

**DEPARTMENTS OF LABOR, HEALTH AND
HUMAN SERVICES, AND EDUCATION, AND
RELATED AGENCIES APPROPRIATIONS FOR
FISCAL YEAR 2021**

WEDNESDAY, SEPTEMBER 16, 2020

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:12 a.m. in room SD-G50, Dirksen Senate Office Building, Hon. Roy Blunt, (chairman) presiding.

Present: Senators Blunt, Alexander, Graham, Moran, Capito, Kennedy, Hyde-Smith, Lankford, Murray, Durbin, Reed, Shaheen, Merkley, Schatz, Baldwin, Murphy, and Manchin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CORONAVIRUS RESPONSE:
A REVIEW OF EFFORTS TO DATE AND NEXT STEPS

OPENING STATEMENT OF SENATOR ROY BLUNT

Senator BLUNT. The Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order.

I want to thank our witnesses for appearing before the subcommittee today to provide an update on where we are on the areas that they are so involved in on COVID-19.

As we continue to be challenged by this pandemic, in the country, we know that 195,961 Americans have died as part of the pandemic and 6.6 million have tested positive during the process of testing in the pandemic. This has rapidly swept across the globe, and even countries who thought their cases were contained are facing new outbreaks and dealing with those new and unanticipated outbreaks.

This is a new disease in many ways, and even after 9 months, we still know relatively little about this disease or coronaviruses generally. This has hindered our public health response. In many ways, this has been like trying to build a plane while we were flying the plane, and that is a challenging, challenging thing to deal with.

That is not to fully exonerate certainly the way the administration has dealt with it or the way it has been funded, and I am sure that justified criticisms can and will be leveled.

But history allows us to look over past events and to put current ones into perspective. If we wanted to look back just 6 years to 2014, for instance, when West Africa faced the largest Ebola outbreak the world had ever seen, and unlike COVID-19, we knew a lot about Ebola at the time. The disease has been around since the mid-1970s. It was a disease that scientifically we knew a lot more about in 2014 than we do about COVID-19 even today.

And frankly, we just did not handle it very well. We made significant mistakes, and we have seen those mistakes occur in other disease areas. Members of Congress used words when they talked about the CDC (Centers for Disease Control and Prevention) response like “cryptic” and “misleading” and thought that the information provided was not enough. We even had an Ebola case that was found in a Dallas hospital, and the CDC Director blamed the hospital. At the same time, one of the nurses in the hospital was allowed to board a commercial flight with CDC’s consent.

So we seem to keep having to learn these lessons over and over again that we have to be better prepared. Public health is hard, and it seems to be hard for us to keep our eye on what might happen in the future once we get beyond that moment. We should have learned and, more importantly, implemented more than we did from Ebola or from H1N1, both of which created real response problems, but real lessons if we had tried to learn them. Hopefully, we will do a better job learning the lessons we need to learn right now.

Neither this administration nor the last one, frankly, prioritized research like this committee has, and we know that in our committee we have worked hard in the last 6 years and in the last five budgets in a bipartisan manner to increase the funding in the annual appropriations bills for the NIH (National Institutes of Health) by nearly 40 percent, for CDC by 21 percent, and for preparedness by 44 percent. But those numbers all have to be coming together before we begin to use them the way that our witnesses today or this committee would like to see them used.

We have proven in our committee that medical research, public health, preparedness are all priorities, and because we have done so, we are more ready than we were at the last time or hopefully more ready in the future for the next pandemic. Right now, 238 FDA (Food and Drug Administration) emergency use authorizations for diagnostic tests and antigen tests are on the market, and every day we get closer to an affordable, reliable rapid test where you can get an answer in a way that allows us to really fight the pandemic rather than have another data point.

In a few years, when someone gives a history lesson about COVID-19 response, there will be criticism. It will go back about 20 years, and it will be significant.

But I know there are things we all agree on. We need to have more investment in testing, more resources for our vaccine candidates to finish their trials, manufacture the vaccine and for CDC to distribute through a vetted, well thought out plan. I hope we learn more about—and I am going to insist that we learn more about—all of those things today.

I had hoped we might be able to include child care in our hearing today. We were not able to do that because of time, but clearly if

you are going to get back to school, back to work, and back to better health, child care has to be part of that and something this committee has to stay focused on.

So, again, I welcome our witnesses.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ROY BLUNT

Good morning. I want to thank our witnesses for appearing before the Subcommittee today to provide an update on COVID-19.

This continues to be an incredibly challenging time for our country. COVID-19 has killed 195,961 Americans and 6.6 million have tested positive. It has rapidly swept across the globe and even countries that thought their cases were contained are facing new outbreaks.

COVID-19 is a new disease and even after 9 months, relatively little is known about it, or even coronaviruses generally. This has hindered our public health response. Trying to find the answers has been like building the plane while flying it.

That comment is not to exonerate this Administration's handling of the response. Can justified criticisms be leveled? Yes.

But history allows us to look at past events to put current ones into perspective. For this history lesson, we only need to remember back 6 years to 2014 when West Africa faced the largest Ebola outbreak the world had ever seen.

Unlike COVID-19, Ebola is a disease that has been around since the mid-1970s. It is a disease that, scientifically, we knew a lot more about in 2014 than we do COVID-19 in 2020.

But even the kindest recollections of our public health response to Ebola would call it flawed. As the threat of an Ebola patient flying to the U.S. was a growing reality, the Obama Administration refused to consider closing borders.

When CDC began implementing infection control guidelines, critics said they were too complicated and too hard to follow. Healthcare worker unions stated that their members had inadequate training and protective equipment. Public health experts said the CDC Director should be more upfront about the unknowns and uncertainties of the disease.

Members of Congress used words like "cryptic" and "misleading" to describe the information that was provided to them by the Administration.

And when a case finally was found in the U.S. at a Dallas hospital, the CDC Director blamed the hospital for a "breach in protocol" that led to the infection of two nurses.

Yet, when one of those nurses wanted to board a commercial flight while running a fever, she was allowed to with the CDC's consent.

This lesson is to illustrate a simple reality: public health is hard. And it is especially difficult for a disease we are still learning about as we fight it in pandemic form. Those in charge of the response are never going to get everything right and it will always be easier for talking heads or other experts to criticize those making the tough decisions.

But we should have learned, and more importantly implemented, more than we did from Ebola and H1N1. For example, the top two lessons learned from the Ebola outbreak in West Africa according to the World Health Organization were: (1) research at the heart of the response; and (2) test results turned around quickly.

Neither this Administration nor the last prioritized medical research. Would we have had a better response if there were more money during the early 2000s for medical research? We'll never know. But I do know that NIH turned its attention from other coronaviruses like MERS or SARS when funding became tight.

And like Ebola, we all know the importance of rapid testing for coronavirus. It can make or break a response. We need to ask ourselves why CDC wasn't more prepared.

As someone who has chaired the LHHS Subcommittee for nearly 6 years, I have tried to refocus our efforts on medical research and preparedness. Over the past 5 years, in a bipartisan manner, the Subcommittee has been able to increase funding in the annual appropriations bills for the National Institutes of Health by nearly 40 percent. CDC funding has increased 21 percent. And preparedness funding is up 44 percent.

I believe the Appropriations Committee's job is to ensure funding is prioritized to the most important activities. If everything is a priority, then nothing is a priority. In the past 5 years, I think we have proven that medical research, public health, and preparedness are the priorities, and have done so in a bipartisan manner.

And because we had done so, we were more ready for an unknown pandemic. This is illustrated by how quickly medical research pushed several vaccine candidates into late-stage development only 6 months after we discovered the disease in this country.

There are now 238 FDA emergency use authorizations for diagnostic and antigen tests on the market, and every day we get closer to an affordable, reliable, rapid test that can be deployed anywhere to be taken at any time.

In a few years, when someone gives a history lesson about the COVID-19 response there will be criticism. And it will be significant.

But I know there are things both sides agree to. This includes a further investment in testing—so it can be as widespread as possible—more resources for our vaccine candidates to finish their trials, manufacture the vaccine, and for CDC to distribute it through a vetted, well thought through plan.

We also know that parents are struggling to return to work without many schools or child care facilities open. Child care programs operated on razor thin margins prior to the pandemic. Now, with additional costs and decreased enrollments, and social distancing, many child care programs are being stretched beyond their breaking point. More investment is needed to help child care providers safely stay open or re-open, and to provide safe, high-quality child care so their parents can return to work.

I know if we focus on COVID-19 related funding, we can reach an agreement with the other side.

I want to once again thank the witnesses for appearing today. I look forward to your testimonies and appreciate your thoughtful dialogue with us. Thank you.

Senator BLUNT. And Senator Murray is joining us from her office, I believe. Senator Murray, we are ready for your opening comments.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Well, thank you very much, Mr. Chairman, and thank you to all of our witnesses who are joining us today.

You know, as our country approaches a tragic milestone in this pandemic, 200,000 dead, I want to recognize that our rising national death count represents countless personal losses. Families have lost parents, grandparents, and children. Communities have lost educators, healthcare providers, and other frontline workers, and people have not only lost loved ones, but many have lost a small solace of being able to visit and comfort those they care about in their final moments. My heart goes out to everyone who is struggling with the hardship caused by this virus whether they are suffering with the loss of life or livelihood.

You all deserve leaders who take this crisis seriously, who take action to support and protect you, your family, and your community, who arm you with the facts you need to stay safe. Unfortunately, we have yet to see that leadership from the President. Like many Americans, I was deeply angered last week to hear President Trump admitting that even though he understood COVID-19 was more deadly than even your strenuous flu—that is a quote—he was intentionally playing down this crisis. But I was not surprised. These recordings were not a revelation. The reality has been painfully obvious for months.

Early on, President Trump not only claimed this virus was contained, controlled, going away, he claimed it was a Democratic hoax. His Vice President wrote an op-ed arguing that there would be no second wave just before we saw a heartbreaking and record-breaking increase in new cases and deaths across our country.

When it came to testing, President Trump did not just say he took no responsibility at all, he said he liked the numbers where

they were. He said he wanted to slow down testing, and he blamed testing for the rising case numbers.

When it came to wearing masks, he not only said that masks caused problems too, he also shared a tweet saying masks represent a culture of silence, slavery, and social death, and a video falsely claiming people do not need to wear masks and there is no cure.

He made false claims on treatments as well, continuing to promote hydroxychloroquine and has suggested we look at bleach as an option.

And he is still—still—downplaying this virus. He is still saying it will just go away. He is saying we are, quote, rounding the final turn. Dr. Fauci has made it clear that is not true and pointed out that we have plateaued at around 40,000 cases a day, that daily deaths are still regularly around 1,000, and experts have warned that we still need to prepare for a fall wave that will coincide with the flu season. But President Trump has not been listening to the public health experts. He has been fighting them, suggesting FDA is part of a deep state conspiracy, and CDC is overstating the death counts.

But not only is he spreading inaccuracies and outright lies at a time when truth is a matter of life and death and trust—trust—in our public health agencies is paramount, his administration has been recklessly interfering with the work of these agencies for political benefit to promote unproven treatments, alter CDC guidance on reopening and testing and more. Just over the last week, we have learned that President Trump put pressure on NIH and FDA to authorize convalescent plasma as a treatment and that political appointees at HHS (Department of Health and Human Services) have worked unsuccessfully to dictate talking points for Dr. Fauci and has succeeded in demanding oversight of and changes to CDC's flagship scientific publication, the Morbidity and Mortality Weekly Report. That publication is a cornerstone of public health work across the world. It is dangerous and unprecedented that political appointees are editing, censoring, and ultimately undermining a report that is intended to give families, public health professionals, researchers, and healthcare providers what they need: the truth.

The Trump administration's political meddling shows a dangerous disregard for truth, facts, science, and most importantly, people's lives. Data and science are key tools in our fight against any health crisis, and the damage being done to public trust in those tools by this administration threatens to undermine our ability to respond to this pandemic, public trust in an eventual vaccine, and public health efforts for years to come.

The Trump administration needs to leave the science to the scientists immediately.

The leaders of our public health agencies need to provide a full account of what political pressure has been applied and what steps they are taking to make sure it does not influence their work or the work of the agencies they lead.

Congress needs to act now to demand the transparency we need to hold this administration accountable. Democrats will be laying out steps soon for how we can do that, and I hope every Republican who has said they believe we need to follow the science will prove

it by working with us on this because you cannot be for science if you are not against political interference.

I also hope Republicans will come to the table to work with us in earnest on a larger COVID-19 package that our communities so desperately need. Unfortunately, they have not taken this seriously so far, and when Democrats put forward the HEROES Act back in May, Republicans said there was no rush, they would wait to see if more was needed. When Republicans finally did put forward a proposal months later, it was woefully inadequate to address the crisis at hand. And while Democrats have moved to find common ground and even offered to negotiate towards a lower top line number, Republicans refused that offer and instead put forward a bill last week that moved us even further away from common ground. This is not serious negotiating, and the ideas that have been put forward are not serious solutions. But the crisis we face remains deadly serious.

We cannot afford to waste any more time. We need to stabilize the child care sector and make sure schools can educate students safely whether remotely or in person. We need to make significant investments in public health, particularly regarding testing and contact tracing, and distributing and administering a safe, effective, and trusted vaccine.

And we need to demand the type of comprehensive national plan for those efforts that has been long overdue. The distribution plan that CDC finally put out just today is a long overdue step forward, but there is still more to do. I am still reviewing this, and I will have more to say. But it is clear this is still not the kind of comprehensive, end-to-end national plan I have called for and that we desperately need. We are still missing important details on research and review like what standards FDA would use to authorize a vaccine for emergency use development, like how we make sure disparities are addressed in clinical trials, and manufacturing, like how we address supply chain issues and avoid bottlenecks. And we still need more details on addressing disparities.

We also need to protect the safety and civil rights of those going to work and provide relief to those who have lost their jobs.

We need to support families who are struggling to make rent and afford healthcare and get nutritional meals.

And we need to address the severe disparities we are seeing and how much harder this crisis is hitting black and Latino and Tribal communities.

We need to provide relief for our State, local, and Tribal governments.

And last but, as we have seen recently, certainly not least, we need to make sure once and for all that political interference from President Trump does not further undermine our response to this crisis.

Now, I am going to have several questions for our witnesses, but I hope we are all able to get more than just answers in the days ahead. I hope we are all able to finally come together and take action before we lose any more time to save lives and prevent costly mistakes.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Murray.

Again, let me welcome our guests today, our witnesses today. Admiral Brett Giroir is the Assistant Secretary for Health. Dr. Robert Kadlec is the Assistant Secretary for Preparedness and Response, and Dr. Robert Redfield is the Director of the Centers for Disease Control and Prevention. We are pleased you are here. I would like to give you time to make an opening statement. We have the statements you have presented. You can summarize those if you want, but we are eager to get to questions, but we are also eager to hear from you. So, Admiral Giroir, why do you not go ahead and start with your opening statement.

STATEMENT OF HON. ADMIRAL BRETT GIROIR, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Admiral GIROIR. Chairman Blunt, Ranking Member Murray, and distinguished members of the subcommittee, I am honored to update you on our Nation's effort to combat COVID-19 with a specific focus on testing.

Testing is an essential component of America's public health response to the pandemic. Recommended practices like wearing a mask, avoiding crowds, especially indoors, and washing your hands, combined with smart testing, is the formula to effectively slow the spread, flatten the curve, and save lives.

By being evidence-based, providing county-specific weekly guidance to governors, expanding supplies, and managing their distribution, providing the right test to the right person at the right time, and developing and allocating safe and effective therapeutics, we are seeing promising results.

Specifically, since the post-Memorial Day peaks in community spread, the number of new COVID-19 cases is down 48 percent. The number of people hospitalized with COVID-19 is down 49 percent. The number of people in an intensive care unit due to COVID is down 62 percent, and deaths associated with COVID are down 33 percent.

But let me say emphatically that these gains could be fleeting or even reversed if we do not continue to follow the national plan and exercise personal responsibility, especially wearing masks and avoiding crowds.

Now, specifically regarding testing, the Nation will surpass 100 million viral tests completed this week. We have purchased and shipped over 95 million swabs and 81 million tubes of media to States, Tribes, and Federal partners. Starting April 7, we have purchased and delivered to public health laboratories and the Indian Health Service 2.3 million Abbott ID NOW point-of-care molecular tests to support outbreak control and rural testing. We have established Federal surge testing in 19 different sites, helping to squelch emerging outbreaks typically among asymptomatic young adults. These sites are in addition to the over 2,700 federally supported or federally enabled community-based testing sites at trusted retailers focused in areas of moderate to high social vulnerability and the literally thousands of HRSA (Health Resources and Services Administration) federally qualified health centers that offer testing to predominantly racial or ethnic minority patients.

We are now at an inflection point in testing. This month we anticipate the availability of approximately 3 million tests per day,

and at least half of these will be rapid point-of-care. We will have available more point-of-care tests in September than the total number of tests performed in August. We have been building towards this inflection point, and I have previously testified to its coming several times over the past months.

As a result of regulatory flexibility, investments in coordination with the public and private sectors, we have implemented comprehensive, cutting-edge testing initiatives to flatten the curve and save lives while supporting reopening of America. Let me discuss just two of these.

Protecting the elderly has been, is, and will continue to be a foremost priority for this administration. So on July 14, we announced that every single eligible nursing home in America would receive a point-of-care instrument and point-of-care testing supplies. We have delivered on this promise. All 13,850 eligible nursing homes have now received a total of 13,985 instruments and over 4.9 million rapid point-of-care tests ahead of schedule.

On August 27, after months of planning and only 1 day after its FDA authorization, the administration announced a \$760 million contract with Abbott for the delivery of 150 million rapid BinaxNOW point-of-care tests. This test is easy to perform, does not require an instrument, delivers test results in 15 minutes or less, and costs 5 bucks. It can easily be deployed to many settings across the country, and it comes with a companion app that enables instantaneous reporting. We have already deployed 50,000 of these tests in support of disaster operations in California, Texas, and Louisiana and now another 15,000 to support wildfire operations in Oregon.

This week, we will ship our first 2 million tests to further prevent spread of COVID in nursing homes, assisted living, and in Tribes. In the coming weeks, we will begin shipping millions of tests per week in support of our teachers and students to open and keep open K through 12 schools and to support vulnerable populations at HBCUs (Historically Black Colleges and Universities).

Thank you for the opportunity to provide these remarks, and I look forward to your questions.

Senator BLUNT. Thank you, Admiral.

Dr. Kadlec.

STATEMENT OF DR. BOB KADLEC, M.D., ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. KADLEC. Thank you, Chairman Blunt, Ranking Member Murray, and distinguished members of the committee. I am Dr. Bob Kadlec, the Assistant Secretary for Preparedness and Response.

As a medical doctor and former Senate staffer, retired military officer, and having served in the White House, I have spent my adult career working to serve and protect the American people.

I appreciate the opportunity to testify before you to highlight ASPR's (Assistant Secretary for Preparedness and Response) response to the COVID-19 pandemic, our progress in vaccine development and our efforts to confront and mitigate this pandemic.

I want to thank this committee for providing both supplemental resources for COVID response, as well as supporting and sustaining the ASPR organization in the past. Your investments have

been critical to support our operations and ensure we have tools available to respond to the COVID-19 pandemic.

Throughout 2020, ASPR has used these resources to protect American lives. We have assisted in the repatriation of Americans from China and Japan at the start of the pandemic. ASPR has provided medical surge support in Louisiana, Texas, and Mississippi after Hurricane Laura, and today we have teams deployed to Louisiana and Mississippi prepared to assist in response and recovery operations following Hurricane Sally. We have deployed personnel and teams to California and Oregon to support wildfire response, and the Secretary has just signed the public health emergency for Oregon to assist in the search and rescue of personnel—of individuals who have been affected there.

We have deployed personnel to Beirut to assist the government in Lebanon with hospital recovery following the catastrophic explosion.

With that, we have supported these calls to action while simultaneously responding to State, local, territorial, and Tribal requests for assistance in the COVID response.

It is an honor to lead this organization. I am truly humbled by the selflessness and dedication of the men and women of ASPR. While we have seen a decline in new cases and deaths and hospitalizations, we know it takes constant vigilance and personal responsibility by every American to wear masks, wash hands, and keep our social distance. But as everyone does their part, ASPR continues to work hard to enhance our country's preparedness and response capabilities. I am proud that ASPR has been part of a driving force in this whole-of-America effort.

Since early 2020, ASPR and BARDA (Biomedical Advanced Research and Development Authority) began working to accelerate vaccine development. This work was foundational to the development of Operation Warp Speed, a whole-of-government approach working with our private sector partners to produce and deliver a safe and effective vaccine as fast as possible.

The supplemental appropriations provided by this committee have been essential in permitting significant advancements under Warp Speed. As a result, America is far better positioned than before to keep Americans safe, protect vulnerable communities and individuals, and defeat the COVID-19 virus. To date, we have awarded \$13.6 billion to support over 50 medical countermeasure projects. Seven of these awards are vaccine contracts. We are making significant progress in advancing these vaccines through a clinical trial process. In fact, three candidates are in phase 3 clinical trials, meaning that we are closer than ever to a safe and effective vaccine available to the public. Three others are in phase 1 and 2.

Safety is our top priority in the development of vaccines and therapeutics, which is why science is driving the development of all COVID-19 countermeasures to ensure they meet FDA's gold standard of approval. In the meantime, we have implemented an intensive, efficient process to promote vaccine development and, in parallel, manufacturing. Supporting these efforts simultaneously ensures we are positioned to distribute and administer the vaccine quickly once approved.

ASPR also continues to support advancements in lifesaving therapeutics. For example, ASPR has taken a data-driven approach to oversee the fair and equitable distribution of remdesivir. To date, we have distributed to States enough remdesivir to treat almost 650,000 patients.

ASPR has also supported the mitigation efforts to slow virus transmission. Since March, ASPR has produced and distributed more than 500 million cloth facial coverings across the country to protect vulnerable populations and essential workers. This month, we are supporting the administration's school facial coverings initiative by sending an additional 125 million cloth facial masks to States and territories for distribution to low-income students in order to support the safe reopening of America's schools.

As the Federal agency leading the emergency support function 8, ASPR is capitalizing on existing relationships with DoD (Department of Defense), VA (Department of Veterans Affairs), and DHS (Department of Homeland Security) to coordinate a more comprehensive medical nationwide response. We have responded to requests from 32 States, three territories, five Tribes with nearly 100 medical support missions with over 5,700 staff from ASPR's national disaster medical teams, the Public Health Service, the VA, and DoD.

We have provided personal protective equipment that I know will be subject to quite a few questions under the SNS (Strategic National Stockpile) 2.0 initiative to expand the depth and breadth of our stockpile, grow the U.S. industrial base, and reduce our vulnerabilities to foreign suppliers. We have used the Defense Production Act as well.

I thank you again for your support and the opportunity to testify before you on ASPR's efforts during this pandemic, and I am happy to answer any questions you may have at this time.

Senator BLUNT. Thank you, Dr. Kadlec.

Dr. Redfield.

STATEMENT OF DR. ROBERT R. REDFIELD, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. REDFIELD. Good morning, Chairman Blunt and Ranking Member Murray and members of the committee. Thank you for the opportunity to be here today.

On behalf of CDC, thank you also for your continued support of our public health professionals and the lifesaving work they are committed to do 24/7.

Over 6,700 CDC staff have been engaged in the agency's COVID-19 response, 1,200 of whom have been deployed to more than 200 locations in the United States and abroad. And I know you share with me the gratitude for their resilience, dedication, and service to our Nation.

Throughout this global pandemic, CDC has brought its scientific expertise to the front lines, conducting rapid investigation of disease outbreaks that identified the highest risk populations and settings. Understanding which populations are at risk and how the virus is spreading in various settings is critical to developing the guidance and protecting the health of Americans.

Today and even after we have a vaccine, CDC encourages all Americans to embrace the powerful tools that we have right now: to wear a mask, particularly when they are in public; maintain social distancing; routine, vigilant hand washing; be smart about crowds; and stay home when you are sick.

And as we move into the fall, we are adding one of the most significant scientific contributions to medicine to our evidence-based mitigation strategies: flu vaccination. Flu vaccine is safe and CDC encourages Americans to embrace flu vaccine with confidence for themselves, their families, and their communities. These simple actions combined could help this Nation avert a very difficult fall, lessening the burden on our healthcare system and saving lives.

CDC has awarded \$140 million to 64 jurisdictions through our existing immunization cooperative agreements to scale up flu vaccination this season. This funding is supporting staff and preparedness with the focus of ensuring that flu vaccine coverages can reach the populations at most risk. This year, CDC purchased an additional 9.3 million doses of adult influenza vaccine, up from the usual annual 500,000-dose purchase in prior years, as well as 18.5 million doses for children.

And CDC has developed a new multiplex laboratory test that can check for three viruses at the same time, influenza A and B, plus SARS-CoV-2, in a single test from a single sample. This test was granted an EUA (Emergency Use Authorization) by the FDA and will save public health laboratories time and resources and help better understand and identify co-infections with influenza 1 and SARS-CoV-2. To date, CDC has distributed over 135 multiplex kits to more than 100 laboratories across the country, with each kit having enough reagents to do approximately 500 tests.

CDC is also working with 64 immunization grant recipients to build readiness for timely and, most importantly, equitable administration when a COVID-19 vaccine becomes available. CDC is leveraging its expertise and immunization infrastructure to support Operation Warp Speed and vaccine promotion, distribution, administration, and monitoring. In coordination with Operation Warp Speed, CDC is working closely with State and local, territorial, Tribal health departments and community organizations to prepare a detailed, yet flexible plan for vaccine distribution to critical infrastructure workers and people at risk, increased risk for serious outcomes.

At this time, CDC continues to support partners with its ongoing community mitigation efforts, including case identification, contact tracing, surveillance, and reporting, as well as testing capacity.

To support these activities on behalf of HHS, CDC has awarded \$12 billion to these jurisdictions in 2020, thanks to the support of Congress. Included in that amount was more than \$200 million to support the American Indian and Alaska Native communities, which have had some of the most significant effects from COVID-19.

Timely, accurate and, most importantly, actionable data are essential if we are going to learn to impact COVID-19 on all Americans, particularly the populations at greater risk such as older Americans, those with chronic medical conditions, racial and ethnic minority populations. CDC reports monthly to the Congress the

most recent data analysis on the impact in racial and ethnic groups.

As I have emphasized in my prior hearings, now is the time to commit to prioritize a sustained investment in the core capabilities of public health, that is, data and data analytics, laboratory resilience, workforce expansion, and rapid response capabilities. Years of under-investment in public health have led to a system that has been sorely tested by the current pandemic. COVID-19 is the most significant public health challenge to face our Nation in more than a century. Now is the time to build not only the public health core capability that our Nation needs, but that the people of our Nation deserve. As we work together collectively to fight COVID-19 to end the pandemic, CDC is committed to the mission to protect all Americans from the disease threats to save lives now and in the future.

Thank you for the opportunity, and I look forward to your questions.

[The statement follows:]

PREPARED STATEMENT OF ADMIRAL BRETT P. GIROIR, M.D., BOB KADLEC, M.D., AND ROBERT REDFIELD, M.D.

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

COVID-19 is a new disease, caused by a novel (or new) coronavirus that has not previously been seen in humans. This new disease, officially named Coronavirus Disease 2019 (COVID-19), is caused by the SARS-CoV-2 virus. There are many types of human coronaviruses including some that commonly cause mild upper-respiratory tract illnesses.

Coronaviruses are a large family of viruses. Some cause illness in people, and others, such as canine and feline coronaviruses, only infect animals. Rarely, coronaviruses that infect animals have emerged to infect people and can spread between people. This is suspected to have occurred for the virus that causes COVID-19. Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS) are two other examples of coronaviruses that originated in animals and then spread to people.

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

CENTERS FOR DISEASE CONTROL AND PREVENTION

CDC is America's health protection agency, and works 24/7 to prevent illness, save lives and protect America from health, safety and security threats. CDC has a key role in preparedness and response in the U.S. and abroad. Addressing infectious diseases like COVID-19 is central to our mission and CDC has decades of leadership in infectious disease response.

When there is an emerging pathogen like the SARS-COV2 virus, CDC expertise lies in our ability to study the new pathogen to understand how it is transmitted, and translate that knowledge into public health action. Since first learning of the cluster of cases in Wuhan, CDC has rapidly advanced the science around this new human pathogen, SARS-CoV-2. CDC has both been on the forefront of understanding this new disease and led the Nation's efforts to protect Americans from in-

fection. Currently, over 6,700 CDC employees have been engaged in the agency's COVID-19 response, and over 1,200 of these staff have been deployed to nearly 200 different locations in the U.S. and abroad. CDC staff have conducted rapid investigations of outbreaks that identified highest-risk priority populations and settings. Understanding specific population-level vulnerabilities and how infections spread in various types of settings has been instrumental in the development of guidance that will help keep the American people healthy and allow critical infrastructure services to be provided safely.

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

In addition to publishing our own scientific information, CDC scientists are monitoring in real time the rapidly expanding scientific literature and have reviewed over 100,000 scientific papers thus far. This approach ensures that CDC responders are armed with the best information available. This comprehensive understanding of the emerging science base helps direct CDC's scientific agenda and informs CDC guidance, and helps guide CDC's direct support of clinicians and the public. CDC's Clinical Response Line has fielded over 32,000 individual inquiries from frontline healthcare providers, and the agency's hotline for public inquiries has responded to nearly 500,000 calls and e-mails.

CDC is drawing on its emergency response capacity and its relationships with State, Tribal, local, and territorial (STLT), global, and private sector partners; and is leveraging our workforce's strengths in public health surveillance, prevention, and laboratory capacity to carry out research and share new knowledge related to this novel pathogen and its consequences. CDC provides guidance for healthcare professionals, essential workers, businesses, schools, and the public to encourage safer practices, improve health outcomes, and save lives. CDC works with partners to develop decision tools to assist STLT officials and other stakeholders with mitigation strategies. Importantly, CDC is preparing the Nation's public health system and the private sector to disseminate a vaccine when one is available. CDC is leveraging investments in global health security and pandemic influenza preparedness infrastructures in over 60 countries to mitigate the effects of COVID-19 and stop the disease from spreading.

As of September 9, 2020, there have been 6,310,633 COVID-19 cases reported and 189,147 deaths attributed to the virus in the U.S. The latest data can be found on CDC's website: <https://www.cdc.gov/covid-data-tracker/index.html>. The U.S. Government has taken unprecedented action to address the public health threat posed by this new coronavirus. CDC has substantial supplemental funding to help respond to this pandemic at home and abroad. This funding supports a federally guided, State managed, and locally implemented response to COVID-19 in the United States.

With funds provided by the Coronavirus Preparedness and Response Supplemental Appropriations Act and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, CDC is providing States with needed resources needed to detect, respond, and prevent the spread of COVID-19 and to inform community mitigation strategies.

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

sponding to COVID-19 outbreaks in high-risk settings and implementing best practices to control the spread.

As a public health agency and the Nation's primary resource for STLT health departments on managing disease outbreaks, CDC provides guidance and support on the development and implementation of effective containment and community mitigation strategies. The goal is for all jurisdictions to have robust public health systems which include a contact tracing infrastructure that meets their unique needs. As of September 2020, CDC has posted over 30 contact tracing guidance documents, including case investigation guidelines, checklists for developing a case investigation and contact tracing plan, digital contact tracing tools, and a Contact Tracing Communications Toolkit for Health Departments. To support these activities, described in further detail below, CDC has awarded \$12.1 billion to these entities in fiscal year 2020, including \$10.25 billion in funds executed on behalf of HHS to be used primarily to support each jurisdiction's testing goals (as outlined in State testing plans).

Testing Strategy

Beginning in April, the White House, and Federal partners including CDC, convened calls with all 50 States, Puerto Rico, and the District of Columbia to identify testing capacities and needs. Through these calls and other outreach efforts, CDC has worked with individual jurisdictions to identify needs, develop plans, and offer technical assistance to enhance testing capacity. CDC, under the leadership of the Office of Assistant Secretary for Health and in collaboration with the Association of Public Health Laboratories, reviewed individual State testing plans with a focus on achieving increased monthly testing targets. These discussions and plans for action emphasized the need to serve vulnerable populations and include focused efforts for long-term care facilities, federally qualified health centers, and Tribal Nations, among others.

CDC is working with STLT health departments to support forward-looking testing strategies that ensure that vulnerable or high-risk populations, such as some racial and ethnic minorities, have adequate access to testing. For example, CDC worked with the Health Resources and Services Administration and health centers to survey health centers and better understand the populations they are serving. Approximately 60 percent of responding FQHCs are in urban areas, where persons of Hispanic or Latinx ethnicity were the largest proportion of individuals testing positive. This information allows STLT health departments to implement strategies to increase testing in FQHCs and provide them with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

CDC has developed a new multiplex laboratory test that checks for three viruses at the same time, two types of influenza viruses (A and B) and SARS-CoV-2, the virus that causes COVID-19, using a single sample collected from an individual. Testing for all three viruses will allow public health laboratories to continue surveillance for influenza while testing for COVID-19. This will save public health laboratories both time and resources, including testing materials that are in short supply. Another benefit of the new test is that laboratories will be better able to find coinfections of influenza and SARS-CoV-2. The FDA issued an Emergency Use Authorization (EUA) for this combined laboratory test on July 2, 2020 and CDC released these reagents for distribution to States' public health laboratories on August 5, 2020. As of August 17, 2020, 135 multiplex kits were shipped to more than 100 laboratories. Each of these kits provides approximately 500 tests. Adjusting for the controls, these 135 kits provide approximately 67,000 tests. CDC has provided these kits to each State's or territory's main public health laboratory, as well as any regional or local laboratories that is approved to provide SARS-CoV-2 surge testing support. Importantly, multiplex assay technical information is publicly available on CDC's website so that commercial developers can use this information in developing proprietary tests. CDC also granted assay manufacturers right of reference to its EUA, allowing developers to use the data CDC submitted to FDA to streamline their efforts when applying for an EUA. CDC took these steps to catalyze the development and validation of these assays by the commercial sector which is better equipped to scale up testing capacity.

In March 2020, CDC and public health partners began seroprevalence surveys of community transmission of SARS-CoV-2. Seroprevalence surveys help identify infections that might be missed due to lack of symptoms or testing not being performed. Serology studies can also help determine risk factors associated with SARS-CoV-2 infection, including transmission in healthcare settings and communities, and inform guidance and mitigation strategies. For example, CDC has published the results from one of the seroprevalence studies that used remnants of samples collected during routine clinical care. This was done in conjunction with two commer-

cial companies and results suggested that greater than 10 times more SARS-CoV-2 infections occurred than the number of reported COVID-19 cases. Another study on healthcare personnel who routinely cared for COVID-19 patients found that 6 percent had evidence of previous SARS-CoV-2 infection. This study identified two factors potentially associated with SARS-CoV-2 infection among HCP: personal protective equipment (PPE) shortages and not wearing a mask while interacting with patients.

Data Collection, Analysis and Understanding of the Pandemic

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

This crisis has highlighted the need to continue efforts to modernize the public health data systems that CDC and States rely on for accurate data. Public health data surveillance and analytical infrastructure modernization efforts started in fiscal year 2020. Timely and accurate data are essential as CDC and the Nation work to understand the impact of COVID-19 on all Americans, particularly for populations at greater risk for severe illness, such as older Americans, those with chronic medical conditions, and some racial and ethnic minorities. Modernization efforts include support for surveillance and data workforce, a key asset of the public health system. For example, CDC is working closely with our partners to help STLT health departments implement the Sara Alert system. Sara Alert is a standards-based, open source tool that increases interoperability among laboratory and clinical systems and automates the process of public health monitoring and reporting individuals exposed to or infected with COVID-19. To date, eleven States and territories, along with nine jurisdictions including one Tribal Nation, have adopted the Sara Alert system. Twenty additional jurisdictions including two territories are in progress of or considering joining. At the current level of participation during an average 10–14 day timeframe, approximately 80,000 individuals are either entering, being monitored by or exiting the system .

CDC's population-based COVID-NET system monitors COVID-19 associated hospitalizations that have a confirmed positive test in greater than 250 acute care hospitals in 99 counties in 14 States. Data gathered provide weekly estimates for age-specific hospitalization rates and describe characteristics of persons hospitalized with COVID-19 illness as well as predictors of those with more severe outcomes. CDC's existing National Healthcare Safety Network (NHSN) continues to collect COVID-19 data from nursing homes and other long-term care facilities. NHSN also continues to collect data from hospitals across the U.S. to address healthcare-associated infections and fight against antibiotic resistance.

The COVID-19 Case Report Form includes variables such as race and ethnicity to enable identification of populations that may be at higher risk for severe illness and risk factors. Though States are not required to report demographic information in the Case Report Form, they have improved the completeness of their reporting. In particular, the percentage of reports that include race data has increased from 21 percent in April to 61 percent in mid-August, while the percentage of reports that include ethnicity data increased from 18 percent to 50 percent during the same time period. While progress has been made, CDC will continue to work with States and other health system partners to improve completeness of the data.

Health Disparities

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

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

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

Children

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

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

Community Mitigation and Workplace Safety

The American people, communities, public health professionals, medical providers, businesses, and schools look to CDC for trusted guidance on responding to COVID-19. CDC is building and using a growing, data-driven evidence base to develop and disseminate guidance for a range of audiences, including business, schools, and healthcare professionals. These recommendations include actions that every American should take, such as wearing a mask, following good personal hygiene practices, staying at home when sick, and practicing social distancing to lower the risk of disease spread. CDC recently released Interim Guidance for Businesses and Employers Responding to COVID-19 to help prevent the spread of COVID-19 in the workplace and protect critical infrastructure workers. CDC guidance specifies that business operation decisions should be based on both the level of disease transmission in the community and their readiness to protect the safety and health of their employees and customers. CDC guidance for businesses is available here: <http://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>.

Vaccine Planning

While surveillance, testing, contact tracing, and community mitigation interventions are the best tools we have right now, looking to the future, CDC continues to work to prepare our Nation's public and private health systems to deliver a COVID-19 vaccine once it is available. CDC is using its expertise in public health preparedness and response, along with its immunization infrastructure, to support Operation Warp Speed in vaccine promotion, distribution, administration, and monitoring. CDC is working closely with the Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts who develop recommendations on the use of vaccines to control disease in the United States. ACIP members have expertise in areas such as vaccinology, immunology, internal medicine, family medicine, virology, public health, infectious diseases, and/or preventive medicine, and one member is a consumer representative who provides perspectives on the social and community aspects of vaccination. An August ACIP meeting focused on post-marketing vaccine safety surveillance, epidemiology of individuals at increased risk of COVID-19, and modelling allocation strategies of the initial COVID-19 vaccine supply. Any recommendations ACIP makes for who should get COVID-19 vaccine and in what order will be grounded in guidance from the country's foremost experts on immunization science.

CDC is working closely with state and local health departments and community organizations to prepare a detailed yet flexible plan for vaccine distribution that will be informed by a prioritization framework recommended by ACIP.

These efforts include working with CDC's 64 immunization grant recipients to help ensure that the U.S. immunization system can mount an effective vaccine delivery program, including vaccine distribution and tracking. State and local health departments have conducted pandemic vaccination planning with immunization and preparedness funding from CDC for over a decade. Updating these vaccination response plans for implementation of a COVID-19 vaccine will build readiness for timely administration when a vaccine becomes available. During August 2020, CDC completed in-person and virtual site visits to assess needs as vaccine planning intensifies. Lessons learned during these site visits will inform CDC's provision of technical assistance to all jurisdictions to aid in the development of State-specific COVID-19 vaccination plans.

In addition, some State and local health department's utilized supplemental resources to build infrastructure that would address current COVID-19 response needs and incorporated planning for future phases. One example is in Chicago, where the health department has developed the Chi COVID Coach app to communicate directly with Chicago's residents who may be COVID-19 positive. The forward-thinking app, built by private sector companies, can be adapted throughout the course of the pandemic. It now allows users to register to receive the vaccine once it becomes available.

While it remains unclear how long the pandemic will last, COVID-19 activity will likely continue for some time. It is also unclear what impact the ongoing COVID-19 pandemic will have on healthcare and public health systems during the upcoming influenza season and beyond. Circulation of COVID-19 and influenza virus at the same time could place a tremendous burden on the healthcare system. Therefore, getting a flu vaccine is especially important. It is important that Americans have confidence in all vaccines. CDC will leverage its immunization program to help maintain high coverage in routine childhood immunizations, promote immunization for adult vaccine-preventable diseases, and increase coverage for flu vaccinations, and prepare for a potential COVID-19 vaccine.

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

Conclusion

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

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Diagnostics and Testing

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

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

To date, the U.S. has accomplished over 95 million tests, at an average current rate of between 700,000—800,000 tests per day, with enough tests in the market

to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. In June, July, and August, States far surpassed their goals for testing. Specifically, State goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, States far exceeded their goals by conducting over 25 million tests. In August the Nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. Over the next several months, the Nation's testing capacity will continue to increase. We anticipate that supplies and reagents will be sufficient to conduct approximately 90 million tests in September. If pooling occurs even for a fraction of these tests, there is capacity to perform much greater than 100 million tests per month today. Turnaround time is improving and continuing to improve. Currently, 97 percent of ACLA tests ordered in the previous week received results within 3 days, and 99 percent received results within 5 days.

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

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

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

The national strategy for testing was further enumerated in the COVID-19 Strategic Testing Plan Report to Congress initially submitted to Congress on May 24th. On August 22nd, HHS submitted the first update to the Strategic Testing Plan. The report outlines how HHS increased domestic testing capacity across the United States and provides additional guidance and information about diagnostic technologies, platforms and inventory that States, territories and tribes can utilize to develop flexible, adaptable, and robust COVID-19 testing plans.

Identifying Newly Emergent Outbreaks

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

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

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

Support Public Health Isolation and Contact Tracing

A key function of testing is to support identification of infected individuals, many of whom may be asymptomatic, in communities identified with outbreaks or emerging outbreaks. In response to "hotspot areas", the Federal Government has set up surge testing to increase baseline testing 2X-5X for short periods of time. Surge testing sites have been implemented in Miami, FL; Jacksonville, FL; Edinburg, TX; Uma County, AZ; Pima County, AZ; Coconino, AZ; Phoenix, AZ; Atlanta, GA; Birmingham, AL; Cochise County, AZ; Mohave County, AZ; Yavapai County, AZ; Baton Rouge, LA; New Orleans, LA; Bakersfield, CA; Houston, TX; Harris County, TX; Clark County, NV; and Honolulu, HI. These 19 sites have conducted approximately

290,000 tests. Surge testing is a supportive adjunctive activity; it cannot substitute for disciplined adherence to mitigation measures including masking, hygiene, avoidance of indoor crowded areas and crowds, and protection of the vulnerable. These mitigation techniques, when combined with selective surge testing—have proven highly effective to reverse recent community outbreaks.

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

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

Diagnose COVID-19 Rapidly in Hospitalized Patients

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

Protect the Vulnerable

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

To ensure that specimens are collected without overburdening the traditional healthcare system, and to ensure testing in the most vulnerable communities, in mid-March, the Federal Government established Community-Based Testing Sites (CBTS) in CDC-prioritized locations across the country. The CBTS model was developed for States, local public health agencies, healthcare systems, and commercial partners as they work together to stop the spread of COVID-19 in their communities, focusing initially on healthcare facility workers and first responders.

The CBTS federally supported, State managed, locally executed model has been a profound success, testing approximately 400,000 individuals. For the initial 41 sites, CBTS 1.0, the Federal Government provided a Federal physician who ordered all of the COVID-19 tests, the Federal contracts for shipping the specimens, laboratory processing, patient notification, and logistics (to include supplies, personal protective equipment, language translation services). The Federal Government also utilized U.S. Public Health Service personnel to provide data management, safety and quality control checks at each site.

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

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

This pharmacy and retail partnership provides convenient access to COVID-19 testing, but it is also a bridge for retailers to implement new regulatory flexibilities and expanded reimbursement options HHS has provided through private insurance,

Medicare, and Medicaid. This partnership also leverages the newly expanded authority given to pharmacists to order and administer COVID-19 testing, this effort is also known as CBTS 3.0. Now, CVS and Walmart have over 1900 sites utilizing these new regulatory and reimbursement options with over 2 million tests performed.

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

To prevent further spread and deaths in nursing homes, CDC and CMS recommended that nursing homes perform baseline testing of all residents and staff, followed by routine testing of staff to reduce outbreaks, morbidity, and mortality. CMS requires a regimen of staff testing based on the degree of community spread. To protect the vulnerable and to assist States in meeting these recommendations and requirements, on July 14, 2020, the Trump Administration announced that HHS would embark on a one-time procurement of rapid point-of-care testing instruments and tests to be distributed to nursing homes using the Defense Production Act.

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

I am pleased to announce that all 13,850 initially eligible nursing homes have received one or more point of care instruments, and nearly 5 million tests. Following this initial distribution, we will facilitate nursing homes being able to reorder supplies via their normal commercial distribution channels.

Vulnerable populations in many underserved communities are suffering disproportionate health impacts resulting from COVID-19, including number of infections, hospitalizations, and deaths. As part of the HHS response to this crisis, on June 23, the HHS Office of Minority Health (OMH) announced the selection of the Morehouse School of Medicine as the awardee for a new \$40 million initiative to fight COVID-19 in racial and ethnic minority, rural and socially vulnerable communities.

Morehouse School of Medicine has entered into a cooperative agreement with OMH to lead the initiative to coordinate a strategic network of national, State, territorial, tribal and local organizations to deliver COVID-19-related information to communities hardest hit by the pandemic. The three-year initiative will include the development and coordination of a strategic and structured network of national, State, territorial, and local public and community based organizations that will help mitigate the impact of COVID-19 on racial and ethnic minorities as well as rural and socially vulnerable communities across the Nation. The initiative also includes a national multi-media outreach and education effort. One of the primary goals of these information dissemination efforts is to provide additional education and community-level information on resources to help fight the pandemic to those who need it most.

Support Safe Reopening of Schools and Businesses

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

Enable State Plans

To enable States to achieve the testing goals developed in coordination with the Federal Government, the Federal Government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collec-

tion supplies; and determined reagent inventory. The Federal Government then provided all information to States so they could better determine how to optimize their testing strategy. The Federal Government also purchased and allocated POC devices and over 2.3 million tests; developed, implemented, and facilitated community-based testing sites across the country; and provided significant guidance and technical assistance for State plans. The increase in the numbers of tests performed since early March is a direct reflection of these efforts.

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

The first iteration of the jurisdictional testing plans for May and June were released to the public on July 10, 2020, and are available for viewing here. The Federal team provided feedback to each State, and each State incorporated this feedback into detailed plans covering July through December. The State plans for July–December have been reviewed and scored and were released to the public on August 10, and are available for viewing here.

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

Moving forward, jurisdictions should use the \$10.25 billion provided to States, territories, and localities by the Federal Government to support the purchase of tests and related supplies, personnel for contact tracing, and reporting infrastructure, etc., for their jurisdictions, as needed to fulfill their approved testing plans.

Other Initiatives

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

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

United States Public Health Service Commissioned Corps

Since the early stages of the COVID–19 outbreak, the Corps has been an indispensable asset leveraged to address the public health needs of the Nation in response to this crisis. The Corps is one of the eight uniformed services of the United States and the only uniformed service committed to protecting, promoting, and advancing the health and safety of the Nation. Corps officers serve throughout the Nation in communities that are most in need by providing essential healthcare services to underserved and vulnerable populations.

In January, the Corps deployed officers to provide expert outbreak response in direct support of CDC. Deployment expanded rapidly from 53 officers on January 24, 2020 to 4,170 officers deployed as of September 8th, with many officers being deployed numerous times. Corps officers provided critical assistance to community-based testing sites throughout the Nation and their contributions to this effort are immeasurable. In response to the escalating crisis, the Corps established COVID–19 Clinical Strike Teams, which include officers from the variety of disciplines needed on the frontlines. This kind of ready-made unit allows the Corps to deploy a “cav-

ally” to support healthcare systems under stress in States across the country. COVID–19 Clinical Strike Teams have deployed to a long-term care facility in Kirkland, Washington, to the Javits Center in New York City, and to the TCF Center in Detroit. At the end of March, the Navajo Nation requested CDC assistance to provide care amidst a surge of COVID–19 cases. Since that time, the Corps has deployed teams to support the response.

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

ASSISTANT SECRETARY FOR PREPAREDNESS RESPONSE

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

For the current COVID–19 domestic response, ASPR funding has been used to accelerate development of medical countermeasures, enter into contracts to resupply personal protective equipment and other critical components deployed from the Strategic National Stockpile (SNS) to aid in the treatment of persons with or suspected of having COVID–19, provide grants to hospital associations and healthcare centers to aid in the ongoing response, and provide support via the National Disaster Medical System (NDMS) to augment care in communities significantly impacted by COVID–19.

It is important to note that while the COVID–19 response remains the primary mission and duty at ASPR today, there are other existing requirements the organization has supported throughout 2020. Throughout 2020, ASPR has assisted in the repatriation of Americans from China and Japan at the start of the COVID–19 outbreak. We deployed personnel to Lebanon in August to assist with response and recovery efforts following the explosion in the Port of Beirut. ASPR provided temporary medical surge support in Louisiana, Texas and Mississippi after Hurricane Laura, and we still have National Disaster Medical System (NDMS) teams deployed to Louisiana to assist with recovery efforts following Tropical Storm Sally. In addition, ASPR deployed personnel to California and Oregon to support search and rescue efforts for the wildfires. We supported these calls for action and support while simultaneously responding to domestic requests for assistance to aid in the COVID–19 response. . ASPR is a unique and nimble organization and has been able to respond to emerging needs throughout the COVID–19 response.

MEDICAL COUNTERMEASURE DEVELOPMENT EFFORTS

Since late January, the Biomedical Advanced Research and Development Authority (BARDA) within ASPR has collaborated with counterparts across the government to identify potential COVID–19 medical countermeasure candidates and accelerate their development. BARDA has a track record of success in delivering effective countermeasures in response to public health emergencies. Past successes include the 2009 H1N1 influenza pandemic, Ebola outbreaks in 2014–2016 in West Africa and in 2018 in the Democratic Republic of the Congo, as well as the Zika outbreak in 2015.

At the onset of the pandemic, BARDA reviewed investments, modified contracts, and began working with Regeneron, Janssen, and Sanofi Pasteur to initiate the development of vaccines and therapeutics for COVID–19. All three have successfully developed both prophylactic and therapeutic medical countermeasures for emerging infectious diseases in the recent past.

To date, utilizing the supplemental funding provided by this Committee, ASPR/BARDA is supporting over 50 medical countermeasure projects for COVID–19 response. All of these contract awards are listed on [medicalcountermeasures.gov](https://www.mediccountermeasures.gov) in detail and include: nine therapeutics, 29 diagnostics, and seven vaccine candidates. Six vaccine candidates are operating under Operation Warp Speed (OWS). In support of securing a safe and effective vaccine as quickly as possible to protect the American people and return to normal operations, we are making significant progress in advancing these vaccines. In fact, three—AstraZeneca, Moderna, and Pfizer—are in Phase 3 meaning that we are closer than ever before in having a safe and effective COVID–19 vaccine available to the public. The remaining three—Novavax, Sanofi Pasteur/GSK, and Janssen are in Phase 1/2.

It is important to note that we are strictly adhering to and following all regulatory and safety requirements to support vaccine development. We are not sacrificing the safety of the vaccine in order to expedite its development. We are instead supporting two steps at the same time: vaccine development and vaccine manufacturing. Supporting these efforts simultaneously ensures we are positioned to produce and manufacture the vaccine quickly and effectively. Specifically, we are making investments in the necessary manufacturing capacity at Federal risk, giving companies confidence that they can invest aggressively in development and allowing faster manufacturing and potential distribution of an eventual vaccine. Specifically, the recent awards to Pfizer, Novavax, AstraZeneca, Moderna, and Sanofi Pasteur/GSK all include product development and investments in large-scale manufacturing capabilities in the contract award.

BARDA is also working with and reviewing the capabilities and capacity of our Centers for Innovation in Advanced Development and Manufacturing (CIADMs). The CIADMs are government-sponsored facilities that were created as public-private partnerships to establish domestic manufacturing capacity and response capabilities in order to ensure the Nation has adequate surge capacity for rapid medical countermeasure production to address pandemics or other biological threats. The two HHS CIADMs are Emergent BioSolutions in Baltimore, MD, and Texas A&M University System in College Station, TX. Currently, AstraZeneca and Janssen have reserved space at the Emergent facility to manufacture vaccines at scale. In addition, in June, BARDA reserved existing vaccine manufacturing capacity as well as expanded manufacturing capacity at the Texas A&M CIADM through OWS, manufacturing capacity at the Department of Defense's (DoD) Advanced Development and Manufacturing facility, Ology Bioservices Inc. could also be utilized if necessary. I would be happy to keep the Committee updated on the progress of utilizing CIADMs as we move forward in this space.

Lastly, ASPR/BARDA is supporting efforts to expand capacity for fill-finish to ensure that, once we have an approved vaccine, we can begin manufacturing without having to wait for ancillary products (e.g. vials, needles, and syringes). Contracts include: capacity expansion for needles and syringes (contracts with Smiths Medical, Inc., Retractable Technologies, Inc., and Becton, Dickinson, and Company); capacity expansion for glass tubing and vials/cartridges (Corning Pharmaceutical Technologies); expansion of sterile injectable capacity (Thermo Fisher Scientific); establishment of manufacturing systems for durable, high-performance glass/plastic vials (S102); and, general capacity expansion and reservations for fill/finish (Grand River Aseptic Manufacturing, Inc.).

RESUPPLY OF THE STRATEGIC NATIONAL STOCKPILE

ASPR, through the Strategic National Stockpile (SNS) maintains a national repository of large quantities of medical countermeasures for a variety of threats (chemical, biological, radiological, and nuclear (CBRN) threats as well as general public health responses) stored in strategic locations around the nation. While SNS assets can be deployed for CBRN incidents, the SNS is also poised to provide assets to support response operations to large-scale public health emergencies, such as those caused by hurricanes, disease outbreaks, or other natural disasters.

Specific to the current COVID-19 response, as of August 18, 2020, and in coordination with interagency partners including the Department of Defense and the Department of Homeland Security, the SNS has provided more than 18.5 thousand tons of personal protective equipment (PPE) and other medical material to support States to aid in medical response as well as the Federal repatriation effort to bring American citizens back from abroad. This deployment of PPE encompassed approximately 90 percent of the total SNS PPE inventory available at the beginning of the COVID-19 pandemic. In addition to PPE, the SNS deployed ventilators and Federal Medical Stations (FMS) to support the response.

To respond and prepare for COVID-19, as well as prepare for any new and emerging public health threat, ASPR/SNS is working to implement SNS 2.0. This initiative has three main objectives:

- Ensure the SNS has the breadth and depth to meet any future pandemic or public health emergency;
- Bolster the U.S. industrial base for critical pharmaceuticals and medical supplies; and,
- Reduce America's vulnerabilities and reliance on foreign suppliers and manufacturers.

Under the first initiative, current planning is underway to achieve a capacity to meet 90 days of need by this fall, which will require a combination of actions to increase the supply of PPE and other critical items in the SNS, in the commercial

supply chain, and at the point of use (such as hospitals). Since the start of the pandemic, orders have been placed for approximately 800 million N95 respirators and face masks for delivery to the SNS. The SNS currently holds approximately 80 million N95 respirators and face masks within the overall stockpile. The SNS is currently on track to have 10 times more masks on hand by the fall of 2020 than were available prior to the start of the COVID-19 pandemic. Additionally, the SNS has received more than 125,000 new ventilators from COVID-19-related contracts awarded in the spring. The SNS currently has more than 130,000 ventilators on hand for deployment, which is more than seven times the quantity held in pre-COVID-19 pandemic inventory. The SNS has also begun procuring necessary testing supplies, including test kits, swabs, and viral transport media, to ensure that Americans have access to the most advanced and robust COVID-19 tests in the world. The SNS inventory is projected to include 44 million swabs and 65.5 million viral transport media by the end of 2020.

To support a number of these contracts, HHS has leveraged and utilized actions under the Defense Production Act (DPA). Title I of the DPA allows the President, among other authorities, to require businesses and corporations to prioritize and accept government contracts for materials and services. HHS has exercised Title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the place of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventilators, are in high demand. A priority rating has at times proved necessary to provide the requested quantities and qualities of these health resources within a specified time period or delivery date. These rated orders are filled first when there are both commercial demands and government demands for the same product, or component(s) of a product. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed.

Under the second initiative, ASPR/SNS is working with DoD to expand domestic manufacturing capacity. The partnership between DoD and HHS, which allowed SNS to tap into DoD's contracting resources and experience with industrial based expansion projects, was critical for the success of the U.S. Government's efforts to expand domestic production capacity of medical supplies during the COVID-19 pandemic. Using CARES Act funding, the SNS has funded a number of projects including:

- Melt blown fiber (MBF)—to date the SNS has expanded the domestic manufacturing capacity to produce MBF, a critical component in N95 and surgical mask production.
- Increased domestic production capacity for surgical masks—to date the SNS has supported contracts to allow manufacturers to stand up additional production lines and production centers to produce surgical masks.
- Increased domestic production capacity for nitrile gloves—to date the supported contracts to increase annual domestic production capacity of nitrile gloves by 450 million starting July 2020, to be completed by July 2021.
- Increased domestic production capacity for testing swabs—to date the SNS has supported an increase domestic production capacity for swabs
- Increased domestic production capacity for rapid point-of-care test kits—to date the SNS has supported an increase in annual domestic production capacity of COVID-19 test kits by 8 million a month by February 2021.

Lastly, to support efforts under the third initiative, ASPR is working in partnership with the HHS Food and Drug Administration (FDA) to understand and identify, as early as possible, supply chain issues. Much of our supplies and medical materiel come from international partners. We must, and will, continually evaluate and understand these dependencies to best inform acquisitions and planned procurements.

PREPARING THE NATION'S HEALTHCARE SYSTEM

ASPR's Hospital Preparedness Program (HPP) strengthens healthcare sector readiness to provide coordinated, life-saving care in the face of emergencies and disasters. As the only source of Federal funding for healthcare system preparedness and response, HPP promotes a consistent national focus to improve patient outcomes during emergencies and disasters and enables rapid recovery.

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. Prior to COVID-19, HPP's annual appropriation supported: the annual cooperative agreement program to 62

State, local, and territorial health department recipients to support healthcare coalitions; the Regional Disaster Health Response System (RDHRS); the National Emerging Special Pathogens Training and Education Center (NETEC); and ten Regional Ebola and Other Special Pathogen Treatment Centers (RESPTCs).

In response to COVID-19, HPP has awarded additional funds COVID-19 supplemental funding to support National Special Pathogen System (NSPS), building upon many of HPP's core programs and activities. Funds were distributed to support the traditional HPP recipients, the 10 RESPTC recipients, the NETEC, and a new funding mechanism to directly support hospitals and other healthcare facilities through 53 hospital associations. The NSPS supports a coordinated national approach to preparing for public health and medical emergencies so that the U.S. has a tiered, capable system that coordinates national expertise, regional capabilities, and State and sub-State healthcare capacity across the public and private sectors in order to drive an effective and safe pandemic response. The NSPS will continue to deploy and enhance capabilities to address continued surge events during the current pandemic—as well as prepare to address potential future special pathogens.

Additional supplemental funding was awarded by HPP to support efforts to secure the Nation's blood supply through a partnership with the American Red Cross. Through this effort, we will be better able to maintain blood operations, enabling hospitals and other healthcare entities to meet demand for blood and avoid shortages of this lifesaving medical resource. Lastly, HPP is also supporting a collaborative effort with DoD to establish a National Emergency Tele-Critical Care Network (NETCCN) to support expanded telehealth capabilities nationally. The NETCCN is comprised of a cloud-based, low-resource, stand-alone health information management system for the creation and coordination of flexible and extendable “virtual critical care wards.” These wards bring high-quality critical care capability to nearly every bedside, whether in a healthcare facility, or in an alternate care site such as a field hospital, or in a gymnasium—enabling critical care anywhere.

ASPR'S SUPPORT FOR COVID-19 RESPONSE

While we await a vaccine, ASPR has supported other efforts to help mitigate the transmission of the virus when and where possible. Beginning in March 2020, ASPR initiated the production and distribution of more than 500 million cloth face masks across the country. Many of these face masks were provided to long term care and dialysis facilities to help protect some of the most vulnerable in our communities. And, more recently, we are sending 125 million cloth face masks to States and territories for distribution to schools.

ASPR also works 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.

At the start of the COVID-19 outbreak in January and February, 2020, NDMS teams were deployed to strategic locations across the country to care for U.S. citizens evacuated from Japan who may have been exposed to SARS-CoV-2, effectively providing medical care and limiting the potential spread of the disease. Overall, HHS deployed over 600 Public Health Service Commission Corps Officers and NDMS personnel to support this repatriation effort. In addition, HHS provided cache equipment, (e.g., medical supplies and resources) to the repatriation sites to aid in the medical needs and care of returning Americans.

As the response shifted and cases increased domestically, NDMS teams have been deployed, when requested by a State, to provide augmented care. Specifically, NDMS has supported hospital augmentation (such duties include: emergency room support, hospital decompression, setting up medical overflow centers for patients, and mortuary support). As of September 10, 2020, ASPR has supported approximately 3200 NDMS deployments of medical, mortuary, and veterinarian specialists to various missions across the country to 18 different States. With the aid of NDMS personnel and resources, communities have been able to continue to provide care to those in need of medical assistance and treatment. NDMS will continue to support such requests, and we appreciate the funding this Committee has provided to date to support these efforts.

CONCLUSION

On behalf of all the witnesses, we thank you again for your support. Whether supporting hurricanes, floods, influenza outbreaks, and other infectious disease outbreaks such as Pandemic Influenza, Ebola, Zika, or the current COVID-19 pan-

demic, we have utilized the authorities and resources provided by Congress to best support the Nation in responding to the threat and mitigating the lasting impact.

Your partnership and support enable our mission accomplishment. We would be happy to answer any additional questions you may have.

Senator BLUNT. Well, thank you, Dr. Redfield.

So we are going to have a series of 5-minute rounds of questions. There are a dozen members either here or virtually here ready to ask questions. There will be an 11:30 vote that we will just kind of work around those votes that come at 11:30, and certainly, we would hope to have an opportunity for a second round of questions if people have them after their first round is gone.

TESTING

Let me start, Admiral Giroir, with you. On tests, I think tests are essential to get back to school, back to work, and for tests to really work, they have to be easily taken. There needs to be a quick response, and they need to be affordable. It seems to me that with the Shark Tank effort that members of this committee, particularly Senator Alexander and I, were involved in trying to encourage looking at ideas that are out there, I think the Shark Tank has approved at least 16 different tests now. In your testimony, you mentioned that a significant number of these tests were point-of-care response tests.

What should we expect in October or this month? I have been told in October, we could reach 100 million tests between the Shark Tank and Abbott alone. Is that a number that you think is close to right?

Admiral GIROIR. Yes, sir. And thank you for the question, and thank you for the support of the Shark Tank and all of the NIH efforts. We have seen just a tremendous blending of programs at DARPA (Defense Advanced Research Projects Agency), at NIH, at CDC, at BARDA and my office with the Defense Production Act, all coming together, and we do meet every week to put these together in a very cogent, synergistic way.

Yes. In October—and again, these are conservative estimates based on what we know has EUAs and what we know the manufacturing will be. In October, we are looking at somewhere in the neighborhood of 125 million to 135 million tests available. That does not mean that 125 million to 135 million tests will be done, but these will be easily and readily available. And the majority of them—we really hit that inflection point—will be point-of-care.

Senator BLUNT. Good.

Admiral GIROIR. Many of them will be the Binax that we talked about. That will be made at approximately 48 million to 50 million per month, again a \$5 test, 15-minute result, no instrument. Very, very important. But we are starting to see the point of tests coming from the RADx program, the Shark Tank, really hitting the street. So the next generation sequencing, the microfluidics platforms like Fluidigm and some advance point-of-care are all starting to hit from Shark Tank.

Senator BLUNT. And I think you said in your testimony that sometime this month we will have passed the first 100 million tests that people have taken. Is that right?

Admiral GIROIR. Yes, sir. Today's total as of about 5 o'clock this morning was 99.3 million tests having been performed in the U.S. Those are viral tests, not serological tests.

Senator BLUNT. And starting the first of the year, sometime—this is from the outbreak of the COVID-19. Right?

Admiral GIROIR. Right. I mean, when I took over on March 12, I think there were 15,000 or 20,000 tests done. It was a very small number. So this has ramped in a historic way not just in number. Numbers are important, but it is the ecosystem, the point-of-care, the laboratory. These all have to fit together in a—

Senator BLUNT. I think I am right in assuming—but the three of you would know this better than anybody—if you take a test and you do not get a result for 3 days or 5 days or 7 days, you find out a data point and you find out for that individual the problem they have, but you have generally done nothing to tell them that they could be spreading this disease. Is that correct?

Admiral GIROIR. Clearly we want tests to be turned around as rapidly as possible, and that is why point-of-care is so important. The issue with most point-of-care tests is they are not as, quote, good, sensitive, and specific as the very important laboratory tests. Now everybody is making progress.

But you are right. We want rapid turnarounds. And because we have more point-of-care tests and because we are doing more in the nursing homes that way, for the major referral labs that had such an issue with turnaround times, our average turnaround time for Quest, Labcorp, et cetera, this month is 1.49 days. So that has been improved dramatically because of expansion of their capability but also the insertion of point-of-care tests.

Senator BLUNT. But again, that is the average. That averages out the point-of-care plus the tests that averages all this down to 1.—

Admiral GIROIR. No, sir. That is just the referral laboratories, Quest, Labcorp—

Senator BLUNT. Got it.

Admiral GIROIR. The other half of testing is either point-of-care at your local hospital, which is generally either 15 minutes or within 24 hours. So the turnaround time, at least right now with all the investments coming together, is under control.

Senator BLUNT. I think our sense—many of the members on this committee—certainly my sense of testing has been we want a test that millions of people can take, maybe dozens of times and get the information at the time they take the test. And it sounds like to me that we are finally getting to where that is a realistic likelihood. All right.

Senator Murray.

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

POLITICAL INTERFERENCE

And let me just say again I am deeply troubled by reports of rampant political interference in scientific decisionmaking at the CDC. It is unprecedented and it is unacceptable. We learned last week that despite knowing in January how serious COVID-19 was, President Trump has been working to downplay this crisis. And on Friday night, we learned that Trump political operatives in HHS's

Communications Office have been manipulating CDC's flagship publication for months to align with that messaging.

Dr. Redfield, did anyone at CDC advise the President to downplay this crisis?

Dr. REDFIELD. No.

Senator MURRAY. Did you agree with the President's decision to downplay it?

Dr. REDFIELD. I am not going to comment on that, but no one advised the President to downplay this crisis.

Senator MURRAY. Well, understanding the dangers, why have you not done more to push back on President Trump's political interference and its efforts to downplay this?

Dr. REDFIELD. I want to make it really clear, Senator—and I appreciate your question and the opportunity—about the respect for the science at CDC and the independent integrity of the MMWR (Morbidity and Mortality Weekly Report). At no time has the scientific integrity of the MMWR been compromised, and I can say that under my watch, it will not be compromised.

Senator MURRAY. Well, I understand the efforts to edit the CDC publication started in response to a May report that reviewed the spread of COVID-19 in the U.S. It was authored by CDC highly respected career deputy, Dr. Schuchat. HHS political officials perceived this report as reflecting negatively on the President.

Dr. Redfield, yes or no. Did that May report, as drafted by Dr. Schuchat, adhere to the agency's strict code of scientific integrity?

Dr. REDFIELD. Yes.

Senator MURRAY. Well, the spokesperson for HHS claimed that there is a resistance unit at CDC and voiced concerns about ulterior deep state motives, and President Trump has bolstered skepticism in the agency's death toll. Do you agree with me that there is no truth to all those claims?

Dr. REDFIELD. Absolutely, Senator. And I want to make a comment that not only is not true, it deeply saddened me when I read those comments because, as I said in my statement, CDC is made up of thousands of dedicated men and women highly competent—it is the premier public health agency in the world—dedicated 24/7 to use their skills to protect the American public and the world from the health issues. And it deeply saddened me that those false accusations were made by a group of really unbelievably professional people that serve this Nation.

Senator MURRAY. Well, I agree.

Let me ask you then, what can Congress do to make sure we are hearing directly from public health officials without political interference?

Dr. REDFIELD. Well, again, I am willing to commit that we are going to continue to give Congress and the Nation the best public health advice. We are not going to let political influence try to modulate that.

As I mentioned, the MMWR—and it is another thing that has saddened me to hear on our watch the concern that somehow—some have that the integrity of this really important publication was somehow compromised. And I just want to assure you and the other Senators and the American public that the scientific integrity of the MMWR has not been compromised. It will not be com-

promised on my watch. And I will stand by the men and women that are the scientific experts that are there to do their job, to express what they know in a way that can be interpreted to the American public.

Senator MURRAY. Well, I hear you, but I do think Congress needs to make clear that there is no political interference there. I will be pursuing that.

SCIENTIFIC INTEGRITY

Admiral Giroir, on the same issue, you are among HHS's top health officials. What are you doing to protect scientific integrity of the work done by the scientists and public health experts at CDC, HRSA, and NIH from political interference?

Admiral GIROIR. Part of my job as the senior scientific advisor to the Secretary is to make sure that he gets the best science and the best evidence base that is unfiltered. I do that every single day. I work with Bob Redfield. I work with Bob Kadlec. Francis Collins and I are on speed dials; Tom Engels, very, very important with HRSA. So you have my commitment, as you always have, Senator, that I will provide the best advice to the decision-makers that will be based on science and evidence, and that is the way we are going to operate going forward.

Senator MURRAY. But can you right now reject the unfounded, harmful conspiracy theory that career professional leadership of CDC or any of our public health agencies have, quote, deep state ulterior motives that compromise their ability to act in the best interest of public health, as other Trump political appointees have claimed? Can you reject that? Yes or no.

Admiral GIROIR. I have not seen anything out of CDC, HRSA, any of the agencies I work with that is anything but people acting in the best interest of the American people. I have certainly not seen anything that you described.

Senator BLUNT. Thank you, Senator Murray.

Senator Alexander.

Senator ALEXANDER. Thank you, Mr. Chairman. And thanks to the witnesses for coming.

PREPARING FOR THE NEXT PANDEMIC

This committee has shown on many occasions a good capacity to work in a bipartisan way. So I would like to say something to my Democratic friends, as well as my Republican colleagues, on a subject that I think we agree on, but the Congress has had a hard time doing over the last 20 years, and that is preparing for the next pandemic.

I have been re-reading Jared Diamond's book, "Guns, Germs, and Steel." And he wrote an article in the "Wall Street Journal" a few months ago about the current infectious disease. He said the most different thing about COVID-19 is not that it is more infectious, but the jet plane is what is different about this disease, that it can spread instantly from Wuhan to San Francisco to Nashville to Boston, and that the next pandemic could be next year.

So we had a hearing about preparing for the next pandemic, and people like Bill Frist, who was majority leader 20 years ago, said we keep trying to do things to prepare for the next pandemic, but

we go, in Dr. Tom Frieden's words, from panic to neglect to panic. In other words, while we are in the middle of a pandemic, it has got our attention, but as soon as it is over, we do not do all the things that we should do.

So my hope is that with any action that we take this year, we would include the three or four things that we should take to make sure that we sustain funding, which is the hardest thing to do. How do you fund for more than 1 year for onshore manufacturing of vaccines, for example, or stockpiles that were depleted between pandemics to making sure that FEMA (Federal Emergency Management Agency) and Dr. Kadlec's organization are aligned properly and operating together? Dr. Redfield has talked about and Mike Leavitt to our committee, the former Governor of Utah, that we have been underfunding public health for 30 or 40 years. I think it is important we do it this year.

And so in the Republican bill that we offered last week, we did have in there some authorization from our committee to fund onshore manufacturing and continuous funding of stockpiles, so they would be full. And I would just like for our committee to give that the same kind of attention in the subcommittee that we gave, for example, to funding for NIH because it will take some sort of mandatory funding or advance appropriation as this committee did under Senator Gregg a few years ago for Bioshield. It is not a lot of money. I think what we suggested was a half billion dollars a year for 10 years for onshore manufacturing.

Why is that important? In 2012, we created three manufacturing plants just for this purpose, but two of them, in Governor Leavitt's words, went cold. They were not available instantly to do what we needed done. And the third one had a hard time finding anything to do between pandemics. So we need some funding for it.

And then for the stockpile, stockpiles got depleted at the Federal level, in hospitals, and States because of budget cuts. And so we were not ready for what we needed to be ready for.

And then public health funding is a separate one. Bioshield is another one.

So I think we are not talking about lots of money. What we are talking about is different is sustained funding for a period of years.

Now, Dr. Kadlec, I have taken most of my time, but would you comment on that? And precisely in the ideal world, what should we do now to prepare for the next pandemic, which Jared Diamond says might be next year?

Dr. KADLEC. Well, thank you very much, Senator Alexander. And I agree entirely with your proposition that we do need to make investments over the long term, that we need to look at this problem as a national security problem as it is a public health problem.

We lose on a day—

Senator ALEXANDER. Yes, but what are the specific things. We have got about 30 seconds.

Dr. KADLEC. Sir, manufacturing, domestic manufacturing, for biologics and vaccines. We also basically need to have a capacity to basically manage those stockpiles effectively through both commercial and State-level processes. And we need to probably require hospitals and other healthcare institutions to have some baseline level of preparedness and stockpile.

Senator ALEXANDER. So we need to keep the stockpiles full. Are we talking about a lot of money?

Dr. KADLEC. No, sir. I think in your bill you have identified about \$2 billion. I think that is where you start. And then again, most of these items are common used anyway daily in hospital use and healthcare use, and just maintaining that stockpile over time. But it does require a business model to support that.

Senator ALEXANDER. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Alexander.

Senator Durbin.

Senator DURBIN. Thanks, Mr. Chairman.

VACCINE TIMING

Dr. Kadlec, last night the President of the United States said—and I quote—we are within weeks of getting a vaccine. Could be 3 weeks, 4 weeks. True or false?

Dr. KADLEC. Sir, it is possible. And so with Operation Warp Speed, we have basically worked to basically do simultaneously the clinical trials as well as doing the manufacturing of vaccines. So if and when, whether that is 2 weeks, 3 weeks, 2 months, or 4 months, once a clinical trial is complete and that scientific data is reviewed by the FDA and approved, then we have vaccine potentially available immediately to use. And that is the strategy that has been adopted in Operation Warp Speed, sir.

Senator DURBIN. So I want to make sure this is on the record.

Dr. KADLEC. Yes, sir.

Senator DURBIN. You are saying 3 weeks to 4 weeks for a vaccine?

Dr. KADLEC. Sir, that is manufactured. Yes, sir. Now, is it approved by the FDA? That is a decision that they will have to do based on the scientific data that they receive from the clinical trials.

Senator DURBIN. So what you are saying to me is they could manufacture it, but before it is approved as being safe and effective for distribution in America is going to be beyond 3 or 4 weeks.

Dr. KADLEC. Sir, it depends on the outcomes of those clinical trials. And so I cannot predict that. They are ongoing right now, some of them complete in October, and the FDA is the one who will make the decision to determine safety and efficacy, sir.

Senator DURBIN. The President predicted it last night.

We have about 4.5 percent of the world's population in the United States. We have more than 20 percent of the deaths from COVID-19. Last night, the President said, we have 20 percent of the cases in the world because of the fact that we do much more testing. If we would not do testing, you would not have cases. You would have very few cases.

So let me ask Admiral Giroir, would ending testing end the spread of the COVID-19 disease?

Admiral GIROIR. No, sir.

Senator DURBIN. Could you explain the President's explanation last night? Does it make any sense to you?

Admiral GIROIR. I did not hear—

Senator DURBIN. Oh, we have heard this over and over again. Come on. He is repeating what he said over and over again.

Admiral GIROIR. So let me just clarify that the number of cases are going to be the number of cases. We do more testing so we could detect more and more cases. That is a good thing. We want to detect as many cases as we can so that they can be appropriately isolated, do contact tracing, et cetera.

It is true that the more testing you do, the more cases you will discover, but the cases are there no matter what.

EXPANDING TESTING

Senator DURBIN. Now, you talked in your testimony here about expanding testing. And I could not endorse that more heartily. The President says just the opposite. If we would not do testing, you would not have cases. I mean, do we not want to create the mindset in America that regular testing to make sure that we are not positive and not spreading this disease should be routine until we come to grips with a therapy or vaccine to deal with this?

Admiral GIROIR. So I do want to state what I did state earlier in multiple testimonies. I have never been asked, told, hinted, suggested that we should decrease testing. In fact, basically every time at the task force, we work to expand testing to the degree possible, investing hundreds, billions of dollars in that. So my job is to expand testing as much as feasibly, even infeasibly, possible and get the right tests to the right people at the right time. And that has been my mission. No one has told me to alter that.

AFFORDABLE CARE ACT REPLACEMENT

Senator DURBIN. In July of 2017, the United States Senate considered the repealing of the Affordable Care Act on the floor of the Senate. I will remember that morning, that night forever. A few feet away from me the late Senator John McCain cast a no vote, and the Affordable Care Act survived.

The President has said repeatedly that he has a replacement plan for the Affordable Care Act. As head of the agencies responsible for dealing with such a public health undertaking, I would like to ask you, does a replacement plan exist that you are aware of? Any of you? Yes or no. Admiral?

Admiral GIROIR. I am not involved in the replacement plan. I do not know what that is. I supply public health advice as much as I can for whatever that plan would be—

Senator DURBIN. Dr. Kadlec, are you aware of such a replacement plan?

Dr. KADLEC. Sir, it is not in my portfolio, and sir, honestly I have been so busy with the other things. I have no awareness of that.

Senator DURBIN. Dr. Redfield, are you aware of a replacement plan?

Dr. REDFIELD. Again, it is really not in my main lane, but I am not aware of one.

VACCINE SAFETY

Senator DURBIN. Just a few weeks ago, the nine major pharmaceutical companies had full-page ads saying they would not bow to political pressure to rush vaccine production. Were any of you con-

sulted before they made the decision to buy that ad across the United States?

Dr. KADLEC. Sir, not consulted, but aware of it. And it conforms with I think the feelings and the commitments that the leadership in Warp Speed and in my organization are committed to as well.

Senator DURBIN. Do you know why they did it?

Dr. KADLEC. Sir, I think to the point of being sure that everyone is believing in the same way, which is a safe and efficacious vaccine, has to be trusted.

Senator DURBIN. Thank you.

Senator BLUNT. Thank you, Senator Durbin.

Senator Capito.

While we are trying to figure out how we get Senator Capito for her questions, Senator Kennedy why do you not go ahead with yours and then we will go to Senator Reed after Senator Kennedy and see if Senator Capito is ready. Senator Kennedy.

Senator KENNEDY. Thank you, Mr. Chairman.

Thank you, gentlemen, for being here today.

You are all M.D.s, medical doctors. Is that correct?

Dr. KADLEC. Yes.

Admiral GIROIR. Yes, sir.

Senator KENNEDY. Would any of you do anything to violate your Hippocratic oath?

Admiral GIROIR. Never.

Dr. KADLEC. No, sir.

Senator KENNEDY. Have any of you, as Senator Murray alleged, recklessly interfered with the treatment or prevention of COVID-19?

Admiral GIROIR. No.

Dr. KADLEC. No, sir.

Dr. REDFIELD. No.

Senator KENNEDY. Do you know of anyone who has in the Trump administration?

Admiral GIROIR. No.

Dr. KADLEC. No, sir.

Dr. REDFIELD. No.

Senator KENNEDY. Okay.

Dr. Redfield, have you ever had polio?

Dr. REDFIELD. No, sir.

Senator KENNEDY. Me neither. Thank you, science.

When the coronavirus was first discovered, we did not have much science about it. Did we?

Dr. REDFIELD. No, sir.

Senator KENNEDY. You could not go to like WebM.D. and look it up. Could you?

Dr. REDFIELD. No, sir.

Senator KENNEDY. We have learned a lot about it. Have we not?

Dr. REDFIELD. Yes, sir.

COVID-19 SPREAD

Senator KENNEDY. Would it be fair to say—and disagree with me—if you do, I know you will—that the coronavirus is a lot more contagious than we originally thought. Is that fair?

Dr. REDFIELD. Yes, sir.

Senator KENNEDY. Now, I read on the CDC site—tell me if I misinterpret this—that out of every 1,000 people who get coronavirus, not out of every 1,000 people but out of every 1,000 people who get the virus, 6 are going to die. Is that accurate?

Dr. REDFIELD. It depends on age group and risk factors, sir. So if you were to look right now, individuals under the age of 18, it is about .01 percent. 19 to, say, 69, it is more like .3 percent. And if you are over the age of 70, it is about 5 percent now.

Senator KENNEDY. But if you look at population as a whole, it is about 6 out 1,000. Is that correct?

Dr. REDFIELD. I would have to get back to you. Overall, we are probably looking at an overall mortality in the range of somewhere between .4 and .6 percent—

Senator KENNEDY. Right. That would be 6 out of 1,000. That is on the high end. Obviously, the older you get, the more at risk you are.

VACCINE TIMING

Tell me when you think we will have a vaccine, as best you can, ready to administer to the public, Dr. Redfield.

Dr. REDFIELD. Well, I think as Dr. Kadlec said, I think there will be vaccine that initially will be available sometime between November and December but very limited supply and will have to be prioritized. If you are asking me when is it going to be generally available to the American public so we can begin to take advantage of vaccine to get back to our regular life, I think we are probably looking at late second quarter, third quarter 2021.

Senator KENNEDY. And so you think by the late second or third quarter, we will have started to vaccinate people?

Dr. REDFIELD. I think the vaccination will begin in November-December, and then we will pick, you know, and it will be in a prioritized way, those first responders and those at greatest risk for death. And then eventually that will expand. You know, there is about—it is hard to believe, but there are about 80 million people in our country that have significant comorbidities that put themselves at risk.

Senator KENNEDY. Right.

Dr. REDFIELD. They have to get vaccinated, and then the general public.

OPERATION WARP SPEED

Senator KENNEDY. But I am about to run out of time.

And what do you call this effort, this worldwide effort led by the United States of America to develop a vaccine? What is the term for it?

Dr. REDFIELD. Operation Warp Speed, sir.

Senator KENNEDY. Have you ever seen anything like Operation Warp Speed?

Dr. REDFIELD. It is unprecedented.

Senator KENNEDY. How long does it usually take—this will be my last question, Mr. Chairman—to develop a vaccine?

Dr. REDFIELD. I think the fastest prior was 2 years and usually 4 to 6 years.

Senator KENNEDY. Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Kennedy.

Senator REED.

Senator REED. Thank you very much, Mr. Chairman, and thank you, gentlemen, for your testimony.

FACE MASKS

I was particularly struck how emphatic you all were insisting that the use of face masks is absolutely critical in a social setting. You are all wearing face masks. I have mine. I took it off so I could question. Yet, last evening, the President once again disparaged the importance of wearing face masks. He does not wear one usually. He has conducted rallies in which many of the participants are not with face masks. He does not have on a face mask.

So let me just ask all of you. Admiral, you are a uniformed officer. Is the President providing appropriate leadership when it comes to this critical issue, one of the most direct and important things anyone can do to protect themselves and the community from this disease?

Admiral GIROIR. Well, as a uniformed officer, I am not going to comment about the President, but I do want to emphasize that wearing a mask is one of the most important things that we can do to prevent spread particularly because people who are asymptomatic—you could feel totally fine but still be spreading the virus, which is why wearing a mask when you cannot physically distance is absolutely critical. And I think I probably speak for my other two colleagues, but you will want them—

Senator REED. I want them to. But I think you just directly contradicted the President's behavior and the President's comments even though you have done it politely.

Doctor.

Dr. KADLEC. Sir, we are supportive of the mask. That is why we produced a half a billion of them and made them available to the American public at large.

Senator REED. But the answer is—

Dr. KADLEC. Yes.

Senator REED. Is the President undercutting what you have all said and you have repeated one of the most important steps that Americans can take to defend themselves and the country against this disease?

Dr. KADLEC. Sir, my view is that he is an individual who can exercise his rights to do what he pleases, as we see other Americans doing that. And so he is—

Senator REED. But it is also the leader of the country trying to cope with a disease, a pandemic that has killed over 100,000 people, and he is rejecting this emphatic advice that you give repeatedly and you yourselves demonstrate.

Dr. Redfield, your comment.

Dr. REDFIELD. I am not going to comment directly about the President, but I am going to comment as the CDC Director that these face masks are the most important powerful public health tool we have. And I will continue to appeal for all Americans, all individuals in our country, to embrace these face coverings. I have said if we did it for 6, 8, 10, 12 weeks, we would bring this pandemic under control. We have clear scientific evidence they work,

and they are our best defense. I might even go so far as to say that this face mask is more guarantee to protect me against COVID than when I take a COVID vaccine because the immunogenicity may be 70 percent, and if I do not get an immune response, the vaccine is not going to protect me. This face mask will. So I do want to keep asking the American public to take the responsibility, particularly the 18 to 25-year-olds where we are seeing the outbreak in America continue to go like this because we have not got the acceptance, the personal responsibility that we need for all Americans to embrace this face mask.

Senator REED. Once again, I think you have refuted the President more eloquently than I have heard. You are the expert. Leaders have to depend on expert advice. That is why they have people like you there, and when they do not take your advice, in fact when they disregard it—and it has been said so emphatically here. It is not a question of any doubt at all in your views, all of you.

STATE DISTRIBUTION PLANNING

Just a final quick question, and I only have a bit of time. Dr. Redfield and Dr. Kadlec, quickly. Your vaccine plan has to involve the States. Can you just very, very briefly, Dr. Redfield—is there a conscious integration of the States in terms of their public health services, and are there resources available for the States in this plan because they will need them?

Dr. REDFIELD. Yes, sir. It is critical. We have done micro-planning already with five jurisdictions, North Dakota, Minnesota, California, Florida, and Philadelphia. And this plan will be going out today to all of the States. I will be talking to the State public health leaders this week. We will be working with them so that they can integrate this plan in their own unique way for their own State, and there will be support to help them begin to resource this plan.

Senator REED. Thank you.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Reed.

Senator CAPITO.

Senator CAPITO. Thank you, Senator Blunt, and thank all of you. I am pleased to be a part of this hearing today.

QUARANTINE GUIDELINES

And I will start off with Dr. Redfield. I am not sure if you are aware, Dr. Redfield, but I am abiding now by the CDC guidelines. I was made aware on Monday that I had been exposed to somebody who tested positive for COVID. According to what the physician told me, I had been in and around that individual for at least 15 minutes within 48 to 72 hours of when he exhibited symptoms. And out of an abundance of caution and I think acceding to your guidelines, I went immediately to the physician at the Capitol who advised me then that I must quarantine for 14 days. I did subsequently take a test and tested negative, which I am very obviously pleased about.

But I want to ask you are your guidelines on quarantining—for those of who are quarantining following the rules, what kind of success does that bring in terms of isolating and containing the

spread? And do you further recommend further testing as people are coming out of their quarantine, and at what points of the quarantine would they need to get retested, if that is necessary?

Dr. REDFIELD. Well, first, I want to thank you for setting the example and embracing these guidelines.

Although misinterpreted, some of the changes that we put in our guideline, the whole purpose of those guidelines was to engage the public health and medical community back into the decisions when people get tested so, as was talked about earlier, there was the appropriate public health action. So the tests led to an action. It was not just a test.

And so I want to thank you for setting that example.

The reality is if you have had close contact, it could take 7 days, it could take 10 days, it could take 12 days before you turn virus-positive. That is why we have our current recommendations, based on the data we have, for isolation for 14 days. And as we get more data, that may change, but the reality is that the data that we have today, we still support the 14 days of isolation.

We do have very good data in our household studies where households that have introduced COVID, where individuals practice masks and hand washing and distancing, we have been able to show there is limited transmission in those household settings. And in households that did not, we have seen attack rates of 20 percent, 30 percent, 40 percent, 50 percent within the household.

So again, that is where the state of knowledge is right now. There may come a time when we have better data that can shorten it. But right now, even if we shortened it to 10 days—and a number of people have asked to look at the data—we would still send home probably 10 to 12 percent of people who would later turn out virus-positive.

Senator CAPITO. Well, thank you for that.

RAPID TESTS

Admiral Giroir, Dr. Redfield brought up an issue that I know is cascading across the country, and that is, as some of our colleges and universities are opening, the incidence in testing and the incidence of positives have gone way up because of some behavioral issues and just the whole atmosphere at times in a college and university setting.

So there is a great interest on tests to get the rapid turnaround test. The Abbott test I know is of interest to the universities.

I know you are beginning to deploy these to nursing homes and highly challenged communities, which I applaud. But how do you deal with a college and university setting in terms of testing, and what do you recommend here? What do you see in the future?

Admiral GIROIR. So thank you for that question.

Universities generally have a very substantial capability to do testing in their research laboratories, in their veterinary diagnostic laboratories. Senator Durbin, the University of Illinois is one of the real leaders in being out front. So we have had multiple calls, seminars, technical webinars to allow the universities to turn on their research equipment. We have done the CLIA waivers. We have done all of that to really use that to support testing.

Eventually we want to get to a point that rapid point-of-care tests are available for everyone. But 50 million a month does not go into 300 million people. So what we are advising universities is to use those rich resources that have been funded by the NIH that they have to use them. A nursing home cannot do that. Many universities, using their veterinary laboratories, which are very successful—and again, the University of Illinois has done just really tremendous. We had them on one of our leadership calls as an example telling the rest of the country.

Senator CAPITO. Thank you very much.

OVERDOSE DEATHS DURING THE PANDEMIC

And just in closing—I know my time is up—I am concerned, Dr. Redfield, as we talked about before. The rise in overdose and overdose deaths during this pandemic is extremely alarming. And I am very concerned, as we keep moving forward, what kind of impacts this is going to have on the addiction community. You and I have talked about it. We got to keep our eye on it. Thank you so much.

Senator BLUNT. Dr. Redfield.

Dr. REDFIELD. Yes. I could not agree with you more. I mean, we have seen an increase of almost 18 percent now, in our suspected overdose—

Senator CAPITO. A lot.

Dr. REDFIELD [continuing]. In admissions into hospitals. Clearly the isolation that has been associated, also the ability to get access to the proper pain control when a lot of the medical services cut back. CDC recently did a survey—and it actually shocked me—just a survey across our Nation, and found that 31 percent of adults reported now significant anxiety and depressive disorders. So this is a significant comorbidity that has been negatively influenced by the COVID response, and it is something that we have to continue to double our efforts to try to prevent death from overdose.

Senator BLUNT. Thank you, Dr. Redfield. Thank you, Senator Capito.

Senator Shaheen.

Senator SHAHEEN. Thank you, Mr. Chairman, and thank you to each of you for being here.

INFECTION CONTROL IN LONG-TERM CARE FACILITIES

Admiral Giroir, in your opening statement, you talked about the importance of protecting the elderly, which I think all of us would agree is critical. And yet, the elderly have been impacted the most by this COVID-19. In New Hampshire, over 80 percent of our deaths from COVID-19 have been in long-term care facilities.

That is why I am so concerned about the slow pace that HHS has provided in giving support for infection control in these facilities. The CARES Act provided up to \$200 million for nursing home infection control efforts, and to date, only \$17 million of that has been spent.

On top of that, HHS has only spent about half of the \$16 billion that Congress has provided for the acquisition of personal protective equipment, which continues to be a need. Nursing facilities and providers across the CARES system in New Hampshire desperately need these supplies.

So, Admiral, the infection control funds are vital to helping our nursing homes reduce the spread of diseases. You have alluded to that. So when can we expect the remaining funds to be distributed?

Admiral GIROIR. I cannot answer that on that specific. I do not know when they will be distributed.

What I can say is that I know even in the last couple of months there have been \$5 billion of extra funding to nursing homes. \$2.5 billion of that is to support testing, which is really in our regime. And we do get—Admiral Polacek, the other admiral on the team with an unpronounceable name—every day we get about 99 percent of nursing homes reporting. So we know exactly what their PPE (Personal Protective Equipment) situation is.

But in terms of that specific fund, I am going to have to have the team get back to you on that.

Senator SHAHEEN. I would appreciate that.

One of the challenges with that \$5 billion that was just distributed is that it can only be used for hiring only, not retention, and the biggest challenge our nursing homes have in New Hampshire is retention of employees. So is there going to be any thought given to providing more flexibility for long-term care facilities in how those funds can be used?

Admiral GIROIR. And I am really sorry. I am going to have to get Seema Verma and the Secretary to respond to that. That is not within my realm of responsibilities.

Senator SHAHEEN. Well, I would urge you to do that because if we are providing funds to long-term care facilities that cannot be used, then it is not accomplishing the concern that all of us share.

PUBLIC RELATIONS CAMPAIGN

I want to go on to another issue because there was a report that just came out about HHS seeking bids for a \$250 million contract for a public relations campaign to defeat fear and inspire hope regarding the pandemic. And while I think all of us want to make sure that Americans know that there is going to be a better time ahead for us, the timing of this contract raises real concerns about the potential intersection with the President's reelection campaign, and more importantly, Congress did not direct HHS to conduct this campaign. So is the \$250 million that is going to that coming from funding that should be going out to our long-term care facilities, to our hospitals, to our medical providers to actually respond to the spread of COVID-19? And what is the purpose of this contract at this time to do a public relations campaign? Would it not be better to give information to the American public about what all of you have said so eloquently this morning about what we need to do to respond to this virus and what we need to do to ensure that people have the health care they need if they contract it? Admiral, can you answer that?

Admiral GIROIR. And, ma'am, I really do apologize, but I do not know anything about public affairs campaigns or where that money comes from or what it is going to do. That is just not something that I deal with. We all try to provide the best information we can through whatever vehicles we can, but I just do not know about public affairs contracts.

Senator SHAHEEN. So you were not aware that the Department is going to be spending \$250 million on that advertising campaign?

Admiral GIROIR. I mean, I am generally aware from what I read in the news, but I am not involved in—I am really not involved in that. All I know about public affairs is that we do want to get all of us in front of the public to make sure, number one, they get their flu vaccines this year because that is really critically important.

Senator SHAHEEN. Thank you. I think that is very helpful.

Dr. Kadlec, were you aware of this expenditure?

Dr. KADLEC. No, ma'am.

Senator SHAHEEN. Mr. Chairman, I would hope that this committee would ask some very tough questions about what is going on here because that is a lot of money for a campaign that we ought to be spending to address this pandemic.

And, Senator Alexander, I totally agree with you on doing some work now to respond to the next pandemic, and I would suggest that we also ought to restore the Global Health Security and Bio-defense Unit either at the National Security Council or somewhere where it can provide an early warning for what is ahead.

Thank you very much.

Senator BLUNT. Thank you, Senator Shaheen.

Senator Hyde-Smith.

Senator HYDE-SMITH. Thank you, Mr. Chairman.

And to the panel, I truly thank you for all you have done and your tremendous tireless efforts of guiding this country through COVID-19. You are to be commended, applauded, and I am certainly one that appreciates you being here today and answering the questions that we have and being willing to serve in the capacity that you serve in.

RURAL HEALTH

I represent Mississippi. We are less than 3 million people. And one of our largest challenges is rural healthcare and getting these vaccines to rural areas such as those in Mississippi. Of course, I am very concerned about the universities and colleges and the protection that we need there through that age population.

But I am just going to ask you, what are your agencies working on to help address the challenges in unique rural America's response to COVID-19? But mainly, how can this subcommittee support you in that? How can we help you address those issues there? And I would like to hear from all three of you on that and getting the vaccines to rural America where it needs to be where we have such a challenge.

Dr. REDFIELD. Thank you very much, Senator.

Very, very important, we have continued to try to develop outreach in vaccine distribution particularly in the hard-to-reach rural areas. This is part of the efforts that we have accelerated with our flu program right now with the idea of how to vaccinate with confidence by trying to protect communities, empower families, and stop myths.

We have developed rural partnerships with the National Rural Health Association, the National Association of Rural Health Clinics, and the National Organization of State Rural Health Offices

with the goal to really work to improve the acceptance of vaccination in general, flu being the important one with confidence.

I do think the recent decision that the Secretary made in expanding the ability of pharmacies to vaccinate down to age 3 to down to age 18 is going to be an important expansion of being able to engage pharmacies throughout our Nation as vaccine centers.

But we are continuing to work with those rural organizations to see if there are other innovative solutions to try to expand vaccination. I am hopeful that the pharmacy expansion is going to have a significant impact.

Senator HYDE-SMITH. Thank you very much.

Dr. KADLEC. Ma'am, with regard to rural healthcare, what ASPR has been doing in the last years prior to the COVID event was trying to expand what would be the regionalization of disaster care, emergency care to really focus on areas where you have critical access hospitals or underserved populations.

In the current COVID event, we have been working with the Department of Defense to employ a system that they originally started, which was called the National Emergency Telecritical Care Network, or NETCCN, which is a means by which to do telemedicine to again rural and critical access hospitals to make them available the best information critical care specialty support, as well as arranging for transportation and referral of cases to a higher level of care. So we are actively doing that right now. We have done it in many parts of the country as a result of our work in COVID response. And we are also trying to do that for ambulatory care telemedicine as well. So by building out our regionalization approach, our hope is to not only create the established referral patterns but also establish telemedicine consulting support so that we can support the rural parts of this country over.

Senator HYDE-SMITH. Thank you.

Admiral GIROIR. And I will add on again with the PREP Act guidance that allowed pharmacists to do COVID vaccines—I issued that last week to get in the pharmacy communities.

But I just want to be a little bit of a cheerleader for federally qualified health centers. We now have 221 federally qualified health center sites in Mississippi performing testing. I think FQHCs are a real gem. They take care of 30 million people and very much of the underserved migrant farm workers, homeless, and they do so at a savings, better outcomes at less cost. So again, that is a major point for us in Mississippi where we are reaching people both urban and rural. And anything I could do something for HRSA and health centers, that is going to be money well invested.

Senator HYDE-SMITH. Thank you all for those answers, and I truly appreciate that because it is one of my top priorities. We had a young lady not long ago that died of an asthma attack because the emergency room had been closed in her area. So I certainly appreciate your work there.

Senator ALEXANDER [presiding]. Thank you, Senator Hyde-Smith.

Senator Merkley.

Senator MERKLEY. Thank you very much.

ASYMPTOMATIC TESTING

Director Redfield, I am concerned that the CDC has revised guidelines that no longer recommend testing for asymptomatic individuals who have been in close contact with a person with COVID-19 infection for at least 15 minutes.

Just a few days ago in a media interview on September 10, Admiral Giroir stated that all of us in the room have been hearing from public health experts we need to test asymptomatic individuals.

So explain this to me. Is the admiral right or wrong?

Dr. REDFIELD. Thank you very much, Senator, for the opportunity to address your question.

I think, first and foremost, I want to say the CDC guidance that came out was clearly misinterpreted, and within 24 hours, I published a statement to try to make it clear what CDC was recommending. We were never recommending not to test asymptomatics, and we were never recommending obviously not to do the public health contact tracing and trace them.

What was attempted was to replace the emphasis of testing so that, as we talked about earlier, testing led to an action. It drove public health objectives. So we placed the emphasis on testing symptomatics, but then we placed the emphasis on individuals with significant exposure—they are asymptomatic—or vulnerable populations, nursing homes, long-term care facilities, critical infrastructure workers, healthcare workers, first responders—they are asymptomatic. And the last group that we talked about was individuals who may be asymptomatic and rather than just get tested, what we asked them to do was consult, like we heard from the Senator from West Virginia—consult with your medical and public health officials and follow their direction because, as you saw with the Senator, when she chose to get tested, even though the test was negative, there was a critical public health action. That was for her to stay home for 14 days.

So we are going to continue to try to make sure our guidance is not interpreted incorrectly because as the admiral said and as I have said, asymptomatic infection and pre-symptomatic infection is a critical component of the transmission cycle of this virus.

Senator MERKLEY. I am going to ask you to stop there because I have got other questions, and I think you have answered it. And even the example you have given shows the positive impact of testing asymptomatic individuals because they can get appropriate guidance on how to behave thereafter. And we know that a tremendous amount of infections are happening from people who are asymptomatic. And so I think that is such an important point to keep driving home.

STATE VACCINE DISTRIBUTION

I wanted to also ask you. You had told governors to prepare for the distribution of COVID-19 vaccine on November 1. It escapes no one's perspective that you are deliberately laying it out 2 days before the election. Who in the administration asked you to choose that particular date?

Dr. REDFIELD. No one, sir.

Senator MERKLEY. You just thought on your own political motivation to try to influence the election in this manner. What happened to science driving decisions?

Dr. REDFIELD. There was no political interest in it whatsoever. It was actually prepared by our subject-matter experts because we wanted to get to the point of realizing that vaccine may be available—we do not know when—and we wanted the governors to be able to not have red tape interfere with the distributor McKesson from setting up their distribution sites.

I will argue that the thing that I was most concerned of and my subject-matter experts were, who actually generated the letter which I signed, was that the worst thing that could happen is we had vaccine delivered and we are still not ready to distribute.

But I can tell you there was absolutely no political thinking about it. You could say in a retroactive—somebody should have thought a little more political. But there was no political intention whatsoever.

Senator MERKLEY. Okay. Well, I must say that I do not find that persuasive. You are saying that there was not a single contact from the administration after the President said I would like to have a vaccine before November, before the election. No one from the administration contacted your team at any level to say can you please emphasize that message. There were no emails, no meetings, no phone calls, not back room chats connected with your choosing that particular date.

Dr. REDFIELD. Absolutely not. It was independently developed by our subject-matter experts that were laying out this document to start to plan for the jurisdictions that we needed to get that letter out so McKesson could get the licensing agreements that they needed to get their distribution sites up. And they drafted the letter—the subject-matter experts—that I signed.

Senator MERKLEY. Yes.

Senator ALEXANDER. Thank you, Senator Merkley.

Senator MERKLEY [continuing]. So much misrepresentation by the administration. I think Americans would find it hard to believe that there were no conversations when the administration is actively pushing every piece of the Federal Government to engage in actions to promote their election. So it undermines your credibility. You should have at least thought about how it undermines your credibility because it is so important to have the CDC be above politics.

Senator ALEXANDER. Thank you, Senator Merkley.

Senator Lankford.

Senator LANKFORD. Thank you.

It has been interesting how much the dialogue today has been about politics and about the election. I do appreciate the work that you are doing regardless of party. I do not find people getting COVID only if they are Republican, Democrat, or independent voters and non-voters. So I appreciate the ongoing work that you have done for a very long time to be able to work us through this. Your days are very long, and your work is very important. So we appreciate the work that you continue to be able to do. And this hearing should not try to be some sort of political trap for the President. It should be about the facts and details. So I appreciate that.

Let me ask you a couple of quick questions on this. One I want to dig into more.

FUNDING FOR VACCINE PRODUCTION AND DISTRIBUTION

The first one is there has been a lot of conversation about the amount of resources that is needed for the vaccines especially and for vaccine production and distribution. What do you still need for vaccine production and distribution as far as supplemental appropriations?

Dr. KADLEC. Senator, thanks for that question.

At this point, we have funded six vaccine candidates for both advanced development and manufacture. I think at this stage the \$13.6 billion that have been appropriated or—pardon me—committed for this purpose is adequate for that, for the initial part of this. If you are talking about at the point in time when one vaccine candidate may fail and we may have to replace it with another candidate or expand production of another, that could basically change our accounting and our calculus for what we would need. But at this stage, we have what we need, and we are poised, at least at this point I think by the end of this month and into early October, to at least have the funds that we need to basically provide for the first several candidates.

Senator LANKFORD. Okay. That is good to know. There are obviously six different candidates going through the vaccine process right now, and because no one knows if any one of them is going to be successful, so you got basically six hooks in the water at this point.

I am going to drill down a little bit on the vaccine candidates that are out there and also some of the treatments.

ETHICAL PRODUCTION OF VACCINES

Some of the pharmaceutical companies have chosen to do ethical production, that is, they are not using tissue from aborted children for the production of the treatment or of the vaccines. Some of them have chosen to use aborted fetal tissue in the production of the vaccines. How are you balancing out to be able to make sure that there will be an ethical alternative for individuals that do not want to take a vaccine that is also produced using the tissue of an aborted child?

Dr. KADLEC. Sir, thank you for that question. I am going to have to take that for the record and bring you back an answer to get more details on those particular matters. I do not have those immediately available, and I do not want to misspeak on this issue.

Senator LANKFORD. That is fair enough.

Dr. Redfield, do you have comments or thoughts on that on the production?

Dr. REDFIELD. Again, I would have to go back and see specifically. I think my recollection is we are going to have a number of candidates. It is not going to compromise one's ethics related to the use of human tissue. But I will have to get back to you too because I do not want to say something that is incorrect.

Senator LANKFORD. No. I get that. And it is not just human tissue in the production. I mean, there are some companies that are using adult stem cells. There are some that are using placentas

from children after birth. Those are not objectionable. I do not find anyone challenging that. So it is not just the use of human tissue. It is specifically the use of tissue that is from aborted children that becomes the challenge. Moderna is using embryonic kidney cells from aborted children. Johnson & Johnson is using aborted children embryonic retinal tissue for its production of the vaccines. There are others that are not choosing to use those tissues from children. So I think there just needs to be as many options out there as we can.

And again, I just wonder on the science side if we do not have to use tissue from aborted children, why would we do that when there are others that are choosing to be able to develop vaccines that are not being used that way.

So I want to be able to follow up with you on that just be able to see what options are out there and how we are handling the funding and what direction that we are going to go. And long term for vaccines, most of the vaccines that we have in America now do not use embryonic tissue in it. There are still some that still do, that that is the line that is still used. And again, when we do not have to do that, why would we do that and to have it as ethical as we possibly can.

So again, I appreciate the work. We will follow up in the days ahead on this particular topic because I think it is very important that as many people get vaccinated as possible. And I do not want to have a reason for people to not go get a vaccine because they are concerned about the origin of the vaccine. I want as many people as possible to actually get a vaccine because I think it is important. And it has been an odd conversation to hear so much of people saying, well, I am challenging whether we are going to get a vaccine because the Trump administration may be rushing this, and so I do not want to go get one. I think we have to have nothing that distracts from the science and the details of this as we walk through it as well.

So I appreciate your work.

Senator ALEXANDER. Thank you, Senator Lankford.

Senator Schatz.

Senator SCHATZ. Thank you, Mr. Chairman. Thank you to the panelists for being here.

TESTING

I will start with Admiral Giroir. You said in July that it was not a question that we would be soon running a million tests per day. We have gone from about 800,000 tests per day to 675,000 tests per day. What is happening?

Admiral GIROIR. I want to be clear that we are talking about capability to produce tests. And I think we need to always draw the distinction between how many tests we have that can be deployed and what the States are doing.

In August, for example, the States' combined goals were in the low 20 millions of tests, which they exceeded to 25 million.

But what we are seeing at some parts of the country is testing is going down. We are trying to change that. I know you are from Hawaii. We have a surge site in Honolulu right now that we can test up to 5,000 per day and moving—

Senator SCHATZ. Right. You are saying this is volitional? I guess the question is, is this a supply chain problem, or are you saying that States are individually deciding to do less testing?

Admiral GIROIR. This is not a supply chain problem. We had double the availability of tests that were done in August, and we will be over 90 million tests available in September. I would presume that a higher proportion will be done because they are going to be very easy to do. They are going to be point-of-care Binax testing and that we are surging nursing homes.

Senator SCHATZ. Can we just talk a little bit about the Binax testing?

Admiral GIROIR. Yes.

Senator SCHATZ. Because I guess where a lot of people are coming from is that we hope you are right that this new test is a game-changer. And we are pleased, and I think it will be very helpful in the context of first responders and in nursing homes and perhaps educational contexts as well. But it is a card, and as you know, you cannot really process that many tests at once this way. And so although it is really useful in certain contexts, it is not going to get you to your 90 million tests goal. I mean, in your testimony today—you say that we should have 90 million tests completed by the end of September.

Admiral GIROIR. I did not say that.

Senator SCHATZ. We are about halfway through September —

Admiral GIROIR. I did not say that.

Senator SCHATZ [continuing]. And we are at 10 million tests.

Admiral GIROIR. I did not say that. I said we have——

Senator SCHATZ. In today's testimony?

Admiral GIROIR. I said we will have the availability of 90 million tests in September. I never stated that we would do 90 million tests in September. We are certainly hoping that the testing goes up.

And let me just say about Binax, it only takes a swab and put it in and wait 15 minutes. I could probably go through this room and swab everyone and do that within about 5 or 10 minutes. So it is a low throughput test, but you could do them very rapidly and quickly. So I would expect that as many of these that get put in the market, particularly used in nursing homes, assisted livings, and to support K through 12, that they would be used very rapidly.

Senator SCHATZ. Just because I have limited time.

Admiral GIROIR. Yes.

AVAILABILITY OF TESTS

Senator SCHATZ. What is the difference between testing availability and tests being completed? Because that seems like a sort of a distinction that is lost on the ground. To know that there are 90 million tests theoretically available but the nursing homes, the schools, the first responders, the firehouses—they do not have the tests available. So what does it mean that it is theoretically available to do 90 million tests and yet people cannot get their hands on a test?

Admiral GIROIR. I do not think that is true. I think people can get their hands on the test. Even with Federal sites, we have 2,700 in retailers. We have surge sites. There is enormous capability in

the referral labs. So the testing is available even when we do surge sites. Unless there is—you know, there is not a public order that demands people to come in and get a swab up their nose. This is voluntary, and sometimes the demand is not there.

But let me just turn that around and say with the Binax, that is one reason why we purchased them all for the Federal Government, the first 150 million, to make sure they got to sites that would use them and really could benefit them like nursing homes, assisted living, Tribes, HBCUs, disaster situations, and in just a couple of weeks, to support K through 12.

Senator SCHATZ. Admiral, I know you are working on this, and I know you are trying to do this in good faith. But I just want to convey to you that when the surge testing happened in the State of Hawaii on the Island of Oahu over the last 2 weeks, it was only then that we were able to test our fire fighters. It was only then that we were able to test our first responders. It was only then that we were able to have the tests available to do what it is that is theoretically possible under other circumstances. And it was only because we saw a precipitous spike in COVID cases. And so it is not true—it is not true—that tests are available for first responders except in certain—

Admiral GIROIR. I respectfully disagree with you that if the State of Hawaii—you have a turnaround time of 124 hours with the ACLA labs. And I am happy to work with your State. But there is no reason before the surge—you could have hired this company to come do the surge for you. We did it, sent it down there. And the demand was great. Hawaii has been unbelievable to work with. We have been doing fully subscribed 5,000 tests a day. But I am very happy to work with Hawaii. The Surgeon General just went down. We are expanding on the big island. But there is no reason that first responders could not have been tested before the surge.

Senator SCHATZ. Well, I will just end with this, and I am sure my time is almost up.

There continues to be a disconnect with how things are represented in this committee, in the United States Congress, and how things are felt on the ground. This was evident in February when we met with HHS, and it continues to be the case here. We hear lots of triumphant statements with lots of data, but on the ground people still lack resources.

Thank you, Mr. Chairman.

Senator BLUNT [presiding]. Senator Baldwin.

Senator BALDWIN. Thank you, Mr. Chairman.

AVAILABILITY OF SUPPLIES

So the administration's failure to confront this deadly pandemic has led to lost lives. There is still an urgent need to provide more support to our communities. And I am increasingly concerned that the funds appropriated thus far have not been handled as well as they could. They have been misused and mishandled.

Last month, I wrote to Vice President Pence about a health system in my State that temporarily suspended COVID testing for patients undergoing surgery because of supply shortages. I have heard from assisted living facilities that they cannot get the tests they have ordered and academic medical centers that are not able

to secure a reliable source of reagent. However, Wisconsin did receive un-requested hydroxychloroquine before it ever received a ventilator.

Congress provided more than \$16 billion for the strategic national stockpile for critical supplies of PPE. Less than \$9 billion of that has been obligated for the stockpile.

Dr. Kadlec, what percentage of the funds appropriated for the stockpile this year have helped States get the PPE and testing supplies they need? As of this moment, what is that percentage?

Dr. KADLEC. Ma'am, I am going to have to get back to you with a percentage. But what we have done in terms of our approach to basically managing the PPE part—and I will defer to Admiral Giroir to talk about the testing piece—is that we have basically made available everything that we had in our stockpile by May. Beginning with March with the monies that were available in the CARES Act and subsequent to CARES Act, we have been basically funding, if you will, the purchase of personal protective equipment to be distributed through commercial distributors directly to hospitals. And only beginning in June and July have we been filling, if you will, replenishing our stockpile as part of a strategy to make available 3 months of supply for the fall and winter, should that be necessary.

We are, by virtue of teletracking, now getting information from hospitals. Last week, about 95 percent of hospitals have been reporting to us. And I am just looking at your State, ma'am. We have identified that 16 percent of hospitals have one shortage of PPE that may be—one type of PPE that may be 3 days of supply or less.

Senator BALDWIN. Right. I am aware of the Wisconsin statistics, but I am also aware of the \$16 billion that we appropriated to address stockpile issues. So you may have chosen a different strategy, but I think when we are 6 months into this pandemic and we still cannot get the supplies we need and you have identified the supplies that are in high demand, that you should use the money we appropriated to obtain those things.

Congress also provided \$1 billion for the Department of Defense for similar purposes. And the President delegated authorities under the Defense Production Act to HHS to increase production of personal protective equipment. The Department of Defense has only used \$300 million for PPE and said they would use the rest to support the defense industrial base.

DOMESTIC MANUFACTURING CAPACITY

Dr. Kadlec, how much funding have you spent on increasing domestic manufacturing capacity using all of the DPA (Defense Production Act) authorities available to you so that we can prepare for the remainder of this pandemic or future pandemics?

Dr. KADLEC. Yes, ma'am. So far we have awarded \$638 million for that purpose, which runs the gamut from addressing shortages of diagnostics and ancillary supplies, N95 respirators, injection technology for the use for vaccine administration, filter media for masks, as well as ventilators, gloves, surgical masks, as well as the ventilator supply chain. There are other things that are being considered at this point in time to use the rest of those funds, but we are trying to be very strategic.

Senator BALDWIN. Dr. Kadlec, what is melt-blown?

Dr. KADLEC. Ma'am, that is the material, the fiber material, that is used in the disposable surgical masks, N95 respirators, as well as ventilators—

Senator BALDWIN. Okay. And have you used the DPA to either increase production of melt-blown in the U.S.? I am not talking about contracting. I am talking about using the DPA authorities.

Dr. KADLEC. Yes, ma'am, we have.

Senator BALDWIN. And have you used DPA authorities to shut off the export of melt-blown when it is obviously so needed here?

Dr. KADLEC. Ma'am, I am going to have to get back to you on a firm answer on that, but my recollection is that we have. We did limit the export of that material, but I have to just be sure and return you a—

Senator BALDWIN. Please do.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Baldwin.

Senator Graham.

Senator GRAHAM. Thank you, Mr. Chairman.

Dr. Redfield, have you been part of the task force since its beginning?

Dr. REDFIELD. Yes, sir.

COVID-19 TIMELINE

Senator GRAHAM. Okay. So see if I have got the timeline right. I believe President Trump was briefed by Mr. O'Brien on January 28 you had a major problem coming out of China when it comes to the coronavirus. He sets up the task force on January 29. Is that correct?

Dr. REDFIELD. That is my recollection, sir.

Senator GRAHAM. On January 31, the President issues an order called the China travel ban. Does that sound right?

Dr. REDFIELD. Yes, sir. 31 of January was when the request was to inhibit travel to China.

Senator GRAHAM. On February the 29, Dr. Fauci was asked by a host of the "Today Show" this is Saturday morning. People are waking up right now were real concerned about this. They want to go to malls and movies, maybe the gym as well. Should we be changing our habits, and if so, how? Dr. Fauci says, February the 29, no, right now at this moment there is no need to change anything that you are doing on a day-by-day basis. Right now, the risk is still low, but this could change.

Is that the general view back on February 29? Did you agree with that assessment?

Dr. REDFIELD. At that time, there was limited evidence of community transmission in the United States.

Senator GRAHAM. So in March, there was an order basically issued declaring this a national emergency. Do you recall that? March 11?

Dr. REDFIELD. Yes, sir. I think Secretary Azar called it a public health emergency. I think it was January 27, and then the President, the national emergency—

Senator GRAHAM. On March the 13. March 11, we do a travel ban from Europe. Is that about right?

Dr. REDFIELD. Yes, sir.

Senator GRAHAM. Between January the 29 and March 13, did the task force ever recommend shutting the country down?

Dr. REDFIELD. No, sir.

Senator GRAHAM. When the task force recommended to the President to declare this a national emergency and to basically encourage shelter-in-place orders, did the President respond to the recommendation of the task force?

Dr. REDFIELD. Yes, sir.

Senator GRAHAM. Was there any time when the President refused to do what the task force recommended about shutting the economy down before he made that decision?

Dr. REDFIELD. Not in the decisions that I was involved in.

Senator GRAHAM. Thank you.

VACCINE DISTRIBUTION

So vaccines. If we found a vaccine, let us say, next month at the end of October, how long would it take for it to be distributed throughout the country and to become effective?

Dr. REDFIELD. Well, I think that is the critical question because currently we have used the supplemental resources to get this distribution capacity up, about \$600 million, but the funds that we currently have are not sufficient for us to get all 64 jurisdictions ready to be able to implement this plan that we issued—

Senator GRAHAM. Right. And I am sure you have made a request of the committee for additional money, and I am sure we will respond.

But what I want the American people to know if a vaccine was developed tomorrow that was considered to be safe and acceptable, how long would it be before it would have a real effect in terms of controlling the virus.

Dr. REDFIELD. I think we have to assume that if we had a vaccine, say, released today that it is going to take us probably in the order of 9 months—6 to 9 months to get the American public vaccinated.

Senator GRAHAM. So I just want everybody to understand that we are working—Operation Warp Speed—do you feel like that it is going well?

Dr. REDFIELD. Yes, sir.

Senator GRAHAM. So if we got a vaccine in the near future, before it would really have a massive impact, it would take 6 to 9 months to get it distributed and for it to begin to take effect, for lack of a better word. Is that accurate?

Dr. REDFIELD. In order to have enough of us immunized so we have immunity, I think it is going to take us 6 to 9 months.

Senator GRAHAM. So during that 6 to 9 month period, we will continue to do sort of basically what we are doing now. Is that correct?

Dr. REDFIELD. Yes, Senator. That is why it is so important to embrace these mitigation steps that we talked about.

ECONOMIC SHUTDOWN

Senator GRAHAM. So is it fair to say that at no time did President Trump reject the recommendation by the task force when it

came to slowing down the economy or putting shelter-in-place orders, that when it was recommended to him to take those actions, he complied? Is that correct?

Dr. REDFIELD. Yes, sir.

Senator GRAHAM. Is it fair to say that as late as February the 29, Dr. Fauci, one of the experts of our time, was telling people it is okay to go to the gym, it is okay to go out and about because at that time, we thought the risk was relatively low?

Dr. REDFIELD. I have to defer that. I didn't follow Dr. Fauci's statements. But I would say in general we all felt—

Senator GRAHAM. That is what he said on national television. That is what he said that day on February the 29. So this idea that President Trump did not respond I think is ridiculous for the President to be shutting the whole economy down when his leading expert is telling people you can go to the gym, you can go to a movie, you go out and about. So let us do not rewrite history here.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Graham.

VACCINE PRIORITY

Before we go to Senator Murphy, Dr. Redfield, let us be sure we are clear here on the vaccine. You are not saying that it would take 6 to 9 months before the vaccine would do any good for anybody, but you are trying to come up with a priority that the country and governors should look at of who is the most at risk that would get that vaccine first. Is that right?

Dr. REDFIELD. Yes, sir.

Senator BLUNT. And if the vaccine works with the efficacy that we would hope for, most of the people that get the vaccine are then protected from the virus for at least the near-term future. Is that right?

Dr. REDFIELD. The FDA has set guidance that if it is 50 percent efficacious, which is similar to the flu vaccine, that that would meet their threshold for approval. And I do want to be clear that as soon as this vaccine gets approved by an EUA or actually approved, we want to be in the position to distribute that within 24 hours because you pointed out very clearly this vaccine has the potential to save a lot of lives in November and December. But we need to be able to get that vaccine, once it is ready to—once it is approved, we need to get it distributed as rapidly as we can.

Senator BLUNT. Right. And in July, at the hearing we had in July, I asked you specifically to focus on being able to report back on a plan that hopefully we will get to later. I just do not want to leave this moment with any thought that just because everybody that wants to have the vaccine might not have it before Memorial Day, that does not mean that many people who do have it—and hopefully would be the most in need—would be substantially better off than they are right now. Is that right?

Dr. REDFIELD. Yes, Mr. Chairman. You are going to have an enormous impact, we believe, on the mortality and the most vulnerable and an enormous impact in protecting those at greater risk of infection. And we should see that impact relatively immediately.

Senator BLUNT. Thank you, sir.

Senator Murphy.

Senator MURPHY. Thank you very much, Mr. Chairman. Thank you for spending so much time with us today.

COVID-19 PUBLIC HEALTH CAMPAIGN

Just first a note on communication to and through Congress and this committee. Senator Shaheen earlier asked about a \$250 million contract that is being awarded by HHS to defeat despair and promote hope, which sounds an awful lot like a political reelection year-oriented message out of the administration. And we have two deputy secretaries of HHS before us today, and neither one of them can testify as to whether that contract was awarded, why it was awarded, what the reasons for it were. It is increasingly impossible for any of us to know who is in charge. We have got two people who are at the highest echelon of HHS and cannot answer a question about a massive contract that has been awarded.

And I think that is the same thing for the American public. Dr. Birx was in charge. Then Vice President Pence was in charge. It is really hard for there to be any accountability around decisions when we cannot get these basic questions answered.

TESTING

I want to come back to Senator Merkley's question regarding the changed guidance, Dr. Redfield. So the President says he wants less testing. He says that out loud. He is asked for clarification. He doubles down and says I want less testing. And then right around that time, you issue this guidance that dramatically scales back recommendations for who gets tested. And the "New York Times" reports that that is because, in part, of instruction from the White House. You say today that that report is in fact untrue.

But to many of us, it just belies reason that we would be encouraging fewer people to get tested today given the massive expansion of this virus. On the day that we passed the CARES Act, there were 10,000 new cases reported in this country. On average, we are seeing 34,000 new cases all across this country today.

Your testimony was that you were not necessarily saying folks who are asymptomatic should not get tested. You are saying they should just see a doctor first. Is that correct? That was your clarification today.

Dr. REDFIELD. No. What I was saying that when you get a test, like any physician who does a test, it needs to be linked to an action. And what we were trying to do is reemphasize that testing is linked to an action, just like the Senator said. She got tested. She was in quarantine. She got tested. She was negative, but that still was linked to an action to stay in quarantine for 14 days. What was happening was people were getting tested, and there was no action. So we were trying to bring action back into testing. We were not trying to limit.

And I will be very clear—

Senator MURPHY. Let me just—before you do that, let me just read you this. This is from a medical journal. This is from the American Journal of Managed Care. Earlier in this week, CDC changed its guidance saying even if you come into contact with an infected individual, a test is not necessary if there are no symptoms.

Dr. REDFIELD. That is not true what the guidance was attempting to say. It is true that some people interpreted it that way, and that is why I issued a very clear statement in 24 hours afterwards to say CDC is not trying to emphasize. I do believe that more tests, as was said by Senator Durbin—more tests actually can lead to less cases if testing is linked to public health actions.

Senator MURPHY. But you did recommend—you did say they do not need a test.

Dr. REDFIELD. No. We said they may not necessarily need a test.

Senator MURPHY. What does that mean? Listen, you are speaking to the American public when you tell them that they do not necessarily need a test.

Dr. REDFIELD. You need to consult a doctor, a public health person to make that decision—

Senator MURPHY. What is the difference?

Dr. REDFIELD [continuing]. So the appropriate public health action can be taken in conjunction—

Senator MURPHY. Okay. When you tell them that it is not automatic that they need a test, that they should see a doctor first, it gets communicated to people that the urgency is much lower.

Dr. REDFIELD. For all contexts, sir, we are recommending all of them be tested. So it was a misinterpretation by some. And again, we are going to continue to clarify because we are not recommending less tests. I do believe more tests ultimately are going to lead to less cases in this country because it is going to allow public health action to happen, just like it did for the Senator. And we can use those tools to stop this pandemic.

WORLD HEALTH ORGANIZATION

Senator MURPHY. I will ask this question for the record, Mr. Chairman, to Admiral Giroir. There was a report earlier this month that the United States is going to scale down its engagement further with the WHO, including recalling detailees from WHO headquarters, regional offices, and country offices, and then reassigning these experts. I acknowledge I do not have time to get the answer today, but I think it is incredibly concerning that we might not have American personnel on the front lines to sort of watch this virus and others through WHO (World Health Organization) field offices. And so I would appreciate an answer for the record regarding who is going to replace those individuals inside countries of concern and how we keep eyes on this virus and future viruses.

Thank you, Mr. Chairman.

Senator BLUNT. Thank you, Senator Murphy.

Senator Moran.

Senator MORAN. Chairman, thank you.

VENTILATORS

Dr. Kadlec, let me start with you. I want to talk a moment about ventilators.

HHS has entered into a number of ventilator contracts, most of which were cancelled a week or so ago before they reached their intended, I guess, conclusion. And is there an accounting of how many ventilators—which is troublesome to me because the signals

even a week before that was fulfill your responsibilities first to USAID (U.S. Agency for International Development) and then come back and finish your contract to us at HHS. And then a week later, the message is we do not want any more ventilators. And it is interesting to me that the contract requires HHS, the taxpayers, to pay for the startup costs, the closing down costs, and all the equipment and materials that have been purchased. So for a marginal amount of money, the contract could be fulfilled.

Setting that aside, what is the accounting on how many ventilators that are high acuity ventilators in the strategic national stockpile? And is there a calculation by HHS as how many need to be this higher acuity as compared to a more standard ventilator with kind of one dial that you adjust?

Dr. KADLEC. Well, thank you, sir, for the question.

And, yes, sir, we have been looking at our ventilator supply. Just to put this in context, when the COVID-19 event occurred in January, we had 17,000 ventilators in our stockpile with another 10,000 ordered. As a consequence of the modeling and the concern that we may need much more ventilators by pre-pandemic calculations for pandemic influenza, it was figured or calculated that you needed about 170,000 ventilators. As the course of this event, there was a concern that we may actually need more than that number, and that is when we went into agreements with seven companies across the country and a few from outside the United States to basically produce over 200,000 ventilators.

As things progressed as we learned more about the disease and, more importantly, how to clinically manage this disease both from a respiratory setting, as well as an intensive care setting, we identified we needed to change maybe our strategy with the ventilators, maybe needing less but also different kinds of machines. And so with your point, the higher acuity kind of ventilators, which we have over 120,000 of at this point, was to basically diversify that so that we could use some that could be used for high flow nasal cannula which seem to have better clinical outcomes.

So adjusting that number with modifications to some of the orders that we made, we basically also identified that we could meet our pandemic requirements of 170,000, make available to other countries an additional 20,000 ventilators, that we decided to then, if you will, cut back on the number of ventilators that we needed to order and to have shipped.

Yes, there is a cost to that, but there is a significant cost on the back end of this with the maintenance requirements that you need to maintain these ventilators.

And so that is why we did it, sir. I am the responsible party. And sir, I will be happy to get with you and your staff to provide you any other details you need.

Senator MORAN. Doctor, thank you.

PROVIDER RELIEF FUND

Let me quickly turn to Admiral Giroir. I think the position the witnesses have taken this morning is that you are incapable of telling us but would take back these issues for the record—you are in capable of telling us about future spending from the provider relief fund.

Let me just suggest to you that please take back for the record that the ability to get information from HHS on any spending from the provider relief fund has been minimal at best. As a United States Senator who appropriates money, who supported the CARES package, my ability to communicate with my constituents as to how you are going to spend the money, what the plan is has been next to nil. And I have not experienced that during coronavirus with other departments, with other agencies, but HHS has failed time and time again to respond to congressional inquiry and provide us with information about how taxpayer money is being spent, about how to help our constituents prepare for what you might be doing or what you are not going to do.

LONG-TERM CARE FACILITIES

Admiral, somewhat in that regard, the increasing costs associated with complying with HHS rules and regulations by our nursing homes, our skilled nursing facilities, our senior living facilities is significant. And my question for HHS, because I would understand that you will defer to somebody else than who is here today to answer the question, is what can they expect to help them pay for the tremendous increase in costs in compliance with COVID regulations in policies that they are attempting to comply with to protect the safety and wellbeing of their residents but have little financial capability to actually pay for?

Admiral GIROIR. Thank you for that question.

Independent of whatever regulations there are nursing homes have the responsibility and the ethical responsibility to do the types of testing that we recommended. It is the only way that you protect the elderly. Full stop.

Number 2, the reason why we distributed point-of-care tests to the nursing homes is because they are about 20 percent of the costs that they would incur as opposed to a laboratory test. The Binax test that we are distributing to all of those right now, 2 million this week, are at no cost to the nursing homes, and they come with automated reporting.

And finally, again I do defer to Seema about sending money, but I know \$5 billion was sent to nursing homes, of which \$2.5 billion was to support testing. That is the level of detail I know, but I am happy to bring anything back from her or from our Assistant Secretary for Finances to you, sir.

Senator MORAN. Admiral, I am using you as a conduit for purposes of expressing my concern and expressing my desire for a lot more information.

Admiral GIROIR. Yes, sir.

Senator MORAN. I would point out that every time that I have raised this issue—these issues with HHS, I talk about senior living, nursing home, and skilled nursing facilities, and every response, just as I think yours was, comes back to what we are doing for nursing homes. And again, I cannot determine if there is any plan to be helpful, which I think is necessary, for example, to senior living.

Admiral GIROIR. So I will bring that back, and we will take it for the record. I do want to let you know that the moment we had the Binax test, we are sending it to 5,000 assisted living centers

this week to support testing in an assisted living environment, not a nursing home environment. There are still 6,000 of those or even more that do not have a CLIA waiver that we need to work with, but we are going to work with them. You know, as soon as we get the technology, it is out the door to support our seniors.

Senator MORAN. Admiral, you caused me just to change my commentary slightly. So every time I raise this topic, now you mentioned two of the three topics, and I still would raise for you and for HHS senior living, which never seems to be a component of any conversation that I have had with—what few conversations I have been able to have with HHS.

Admiral GIROIR. Yes, sir.

Senator BLUNT. Thank you, Senator Moran.

Senator MORAN. My time has expired.

Senator BLUNT. Thank you.

I have got a couple of other questions and Senator Murray has another question or two.

FUNDING FLEXIBILITY

On the point that Senator Moran raised, what is going to happen at the Department is going to be an increasing reluctance by this committee to appropriate money and give the Department flexibility. You know, when we appropriate money for the provider fund, we expect that money to go to the provider fund, not to go to whatever other fund the Department think it is better spent. So in fact, when we appropriated the second \$75 billion to the provider fund, we absolutely prohibited spending that money any other way or some language close to that. And that is all because of the Department's actions. The appropriating committee appropriates, based on your request and responds to that request, in ways we think it is appropriate, and you cannot just decide to ignore that.

On the vaccine, Dr. Kadlec, we specifically did not appropriate to Warp Speed. We appropriated money to the partners, NIH and BARDA. My understanding is that at least \$16 billion has come through those agencies for the vaccine up until now. HHS has told us that to have 300 million copies of vaccine available, they need another \$20 billion that they do not have in any specifically appropriated line. Do you agree with that number?

Dr. KADLEC. Sir, based on the current situation, yes, sir, that seems to be the number.

Senator BLUNT. All right.

STATE VACCINATION PLANS

Dr. Redfield, the plans you expect to get back from the States by November 1 on distribution of the vaccine—do you think you will be ready shortly after that to announce your final distribution plan for vaccine?

Dr. REDFIELD. Senator, it is going to be dependent on the Advisory Committee of Immunization Practices, which will make the final recommendation for prioritization. We will—

VACCINE PRIORITIZATION

Senator BLUNT. I think I am asking another question. Maybe I did not ask it well. Prioritization—I want to talk about that too, but surely prioritization will not impact how you send this out to the States. It might impact the number they get, but in terms of the protection of the vaccine, the way it is distributed, to be sure that you have a plan to get this in response to all these State plans as soon as possible, is that your intention?

Dr. REDFIELD. Yes, sir. Obviously, the issue that I tried to mention earlier is that—and I have said this in our earlier testimony. Some people—it does not seem like they see this. Just as it was important—

Senator BLUNT. It is important. It is a second issue, but it is really important. And that was my next question.

Where are we on the prioritization? And that will be recommended to the States or will that be a prioritization we expect the States to comply with?

Dr. REDFIELD. Yes. It will be in a recommendation of the advisory committee for how this vaccine, whichever ones are approved, are recommended to be used.

Senator BLUNT. And when will that be available?

Dr. REDFIELD. That will be available after the committee gets to see the data on the particular vaccine.

But to answer your first question, because I think it was really important and I want to get to it, this plan for distribution is what we are now to get. And what I was trying to say is I said before this committee it is as important that we start that plan back in June as manufacturing. And right now, we have leveraged about \$600 million, but we do not have the resources to support 64 jurisdictions to get this plan operational. So to me it is an urgency, you know, that we get that. We have done this in the past. We have experience in what it is going to take for us to do distribution and monitoring safety and get the vaccines. As I mentioned, we distribute 80 million doses of vaccine a year at CDC. We have an idea. But this is going to take substantial resources, and like I suggested in June, the time is now for us to be able to get those resources out to the States, and we currently do not have those resources.

VACCINE DISTRIBUTION FUNDING

Senator BLUNT. The best I could tell, there were no resources provided in the HEROES Act in the House. In both the bill we voted on in the Senate and the bigger bill we proposed in the Senate, we had roughly \$6 billion for distribution. Is that the right number, or is that close to the right number?

Dr. REDFIELD. Senator, in my professional opinion, I think you have got that really nailed. Somewhere between \$5.5 million and \$6 million is what I think it is going to take to distribute this vaccine.

Senator BLUNT. And you do not have that money right now.

Dr. REDFIELD. No, sir.

Senator BLUNT. And you need it to distribute the vaccine.

Dr. REDFIELD. I think it is as urgent as getting these manufacturing facilities up.

Senator BLUNT. I think I said in July—and you agreed—that if you have the vaccine and do not have either the plan or the resources to distribute it, that is a huge failure on the part of the Congress to provide the resources that we know are going to be necessary. I hope it is a part of whatever package we put together this very month to be sure you have the capacity to do that.

Senator Murray.

Senator BLUNT. She may have gone to vote.

Senator MURRAY. Mr. Chairman, can you see me?

Senator BLUNT. There you are. I see you now.

Senator MURRAY. Well, thank you so much. I appreciate it, and I am just getting back to my desk here so hold on one second.

Thank you very much. I appreciate it.

PUBLIC HEALTH CAMPAIGN

Listen, I wanted to follow up on Senator Shaheen's question regarding HHS' \$250 million contract for public service advertisements to, quote, defeat despair and inspire hope amid the coronavirus pandemic.

Based on comments made by Michael Caputo, it looks like the administration intends to use a quarter of a billion dollars on a massive media campaign to mislead the public, to actually downplay the pandemic, and that is really unacceptable. Congress provided these funds to fight COVID-19, not to support any kind of campaign or reelection campaign.

Dr. Redfield, let me just ask you, can you clarify if CDC was tapped to provide that funding?

Dr. REDFIELD. Thank you, Senator.

CDC received the direction from HHS and OMB (Office of Management and Budget) to transfer \$300 million to HHS ASPA.

Senator MURRAY. What role has CDC played in the award process and developing that media campaign?

Dr. REDFIELD. We have not played a role. We were just, as I mentioned, instructed by HHS and OMB to transfer the funds to HHS ASPA.

Senator MURRAY. Well, then what role is CDC going to play in making sure the messages put out will include accurate public health information based on science?

Dr. REDFIELD. Again, Senator, at this moment, we have not been involved other than given the directive from HHS and OMB to transfer the funds.

Senator MURRAY. So funds only. You are not going to help them with information to make sure it is accurate?

Dr. REDFIELD. Well, again, I would assume that they would want our instruction to do all of that, but we have not been involved in this other than the extent that the funds were transferred to HHS ASPA. I assume that they are going to come back to the different subject-matter experts, but again, we have not been involved in that.

Senator MURRAY. Okay.

Dr. Giroir, what role are you going to play in making sure the media campaign will only be used to disseminate public health information based on science?

Admiral GIROIR. Thank you, Senator.

I have not been involved in any discussions. I have only been asked peripherally, which I think is the same campaign, to be subject to questions and to have a dialogue about public health issues. But I have not been involved in the development of the content, the same way that Dr. Redfield mentioned.

Senator MURRAY. Do you think it is your role, either of you, to weigh in to make sure this is accurate?

Admiral GIROIR. I certainly believe that the CDC Director has an important role in messaging, and I am the senior public health advisor to the Secretary. So we certainly would welcome the opportunity to help support the correct messages to the American people. I do not mean to speak for Bob.

Dr. REDFIELD. Again, I would echo that, you know, if given the opportunity, the CDC would obviously want to put forth the accurate messaging for the American public.

VACCINE DISTRIBUTION

Senator MURRAY. Well, finally, Dr. Redfield, public health groups have really raised the alarm that billions of dollars are needed for vaccine distribution and administration. CDC should be leading that effort, and I wanted to know what activities should be included in a distribution campaign and how you plan to make sure you are involved.

Dr. REDFIELD. Thank you very much, Senator.

I think it is critical. CDC does have the lead within Operation Warp Speed. Again, the playbook that we put out is in its version 1. It is going to go through, I am sure, iterations as the States get involved and help improve the plan. And so CDC is in the lead of working with the State and territorials to do this.

As I mentioned, since the last time—I think it was June—when you asked me and we really did not have funds, and we have been able to leverage about \$600 million to start some of the most critical activity. But as I mentioned to the chairman just a minute—now is the time. It is now. I mean, the rubber is hitting the road now to get these 64 jurisdictions up to speed. This is going to be a very resource-intensive distribution. We have never tried to distribute a vaccine that has a cold chain requirement like this one does, minus 80 degrees potentially for one of the vaccines. And so we are prepared. We did meet with five of the jurisdictions, North Dakota, California, Minnesota, Florida, and Philadelphia, to go down to micro-planning. So we got a pretty good idea. But now we are getting the plans for the rest of the 61 jurisdictions. And it really is going to require resources. These jurisdictions are not going to be able to put these plans in place without resources.

Admiral GIROIR. Senator Murray—

Senator MURRAY. Mr. Chairman, let me emphasize that response because as we just heard, one of these vaccines is going to require very cold storage. I think you said minus 60 or minus 80 degrees. Distribution across this country is going to be extremely challenging, and we need to make sure the resources are there and that it is planned at a national—has a national plan for distribution and that communities that do not actually have often access to healthcare really get access to this and the distribution and storage and all the things that go along with this is going to be very

complex, will require resources, and it, again, requires a national plan.

Senator BLUNT. Thank you, Senator Murray. I could not agree more. It is all about priorities, and this should be one of our top priorities at this moment.

Senator Moran for the last question.

Senator MORAN. Mr. Chairman, thank you for that courtesy. And I know the second vote has been called.

LABORATORY SCALE UP

So this question is for the admiral, and I think it should be brief, at least if I would start asking it. Admiral, we were alerted just recently about an HHS request for information that was posted. I think it was posted last week. It was soliciting interests from laboratories that could scale up with additional equipment from Thermo Fisher Scientific. Thermo Fisher is located in Kansas, and just recently they had an expansion to create more test tubes to do the test results.

Could you tell me what the ultimate plans are, assuming that you receive interest from these laboratories, and more specifically, what is the budget for this strategy? How many labs do you intend to support, and how much more testing will be accomplished?

Admiral GIROIR. So let me just say first it was an NIH solicitation, and we received information from about 27 universities that had interest.

Let me just say a top line piece particularly now is that there are certain types of assays like Hologic, like Roche, like Cepheid that are relatively flat, but there is a huge supply of other outstanding assays, of which Thermo Fisher has. They have a huge industrial capability. They have instruments. They have everything that goes with it, soup to nuts, a full Happy Meal, however you want to say it. So we are trying to encourage laboratories around the country, including universities, to use these because Thermo Fisher can make tens of millions of high quality laboratory-based assays.

We have supplied some of these to private laboratories like Sonic and Aegis, and we are trying to make sure that the universities use what they have, but also if they need help, we are happy to fund this. This is a relatively small amount of money to get them the capability to do assays. And Thermo Fisher has been really good to work with about really knocking down the prices, particularly for surveillance.

So it is really another way to try to get the message out. We talk of thousands of universities. But Thermo is just one of those assets that we have a lot of. It is an excellent test. It is a great company. We want people to use it.

Senator MORAN. And too early to tell whether there is a response, whether your outreach is having any effect?

Admiral GIROIR. Seriously, probably three times a week we match a major laboratory up with Thermo Fisher, getting their instruments together with their supplies. So it is absolutely having effect. Again, we have a lot of capability. We just want to make sure that people understand where the capabilities are, and Thermo is one of them.

Senator MORAN. Admiral, thank you for your work.

Senator BLUNT. Thank you, Senator Moran.

I think I am going to turn to Senator Alexander for a final question, but before I do that, we are going to go vote. And I want to thank all of you for being here. The country is depending on all three of you to lead in these critically important issues. As Dr. Redfield and one way or another all of you have said this—we are at a critical moment in testing and vaccines and therapeutics and distribution and prioritization. All these things need to come to as much of a conclusion as they can so we can move forward.

I think you have all been great witnesses today. There were questions that were asked that were outside of your area of responsibility, and of course, the proper answer to that is that is not what I am doing every day and that is totally fine. We are grateful for your time. I know this is a critical time for all of you, and I am grateful to you for having been here.

Senator Alexander will mention that the record will stay open for a week for additional questions, but we hope you will respond as quickly as possible to those questions. We are intensely involved in being your partner in this effort, but we need to know what we need to do so we can do it and do it in the right way.

Senator Alexander.

Senator ALEXANDER [presiding]. Thank you, Mr. Chairman. And thanks to Senator Blunt for being aggressive on all these issues and leading especially in the area of support for the maximum number of tests.

I do have some wrap-up questions.

VACCINE DISTRIBUTION

Dr. Redfield, I heard the questions that Senator Merkley asked you about whether there was some invidious scheme in asking the States to get ready to receive the vaccine, and you said no, that it had been recommended.

Am I remembering right that when we had a problem with a virus called H1N1 that the administration and the companies had a vaccine to distribute, but the States were not ready to receive it and that was a big problem. Is that right?

Dr. REDFIELD. Yes, Senator.

Senator ALEXANDER. When was that?

Dr. REDFIELD. 2009, 2010.

Senator ALEXANDER. And what happened.

Dr. REDFIELD. Well, I was not there, but we are very fortunate to have the gentleman that was part of that and had the opportunity to learn from all of the experiences now leading our distribution for this to ensure that we do not have the same hiccups. That is why I was stressing how important it is for us now to be able to operationalize this plan.

Senator ALEXANDER. Yes, more than a hiccup. I mean, it would be a tragedy if we had vaccines ready and available and we could not distribute them because no one had asked the States to be ready.

Now, I believe you said, Dr. Kadlec said—I believe you said that vaccines could be ready as early as November-December. Is that correct?

Dr. KADLEC. Yes, sir.

Senator ALEXANDER. And they would be ready in much larger volume most likely after the first of the year and then on into the second and third quarter. Correct?

Dr. KADLEC. Yes, sir.

Senator ALEXANDER. And how long does it take a State to get ready to manage the distribution of these vaccines and make sure they go properly to the right people with the right equipment at the right time?

Dr. KADLEC. I will defer to Dr. Redfield.

Dr. REDFIELD. Senator, I think this is why I have said it is urgent. I mean, when we say that the vaccine could be ready in November, you know, that is really 6 weeks away.

Senator ALEXANDER. Yes.

Dr. REDFIELD. So it is really urgent that we operationalize as rapidly as possible.

Senator ALEXANDER. What do you suppose this committee and many others would say to you if you had a vaccine ready in November and December and you had not asked the States to get ready to receive it?

Dr. REDFIELD. You would probably be recommending that I get replaced.

Senator ALEXANDER. I think so. I think so. So I think this criticism of you and the professionals at the CDC for asking States to get ready to receive the vaccine, when we know full well that it is likely to begin to be available in November and December, is very misplaced. And I appreciated your comments and the way you handled them.

COVID-19 TRANSMISSIBILITY

A dentist told me that there is no evidence, Dr. Redfield, of transmissibility of COVID-19 in a dentist office. Is that true?

Dr. REDFIELD. I would not necessarily have stated that. I think the dentist is probably going to say there has been no proven transmission in a dentist's office.

Senator ALEXANDER. So I was a little surprised by that. The dentist said that dentists have a history of handling infections all the time, all the way back to HIV, and so they are trained to do that and they know how to wear protective equipment and they know how to adopt practices.

Do you any of you know whether it is true that in other parts of the world and the United States, there have been problems with going to the dentist because of transmissibility of COVID?

Dr. REDFIELD. I would just come back to the statement I tried to make earlier. These masks work, and one thing you will know about when you go to a dentist, everyone is masked up. So I can say that we have not had evidence—outbreaks that we have linked back to dentists. I am not going to say it will never happen. But just like we reported recently, two hair salon people that were highly infected—they went and did their work to do, I think, over 150 people, but they wore masks. And there was no evidence of transmission. So I keep coming back to the importance of wearing masks.

Senator ALEXANDER. And I have one last question, and I understand Senator Murray would like to make a closing statement or question. So I will go to her when I finish.

ASYMPTOMATIC TESTING

I want to go back to the CDC guidance on asymptomatic testing, which you acknowledged has created confusion. And I wonder what else you might be able to do to eliminate that confusion. And let me tell you why I think it is important.

My feeling all along has been that it was a good idea to produce tens of millions of rapid tests so that anybody who wanted a test could get one basically. Now, from a medical point of view, there is no reason to do that. But that is not the only concern we have in the United States right now. I mean, we would like to go back to school. We would like to go back to college. We would like to go back to child care. We would like to go back to work. We would like to go out to eat. And if by frequent testing or surveillance testing or any of a whole number of strategies that test a lot of people who do not have symptoms, we build confidence that your school is a safe place, your college campus is a safe place, that your child care center is a safe place, that your workplace is safe, that your restaurant is safe. If we build confidence, we will have better lives.

And so it seems to me, particularly since Admiral Giroir has said that we are now heading toward a situation where we may have 120 million, 150 million tests a month, we are going to have plenty of tests. We are going to have capacity for plenty of tests. And by frequent tests, I mean what if a school wanted to test every student at the beginning of school or at the beginning of a week for 2 or 3 weeks just to make sure that there was not some spreading and wanted to create a regime where you do random testing—surveillance testing is I think a word for it—of the kind of testing—when you go through the airport, for example, they pull you out of line every now and then and check to see if you have got explosives on your hands. That makes us feel better when we get on an airplane that we are not going to blow up. And so people fly, 2 million a day, without worrying too much about getting blown up by passengers with explosives on their hands.

The University of Illinois, as one of you have mentioned, is I think testing twice a week. I think the University of Illinois must have 40,000–50,000 students and faculty members and staff on that campus. I know the President of Brown said she wanted to test everybody before they came back. I can imagine in a workplace that somebody would worry about working next to somebody who is infected and worry they might have—just be afraid that they might have COVID, and would it not be a good idea for the manager to say come in here and take a 15-minute test and you do not have it today? That is all that means. Or you could say to all your employees we give you tests if you are symptomatic, but we also give random tests on a regular basis throughout the plant so you can have more confidence when you come back to work.

So it seems to me that it is a good thing for our country to have more tests than we need, more rapid tests than we need so that anyone who wants a test can get one if they feel it is necessary.

Now, I think once they know that they can, they will not want one. And I think that is one reason we are seeing a lower demand in other parts of the country because people understand the limited value of a diagnostic test. It just tells you on that one day whether you have it.

But this is a little bit of a long question, but what I am trying to get around to, is there some way that the CDC could clear up whatever confusion has been caused and make it clear that since we now have such a large supply of tests, that different strategies for testing people without symptoms is a perfectly good idea and does not take tests away from healthcare professionals or people in nursing homes or assisted living or people like that? That clearly would help I think, as we move into October, November, and December, to encourage people to use this growing number especially of rapid tests that we have to build confidence that the school, the college, the child care center, the workplace, and the restaurant are safe places to go regularly check, and that would help us restore our economy. What could you do about clearing up the confusion?

Dr. REDFIELD. Yes. I appreciate the comment, Senator.

First—there are three areas here, but I will be very brief.

First is we are working on a clarification document related to the diagnostic and public health use of testing. And again, we have never recommended against asymptomatic testing. You will see in the clarification it is very clear that we make it very clear that asymptomatic and pre-symptomatic transmission is important. We make it very clear that if you have been exposed to somebody, you need to be tested and contact traced. So that is going to come out hopefully—you know, I have done my clarification statement 24 hours after, but it did not solve the problem. So we are going to come out with that hopefully sometime in the next—I hope before the end of the week.

Secondly—and the Admiral may want to comment—we are working on guidance because in addition diagnosis—public health, as you pointed out there is screening. And screening can be very powerful for maybe non-public health reasons, maybe getting us back to life and screening in schools, K through 12, screening in universities, screening in business. So you will see that CDC will be coming out, in conjunction with the Admiral—we will be coming out with some guidance around screening.

Then there is the other word that you used, which we also believe is really important, which is surveillance where you can actually systematically begin to look at random individuals to get an idea is this outbreak starting to pop into a new community.

So all three of those are important. All three of those you are going to see that we are developing follow-up guidance for. It really was not possible to really have a lot of that guidance when there was no test.

Senator ALEXANDER. Right.

Dr. REDFIELD. But as you point out, Admiral Giroir has really done a yeoman's job with the private sector and really has gotten to the point now so that we have—we are going to try to clarify the clinical public health use. We are going to try to give guidance to screening particularly in K through 12s and universities, but it is also going to have a role in businesses and also in entertainment

activity like sports. And then there is the other side of how to set up systematic surveillance so that we do not get blindsided by all of a sudden finding that there was a huge, new outbreak that we just did not have eyes on until it got too big.

But, Admiral, do you want to—

Senator ALEXANDER. Admiral, do you want to add to that?

Admiral GIROIR. I just agree 100 percent with everything that has been said. We are going to continue to invest in a number of different types of platforms, but clearly low-cost, ultra-available, sensitive and specific tests like the BinaxNOW—and there are going to be more like that coming through. And again, we are going to increase that supply as much as possible. There also are going to be some new point-of-care tests that are actually very sophisticated and very sensitive and specific that could be layered on top of the Binax. And our goal is to provide as many tools as possible in the right domain so we could implement this type of guidance.

Again, in March, it does not make sense to talk about random screening of children going to school because you did not have that available. Now that we have a very robust ecosystem of testing, this is the exact right time, which is why we purchased 150 million of those card-based tests while we have point-of-care and distributing them first to protect the vulnerable, but then within a couple weeks, they are going out to States to support school reopening and other infrastructure according to their priorities. We are at that point.

DISTRIBUTION OF TESTS

Senator ALEXANDER. Now, how many will be going out to States in a couple of weeks? Could you give me a rough idea?

Admiral GIROIR. So when Binax—when Abbott gets to their full production capability, about 12 million per week, which will be within a few weeks, we anticipate, depending on how things go with the nursing homes, et cetera, somewhere between 5 million to 8 million per week going to States that we could provide them for those needs. Again, if the cases continue to go down in nursing homes, we will need less and less tests to protect the nursing homes. If it stays high—

Senator ALEXANDER. So that is 5 million to 8 million a week?

Admiral GIROIR. Yes, sir.

Senator ALEXANDER. Well, 5 million to 8 million a week—Tennessee is usually about 2 percent of everything. So that would mean a State like Tennessee would be getting a few hundred thousand tests a week or several hundred thousand tests a month at least that the State could distribute according to its priorities. Is that the general idea after you have—with that 5 million to 8 million?

Admiral GIROIR. Yes, sir. There is some policy discussion. We certainly want to support the States but we think it is a priority, as I know you do, to open education, K through 12, even pre-school and potentially universities. But I think universities are in a different class because they have resources. So we do want to emphasize very strongly the protection of teachers and the reopening of K through 12 as a significant priority.

Senator ALEXANDER. Well, I certainly do too. But some States are doing some things; some States are doing others. I think it is a good idea to reserve some of—first, I congratulate the administration on buying the full 3 months' supply of that which is, as I understand it, about 50 million tests a month starting in October, with several million this month, and then assigning it to the priorities like nursing homes, et cetera, and then giving a lot to States, which would be—I mean, if the State of Tennessee got 200,000 tests a week that it knew it could distribute during the rest of this school semester, my guess is many of them would go to schools because the ones who are most worried about that are not the kids, it is the teachers and the parents and the grandparents when the kids go home. So I think that is a tremendously reassuring prospect that a State might receive that many rapid tests just from that source.

And, Dr. Redfield—and we will conclude with this because I think Senator Murray does not want to say anything now. But one time, you and I had a discussion about a guidance that used examples. I think we talked about colleges, and I think you did that. And maybe one way to help clarify the use of tests for asymptomatic individuals would be to list five, six, eight, ten examples of schools, colleges, workplaces that are doing that now. That makes sense whether—and I will let you decide what those might be, and it would not be only those things. But I think if you said these are all the kinds of ways that this large number of tests that we have may be used effectively and sensibly to build confidence in going back to school, work, child care, and out to eat. That might be easier for people to read and understand than the words in a guidance. So the use of examples is a suggestion I would make.

Dr. REDFIELD. I appreciate your advice, sir.

Senator ALEXANDER. Thanks to the three of you. As Senator Blunt said, we are grateful to you for your long hours, for your effective work, for your planning. And if the money that this appropriations subcommittee has targeted for you is not forthcoming in the way the Congress intended for it to be, we expect you to let Senator Blunt, Senator Murray, and others of us on the subcommittee know that.

ADDITIONAL COMMITTEE QUESTIONS

The record will stay open for 1 week.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED TO ADMIRAL BRETT GIROIR, M.D.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

VACCINE DISTRIBUTION

Question. Which agency is lead for managing the vaccine distribution plan?

Answer. Operation Warp Speed (OWS) is a joint effort that utilizes a whole-of-America approach that leverages the expertise and experience of the Department of Health and Human Services (HHS) and the Department of Defense. As the vaccine manufacturing process continues, the focus of OWS moves to supporting the Centers for Disease Control and Prevention (CDC) in planning and execution of the distribu-

tion and administration of any Food and Drug Administration (FDA) approved or authorized COVID-19 vaccine.

CDC has successfully utilized both public and private infrastructure to deliver vaccines in the past, and the current planning efforts within the CDC jurisdictional framework builds upon the existing CDC structure in the distribution of COVID-19 vaccines. As the distribution of these crucial life-saving vaccines begins, CDC will execute the distribution plan.

Question. What assumptions is HHS making about the quantity of vaccine that will be distributed in November and December?

Answer. Biological science is an unpredictable art, and the process of developing an FDA licensed or authorized vaccine can involve unanticipated issues. The highest standards of science drive the decisions being made regarding these vaccines; this process results in an imprecise timeline for vaccine approval. Currently, there are four vaccine candidates in Phase III clinical trials and two additional candidates approaching this critical milestone. All six of these vaccine candidates are in the process of being manufactured at-scale.

Based on the data from these clinical trials, a vaccine manufacturer will submit to FDA either a request for an Emergency Use Authorization (EUA) or a Biologics License Application (BLA). After authorization or licensure of a candidate vaccine, demand will most likely outweigh supply, necessitating allocation of the limited number of initially available doses. A prioritization policy will be informed by the National Academies of Sciences, Engineering, and Medicine (NASEM), and a formal recommendation by the independent Advisory Committee on Immunization Practices (ACIP) that has been adopted by the CDC Director.

REAGENT SUPPLY

Question. We have seen, firsthand, during the COVID-19 pandemic supply shortages affecting the ability to do wide scale testing. In particular, I'm concerned with the upcoming flu season we may continue to experience strain on the supply chain for raw materials. Can you discuss the importance of these raw materials if we need to ramp up testing and what we are doing to address another sharp spike in demand?

Answer. To enable States to achieve the testing goals developed in coordination with the Federal Government, the Federal Government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The Federal Government then provided all information to States so they could better determine how to optimize their testing strategy. States, including the District of Columbia, selected large cities and territories have now submitted two iterations of their testing plans. These plans were developed in collaboration with Federal multidisciplinary experts through teleconferences and other meetings. Plans were reviewed by a multidisciplinary Federal team that included leadership from CDC, the Immediate Office of the Secretary, and the Office of the Assistant Secretary for Health. To ensure that jurisdictions meet their testing goals, the Federal Government procured swabs and transport media, and is distributing these supplies to a single location in each State determined by the Governor or Mayor's office. Starting in May and through September 11, the Federal Government has distributed over 95 million swabs and more than 77 million tubes of transport media. These supplies were provided to jurisdictions over the course of each month to equip them with sufficient materials to meet their specific testing goals.

To further secure and galvanize the testing supply chain in the United States, the Federal Government used the Defense Production Act (DPA). One example of leveraging the DPA to increase the production of supplies was the investment in Puritan Medical Products. After in-depth market research on testing availability and producibility, the Federal Government applied DPA title III authorities to award a \$75.5 million contract to Puritan Medical Products to increase foam specimen collection swab manufacturing capacity by 20 million swabs per month. An additional swab requirement was identified for both COVID-19 and influenza specimen collection; a second expansion investment of \$51.15 million CARES Act funds in Puritan (the only U.S. based manufacturer of flock tip swabs) to produce an additional 45 million flock tip swabs per month. HHS is leveraging all authorities, including DPA title III, to acquire additional testing capability. HHS has exercised title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the place of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventila-

tors, are in high demand. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed.

Because the Federal Government has equipped jurisdictions with the materials they need to meet or exceed their State testing plans each month, the United States has conducted over 125 million COVID-19 tests and capacity continues to increase. Since early March, we have increased our daily testing by over 30,000 percent. These efforts and the increased availability of point of care testing will ensure the United States will be equipped to conduct the amount of testing needed during flu season and if there is a spike in cases.

The supply chain for raw components and consumables, the manufacturing capacity to produce diagnostic tests, and, in many cases, the instrument systems needed to perform the tests are to a great extent common for both SARS-CoV-2 and Influenza testing. Because existing manufacturing capacity is operating at maximum for SARS-CoV-2 response, influenza testing with a separate test would reduce available COVID-19 testing capacity. Foreseeing this issue, ASPR/BARDA, CDC, and industry began work in the summer to develop multiplexed tests that test for both SARS-CoV-2 and influenza simultaneously in one testing action. Though there are a small additional amount of reagents needed for these multiplexed tests, the majority of the components that are in short supply (e.g. swabs, plastic consumables, pipette tips, etc.) can be used for both tests and no additional supply is needed. These multiplexed tests can also be performed in the same amount of time as one single test so no testing capacity negative impact either. Three multiplex tests ASPR/BARDA has funded have received emergency use authorization (EUA) so far, CDC has developed and received an EUA for a multiplexed test for public health lab use, and industry has developed and received EUAs for an additional three multiplexed tests so far in preparation for influenza season. More multiplexed tests are in development.

Question. Admiral Giroir and Dr. Redfield, we all hope and expect that the U.S. will develop a safe and effective COVID-19 vaccine first. When that happens, what is our strategy for deploying this vaccine internationally and how is its coordination being implemented? What discussions have you had with other countries or international organizations about the plan to ensure that a vaccine is distributed to more countries than those that can produce them or afford to buy them?

Answer. CDC is building on its longstanding global immunization efforts focused on polio, measles, influenza, and other priorities, and is planning to use CARES Act funding to provide technical assistance and help ensure select low- and middle-income countries are ready and able to deploy and evaluate COVID-19 vaccines when they become available. Through CDC country offices around the world, and through headquarters-based subject matter experts, CDC is beginning to engage international organizations and select low- and middle-income partner countries to support these efforts.

The COVID-19 pandemic has demonstrated once again that infectious diseases do not respect borders and threaten local, regional, and global economies. Recognizing the critical role that medical countermeasures play in controlling and ending a public health emergency, especially in a pandemic, the U.S. Government remains committed to working closely with partners overseas to mitigate the impact of this devastating pandemic.

Question. Admiral Giroir, even though the Chinese have not yet developed a safe and effective coronavirus vaccine, they have already started a so-called charm offensive to provide access to a Chinese vaccine to pro-Chinese nations as well as using it to repair damaged diplomatic ties with other nations. What steps are we taking to counter China's aggressive COVID-diplomacy? And how is the Department working with USAID and the State Department on the international response?

Answer. HHS is working with other countries in the Indo-Pacific and around the world to communicate U.S. values and to highlight successful COVID-19 responses among friendly nations. Most significantly, in August, Secretary Azar became the highest ranking Cabinet Secretary to travel to Taiwan since the U.S. established diplomatic relations with the People's Republic of China in 1979. His trip emphasized U.S. support for Taiwan's role as a leader in COVID-19 response, as evidenced by their transparent and highly effective evidence based COVID-19 response and Taiwan's ability to access a COVID-19 vaccine when a safe and effective vaccine becomes available. HHS also has been working through regional bodies in Asia to support other like-minded country responses and to counter Chinese narratives that falsely assert their leadership in the global response to COVID-19. Misinformation and disinformation have been serious problems throughout the pandemic, especially regarding the development of COVID-19 vaccine candidates. The urgent need exists to address and manage COVID-19 misinformation and disinformation, and to continuously dispel myths and re-assert facts with evidence.

PROVIDER RELIEF FUND

Question. Admiral Giroir, by my count, HHS has yet to announce how \$52 billion of the Provider Relief Fund will be allocated. Hospitals need funding now. Can you outline how and when you think the remaining resources will be distributed to providers?

I am concerned that HHS is holding back the Provider Relief funding because you may be planning to transfer it to another account. Should I be concerned?

Answer. From the very start of this pandemic, HHS has led a whole-of-government, whole-of-America approach to defeating the virus. A critical part of that work includes ensuring that our healthcare system remains strong and financially viable during this unprecedented time. HHS is distributing \$175 billion to hospitals and healthcare providers on the front lines of the COVID-19 response via the Provider Relief Fund (www.hhs.gov/providerrelief).

HHS acted quickly to distribute the Phase 1 General Distribution payments on a rolling basis beginning on April 10, 2020. These payments were made to providers who billed Medicare on a fee-for-service basis (Parts A or B) in Calendar Year 2019. For example, as of September 14, 2020, HHS has made 16,472 payments totaling more than \$2.1 billion to healthcare providers in Pennsylvania.

In June, HHS began making General Distribution payments to Medicaid and Children's Health Insurance Program providers, dentists, and assisted living facilities. HHS further expanded this Phase 2 General Distribution to Medicare providers that have not received a full payment, including Medicare Part A providers who experienced a change of ownership in 2019 or 2020 that was approved by the Centers for Medicare & Medicaid Services as of August 10, 2020. Phase 2 payments are made on a rolling basis to providers based on approximately 2 percent of a provider's annual revenue from patient care. As of September 14, 2020, HRSA has distributed more than \$104 million to 2,191 providers in Pennsylvania as part of this distribution.

On October 1, HHS announced \$20 billion for another General Distribution allocation of the Provider Relief Fund. For this Phase 3 funding, applicants that have not yet received payments of 2 percent of patient revenue will receive a payment that, when combined with prior payments (if any), equals 2 percent of patient revenue. Phase 3 payments will also consider changes in patient care revenues and increased expenses incurred related to the coronavirus. Providers will have from October 5, 2020 through November 6, 2020 to apply for Phase 3 General Distribution funding.

Question. Beyond the General Distributions, HHS made several Targeted Distributions to facilities and geographic areas that have been particularly susceptible to lost revenue or increased healthcare expenses as a result of the pandemic. Admiral Giroir, Congress appropriated \$175 billion for the Provider Relief Fund to make sure our healthcare providers keep their doors open as coronavirus continues to change how frequently patients go to their doctors. I want to acknowledge the challenges the Department has faced in executing these funds and the effort made to get funds to those who need it. At the same time, I hear from many different providers, particularly behavioral health providers, that they continue to have challenges accessing funds. What more can HHS do to make sure all providers are being treated equally and that providers that focus on mental health services are not overlooked?

Answer. In the Phase 3 General Distribution, an expanded group of behavioral health and other providers will be eligible for relief payments. While behavioral health providers who participate in Medicare, Medicaid, and Children's Health Insurance Program (CHIP) have had the opportunity to apply for prior General Distribution payments, others have not. Working with the Substance Abuse and Mental Health Services Administration (SAMHSA), HRSA developed a list of the nation's behavioral health providers now eligible for funding, which includes, for example, addiction counseling centers, mental health counselors, and psychiatrists.

Phase 3 will take into account documentation of the financial impact of COVID-19 by assessing a provider's change in operating revenues and expenses. The Phase 3 payment methodology also ensures providers have received 2 percent of annual revenue from patient care.

Question. I applaud the Department's release of a comprehensive Rural Action Plan earlier this month. It is important to note the significant challenges rural communities face with regard to the healthcare infrastructure and that nearly 1 in 5 Americans live in a rural community. COVID-19 is only exacerbating the challenges facing rural healthcare providers. Can you speak to the targeted distribution of provider relief funds to rural communities and any ongoing gaps in funding to rural healthcare providers? HHS has targeted \$11 billion to rural healthcare providers

that is less than 10 percent of the Provider Relief Fund. Can we anticipate another tranche of funding to rural communities specifically and when would this occur?

Answer. HHS identified 4,460 organizations that were eligible for the Rural Targeted Distribution. These organizations operate 11,640 healthcare delivery sites including 2,374 rural hospitals and critical access hospitals, 383 hospitals in small metro areas or with Medicare special payment designations, 4,655 Rural Health Clinics, and 4,228 Community Health Center sites in rural areas.

Rural providers were also eligible for other General and Targeted Distributions. As of November 17, 2020, providers located in rural and frontier areas received approximately \$21 billion across all Provider Relief Fund distributions.

At this point, HHS does not anticipate an additional Targeted Distribution for rural communities. Providers in rural areas are eligible to apply for Phase 3 General Distribution payments.

TESTING

Question. The Paycheck Protection Program and Health Care Enhancement Act included over \$8 billion to give flexibility to the Administration to address future testing needs. How much of that funding remains unspent? What is the plan and timing for allocation of those resources? Why is HHS not spending this funding when we know that testing is still in short supply across the country?

Answer. The testing infrastructure in the United States has been galvanized and has reached unprecedented levels. The U.S. has conducted over 125 million tests, at an average current rate of about 1 million tests per day, with enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. Turnaround time in providing test results continues to improve. Currently, in the cases of 97 percent of tests that were performed by American Clinical Laboratory Association laboratories and that were ordered in the previous week, the individuals received results within 3 days, and 99 percent received results within 5 days. In June, July, and August, States far surpassed their goals for testing. Specifically, State goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, States far exceeded their goals by conducting over 25 million tests. In August the nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. The United States continues to conduct testing at a large scale and as more point of care tests are developed and become available, the testing capacity will continue to increase HHS continues to leverage funds to support, grow, and drive the testing infrastructure in the United States.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Admiral Giroir, I want to commend you for your efforts in supporting the manufacturing of vaccine candidates to ensure a sufficient supply upon approval. I believe a safe and effective vaccine is the pathway for America's return to normal daily life. But there are still people that are vulnerable to the virus who become infected and could greatly benefit from a treatment. I think vaccines and therapeutics can both be a priority. I understand that there are some therapeutic candidates currently undergoing stage III clinical trials that have shown promising results. Why is OWS not funding the manufacturing of promising therapeutic candidates to prepare for the winter season?

Answer. BARDA, in conjunction with OWS, has a strong ongoing effort to support development of many therapeutic candidates. OWS and BARDA are supporting platform clinical trials under the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public private partnership, which was announced in April 2020 by the National Institutes of Health (NIH), and is being coordinated by the Foundation for NIH. The five platform trials (ACTIV 1 through 5) allow for testing multiple therapeutics in the same trial. This is the most efficient use of funding and clinical resources, which have been stretched thin throughout the pandemic response.

Individual funding awards to companies for research and development have focused on candidate therapeutics with the highest likelihood of success, such as the monoclonal antibody therapeutics that are being developed using platform technologies that were established for other pathogens like influenza and Ebola.

Additionally, the antibody testing and collection of convalescent plasma has been a pillar of the OWS therapeutic response. While we are still investing in randomized, controlled clinical trials to study the safety and effectiveness of this investigational product, which was issued an EUA, we are encouraged by the early results from the expanded access protocol. The therapeutic portfolio will continue to evolve in the coming weeks as results from clinical trials become available.

Lastly, OWS provided PPE and COVID-19 test capabilities critical to the clinical teams executing therapeutics trials and staffed a logistics support element dedicated solely to the advancement of the therapeutics effort's clinical trial needs. That team is posturing to deliver trial-site expansion capabilities to prospective test locations to advance and accelerate their programs' subject enrollment.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

UNSPENT TESTING FUNDS

Question. Admiral Giroir, 5 months ago Congress appropriated \$25 billion to expand COVID-19 testing capacity through the Paycheck Protection Program and Health Care Enhancement Act. To date, the Department has yet to spend approximately \$12 billion of this funding. HHS' spend plans submitted to this committee outline comprehensive testing-related activities focused on procurement and distribution, POC diagnostics, serological testing, community based testing, and building future capacity all from a large \$8.3 billion flexible pot of funding that was provided to the Department.

How much of the \$8.3 billion in "other activities" funding provided to HHS under the Public Health and Social Services Emergency Fund through the Paycheck Protection Program and Health Care Enhancement Act have been obligated?

Why, as States across the country grapple with trying to get this virus under control, has HHS not spent more of these resources to build up our testing capacity?

To date, none of the \$1 billion provided for testing for the uninsured has been obligated. Please explain why these funds continue to languish in Federal coffers.

Answer. The testing infrastructure in the United States has been galvanized and has reached unprecedented levels. The U.S. has conducted over 125 million tests, at an average current rate of about 1 million tests per day, with enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. Turnaround time in providing test results continues to improve. Currently, in the cases of 97 percent of tests that were performed by American Clinical Laboratory Association laboratories and that were ordered in the previous week, the individuals received results within 3 days, and 99 percent received results within 5 days. In June, July, and August, States far surpassed their goals for testing. Specifically, State goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, States far exceeded their goals by conducting over 25 million tests. In August the nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. The United States continues to conduct testing at a large scale and as more point of care tests are developed and become available, the testing capacity will continue to increase.

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

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

EXPEDITING ALLOCATION OF COVID-19 TESTING FUNDING

Question. Continued expansion of testing capacity and improved contact tracing will be critically important to our effort to mitigate the spread of COVID-19 this fall. That's why I'm concerned with the slow pace at which HHS is distributing the \$25 billion that Congress provided in COVID-19 testing funding. It's been almost 5 months, and to date, HHS has only allocated about half of the money.

Dr. Giroir, when will HHS distribute the rest of the testing dollars?

Answer. As new technologies and opportunities arise, HHS will allocate funds based on the needs of the United States and based on the current data on the pandemic and the options available. The testing infrastructure in the United States has been galvanized and has reached unprecedented levels. The U.S. has conducted over 125 million tests, at an average current rate of about 1 million tests per day, with

enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. Why have daily testing numbers declined between the summer and September?

Answer. As of October 13, 2020 the 7 day average for COVID-19 tests has exceeded 1 million tests, and continues to grow. Since early March, we have increased our daily testing by over 30,000 percent. Daily testing numbers continue to increase and the turnaround times are continuing to improve as well. The United States has conducted over 125 million COVID-19 and with the investments made by the Federal Government, the success in galvanizing the testing infrastructure in the United States, and the introduction of new technologies, testing numbers will continue to increase.

Question. At the hearing, Admiral Giroir stated that supply chain issues have not played a role in declines in the number of new tests, yet this is not consistent with the experience of labs in Hawaii, which recently faced significant supply chain shortages of pipette tips and test kits that meant they could not maximize their testing capacity. In addition, a recent survey found that 67 percent of labs surveyed reported issues getting test kits and reagents and that shortages had recently become worse.¹ Why did Admiral Giroir state that there are no supply chain issues?

Answer. To enable States to achieve the testing goals developed in coordination with the Federal government, the Federal government has worked with manufacturers to gain insight into diagnostic instrument install bases; procured and shipped collection supplies; and determined reagent inventory. The Federal Government then provided all information to States so they could better determine how to optimize their testing strategy. States and territories have now submitted two iterations of their testing plans. These plans were developed in collaboration with Federal multidisciplinary experts through teleconferences and other meetings. Plans were reviewed by a multidisciplinary Federal team that included leadership from CDC, the Immediate Office of the Secretary, and the Office of the Assistant Secretary for Health. To ensure States meet their testing goals, the Federal Government procured swabs and transport media, and is distributing these supplies to a single location in each State determined by the Governor's office. Starting in May and through September 11, the Federal Government has distributed over 95 million swabs and more than 77 million tubes of transport media. These supplies are provided to States throughout the month to equip them with sufficient materials to meet their specific testing goals.

To further secure and galvanize the testing supply chain in the United States, the Federal Government has utilized the Defense Production Act. One example of leveraging the DPA to increase the production of supplies was the investment in Puritan Medical Products. After in-depth market research on testing availability and producibility, the Federal Government applied DPA title III authorities to award a \$75.5 million contract to Puritan Medical Products to increase foam specimen collection swab manufacturing capacity by 20 million swabs per month. An additional swab requirement was identified for both COVID-19 and flu specimen collection; a second expansion investment of \$51.15 million CARES Act funds in Puritan (the only U.S. based manufacturer of flock tip swabs) to produce an additional 45 million flock tip swabs per month. HHS is leveraging all authorities, including DPA title III, to acquire additional testing capability. HHS has exercised title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the place of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventilators, are in high demand. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed.

Because the Federal Government has equipped States with the materials they need to meet or exceed their State testing plans each month, the United States has conducted over 125 million COVID-19 tests and capacity continues to increase. Since early March, we have increased our daily testing by over 30,000 percent. Turnaround time in providing test results continues to improve. Currently, in the cases of 97 percent of tests that were performed by American Clinical Laboratory Association laboratories and that were ordered in the previous week, the individuals

¹ <https://www.wsj.com/articles/covid-19-testing-is-hampered-by-shortages-of-critical-ingredient-11600772400>.

received results within 3 days, and 99 percent received results within 5 days. These efforts and the increased availability of point of care testing will ensure the United States will be equipped to conduct the amount of testing needed during flu season and if there is a spike in cases.

Question. Has the administration taken every step possible to ramp up manufacturing of tests, including utilizing the Defense Production Act to the fullest extent? Has the DPA been used to increase manufacturing of pipette tips?

Answer. One example of leveraging the DPA to increase the production of supplies was the investment in Puritan Medical Products. After in-depth market research on testing availability and producibility, the Federal Government applied DPA title III authorities to award a \$75.5 million contract to Puritan Medical Products to increase foam specimen collection swab manufacturing capacity by 20 million swabs per month. An additional swab requirement was identified for both COVID-19 and flu specimen collection; a second expansion investment of \$51.15 million CARES Act funds in Puritan (the ONLY U.S. based manufacturer of flock tip swabs) to produce an additional 45 million flock tip swabs per month. HHS is leveraging all authorities, including DPA title III, to acquire additional testing capability. HHS has exercised title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the place of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventilators, are in high demand. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed.

Information in regards to the use of the DPA as it relates to testing and related materials can be found in the numerous National Testing Strategy Reports to Congress that have been submitted.

Question. Why has HHS failed to obligate almost half of the \$25 billion in funding that Congress appropriated for testing? When does HHS plan to spend those funds?

Answer. The testing infrastructure in the United States has been galvanized and has reached unprecedented levels. The U.S. has conducted over 125 million tests, at an average current rate of about 1 million tests per day, with enough tests in the market to perform three to four times that amount. Since early March, we have increased our daily testing by over 30,000 percent. Turnaround time in providing test results continues to improve. Currently, in the cases of 97 percent of tests that were performed by American Clinical Laboratory Association laboratories and that were ordered in the previous week, the individuals received results within 3 days, and 99 percent received results within 5 days. In June, July, and August, States far surpassed their goals for testing. Specifically, State goals for June were 12.9 million tests, and nearly 16 million were actually performed. The goals for July were 13.7 million tests; again, States far exceeded their goals by conducting over 25 million tests. In August the nation completed over 25.2 million tests, far exceeding the August goal of 21.1 million tests. The United States continues to conduct testing at a large scale and as more point of care tests are developed and become available, the testing capacity will continue to increase.

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

To further secure and galvanize the testing supply chain in the United States, the Federal Government has utilized the Defense Production Act. One example of leveraging the DPA to increase the production of supplies was the investment in Puritan Medical Products. After in-depth market research on testing availability and producibility, the Federal Government applied DPA Title III authorities to award a \$75.5 million contract to Puritan Medical Products to increase foam specimen collection swab manufacturing capacity by 20 million swabs per month. An additional swab requirement was identified for both COVID-19 and flu specimen collection; a second expansion investment of \$51.15 million CARES Act funds in Puritan (the only U.S. based manufacturer of flock tip swabs) to produce an additional 45 million flock tip swabs per month. HHS is leveraging all authorities, including DPA title III, to acquire additional testing capability.

HHS is utilizing funds based on available technologies, data and the needs across the country. We will continue to ensure that the testing infrastructure throughout the country is supported and grows.

Question. Why hasn't HHS developed a national testing plan, which States and public health experts have pleaded for?

Answer. HHS and the Federal Government have released numerous documents enumerating and laying out the national testing plan. The administration released the Opening Up America Again Guidelines: Testing Overview on April 27, 2020 and on that same day the Opening America Again Guidelines: Testing Blueprint was released. These documents outline the test strategy early on in the pandemic and several documents have followed that provided further detail. On June 15, 2020 the Addendum to the Testing Blueprint was released which provided more details to the national testing strategy. Furthermore, HHS submitted on May 24, 2020 the COVID-19 Strategic Testing Plan Report to Congress, this 84 page document clearly lays out and provides information about the national testing plan. On August 22, 2020 the first update to the COVID-19 Strategic Testing Plan Report to Congress was submitted. This first update to the report was 142 pages of information about the national testing plan. On November 20, 2020 the second update to the COVID-19 Strategic Testing Plan Report to Congress was submitted. This second update was 22 pages of additional information in regards to the national testing plan. All of these documents have been made widely available to Congress, States, and the American people.

The CDC has also released many testing related guidance documents and technical assistance that further provide States and public health experts with information on how to implement testing in a variety of settings.

Question. How is it effective for States, cities, schools, and other institutions to compete against each other and individually manage testing resources?

Answer. To ensure States meet their testing goals, the Federal Government procured swabs and transport media, and is distributing these supplies to a single location in each State determined by the Governor's office. Starting in May and through September 11, the Federal Government has distributed over 95 million swabs and more than 77 million tubes of transport media. These supplies are provided to States throughout the month to equip them with sufficient materials to meet their specific testing goals and many States have continued to exceed their testing goals each month. Equipping States with the materials they need to meet or exceed their testing goals has reduced competition for supplies and for the governors of each State to determine how best to meet the needs of their State. Also, as stated before, there are currently more tests in the market place to test three to four times the amount typically tested each day.

On August 27, 2020, the Administration announced that a \$760 million contract was awarded to Abbott for the delivery of 150 million rapid BinaxNOW COVID-19 Ag Card point-of-care tests. HHS will distribute approximately 100 million tests to States and territories through the end of December 2020, distributed by proportion of their population. Governors will determine the best use of tests for their States; suggested deployment includes use cases for which a low-cost, rapid, easily administered test is uniquely able to fill State needs, such as opening of K-through-12 schools through testing of teachers, staff, and students, protecting first responders, supporting critical infrastructure, enhancing higher education programs, and other priorities the governors deem fit. Overall, we have distributed over 58 million BinaxNOW tests to date.

Question. What is HHS' exact role in the allocation and distribution of diagnostic tests and testing supplies from private companies to labs across the country?

Does HHS instruct diagnostic and medical supply companies how to allocate test kits and testing instruments? How are these decisions made?

What improvements should HHS make in its testing distribution process?

Answer. HHS has exercised title I DPA authorities using the Health Resource Priority and Allocations System (HRPAS) in order to prioritize contract action to compel a direct response to the place of greatest need. A number of health resource materials have been identified that are essential to respond to the COVID-19 pandemic; however, these items, like PPE and ventilators, are in high demand. Utilizing this authority has enhanced national preparedness and is helping ensure there is product available if and when it is needed. Allocation and prioritization, when used, are based off of data and where these supplies are needed the most and decisions are made by the Coronavirus Taskforce. Testing distribution is guided by the national testing strategy and implemented by States based off of their testing plans that have been reviewed by experts at HHS and CDC.

Question. At the beginning of the pandemic, did State public health departments have adequate staff capacity, resources, and infrastructure to respond to a crisis of this magnitude?

Answer. The COVID-19 pandemic put a spotlight on the needs and disparities in public health infrastructure and highlighted the importance of public health core capabilities across the country and throughout the world. These core capabilities form the backbone of CDC's capacity to protect America's health. A strong public health system includes robust data and analytics, laboratory capacity, a top-tier workforce, rapid response capabilities and a broad global footprint to stop disease at its source. The Administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19.

Question. To what extent has the lack of investment in public health increased spending, delays, and ultimately the loss of life as health departments struggled to hire staff and upgrade technology during the pandemic?

Answer. The COVID-19 pandemic put a spotlight on the needs and disparities in public health infrastructure across the country and throughout the world. The Administration worked closely with Congress to ensure that State and local public health departments had necessary resources to respond to COVID-19.

Question. Public health experts have proposed that key health defense line items at CDC, BARDA, and NIH should not be subject to annual budget caps in order to sufficiently invest in the country's health security. Does HHS agree that this proposal would be beneficial, and would it help us prepare for the next pandemic?

Answer. The structure of the President's Budget and current Congressional appropriations does not contemplate excluding health line items in HHS from annual budget caps.

QUESTIONS SUBMITTED BY SENATOR JOE MANCHIN, III

DRUG EPIDEMIC

Question. A majority of adults believe the pandemic is taking a toll on their mental health and one in three adults report symptoms of anxiety (up from one in twelve last summer). Reports of drug overdoses are on the rise as well, triggered by the factors that are contributing to mental health issues, with recent reports estimating that 75,000 Americans are at risk of drug overdose and suicide due to this pandemic. Social isolation, increased anxiety, and economic and social pressure have created what experts are calling a "perfect storm" for suicide and substance misuse. West Virginia has been ravaged by the drug epidemic and we already have some of the highest suicide rates in the country. Now we are facing these two public health crises at the same time as we combat the ongoing COVID-19 pandemic. What can we do to help ensure patients suffering from substance use disorder get the resources they need?

Answer. During the COVID-19 pandemic, normal resources that individuals may use to manage treatment or distraction from harmful substance using behaviors may no longer be available or have changed in important ways (e.g., no face-to-face contact). Lockdowns, shelter-in-place orders, and social distancing have forced treatment facilities, social services, and support groups to shut down, reduce hours, or move online-leaving people who use drugs and those in recovery to face greater risks with less support. As CDC continues to work with states, territories, and localities to provide technical assistance to identify mitigation strategies. For example, one State is now using social media and other virtual communications to message the importance of naloxone.

Harm reduction organizations, including syringe service programs (SSPs) and facilities that provide medications for opioid use disorder (MOUD), have had to adapt in the wake of this pandemic and change their practices in order to continue to serve their clients. In response, CDC is working to identify and support innovative and emerging practices. Strategies will be summarized in technical assistance tools for dissemination to partners.

CDC is also working to curb and lower substance use patterns and attitudes among youth whose use has risen during COVID-19. CDC is working with States engaged in Overdose Data to Action (OD2A), a 3-year cooperative agreement that began in September 2019 and focuses on the drug overdose epidemic, to respond to the realities of how their work is changing in this environment. This includes assessing overdose data and to understand trends in light of COVID-19, as well as working with our 66 funded jurisdictions to provide flexibilities where needed and technical assistance to inform public health action during the pandemic.

CDC Foundation has collaborated on a new initiative, called How Right Now, that addresses people's feelings of grief, loneliness, stress, and worry during the pandemic. This initiative is managed by NORC at the University of Chicago, with support from the CDC Foundation. CDC is providing technical assistance. The initiative offers information and resources (in English and Spanish) to help people cope and be resilient during this time, including a comprehensive suite of culturally appropriate materials from a variety of national partners.

The current pandemic is unprecedented and it is likely to impact the health, safety, and well-being of individuals and communities for many years to come. The effects of emotional isolation, insecurity, economic hardship, school closures, furlough, unemployment, and reduced access to resources will translate into an array of emotional reactions (such as distress or psychiatric conditions), unhealthy behaviors (such as excessive substance use), and noncompliance with public health directives (such as home confinement and vaccination) among people directly and indirectly impacted by COVID-19. Extensive research in disaster mental health has established that emotional distress is ubiquitous in affected populations and that such times are associated with increased rates of substance abuse and treatment relapse.²

Some groups may be more vulnerable than others to the psychosocial effects of a pandemic. In particular, people who contract the disease, those at heightened risk for it (including the elderly, people with compromised immune function, and those living or receiving care in group settings), and people with preexisting medical, psychiatric, or substance use problems are at increased risk for adverse psychosocial outcomes. Beyond this, mass home-confinement directives (including stay-at-home orders, quarantine, and isolation) raise concern about how people will react individually and collectively. A recent review of psychological sequelae in samples of quarantined people and of healthcare providers revealed numerous emotional outcomes, including stress, depression, irritability, insomnia, fear, confusion, anger, frustration, boredom, and stigma associated with quarantine, some of which persisted after the quarantine was lifted.² Specific stressors include greater duration of confinement, having inadequate supplies, difficulty securing medical care and medications, and resulting financial losses.^{2,3} Such conditions are also known to potentiate substance abuse or to be a risk factor for relapse.⁴ Moreover, social distancing measures can limit access to meetings of peer-support groups or other sources of social connection that are important to those in recovery from substance use disorders.

In recognition of these potential impacts, the Substance Abuse and Mental Health Services Administration (SAMHSA) has not only provided \$425,000,000 in emergency grants and funding to the States and tribes since the start of the pandemic, but it has also supported rules that allow the provision and monitoring of evidence-based treatments through telemedicine and remote platforms. SAMHSA has also issued new regulations at 42 C.F.R. part 2 around the management of patients so that treatment and services will not be substantially limited by illness or quarantine measures.

In the current environment most psychosocial services, which are increasingly delivered in primary care settings, are being offered by means of telemedicine. In the context of COVID-19, psychosocial assessment and monitoring should include queries about COVID-19-related stressors (such as exposures to infected sources, infected family members, loss of loved ones, and physical distancing), secondary adversities (economic loss, for example), psychosocial effects (such as depression, anxiety, psychosomatic preoccupations, insomnia, increased substance use, and domestic violence), and indicators of vulnerability (such as preexisting physical or psychological conditions). Some patients will need referral for formal mental health evaluation and care, while others may benefit from supportive interventions designed to promote wellness and enhance coping (such as psychoeducation or cognitive behavioral techniques). In light of the widening economic crisis and numerous uncertainties surrounding this pandemic, suicidal ideation may emerge and necessitate immediate consultation with a mental health professional or referral for possible emergency psychiatric hospitalization. State programs can support these activities while also ensuring timely access to substance abuse and mental health services.

Many of the experiences of patients, family members, and the public can be compassionately normalized by providing information about usual reactions to this kind

²Brooks SK, Webster RK, Smith LE, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *Lancet* 2020;395:912–920.

³DiGiovanni C, Conley J, Chiu D, Zaborski J. Factors influencing compliance with quarantine in Toronto during the 2003 SARS outbreak. *Biosecur Bioterror* 2004;2:265–272.

⁴Volkow ND. Collision of the COVID-19 and Addiction Epidemics. *Ann Intern Med*. 2020;173(1):61–62.

of stress and by pointing out that people can and do manage even in the midst of dire circumstances. Healthcare providers can offer suggestions for stress management and coping (such as structuring activities and maintaining routines), link patients to social and mental health services, and counsel patients to seek professional mental health assistance when needed. Such interventions should be supported by consistent messaging across the public and private sector while also providing reassurance.

Given that most COVID-19 cases will be identified and treated in healthcare settings by workers with little mental health training, it is imperative that assessment and intervention for psychosocial and substance abuse concerns be administered in those settings. Ideally, the integration of mental health considerations into COVID-19 care will be addressed at the organizational level through State and local planning; mechanisms for identifying, referring, and treating severe psychosocial consequences; and ensuring the capacity for consulting with specialists.⁵ To this end, education and training regarding psychosocial issues should be provided to health system leaders, first responders, and healthcare professionals. The mental health and emergency management communities should work together to identify, develop, and disseminate evidence-based resources related to disaster mental health, mental health and substance abuse triage and referral, the needs of special populations, and bereavement care. Risk-communication efforts should anticipate the complexities of emerging issues such as prevention directives, vaccine availability and acceptability, and they should address a range of psychosocial and substance abuse concerns. Mental health professionals can help craft messages to be delivered by trusted leaders.⁴

The COVID-19 pandemic imparts both current and long-term implications for individual and collective health, as well as emotional and social functioning. Rates of substance abuse should not be looked at in isolation, since they are linked to psychological wellbeing, community health and access to resources. In this way, the already stretched health system has an important role in monitoring psychosocial needs and delivering support to their patients, healthcare providers, and the public. Such activities should be integrated into general pandemic healthcare and delivered in a variety of settings and through different platforms. An integrated approach between government officials and health system leaders can facilitate this while also creating the foundation for longer-term coordinated care platforms.

Question. What financial resources is HHS providing to our behavioral health and recovery services to continue treating patients during this time?

Answer. In one example, CDC provided \$12 million to tribal-health-serving consortia organizations to build public health capacity in the COVID-19 response in preventing injuries and violence, focusing on suicide, adverse childhood experiences, and intimate partner violence. In addition, CDC is funding two projects to prevent substance use during this COVID-19 pandemic, Novel Harm Reduction and Treatment Strategies to Support Individual with Opioid Use Disorder and Youth Substance Use and Messaging Development during COVID-19.

The Substance Abuse and Mental Health Services Administration (SAMHSA) is a grant-making agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act provided \$425 million in funding to SAMHSA to address the mental health and substance use disorder effects of COVID-19.

To date, SAMHSA has awarded \$424,244,671 in Emergency Grants to Address Mental and Substance Use Disorders during COVID-19 to the following:

- Certified Community Behavioral Health Clinics (CCBHC COVID) Expansion Grants totaling \$249,657,910 to provide a comprehensive range of mental health and substance use disorder services to vulnerable individuals;
- Tribal Behavioral Health (TBH COVID) supplements totaling \$14,999,908 to meet the increased mental and substance use disorders of tribes during the COVID-19 pandemic;
- Suicide Prevention Lifeline Crisis Center Follow-Up (CCF-COVID) Expansion Grants totaling \$2,978,828;
- Suicide Lifeline/Disaster Distress Helpline (SPH COVID) supplement totaling \$12,077,216 to support the Lifeline's use of text messaging and expand access to the Lifeline's suicide prevention services;

⁵ Pfefferbaum B, Schonfeld D, Flynn BW, et al. The H1N1 crisis: a case study of the integration of mental and behavioral health in public health crises. *Disaster Med Public Health Prep* 2012;6:67-71.

—COVID–19 Emergency Response for Suicide Prevention (ERSP) Grants totaling \$40 million to support States and communities during the COVID–19 pandemic in advancing efforts to prevent suicide, suicide attempts and domestic violence.

RURAL HEALTH

Question. In West Virginia, we have had 3 hospitals shut down this year alone. Many more rural hospitals and health centers are operating on shoestring budgets. Congress provided \$175 billion to the Provider Relief Fund to directly support health providers responding to the pandemic. So far, only \$11 billion has been allocated directly to rural health providers. With 20 percent of Americans living in rural America, their access to care is in jeopardy if their hospitals shut down. That is why I have asked HHS to allocate at least 20 percent of the Provider Relief Fund to rural providers. The Save Our Rural Providers Act is a bipartisan, bicameral legislation targeting these funds to rural providers who serve high rates of Medicaid and vulnerable patients. Are there plans to direct more resources to our struggling rural providers?

Answer. Rural hospitals, many of whom were operating on thin margins prior to COVID–19, have also been particularly devastated by this pandemic. As healthy patients delay care and cancel elective services, rural hospitals are struggling to keep their doors open. Acknowledging these unique barriers, HHS distributed \$11 billion through two Rural Targeted Distributions.

Organizations that received these targeted distributions operate 11,640 healthcare delivery sites including 2,374 rural hospitals and critical access hospitals, 383 hospitals in small metro areas or with Medicare special payment designations, 4,655 Rural Health Clinics, and 4,228 Community Health Center sites in rural areas.

In addition to targeted rural distributions, rural providers are also eligible for other General and Targeted Distributions. As of November 17, 2020, providers located in rural and frontier areas received approximately \$21 billion across all Provider Relief Fund distributions.

At this point, HHS does not anticipate an additional Targeted Distribution for rural communities. Providers in rural areas may be eligible to apply for Phase 3 General Distribution payments.

Question. What other actions is HHS taking to support rural health providers in West Virginia and across America to prevent more hospitals from shutting down?

Answer. As of October 5, 2020, West Virginia providers received and attested to 2,615 Provider Relief Fund payments totaling \$622,122,647.10. Payments to rural providers account for 24 percent of all attested payments in West Virginia. This includes 78 payments to organizations operating 294 healthcare delivery sites under the Rural Targeted Distribution totaling \$152,080,433.20, as well as 13 payments to hospitals under the Safety Net Hospital Targeted Distribution totaling \$192,273,920.32.

In May, HRSA made \$225 million available to over 4,500 RHCs across the country to support COVID–19 testing efforts and expand access to testing in rural communities. In addition, under HRSA's Health Center Program, 84 HRSA-funded health centers in West Virginia received COVID–19 supplemental funding grants totaling \$33,712,162.

In addition to grants and payments, HRSA also has three programs that provide support to hospitals in West Virginia or other parts of the country.

The Vulnerable Rural Hospital Assistance Program (VRHAP) provides targeted assistance to at-risk rural hospitals struggling to maintain healthcare services. VRHAP works with hospitals and their communities to understand community health needs and resources, ensure hospitals and communities can keep needed healthcare local, and address economic challenges. Solutions may include assessing key healthcare services to provide, identifying cost efficiencies, exploring other mechanisms to meet community healthcare needs. This \$800,000 per year award supports one awardee to provide consultative support to five hospitals in depth and 25 hospitals virtually in groups. A hospital in West Virginia is part of the five selected for comprehensive support for the current program year (Sept 2020–August 2021).

The Rural Healthcare Provider Transition Project is new in Fiscal Year (FY) 2020. This project provides technical assistance to assist eligible small rural hospitals and RHCs in strengthening key elements of value-based care: quality, efficiency, patient experience, and patient safety. Technical assistance will be designed to give hospitals and RHCs a clear understanding of value-based care and the strategies they can implement to be effective participants in a healthcare system focused on value. This program will target hospitals and RHCs that are not yet at the level to partici-

pate in value-based programs. HRSA awarded \$800,000 in 2020, with technical assistance to begin later this year.

The Federal Office of Rural Health Policy in partnership with the Delta Regional Authority administers the Delta Region Community Health Systems Development Program. The program provides technical assistance through comprehensive onsite consultations to eligible healthcare facilities located in the 252 counties and parishes across eight States served by the Delta Regional Authority. The program supports capacity building for healthcare facilities around quality improvement, financial and operational improvement, telehealth, community care coordination, workforce, emergency medical services, and population health.

COVID TESTING

Question. National testing reports have consistently fallen far below even the lowest estimated targets, and supply limitations and lengthy test turnaround times continue to be an obstacle for frontline providers and patients. HHS funding for expanded testing capacity has helped to alleviate existing shortages but capacity remains insufficient for a long-term, strategic response. Beyond the immediate challenges, a successful national testing strategy must consider medium- and long-term planning for capacity, including for supply stockpiles, public health workforce and infrastructure, health system preparedness, and more. How are CDC and ASPR supporting State and local health departments to ensure they have adequate capacity for widespread COVID-19 testing and what additional resources are required to increase testing for all populations?

Answer. The majority of COVID funds CDC awarded to date—over \$12 billion—has gone directly to States, tribes, territories, and localities to support a wide range of COVID-19 response activities including testing, reporting data, contact tracing, personnel, and health department readiness and coordination. These funds also help health departments respond to current COVID-19 outbreaks and prepare for future outbreaks, including supporting accelerated laboratory testing, data collection, and real-time reporting to CDC for identification and tracking of COVID-19 cases in the community, as well as supporting implementation of COVID-19 community intervention plans. CDC also works with State, tribal, local, and territorial health departments to provide guidance, detect and investigate cases, implement mitigation measures, identify needs for surge staff, develop new resources and tools, support epidemiologic investigations and data analysis efforts, and more.

LOCAL HEALTH DEPARTMENT FUNDING

Question. Congress has appropriated billions of dollars for COVID response to State and local health departments. So far, funding has gone out to States and territories that are either battling outbreaks of the virus or at risk for an outbreak. However, since many communities are dependent on States to pass through Federal dollars, there are vast inconsistencies across the country with Federal funds making it to local health departments to support this response. For example, in my home State of West Virginia, 50 percent of our local health departments only have 90 days of cash on hand, and 13 percent have only 30 days of cash hand. What can CDC do to ensure in the future that local health departments have the resources they need to protect the public from COVID-19?

Answer. The majority of COVID funds CDC awarded to date—over \$12 billion—went directly to States, tribes, territories, and localities to support a wide range of COVID response activities including testing, reporting data, contact tracing, personnel, and health department readiness and coordination. CDC has, and will continue to, encourage States to support their local health departments with these supplemental funds.

QUESTIONS SUBMITTED TO BOB KADLEC, M.D.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

CHINESE VACCINE AND INTERNATIONAL STRATEGY

Question. Dr. Kadlec, the U.S. has invested in several strong contenders in the race to get a vaccine. However, of the eight vaccines in Phase III trials, half are Chinese. That makes it entirely possible that a Chinese vaccine could be the first to succeed. What happens if China gets the vaccine first?

Answer. The U.S. Government is focused on developing a safe and effective vaccine as quickly as possible. It is not a competition. Through Operation Warp Speed (OWS), the U.S. Government has invested in multiple COVID-19 candidate vaccines

using different platform technologies, so that we have the best chance of securing at least one safe and effective COVID-19 vaccine for the American people. Of the four Chinese-developed vaccine candidates currently in Phase 3 trials, three are developed using an inactivated SARS-CoV-2 platform, which some researchers feel has a higher potential of significant safety concerns, including antibody-dependent enhancement of disease. For this reason, OWS has deliberately chosen not to invest in vaccine candidates that are developed using this platform, including inactivated vaccine candidates from companies outside China. Under OWS, we also continue to increase our domestic manufacturing capacities for COVID-19 vaccines, to maintain availability of a reliable vaccine supply for the American people.

We are aware that several of the Chinese-developed vaccine candidates have been used outside of clinical trials to vaccinate individuals in China and the United Arab Emirates under their respective emergency use programs. Russia approved a vaccine candidate before large-scale phase 3 safety trials of the vaccine had been completed, with several countries planning to acquire the vaccine. Making such vaccines available to the public prior to completion of clinical trials is a risky approach when data on safety and effectiveness are still pending that could set back confidence in vaccines everywhere and damage the global fight against COVID-19.

VACCINE DEVELOPMENT

Question. Dr. Kadlec, both the HEALS Act and the targeted supplemental that received a majority of votes in the Senate last week provides an additional \$20 billion to BARDA to continue investing in vaccine manufacturing and purchasing. HHS has reached agreement to purchase roughly 100 million doses of various vaccine candidates. Knowing that HHS is nearly out of funding specifically appropriated for vaccine manufacturing and purchase, are you concerned that HHS does not have the resources from such accounts to purchase vaccine in the event that only one or two candidates are successful?

When do you need additional funding to avoid delays in either vaccine, therapeutic, or diagnostic development, manufacturing, or purchase?

Answer. To accelerate the development and subsequent production of a vaccine for COVID-19, in mid-May, President Trump announced Operation Warp Speed (OWS), which aims to deliver up to 300 million doses of a safe and effective vaccine for COVID-19 in early 2021. OWS is a partnership among components of the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD), with the aim of a unified government approach to respond to the pandemic. OWS engages with private sector partners and other Federal agencies, including the Department of Agriculture, the Department of Energy, and the Department of Veterans Affairs.

BARDA supported early research and development for five of these candidates prior to OWS and has continued and expanded these partnerships to include large-scale prototype manufacturing. Unlike the typical sequential vaccine development pathway, which can take up to 10 years, the U.S. Government is asking its industry partners to develop and manufacture their vaccine candidates in parallel to rapidly accelerate this process into less than 1 year. Rapid acceleration of manufacturing while clinical trials to test the safety and efficacy of candidate vaccines are still underway is a financially high risk proposition. To mitigate this risk for our partners, multi-billion dollar investments were required to secure the necessary manufacturing capacity for drug substance and fill-finish capacity for final drug products as well as to secure the supply chain needed to produce hundreds of millions of vaccine doses. The U.S. Government has contracted with its partners for 100 million doses of the Moderna, Janssen, Pfizer, Novavax and Sanofi/GSK vaccines and 300 million doses of the AstraZeneca vaccine at the Government's financial risk. Once the safety, efficacy, and large-scale manufacturability of one or more of the candidates are confirmed, the Government may procure additional vaccine doses to ensure enough doses are available for every American who wishes to be vaccinated.

Specific to manufacturing efforts, OWS continues to analyze and engage domestic pharmaceutical manufacturing and fill/finish capacity across the vaccines landscape. OWS is also identifying suppliers of secondary items for administration of any authorized or licensed vaccines, and providers of pharmaceutical distribution to ensure sufficient capacity exists once products have been granted FDA EUA or licensure/approval. HHS is procuring secondary items (syringes, needles and other ancillary supplies) and investing in the expansion of domestic manufacturing capacity while countermeasures are still in clinical development to maximize domestic supply

chains and ensure that the American people are poised to receive safe and effective vaccine(s) as soon as possible.

HHS has accelerated the availability of diagnostics for the COVID-19 response. ASPR/BARDA is funding established and newly emerging diagnostics test manufacturers to develop COVID-19 diagnostic tests, which has resulted in more than 45 million tests being available to test Americans. ASPR/BARDA, with the assistance of DoD, is working to expand domestic manufacturing capacity with many of these diagnostics developers to further increase the rate that tests are available. One company that ASPR/BARDA funded to develop a SARS-CoV-2 test was just awarded a DoD/OASH contract to increase manufacturing capacity to over 100,000 tests per day for use in non-traditional testing sites.

THERAPEUTIC DEVELOPMENT

Question. Dr. Kadlec, the Committee has provided \$6.5 billion to BARDA for the development and manufacturing of vaccines, therapeutics, and diagnostics. As I said in our last hearing on COVID-19 and during this hearing, our priority should be vaccine development, manufacturing, and distribution. However, we should not put all our eggs in one basket. Until every American who wants a vaccine receives one, we need to have readily available treatments for those who are sick. But it appears that the vast majority of the money we provided to BARDA has gone to vaccines. What is the plan for therapeutics development? Why is there not more focus on this area? Is it because you're lacking resources or because it is lacking priority?

Answer. BARDA, in conjunction with OWS, has a strong ongoing effort to support development of many therapeutic candidates. OWS and BARDA are supporting platform clinical trials under the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public private partnership, which was announced in April 2020 by the National Institutes of Health (NIH), and is being coordinated by the Foundation for NIH. The five platform trials (ACTIV 1 through 5) allow for testing multiple therapeutics in the same trial. This is the most efficient use of funding and clinical resources, which have been stretched thin throughout the pandemic response.

Individual funding awards to companies for research and development have focused on candidate therapeutics with the highest likelihood of success, such as the monoclonal antibody therapeutics that are being developed using platform technologies that were established for other pathogens like influenza and Ebola.

Additionally, the testing and collection of convalescent plasma has been a pillar of the OWS therapeutic response. While we are still investing in randomized, controlled clinical trials, we are encouraged by the early results from the expanded access protocol. The therapeutic portfolio will continue to evolve in the coming weeks as results from clinical trials become available.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Kadlec, we are in the middle of the worst pandemic in a century. You predicted this, but you thought it was going to be the flu just as so many in public health did. Can you speak for a minute or two on your thoughts on our current state of pandemic flu preparedness and whether you think we have the medical countermeasures, public health infrastructure, and perhaps most importantly sustainable resources our nation needs to help prevent what is likely an inevitable influenza pandemic that could happen 5 years from now, or 5 months from now.

Answer. ASPR's priorities include helping to meet the requirements of Executive Order (EO) 13887, Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, signed by President Trump on September 19, 2019. Influenza is a very serious threat to human health and poses a significant national security risk, it leads to hundreds of thousands of hospitalizations, placing a significant strain on our healthcare system. Mitigating the impact of both seasonal and pandemic influenza is critical to saving lives and reducing economic and healthcare burdens. To mitigate such risks, EO 13887 requires accelerated vaccine development of faster, more scalable platforms to expand domestic manufacturing. Consistent with the EO, ASPR promotes the modernization of facilities and infrastructure in ways that expand the domestic manufacturing capacity for non-egg based vaccines and adjuvants. ASPR is dedicated to advancing the development of broad-acting antivirals, transition to near-patient or in-home diagnostics, and addressing gaps in capabilities.

The National Influenza Vaccine Task Force-established by the EO 13887 and chaired by Secretaries of Defense and Health and Human Services-published the National Influenza Vaccine Modernization Strategy 2020-2030. This ten-year strategy prioritizes U.S. Government efforts toward (1) strengthening domestic advanced

manufacturing of influenza medical countermeasures, (2) promoting innovative technologies to detect, prevent, and respond to influenza, and (3) increasing influenza vaccine access and coverage across all populations. The Task Force—with representation from the Departments of Health and Human Services, Agriculture, Defense, Homeland Security, Justice, State, and Veterans Affairs, and the National Security Council—is responsible for implementation of the strategy through an iterative process. The Task Force has identified short-, mid-, and long-term activities necessary to accomplish the above priorities, and will consult with State, local, tribal, and territorial government officials as well as industry leaders as appropriate to coordinate actions. Progress will be reported to the White House on an annual basis.

ASPR's investments in pandemic influenza preparedness to date have made our nation significantly prepared for an outbreak. These include:

- Built dual-purpose infrastructure and capabilities that were utilized to support the COVID-19 response;
- Developed a standard process to rapidly develop vaccine banks for different production platforms. As a result, multiple vaccine seed stocks are readily available for rapid vaccine production as the need arises, including against H5N1, H5N6, and H7N9;
- Developed and purchased H5N1, H5N6, and H7N9 influenza bulk vaccine antigen (the component of vaccine that stimulates the human immune system) for the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS);
- With FDA licensure, developed new seasonal and pandemic influenza vaccines using modern cell- and recombinant-based production technologies to expedite and expand domestic production capacity;
- Supported improved assessment of the relative effectiveness of newly licensed influenza vaccines produced in cell cultures or recombinant platforms as compared to traditional egg-based vaccines; Advanced the development of sensitive diagnostic tests to detect influenza viruses that can be used in near-patient settings, and high-throughput diagnostics capable of detecting influenza strains at hospital-based, reference, and public health laboratories;
- Developed, tested, and stockpiled new antigen-sparing adjuvants that are required for vaccines to stimulate sufficient immunity and decrease the amount of antigen needed in each vaccine dose for the vaccine to be effective;
- Expanded the surge capacity of domestic vaccine manufacturing, while increasing its flexibility to help manufacture pandemic influenza vaccines as quickly as possible;
- Supported development of new technologies that will help influenza vaccines become available faster than currently possible in response to a pandemic or other public health emergency;
- Conducted clinical trials for stockpiled and newly manufactured adjuvanted H5N1 and H7N9 vaccines in response to an emerging pandemic;
- Supported development of broad-spectrum monoclonal antibodies, host-targeted therapeutic drug candidates, and small molecule antivirals with novel mechanisms of action—when compared to currently licensed influenza antiviral drugs these candidates have shown activity against drug-resistant influenza viruses and are currently under evaluation in phase two and phase three clinical trials;
- To significantly increase the supply of respirators available during an influenza pandemic, supported the development of technology and processes that promote rapid production of N95 respirators;
- Supported the development through FDA authorization of next-generation portable ventilators needed for a surge in hospitalized patients of all ages during a pandemic;
- Supported development of re-usable elastomeric respirator masks;
- Responded to the 2017 H7N9 influenza threat, with production, stockpiling and clinical trial testing of vaccine antigen for H7N9 influenza vaccine from the 2016–2017 Yangtze River Delta virus lineage candidate vaccine virus provided by CDC. ASPR worked with partners to improve preparedness at the local, State, and international levels, including:
 - Improved technical knowledge and capacity for manufacturing in developing countries in order to increase global pandemic influenza vaccine capacity;
 - Conducted surveillance, research, and international collaboration on policies, plans, and training;
 - Provided risk communication to improve public understanding of the actions that individuals, businesses, and organizations can take to protect the public from emerging infectious diseases, including those with pandemic potential;
 - Supported development, through FDA authorization, of point-of-care clinical diagnostics;

- Increased stockpiling of vaccines, next-generation ventilators, and medical supplies, including adjuvants and antiviral drugs, and,
- Through capacity expansion and support of adjuvant production, enabled development of additional seasonal influenza vaccine products.

All of these investments have led and contributed to innovative technologic advancements for pandemic influenza MCMs including, inter alia, cell-based and recombinant vaccine technology, vaccine adjuvants, advanced development and manufacturing, and vaccine surge capacity.

The rapid vaccine development response to COVID-19 has, further, revealed the value of new manufacturing technologies. We may be nearing the dawn of a new era in response capability if the “genetic vaccines” whose development is being supported by Operation Warp Speed prove to be safe and effective, because these production approaches can be applied to pandemic influenza.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

ANTIVIRALS FOR INFLUENZA

Question. Dr. Kadlec, as devastating as the coronavirus pandemic has been to date, the situation could get even worse this fall and winter, when the nation is expected to face a “twindemic” of COVID-19 and the annual influenza season. If the nation could—to the extent possible—mitigate the impact of flu, that would greatly improve our ability to address COVID-19’s second wave. Flu vaccinations are, of course, a critical component of that strategy, and I commend ASPR for allocating additional funding to procure vaccines. You have stated many times that we also need significantly more antivirals, especially for high-risk populations, to treat influenza.

How much funding does ASPR need to procure a sufficient number of antivirals for this flu season?

Does ASPR currently have the necessary funding on hand—either in emergency or regular annual funds—and at the President’s fiscal year 2021 request level?

Answer. ASPR/BARDA supports efforts to address the threat of a pandemic influenza. While these efforts generally augment the annual influenza response, ASPR/BARDA does not procure or support the development of antivirals for the common flu. Rather, ASPR/BARDA is supporting innovative manufacturing capabilities to rapidly manufacture and produce vaccine for an influenza event, as well as novel technologies to enhance such production (such as cell-based technologies).

The commercial market for influenza antivirals can support the needs of a typical influenza season. If we have a pandemic level event, there are millions of influenza antiviral treatment courses in the Strategic National Stockpile (SNS). SNS resources can be activated if the commercial market cannot keep up with demand.

The SNS lacks diversity in its influenza antiviral stockpile. A diverse antiviral stockpile will allow the U.S. Government to respond if the pandemic virus is resistant to any one mechanism of action.

ASPR/SNS seeks to maximize the value of the SNS appropriation in collaboration with the Food and Drug Administration (FDA) through the Shelf Life Extension Program (SLEP). In December 2019, prior to the COVID-19 pandemic, the FDA reviewed pertinent data and agreed to extend the shelf life for some influenza antivirals for use during emergency responses. This action represents a significant cost avoidance in fiscal year 2020 and beyond, as large volumes of SNS held antivirals approaching final expiration in 2019 and 2020 will remain viable for additional years without replacement. In addition, pending availability of funding in fiscal year 2021, SNS plans to expand its holdings of antivirals to respond to pandemic influenza.

RAPID DIAGNOSTICS

Question. Dr. Kadlec, the availability of point-of-care and over-the-counter tests would allow people to be screened for COVID-19 easily and quickly by yielding results in minutes instead of days. In short, if these kinds of tests were reliable and widely available, they would be game-changing for our testing capacity. BARDA currently has 29 diagnostics in its COVID-19 countermeasure portfolio and some of them offer rapid point of care options that require no equipment, processing, or refrigeration, and can be deployed in homes or the workplace to deliver lab quality results in minutes.

How much of the \$16 billion that has been spent by BARDA for developing medical countermeasures against COVID-19 has gone toward diagnostics?

Answer. ASPR has obligated approximately \$370 million on diagnostics to date.

Question. How much of the \$16 billion has gone toward therapeutics and vaccines?

Answer. ASPR has obligated approximately \$15.7 billion on vaccines and therapeutics to date.

Question. Could rapid antigen tests obviate some of the supply chain issues that have emerged with processing molecular PCR tests?

Answer. Rapid antigen tests (RATs) would obviate some supply chain issues that are being experienced with molecular tests, such as shortages of pipette tips, but shortages of other supplies (like swabs and viral transport medium) are also applicable to RATs.

Question. How does HHS plan to address any new or unique supply chain issues that emerge with rapid antigen tests?

Answer. ASPR is working with the Joint Acquisition Task Force to reduce supply chain issues for diagnostics tests. This includes investments in manufacturing capacity for swabs, viral transport media, and pipette tips.

Question. How does the cost of running the traditional molecular PCR test for coronavirus compare to one of these rapid antigen tests? What is the estimated cost per test for each of them?

OWS SPEND PLAN

Please provide a detailed obligations table and spend plan of obligated and anticipated uses of any appropriated supplemental funds made available for Operation Warp Speed by HHS, including estimated personnel and administrative costs and contract obligations that exceed \$5,000,000. Please include any inter-agency transfers or IAAs of funds, and a breakdown of medical countermeasure activities by therapeutics and vaccines.

Answer. Please see attached PDF labeled, “QFR OWS—Contracts Over \$5 million.” Note, the response was drafted as of the date of the hearing (i.e. September 16, 2020).

QUESTION SUBMITTED BY SENATOR JEANNE SHAHEEN

Question. Dr. Kadlec, has anyone from the White House or HHS asked the companies or researchers participating in Operation Warp Speed to seek FDA review of the company’s vaccine candidate by a certain date or time on the calendar?

Answer. No. We are adhering to and following all required regulatory and safety requirements required for vaccine development. We are not sacrificing the safety of the vaccine in order to expedite its development.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. What are the key steps in setting up the vaccine distribution network, and what is the status of each step?

Answer. OWS, through the CDC, is establishing a central distribution network through the McKesson Corporation, our primary distributor under contract. The key steps in establishing the network are bringing into operation the McKesson facilities that will distribute COVID vaccines and supporting ancillary supply kits. Select facilities will be ready to conduct operations in November 2020, and all will be operational no later than early in 2021. Additionally, States and Territories are in the process of identifying the locations to which vaccines will be distributed and from which they will be administered. The initial versions of these plans were completed and submitted to the CDC from all jurisdictions in mid-October 2020.

Question. Do we currently have sufficient amounts of all of the equipment and materials needed for vaccine administration—such as syringes, glass vials, and refrigerators? How will those materials be distributed to States?

Answer. Supporting and securing an adequate supply of ancillary products is a collaborative, interagency effort.

Specific to securing needles and syringes, to date, BARDA has awarded four large task orders for such products. Going forward, BARDA will support additional solicitations, in coordination with the Strategic National Stockpile (SNS), to maximize the availability of needles and syringes toward the end of 2020. BARDA and the DoD Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) CBRND, on behalf of HHS, have awarded three agreements to increase needle and syringe capacity in the United States for the future, some of which will be available in time to support the COVID-19 vaccination in early 2021. Lastly, BARDA and JPEO-CBRND, on behalf of HHS, have awarded

agreements with two domestic manufacturers of vials to increase production capacity of vials to support multiple vaccine candidates.

To specifically support domestic manufacturing efforts for active pharmaceutical ingredients and other essential medicines, May 19, 2020, BARDA announced a \$354 million four-year contract with Phlow Corporation and its partners-including CivicaRx, Virginia Commonwealth University's Medicines for All Institute, and AMPAC Fine Chemicals. The partnership with Phlow allows flexibility in selecting and prioritizing active pharmaceutical ingredients and finished drugs for manufacturing to allow for rapid response to situations such as the current COVID-19 public health emergency. Phlow's criteria for prioritizing APIs and finished drugs for early manufacturing are based on data on essential medicines shortages that have been exacerbated by COVID-19-associated increases in hospitalized patients.

Projected administration sites include pharmacies, public and private clinics, hospitals, and doctor's offices, the vast majority of which have refrigerated storage capacity. Jurisdiction planning that is currently ongoing will further refine potential administration sites to identify those that are planned for use for both refrigerated and frozen vaccines. All jurisdictions have submitted vaccine distribution plans or playbooks to CDC. Executive summaries have been published here: COVID-19 Vaccination Program Operational Guidance ([cdc.gov](https://www.cdc.gov)). OWS and CDC continue to provide technical assistance to all jurisdictions to ensure initial readiness for vaccine allocations. There is no identified need, or current plan, to acquire and distribute refrigerators to jurisdictions.

QUESTIONS SUBMITTED TO ROBERT R. REDFIELD, M.D.

QUESTIONS SUBMITTED BY SENATOR ROY BLUNT

Question. How much has CDC obligated in supplemental resources for this effort? Please provide by specific activity. How much does CDC have available to spend for this purpose?

Answer. As of October 1, 2020, more than \$500 million has been invested in the COVID-19 vaccination effort to support distribution, vaccine safety and effectiveness, and investment in tracking systems. On June 4, 2020, CDC awarded \$140 million to 64 jurisdictions through CDC's existing immunization cooperative agreement to enable State including the District of Columbia, tribal, local, and territorial health departments to enhance their immunization programs, including launching an initial scale-up for influenza season, given the increased risk of COVID-19. On September 23, 2020, CDC also awarded \$200 million to 64 jurisdictions through the existing Immunizations and Vaccines for Children cooperative agreements. These funds, along with the previous support CDC has provided, will help jurisdictions plan for and implement COVID-19 vaccination services. In addition, CDC invested \$180 million in a centralized depot for distribution of 200 million refrigerated vaccine doses and \$21 million in vaccine safety surveillance ramp up.

Question. What deadline has CDC established for the Federal Government to be ready to roll out all of the requirements necessary for successful vaccine distribution and administration?

Answer. Based on early data from OWS that vaccine could be available in November, CDC had asked that all jurisdictions be prepared to distribute initial doses of vaccine to prioritized populations by November 1, 2020.

Question. Dr. Redfield, on April 28th, President Trump issued an Executive order under section 101(b) of the Defense Production Act to "take all appropriate action under that section to ensure that meat and poultry processors continue operations consistent with the guidance for their operations jointly issued by the CDC and OSHA." How will CDC take into account industries like meat and poultry processors specifically, but any industry deemed critical generally, into their vaccination distribution plan?

Answer. CDC is planning for the many logistical considerations involved in implementation of COVID-19 vaccination. After FDA authorization or approval of a COVID-19 vaccine, ACIP will review and provide its recommendations to the CDC Director for adoption. Within this recommendation, ACIP may prioritize certain groups of the population, such as essential workers (including those working in the food industry), while COVID-19 vaccines are limited. The National Institute for Occupational Safety and Health at CDC will assist with dissemination of information to all Americans, including essential industries and workers via well-established partnerships, and with development of customized communications materials. CDC also plans to help with development of workplace-specific guidance and will conduct surveillance to track vaccine uptake in various occupational groups.

Question. Some poll results show that anywhere between 25–35 percent of Americans have no interest in getting a vaccine which could be a major setback to protect Americans from this virus. Specifically, what steps has the CDC taken to engage community groups, physicians, and the general public about the importance of being vaccinated?

Answer. Understanding public confidence in any and all vaccines is necessary for promoting high vaccine uptake, and CDC is adapting its strategic framework, *Vaccinate with Confidence*, to strengthen public trust in COVID–19 vaccines. The framework emphasizes three key priorities: reinforcing communication to the public about the vaccine’s rollout and its safety and benefits, empowering healthcare providers to communicate effectively with patients about the vaccine and engaging with individuals and communities. Because COVID–19 affects so many aspects of society, CDC is engaging with a wide breadth of community groups, local partners and stakeholders, and trusted messengers to conduct communications about the vaccine development process and roll out, promote vaccine uptake with a focus on priority populations, and increase confidence in the vaccine. Building confidence is inherent to all our work, and CDC will continue to build upon the investments of our immunization program as we prepare both the nation’s public health system and the private sector to disseminate a safe and effective COVID–19 vaccine.

As COVID–19 vaccine developments continue, CDC is working with OWS to ensure community groups, healthcare providers, and the general public receive the most up to date guidance and data on available prevention measures that can help reduce COVID–19 infection and spread. Adapting from approaches used with past coronavirus-related threats, CDC will work with its public health partners to deliver resources on COVID–19 vaccine that assist physicians with proper vaccine administration and enhances public confidence in COVID–19 vaccine uptake.

Question. What are CDC goals for getting Americans vaccinated in 2021? Given that less than half of Americans took a seasonal flu vaccine last year, what percentage of the population is CDC targeting to have received the vaccine by this time next year?

Answer. While influenza vaccination is always important, getting vaccinated this season is more important than ever, especially for people who are at higher risk of exposure or serious complications from influenza and COVID–19. Co-circulation of the viruses that cause COVID–19 and influenza could place a tremendous burden on the healthcare system and result in many illnesses, hospitalizations, and deaths. In addition to prolonging the influenza vaccine season into spring 2021, CDC is working across various fronts to increase influenza vaccination coverage. CDC’s goal is that 70 percent of adults ages 18 years and older are vaccinated annually against seasonal influenza.

Vaccine manufacturers are maximizing the available number of doses for all age groups to accommodate increased demand. CDC is projecting this will increase available doses to 194–198 million this season, about 12 percent more than last year. CDC has also purchased an additional two million pediatric and 9.3 million adult doses of influenza vaccine to enhance coverage in under-served and under-vaccinated communities. This includes optimizing the use of federally procured vaccine through promotion of influenza vaccination within the *Vaccines for Children* program and expanding partnerships to increase vaccine utilization by community health centers. A critical component of the effort is to ensure that parents who are newly unemployed are informed about the *Vaccines for Children* safety net program that provides access for uninsured or underinsured children.

SEASONAL INFLUENZA

Question. Dr. Redfield, what efforts are currently underway at CDC to improve seasonal influenza vaccination?

Answer. While flu vaccination is always important, getting vaccinated this season is more important than ever, especially for people who are at higher risk of exposure to or serious complications from flu and COVID–19. Co-circulation of COVID–19 and flu could place a tremendous burden on the healthcare system and result in many illnesses, hospitalizations, and deaths. In addition to vaccine manufacturers maximizing the available number of doses for all age groups and CDC purchasing additional doses of influenza vaccine, CDC is working across various fronts to increase influenza vaccination coverage.

Regarding the focus on high-risk patient categories and other critical populations (e.g., healthcare workers), CDC collaborated with CMS to develop an additional module in CDC’s National Healthcare Safety Network (NHSN) for long-term care facilities’ (LTCF) resident and healthcare practitioner influenza vaccination reporting data. The module adapts the current NHSN module used by acute care facilities

for healthcare practitioner influenza vaccination reporting. Currently, all CMS-certified nursing homes (~15,400) already use the existing NHSN LTCF component for other required weekly COVID-19 reporting. CDC also updated and augmented the LTCF Flu Vaccination Toolkit for posting on the web and dissemination to partners.

CDC is leveraging a number of new and existing partnerships to promote influenza vaccination among communities of color. For example, CDC is working with the Million Hearts Campaign to address sociodemographic disparities in influenza vaccines among adults with Atherosclerotic Cardiovascular Disease. CDC is also collaborating with partners to explore strategies to reduce racial and ethnic disparities in adult immunization. Additionally, this year's flu communication campaign will be enhanced through a partnership with the American Medical Association and the Ad Council and include messaging tailored to African American and Hispanic audiences as these groups have lower rates of flu vaccination, but higher risk for COVID-19 complications. While CDC is updating guidance and providing messaging toolkits to partners, engaging local communities and leveraging trusted messengers at the ground level will be critical to expanding coverage.

Question. The HEALS bill included \$500 million to bolster CDC's efforts to increase seasonal influenza vaccination rates. How would CDC use those resources for seasonal influenza and why are they needed sooner rather than later?

Answer. If additional funds were appropriated, CDC would allocate them consistent with the purpose outlined in relevant appropriations language. In this case, additional funds would support CDC's work to increase seasonal influenza vaccination coverage.

QUESTIONS SUBMITTED BY SENATOR CINDY HYDE-SMITH

Question. Dr. Redfield, Do you anticipate additional support for State governments to support and implement COVID-19 vaccine mass administration once effective and safe vaccines are available in large numbers?

Answer. Yes.

Question. Dr. Redfield, I have been hearing from a lot of my constituents that they have concerned with coronavirus vaccines being developed using aborted cell lines. From what I understand, there are several candidates moving along the process some using ethical sources and others using aborted cell lines. I know the need for getting a vaccine to market as quickly as possible but the pro-life community does very much care about if the vaccine is ethically sourced. Are Federal funds being used to develop coronavirus vaccines that use aborted fetal cell lines?

If so what are those specific trials and what is their status?

Answer. President Trump announced Operation Warp Speed (OWS) to accelerate the development and subsequent production of a vaccine for COVID-19. OWS aims to deliver up to 300 million doses of a safe and effective vaccine for COVID-19 in early 2021, as part of a broader strategy to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (collectively known as countermeasures). This unprecedented action by the Administration means we are closer than ever before to having a vaccine for COVID-19 in the coming months.

Because there are no guarantees of successful development of any particular vaccine, and vaccines may impact populations differently, it is only prudent to pursue a number of vaccine candidates.

With this in mind, we would like to emphasize that, as an Administration, we are proud to have the highest commitment to protecting the life of the unborn through our policies across the departments. HHS and the Trump Administration have taken multiple steps to protect life, and one clear action relevant to this discussion is the policy we announced last year with regard to the use of fetal tissue in research. NIH-employed scientists may no longer use fetal tissue from elective abortions in their research. Research grants made by NIH to outside institutions and scientists follow a statutory policy requiring an ethics advisory board comprised of individuals who are not Federal employees to review new grant applications or current research projects in the competitive renewal process that propose to use fetal tissue and recommend whether, in light of the ethical considerations, NIH should fund the research.

Among the COVID-19 vaccine candidates being developed by the seven companies which are receiving Federal support (both through OWS and BARDA), five companies do not use any cell lines developed from human fetal tissue from elective abortions. These candidates are vaccines being developed by Moderna, Pfizer, Novavax,

Sanofi, and Merck.⁶ Two of the companies receiving Federal dollars use established fetal cell lines in their vaccine candidates. Those vaccine candidates are from Jansen/Johnson & Johnson and AstraZeneca.

The Department's support for the development of COVID-19 vaccines is consistent with the Administration's policy on the use of human fetal tissue from elective abortions in research. The policy specifically excluded "already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines)." Both AstraZeneca and Jansen/Johnson & Johnson use such "already-established" human fetal cell lines.

Scientific evidence will determine the FDA's approval of any vaccine, but with five of the seven vaccine companies not using fetal cell lines in the development of their vaccine candidates, we are hopeful we will see an option for individuals who do not wish to take a vaccine that has been developed with human fetal tissue from elective abortions. Part of the OWS strategy has been to plan for approval of more than one vaccine, knowing that different vaccines may work better in specific populations.

Question. Dr. Redfield, as we look at this seasons flu campaign, CDC is taking special efforts increase vaccination rates among higher risk populations for Covid-19 and/or flu-related complications. As I understand it the CDC recently purchased as many as 9 million flu vaccine doses to target these at-risk populations. Can you speak for a minute or so on how CDC plans to ensure the unprecedented number of influenza doses, over 190M manufactured and under distribution will be administered? What efforts are planned to drive an extended season campaign?

Answer. CDC has a strong vaccine delivery infrastructure connecting public health departments, healthcare providers, community groups, pharmacists/chain drug stores, and others that can be used to efficiently reach the population. During an emergency, this proven system can be scaled up and expedited to manage and distribute many more doses of vaccine than in a typical year.

CDC is enhancing communications efforts to target special audiences, including older Americans, people of any age with underlying health conditions, workers in long-term care facilities, and other essential workers. Targeted communication and education efforts will be implemented for African American and Hispanic/Latino communities as these groups have lower rates of flu vaccination, but higher risk for COVID-19 complications. CDC is testing flu vaccine messages to learn what impacts the pandemic may have on the intent to vaccinate, including fears about getting vaccinated in a safe environment, and CDC will continue to work with our public health and clinical partners to eliminate barriers to vaccination. CDC has expanded outreach to populations at high risk of severe COVID-19 by working with new and existing partners, including leveraging existing partnerships with the National Association of Community Health Centers (NACHC) and State and local immunization programs to distribute 9.3 million supplemental influenza vaccine doses to those seeking care at community health centers.

Congress's recent investments through the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) have allowed CDC to provide its immunization awardees \$140 million in supplemental funding to support and enhance their immunization programs.

In addition, CDC has been working with influenza vaccine manufacturers to maximize influenza vaccine supply; CDC is projecting this will increase available doses to 194-198 million this season, about 12 percent more than last year. CDC is also increasing the length of the vaccination season through the duration of flu season, into spring 2021. CDC also purchased an additional 2 million pediatric doses and 9.3 million adult doses to enhance influenza vaccine coverage in under-vaccinated communities. This includes optimizing the use of federally procured vaccine through promotion of influenza vaccination within the Vaccines for Children (VFC) program and expanding partnerships to increase vaccine utilization by community health centers.

CDC is providing increased support and resources for immunization programs and partners, including disseminating guidance for safe immunization services, encouraging vaccination where it is most convenient to maximize vaccine uptake, and developing and disseminating guidance for planning vaccination clinics held at satellite, temporary, or off-site locations.

Question. What is the outreach plan to these communities to reach your stated goal of 65 percent total flu vaccination this year which is so important?

Answer. CDC will be working with the National Association for Community Health Centers to implement evidence-based strategies to increase adult vaccination

⁶The Merck vaccine has received support only through BARDA.

coverage among underserved priority populations. CDC will engage in individual expert consultation to develop strategies for addressing racial and ethnic disparities in adult immunization by soliciting simultaneous individual expert opinions from 15 national leaders in health disparities, health equity, and social determinants of health.

CDC is also working with Vaccines for Children program providers to ensure they are prepared for a potential increased number of eligible children due to the economic impact of the pandemic. Children and adults with private insurance should be able to access the flu vaccine at no cost if they are seen at in-network providers.

CDC is also enhancing its efforts in promoting influenza vaccination in high-risk populations. CDC collaborated with CMS to develop an additional module in CDC's National Healthcare Safety Network (NHSN) for long-term care facilities' (LTCF) resident and healthcare practitioner influenza vaccination reporting data. The module adapts the current NHSN module used by acute care facilities for healthcare practitioner influenza vaccination reporting. Currently, all CMS-certified nursing homes (~15,400) already use the existing NHSN LTCF Component for other required weekly COVID-19 reporting. CDC also updated and augmented the LTCF Flu Vaccination Toolkit for posting on the web and dissemination to partners.

With respect to communities of color, CDC is leveraging a number of new and existing partnerships to promote influenza vaccination. For example, CDC is working with the Million Hearts Campaign to address sociodemographic disparities in influenza vaccines among adults with Atherosclerotic Cardiovascular Disease. CDC is collaborating with partners to speak with Health Equity Directors to explore strategies to reduce racial and ethnic disparities in adult immunization. Additionally, this year's flu communication campaign will be enhanced through a partnership with the American Medical Association and the Ad Council and include messaging tailored to African American and Hispanic audiences as these groups have lower rates of flu vaccination, but higher risk for COVID-19 complications. While CDC is updating guidance and providing messaging toolkits to partners, engaging within local communities and leveraging trusted messengers at the ground level will be critical to expanding coverage.

Question. Additionally, how do you plan to monitor influenza vaccine doses administered assure we are on track in real time, and do you need additional resources for to collect data from each State Immunization Information Systems (IIS) program to collect State and national aggregate numbers of doses administered?

Answer. Data sharing through vaccine tracking is a critical component of CDC's COVID-19 vaccination initiative. CDC is actively working to improve the data infrastructure needed to better track vaccines, vaccination, and related information. For example, the Immunization Gateway is a data exchange hub that routes messages between State immunization registries and multi-State providers and allows consumers to access their immunization record. The support of the COVID-19 vaccine response requires significant enhancement of the Gateway's infrastructure and rapid onboarding of State immunization registries and multi-State providers. Enhancements and data exchange are critical for a multi-dose candidate to ensure proper administration of the second dose.

Question. Dr. Redfield, the flu and Covid-19 look very similar and most public health experts believe that Covid-19 and influenza will circulate widely this upcoming fall and winter. What are your views on how medical professionals can further distinguish flu diagnoses from Covid-19 diagnoses?

Answer. Because some of the symptoms of flu and COVID-19 are similar, it may be hard to tell the difference between them based on symptoms alone, and testing may be needed to help confirm a diagnosis. CDC has developed a new diagnostic laboratory test (multiplex PCR assay) to assist with efforts to determine if an individual is infected with SARS-CoV-2, the virus that causes COVID-19. The diagnostic test can identify three viruses: Influenza A, Influenza B, and SARS-CoV-2. Although flu and COVID-19 share many characteristics, there are some key differences between the two. While more is learned every day, there is still a lot that is unknown about COVID-19 and the virus that causes it. This table compares COVID-19 and flu, given the best available information to date.

Question. What will CDC's guidance be on things like antivirals for instance—will someone with influenza and COVID like symptoms be advised to get an antiviral by default?

Answer. CDC developed guidance for clinicians during times when influenza viruses and SARS-CoV-2 are in co-circulation. The guidance includes information on testing to help distinguish between influenza virus infection and SARS-CoV-2 infection and provides information about initiating empiric antiviral treatment for influenza in priority groups. People who fall into priority groups include hospitalized patients with respiratory illness; outpatients with severe, complicated, or progressive

respiratory illness; and outpatients at higher risk for influenza complications who present with any acute respiratory illness symptoms (with or without fever).

Question. Do we have enough antivirals to achieve that?

Answer. CDC is in regular contact with influenza antiviral manufacturers regarding supply and other issues. There are currently no major market shortages of antiviral drugs for treatment of influenza being reported. CDC provides information on antiviral drug supply on our website and will update as needed with respect to influenza antiviral supply this season.

QUESTIONS SUBMITTED BY SENATOR PATTY MURRAY

GUIDANCE TO CHILD CARE CENTERS

Question. Child care providers are confused by conflicting public health guidance that CDC has provided to date and are waiting for concrete actions and practices they can take to keep children and staff safe. While a CDC study of reopened childcare centers in Rhode Island showed that resuming operation at a time of low community spread can successfully limit new coronavirus cases, providers still need clear guidance on how to translate health and safety precautions that have become widely accepted for adults to young children. Dr. Redfield, I sent you a letter with dozens of other lawmakers on this topic last month.

It's now mid-September, 7 months into the pandemic. Why haven't you already issued comprehensive guidance for child care centers?

When is the CDC going to issue this guidance?

Answer. CDC has developed guidance to assist childcare centers: (www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/guidance-for-childcare.html). In part, this guidance includes considerations to help childcare programs promote behaviors that reduce the spread of COVID-19 and maintain healthy environments, as well as monitor and prepare for absenteeism among staff. CDC will update this and other resources as new evidence becomes available.

In addition, CDC collaborated with the Administration for Children and Families (ACF) within HHS on the development and periodic updating of the CDC guidance for childcare providers. ACF has also shared the CDC Foundation's webinar, *Adapting, Evolving, and Thriving: Tools to Evolve Your COVID-19 Child Care Strategy* (<https://childcareta.acf.hhs.gov/covid-19-resources>), to their partners and grantees. This webinar provides strategies for childcare providers to make evidence-based, actionable decisions, grounded in the CDC guidance, to keep staff and children safer in childcare programs regardless of provider type.

CDC recognizes that there is no one-size-fits-all national solution for childcare providers during this time. Differences exist among types of childcare providers, and local contexts vary in terms of the levels of transmission of COVID-19 and community mitigation strategies that may already be in place. Many other factors, such as socioeconomic status, the availability of personal protective equipment and supplies and childcare staffing capacity, including the health status and age of individual providers, also shape decisions about how to safely reopen and continue the operation of childcare programs.

As childcare providers think about how and when to open or have questions about operating during this time, we encourage them to consult State and local health officials and their local childcare licensing agency for data on community transmission, as well as support for implementing mitigation strategies and other guidance to promote the health and safety of children, staff, and their community.

As more data becomes available and our scientific understanding of COVID-19 evolves, CDC is committed to sharing additional evidence-informed guidance to childcare program administrators, staff, and families to help keep them as safe and healthy as possible.

QUESTIONS SUBMITTED BY SENATOR JEANNE SHAHEEN

ENSURING VACCINE REVIEW AND DISTRIBUTION IS FREE OF POLITICAL PRESSURE

Question. Dr. Redfield, last month, you told governors to prepare for distribution of a COVID-19 vaccine by November 1st. Yet, Dr. Moncef Slaoui, the chief advisor for Operation Warp Speed, said that this timeline is "extremely unlikely" and public health experts make it clear that despite President Trump's predictions, a vaccine may not be available on election day.

Dr. Redfield, what is CDC doing right now to build trust with the American people and ensure that science and public health—not politics—is dictating decision-making for distributing and administering a vaccine?

Answer. CDC continues to fulfill its mission as a data-driven, science-based agency. Our scientists are working 24/7 to respond to the current COVID-19 pandemic, and we are proud of the long history of scientific integrity in our guidance and our publications.

CDC will receive recommendations regarding any potentially licensed or authorized COVID-19 vaccine from both the Advisory Committee on Immunization Practices (ACIP) and the National Academies of Science, Engineering, and Medicine (NASEM).

As outlined in our Vaccination Program Interim Playbook, published on September 16, 2020, we have prepared a vaccination program communication designed to build trust and confidence in the process, and to guide jurisdictions including State, local, and tribal partners to share useful, actionable information with their constituents:

- We recognize the importance of messaging through partners and trusted sources,
- We emphasize key crisis communication principles: be first, be right, be credible, express empathy, and show respect,
- We describe the different phases of communication that will be required through the vaccine rollout process, and
- We encourage development of culturally relevant and sensitive messages.

RECENT CHANGES IN PPE ASSISTANCE FROM FEMA

Question. Dr. Redfield, I am deeply concerned with the administration's decision to stop FEMA reimbursements for purchases of PPE and other medical equipment for what it considers to be non-emergency work. Manchester, NH alone expects approximately \$11 million in COVID-19 related expenditures over fiscal years 2020 and 2021, some of which the City expected FEMA to reimburse. This decision is particularly reckless as communities attempt to reopen schools safely.

Dr. Redfield, do you agree with the administration's decision to stop reimbursement for purchases of PPE that go towards protecting our schools and other critical institutions?

Answer. Employers are responsible for providing a safe and healthy workforce. Some school staff need PPE to perform their jobs safely, such as janitorial and maintenance staff. In light of potential PPE shortages, school administrators should consider modifying staff and student interaction and use engineering and administrative controls as primary prevention and control measures that reduce the need for PPE.

When engineering and administrative controls cannot be implemented or are not fully protective, employers are required by OSHA standards (29 CFR part 1910, Subpart I) to:

- Determine what PPE is needed for their specific job duties
- Select and provide appropriate PPE to staff at no cost, if required
- Train their staff on hazard identification and correct use (including putting on and removing) of PPE.

RELATIONSHIP BETWEEN SUBSTANCE USE DISORDERS AND COVID-19 RISKS

Question. This week, the National Institutes of Health released a study showing that people with a history of substance use disorder were more susceptible to COVID-19 infection. People with substance use disorders made up 10.3 percent of the study's participants, but accounted for 15.6 percent of COVID-19 infected individuals in the study.

Dr. Redfield, what is the CDC doing to support State efforts to mitigate the spread of COVID-19 among people with behavioral health and substance misuse issues?

Answer. CDC shares your concern about the intersection of drug misuse and the COVID-19 pandemic. CDC is monitoring data closely. CDC is working with States, territories, and localities to provide technical assistance to identify mitigation strategies. For example, one State is now using social media and other virtual communications to message the importance of naloxone. CDC is also supporting work to track youth substance use during COVID-19 to intervene and prevent long-term issues.

Harm reduction organizations, including syringe service programs (SSPs) and facilities that provide medications for opioid use disorder (MOUD), have had to adapt in the wake of this pandemic and change their practices to continue serving their

clients. In response, CDC is working to identify and support innovative and emerging practices; up to 15 organizations will be funded. Strategies will be summarized in technical assistance tools for dissemination to partners.

CDC is also working to curb and lower substance use patterns and attitudes among youth whose use has risen during COVID-19.

CDC is working with States engaged in Overdose Data to Action (OD2A), a 3-year cooperative agreement that began in September 2019 and focuses on the drug overdose epidemic, to respond to the realities of how their work is changing in this environment. This includes assessing overdose data to understand trends in light of COVID-19, as well as working with our 66 funded jurisdictions to provide flexibilities where needed and technical assistance to inform public health action during the pandemic.

ADDRESSING CONNECTION BETWEEN COVID-19 AND PFAS EXPOSURE

Question. Dr. Redfield, last time you were here before the Subcommittee, I asked you about a statement from your agency indicating that “exposure to high levels of PFAS may impact the immune system” and “more research is needed to understand how PFAS exposure may affect illness from COVID-19.” At that time, you said the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) were examining those connections.

Dr. Redfield, will CDC and ATSDR help facilitate COVID-19 serological testing for participants in the Pease PFAS Study and the nationwide Multi-Site PFAS Study? Getting serological testing would help determine whether these individuals with known PFAS exposures are more likely to have contracted COVID-19.

Answer. CDC and ATSDR are not currently planning any serological testing for COVID-19 in the Pease Study. The agency is focused on getting back in the field to conduct the PFAS study using the appropriate safety measures to keep staff and community members safe at the Pease Study office by following CDC COVID-19 guidance. At this time, there would be significant challenges to including serological testing for participants in the study, including amending the Office of Management and Budget (OMB) and Institutional Review Board (IRB) protocol which would further delay implementing the study in the field. We continue to explore the possibility of including cohorts, such as those captured in the Pease Study and the multi-site study, in a future study on PFAS and SARS-CoV-2 exposure.

QUESTIONS SUBMITTED BY SENATOR BRIAN SCHATZ

Question. A recent poll found that public confidence in the CDC has dropped significantly since April. What actions has Dr. Redfield taken to increase public confidence in the CDC?

Answer. CDC is providing the American public with the information and assistance it needs to address COVID-19 head on and continues to issue guidance and recommendations based on the best available science and data. As we work together to fight COVID-19 and end this pandemic, CDC is committed to its mission to protect all Americans from disease threats and to save lives.

Question. Given President Trump’s statements contradicting Dr. Redfield’s statements on masks and vaccines at the hearing, does Dr. Redfield maintain his statements?

Answer. Dr. Redfield fully believes in the importance of vaccines and the importance of a COVID-19 vaccine. A COVID-19 vaccine is one tool to helping Americans get back to normal everyday life. The best defense we currently have against this virus are the important mitigation efforts of wearing a mask, washing your hands, practicing social distancing and avoiding large gatherings.

Question. Was the White House, in any way, involved in the CDC’s removal of guidance from its website on how COVID-19 spreads?

Answer. The airborne transmission information posted in late September to the CDC website was posted in error. The guidance had not yet completed appropriate technical review by CDC. Thus, CDC reverted to the guidance that had been technically reviewed. We are reviewing our protocols to prevent this from happening again. Appropriate technical review has now occurred on this topic, and CDC posted updated information to the website October 5: <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html>.

Question. Does the CDC believe that the main way that COVID-19 spreads is through airborne transmission of droplets and aerosols?

Answer. COVID-19 is thought to spread mainly through close contact from person to person, including between people who are physically near each other (within about 6 feet). People who are infected but do not show symptoms can spread the

virus to others. Infections occur mainly through exposure to respiratory droplets when a person is in close contact with someone who has COVID-19. When people with COVID-19 cough, sneeze, sing, talk, or breathe, they produce respiratory droplets. As droplets travel further from the person with COVID-19, the concentration of these droplets decreases. These droplets can range in size from larger droplets, which fall out of the air due to gravity, to smaller droplets which spread apart in the air. Small droplets can also form particles when they dry very quickly in the airstream.

Some infections can be spread by exposure to virus in small droplets and particles that can linger in the air for minutes to hours. This kind of spread is referred to as airborne transmission. These viruses may be able to infect people who are further than 6 feet away from the person who is infected or after that person has left the space. There is evidence that under certain conditions, people with COVID-19 seem to have infected others who were more than 6 feet away. These transmissions occurred within enclosed spaces that had inadequate ventilation. Sometimes the infected person was breathing heavily, for example while singing or exercising. Under these circumstances, scientists believe that the amount of infectious smaller droplets and particles produced by the people with COVID-19 became concentrated enough to spread the virus to other people. However, available data indicate that it is much more common for the virus to spread through close contact with a person who has COVID-19 than through airborne transmission.

Question. There have been major cuts to the public health workforce and State and local health departments are overwhelmed in responding to the pandemic. How is the CDC supporting State and local health departments in carrying out a vast vaccination program?

Answer. CDC has worked for decades with its State and local partners to ensure public health systems are prepared with plans, trained personnel, strategic relationships and partnerships, data systems, and other resources needed for sustaining a successful routine immunization infrastructure. This will help ensure that effective distribution can occur once a safe and effective COVID-19 vaccine is available. CDC is working closely with our government partners in response to this pandemic, including with our sister agencies at HHS. CDC has provided its immunization awardees \$140 million in supplemental funding to support and enhance their immunization programs. This supplemental funding will be used to support awardee and local health department staffing, communications campaigns, pandemic preparedness, and mass vaccination. In addition to other COVID-19 vaccine response work, awardee activities will include a specific focus on significantly enhancing influenza coverage and enrolling and working with additional vaccinators (e.g., pharmacists).

SUBCOMMITTEE RECESS

Senator ALEXANDER. The subcommittee stands adjourned.

[Whereupon, at 12:56 p.m., Wednesday, September 16, the subcommittee was recessed, to reconvene subject to the call of the Chair.]

MATERIAL SUBMITTED SUBSEQUENT TO THE HEARING

[CLERK'S NOTE.—The following outside witness testimony was received subsequent to the hearing for inclusion in the record.]

PREPARED STATEMENT OF THE ALZHEIMER'S ASSOCIATION AND ALZHEIMER'S IMPACT MOVEMENT

The Alzheimer's Association and Alzheimer's Impact Movement (AIM) appreciate the opportunity to submit this statement for the record for the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies hearing entitled "Review of Coronavirus Response Efforts." The Association and AIM thank the Subcommittee for its continued leadership on issues important to the millions of people living with Alzheimer's and other dementia and their caregivers. This statement provides an overview of urgent policies that are needed now to protect this vulnerable population during the COVID-19 pandemic and beyond, including actions for the long-term care community, robust fiscal year 2021 funding for Alzheimer's activities at the CDC and NIH, and efforts to expand capacity for health outcomes through Project ECHO.

Founded in 1980, the Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support, and research. Our mission is to eliminate Alzheimer's and other dementia through the advancement of research to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. AIM is the Association's sister organization, working in strategic partnership to make Alzheimer's a national priority. Together, the Alzheimer's Association and AIM advocate for policies to fight Alzheimer's disease, including increased investment in research, improved care and support, and development of approaches to reduce the risk of developing dementia.

COVID-19 IMPACT ON LONG-TERM CARE

Nursing homes and assisted living communities are on the frontlines of the COVID-19 crisis, where 48 percent of nursing home residents are living with dementia, and 42 percent of residents in residential care facilities have Alzheimer's or another dementia. Residents with dementia are particularly susceptible to COVID-19 due to their typical age, their significantly increased likelihood of coexisting chronic conditions, and the community nature of long-term care settings. Across the country these facilities, their staff, and their residents are experiencing a crisis due to a lack of transparency, an inability to access the necessary testing, inaccurate reporting, and more. According to some reports, nearly 70,000 residents and employees of nursing homes and long-term care facilities have died, representing more than 40 percent of the total death toll in the United States.

The Alzheimer's Association released policy recommendations, *Improving the State and Federal Response to COVID-19 in Long-Term Care Settings*, to address both the immediate and long-term issues impacting these settings during the COVID-19 pandemic. These recommendations focus on four main areas: enhancing rapid, point-of-care testing in long-term care community settings; implementing timely reporting; developing protocols to respond to a rise in cases; and ensuring all facilities have necessary support, like personal protective equipment (PPE) and tele-visitation services.

It is absolutely imperative that each nursing home and residential care community have the onsite testing capability to verify that all residents, staff, and visitors are free of COVID-19 infection, whether or not they are symptomatic. We appreciate the Administration's recent purchase of 150 million rapid tests, a portion of which we expect will be directed to long-term care settings. We also appreciate the recent announcement by the Centers for Medicare and Medicaid Services (CMS) that certain nursing home workers should receive testing as frequently as twice a week. However these actions still fall woefully short of what is urgently needed to protect the vulnerable Americans living in long-term care communities. We continue to advocate for the "White House Standard" of daily rapid-response testing for all new individuals who come onsite, and retesting for returning individuals who enter the facility, in accordance with local guidance. We also support the immediate and accurate reporting of long-term care COVID-19 cases. These reports should be updated upon remission, death, transfer, or other appropriate status update. With all appropriate privacy safeguards for individuals, this reported data should be freely and immediately accessible to everyone, down to the facility level. Any reported

cases should trigger careful, ongoing monitoring and, if conditions warrant, “strike teams” should be deployed to provide needed support until the outbreak is appropriately contained and eliminated. It is also essential that all nursing homes and residential living communities have full, timely access to all needed PPE, testing equipment, training, and external support to keep them COVID-19-free. Importantly, this includes requiring these settings to address social isolation and ensure people with Alzheimer’s and other dementia are able to communicate with their family and friends.

FISCAL YEAR 2021 ALZHEIMER’S APPROPRIATIONS AT CDC AND NIH

Now more than ever it is apparent how crucial it is to have an established infrastructure in place to respond to public health threats. Public health plays an important role in promoting cognitive function and reducing the risk of cognitive decline. Investing in a nationwide Alzheimer’s public health response will help create population-level improvements, achieve a higher quality of life for those living with the disease and their caregivers, and reduce associated costs. The Alzheimer’s Association and AIM thank the Subcommittee for its leadership in providing the Centers for Disease Control and Prevention (CDC) \$10 million in fiscal year 2020 to implement the first year of the BOLD Infrastructure for Alzheimer’s Act (Public Law 115-406). This funding enabled CDC to recently award three Public Health Centers of Excellence, one focused on Dementia Risk Reduction, one on Dementia Caregiving and one on Early Detection of Dementia. CDC also awarded BOLD funding to 16 public health departments at the State, local and Tribal level. While this funding is an important step forward, CDC must receive the full \$20 million authorized for fiscal year 2021 to ensure the meaningful impact that Congress intended.

Furthermore, as the current pandemic has shown, continued investment in medical research is absolutely critical to understanding and responding to diseases. We thank the Subcommittee for its leadership in providing a \$350 million increase in Alzheimer’s research funding at the National Institutes of Health (NIH) in fiscal year 2020. However, if America is going to succeed in the fight against Alzheimer’s, Congress must continue to provide the resources scientists need to do their work. Therefore we urge the Subcommittee to fund the research targets outlined in the Alzheimer’s Professional Judgment Budget by supporting an additional \$354 million for NIH Alzheimer’s funding in fiscal year 2021.

EXPANDING CAPACITY FOR HEALTH OUTCOMES (PROJECT ECHO)

Finally, we ask the Subcommittee to support provisions to expand the use of technology-enabled collaborative learning and capacity-building models. These education models, often referred to as Project ECHO, can improve the capacity of providers, especially those in rural and underserved areas, on how to best meet the needs of people living with Alzheimer’s. During the COVID-19 pandemic, Project ECHO is helping primary care physicians in real-time understand how to use validated assessment tools appropriate for virtual use to make early and accurate diagnoses, educate families about the diagnosis and home management strategies, and help caregivers understand the behavioral changes associated with Alzheimer’s, which can be heightened during isolation. Project ECHO is also helping long-term care providers understand in real-time how to train temporary staff that may not be familiar with how to best care for people with Alzheimer’s, implement important health strategies such as hand-washing and social distancing for people with Alzheimer’s, and effectively communicate with residents to help them understand the COVID-19 pandemic. In fact, the Alzheimer’s Association developed a special topic Project ECHO dementia series to help assisted living communities during COVID-19 based on our guidelines, Emergency Preparedness: Caring for persons living with dementia in a long-term or community-based care setting.

CONCLUSION

The Alzheimer’s Association and AIM appreciate the steadfast support of the Subcommittee and its priority setting activities, especially during this time. However, our Nation must do more to support the millions of Americans living with Alzheimer’s and other dementia, and their caregivers. We urge the Subcommittee and other members of Congress to work in a bipartisan way to advance policies that will help protect this vulnerable population during the COVID-19 pandemic and beyond, including actions for the long-term care community, robust fiscal year 2021 funding for Alzheimer’s activities at the CDC and NIH, and efforts to expand capacity for health outcomes through Project ECHO.

PREPARED STATEMENT OF THE NORTH AMERICAN MEAT INSTITUTE

Chairman Blunt, Ranking Member Murray, and Members of the Committee:

Thank you for holding the hearing, “Review of Coronavirus Response Efforts.” The North American Meat Institute (Meat Institute) appreciates your leadership as the Nation has responded to the novel coronavirus, COVID-19.

The Meat Institute is the Nation’s oldest and largest trade association representing packers and processors of beef, pork, lamb, veal, turkey, and processed meat products, and Meat Institute member companies account for more than 95 percent of United States output of these products. The Meat Institute provides regulatory, scientific, legislative, public relations, and educational services to the meat and poultry packing and processing industry.

On March 18, 2020, the Department of Homeland Security identified food manufacturing as a critical infrastructure sector, which included meat and poultry workers.¹ Those employees have been on the front lines, working in plants and ensuring Americans have access to safe, nutritious, and affordable food. Despite a range of challenges fulfilling unprecedented demand during the pandemic, the industry has proven to be resilient and the supply chain remains intact.

Developing an effective vaccine to COVID-19 is priority 1; developing an effective plan for its distribution is priority 1A. The many workers in the food sector, including those who work in meat and poultry processing plants, should be a top priority for receiving a vaccine. Specifically, meat and poultry workers and USDA inspectors should be given the highest priority for vaccinations in the Tier 2 population.

The National Academies of Sciences, Engineering, and Medicine (NASEM) got it right when NASEM asserted that workers in the population group that includes meat and poultry workers “need to be provided the vaccine, and special efforts must be made to reach these workers in ways that encourage them to be vaccinated.”²

Thank you again for leadership during the pandemic and holding the hearing to review the coronavirus response. The Meat Institute hopes this statement is helpful as the Subcommittee considers COVID-19 vaccine distribution.

PREPARED STATEMENT OF PATIENT ID NOW COALITION

On behalf of the Patient ID Now coalition, thank you for the opportunity to provide written testimony regarding the U.S. Senate’s Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Labor-HHS) hearing, “Review of Coronavirus Response Efforts.”

Patient ID Now is a coalition of healthcare organizations that represents a wide range of healthcare stakeholders committed to advancing through legislation and regulations the development and implementation of a national strategy to address patient identification and matching.

The response to the COVID-19 pandemic has highlighted the need to address patient misidentification throughout the health system. Accurate identification of patients is one of the most difficult operational issues during a public health emergency, including the gathering of patient demographic information (e.g.—address, phone, email, etc.) and ensuring such information remains attached to the correct patient. Field hospitals and temporary testing sites in parks, convention centers, and parking lots have exacerbated these challenges.

Without the ability to accurately identify and match patients to their health information, this critical information becomes lost and safe, effective and timely diagnosis and is jeopardized. For example, there are reports of instances where patient specimens are collected for COVID-19 testing in temporary sites and then sent off-site to a public health lab for testing. Once the results were returned, there have been difficulties matching the results to the correct patient given the inconsistent and scant amount of demographic information included with the sample. This has resulted not only in a backlog of COVID-19 results unable to be sent to patients, but even results being sent to the wrong patient, increasing the privacy and safety risks to the entire community. Without test results being returned to the correct patients, contact tracing and individuals’ own ability to quarantine effectively is hindered.

Correctly matching patients to their information is not just vital for the initial COVID-19 diagnosis. Ensuring the correct patient medical history is accurately matched to the patient is also critical for future patient care, claims billing, patients’

¹ Cybersecurity & Infrastructure Security Agency. <https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>.

² National Academies of Sciences, Engineering, and Medicine, Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine, p. 67.

long-term access to their complete health record, and for tracking the long-term health effects of COVID-19, which the medical community does not currently know.

Furthermore, the nationwide response in the coming months to the COVID-19 pandemic hinges on accurate information. For example, once a vaccine is created, any large-scale immunization programs will depend on accurate patient information to identify who has had the disease, who has been vaccinated, and what their outcomes are. Multiple dose vaccines will rely even more heavily on patient records being complete to ensure the correct timing and dosage for patients to be fully protected. As public health systems increasingly rely on patient data pulled from electronic health records (EHRs), we must make sure that the patient information within these EHRs is accurate in order to have the best public health response to these emergencies.

The COVID-19 pandemic has also laid bare healthcare disparities in underserved communities and populations. As the coronavirus has disproportionately affected these communities, so has patient misidentification, increasingly putting these patients' health at higher risk. According to OCHIN, a national, non-for-profit, health IT service provider for a national network of more than 500 healthcare delivery sites across the country—

- Black patients make up 13 percent of their patient population but 21 percent of duplicate records;
- Hispanic/Latino patients make up 21 percent of the population that OCHIN's members serve, yet they make up 35 percent of duplicates;
- The homeless population makes up 4.3 percent of OCHIN patients, but 12 percent of its duplicates (almost three times the expected rate); and
- Migrant patients make up 2.1 percent of the OCHIN patient population but 3.6 percent of its duplicates.

Failure to accurately identify and match patients to their health information raises serious quality of care and patient safety concerns, which must be a top priority during a pandemic. Difficulties in correctly matching patients to their health information across health information technology systems limits health information exchange, which can result in medical errors, delayed or lost diagnoses, duplicative testing, and wrong patient orders. The problem of patient misidentification is so dire that one of the Nation's leading patient safety organizations, the ECRI Institute, named patient misidentification among the top ten threats to patient safety.¹ Patient matching issues can cause everything from delayed or unnecessary care, to adverse drug events, to even death.²

The problem of patient misidentification extends to hospitals and providers that are already overburdened during this health crisis. Approximately 33 percent of all denied hospital claims are associated with inaccurate patient identification, costing the average hospital \$1.5 million each year, and the healthcare system more than \$6 billion.³ Patient misidentification costs the average clinician almost half an hour in wasted time per shift at a time when many providers are already stretched thin.⁴

Finally, patient privacy must continue to be a priority during a pandemic. Without a national strategy addressing patient identification and matching, the healthcare ecosystem faces an "inverse" privacy problem, whereby individuals must repeatedly disclose individually identifiable information to each healthcare provider they see to accurately match the patients to their medical record. Furthermore, each payer still maintains separate proprietary identifiers for patients, increasing the number of identifiers in use. Even more worrying for patient privacy is risk of overlays—i.e.—the merging of multiple patients' data into one medical record, causing patients to have access to other patients' health information, which could result in an unauthorized disclosure under HIPAA.

The issues around patient identification arise due to a narrow interpretation of a two-decade old appropriations restriction included in Section 510 of the Labor-HHS appropriations bill that prohibits the U.S. Department of Health and Human Services from spending Federal dollars to promulgate or adopt a unique health identifier for individuals. This archaic ban has had a detrimental impact across the healthcare system to patients, providers, and public health. Striking Section 510 from the Labor-HHS appropriations bill will provide the U.S. Department of Health and Human Services the ability to evaluate a full range of patient matching solu-

¹Top 10 Patient Safety Concerns for Healthcare Organizations, Available at: https://www.ecri.org/EmailResources/PSRQ/Top10/2017_PSTop10_ExecutiveBrief.pdf.

²<http://www.healthcarebusinesstech.com/patient-identification-errors/>.

³<https://www.securitymagazine.com/articles/88999-inaccurate-patient-ids-cost-hospitals-15m-a-year>.

⁴<https://www.imprivata.com/company/press/positive-patient-identification-can-dramatically-improve-patient-care-and-hospital%E2%80%99s>.

tions and enable it to work with the private sector to identify a nationwide strategy that is cost-effective, scalable, secure and one that protects patient privacy.

Accurate patient identification and matching must be a top priority during public health emergencies to protect patient safety, patient privacy, and strengthen the public health response. While Section 510 remains in the Labor-HHS appropriations bill, the ability to address these issues will continue to be stifled.

We appreciate the opportunity to provide comments on the issue of patient identity and matching as it relates to the national coronavirus response. We look forward to working with you and acting as a resource on patient identification. Should you or your staff have any additional questions or comments, please contact Kate McFadyen, Director, Government Affairs, AHIMA, at kate.mcfadyen@ahima.org.

PREPARED STATEMENT OF THE PREMIER HEALTHCARE ALLIANCE

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies hearing titled “Hearing to review Coronavirus Response Efforts” scheduled for September 16, 2020. We applaud the leadership of Chairman Blunt, Ranking Member Murray and members of the Subcommittee for holding this hearing to examine the Nation’s response to the COVID-19 pandemic.

The Premier healthcare alliance is a leading healthcare improvement company, uniting an alliance of more than 4,100 U.S. hospitals and health systems and approximately 200,000 other providers and organizations to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide.

COVID-19 has exposed one of healthcare’s fundamental weaknesses: the fragmented and siloed nature of care delivery and the lack of centralized coordination when it comes to managing and preventing disease spread. The public health system continues to rely on flawed data and obsolete technology that consistently fails to accurately identify and track current cases, monitor disease progression, or predict future surges. Not only do these blind spots create opportunities for the disease to spread, they also undermine the ability to safely plan for economic recovery and re-opening of the country.

America Needs to Modernize its Disease Surveillance Process Using the Existing HIT Infrastructure

The COVID-19 public health emergency has heightened the awareness of the need to modernize our public health surveillance capabilities. America needs an automated, near real-time means to collect this symptom and confirmed case information consistently and comprehensively so that it can be shared between and among multiple stakeholders, including Federal, State, local, and tribal public health agencies and authorities. Existing health IT infrastructure and policies governing interoperability, standards and electronic health records (EHRs) can be leveraged to achieve effective and efficient public health systems modernization. The modernized public health infrastructure should include the following components.

- Collection and reporting of standardized and consistent data for use by Federal, State, local and tribal health agencies and authorities.
- Ensure that nationwide syndromic surveillance is achieved by beginning with the collection of signs and symptoms data and add confirmed cases as testing results become available.
- Provide clinical decision support (CDS) to help clinicians follow the latest evidence-based guidelines at the point of care.

Inaccurate patient matching is widespread, disrupts the coordination and quality of care during the COVID-19 pandemic, can cause serious safety events and is costly to the healthcare system

One of the most significant challenges impeding the safe, secure and efficient electronic exchange of health information is the lack of a consistent, national approach to patient data matching. As our Nation’s healthcare providers innovate care to treat and prevent the spread of COVID-19, patient identification and data matching errors have become exponentially more problematic and dangerous.

These challenges stem from a narrow interpretation of archaic language that has been included in Labor- HHS Appropriations bills since fiscal year 1999. We urge the Senate to follow the House of Representatives’ lead and remove the language

from the fiscal year 2021 Labor-HHS Appropriations bill that prohibits spending Federal dollars to promulgate or adopt standards for a national unique patient identifier (UPI) to help improve the Nation's pandemic response and overall public safety. This effort is widely backed by a broad array of healthcare leaders who are united in their commitment to improve safety processes for our Nation's healthcare providers and the patients they serve.

While the issue has received little attention, accurately matching patients to their records is an ongoing challenge for providers and patient mismatching happens at an alarming rate. The Government Accountability Office found that inaccurate, incomplete or inconsistently formatted demographic information in patients' records can pose challenges to accurate matching. When records for different patients are mistakenly matched, or records for the same patient are not matched, it can adversely affect the patient's care. A Pew Charitable Trusts study found that patient matching rates can fall as low as 80 percent, leaving as many as one in five patients not matched to the correct record when receiving care from different providers.

The problem is so serious in fact, that the ECRI Institute, a widely respected national safety patient organization, ranked patient misidentification as one of the top ten patient safety concerns for healthcare organizations. Not only is the lack of unique patient identifiers putting patients in danger and compromising their privacy, misidentification costs the average healthcare facility \$17.4 million per year in denied claims and potential lost revenue. The adoption of electronic health records and the exchange of electronic health information to better coordinate care and encourage value-based payment arrangements is also suffering due to the lack of a national strategy for patient matching and identification.

COVID-19 Elevates the Urgency to Remove the Ban that Threatens the Lives of Americans

As patients' information is exchanged among various types of providers—including hospitals, primary care physicians, specialty physicians, pharmacies, and laboratories—it's imperative that the healthcare information belonging to the same patient is correctly matched. This has never been so critical than during the current public health emergency. With patients getting tested for COVID-19 in different settings such as drive-through and other makeshift testing sites and being treated in field hospitals, ensuring that healthcare records follow the right patient has become extremely problematic.

Providers treating COVID-19 patients in hospitals or other facilities urgently need current and accurate information about patients' laboratory or other diagnostic test results, their medication history and any comorbidities or diagnosed medical conditions to inform their treatment decisions. Public health experts must similarly rely on accurate and timely information on patients to conduct contact tracing and track outbreaks to stem the spread of the disease. Once a vaccine is developed, records must be accurately matched to the correct patient in order to identify who has been infected, who has been vaccinated, and what are the clinical outcomes.

Implementing unique patient identifiers will also help the Nation address the disparate impact of COVID-19 that the Administration has identified during the pandemic. According to OCHIN, the Black, Hispanic/Latino, homeless and migrant population make up a disproportionate share of those who experienced duplication of healthcare records.

Premier urges Congress to remove the ban in the appropriation process to finally address the impediment to patient matching and identification which is putting patients at risk, increasing costs to the healthcare system, perpetuating inefficiencies in care delivery and coordination, and undermining efforts to achieve nationwide interoperability.

CONCLUSION

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies hearing on the response to the coronavirus. Premier is available as a resource and looks forward to working with Congress as it considers policy options to continue to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Duanne Pearson at duanne_pearson@premierinc.com.