlled clinical trial to evaluate the safety and efficacy of the antiviral drug remdesivir for the treatment of COVID–19 in hospitalized adults with laboratory-confirmed SARS–CoV–2 illness. The adaptive design of this trial will enable the evaluation of additional promising therapies. NIAID plans to assess other existing antivirals for activity against SARS–CoV–2, and NIAID scientists are working to identify monoclonal antibodies with therapeutic potential from COVID–19 patient samples as well as historical SARS patient samples. NIAID-funded scientists also aim to delineate new viral targets to facilitate the development of novel therapeutics with broad activity against coronaviruses. Finally, NIAID is expanding its suite of preclinical services to add assays that investigators can use to accelerate research and development of therapeutics for COVID–19.

A safe and effective vaccine for SARS–CoV–2 would be an extremely valuable tool to stop the spread of infection and prevent future outbreaks. Public and private entities across the globe have announced plans to develop SARS–CoV–2 vaccine candidates following the release of the SARS–CoV–2 genetic sequence. NIAID is supporting development of several SARS- CoV–2 vaccine candidates, and is utilizing vaccine platform technologies that have shown promise against the coronaviruses that cause SARS and MERS.

The NIAID Vaccine Research Center (VRC) is collaborating with the biotechnology company Moderna, Inc., on the development of a vaccine candidate using a messenger RNA (mRNA) vaccine platform containing the gene that expresses the VRC-designed spike protein of SARS–CoV–2. NIAID anticipates the experimental vaccine will be ready for clinical testing in the NIAID VTEUs within the next two months and will conduct preclinical studies as well as a first-in-human study of this COVID–19 vaccine candidate. The Coalition for Epidemic Preparedness Innovations (CEPI) will fund the manufacture of the first clinical production lot of this mRNA-based vaccine candidate using the Moderna rapid manufacturing facility.

NIAID Rocky Mountain Laboratories (RML) scientists are collaborating with Oxford University investigators to develop a chimpanzee adenovirus-vectored vaccine

candidate against SARS–CoV–2; in addition, they have partnered with CureVac on an mRNA vaccine candidate. RML investigators also have launched a collaboration with the University of Washington and have begun early-stage testing of an RNA vaccine candidate against SARS- CoV–2. In addition, NIAID-supported scientists at Baylor College of Medicine and their collaborators are evaluating an experimental SARS–CoV recombinant protein vaccine to determine if it also provides protection against SARS–CoV–2. NIAID is exploring additional collaborations with extramural research and industry partners on other vaccine concepts. NIAID also is supporting the development of standardized assays and animal models that will be utilized to evaluate vaccine candidates.

With all these efforts, NIAID is coordinating closely with colleagues at the CDC, BARDA, FDA, DOD, and other federal and international partners.

To achieve the ultimate goal of having a SARS–CoV–2 vaccine available to the public, it is important that NIAID and the entire biomedical research community pursue a range of vaccine strategies in order to be better positioned to overcome the scientific or technical challenges associated with any particular vaccine approach. In this regard, NIAID has dedicated resources toward preclinical research to advance a robust pipeline of vaccine candidates into Phase 1 clinical evaluation. Further vaccine research, including Phase 2 clinical trials, will then be required. Additional research also is needed to better understand the fundamental biology of coronaviruses and to facilitate the design of vaccines that elicit optimal immune responses and protect against infection.

While ongoing SARS–CoV–2 vaccine research efforts are promising, it is important to realize that the development of investigational vaccines and the clinical testing to establish their safety and efficacy take time. Although we plan to begin early-stage clinical testing of an NIAID-supported vaccine candidate in the next few months, a safe and effective, fully licensed SARS–CoV–2 vaccine will likely not be available for some time. Currently, the COVID–19 outbreak response in the United States remains focused on the proven public health practices of containment – identifying cases, isolating patients, and tracing contacts.

NIH is committed to continued collaboration with other HHS agencies and additional partners across the U.S. government and international community to advance research to address COVID–19. As part of its mission to respond rapidly to emerging and re-emerging infectious diseases throughout the world, NIAID is expanding our efforts to elucidate the biology of SARS- CoV–2 and employ this knowledge to develop the tools needed to diagnose, treat, and prevent disease caused by this virus. NIAID is particularly focused on developing safe and effective COVID–19 vaccines. These efforts also help to expand our knowledge base and improve our continued preparedness for the next inevitable emerging disease outbreak.

The CHAIRMAN. Thank you, Dr. Fauci.

Dr. Kadlec, welcome.

STATEMENT OF DR. ROBERT KADLEC, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. KADLEC. Thank you, Chairman Alexander, Ranking Member Murray, and distinguished Members of the Committee. I really appreciate the opportunity to testify before you today on how ASPR is supporting the HHS in whole-of-government response to the coronavirus situation.

I think you heard from Dr. Schuchat very well, and Dr. Fauci, in terms of the evolving, rapidly evolving domestic situation, and this morning I'll just take a couple of minutes to give you an idea about how we're trying to address this problem from a point of strategic anticipation, to Senator Murray's point.

ASPR has a four-pronged approach to basically manage and support the domestic preparedness and response, incident management, direct support to states and other entities, supporting the healthcare system of the United States, and also medical countermeasure development.

In the area of developing counter measures, we are working very closely with Dr. Fauci at NIH and our DOD colleagues to see what kind of therapeutics and specifically diagnostics we can rapidly bring to bear to this problem and see how quickly we can field additional capabilities that CDC has already fielded with commercial activities.

Specifically, we're looking at areas that would allow us to do point-of-care diagnostics, which I think Senator Murray has talked about, and we have some very promising candidates that will take several months to bring online. But we're also identifying potential therapeutics. Dr. Fauci has talked about remdesivir. We're also working with a company on monoclonal antibodies and looking at two potential vaccine candidates, one that was a product of the investments that Congress made in pandemic influenza with a recombinant vaccine that is licensed by the FDA and made by Sanofi, and another one that is a product of the candidate vaccine that was developed for the Ebola crisis made by Janssen.

Those are very important and very active activities we're moving on, first of all.

Second, we're looking at how do we support America's healthcare system. Through the Hospital Preparedness Program, working in coordination with the Public Health Emergency Preparedness Program at CDC, we've been looking at how can we basically work better to improve collaboration and coordination amongst hospitals and the public health sector and other entities like emergency medical services.

I just want to highlight one area that, again, Congress was very crucial in developing and employing during the Ebola crisis, which is the National Ebola Treatment Network. That has proved to be vital in terms of our ability to manage this not only through the repatriation of Americans who were taken from Wuhan, but also from the Diamond Princess. That capacity and that capability and that, if you will, education and training were vital in how we managed it at the locations on those military bases, as well as I think Spokane, Washington actually housed a number of people through the Regional Ebola Treatment Network, and that was vital in terms of how we could do that.

The other issue is around how are we doing incident management. Since this had started, we've been working with FEMA to actually put in place, and we have activated formally as of yesterday, an incident management network that really is based on the national response framework. It's how can we bring the whole of government to respond. This is the first time we've done it formally. We've done it under exercises, but it's a means by which we can leverage FEMA and all the emergency support functions that may be necessary by states, when asked, to basically employ responders to assist them in dealing with this crisis.

The last area I'll just highlight is really around the direct support to states and other entities. I mentioned our repatriation efforts, 1,100 Americans brought back under very difficult circumstances from Wuhan and from the Diamond Princess, the first time that was ever done. But we had been working 2 years in advance across HHS and with our Japanese colleagues to actually prepare for such an event, and we're actually supposed to have an

exercise in March of this year to actually employ this as a test case, but we actually got to do it as a real thing. And so we executed that.

But more importantly, we're now focused on how do we provide direct State aid. And so with the State of Washington, we've used the Strategic National Stockpile to deploy personal protective equipment to protect healthcare workers. To highlight what Dr. Schuchat has said, we are very concerned about how do we work proactively with healthcare entities like long-term care facilities, like elder care areas, where we know the most vulnerable populations reside, and how do we shield them from the effects of this potential virus.

Last, we're looking to actually employ and deploy some of our national disaster medical system personnel, as well as other Federal healthcare personnel to assist at the Evergreen long-term treatment facility. So we're doing all these things really together as a team to respond to this.

With that I'll pause and yield back the rest of my time. Thank you, sir.

[The prepared statement of Dr. Kadlec follows:]

PREPARED STATEMENT OF ROBERT KADLEC

Currently, there are no vaccines or therapeutics approved by the FDA to treat or prevent novel coronavirus infections. The Biomedical Advanced Research and Development Authority (BARDA), part of ASPR, is working with counterparts across the government, including within HHS and with the Department of Defense (DOD). The team is reviewing potential vaccines, treatments, and diagnostics from across the public and private sectors to identify promising candidates that could be developed to detect, protect against, or treat people with coronavirus infections. BARDA is working closely across the U.S. Government to assess and identify potential partners and technologies suitable to address the COVID–19 outbreak – both for prevention and treatment.

This has allowed BARDA to leverage existing partnerships, accelerating the development of COVID–19 medical countermeasures, including diagnostics, therapeutics, and vaccines.

Established partners, including Regeneron, Janssen, and Sanofi Pasteur, have shown success in developing both prophylactic and therapeutic medical countermeasures for emerging infectious diseases.

BARDA is collaborating with Regeneron to leverage their partnership agreement to develop multiple monoclonal antibodies that, individually or in combination, could be used to treat this emerging coronavirus. Regeneron's monoclonal antibody discovery platform, called VelocImmune, was used to develop a promising investigational three-antibody therapeutic which was deployed to treat Ebola in the most recent outbreak in the Democratic Republic of the Congo, and an investigational two-antibody therapeutic to treat MERS. The technology shortened multiple aspects of the product development timeline for therapeutics to treat MERS and Ebola from years to months. The technology helped shorten certain stages of drug development, including the process of antibody discovery and selection, preclinical-scale manufacturing, and clinical-scale manufacturing. BARDA and Regeneron are working to utilize these monoclonal antibodies, produced by a single clone of cells or a cell line with identical antibody molecules, which will bind to certain proteins of a virus, reducing the ability of the COVID–19 virus to infect human cells.

BARDA is working with Janssen to leverage their Ebola, Zika, HIV vaccine platform to expedite development of vaccines that protect against the SARS–CoV–2 virus. Using existing resources, BARDA will share research and development costs and expertise with Janssen to help accelerate Janssen's investigational COVID–19 vaccine into clinical evaluation. Janssen will also scale-up production and manufacturing capacities required to manufacture the candidate vaccine. This same approach was used to develop and manufacture Janssen's investigational Ebola vaccine with BARDA support; that vaccine is being used in the Democratic Republic of the Congo as part of the current Ebola outbreak response. Additionally, BARDA and Janssen are working together to help develop treatments for coronavirus infec-

tions. Janssen will conduct high throughput screening on thousands of potential antiviral compounds in order to identify medicines that could safely and effectively be used to reduce the severity of illness and treat COVID–19 infections, as well as identify compounds that have antiviral activity against SARS- CoV–2 as an initial step in developing new treatments. These products include those in development to treat and prevent MERS or SARS, which are caused by coronaviruses also related to COVID–19.

Finally, in their work with Sanofi Pasteur, BARDA is able to leverage a licensed recombinant influenza vaccine platform to produce a recombinant SARS–CoV–2 vaccine candidate. The technology produces an exact genetic match to proteins of the virus. DNA encoding the protein will be combined with DNA from a virus harmless to humans, and used to rapidly produce large quantities of antigen which stimulate the immune system to protect against the virus. The antigens will be separated and collected from these cells and purified to create working stocks of vaccine for advanced development.

BARDA has initiated early steps of medical countermeasures development with partners and will continue to work to accelerate this process. Availability of these medical countermeasures is essential to save lives and protect Americans against 21st century public health threats.

Our nation's healthcare system is better prepared than it has ever been. For example, all 50 states have Pandemic Plans, as a requirement of CDC's Public Health Emergency Preparedness Program (PHEP) and ASPR's Hospital Preparedness Program (HPP). HPP was established after the September 11, 2001, terrorist attacks, with the goal of improving the capacity of local hospitals across the country to deal with disasters and a large influx of patients in an emergency. Using HPP funding, state grantees initially purchased equipment and supplies needed for emergency medical surge capacity. Over time, the program has successfully evolved to support local, coordinated healthcare coalitions, including hospitals, public health facilities, emergency management agencies, and emergency medical services providers. Investments administered through PHEP and HPP have improved individual healthcare entities' preparedness and have built a system for coordinated healthcare system readiness. HPP is the only source of federal funding to prepare the nation's mostly private healthcare system to respond to emergencies, including COVID–19.

Beginning in 2018, ASPR has been supporting Regional Disaster Health Response Systems (RDHRS) pilot projects. The RDHRS concept aims to provide funding directly to hospitals and healthcare systems to establish multi-state regional partnerships to increase preparedness and response capability and capacity for hospitals and healthcare facilities in advance of, during, or immediately following incidents, including emerging infectious diseases. Two sites were selected in September 2018 to begin development of RDHRS pilots. In 2019, two grants were awarded to support new centers of excellence pilots focused on pediatric disaster care. The RDHRS and Pediatric Disaster Care Center of Excellence cooperative agreement requirements are intentionally aligned to ensure synergy between the programs and collaboration between all sites and facilities. Ultimately, these efforts inform best practices to help ready healthcare delivery systems for disasters and emergencies and are critical in aiding response and limiting the impact of disaster. As you all are aware, the United States is in the middle of influenza season. Many emergency departments are at 90 percent capacity. If influenza worsens, or if COVID–19 intensifies domestically, emergency departments would be severely strained, which is why supporting models such as the Hospital Preparedness Program healthcare coalition network is so important.

The National Ebola Training and Education Center (NETEC) combines the resources of healthcare institutions experienced in treating Ebola to offer training, readiness consultations, and expertise to help facilities prepare for Ebola and other special pathogens. The regional Ebola and other special pathogen treatment centers, of which ASPR and CDC funded 10 across the country, all have respiratory infectious disease isolation capacity or negative pressure rooms for at least 10 patients, including pediatric patients. The NETEC and the regional Ebola and other special pathogen treatment centers have been used to support recent quarantine efforts.

Should the coronavirus infections increase domestically, these centers will become critical in isolating infected persons and providing adequate treatment.

ASPR and CDC also work to enhance medical surge capacity by organizing, training, equipping, and deploying Federal public health and medical personnel, such as National Disaster Medical System (NDMS) teams, and providing logistical support for federal responses to public health emergencies. NDMS was originally created during the Cold War to take care of military casualties from overseas in U.S. civilian hospitals. Today, NDMS teams are deployed to strategic locations across the

country, caring for U.S. citizens who may have been exposed to SARS–CoV–2, effectively providing medical care and limiting the potential spread of the disease.

Recently, to assist in the repatriation effort, ASPR stood up a National HHS Incident Management Team (IMT) located in Washington, DC. The IMT serves as the national command and control element, deploying Public Health Service Commission Corps Officers and NDMS personnel.

In addition, HHS provided cache equipment, (e.g., medical supplies and resources) to Travis AFB, Marine Corps Air Station Miramar, Lackland, Air Force Base, and Camp Ashland to support evacuees quarantined at these facilities. HHS deployed one Disaster Medical Assistance Team (DMAT) and one IMT on February 12, 2020, to support American citizens in Japan on the Diamond Princess cruise ship, as well as the U.S. Embassy, to provide medical care, prescriptions, and behavioral health support.

Many active pharmaceutical ingredients and medical supplies, including auxiliary supplies such as syringes and gloves, come from China and India. This outbreak demonstrates why ASPR is seeking innovative solutions and partnerships to better protect national security. ASPR is working to increase access to personal protective equipment (PPE) by:

- Coordinating with CDC and other Federal agencies to share information about optimization of PPE, to prevent overbuying and overuse of existing supplies
- Engaging private sector partners who manufacture and distribute PPE to share information and concerns, and to explore options to anticipate and meet the needs of the U.S. healthcare sector more effectively. During recent discussions, for example, distributors informed us that they have implemented allocations to help prevent stockpiling at healthcare facilities. The allocation is a percentage of a customer's previous orders and is designed to help protect the healthcare supply chain and ensure the right supplies are available for those who need it.
- We are also partnering with other Federal agencies such as DHS, DOD and the U.S. Department of Veterans Affairs who are large buyers of PPE, to develop acquisition strategies that incentivize industry to expand PPE production while not exacerbating supply challenges.

The Strategic National Stockpile (SNS) holds thousands of deployable face masks, N95 respirators, gloves, and surgical gowns that could be deployed if state and local supplies are diminished due to the current COVID–19 response and commercial supplies are exhausted. The SNS is working hand-in-hand with commercial supply chain partners and other Federal agencies to continue monitoring supply levels and to prepare for a potential deployment of SNS personal protective gear if it is needed.

The CHAIRMAN. Thank you, Dr. Kadlec.

Dr. Hahn, welcome.

STATEMENT OF DR. STEPHEN HAHN, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. HAHN. Thank you, Chairman Alexander, Ranking Member Murray, and other Members of the Committee. I really appreciate the opportunity to speak to you today about FDA's efforts.

First of all, on behalf of the 15,000 FDA employees, our hearts go out to those who have been affected by the novel coronavirus and those who have lost their lives. That's why we have deployed thousands of FDA career men and women to address this and to proactively look at aspects of diagnostics, as well as the medical supply chain.

I will focus today's update on areas where FDA has recently communicated new information, supply chain impacts, and expediting the availability of certain laboratory-developed diagnostic tests. Please remember that some of this information that I can share now does change quickly, but it is my hope that this information will help Members of this Committee, as well as the American people, have better visibility into the emerging situation.

Regarding the drug supply, we have been and continue to be proactive in contacting manufacturers not only to remind them of the applicable reporting requirements, but also to ask them to assess their entire supply chain, and much of what we're asking manufacturers they are not required to tell us but, as you might expect, they've been very forthcoming in these discussions.

Since January 24th, FDA has been in touch with more than 180 manufacturers of human drugs to assess whether they face any drug shortages due to the outbreak. As a result of this outreach, last week one manufacturer did tell us about a shortage related to the novel coronavirus. That was reported and immediately disclosed to the American public through our Drug Shortage List.

The good news about that is that we are working very closely with that manufacturer, and we expect that to be resolved in a very short period of time. The other good news is that there are alternatives to that drug that are available to providers and patients.

I know that there is interest in additional details surrounding this drug, but I can't provide the name because it's confidential commercial information.

I think this also highlights what we put in the budget proposals regarding the authorities that the FDA has here. We do not have the authorities to actually require manufacturers of devices to tell us about shortages. Again, they've been very cooperative with us, as have the drug companies with respect to giving us the information that we need.

Please be assured that if other potential shortages or disruptions in medical products are identified by the FDA, we will be very transparent about this and we will quickly share that information with you.

A fast-breaking bit of information that we just found out this morning is that India has restricted the export of 26 active pharmaceutical ingredients for export, which represents about 10 percent of their export capacity. We're working very closely to look at that list to assess how that will affect the medical supply chain.

Regarding devices, we have been in touch with 63 manufacturers of essential medical devices. We've been aware and have been told of no shortages of those devices, although we understand on the demand side particularly, on personal protective equipment and masks, that there is significant pressure and demand, particularly domestically. But we're working very closely with those manufacturers. What we have found is that some of the manufacturers in China have reported disruptions in the workforce, as you might expect, particularly in Wuhan Province.

In an effort to mitigate any potential shortage of anything—respirators, other personal protective equipment for healthcare—FDA, as you know, yesterday issued an emergency use authorization to allow the use of NIOSH-approved disposal filtering face-piece respirators—masks, basically—and to allow some flexibility for healthcare workers, and to increase the supply within the Nation. We have a lot of information that we're communicating to hospitals and healthcare workers about that, but that should increase the capacity for the healthcare system.

Regarding diagnostic tests, on February 4th, as was mentioned by Chairman Alexander, the FDA issued an EUA to enable immediate use of a diagnostic test that was developed by CDC, and facilitating the ability for this test to be used in CDC-qualified public health labs. On February 29th we also issued an EUA to authorize testing for the COVID–19 at two public health labs in New York, and since that time additional labs on the West Coast, Washington and California, have also notified that they have begun testing using this emergency EUA approach.

We've had a lot of contact with both private and public and academic centers with respect to the development of these tests. As I mentioned yesterday, we've seen, in cooperation with CDC, a significant expansion in the ability to perform those tests. We have one manufacturer who is working closely with the CDC to expand that over this upcoming week, and we expect that to be available, those kits, to providers by the end of the week, and that expansion will continue.

Thank you for the opportunity to update the Committee on the FDA's response to this crisis, and I look forward to answering your questions.

[The prepared statement of Dr. Hahn follows:]

PREPARED STATEMENT OF STEPHEN HAHN

The FDA plays a critical role in overseeing our Nation's FDA-regulated products as part of our vital mission to protect and promote public health, including during public health emergencies. Our work primarily focuses on four key areas: first, actively facilitating efforts to diagnose, treat, and prevent the disease; second, surveilling product supply chains for potential shortages or disruptions and helping to mitigate such impacts, as necessary; third, conducting inspections and monitoring compliance, including of facilities that manufacture FDA-regulated products overseas; fourth, helping to ensure the safety of consumer products.

A key focus area for the FDA is helping to expedite the development and availability of medical products needed to diagnose, treat, and prevent this disease. We're committed to helping foster the development of critical medical countermeasures as quickly as possible to protect public health. We provide regulatory advice, guidance, and technical assistance to sponsors in order to advance the development and availability of vaccines, therapies, and diagnostic tests for this novel virus.

On February 4, 2020, the FDA issued an emergency use authorization (EUA) to enable immediate use of a diagnostic test developed by the CDC, facilitating the ability for this test to be used in CDC-qualified laboratories.[1] The FDA is dedicated to actively working with other COVID–19 diagnostic developers to help accelerate development programs and requests for EUAs. We have developed an EUA review template for tests to detect the virus, which outlines the data requirements for a Pre-EUA package that is available to developers upon request. To date, we have shared the EUA review template with more than 100 developers who have expressed interest in developing diagnostics for this virus.

The medical product supply chain is always potentially vulnerable to disruption, which makes our surveillance work and collaboration with industry critical and why the Agency takes a proactive stance on any potential impact or disruption to the supply chain. An outbreak of this global scale has an impact on the medical product supply chains, including potential disruptions to supply or shortages of critical medical products in the United States. We are in contact with manufacturers; global regulators, like the European Medicines Agency; healthcare delivery organizations; and other participants in the medical product supply chains to quickly identify and

[1] FDA. 2019 Novel Coronavirus Emergency Use Authorization. February 4, 2020. *https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-coronavirus2019.* FDA Takes Significant Step in Coronavirus Response Efforts, Issues Emergency Use Authorization for the First 2019 Novel Coronavirus Diagnostic: Critical Milestone Reached in Response to this Outbreak. *https://www.fda.gov/news-events/press-announcements/fda-takes-significant-step-coronavirus-response-efforts-issues-emergency-use-authorization-first.*

address any supply concerns that come from issues related to China and other locations in Southeast Asia sourcing raw materials for manufacturing drugs.

We are also tracking reports of increased ordering of some essential medical devices through distributors, such as personal protective equipment (PPE) (e.g., respirators and surgical gowns, gloves and masks). FDA is working proactively to stay ahead of potential shortages or disruptions of medical products. The agency will use all available authorities to react swiftly and mitigate the impact to U.S. patients and healthcare professionals as these threats arise.

Monitoring the safety of FDA-regulated product supply chains is one of the FDA's highest priorities. The FDA utilizes risk-based models to identify firms for inspection and prioritizes inspections based on specific criteria. Because of travel restrictions to China, the Agency has postponed planned inspection activities in China. However, we are currently continuing inspection and enforcement activities as normal for the rest of our operations.

Inspections of facilities in China remain prioritized in our site selection model and, when travel restrictions are lifted, inspections of facilities in China will resume. Any travel to China that is deemed to be mission-critical is being assessed on a case-by-case basis in close coordination with other HHS components and with the Department of State. FDA is committed to maintaining its scheduled inspections around the globe to the extent possible, while maintaining the safety of the staff involved. We will revisit this approach and adjust as necessary as this outbreak continues to unfold. In the meantime, FDA is working with our partner government agency, U.S. Customs and Border Protection (CBP), to evaluate and adjust our risk-based targeting strategy to ensure FDA-regulated products are safe when entering the United States.

While the outbreak is impacting our ability to conduct inspections in China, it's important to underscore that the FDA's regular risk-based process of surveillance testing of imported products, including those from China, continues.

Inspections are one of many tools that the Agency uses to inform its risk strategy for imported FDA-regulated products and to help prevent products that do not meet the FDA's standards from entering the U.S. market. Other tools include: import alerts, increased import sampling, and screening. Inspections are also part of, among other things, the new and generic drug approval process. While such pre-approval inspections are on hold in China, we are working to mitigate the impact on new and generic drug approval decisions by requesting records that may be used in lieu of an inspection, depending on the circumstances. Based on our evaluation of previous FDA inspection history, a firm's previous compliance history and information from foreign health authorities with which we have mutual recognition agreements, we determine if the totality of the information would suffice in lieu of such a pre-approval inspection.

All products offered for entry into the United States, including items for personal use, are subject to the regulatory requirements of CBP. Imported shipments of FDA-regulated products referred by CBP, including those from China, are then reviewed by the FDA and must comply with the same standards as domestic products. At this time, we want to reassure the public that there is no evidence to support transmission of COVID–19 associated with imported goods, including food and drugs for people or pets, and there have not been any cases of COVID–19 in the U.S. associated with imported goods.

We established a cross-agency task force to closely monitor for fraudulent FDA-regulated products and false product claims related to COVID–19 and we have already reached out to major retailers to ask for their help in monitoring their online marketplaces for fraudulent products with coronavirus and other pathogen claims.

FDA is utilizing all our existing authorities to address COVID–19 and we welcome the opportunity to work with Congress to strengthen our response capabilities. There are four specific proposals included in the President's Budget that would better equip the Agency to prevent or mitigate medical product shortages.

(1) Lengthen Expiration Dates to Mitigate Critical Drug Shortages
Shortages of critical drugs can be exacerbated when drugs must be discarded because they exceed a labeled shelf-life due to unnecessarily short expiration dates. By expanding FDA's authority to require, when likely to help prevent or mitigate a shortage, that an applicant evaluate, submit studies to FDA, and label a product with the longest possible expiration date that FDA agrees is scientifically justified, there could be more supply available to alleviate the drug shortage or the severity of a shortage.

(2) Improving Critical Infrastructure by Requiring Risk Management Plans

Enabling FDA to require application holders of certain drugs to conduct periodic risk assessments to identify the vulnerabilities in their manufacturing supply chain (inclusive of contract manufacturing facilities) and develop plans to mitigate the risks associated with the identified vulnerabilities would enable the Agency to strengthen the supply chain by integrating contingencies for emergency situations. Currently, many applicants lack plans to assess and address vulnerabilities in their manufacturing supply chain, putting them, and American patients, at risk for drug supply disruptions following disasters (e.g., hurricanes) or in other circumstances.

(3) Improving Critical Infrastructure Through Improved Data Sharing: Requiring More Accurate Supply Chain Information

Empowering FDA to require information to assess critical infrastructure, as well as manufacturing quality and capacity, would facilitate more accurate and timely supply chain monitoring and improve our ability to recognize shortage signals.

(4) Device Shortages

FDA does not have the same authorities for medical device shortages as it does for drugs and biological products. For instance, medical device manufacturers are not required to notify FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the United States, nor are they required to respond to inquiries from FDA about the availability of devices. Enabling FDA to have timely and accurate information about likely or confirmed national shortages of essential devices would allow the Agency to take steps to promote the continued availability of devices of public health importance. Among other things, FDA proposes to require that firms notify the agency of an anticipated meaningful interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and authorize the temporary importation of certain devices where the benefits of the device in mitigating a shortage outweigh the risks presented by the device that could otherwise result in denial of importation of the device into the United States.

The CHAIRMAN. Thank you, Dr. Hahn.

We have very good attendance by Senators. We're going to continue the hearing until 12:30 in hopes that every Senator will have a chance to ask questions.

I know that the witnesses have been asked to go to Senators' lunches with the Vice President, but that's us. So we'd like for you to stay here until you answer our questions and then go to lunch with us and answer our questions further, and I think we can complete that by 12:30.

I'm going to ask Senators to keep the total amount of time for each one on questions and answers to 5 minutes each so every Senator has a chance to ask questions.

Dr. Fauci, I'm going to ask you a series of questions within my 5 minutes, and these are the kind of questions I get at home, or sometimes here. Senator Roberts asked me yesterday, and I couldn't give him the exact answer, what do we mean by community transmission?

Dr. FAUCI. Community transmission means when there are cases that are in the community for which the original source is not known. If you get someone who travels let's say from Wuhan to the United States and you know they're a travel case, and one of their contacts gets infected, you know the source; whereas if all of a sudden——

The CHAIRMAN. Let's talk about person to person. That means we know who it is.

Dr. FAUCI. Person to person, but you don't know what the original source is. In the State of Washington——

The CHAIRMAN. No, that's good. I thought there was a difference between person to person and community transmission.

Dr. FAUCI. No. Any transmission of an infection is from a person to a person, except——

The CHAIRMAN. What if you do know who it is? What do you call that?

Dr. FAUCI. Well, if you're able to identify them, that is not so-called "community." But if it's community, you might have a cluster in the community——

The CHAIRMAN. I understand that. But what do you call it if Senator Murray has it and gives it to me? What do you call that?

Dr. FAUCI. That's person-to-person transmission.

The CHAIRMAN. All right. And community transmission means if I get it and we don't know who caused it—is that right?

Dr. FAUCI. Right, exactly, you don't know what the original source is.

The CHAIRMAN. Well, are we at the peak of the flu season?

Dr. FAUCI. Well, the answer is likely, and maybe even on the way down. If you look at the curves——

The CHAIRMAN. We're just over the peak of——

Dr. FAUCI. Well, it went up, it went down, it went up, and it's starting to come back down again.

The CHAIRMAN. I'm talking about the ordinary flu we have every year. About how many Americans, if you had to estimate, have flu this year?

Dr. FAUCI. There are probably around 30-plus million infections, a couple of hundred thousand hospitalizations.

The CHAIRMAN. In the United States?

Dr. FAUCI. In the United States.

The CHAIRMAN. How many Americans die every year from what we call the flu?

Dr. FAUCI. You know, it ranges from a low of 15,000 to 20,000, to the high year that we had in 2017–2018, which was about 70,000-plus people.

The CHAIRMAN. About 70,000 people.

Dr. FAUCI. In one of the worst years.

The CHAIRMAN. In one of the worst years.

Dr. FAUCI. Yes.

The CHAIRMAN. The flu is a respiratory disease like coronavirus; is that correct?

Dr. FAUCI. That is correct.

The CHAIRMAN. Well, how do you know if you have the flu as opposed to coronavirus?

Dr. FAUCI. Well, the definitive test would be to get a test of the flu or a test of the coronavirus.

The CHAIRMAN. You'd need a test.

Dr. FAUCI. There is overlap in symptoms. The situation with coronavirus is predominantly fever and a lower respiratory infection, as opposed to an upper respiratory infection starting off with, and then you might get a pulmonary involvement, which is flu.

The CHAIRMAN. What's a lower respiratory——

Dr. FAUCI. Your lung, as opposed to sore throat, sinusitis, sneezing. When you have lung involvement, you can get that with flu, but usually it's upper respiratory, and then——

The CHAIRMAN. Fever and a cough is——

Dr. FAUCI. Fever and a cough can be either of them.

The CHAIRMAN. Okay. What should you do if you have fever and a cough?

Dr. FAUCI. Well, it depends on the circumstance. I mean, if you're in the middle of a flu season right now and you have fever and a cough, obviously if you have a cough it could be pneumonia. You should see a physician. Certainly if you're a person in a risk group—elderly or underlying condition—during the flu season, you should see a physician because we do have antivirals for flu, and you could be helped by doing that.

The CHAIRMAN. Should we all be wearing masks?

Dr. FAUCI. No.

The CHAIRMAN. Why?

Dr. FAUCI. Because right now there isn't anything going around in the community, certainly not coronavirus, that is calling for the broad use of masks in the community.

The CHAIRMAN. Why do healthcare workers wear masks in the hospital, then?

Dr. FAUCI. Well, because a healthcare worker who is taking care of someone who is known infected with a transmissible virus, that's different from walking around in the streets wearing a mask.

The CHAIRMAN. Are children getting the coronavirus?

Dr. FAUCI. To a much lesser extent than adults, and for reasons that are still unclear. It may be that they are getting infected but their symptoms are so low they're not being recognized. But in a number of reports that have come out from China, there are very few cases less than 15 years old. You'll always find the exception, but most of the cases are a mean age of about 50.

The CHAIRMAN. What can we do or what can our families do to protect ourselves? What's the most effective thing?

Dr. FAUCI. Right now, and I think the question you asked about flu is important, right now we are still in the flu season. What you can do to protect yourself against the possibility of coronavirus is the kinds of things you would do to protect yourself against flu. Now, obviously you get a flu shot. You can at least protect yourself against flu. But also things like—we always say it; it sounds simplistic, but it's true—washing of hands, if possible staying away from people who are coughing and sneezing. If you yourself are infected, stay out of work. Don't send your children to school if they're infected.

The CHAIRMAN. My time is up.

Senator Murray.

Senator MURRAY. Thank you, Mr. Chairman. I'm going to yield the first questioning to Senator Jones, who has to leave for a flight. I will take the second round.

Senator JONES. Thank you, Senator Murray.

Dr. Fauci, I'd like to follow-up on that real quickly. So if somebody right now in Alabama presents, they didn't get their flu shot, so all of a sudden they've got fever and they've got a cough, they

go get a flu test. Will that test, if they don't have the flu but have coronavirus, will that test come back negative?

Dr. FAUCI. If they don't have the flu, the flu test will come back negative.

Senator JONES. They should be concerned if they present some symptoms for the flu and that comes back negative.

A follow-up question on that is about testing. I didn't hear a lot about the testing. We've had some concerns in this country about testing. It's inadequate, to say the least, right now, but I know there are efforts. What capacity do we have to do the testing as you sit here today, and how are we working to expand that, and when will that all happen?

Dr. SCHUCHAT. Yes, thank you. The CDC's piece in this is to supply the public health labs with tests, and we are rapidly doing so. We developed the test very quickly and then detected some problems after the quality control steps were measured. So by the end of this week, really, all of the state labs, the public health labs, should be able to do testing.

But I think for context it's important to understand what the clinical labs do in respiratory testing. Last week in the United States, clinical labs tested 42,000 respiratory specimens for influenza, and 11,000 of those were positive for influenza. And so far this year, the clinical labs have tested almost a million respiratory specimens, and about 200,000 were positive.

Public health labs, as opposed to a million so far this year, tested about 62,000. Public health labs are a tiny piece of the testing world. That said, most people with influenza don't actually get tested. We have about 30 million people with influenza so far this year, and as I said, about a million tests. So I think the public health issue is to detect early when there is emergence of this virus, recognize it in travelers or in the community, as we've said, and then right now we're really keen, with the FDA's assistance, to get those clinical labs up and running, and that's really an FDA and a BARDA issue.

Senator JONES. How will the testing—how much more capacity will we have by the end of this week versus 2 weeks, 3 weeks from now?

Dr. Hahn.

Dr. HAHN. Yes, Senator. We work with the CDC on their test. The outside manufacturers, private companies, are using their platform right now to further develop the test. Our expectation in talking to the company that's scaling this up is that we should have the capacity by the end of the week to have kits available to the laboratories to perform about a million tests.

Senator JONES. All right. Great. One thing I would urge to please continue, as I think both Senator Alexander and Senator Murray said, please get information out there. We're about to head into the allergy season as well, and I just can tell you people are so scared out there right now that the first time they sneeze with an allergy they're going to think that they've got this. We've got to make sure that we try to educate folks so that those tests that we have, those limited ones, are for the right reasons.

The second question I have, it concerns rural areas. In my State alone, we have another rural hospital closing this week in the State

of Alabama. Are there specific things that you guys are doing to make sure that rural hospitals, who are living from paycheck to paycheck almost, have the resources that they need, the financial resources and the tools that they need to make sure their communities are protected as well?

I will ask Dr. Kadlec.

Dr. KADLEC. Yes, sir. Thank you for the question. Frankly, we've been monitoring that situation very carefully with our healthcare coalitions that are funded by the Hospital Preparedness Program, and we do recognize there is a paucity in some areas of resources, as well as assets and staff. So we're looking and investigating telemedicine and how we can basically make that available.

As Dr. Fauci said, the majority of individuals with the coronavirus don't need care, but the critical thing is identifying those people who can, and that is something that CDC has been working on messaging to kind of identify guidelines. Individuals who may be at risk, particularly for severe disease, should seek hospital care.

If Dr. Schuchat would like to follow-up on that, but we're looking at telemedicine options as one piece of the puzzle that would help us fill in the gap. But there needs to be a long-term solution to that challenge.

Senator JONES. In that regard, I appreciate that. I had a question on that, but I also would encourage you to get with CMS and have them allow for reimbursements for telemedicine. They don't do that right now, and that could be a really important factor.

Dr. KADLEC. We're in conversations with them on that.

Senator JONES. Perfect. Thank you.

That's all I have. Thank you.

The CHAIRMAN. Thank you, Senator Jones.

Senator Burr.

Senator BURR. Mr. Chairman, before my 5 minutes starts, can I ask unanimous consent that I enter a statement into the record and that I ask on behalf of all Members that if they want to enter a statement into the record, that they can? And just remind Members that in 2005, when Senator Kennedy and I passed PAHPA, it was with this day in mind, that we would be faced with a pandemic, and we're close to that determination. And I would only say the temptations to do legislation are great. Before you do it, read what the statute says. Read what the latitude is that our responders have. Let them do their jobs. Dr. Hahn expressed that he just did two emergency use authorizations. That's part of the work of this Committee. So let's not be too quick to go out and encumber them with micro-managing what they do.

The CHAIRMAN. So ordered. We'll go ahead with the unanimous consent and put that in, and I look forward to reading it.

Senator BURR. Thank you, Mr. Chairman.

Senator BURR. Dr. Schuchat, I heard you say that you're rapidly trying to reach testing. Now, as of March the 1st, CDC's website had total tested up on their website. It was 472, even though Secretary Azar said last night 3,600. I don't know which one is right.

What I'm curious about is why on March the 2d did you take the total number tested off the CDC website?

Dr. SCHUCHAT. Thank you for that question. Let me clarify. There's a lot of numbers out there. There's a difference between persons under investigation who have been tested and all of the tests that we have run. For instance, an individual case, the first 12 cases that we saw here, we did serial testing on them to understand how long the virus was present and when it was safe for them to leave the hospital or when they no longer needed isolation. We collected multiple specimens so we understood with this very new virus is it the upper respiratory, the lower respiratory. We also collected other specimens from them.

The over 3,000 tests run is correct. We've tested way more than the 500-some persons under investigation. We've also tested some of the hot cohorts or the hot-risk cohorts like the repatriation individuals from the Diamond Princess.

Senator BURR. Dr. Schuchat, you've known about this potential threat since early January, if not in December with what we're looking back at now. Diagnostics had to have been one of the things that we were looking at, saying we've got to be able to do this, and we devote through PAHPA $150 million each year to strengthen the surveillance capabilities at the state level. How can we have a situation like Washington State where we've known for up to 6 weeks, reaching possibly 1,500 individuals, yet we experienced what we have with this long-term care facility, and clearly a cluster that we don't know the magnitude of? How can that happen when we've invested so much and been there early on and understanding we have to be prepared?

Dr. SCHUCHAT. CDC very rapidly developed a new PCR for a completely new virus. We posted the instructions for that PCR on the website so other labs, academic labs, commercial labs, research labs, could similarly develop tests. BARDA has the responsibility to work with the private sector to get commercial labs up and running, and the CDC has supplied the public health labs with the ability to do the testing.

The situation in Washington State is tragic. An outbreak in a long-term care facility is one of the things we have been worried about from day one. We learned from the SARS experience in 2003 that super-spreading events or super-spreading individuals could cause very large amplification rapidly. And so the concern about healthcare settings has been foremost in our minds.

Senator BURR. Dr. Schuchat, I believe you. I'm only looking at were we better prepared for this happening, and it doesn't seem to be that we were.

Now PAHPA, also in the reauthorization, provided direct hiring authority for 30 new employees at CDC dedicated to development of a bio-surveillance system at CDC. Of those 30 slots, how many have you filled?

Dr. SCHUCHAT. I don't have that information, but I can tell you that the laboratory activities for the coronavirus are not one of the larger parts of our program. We have really built our response around our influenza capacity, which has really grown with the generosity of the American people through Congress. So our coronavirus capacity is relatively small. We built it up a little bit after MERS, but we're not able to sustain that. So we really appre-

ciate the support from Congress to strengthen that public health infrastructure both at CDC and at the states.

Senator BURR. I personally was shocked, and I like to think that I'm fairly knowledgeable of everything that we instruct and provide for agencies. I was shocked to find out that in the normal appropriations, this $150 million, that can also be used for CDC facility construction. You know, it's a little misleading to say this went for surveillance when the flexibility exists for some of it to go for facility construction. Do you know what portion of the $150 million did not go directly to fund surveillance?

Dr. SCHUCHAT. I'm not sure what the $150 million line is. I think I'm going to need to get back to you on that. Our construction/renovation appropriations are separate. So I will need to get back to you on that.

Senator BURR. I think if you'll check the appropriations in all appropriations that go to CDC, there is an ability to move money from that to construction facilities, and I would encourage the appropriators on this Committee, especially as we look at the emergency funding, for God's sake, let's make sure it goes to response and not construction of a campus at this time.

I yield back, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Burr.

Did you have something else?

Dr. SCHUCHAT. No, just that we'll follow-up for the record with the accurate information.

The CHAIRMAN. Senator Murray.

Senator MURRAY. Thank you.

Dr. Hahn, as you heard, I am very concerned about the delays in testing. I have people in my state who may have been exposed. They cannot get answers about where to go, and health officials are telling us that they fear that this virus has been circulating for weeks undetected. We were relieved a month ago when CDC began to ship diagnostic tests to our State and local labs, but within days many labs reported validation issues with those tests, leading to inconclusive results, and CDC and FDA began to work on remedying that.

But it wasn't until February 27th that CDC began distributing new test kits, and at the same time academic medical centers across the country were raising concerns about the lack of availability of diagnostic testing and burdensome requirements FDA was imposing. For example, FDA asked labs to submit information about 100 tests at a time when only 15 people in the U.S. were known to be infected.

FDA has worked to address these issues with the Guidance on Lab Testing that it issued this past weekend, but press reports now indicate the publication of this guidance was delayed within HHS. I was glad to read last night that you now believe you're going to be able to do a million tests by the end of the week, but frankly I'm hearing from professionals that is unrealistic.

I wanted to ask you, first of all, what happened at the Department that created these delays, and how can you clarify that estimate of a million tests is accurate?

Dr. HAHN. Thank you, Senator. First of all, with respect to the timeline of the development of the test, CDC obtains the sequence

of the virus—that's where it starts—and they're able to develop a test based upon the identification of that sequence. They moved rapidly to develop this PCR-based test, as was just described.

We received the validation information around that test on February 3d, and on February 4th we issued the Emergency Use Authorization to allow that test to be used. During the scale-up process, which occurred in the week or so afterward in sending it out to the public health labs, as you mentioned, it was identified that some of the public health labs, not all of them, that they weren't able to reproduce and validate the test.

CDC heard that information, came to FDA, and we worked to correct that issue. At the same time, simultaneously, we were working with the private sector to actually scale up the use of the CDC-based test, and that's where we came into the most recent estimate regarding how we can scale up——

Senator MURRAY. I understand that. Was the publication of the guidance delayed within HHS? Was it? Yes or no?

Dr. HAHN. No, it was not.

Senator MURRAY. It was not delayed?

Dr. HAHN. No.

Senator MURRAY. Do you really believe that a million tests will be available by the end of this week?

Dr. HAHN. Senator, let me just explain that one. So, the companies that we're working with on this, they have the capacity to develop enough test kits to send out by the end of the week—and this is a dynamic process; every day we're hearing from additional manufacturers that they can do this—2,500 test kits by the end of the week. That should give us the capacity in the hands of laboratories, once they validate, to perform up to a million tests.

Senator MURRAY. Twenty-five hundred kits will?

Dr. HAHN. Yes, a 500-test kit.

Senator MURRAY. Well, I heard Dr. Kadlec say that the point of where someone goes in to get a test on a rapid, we are months away from that. Correct,

Dr. Kadlec.

Dr. KADLEC. Yes, ma'am.

Senator MURRAY. Well, I'm hearing from a lot of people in my state who are really concerned about what they should do if they are infected or if they know they were within range of someone with coronavirus. Right now the CDC's website says if you suspect you are infected, you should "stay home, except to get medical care." Well, right now, we know that 27 percent of the private-sector workforce in the U.S. do not have the ability to stay home from work without losing pay or if they have a loved one who is sick. In fact, the U.S. is one of only two OECD countries that doesn't provide paid leave for personal illness.

If we are telling people to stay home, just think about the facility that's been impacted. It's a senior center, low-income workers there. All of them are being told to stay home for 2 weeks.

Dr. Schuchat, I just have to ask you, would it be efficient for a public health reason right now while we combat this to have policies in place to make it possible for people to stay home from work without losing a paycheck?

Dr. SCHUCHAT. Yes, absolutely.

Senator MURRAY. Okay. Well, I think that's something we do need to consider with this.

Dr. Schuchat, I want to ask you also, I am very concerned by news reports about HHS staff who were deployed to assist with potentially infected passengers returning from abroad, and despite face-to-face contact with passengers, the staff were reportedly not appropriately trained to handle this type of public health emergency or in how to wear protective equipment. They were not quarantined, monitored, or tested for the virus, and some have since taken commercial flights and returned to work.

It is not clear to me that HHS took necessary steps to protect staff and the public either during this time or after concerns were raised with senior leadership about what happened.

I'll ask both Dr. Kadlec and Dr. Schuchat, is the situation I've just described consistent with protocol? And what should have been done once the senior leadership were aware that frontline staff may have been exposed?

Dr. SCHUCHAT. I can speak for CDC that we take the health of our workforce very seriously, the health and safety, and have predeployment, deployment, and post-deployment guidance. This is a totally new virus, and so we're learning as we go. But when we identify problems, we want to resolve them absolutely quickly.

Senator MURRAY. But is what I just described to you consistent with the protocols?

Dr. SCHUCHAT. I don't have the full information of that, but I believe Dr. Kadlec can probably say more.

Senator MURRAY. Dr. Kadlec.

Dr. KADLEC. Ma'am, I'll just say we're looking into that very closely because, again, to echo what Dr. Schuchat has said, we take the protection of our healthcare workers in HHS very seriously, and during that operation in particular we are evaluating what may have been a breach, and we owe it to you, as well as what's been identified by the whistleblower report, to report back to you on that.

Senator MURRAY. Mr. Chairman, I would just say that we need people to speak up when they see these situations. It is unacceptable if any of these workers on the front lines are intimidated into staying silent or believe that they're going to be retaliated against on these issues. We have to keep the protection of the public first and foremost in our minds, and I want this looked at, and I want to make sure anybody who speaks up is protected.

The CHAIRMAN. Thank you, Senator Murray.

Senator Paul.

Senator PAUL. Dr. Fauci, you mentioned remdesivir, and I'm intrigued by the fact that they say it's effective against MERS and SARS in animal models. Do you take that as a very encouraging sign that it may work in humans too?

Dr. FAUCI. Yes, I do, I do.

Senator PAUL. Okay. With regard to the children, I think it's fascinating that there aren't many cases, and I would suspect that it would be improbable that they're not being infected, that somehow they have some blanket immunity. One important thing of maybe putting this into perspective, maybe putting a better look on the overall outbreak, would be if we had numbers. I don't know if

someone would suggest to China that they do some random testing of kids in a real hotbed where there's a huge number to see, because if we got 10,000 kids who weren't getting sick, or 100,000 kids, our percentage on fatality would go way down.

Dr. FAUCI. Right.

Senator PAUL. Do you have a comment, Dr. Schuchat?

Dr. SCHUCHAT. Yes. There are some data about that, that attack rates may not be zero in children but they may be asymptomatic. So there are data from a few places that are looking at that.

Senator PAUL. It's more likely that they're asymptomatic, or less symptomatic.

Dr. FAUCI. I think we're going to get some data from the Chinese. They have actually been quite cooperative in sharing data. We had a group that was under the auspices of the WHO that went to China. There was an individual from the CDC and an individual from the NIH who have now returned, and we'll soon get a good look at the report of what they've had, and that was one of the questions we asked because, as you mentioned, Senator, that's a very important issue.

Senator PAUL. With regard to treating the severe and potentially fatal cases in bacterial or viral infections, sometimes it's sort of trying to fight off the cause of the infection as well as the body's response to that. In some bacterial infections, like with the flesh-eating strep, sometimes you actually have massive steroids inside, in the setting of an infection, and some of these people survive. In the fatal cases, are they finding that steroids in addition—well, we don't really have an antiviral treatment, but are they using some steroid treatment in the real severe cases and having any success?

Dr. FAUCI. They've done it in an empiric, non-controlled way, and there doesn't seem to be any difference, that there's any effect positive or negative.

Senator PAUL. Right. I guess in a bacterial infection we would never do it unless we were also giving antibiotics. An antiviral plus steroids might be a different scenario.

Thank you. That's all I have.

The CHAIRMAN. Thank you, Senator Paul.

Senator Casey.

Senator CASEY. Thanks very much. I want to thank the Chairman and the Ranking Member for the hearing, and obviously our witnesses for their expertise and the work by each individual here for many years.

I think I'll start today with what is the obligation of every elected official in the Federal Government. We've got Members of the House and the Senate in both parties, and we have two individuals in the executive branch, the President and the Vice President. And the obligation is real simple here, by every elected official. Every one of us is charged with working constructively to at least do the following: slow the spread of the virus, taking steps to do that working with all of you and the folks you work with; No. 2, to support State and local preparedness efforts; and three, provide complete and accurate, always, always accurate information to the public to address their concerns about this challenge.

I know this Committee has worked in a bipartisan fashion on a range of issues for years. We're continuing that today. I appreciate

especially the work that Senator Burr has done, working with him, as I have for the last number of years on the Pandemic and All Hazards Preparedness Act and the reauthorizations. But we've got to make sure we do our job even as we're indicating what should come next.

I want to start with Dr. Kadlec and Dr. Schuchat with regard to the tragedy that has unfolded in the State of Washington in nursing homes, as Senator Murray outlined. I guess I want to start with just that venue for this challenge. We know that the early indications suggest that the virus poses a significant and even deadly risk to, No. 1, older adults; No. 2, people with disabilities; and No. 3, folks with underlying health conditions.

The risk obviously is heightened in nursing homes, where residents and workers don't have the option to distance themselves, the residents in particular. They're in their home, so there's no staying home to avoid it, and obviously the workers have a challenge.

Dr. Schuchat or Dr. Kadlec, depending on who wants to go first, tell me two things about what the Administration is doing. What's the Administration doing to protect both, No. 1, the residents, and No. 2, the workers in long-term care settings?

Dr. KADLEC. I'll start and then turn it over to Dr. Schuchat. I think the key thing is that as we've learned more about this outbreak, and last Thursday the Chinese posted a fairly significant report on the epidemiology of their outbreak that included a record of 44,000 confirmed cases in China, which gave us a pretty good understanding of what are the relative risks. To Dr. Fauci's point earlier, about 20 to 15 percent of people who are over the age of 70 in particular, and with comorbidities, are at risk, and from that I think Saturday—and I won't steal Dr. Schuchat's thunder—they released guidelines on how we could basically warn and inform people with vulnerabilities, and we have actively worked to reach out to them specifically through mass calls and through briefings to inform them of those risks and guidelines they can follow, which are CDC guidelines.

We've been very proactive and aggressive in trying to respond to this as we learn more in a way that would ensure that we can warn proprietors of those facilities. But it's not just long-term care facilities. It's potentially dialysis clinics and other areas where we have cancer therapies given where people who are immunologically at risk can basically be taken care of and shielded from this virus.

Dr. Schuchat.

Dr. SCHUCHAT. Yes, just to say that CDC has issued a number of guidance documents and for the past several weeks has been doing outreach with clinicians and health systems. Through the weekend I spoke many times with Seema Verma from CMS, and the full armamentarium of assets that CMS has, including inspectors and so forth, is being directed to help us with this challenge. Obviously, individuals in the skilled nursing facilities and acute hospitals have lots of other things going on, and the best we can do to protect them from infections acquired there, it's really our responsibility.

Senator CASEY. I'll just make a comment, and then I just have one question for Dr. Hahn. You know, we've had a debate about

healthcare, and I've been working, as many have, to combat the use of these so-called "junk plans." We got a report where a guy got tested for the flu to make sure he didn't have coronavirus. He finds out that his insurance has—it's one of those short-term, limited-duration plans. It doesn't cover basic testing. You get the picture. These junk plans are a problem. I hope this challenge we're facing will convince the Administration that junk plans or the advancement of junk plans are really dangerous, especially when we face this kind of a threat. I would hope they would rethink their regulatory strategy going forward.

But, Dr. Hahn, one last——

The CHAIRMAN. Senator Casey, we're over time. I'm trying to keep everybody to 5 minutes.

Senator CASEY. One last question on testing.

The CHAIRMAN. If we have a succinct answer.

Senator CASEY. How many people this week can be tested in the United States of America, this week?

Dr. HAHN. Senator, that depends upon the deployment by the manufacturer to private companies, academic centers, et cetera, and their ability to validate it and do the test. The capacity will be there by the end of the week, but those are the necessary steps to actually get that deployed to the American people.

Senator CASEY. I hope we can get a number on people.

The CHAIRMAN. Thank you, Senator Casey.

Senator Cassidy.

Senator CASSIDY. Thank you all. I have about seven or eight questions, so I'll ask you to be succinct in your answers. And if I interrupt, it's not to be rude.

CDC, we discussed beforehand, I discovered that the Canadians have not been as strict as far as people returning from Hubei Province. If you're febrile, they quarantine you. If you've just been there and you're not febrile, God bless you, go home, and don't infect anybody.

Now, you had mentioned that there is screening at the U.S.-Canadian border. What percent of those folks coming from Canada and, say, Washington State are actually being screened either by questionnaire as to travel history, exposure, and/or temperature, et cetera?

Dr. SCHUCHAT. Yes. I don't have the percent, but we've worked closely with Dr. Kadlec's team and the U.S. Public Health Service, as well as the CDC——

Senator CASSIDY. Can you give me a ballpark? Is it 10 percent? Fifty percent?

Dr. SCHUCHAT. There's a protocol that is assessing everybody who's crossing at the key borders to alert it to where the flights are coming in and so forth. But I can't give you a percentage; sorry.

Senator CASSIDY. But it could be as low as 5 percent.

Dr. SCHUCHAT. It could be.

Senator CASSIDY. Second, is CDC using Google location data or something similar in terms of tracking contacts?

Dr. SCHUCHAT. Not for contacts. We are for travel patterns and other means——

Senator CASSIDY. Going to this nursing home in Seattle, clearly somebody came who had been exposed to coronavirus. Law enforce-

ment at the scene of a crime will get a warrant and will ask Google to give this data. We've been reviewing the statutes. So just to be clear, CDC is not currently using that same sort of thing law enforcement is to track contacts?

Dr. SCHUCHAT. You have to recognize that right now the chances that a person with a fever and cough have coronavirus versus influenza are very low, so exactly what we'd be tracking, I'm not sure.

Senator CASSIDY. The point is if somebody went to that nursing home and you can follow their location data, and it turns out they had contact with somebody who had traveled to Hubei, perhaps in Canada, they had gone back and forth, then they're obviously a candidate to be in the vector. So I would encourage, because I think the answer is no, that you do not use that location data. It seems as if that would expedite the epidemiology of how this is being spread among the community.

Next, Dr. Hahn, those 26 APIs that India is not allowing to be exported, are any of those the active pharmaceutical ingredient for any of the candidate therapeutic drugs?

Dr. HAHN. Senator, I don't know the answer to that question. We're going through that list right now to actually assess the effect on essential medications.

Senator CASSIDY. Okay. Next, one of the recommendations that Senator Murphy and I had in a request in a drug shortage report from FDA which was released last year, recommendation number 2, was to establish a quality supply chain rating system. Now, should Congress enact this quickly? Because, clearly, if we've got supply chains overseas that we can't inspect and/or they are basically interdicting the flow of that active pharmaceutical ingredient to the U.S., and it could be one of these candidate drugs, again, should we now enact that recommendation number 2?

Dr. HAHN. Senator, we stand behind and are working on the development of this rating system. We also have some legislative proposals as part of the President's budget that relate to this.

Senator CASSIDY. Okay. Next, we have a problem with antibiotics in which if you have a very expensive antibiotic for some terribly resistant drug, it's difficult for us to currently pay for them with capitated payments to MA plans, for example, or DRGs at the hospitals. We could have the same situation with antivirals whereby the antiviral might be very expensive, and that would kind of blow the lid off of a DRG or—you see where I'm going with this.

Again, I would like Congress to act upon this quickly to create some sort of carve-out for these essential but expensive drugs to develop. Your thoughts?

Dr. HAHN. We have implemented the authorities given to us in the GAIN Act, and also in the CURES Act, to help with this, and we are very much facilitating the development of antibiotics——

Senator CASSIDY. But I think this would be a payment policy on the part of CMS. I think we'd have to give them the authority to do an epi-payment, if you will, for the use of such drugs.

Dr. HAHN. I know that we have a pilot project with CMS to bridge this gap to the payment side. I defer the payment questions to CMS, sir.

Senator CASSIDY. Dr. Fauci, we're looking for quick diagnostics. Obviously, a PCR takes a little bit longer than a swab or a blood

test for an IgM or an IgG. How close are we to having an IgG or an IgM blood test that could be quickly turned around in a community hospital?

Dr. FAUCI. I think pretty close because that's clearly one of the things we want to get, and in fact it will be very important for broader surveillance in the country of exposed people who never come to medical care.

Senator CASSIDY. I would finish up by saying this. We need to know from you all what authorities we need. As I look at this, we need expanded telehealth with expanded use authority. We need to get appropriate reimbursement for that telehealth. Granted that's all CMS, but we also need home health.

Ms. Murray was saying how we've got to send people home. I think we need to do something there, and I think those are my questions. If you need authority from us, please let us know. It may be the expanded authority Senator Burr already referred to, but we need to know what else you need.

I yield back. Thank you.

The CHAIRMAN. Thank you, Senator Cassidy.

Senator Murphy.

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

Thank you so much for your service. Thank you for being here today.

Dr. Fauci, thank you for your, I think, very clear articulation this morning about a realistic timeline for treatment and vaccine. I do think it's worth saying that it is pretty extraordinary that we have to have our medical and health professionals counter-message the President of the United States, that they have to spend their time trying to correct the record. We have become normalized to this Administration's, to this President's loose association with the truth, but it becomes particularly dangerous in the middle of a pandemic response. Thank you for being here and sharing facts with us today.

We all have lots of questions, so we'll all try to get in as many as we can.

Dr. Hahn, let me follow-up on Senator Cassidy's questions about new authorities. One of the things you said in your testimony was that while you feel you've gotten good cooperation from medical device and equipment companies, they're not required to tell you when there's a shortage. Senator Rubio and I had sent you a letter thanking you for your response about trying to catalogue the shortage areas. It sounds like it would be helpful to have a simple, easy legal requirement that they alert you ahead of time when they see a shortage coming.

Dr. HAHN. Senator, thank you for the question. We have sent several legislative proposals as part of the budget, and I think one of the things we've learned from this and other shortages is that it's a very complicated supply chain. The most important thing is redundancy, and also an effort around advanced manufacturing. We have had great cooperation, but this is complicated.

For example, the one drug that is currently in shortage related to this isn't actually related to an API or the final drug form. It's related to a chemical that's before the active pharmaceutical agree-

ment. So the whole supply chain is complicated, and more information would be better.

Senator MURPHY. Great. I think Senator Murray asked you a question that you might not have gotten around to answering, and I think it's an important one. The right information is key, but also setting realistic expectations is key as well. Your estimate that by the end of the week there are going to be a million tests out there does sound a little aggressive given the fact that we've only tested 3,000 people, and New York State is saying their goal is to do 1,000 a day.

Tell us why you think by Friday of this week we're going to have a million tests when thus far we've only done 3,000.

Dr. HAHN. I again want to distinguish between the ability to get the test kits out to the laboratories with the ability of the labs to actually do the tests. But we have been working very closely, Senator, for the last three or 4 weeks with all manufacturers—private, academic, et cetera, CDC—to build on this platform that CDC has developed. We have been in touch with this particular manufacturer over the last three or 4 days. We have reiterated this. We've worked with them closely. We know them well. They have estimated that they are going to be able to scale up to deliver 2,500 kits by the end of the week to providers of the test.

Senator MURPHY. Dr. Schuchat, let me ask you, how do we know that those are in the right hands?

Dr. SCHUCHAT. Yes, thanks. CDC has been providing the public health labs with kits and expects by the end of this week that there would be sufficient for 75,000 people to be tested. But as you say, not everyone needs a test, and we don't want to go through all our tests on low-risk situations and not be able to really address the care and the contacts that are going to be critical.

We have guidelines for this kind of thing for influenza about who needs to seek care, who can stay home, and have adapted them for this. We've also broadened our definition of who we think is what we call a person under investigation that really needs to be tested, not just related to travel to China but all the other areas. And also to say people with severe respiratory disease who don't have an obvious diagnosis should be tested, and we know that many of the cases in Washington State are detected through that, or because there was an outbreak being investigated.

Senator MURPHY. I think this question of where these tests end up and making sure that they're in the right hands is going to be a really important one for us and you to have oversight on.

Finally, Dr. Schuchat, let me ask you a question about protocols that we're recommending to school districts. One of the biggest disruptions that can happen in a family's life is the closure of a school. And as Senator Murray pointed out, given the fact that many families have two parents working, that's really difficult for a day, never mind a week.

What are the recommendations and protocols that we are telling school districts about what they should do if they have a child who tests positive, a family member, a teacher who tests positive? What's the best protocol today?

Dr. SCHUCHAT. Thank you. We absolutely recommend a child who is ill should stay home, whatever they have, so that they don't

spread. But we have worked closely with local and State public health on this issue, and essentially decisions about school dismissals, school closures, or changes in school policies are very much locally driven. But we provide guidance, and——

Senator MURPHY. But what is the guidance, though?

Dr. SCHUCHAT. Yes. So the general principle is to minimize disruption. You have this balance between the earlier you act, the more impact it can have in slowing the spread, and the enormous disruption we see with school closures. You may remember in 2009 we saw hundreds of thousands of students sent home in the first couple of weeks of the pandemic. As we learned more about the virus and its spread, we realized that was too disruptive. The virus was relatively mild compared to what we were expecting, and we dialed that back to instead shift to stay home when you're sick, perhaps canceling assemblies, changing the patterns of what's done in class, but trying to keep classes going, because so many depend on school lunches and other services that are in schools.

It's a local decision. If there are too many people sick, of course, you can't keep going, but really trying to protect the vulnerable and reduce the spread but not disrupt families and all those parents who will be staying home if their kids are home.

Senator MURPHY. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Murphy. I let that go on because that's such an important answer, but I hope everyone will try to stick to 5 minutes so that we can allow all Senators to ask their questions.

Senator Roberts.

Senator ROBERTS. Mr. Chairman, I think I can do that right off the bat. You asked my question and got a pretty good answer, and then Senator Jones stole my rural question. Bob Casey summed up where we ought to be. The distinguished Ranking Member said, look, we ought to get this money appropriated and get it to the President. The President, by the way, said whatever figure you give me, I'll take it, we'll work with it.

I just want to thank you both. You indicated we needed information. I think we're doing that in this process largely because of the wonderful job that these witnesses do. And I want to thank Senator Murray for that.

This is a very unique Committee, along with a sometimes powerful Senate Agriculture Committee. We are bipartisan. There's a lot of partisan elbows out there right now. We don't need to politicize a pandemic. I would recommend that we monitor what people say, and I would yield to the Chairman for that decision, along with the Ranking Member, and maybe we ought to quarantine people for 14 days if they just shut up about the politics and tossing around the partisan things.

We can do better. I think we need to get the funding to the President, and then let's get these kits out, a million by the end of the week. That's good progress.

Dr. Schuchat and Dr. Kadlec, I do want to underscore again our rural areas. We have 83 critical access hospitals in Kansas. Probably that will be reduced just simply because of what's going on. We're older, a lot of nursing homes, a lot of long-term care enterprises. That's just ripe for this kind of thing. I might point out in

the Senate we have quite a few people who have reached that age as well.

But I hope that we can follow the chart here that the good Senator Cassidy has suggested. I think that's an awfully good thing.

I'd say one other thing. I think part of our job is to stand with you when you're taking the boos, and stand behind you when you're taking the bows. All of you should take a bow. I think we ought to have this situation where we have your back not so much to criticize. We're trying to work with you.

We're going to get this done. We are going to get this done.

I would say, Mr. Chairman, that in today's Wall Street Journal, last summer, for seven bucks, $7.85—where is that?—you can get this for $7.85. If you want to go to Amazon today, it's $114.97.

Senator CASSIDY. I'll give it to you for $50.

[Laughter.]

Senator ROBERTS. If you bought a liter of this, it was $14.00. Now it's $229. That's ridiculous. I guess that's the supply situation that Amazon thinks would be the case.

I wanted to ask one other thing. The term that I was and that I think a lot of people are confused about is community spread. "Spread" is a verb, but it doesn't mean that the whole community—that this disease will spread throughout the community. It just indicates there's one person where we don't know where the source was. Is that correct?

Dr. SCHUCHAT. Yes, that's right. We're really just differentiating it from spread from a close contact or travel associated. It doesn't mean the whole community is affected, and what it really means is that if we threw enormous resources at it we could probably map out each of the links, but it's more important to go from man to man to zone when you start to see that community recognition, to put the most effort where it can be the most impactful and perhaps less on the individual contact tracing and more on readying the healthcare system, readying the schools and so forth.

Senator ROBERTS. I thank you very much.

I yield back.

The CHAIRMAN. Senator Roberts, you did a better job of asking your own question than I did, so thank you for doing that.

Senator Kaine.

Senator KAINE. Thank you, Mr. Chairman. Mr. Chair, I express condolences about the tornados in Tennessee yesterday that were devastating.

The CHAIRMAN. Thank you.

Senator KAINE. I want to thank the witnesses and actually thank the Chair and Ranking. This Committee has had a number of roundtable sessions, and these witnesses have been here and presented to us. The first one was on the 24th of January. That's positive.

I will say when we had that briefing on the 24th, and we've had briefings since, and then when the White House appointed the special committee on the 29th, it made me surprised when I looked at the President's budget that came to us on the 10th of February to see that in that budget there was a 52 percent proposed cut to the World Health Organization and cuts between 5 and 10 percent to the NIH, the CDC, and the overall HHS budget. It does not seem

to me to be a wise time to take a scalpel or a meat axe to the public health infrastructure. So I hope we're looking at what we do from an appropriations standpoint not only on coronavirus but also looking at the pieces of the budget that fund the public health infrastructure so that we don't do damage to that at this time.

Similarly, the budget contains significant cuts to Medicaid. And although it's described somewhat euphemistically, it's pretty clear that the Medicaid cuts are going to cut people in states that have adopted Medicaid expansion under the Affordable Care Act, and the Administration is right now in courts, as they've been every day during this Administration, trying to eliminate the Affordable Care Act. The Supreme Court announced yesterday that it will take up the case later this year.

It is not a good time. It is not a good time to take a meat axe or a scalpel to the public health infrastructure. It is not a good time to scare people about whether or not they're going to have health insurance. I'm not sure there is a good time to do that, but you cannot do it at a worse time than when you're doing it at a time when people are concerned about a pandemic.

Dr. Fauci, I want to ask you a question. Like Senator Alexander, I was looking forward to your presentation at the Senate lunches today. But during the middle of this hearing I got a notice, and I don't know if it's accurate, that you will no longer be presenting at the Democratic lunch. Is that accurate?

Dr. FAUCI. To my knowledge, no. I mean, I'm planning on leaving here and being at both lunches.

Senator KAINE. Okay.

Dr. FAUCI. This is—right? Yes?

I'm just told it's changed, but I don't know why.

Senator KAINE. I just want to be clear about this. I was notified yesterday that you and the Vice President would be presenting to both the Democratic and Republican lunches. I got a note from the Democratic leader that came in to all of us at about 9:25 that said you would no longer be presenting and Ambassador Birx would be presenting. But that's the first you've heard of this right now?

Dr. FAUCI. What you just mentioned to me is the first I've heard of it, yes.

Senator KAINE. Do you have any idea why you've been disinvited to the lunches?

Dr. FAUCI. I don't know.

Senator KAINE. All right. Let me ask a question about a population that—I will say, that is not a confidence builder. It is not a confidence builder when the person who—let me finish—when the person who we have a lot of faith in and really knowing this stuff, who has done it for presidents of both parties for decades, who is advertised as coming to advise us at lunch, we are now notified you are not coming to lunch.

Dr. FAUCI. One correction. I'm sorry, but it took me by surprise.

Am I going?

I'm going.

Senator KAINE. You're going, but I thought your staff told you that you weren't going 30 seconds ago. So what is the answer to this?

Dr. FAUCI. I am invited, yes.

Senator KAINE. Why did your staff tell you that you were not invited and then 30 seconds later change it? Am I that persuasive?

[Laughter.]

Senator KAINE. Well, we'll see what happens at lunch. It's not a confidence builder. I will say it's not a confidence builder.

Let me ask about a population that is of significance to Virginia and everybody here, which is the military. We don't have a DOD person here, but I know you must be working in tandem. We have a lot of Virginians who are deployed in Vicenza, Italy. We have a lot of Virginians who are deployed in South Korea. We have a lot of Virginians deployed in Sicily, Italy. So I'm just thinking of two of the countries that have been mentioned as places where there is significant coronavirus. My understanding is, at least at the Vicenza base, families are being urged to stay on base.

Talk a little bit about your interaction, any of you who deal with this, your interaction with the DOD. Are we likely to see more of this, and is there a quarantine where you stay on the base in South Korea? Are we likely to see it in Germany? That's the last question I have.

Dr. KADLEC. First of all, my interaction with DOD is daily. We basically have a call at 12 o'clock with the entire enterprise of the Department of Defense, Office of Secretary of Defense, Joint Staff, Defense Health Agency, Defense and Logistics Agency. So what they're doing is basically abiding by CDC's rules and guidelines in these circumstances. Obviously, a base circumstance is different, particularly overseas where you have the means to basically isolate the population there.

Senator KAINE. Are we doing "please stay on base" other than in Vicenza right now?

Dr. KADLEC. Sir, I don't know the particulars of that base, but we can certainly get——

Senator KAINE. I'll ask them.

Dr. KADLEC. But they do conform with CDC's guidelines and what should be done to protect their military force.

Senator KAINE. My time has expired.

The CHAIRMAN. Thank you, Senator Kaine.

Senator Romney.

Senator ROMNEY. Thank you, Mr. Chairman.

I appreciate the work that's been done by the public health community in our country to delay the arrival of the COVID–19 in the United States. It's really quite remarkable to me that while other countries have seen so many cases, whether it's Italy or Iran, South Korea, Japan, that we have been able to delay it. Clearly, you can't keep it away forever, and we already have the community transmission, which you predicted.

I want to turn to another issue, however, which is whether we as Congress and administrations, Republican and Democrat, have done enough to prepare protective equipment for our medical professionals and for our public at large. I don't point to anybody. This isn't you; this is us responsible for funding. Given the fact that our medical professionals need masks, gowns, gloves and so forth, what percent of what would be needed by medical professionals if we were to have a full-blown pandemic—and I hope we don't. But if

we were to have one, what percentage of what we would need for our medical professionals is in the Strategic National Stockpile?

Dr. KADLEC. Sir, I can give you a rough order of magnitude. It depends what kind of—like you said, severe pandemic, 10 percent of what we need right now. If it were to be a severe event, we would need $3.5 billion in 95 respirators. We have about 35——

Senator ROMNEY. About 10 percent.

Dr. KADLEC. Ten percent, and they're working actively to——

Senator ROMNEY. That scenario is where I've been most concerned. It strikes me that we should have substantially more than 10 percent, what would be needed for a substantial pandemic, that we should have that in stock. I can't believe that we, Congress—I'm not blaming the Administration. This is Congress and appropriating, and it's prior administrations as well. That should be in place.

Do masks help for the general public? Let's say we have a major pandemic and people are concerned. They're going to the grocery store, they know other people there, it might be infected. Do masks actually help? Do they prevent or reduce the likelihood of being exposed to the disease, Dr. Fauci?

Dr. FAUCI. It depends on the mask. If you look at the N95 masks, they're much better than those sort of floppy masks. In general, right now, I think the question you're asking——

Senator ROMNEY. No. I'm really asking if we were to have a major outbreak of some kind——

Dr. FAUCI. Yes. The most important thing for a mask would be, if someone is infected, to prevent them from infecting others. The other is the healthcare provider, to protect them.

Senator ROMNEY. Of course.

Dr. FAUCI. The general public who can wear them, that could certainly prevent gross droplets from going when someone sneezes and coughs on you. But it doesn't provide the kind of protection that people think it does. Therefore, there are some downsides, because people keep fussing with the masks, and you could——

Senator ROMNEY. Better than nothing.

Dr. FAUCI. Yes.

Senator ROMNEY. Do we have masks in our Strategic National Stockpile for the general public? We do not. Okay.

Let's turn to aircraft. If someone on an aircraft is infected and sneezes, how many people are going to be exposed to that disease? Is it just a couple of people, the people sitting next to them? Is it the whole aircraft?

Dr. SCHUCHAT. For this kind of virus, we're thinking just the couple of rows around it. For other types of infections, it might be broader.

Senator ROMNEY. Should our flight attendants, not on our instruction, tell them not just to fasten their seatbelt but that if you cough or sneeze, you should cough into fabric or into your sleeve or whatever? I mean, I keep going onto airplanes, someone coughs or sneezes and I hear it barking out. It's like, my goodness, in conditions like this, just the general flu, given the fact that we have the flu going on, and colds, should we not be telling people on airplanes you may not cough or sneeze unless you're covering your mouth?

I think I know the answer to that.

[Laughter.]

Senator ROMNEY. Let me ask another question, which is let's say we do get a vaccine that tests positively and so forth, and goes through Phase 1 and Phase 2 clinical trials. What does it take to get a major production done? How long does it take to actually kick the production up? How long does that take, and who does that? Who is doing the manufacturing once we know this is a vaccine that works?

Dr. FAUCI. That's a very good question, Senator, and that was really one of the things that was discussed yesterday when the President and the Vice President brought in the CEOs of a number of companies. And that's really important, because what I was talking about, a year to a year-and-a-half, if you don't have the production capacity to make tens and tens of millions of doses, it may take even longer. And the ones who can do that, essentially, are the pharmaceutical companies. The Federal Government is not going to be able to make hundreds of millions of doses. It's going to have to be partnership with the private sector.

Senator ROMNEY. Do we have that capacity in the United States? Is this capacity outside the U.S.? I guess the question I'm looking for is whether legislatively or from an appropriations standpoint we should provide funding to have the capacity to make large numbers of vaccines, we should have that capacity in the U.S. and have it ready at the go in case—if this isn't the pandemic that we're worried about, if another one comes down the road, is this something we should actually have ready to go?

Dr. KADLEC. Yes, sir. In fact, right now the only capacity we have is really egg production, which wouldn't be relevant to the vaccine candidate or the candidates that we at BARDA are pursuing. So we'd have a longer than 6-month wait to basically produce vaccines on scale.

Senator ROMNEY. Yes, Okay. I want to underscore that is an area that we ought to consider making an investment in.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Romney.

Senator Smith.

Senator SMITH. Thank you very much, Chair Alexander and Ranking Member Murray.

I want to just thank again all of you for being here today, and also please extend my thanks to your amazingly hard-working, professional staff, who I can only imagine have just been going nonstop for months now. So, thank you.

I want to start by asking a question about the misinformation and flat-out falsehoods about the coronavirus that have been circulating, and amplified. I worry that it's being amplified for political reasons, to the point of Senator Roberts and others that we don't want to politicize this.

My question is what is the impact of this misinformation, and what should we do about it? I'm sort of looking at Dr. Schuchat and Dr. Fauci in particular. I mean, it's embarrassing to go through all of the things that have been said on national media, including, honestly, by our President.

Dr. Fauci, it's not true, is it, that this is just like a common cold and that we can expect that this is going to be gone when the weather warms up? Is that true or not?

Dr. FAUCI. Let me explain. In general, respiratory illnesses such as the prototypic influenza virus is seasonal, and when the weather gets warmer, as will happen in March, April and May, you will inevitably see a marked diminution in influenza. The same holds true for other respiratory viruses, including some of the common cold coronaviruses.

This could happen with this, but we don't know it. And the reason we don't know it is because this is a brand new virus with which we have no experience. So even though the concept that when warm weather comes many respiratory viruses diminish, we have no guarantee at all that this is going to happen with this virus.

Senator SMITH. It might come back again.

Dr. FAUCI. It certainly might.

Senator SMITH. It's not like we're going to all be—we're not going to worry about——

Dr. FAUCI. It is conceivable given the degree and the efficiency of transmissibility of this virus that we might have a cycle. It may come and be seasonal and come back. That's quite possible. We don't know that, but that's possible.

Senator SMITH. We've heard so much misinformation. I mean, it's been said that this virus was developed as a tool to wage economic war on the United States. It's been said that this is part of a strategy to try to bring down the economy. I mean, it's ridiculous, and it's harmful.

Could you as public health professionals comment on why this makes it more difficult for us to address this epidemic, and what we should do to combat this kind of misinformation?

Dr. FAUCI. I think we need to speak out often and loudly about how much nonsense this is. This is not new with coronavirus. There are always conspiracy theories when there's a new disease that people are afraid of and that is really novel to them.

I have to say, I'm thinking back now about 35 or 37 years ago. I sat in this room and tried to explain to the Committee then that HIV was not a virus that was developed by the CIA to essentially eliminate certain populations. It's crazy, but this is what happens when you have outbreaks. There's a lot of misinformation.

Senator SMITH. Then there's consequence. My point is that there's consequence to this misinformation that makes it more difficult for public health professionals to respond and to take care of the population in the ways that we need to, and that's what worries me.

I want to just—I know I don't have much time, but I want to ask about another issue that is extremely important to my folks at home. I'm very proud of the Minnesota Department of Health. They do great work, and they're very worried about what's going to happen, the capacity pressures that they're going to be experiencing as they try to address the coronavirus on top of everything else that they're addressing.

My question is first that it's not only a question of getting the diagnostic tests out so that people can respond, but also these labs

need to have the people in order to do the testing, because they're already—it's not like they're sitting around with nothing to do right now, right?

Dr. SCHUCHAT. Yes, absolutely. The public health labs are short staffed on a good day, and so this is a very big challenge, and that is one of the reasons that we are keen to get the clinical labs up and running with the tests. I think you bring out the point that it's not just the laboratory capacity for public health, but it's all the other things they do. They're very busy with contact tracing. They're busy with following up with the people who traveled who they're supposed to follow. They're spread really thin, and I think it illustrates the principle that in this type of evolving situation, we really need to put the most effort where it can do the most good and not get distracted with smaller things.

Senator SMITH. It's also why it's so important as we work on these emergency appropriations that we're making sure that these departments at the local level are reimbursed for the work that they've already done, right?

Dr. SCHUCHAT. Yes, absolutely.

Senator SMITH. Absolutely, and that they have sufficient dollars so that they're not dipping into money they would have gotten anyway to do the work that they don't really have the funding to do right now.

Thank you very much.

The CHAIRMAN. Thank you, Senator Smith.

Senator Scott.

Senator SCOTT. Thank you, Mr. Chairman. And thank you to the panel for being here this afternoon, almost. You've spent quite an amount of time with us.

The one thing I'm not concerned about, frankly, is whether or not Congress will provide the necessary resources in a timely manner to deal with the challenges that we face with the coronavirus.

I'm not going to ask you questions that have been asked several times by several different Senators as it relates to what will happen if. I do think what we have not had a lot of conversation about is putting this virus in context, context that the average person in this Nation can digest very quickly and understand the actual risks that are associated with the virus.

Whether it's the 2003 SARS or the 2009 swine flu, whether it's the current flu season, the number of Americans that have died because of the flu, whether it's even that overnight Tennessee lost 19 people because of a tornado, I would appreciate it if you all would just take my time to help us put in context what 80 percent of the people would experience if they were infected by the coronavirus, which seems to be a fever and a cough. Maybe that's downplaying it. If it is, please let me know. And then the 20 percent of folks who are elderly, who may have disabilities and comorbidities that may be at a heightened risk.

If you would just use my 3 minutes that I will have left by the time I finish with my opening comments to help me and the rest of the folks in South Carolina who are seeing this issue on every screen, and oftentimes seeing it, really from my perspective, hyped up in a way that is not helpful.

I'll close with this. I think there are those who are alarmist who are really painting a picture that is very difficult to digest, and then there are those who are acting with a sense of urgency. I think the four of you are acting with a sense of urgency but not being alarmist at all. Can you now use 2 minutes and 48 seconds to help me understand the situation?

I'll start with Dr. Hahn and maybe work my way through.

Dr. HAHN. Senator Scott, I can address the regulatory issues. We have worked with urgency. We've issued two EUAs to help facilitate both masks and diagnostic tests——

Senator SCOTT. Absolutely.

Dr. HAHN ——in support of these terrific public health colleagues.

Dr. KADLEC. Sir, I'm going to yield my time to Dr. Fauci and Dr. Schuchat. My job is to think of the worst case, so I'll let them talk about the real case.

Senator SCOTT. Thank you.

Dr. FAUCI. Senator Scott, you really bring up a good point, and it really has to do with what you consider relative risk and how that relates to the unknown.

Senator SCOTT. Yes.

Dr. FAUCI. The thing about what's going on now is that since it is a new virus, we don't really know exactly where it's going to go. If you look at the disease burden, morbidity and mortality, every single year influenza does a significant amount of health damage not only to our country but to the rest of the world. The thing about influenza is that although there are many things about it that are unpredictable, we kind of know the bracket of how many people are going to get sick and how many people are going to die. It's tragic, it's death, it's suffering, we don't like it, but we kind of know.

When you're in the area of the unknown, you have to walk a delicate balance——

Senator SCOTT. Yes.

Dr. FAUCI ——of not overshooting and having panic, but not also undershooting and be in a situation where you don't respond as aggressively as you should.

Senator SCOTT. A sense of urgency.

Dr. FAUCI. Yes.

Dr. SCHUCHAT. Just to add that while in a large population most people who get infected will probably have very mild symptoms, some will have severe illness, pneumonia, and be critically ill, and what's unknown right now is what that total will be. Will we have many more cases a year than we have with flu, which would be very difficult to handle, or will we be able to slow the spread and protect the healthcare system? And it's this balance that Dr. Fauci mentioned of not overreacting but not underreacting, because the risks of underreacting could be that we have second-and third-order complications. We don't want to have the healthcare system flooded with people who don't need to be there, but we really need to build it up because if this is going to be like a really bad flu, we are going to need to buildup that healthcare system.

Senator SCOTT. It seems to me, out of the 90,000 known cases, we've had how many deaths?

Dr. SCHUCHAT. Right now it's about 3,000.

Senator SCOTT. Three thousand?

Dr. SCHUCHAT. There are biases in the early information. Some countries have good information about very mild disease——

Senator SCOTT. A lot of countries do not.

Dr. SCHUCHAT ——and others you can only keep up with the severe disease.

Senator SCOTT. I would just end my comments, Mr. Chairman, with the fact that I think 3,000 deaths should get everyone's attention, and we should be acting with a sense of urgency but not buying into hysteria that will make it even more difficult for healthcare providers—my mother has worked at a hospital for about 45 years—make it more difficult for healthcare providers to have the resources and the equipment necessary for them to take care of those folks who walk into hospitals needing assistance. Thank you.

The CHAIRMAN. Thank you, Senator Scott.

Senator Hassan.

Senator HASSAN. Well, thank you, Mr. Chair and Ranking Member Murray.

Thank you to the panelists and your entire teams. You all have been working tirelessly, and we know that, and we are very, very grateful.

I wanted to start to get at the issue, Dr. Schuchat, with you of diagnostic testing capacity. I know the Administration has ordered an independent review of the CDC lab about problems that arose in the manufacturing of the diagnostic test kit. What is clear at this point is that the domestic testing capacity has been significantly lower here in the United States than what we've seen in countries like South Korea and Italy.

Dr. Schuchat, are you confident that the policies put in place by CDC and FDA over the past few days will allow states to test for coronavirus at a level commensurate with what this rapidly evolving outbreak requires?

Dr. SCHUCHAT. I am optimistic, but I want to remain humble because we see in emerging infectious diseases surprises.

Senator HASSAN. Right. And one of the things that we're dealing with right now—so, for instance, my State, which had its first confirmed case yesterday, has a dwindling number of kits, and they tell me they have to do two tests per patient, because if you get a negative, then you're going to re-test the next day, and we're still having to send tests into CDC for confirmation even when we do them at the state level.

When do you expect to reach a point where CDC will no longer have to perform confirmatory testing on samples from State labs?

Dr. SCHUCHAT. That should be very soon, State by State, as they verify their procedures, and we've worked closely with FDA to expedite that.

Senator HASSAN. Okay. And has a lack of Federal resources or personnel within CDC played a role in what appears to have been a lack of ability to scale response efforts in order to meet the demand for diagnostic testing across the country?

Dr. SCHUCHAT. Not to my knowledge.

Senator HASSAN. Okay. To Dr. Fauci and Dr. Kadlec, I'm concerned that the delays in making test kits widely available means we don't yet have a full sense of the scope of the problem. I mean, if we can't test everybody who has these symptoms yet, we may not know what the full scope is. And having an accurate accounting of the problem we face is critical for your ongoing preparedness and response efforts.

Dr. Fauci, and then Dr. Kadlec, how has our limited diagnostic testing capacity impacted your response efforts, and what steps are you taking to mitigate those challenges?

Dr. FAUCI. That's actually not something that I'm involved with, but I'd be happy to give you an opinion of that. I mean, obviously you would want to be able to have as many tests as you need to be able to do, and that's what the CDC right now is ramping up, in collaboration with the state and local health departments. The first level is to get individuals in multiple states—they started off with six, and it will probably be more, if I'm not mistaken—to be able to test people who come in with symptoms that would be suggestive of a respiratory illness, either flu or coronavirus, and if they don't have flu, to determine if in fact it is coronavirus. As we improve and get better and better at that capacity, we'll have a much more accurate assessment of what is going on in the community.

Senator HASSAN. Thank you.

Dr. Kadlec, briefly?

Dr. KADLEC. Yes, ma'am. I think the thing is there are two elements there. One is the trigger in terms of action, how do you respond and early warning, and I think one of the things that CDC has been doing—and I'll let Dr. Schuchat comment on this—is using its influenza-like illness network and the tests that they do there to be able to test broadly to see surveillance. So there's a trigger to respond, and then there's the more important one, I think, in terms of understanding what's circulating, which is really seroprevalence of this virus in terms of being able to detect antibodies in people's blood broadly to understand what's the denominator of people who may be asymptomatic. So both of those have a significant importance.

For our part with BARDA, we basically are funding commercial laboratories and basically trying to develop point-of-care diagnostics to advance that.

Dr. Schuchat.

Senator HASSAN. Quickly, because I have another question to get to.

Dr. SCHUCHAT. Yes. We're doing that community surveillance in the cities and hope to expand it broader so we see what the tip of the iceberg—what the bottom of the iceberg really is.

Senator HASSAN. Thank you. I wanted to turn to Commissioner Hahn for just a moment. The FDA has such an important and wide-ranging role to play in our ongoing response efforts. As you know, your announcement last week regarding an unnamed drug shortage that was attributed to disruptions in China due to the coronavirus caused some confusion among public health experts. And just now you said you couldn't name it, and for those of us who either ourselves or have loved ones who have multiple medications, the notion that there's a shortage but we don't know if it's

ours is a really difficult thing for the public and for people who depend on pharmaceuticals.

Yesterday you stated that the U.S. labs could perform up to 1 million tests this week, while public health experts have said that they hope to see U.S. labs complete 10,000 tests per day, and tests take time, and they take staff. So I understand it's fast moving, but it does seem to me like FDA's messaging has been confusing and at times contradictory over the past few days.

I am over time, so I actually won't ask you to respond right now, but I would urge you—and perhaps we can have this conversation offline—to get a process in place so that you are making sure that your communications are clear to the public and that they're integrated. I look forward to having that conversation with you a little bit later.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Hassan.

Senator Loeffler.

Senator LOEFFLER. Thank you, Chairman Alexander, Ranking Member Murray.

Chairman Alexander, I want to express my condolences to your State for the loss in the tornados this morning. I know we're all monitoring that situation.

Thank you all for your time here today.

If you look at where we are now in terms of the capacity for preparedness, for response, we've obviously come a long way. However, the evolving nature of infectious diseases means that we need to continue to innovate. Your agencies have taken significant strides to improve our national health security capacity, but in America much innovation also comes from the private sector.

I commend your steps taken with this Administration to address this emergency. What can we do, however, to ensure that the private sector supports the response and, in these situations going forward, that these innovations can quickly reach the American people?

Dr. SCHUCHAT. Sure, I can start. You know, we've been taking steps to reach out to the business community, the private-sector community. Just yesterday I was on a call with over 1,000 companies about what this epidemic means to them, and also how they can help. We also, a few of us, met with the pharmaceutical industry yesterday, a number of the big companies, about both drugs and therapeutics. Knowing that you're from Georgia, we have a really phenomenal collaboration with Georgia Tech Research Institute, really to help us modernize some of the data challenges that plague public health. So those are a few areas to mention.

You may want to go on.

Dr. FAUCI. Just to underscore that I was very encouraged by the enthusiasm of the CEOs of the pharmaceutical companies yesterday when we met in the Cabinet Room of the White House. It was really very gratifying to see the fact that they really wanted to do anything they could to help us. And as I mentioned in response to a previous question, we're not going to get the kind of production of interventions unless we partner with the pharmaceutical companies.

Dr. KADLEC. Ma'am, if I could just comment on one thing, two programs with ASPR, BARDA DRIVe and ASPR Next, are two things that are looking specifically at innovations around medical counter-measures and other things that would enhance our responses. BARDA DRIVe basically met with 1,500 companies looking for particular things, diagnostics, to work on this, and ASPR Next is looking particularly at the supply chain issues as it relates to pharmaceuticals.

Dr. HAHN. We've been working with diagnostic companies with vaccines, biologics, and with drug manufacturers both around the development issues, but the development of products to address this outbreak.

Senator LOEFFLER. Thank you all.

The CHAIRMAN. Thank you, Senator Loeffler.

Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

I want to start with the idea of the fact that we have an emergency spending bill going through the Congress quite rapidly, and some of the issues that have been raised, I'm hoping that we will properly address those in this appropriations bill, but also then be able to follow-up and make sure that the right policies are in place.

I want to start with a discussion we've been having about domestic production of things that are essential in fighting epidemics. I remember in my former life as a Member of the House of Representatives an instance where one of the manufacturers of flu vaccine in England was shut down and there was a shortage, and there was a lot of worry, and we rationed the flu vaccine that year, changed the standards of who should seek one and who should not.

I remember, also in the year that I believe we were fearing a very serious strain of flu, inquiring about our domestic production capacity for the flu vaccine, and we had none—none. And I asked should we—I think I might have even asked this to you, Dr. Schuchat, all those years ago, that should we assume that if we had put in an order with a foreign manufacturer for however many doses but there was a huge outbreak in that foreign country, that they will commandeer that for their own public health purposes, and I think the answer I got at the time was yes, that would be a prudent and safe assumption on the part of policymakers.

As we're moving forward with a very significant, I hope, appropriation of funds to address this emergency, I hope that we assure that we don't make those mistakes again. I think I heard all of you testify that having domestic capacity is very crucial in this. Am I correct?

Everyone is nodding. Okay.

The second thing I wanted to get into is we've talked about lab and testing capacity in the U.S. I'm not sure we're all agreeing on the meaning of the words and things. So, for example, when I heard the interchange between Senator/Dr. Cassidy—there's a lot of initials—I understand PCR to be polymerase chain reaction-based testing, IgG to be immunoglobulin, whatever. And it's IgG, IgM, and IgA, and he was talking about can we have that test soon. So that's a blood test, if I recall.

CDC is using a three-sample test—is that correct?—that has a nasal swab, a throat swab, and a blood sample?

Dr. SCHUCHAT. There's a difference. We're recommending a throat swab and a nose swab for that polymerase chain reaction. We have been developing a serologic test for those antibodies that Dr. Cassidy was talking about, the IgG, or it could be IgM, and that's really more for the population level to understand who is already immune, how much disease has there been that didn't even come to care.

Senator BALDWIN. Since I want to get in a couple more questions, can I just assume that we're going to have a PCR test for a while that we rely on?

Dr. SCHUCHAT. PCR is a key tool for a while with the private sector and public sector, and then potentially a point-of-care some years ahead.

Senator BALDWIN. Okay. I wanted to get into the lab capacity. We've talked about public health labs, clinical labs, there's been a reference to academic labs, private labs. I don't know if those are four separate classes of labs. If they are, I want to add one other idea if we need to surge our capacity for testing, and that is I'm aware of veterinary labs that look at these same sort of tests, but they're not usually looking at humans. They're looking at either pets at veterinary clinics, domesticated animals, or the Fish and Wildlife Service also studies zoological infections.

If there were an emergency, I don't know if you've ever thought about tapping into that capacity, but I'm thinking particularly of the skilled workforce that deals with Level 3 labs, et cetera. That may be a crazy idea. If it's not, I hope you discuss it and think about it if we need to have a surge in our capacity to surveil the transmission of this disease.

The CHAIRMAN. Thank you, Senator Baldwin.

Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Dr. Hahn, I'm going to follow-up on the first question that Senator Baldwin raised with you. The FDA reported its first coronavirus-related drug shortage last week, and this morning you indicated that India had restricted a number of active pharmaceutical ingredients. The FDA has testified previously that only 28 percent of the manufacturing facilities making APIs to supply the U.S. market are located in our country. By contrast, the remaining 72 percent of API manufacturers supplying our American market are overseas, and 13 percent are in China.

You and I have discussed previously the legislation that I've introduced with Senator Smith, the Mitigating Emergency Drug Shortages, or MEDS Act, which has been endorsed by more than 50 organizations. Our bill contains new reporting requirements that would help FDA gain far greater visibility into the drug supply chain, including where certain critical drugs are manufactured, the source of active pharmaceutical ingredients, and manufacturing contingency and redundancy plans.

Given the problems that we're already seeing, do you believe that the concepts included in our legislation, our MEDS drug shortage bill that I've introduced with Senator Smith, would be helpful?

Dr. HAHN. Senator, thank you for your question. We really appreciate your leadership on this issue. This has been an ongoing

problem prior to the coronavirus outbreak and continues to be, just as highlighted by what we've seen over the last several weeks.

The agency totally shares your goal with mitigating and increasing redundancy for manufacturing, particularly in the area of advanced manufacturing. We look forward to working with you on that.

With respect to your particular bill, you know that we're going to be generating written response to that so that we can provide the technical assistance, and we very much look forward to working on that bill with you, Senator.

With respect to the one drug that you mentioned that we last week announced was in short supply because of the coronavirus outbreak, we—and I mentioned this before, and again this morning—we have already listed that on our drug shortage list that is available to the American public and the American providers, and have done so since the beginning of the time when we identified that as a shortage.

Senator COLLINS. Thank you.

Mr. Chairman, I'm hopeful that we might be able to move that bipartisan bill.

Dr. Schuchat, in mainland China, the coronavirus case fatality rate among older patients is significantly higher. The estimate I've seen is that 15 percent of patients 80 and older do not survive, compared to just over 2 percent in the general population of patients. In addition to the figure from China, there is the tragic situation evolving in Washington State regarding the spread of the virus in a long-term care facility. This is of particular interest to me because I represent the state that is the oldest in the Nation by median age, and I also chair the Senate Aging Committee. I know Senator Casey brought this up generally with you as well.

My question for you is what is the Administration doing, and what is the CDC doing, in all aspects of response to ensure that we have best practices in assisted living facilities and nursing homes or long-term care facilities?

Dr. SCHUCHAT. Yes. Thank you so much for that question. I've been speaking regularly to the Administrator of CMS, Seema Verma, who is extremely concerned about this issue as well, and they are sending a liaison to our emergency response, and we are using our guidance adapted to the situation. They're using their field staff to make sure that practices around the country are best practices suited for this concern. Infection control is always an issue in the different levels of healthcare, and the elderly are very vulnerable to respiratory viruses. We see that same differentiation in mortality with influenza as well, that the elderly are very, very vulnerable.

Senator COLLINS. Thank you.

The CHAIRMAN. Thank you, Senator Collins.

Senator Rosen will ask our last round of questions so that our respected professionals who are here, some of them are going to go have lunch with United States Senators and explain more. We'll be able to finish by 12:30. Then I'll call on Senator Murray for any questions or comments she has. We'll wrap up by about 12:30 so that you can leave.

Senator Rosen.

Senator ROSEN. Thank you. Thank you for bringing this hearing here. Thank you for your round-the-clock work on this. We are so very grateful for a lifetime of work and care in this avenue.

But I want to speak about the issue of access and capacity and how we can use telehealth in our evaluations to potentiate our response, because many of our constituents are worried about the spread of coronavirus. They have questions about their own health. And since the symptoms of coronavirus can present like a cold or the flu, I can only imagine, with what people are seeing in the news, that they're going to seek out care. People are a little nervous, needless to say.

In Nevada we have large areas of rural population far away from city centers, and an increase in those seeking care and having to travel is not only hard on them but creates a burden on the system. So depending on how easily this virus spreads, how can we use telehealth as a first response to help people in their own homes? This could contain the virus, relieve a burden on our emergency rooms.

What are your recommendations—I have a two-part question—on addressing the barriers to accessing telehealth? And do you have any plans potentially to operate a national hotline or a web portal for initial screenings through some kind of telehealth hub? And then people could be referred to their local care or further out if needed.

Dr. SCHUCHAT. We've made a lot of progress since the 2009 pandemic, where this was a huge issue. Just getting a nurse triage line developed in one State, we had more lawyers than we had health people trying to figure out how to do that. But most of the health plans have actually worked out some of these kinks, and we've already been contacted by a number that are adapting their nurse triage lines, the hotlines that you talk about, really for their State or for their clinically covered individuals.

We also have been working with telehealth together with other parts of government to try to understand what kind of approaches are appropriate in the rural areas, as well as what the coverage will be, and that's one of the things that the CMS is looking at now.

Dr. KADLEC. Ma'am, one thing that we've been doing for the last 2 years, we funded two pilot programs called the Regional Disaster Health Response System, one in Mass General and one in University of Nebraska, in Nebraska particularly looking at the nuances of how we could use telehealth to expand outreach to not only Nebraska but to other parts of the region in that way and evaluating what are both the legal and practical limitations to that.

Senator ROSEN. Can I ask a question about telehealth? Because this would have to do with insurance and telehealth. Considering that this could be a global pandemic, or we have other issues, regional issues, rural issues, I wouldn't want insurance to be a barrier to someone being able to at least access a telehealth hub or get the care, because germs do not care whether you're insured or not, Democrat or Republican, old or young, et cetera, et cetera. So how do we address this issue of people feeling like they couldn't call or use this because of insurance limitations?

Dr. SCHUCHAT. Yes, I can just say the strategy that we're thinking through at CDC is really trying to identify the right level of care for the right situation, whether it's telehealth, urgent care, nurse hotline, or emergency room or office. In the circumstances that we could see, keeping people out of the healthcare system physically could be in everybody's interest, to preserve it for those who need it most. The insurance issues in a pandemic would probably be somewhat different than in routine times.

It looks like Dr. Kadlec wants to say something there.

Senator ROSEN. Yes.

Dr. KADLEC. I would just like to add that in declared disasters, we have the opportunity to declare individuals as NDMS patients, National Disaster Medical System patients, where they get reimbursed, the provider gets reimbursed for 110 percent of Medicare rates. That would be an interesting way to look at how you could evaluate it in a pandemic or something of this sort to use that, and we're in conversations, initial conversations with CMS to understand if that could be utilized in this way.

Senator ROSEN. It could be really impactful, negatively or positively, if we don't address this in the right way. So understanding that, what additional resources or what should we be looking at as we're going to be voting on some funding and resources hopefully this week or next week that you would need to address this issue? Anyone?

Dr. KADLEC. Ma'am, can I get back to you on that?

Senator ROSEN. Yes.

Dr. KADLEC. Thank you.

Senator ROSEN. Perfect. Thank you.

I yield back.

The CHAIRMAN. Thank you very much, Senator Rosen.

Senator Murray.

Senator MURRAY. Mr. Chairman, first of all, thank you for having the hearing.

I do have to ask each one of you, because this is a very serious challenge. We're seeing the impact in my state. Even though it may not be a serious illness for each individual that has it, they can come in contact with somebody who is medically fragile, so containing this is absolutely critical. I just think it's really important right now, and I'm concerned that people trust the information that they are hearing so they do the right thing for themselves and their communities and our country as this moves forward. I mean, where do you turn for trusted information? It's the experts like all of you, and that's who people need to be listening to. I think you have heard the concern expressed here that the President has made some statements contradicting all of you. Our nation's top experts have even criticized the media for covering this. So I just think it's really important for us to hear from all of you, yes or no, can the American people count on you to be 100 percent transparent on this virus and the government's response, even if you have to contradict a tweet or something that someone says?

Dr. SCHUCHAT. Yes.

Dr. FAUCI. Absolutely.

Dr. HAHN. Yes.

Dr. KADLEC. Yes, Senator.

Senator MURRAY. Thank you. And we need to count on that because this virus is moving quickly and we're seeing it in my state, we will see it in others, and I think that's so important.

Mr. Chairman, as families across the country watch the latest news and worry about the threat of this coronavirus, I'm really glad that we are taking the opportunity in this Committee to ask some of these urgent questions that I've been hearing from home and we're all going to continue to hear, and to talk about what we are doing as well and how we can prepare for the rest.

I would tell all of you that since we have been in this room in this hearing since this started, we have now learned of the first full closure of a Federal facility due to this virus. It's a DHS center in Tukwila, Washington, in my home State. It was just closed a short time ago.

It really is clear by the minute just how serious this is for people in my State of Washington, as well as the rest of the country. And this Administration, as you all know, owes some answers about the coronavirus, and they're going to keep hearing from me until I get the answers, including apparently from Vice President Pence shortly and several of you. This is really critical, and we need to stay on top of it.

I want to say again thank you to Senator Alexander. As he said, he and I have been holding bipartisan meetings on this. We want to continue to work together. Having that information, I can't tell you, is so important for the people in my State of Washington. We need to get these tests out, people need to know the answers. There are real-time decisions being made right now in my home State about school closures, about whether to go to entertainment, about what businesses should be telling people, and as these numbers continue to grow this is only going to be more intense. So we're counting on all of you.

The CHAIRMAN. Thank you, Senator Murray.

At a time when we're not in the middle of what we're in the middle of now, I want to have some more discussion about the extent to which we rely on other countries for our medical supplies and medicines and what we should be doing about it that we're not. It's an interesting twist. We have debates in this Committee about importing prescription drugs, and I've often thought that the way we talk about that is all mixed up because we import a lot of drugs, as we now see. But the difference is they're manufactured under FDA supervision, and they have a supply line that FDA supervises to make sure they're safe. When we do that, we have lots of drugs that are made overseas.

Maybe the National Academy should do a study on this. I've talked to some other Senators who are concerned about it. But I think one of the areas that this Committee should look at, and several Senators have mentioned it, is the extent to which we rely on other countries as sole sources of supply. When Chick-fil-A sells mac and cheese, it doesn't have one source of mac and cheese. It has at least two to make sure it doesn't run out, and we should certainly do the same with lifesaving drugs.

I also want to endorse what Senator Murray said about our appreciation for you telling us the truth and giving us accurate information about what's going on. We believe you do that. That's why

we have such respect for you and your professionalism. That's why you're here today. This hearing has been all about how do we provide accurate information to the American people so they can know what to do, and how do we provide accurate information to Congress so we can know what else we need to do. And we expect you tell us that whether it's unpleasant news or not.

We thank you for your professionalism, your extra hours during this period of time. Thank you for coming today. I read at the beginning of the hearing the comment on the front of the New York Times Sunday that said most experts agree the United States is among the countries best prepared to prevent or manage such an epidemic. Your performance today suggests why that is true.

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.

QUESTIONS AND ANSWERS

QUESTIONS BY SENATOR MURKOWSKI TO ANNE SCHUCHAT, ANTHONY FAUCI, ROBERT KADLEC, AND STEPHEN HAHN [1]

(1) Although there is debate from public health groups, Republicans, and Democrats, on the amount we need to appropriate to address this public health threat, my biggest concern is that the State of Alaska has the resources it needs to continue a sustainable response. We need to work together to ensure that Alaska has the funding to create quarantine facilities, invest in equipment, and invest in supplies for a sustained response. I also want to make sure that tribes and tribal organizations have access to supplemental funding and that our rural areas are prepared for a response. My understanding is that by declaring a public health emergency under the Public Health Service Act, states have been instructed to reallocate funding from current CDC grants to respond to the virus. However, there are many unanswered questions surrounding this instruction. Is it practical or ethical to ask states to use funding that has already been allocated for this year to public health prevention programs, to be used for their response?

(2) My good friend and the other Senator from Alaska, Senator Sullivan, has consistently raised an issue in which a "loophole" is allowing cargo plane crew members from China to disembark their planes in Anchorage without any screenings. Alaska is a hub for cargo planes and cargo ships. One of these ports is the International Port of Dutch Harbor in Unalaska. This port is the No. 1 fishing port in the United States, but is extremely isolated. Currently, there is no Federal agency in Dutch Harbor to ensure that the international crews coming to port are in compliance with Federal guidelines to protect the community from the virus. I am concerned about inter—agency coordination on guidance and protocol moving forward. From working with DHS, FAA, the Coast Guard, DOD, State Department—how will CDC make sure that the Fed-

[1] Witnesses did not submit written responses

eral Government is communicating a clear message through all of the Federal guidance being issued?

(3) Doctors, while the protection of our children from infection must be a top priority, I want to bring to your attention another high-priority issue-the food insecurity of far too many children across the country. As you may be aware, many families rely on the USDA's child nutrition programs to help stretch their meager household budget and ensure their children are able to access enough nutritious food to get them through the school day and school vacations. As we learned after the November, 2018 earthquake that hit Alaska, schools and community groups that provide these programs are not reimbursed unless the children eat in a congregate setting or the President has issued a disaster declaration. As the earthquake happened during the government shutdown, FEMA did not transmit the disaster declaration to the White House timely. As a result, students in Anchorage were required to be fed on running school busses parked outside their schools in the middle of an Alaska winter. My question is this: Given that closing schools for an extended period of time to avoid having children congregate during a viral outbreak may be the prudent thing to do, how will you help ensure that food-insecure children do not go hungry.

[Whereupon, at 12:30 p.m., the hearing was adjourned.]

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