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THE PATH FORWARD: A FEDERAL PERSPECTIVE ON THE COVID–19 RESPONSE

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING A FEDERAL PERSPECTIVE ON THE COVID-19 RESPONSE, FOCUSING ON THE PATH FORWARD, AFTER RECEIVING TESTIMONY FROM ROCHELLE P. WALENSKY, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH, JANET WOODCOCK, ACTING COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, AND DAWN O'CONNELL, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, ALL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

JULY 20, 2021

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C O N T E N T S

STATEMENTS

TUESDAY, JULY 20, 2021

THE PATH FORWARD: A FEDERAL PERSPECTIVE ON THE COVID–19 RESPONSE

Tuesday, July 20, 2021

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

The Committee met, pursuant to notice, at 10 a.m., in room 430, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Casey, Baldwin, Kaine, Hassan, Smith, Rosen, Lujan, Hickenlooper, Burr, Paul, Cassidy, Braun, Marshall, Romney, Tuberville, and Moran.

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. Senate Health, Education, Labor, and Pensions Committee will please come to order. Today we are holding a hearing on our Federal response to the COVID–19 pandemic. Ranking Member Burr and I will each have an opening statement and I will introduce our witnesses. After they give their testimony, Senators will each have 5 minutes for a round of questions.

While we are yet unable to have the hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at *help.senate.gov*. And if anyone is in need of accommodations, including closed captioning, please reach out to the Committee or the Office of Congressional Accessibility Services.

We are at a point of great promise and peril in the fight against COVID–19. While I am encouraged by the fact that two-thirds of adults in our Country have received their first dose of vaccine, I am alarmed by how the rate of vaccination has been slowing, and how driven by the delta variant, rates of COVID–19 cases and deaths are once again on the rise. Five counties in my state currently have high levels of transmission according to the Centers for Disease Control and Prevention. For example, in Walla Walla County, cases are up in July from June, and they were up in June from April and May.

Even though 99 percent of the COVID deaths nationwide last month were among people who had not gotten vaccinated, we are still seeing fear and misinformation hold people back, huge disparities in vaccination rates among communities of color and rural communities, skepticism about vaccines among some religious and conservative communities, and slow uptake among youth—young adults. Vaccines are safe, effective and free and easy to get. We

need to make sure people know that. And we also need to make sure they understand. Choosing not to get vaccinated doesn't just put themselves at risk, it puts the people around them at risk and including people who are immunocompromised like those fighting cancer and kids who are not yet eligible for vaccines.

We also have to remember vaccinations are just one front of this fight. Local health departments need the capacity to track emerging outbreaks quickly through contract tracing sequence, virus samples to identify variants, help isolate ill people, and track vaccination progress. And more experts need to evaluate the longevity of immunity, especially in the face of new variants and the potential value of booster shots.

Researchers need to study the long term impacts of this disease and how to treat long haul COVID–19 or PASC. And perhaps most importantly, we as a Nation need to fully learn the lessons of this pandemic and take action so we are never in this situation again. That is why Senator Burr and I have been working on bipartisan legislation and oversight to build the world class public health and preparedness infrastructure our people deserve. It is my hope that through this work, we will not only address challenges we faced during this pandemic but build on progress we saw in some states across the country.

In my home State of Washington, they worked to overcome challenges with sharing critical COVID data among health departments, labs, and hospitals to improve how data was used to allocate critical medical supplies like respirators and develop a more complete dashboard for demographic data that broke out numbers, for example, for the Pacific Islander community. Michigan created a task force on racial disparities early on in the pandemic to ensure they were reaching communities of color for testing and contact tracing.

Alaska literally employed every mode of transportation to deliver vaccines to hard-to-reach communities. One of the clearest lessons from this crisis is that you should have the same protection from a pandemic, chronic disease, or public health threat, regardless of where you live, who you are, or what your income is. And one of the best ways of providing that level of protection is through strong public health infrastructure.

The stronger our health departments are at every level, the more effectively they can work to use sequencing technology and modern data systems to track the spread of diseases and monitor the success of vaccination efforts, stand up testing and contact tracing to stop disease outbreaks, develop science based guidelines to address local needs, build partnerships in hard to reach communities, and build trust as communicators and fight misinformation. There is a saying in health care, an ounce of prevention is worth a pound of cure. We need to have that same mindset when it comes to public health. That is why I have pushed for more funding for public health departments throughout our COVID response packages.

It is why earlier this year I reintroduced legislation to end the cycle of crisis and complacency in public health funding by providing $4.5 billion in dedicated annual funding and is why I am going to continue pushing for us to make these critical investments. We all want this pandemic to end. And it is clear, despite the in-

credible progress we have made in the last few months, we still have a lot more work to do. But even after we are through this crisis, our work won't be done. We have to make sure we learn from this history and take action, so we never repeat it.

This crisis has cost too much, has taken too many lives for us to do anything less. I look forward to hearing from all of our witnesses today. Thank you for being here. We want to hear about our response to this pandemic so far, the path forward, and how we better prepare for threats like this in the future. With that, I will turn it over to Ranking Member Burr for his opening remarks.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Well, thank you, Madam Chair. I am pleased that we are holding this hearing today. Our third panel with members of the Administration, this Congress on COVID–19. To our witnesses, welcome. Welcome back. Some of you are old hands at this now and others are relatively new. Dr. Fauci, Dr. Walensky, thank you for returning to the Committee for the third time this year to discuss this pressing matter. Ms., O'Connell, welcome. This is your first hearing before the Committee in your newly confirmed role as the ASPER.

I am glad that we are able to get you confirmed so quickly. You have a lot of work in front of you and all of us, Republicans and Democrats, are ready to help you and the fine folks at ASPER get the job done. Dr. Woodcock, welcome back to the HELP Committee. The FDA has benefited from your leadership, and you are the right person at the helm as we continue to grapple with the pandemic.

I hope that we will see you again at another hearing to talk about the great things that you are doing at the FDA, preferably a confirmation hearing. I look forward to hearing from each of you on your perspectives of the current response to COVID–19 and what we—where we should go from here. I have spent the better part of my career in Congress working to prepare our Country for the unthinkable and anticipating what we may need to respond to it. These early efforts had the support and leadership of many of my colleagues here now, including Senator Collins, our Chair, Senator Murray, Senator Casey have all been important partners on preparedness with me, working to reauthorize PAHPRA and continue to keep a focus on these items during peacetime. All of this effort was with the hope that we would never have to act on the authorities we provided. But it was also with an eye to what may be around the corner. Each law we wrote was designed to build on the lessons that we learned from each event, Zika, West Nile, SARS and the anthrax attacks.

We tried to anticipate what we didn't think of last time around so that we could be better prepared for when the big one came. This Committee has been holding hearings on COVID–19 response since March 2020, at the very first hearing that raised concerns with our ability to keep pace with the virus, to track its whereabouts, and understand the impact it would have on the lives of the American people. We have the authorities needed, but we were and still are faced with many unknowns.

Each step of the way, we need to look around the corner and ask ourselves, what do we need to do today to keep us up with the

virus 30, 60, and 90 days from now? CDC estimated in mid-June the delta virus, the variant accounted for more than 30 percent of all covered infections. As of mid-July, the cases caused by delta variant may be approaching 60 percent of all cases. The good news is the cases are down significantly since the peak. The bad news is the delta virus—variant is surging and vaccines have slowed because of hesitancy of resistance. I can tell you that the next few weeks and months will require us to answer some very difficult questions, especially as we work toward the last few miles of administering the vaccine in this country. COVID won't just go away.

We need all Americans who can get the vaccine to get the vaccine. If you won't do it for yourself, do it for your friends, your families, for your neighbors, and your local community. Do it for your grandchildren so they can go back to school. Do it for your grandparents so they can finally go out and eat. Not only is a delta variant a concern, but we need to look around the corner to the next mutation of the disease.

I would like to know if we are performing enough sequencing to be able to quickly detect the presence of variants. And are we tracking the right metrics to understand the shift and drift of the virus so that we can see in real time what new variants may mean for our response? Last week, one vaccine company announced it was ready to file for FDA emergency use for booster shot. Do we need booster shots, when do we need them? What does this mean for a widely available vaccine? Israel started offering booster shots last week.

I am worried that American leadership is no longer what it once was when it comes to public health and other countries are outpacing us. We have the same data as Israel. Why aren't we making the same decisions? Messages from public health experts won't be followed if Americans don't believe in the experts. The White House has the power to shape messaging, but it doesn't and shouldn't shape science in any administration. The last Administration lost the attention and trust of the American people with 2 hour press briefings. This Administration shouldn't lose theirs for the sake of the teachers' union. We need to know what we are being told by experts is the unvarnished truth. Don't tell us what you don't think we can handle. Don't tell us what the Administration thinks we should hear. Level with us.

As we sit here today, we are just months away from flu season. How do we get ready for the colder months ahead of us and the flu and cold season that it will bring along with it? Are the flu shots ready? Will we have enough? These questions should have been thought about weeks ago as they are already on our doorstep. The same is true for our legislative efforts and the long term changes we need to make now. While lessons learned from COVID response are top of our mind, the ASPER must play a more prominent role managing the threat landscape in peacetime and commanding the public health and medical response during the emergencies with better coordination among Federal agencies, better availability of data and public health surveillance, stronger partnerships with innovators in the private sector, building on the good work of BARDA, and visibility into our supply chain for critical

drug supplies, which are also—which also need to be more sustainable.

The CDC must be reformed to become a more focused, accountable, and transparent partner in public health and public health preparedness and learn to adopt and leverage 21st century technologies. The NIH should build on its ability to accelerate basic research, leaning on its long expertise in partnering with academia to better understand the pathogens that pose the greatest risk and what tools we may have in the research bench to combat them. And the FDA should build on the great success that we have had, staying the more nimble and creative agency it has become during the COVID–19 response.

This is especially important as the agency works to make final its user fee agreements and transmit them to Congress for our approval next year. Now is the time to anticipate what is next. I encourage each of you, in this critical role that you play to engage with this Committee to provide the insight into the COVID response as you have over the last 18 months, but more importantly, to look ahead. We have a window to update our public health and medical preparedness policies, taking into account the lessons learned from COVID–19 and this Committee intends to act before the attention of Congress turns to other matters.

It is hard to believe, but memories will fade. I have had to fight to keep funding for pandemic and threat awareness too many times to count. I hope to pass that baton onto one of my colleagues to protect these important programs. But before I leave, I feel a great responsibility to make things better in one final bill.

I am glad that the Chair is an active and able partner in that effort. I appreciate her commitment to this bipartisan concern. And I think we have a real opportunity to make improvements. This effort will be our focus going into the fall.

We welcome your feedback, your insight, and most importantly, your expertise. There is nothing more important than the health and security of our Nation. With that, I thank the Chair and I yield.

The CHAIR. Thank you, Senator. With that, I will introduce today's witnesses. We will begin with Dr. Rochelle Walensky. She is the Director of the Centers for Disease Control and Prevention and the Administrator of the Agency for Toxic Substances and Disease Registry. Dr. Walensky, welcome back. Thank you for joining us.

Next, I would like to introduce Dr. Anthony Fauci, who is the Director of the National Institute of Allergy and Infectious Diseases and the Chief Medical Advisor in President Biden's COVID–19 response team. Dr. Fauci, it is good to have you back before the Committee. Thank you for joining us.

Our next witness is Dr. Janet Woodcock, the Acting Commissioner of the Food and Drug Administration. Dr. Woodcock, thank you for being here. I look forward to your testimony. Finally, we have the Assistant Secretary for Preparedness and Response, John O'Connell. It is good to see you, Assistant Secretary O'Connell.

Thank you for joining us. I am pleased to welcome you back to the Committee following your confirmation to this new role. With that. Dr. Walensky, you may begin your opening statement.

STATEMENT OF ROCHELLE WALENSKY, M.D., MPH, DIRECTOR, UNITED STATES CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA

Dr. WALENSKY. Good morning. Chair Murray, Ranking Member Burr, Members of the Senate Health Committee. I am honored to join you today to provide an update on the COVID–19 pandemic and our four priorities of CDC's ongoing response, tracking and preventing further spread of COVID, creating access to and confidence in vaccines, advancing health equity, and getting our children back to school. The current data reveal two divergent truths.

Since the epidemic peaked in January 2021, we have seen large reductions in COVID–19 cases, hospitalizations, and deaths. And these trends are a testament to the success of our vaccination program and the tireless effort of professionals from across health, business, and Government sectors who have come together to respond.

On the other hand, our progress across the country is not uniform. Vaccine coverage varies by state and by county. Communities where people remain unvaccinated, are most vulnerable and most likely to experience increase in case counts. As of last week, nearly 50 percent of vaccine eligible population in this country is now fully vaccinated. 160 million people and still nearly two-thirds of counties in the United States have vaccine coverage less than 40 percent.

In areas where vaccine coverage is low, cases and hospitalizations are starting to climb again. Over the last week, we have averaged 239 deaths per day, an increase of nearly 48 percent over the prior week. Each death is tragic and even more heartbreaking when we know that the majority of these deaths could be prevented with a simple, safe, available vaccine. Areas with limited vaccine coverage are allowing for the emergence and rapid spread of the highly transmissible delta variant. CDC has released estimates of variance across the country and predicted the delta variant now represents 83 percent of sequenced cases.

This is a dramatic increase, up from 50 percent for the week of July 3rd. In some parts of the country, the percentage is even higher, particularly in areas of low vaccination rates. To date, our data indicates that vaccines are available to neutralize but circulating variants in the United States and provide protection against severe disease, hospitalization, and death. The message from CDC remains clear, the best way to prevent the spread of COVID–19 variants is to prevent the spread of disease. And vaccination is the most powerful tool we have.

We must continue to expand vaccine coverage by building trust and confidence in COVID–19 vaccines. And this is particularly important in communities of color, rural communities, and other population groups at risk. CDC is engaging trusted community leaders to reinforce messages about the safety, efficacy, and importance of vaccination. CDC remains committed to ensuring all of our work advances health equity. Thanks to supplemental resources, CDC has provided additional support to health departments to address health disparities and improve health equity among historically underserved populations at elevated risk. That includes racial and ethnic minority groups and people living in rural areas.

We are training and integrating community health workers into care teams, collaborating with partner organizations to improve vaccine access, and building vaccine confidence among medically underserved communities and disproportionately affected populations. As the Director of the CDC, it is my priority to get our children back to school for safe in-person learning. Earlier this month, the CDC released updated guidance to reflect the latest science on COVID–19 and the widespread availability of safe and effective vaccines for those ages 12 and over.

We continue to recommend that schools implement layered prevention strategies to protect those who are not fully vaccinated and encourage vaccination for those who are eligible. Masks continue to be a critical part of these layered prevention strategies. Working together, school administrators and public health workers can carefully consider community transmission rates, local vaccine coverage, and occurrence of outbreaks when deciding what strategies are needed to help prevent the spread of COVID–19 and safeguard in-person education.

In summary, the overwhelming majority of deaths from COVID–19 are now occurring in unvaccinated people. Vaccines are widely available across the country, and the suffering and loss is simply entirely preventable, nearly.

For our entire Nation to heal and move forward, we must do all our part to get our Country vaccinated. Thank you and I look forward to your questions.

[The prepared statement of Dr. Walensky follows:]

PREPARED STATEMENT OF ROCHELLE WALENSKY

Chair Murray, Ranking Member Burr, and distinguished Members of the Committee. It is an honor to appear before you again today to discuss the Centers for Disease Control and Prevention's (CDC) ongoing response to the COVID–19 pandemic. It is my privilege to represent CDC, America's health protection agency. We work 24/7 to prevent illness, save lives, and protect America from threats to health, safety, and security. CDC is proud of its key role in preparedness and response to public health concerns here in the United States and abroad.

CDC Efforts to Date

Since we last met, COVID–19 cases have decreased from the spring to summer, and we have made tremendous strides in getting people vaccinated, which has allowed many people to resume their daily activities safely. We are hopeful and have made incredible progress toward controlling this pandemic. However, many states and communities continue to have low vaccination rates, and the threat of variants is growing. We are now witnessing concerning increases in a number of jurisdictions and given the threat of variants, including the increased prevalence of the hypertransmissible Delta variant, we must remain diligent as we continue to fight this virus.

On June 23rd we officially passed the heart wrenching milestone of over 600,000 deaths from COVID–19 in the United States. This tragic reminder is a powerful motivator for us all to continue to push to achieve higher vaccination rates and prevent the loss of as many more of our loved ones as possible.

As of July 15, about 89 percent of the U.S. population 65 years and older, 68 percent of those 18 years and older, 65 percent of those 12 years and older, and nearly 56 percent of the total U.S. population received at least one dose of a COVID–19 vaccine. This is good news and demonstrative of continued progress. These gains are thanks to the tireless efforts of professionals from across the public health, medical, business, and multisectoral levels of government who have come together across the country to respond to this pandemic. However, looking state-by-state and county-by-county, it is clear that communities where people remain unvaccinated are communities that remain vulnerable and, in many cases, are experiencing increased num-

bers of cases. Preliminary data from a collection of states over the last several months suggest the overwhelming majority of deaths from COVID–19 in the United States have occurred in unvaccinated people. Any suffering or death from COVID–19 is tragic. With vaccines available across the country, the suffering and loss are nearly entirely avoidable.

Currently, nearly two-thirds of counties in the United States have vaccination coverage less than 40 percent. We are seeing increasing rates of disease in different areas across the country, primarily in counties with low vaccination coverage. As the Delta variant continues to spread across the country, we expect to see increased transmission in these communities unless we can vaccinate more people. Our authorized vaccines provide protection against the variants circulating in this country—including Delta. Vaccination is the key to protecting these vulnerable individuals, families, and communities and preventing severe disease, hospitalizations, and death from COVID–19. The scale of this unprecedented public health emergency requires unprecedented action—at CDC, 9,300 CDC personnel have been part of our COVID–19 response, both at CDC headquarters and in the field. About 1,700 staff have taken part in over 3,600 deployments to more than 300 locations across the United States and around the world.

As we well know and the world has learned from this pandemic, a public health threat anywhere is a threat everywhere. To support the prevention of international spread, CDC is working around the world with global partners and many low-and middle-income countries to support the planning, implementation, and evaluation of COVID–19 vaccine programs. We will continue working to facilitate lesson sharing across countries to increase vaccine access to all, both here and abroad. CDC is working to ensure that public health decisions are based on the highest-quality scientific information. Since the start of the pandemic, over 300 COVID–19 studies have been published in the *Morbidity and Mortality Weekly Report* (MMWR) on topics ranging from health disparities exacerbated during the pandemic, to prevention strategies, including the safety and effectiveness of COVID–19 vaccines, to emergence of new variants. CDC has also produced more than 6,000 documents to provide information and guidance for government agencies, businesses, and the public. CDC is actively studying the epidemiology of post-COVID conditions (often referred to as long COVID), including the prevalence, duration, and severity of symptoms following acute SARS-CoV–2 infection, as well as risk factors for developing post-COVID conditions. This work will help to establish a more complete understanding of the natural history of SARS-CoV–2 infection and post-COVID conditions, which can inform healthcare strategies, clinical decision-making, and the public health response to this virus that will be required over the long term. A recent MMWR article comparing patients who have had COVID–19 with cancer rehabilitation patients and the general adult population found that post-COVID patients had poorer physical health, more pain, and greater difficulty with physical activities.

CDC has provided new guidance to assist healthcare professionals in evaluating and caring for patients with post-COVID conditions. Recognizing and confirming the impact that post-COVID conditions can have on quality of life is important. The goal of managing post-COVID conditions is to help patients function in the best way possible and improve quality of life.

Now I want to take a moment to give you a more in-depth update on some key areas for the COVID–19 response.

Variants

COVID–19 has brought to the forefront how interconnected we are as a global community and the importance of our international scientific relationships.

In the fall of 2020, several SARS-CoV–2 variants emerged, some of which appear to spread more easily than others. The emergence of variants is, of course, concerning, and it underscores the critical need for genomic surveillance and increased vigilance in the implementation of public health prevention measures.

We are monitoring dozens of variants and conducting ongoing and comprehensive risk assessments through the SARS-CoV–2 Interagency Group comprised of CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Biomedical Advanced Research and Development Authority (BARDA), the United States Department of Agriculture, and the Department of Defense. We are also in consultation with many of our international colleagues. Of the emerging variants, four have captured our attention and have the highest risk to public health: B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), and B.1.617.2 (Delta).

The Alpha variant, originally identified in the United Kingdom, was first identified in the United States in December 2020, and quickly became the predominant variant. However, based on CDC's most recent data, the Delta variant is now predicted to be the predominant lineage circulating in the United States. The Delta variant was originally detected in India and the earliest known case in the United States was in February 2021. According to CDC's Nowcast model for the two-week period ending July 3, the national proportion of the Delta variant is projected to be 51.7 percent of cases, with the Alpha variant being the second-most predominant variant at 28.7 percent. The third most prevalent variant in the United States is the Gamma variant, with a projected national proportion of 8.9 percent for the two-week period ending July 3. The fourth variant of concern, Beta, is projected to be well below 1 percent.

Available data indicate that antibodies elicited shortly after vaccination with the currently authorized vaccines are able to neutralize the circulating variants, although some have a reduced neutralization against the Beta and Gamma variants in laboratory studies. A recent study from the United Kingdom indicated that the Pfizer vaccine was 93 percent effective at preventing symptomatic infection with the Alpha variant and 88 percent effective at preventing symptomatic infection with the Delta variant, and a related study indicated that the Pfizer vaccine was greater than 95 percent effective at preventing hospitalization when infected with either the Alpha or Delta variants. Based on preliminary data from a Johnson & Johnson vaccine clinical trial in South Africa where the prevalence of the Beta variant was estimated to be 95 percent, the vaccine was 64 percent effective in preventing infection and 81.7 percent effective in preventing severe disease. Additional data from among healthcare workers in South Africa vaccinated with the Johnson & Johnson vaccine demonstrate that 94 percent of breakthrough infections are mild, in a setting with a high prevalence of the Delta variant. Studies are currently underway to understand the impact on the real-world effectiveness of current vaccines against variants and to better understand the impact of the variants on medical countermeasures.

Since January 2021, CDC has dramatically built up our domestic genomic surveillance platforms to monitor circulating variants. While the decline in SARS-CoV–2 cases compared to the high peak this past winter means that the number of specimens available for sequencing has declined, CDC continues to generate enough sequences to detect emerging variants through the National SARS-CoV–2 Strain Surveillance (NS3) program and contracts with commercial diagnostic laboratories.

With the funding provided by the American Rescue Plan Act, we are further investing in public health infrastructure to strengthen genomic sequencing and bioinformatics capacity. We have issued 29 awards, totaling approximately $37 million, as part of the SARS-CoV–2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) Initiative. These awards are intended to fill knowledge gaps and promote innovation in the U.S. response to the COVID–19 pandemic, and will help integrate next-generation genomic sequencing technologies with bioinformatics and epidemiology expertise across the US public health system.

On July 1, to address low vaccination coverage and increasing cases due to spread of the Delta variant in some communities, CDC, along with other Federal partners, intensified our efforts to help states prevent, detect, and respond to hotspots among the unvaccinated by launching COVID–19 Surge Response Teams. With this interagency initiative, CDC will participate in teams at-the-ready to deploy resources and personnel to communities at higher risk for—or already experiencing—outbreaks due to the spread of the Delta variant and under-vaccination. In collaboration with state, tribal, local, and territorial health department partners, interagency teams will define the needs on the ground and work to address these gaps. The most important step we can take to prevent these outbreaks is for everyone eligible to get vaccinated, and we continue to work with communities across the country on that goal.

Health Equity

Data continue to show the disproportionate impact of COVID–19 on racial and ethnic minority populations, as well as other population groups such as people living in rural or frontier areas, people experiencing homelessness, essential and frontline workers, people with disabilities, people with substance use disorders, people who are incarcerated, and non-U.S.-born persons.

In June 2021, CDC began providing additional resources to health departments to address COVID–19-related health disparities and advance health equity among populations that are underserved and facing conditions that place them at elevated

risk, including racial and ethnic minority groups and people living in rural areas. This funding represents an investment by CDC—$2.25 billion over 2 years—to support communities affected by COVID–19-related health disparities. CDC's new National Initiative to Address COVID–19 Health Disparities Among Populations at High-Risk and Underserved Communities, Including Racial and Ethnic Minority Populations and Rural Communities, is providing grants to local and state public health departments to work in partnerships with members of the affected communities to improve testing and contact tracing capabilities; develop innovative mitigation and prevention resources and services; improve data collection and reporting; build, leverage, and expand infrastructure support; and collaborate with partners to advance health equity and address social determinants of health as they relate to COVID–19.

Community Health Workers (CHW) have a demonstrated impact in the communities they serve yet persistent barriers have left them underutilized in addressing health disparities. In May 2020, CDC announced $332 million dollars in CARES Act funding for a grant program and evaluation to support Community Health Workers for COVID Response and Resilient Communities. The program will support the training and deployment of CHWs to bolster response efforts and strengthen community resilience to fight COVID–19 by addressing existing health disparities. CHWs are well-positioned to reach communities, especially those disproportionately impacted by COVID–19. CHW interventions can improve uptake and access to health care services, improve communication between community members and health providers, reduce the need for emergency and specialty services, and improve adherence to health recommendations.

As of May 2021, CDC has released several publications examining vaccination rates in certain population groups to monitor disparities and track progress toward health equity. The first study, *Demographic and Social Factors Associated with COVID–19 Vaccination Initiation Among Adults Aged* ≤65 Years—United States, December 14, 2020–April 10, 2021, found that after the first 3.5 months of the U.S. COVID–19 vaccination program, 79.1 percent of adults aged ≤65 years had received ≤1 dose, with higher vaccination initiation among men. Counties with lower vaccination initiation rates had higher percentages of older adults with social vulnerabilities. The second study, *Disparities in COVID–19 Vaccination Coverage Between Urban and Rural Counties—United States, December 14, 2020–April 10, 2021*, found that COVID–19 vaccination coverage was lower in rural counties (38.9 percent) than in urban counties (45.7 percent) and that disparities persisted among age groups and by sex. A third study, *Patterns in COVID–19 Vaccination Coverage, by Social Vulnerability and Urbanicity—United States, December 14, 2020–May 1, 2021*, found disparities in county-level vaccination coverage by social vulnerability have increased as vaccine eligibility has expanded, especially in large fringe metropolitan (areas surrounding large cities, e.g., suburban) and nonmetropolitan counties. By May 1, 2021, vaccination coverage among adults was lower among those living in counties with lower socioeconomic status and with higher percentages of households with children, single parents, and persons with disabilities.

Collectively, these findings highlight the need to continue monitoring demographic and social factors affecting COVID–19 vaccine access; to prioritize efforts to ensure equitable access to COVID–19 vaccine; to tailor public health messaging for local populations and counties with high social vulnerability; and the need for public health practitioners to collaborate with health care providers, pharmacies, employers, faith leaders, and other community partners to identify and address barriers to COVID–19 vaccination in rural areas.

While these data indicate additional work that lies ahead to achieve greater vaccination rates in certain population groups, we know there are communities that have been successful in their vaccination efforts. In June 2021, as part of the National Month of Action, CDC hosted a webinar as a call to action to increase the number of vaccinated people in Black or African American and Hispanic or Latino communities. The webinar highlighted organizations that have conducted successful mass vaccination activities for Black or African American and Hispanic or Latino people. These organizations shared their successes, challenges, and strategies used to increase vaccine education, awareness, and uptake with the nearly 500 participants from public health, healthcare, clinical, and community organization leadership. This effort is part of CDC's ongoing work to share best practices around the country to help all communities achieve the highest rates of vaccination possible.

To assist decision-makers and researchers, CDC also launched a Health Equity page on our COVID Data Tracker. The page catalogs current health equity-related data that align with populations and place-based focus groups identified in CDC's COVID–19 Response Health Equity Strategy.

Vaccines

Vaccination is a critical tool in bringing this unprecedented pandemic to an end. As of May 10, every person aged 12 and over in every state and territory is eligible to get vaccinated. CDC has continued to improve accessibility by increasing distribution of vaccines to medical offices. We have increased the number of medical practices receiving vaccine by nearly 85 percent since early April and now have over 10,000 medical practices served by primary care doctors, administering vaccine alongside other routine medical care. The country exceeded President Biden's goal of administering 200 million shots in the first 100 days of his Administration. A CDC study [1] reviewing data from 2 months of early vaccinations among health care personnel found that both Moderna and Pfizer vaccines were 94 percent effective in preventing symptomatic SARS-CoV–2 infection, seven or more days after the second dose. In addition, another CDC study [2] found these two vaccines were 94 percent effective against hospitalization among fully vaccinated adults aged 65 years and older. These findings demonstrate the high, real-world effectiveness of these vaccines.

CDC will continue working with partners to monitor how well COVID–19 vaccines work in real-word conditions through multiple studies looking at vaccine effectiveness in various populations, locations, and settings. Through these studies, CDC can obtain more representative, scientifically valid, and complete information about vaccine effectiveness, including factors associated with vaccine breakthrough.

Vaccinations are highly effective against severe disease including hospitalizations and death, thus protecting even the limited number of people who are vaccinated but still get COVID–19. A recent analysis led by CDC published in the New England Journal of Medicine found that mRNA COVID–19 vaccines show secondary benefits of vaccination for people who were fully or partially vaccinated and still got COVID–19. Secondary benefits included having shorter and milder illness and potentially being less likely to spread the virus to others compared to unvaccinated people with COVID–19.

COVID–19 vaccine safety is a top priority for the Federal Government, and we take all reports of health problems following COVID–19 vaccination seriously. Since April 2021, increased cases of inflammation of the heart muscle, called myocarditis, or outer lining, called pericarditis,—have been reported in the U.S. following mRNA COVID–19 vaccination (Pfizer or Moderna). This is a rare condition and reported cases have occurred predominantly in male adolescents and young adults. Following a thorough safety review and meeting of CDC's Advisory Committee on Immunization Practices, which found the benefits of mRNA vaccination greatly outweighed the risks, CDC continues to recommend COVID–19 vaccination for everyone 12 years of age and older, given the risk of COVID–19 illness and related, possibly severe complications. FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events.

CDC and FDA are monitoring reports of Guillain-Barré Syndrome (GBS) after receiving Johnson & Johnson's Janssen (J&J/Janssen) COVID–19 Vaccine. GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness or in the most severe cases paralysis. Reports of GBS after receipt of the J&J/Janssen COVID–19 Vaccine in the Vaccine Adverse Event Reporting System (VAERS) are rare, but do likely indicate a small possible risk of this side effect following this vaccine. Around 100 preliminary reports of GBS, mostly in males, many aged 50 years and older, have been detected in VAERS after 12.8 million doses of J&J/Janssen COVID–19 Vaccine administered. Available data do not show a similar pattern with mRNA vaccines (Pfizer-BioNTech and Moderna). On July 13, the FDA updated the label of the Johnson & Johnson vaccine to add a new warning suggesting an increased risk of Guillain-Barré Syndrome within 42 days following vaccination. This issue will be discussed as part of an upcoming meeting of CDC's Advisory Committee on Immunization Practices (ACIP) later in July. The detection of rare complications, such as myocarditis, thrombosis-thrombocytopenia syndrome (a rare and severe type of blood clot), and GBS, is an important validation of the sensitivity of vaccine safety monitoring systems to be able to pick up even very small numbers of potential vaccine safety concerns.

Building on long-standing relationships with state and local partners, CDC has worked tirelessly to ensure that we are getting vaccines to people as quickly, safely, and equitably as possible. As of July 16, 2021, about 389 million doses have been

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[1] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm's-cid=mm7020e2-w.*
[2] *https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm's-cid=mm7018e1-w.*

delivered, and more than 336 million doses of COVID–19 vaccine have been administered. About 79 percent of all Americans age 65 years and older were fully vaccinated by this date, and about 68 percent of adult Americans had received at least one vaccine. This is a whole-of-society effort, and it is inspiring to see people across government, business, and communities coming together to complete this important lifesaving task.

Strong confidence in vaccines within communities leads to more people getting vaccinated, and to fewer COVID–19 illnesses, hospitalizations, and deaths. CDC is working in coordination with national, state, tribal, local, and territorial governmental and non-governmental partners to build trust in the vaccine, the vaccinator, and the vaccination system. We will continue to work with these critical partners to address barriers to vaccinations, including in communities of color and disproportionally affected groups. It is important that we continually deliver the message that vaccines are rigorously studied during clinical trials, and there is a vast network of safety systems that monitor vaccines once they are in use and safety protocols to monitor people when they receive the vaccine. In order to address vaccine hesitancy, it is crucial to provide accurate scientific messaging across all sectors and multiple platforms, using creative communications approaches such as enlisting trusted community members to help address concerns over COVID–19 vaccines. Listening to, and patiently addressing concerns, including on an individual basis, is a vital method that should be used to build confidence in vaccines.

Further supporting efforts to prioritize equity in our vaccine strategy, in early April CDC awarded $3.15 billion directly to states, territories, and some large cities to support local efforts to increase vaccine access, uptake, and equity. The funding focused on reaching communities hit hardest by the pandemic, including those with a high Social Vulnerability Index, minority communities, and rural areas.

In order to enhance vaccine uptake among underserved communities of color and to build trust and confidence in the authorized COVID–19 vaccines, CDC has developed a comprehensive program of approximately 20 national organizations that support hundreds of local and community-based organizations to improve both COVID–19 and influenza vaccination coverage among racial and ethnic groups who have historically had, and continue to experience, health disparities. Jurisdictions are also encouraged to consider factors such as the Social Vulnerability Index and current administration rates in local communities when reaching out to enroll providers. Guidance was disseminated to jurisdictions on increasing the proportion of vaccines allocated to providers who are located in socially vulnerable communities. In July, CDC added a new Vaccination Equity tab to display Social Vulnerability Index and vaccination coverage maps to the COVID Data Tracker. Improving access to underserved communities and populations that have historically experienced greater barriers to healthcare access is another critical component to prioritizing equity in vaccine distribution. Improving access also requires a multi-pronged approach. For example, CDC partners with the Health Resources and Services Administration (HRSA) to provide COVID–19 vaccinations and technical assistance to interested HRSA-funded health centers, with the goal of bringing vaccines to communities and improving access for populations disproportionately impacted by COVID–19. As of June 29, roughly 7 million doses had been distributed to 2,200 HRSA-funded health centers across the Nation.

The Federal Retail Pharmacy Program is integral to the work CDC is doing to maximize access to COVID–19 vaccines in all communities, including communities of color and other underserved populations, such as rural communities. CDC partnered with 21 national pharmacy organizations and independent pharmacy networks that represent over 40,000 locations nationwide—to ensure that the public has access to COVID–19 vaccines in a familiar setting. Almost 90 percent of Americans live within five miles of a retail pharmacy. These pharmacies continue to reach out to communities, administering almost 3 million doses at nearly 10,000 mobile pop-up clinics, with 58 percent of people vaccinated by pharmacies in the last 2 weeks of June being in a minority group.

On May 13th, CDC released new guidance for fully vaccinated people, which said that, anyone who is fully vaccinated can resume activities—indoor or outdoor—safely without a mask or physical distancing, except where required by Federal, state, local, tribal, or territorial laws, rules and regulations, including local business and workplace guidance. This decision was based on three major scientific developments: (1) Our vaccines working in the real world, with studies showing them to be >90 percent effective in the real-world settings in preventing mild and severe disease, hospitalization, and death, (2) Our vaccines proving to be effective against the SARS-CoV–2 variants currently circulating in the country, and (3) Research showing that if you are vaccinated, you are less likely to spread the virus. A growing

body of evidence suggests that fully vaccinated people are less likely to have asymptomatic infection and to be able to transmit SARS-CoV–2 to others. While we hope this was encouraging news for the country, we must remain vigilant in our efforts to continue increasing vaccination if we want to continue returning to normal. At this time, CDC sees no need to change our fully vaccinated guidance; however we will continue to monitor all indicators and data closely.

Schools

Since becoming the director of CDC, I have stressed the importance of getting children back to school for in-person learning. The safest way to open schools is to ensure that there is as little disease as possible in the community. With the widespread availability of safe and effective vaccines, we have seen reductions in COVID–19 cases, hospitalizations, and deaths. If vaccination rates continue to increase and community transmission rates decrease, the risk in schools is expected to decrease as well.

CDC began working on guidance, resources, and tools for safe school reopening in March 2020 when the first schools closed. As CDC learned more about COVID–19, we continually updated our guidance, resources, and tools for schools, parents, teachers, and other staff. Earlier this month, CDC released updated guidance to help prevent the spread of COVID–19 and safeguard in-person learning. CDC's *Guidance for COVID–19 Prevention in K–12 Schools* is now updated to reflect the latest science on COVID–19, lessons learned from schools implementing COVID–19 prevention strategies, and the widespread availability of safe and effective COVID–19 vaccines for those aged 12 years and older. Reports suggest that limited in—person instruction during the pandemic may have had a negative effect on learning for children and on the mental and emotional well-being of both parents and children. In addition, many K–12 schools globally implemented layered COVID–19 prevention strategies during the 2020–2021 academic year. These schools' experiences contributed to our knowledge of the nature of SARS-CoV–2 transmission in schools and informed updates to the K–12 guidance, which emphasizes the importance of offering in-person learning in K–12 schools.

CDC recommends schools implement layered prevention strategies to protect people who are not fully vaccinated, including students, teachers, staff, and other members of their households. These strategies include vaccination for children and adults ages 12 and up, the correct use of masks, physical distancing, handwashing and respiratory etiquette, cleaning and maintaining healthy facilities (including proper ventilation), and contact tracing, in combination with screening testing, isolation, and quarantine for those exposed and not vaccinated. The guidance emphasizes the need for localities to monitor community transmission, vaccination coverage, screening testing, and occurrence of outbreaks to guide decisions on the level of layered prevention strategies.

Mask use and physical distancing are two key prevention strategies for reducing SARS-CoV–2 transmission, but a layered approach that uses several strategies will provide the greatest level of protection. Schools where not everyone is fully vaccinated should implement physical distancing to the extent possible within their structures, in addition to masking and other prevention strategies. If it is not possible to maintain adequate physical distancing, it is especially important that schools layer multiple other prevention strategies, such as masking and screening testing, to help ensure that no students need be excluded from in-person learning.

In April, CDC provided $10 billion to states and jurisdictions to support COVID–19 screening testing for K–12 teachers, staff, and students to assist schools in reopening safely for in-person instruction. In May, CDC also awarded $500 million to jurisdictions to expand the school-based public health workforce, including nurses and other health personnel. Combined, we believe these resources will provide substantial help to schools around the Nation as they open in the fall.

SARS-CoV–2 is still a relatively new pathogen, and we are learning more about it and how it impacts different people and communities all the time. CDC's Guidance for COVID–19 Prevention in K–12 Schools presents recommendations based on the best-available evidence at the time of release. As science and data on SARS-CoV–2 and COVID–19 continue to evolve, we will update our guidance and recommendations to reflect new evidence. CDC stands committed to providing the best, most current data and scientific understanding available to protect the health, safety, and well-being of our communities, including our students, teachers, and school staff.

Conclusion

In closing, I want to emphasize that with increased vaccinations nationwide, we can look forward to seeing more kids in school, more families able to connect with one another safely, and our Nation beginning to move forward and heal. But we have to ensure that we are stamping out COVID–19 in all communities, not just some communities. We cannot risk only keeping parts of the U.S. moving forward safely while other parts of the country continue to see tragic numbers of cases and deaths from COVID–19. This will require sustained efforts from all stakeholders and across all levels of government and most importantly individuals making the decision to get vaccinated to protect themselves, their loved ones, and their communities.

We also must address the long-standing vulnerabilities in our public health system and the conditions that led to disproportionate burden of COVID–19 illness and death in some communities. The Fiscal Year 2022 President's Budget Request includes an increase of nearly $1.7 billion for CDC to invest across the public health system. This is an important first step in building back a better public health system that can deliver health security to all Americans.

The CHAIR. Thank you.
Dr. Fauci.

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

Dr. FAUCI. Thank you very much, Madam Chair, Ranking Member Burr, Members of the Committee. Thank you for giving me the opportunity to discuss with you again the role of the National Institute of Allergy and Infectious Diseases in the research response addressing COVID–19. As I have mentioned to this Committee on prior hearings, the strategic plan for research for NIAID involves research on fundamental basic knowledge regarding the virus to development of diagnostics, therapeutics, and vaccines.

For the purposes of today's discussion and my presentation, I would like to focus on three vaccines that you know have been approved through the emergency use authorization for use in the United States, and that is the two mRNA vaccines from Pfizer, Biogenetic, and Moderna, and the J&J vaccine, which is a human adenovirus vector vaccine. As I mentioned to this Committee on prior hearings, the clinical trials that proved the extraordinary efficaciousness of these vaccines to the tune of 93 and 94 percent are very, very clear right now.

What I would like to emphasize today is what has transpired since the last hearing, and that is the accumulation of data on the real world effectiveness of these vaccines. In a situation we are confronted with a historic pandemic. And that is seen not only in the United States, but also in the UK in the form of England and Scotland, in Israel, Qatar, and other places.

When one looks at the data, and one good example is the cohort study from Israel in which the mRNA vaccine used in that population was highly effective in the real world beyond the clinical trial, including among asymptomatic, early symptomatic advanced disease, intensive care, and even deaths, and if one looked across the cohort, you saw that it was effective in essentially every age group from young individuals, middle aged, and even the elderly. That is the good news. The sobering news that you have already heard of is the fact that we are now challenged with a very difficult

and problematic variant referred to as the delta variant. It has now been detected in at least 90 plus countries throughout the world.

The reason it is so formidable is the fact that it has the capability of transmitting efficiently from human to human in an extraordinary manner, well beyond any of the other variants that we have experienced up to now, which has led to its becoming the dominant variant in this country. When I spoke to you last time, it was about 1 to 3 percent of the variance in the population. Right now it has gone to over 80 percent, and in some regions of the country, as high as 90 percent. That is the troubling news.

The fact is that, however, and the importance of vaccination is that our vaccines that we are using in this country are very effective against this variant, particularly, I point out, to the situation regarding advanced disease leading to hospitalizations and deaths where it is still well in the 90 percent of effectiveness. I would like to close with just one or two comments that we have been hearing about regarding the situation of booster or an additional third dose superimposed upon the double doses of the mRNA and the single dose of the J&J.

Right now, we are doing studies to determine whether or not we will need boosters to increase the durability of protection. We don't want people to believe that when you are talking about boosters, that means that the vaccines are not effective. They are highly effective. We are talking about the durability of that. And we are doing studies now to determine that.

In addition, there are individuals who are immunosuppressed, people who are on cancer, chemotherapy, a variety of other individuals, transplant individuals who may actually need a boost as part of their initial regimen in the sense of getting them up to the point where they are protected. So in closing, I want to underscore what Dr. Walensky just said a few moments ago, the extraordinary importance of getting as many people vaccinated as we possibly can.

We have the tools to end this epidemic. It is up to us to utilize those tools to the maximum. Thank you very much, Madam Chair.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY FAUCI

Madam Chair, Ranking Member Burr, and Members of the Committee:

Thank you for the opportunity to discuss the role of the National Institute of Allergy and Infectious Diseases (NIAID) in the research response to coronavirus disease 2019 (COVID–19) and its etiologic agent, severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2). Within the Department of Health and Human Services (HHS) and the National Institutes of Health (NIH), NIAID is responsible for conducting and supporting basic and clinical research on emerging and re-emerging infectious diseases, including COVID–19. As the Director of NIAID and the Chief Medical Advisor to the President, I am pleased to discuss NIAID's research addressing this pandemic.

COVID–19 is a once-in-a-lifetime global infectious disease pandemic requiring an unprecedented public-private research effort. NIAID plays a central and important role in the public health response to COVID–19. NIAID has capitalized on decades of investment in fundamental basic research, including groundbreaking structure-based vaccine design at the NIAID Vaccine Research Center (VRC); engaged domestic and international research infrastructure; and leveraged highly productive partnerships with industry and longstanding relationships with community partners. NIAID utilized its existing domestic and international clinical trials infrastructure, originally established to conduct research on HIV and influenza, and worked with partners in the public and private sectors to establish the COVID–19 Prevention Network (CoVPN). The CoVPN has supported multiple COVID–19 vaccine can-

didates to progress in record time from concept to authorization for emergency use by the U.S. Food and Drug Administration (FDA). NIAID also has built on its long-standing relationships with community partners to successfully conduct these crucial clinical trials. NIAID initiated clinical trials with creative and adaptive designs, allowing the evaluation of multiple new and existing therapeutics for use against COVID–19. Several of these trials provided evidence of safety and efficacy of COVID–19 therapeutics and helped support authorization by the FDA.

These successes have helped slow the progression of the pandemic in the United States. Currently, more than 67 percent of U.S. adults have received at least one dose of a COVID–19 vaccine, and we must continue to vaccinate as many people as we can, as quickly as possible. FDA-authorized COVID–19 vaccines meet FDA's rigorous standards for safety and efficacy. The high levels of vaccine efficacy observed in the carefully controlled conditions of clinical trials have been subsequently confirmed by their effectiveness in studies of vaccines administered to broad segments of the public in the United States and other countries. Vaccination and adherence to public health measures are the proven interventions that will be particularly important as we work to address the SARS-CoV–2 Delta (or B.1.617.2) variant and other variants with increased transmissibility or pathogenicity that may emerge.

While we are cautiously optimistic about the future, we know that many challenges remain. One of the most concerning developments of the ongoing pandemic is the spread of variants of SARS-CoV–2 such as the Delta (B.1.617.2) variant. So far, scientific evidence suggests that the COVID–19 vaccines distributed in the United States under FDA Emergency Use Authorizations (EUA) continue to be effective against severe disease caused by these variants, but we must remain vigilant. NIAID is rapidly conducting research to better understand these emerging variants, how they interact with the immune system, and their implications for COVID–19 therapeutic and vaccine formulations.

We also know that our fellow Americans in underserved and minority communities have been disproportionally affected by this pandemic. NIAID is committed to continuing to work directly with these communities and partnering with other agencies in the Federal Government, and with industry and academia to ensure that nobody in vulnerable communities is left behind as we move forward toward defeating the COVID–19 pandemic. NIAID also recognizes that while many individuals with SARS-CoV–2 infection fully recover after a relatively short time period, some individuals suffer longer-term effects after the initial phase of illness. NIAID is supporting collaborative efforts to study COVID–19 outcomes in patients across all ages, genders, and co-morbid conditions. These studies include people who experienced a broad range of COVID–19 disease severity so we can identify and characterize post-acute sequelae of SARS-CoV–2 infection (PASC) and develop effective strategies to address them.

Developing Vaccines and Monoclonal Antibodies to Prevent COVID–19

Sustained research investments by NIAID in the years prior to the emergence of SARS-CoV–2 enabled the unprecedented pace of COVID–19 vaccine development. Two activities in particular predate successful COVID–19 vaccines: the development of versatile vaccine platforms and the adaptation of structural biology tools to design specific proteins (immunogens) that powerfully stimulate the immune system. Long before the pandemic, NIAID VRC scientists and their collaborators made the critical scientific discovery of how to stabilize—in a highly immunogenic form—viral proteins that are important for infection. These included the spike protein of Middle East respiratory syndrome coronavirus (MERS-CoV), which was stabilized using a double mutation known as S2P. This key finding facilitated the design of vaccine candidates that generate robust immune responses not only against coronaviruses but also other viruses of public health importance such as respiratory syncytial virus. As soon as the sequence of SARS-CoV–2 was made available in January 2020, VRC researchers rapidly generated a stabilized SARS-CoV–2 spike protein for use in COVID–19 vaccine development. This crucial breakthrough in structure-based vaccine design for coronaviruses led to the development of safe and effective COVID–19 vaccine candidates across a range of vaccine platforms.

Six candidate COVID–19 vaccines have been or are in the process of being assessed in large-scale Phase 3 clinical trials in the United States thus far, and three have received EUAs from the FDA. Clinical trials to test COVID–19 vaccine candidates in pediatric populations are ongoing. On December 11, 2020, based on data from a Pfizer-supported Phase 3 clinical trial, an investigational vaccine developed by Pfizer and BioNTech became the first to receive an EUA from the FDA for the

prevention of COVID–19. This vaccine is now authorized for emergency use in individuals 12 years of age and older. NIAID has helped to advance five additional COVID–19 vaccine candidates through support for research on the foundational biology underlying the vaccine concepts, as well as for clinical testing through the CoVPN. Two of these vaccine candidates, those from Moderna, Inc., and Johnson & Johnson/Janssen, have received EUAs.

Utilizing the CoVPN, NIAID is participating in the implementation of harmonized protocols to test investigational vaccines and preventive interventions against SARS-CoV–2. These protocols were developed in collaboration with the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, vaccine manufacturers, and the Biomedical Advanced Research and Development Authority (BARDA). NIAID also supports the underlying critical infrastructure for these clinical trials, such as a common Data and Safety Monitoring Board (DSMB), an independent group that periodically reviews data from the ongoing trials to ensure the safety of study volunteers and to determine whether efficacy has been achieved. The CoVPN has enrolled tens of thousands of volunteers across the United States and internationally in clinical trials testing multiple investigational vaccines and monoclonal antibodies intended to protect people from COVID–19. The CoVPN also has developed an extensive community engagement framework to reach out to the underserved and minority communities disproportionally affected by COVID–19; to better understand their interest in, and concerns about, research participation; and to partner with them to ensure that their vital input is reflected in the conduct of these clinical studies.

To further address the critical challenges of participation in clinical trials as well as vaccine acceptance and vaccine hesitancy, NIH established the Community Engagement Alliance Against COVID–19 Disparities (CEAL) initiative, led by the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute on Minority Health and Health Disparities. CEAL brings together trusted community leaders to serve as champions who share information about the importance of participating in COVID–19 research and communicate data on the safety and efficacy of authorized COVID–19 vaccines.

mRNA–1273 (Moderna)

As part of a longstanding collaboration, the NIAID VRC worked with the biotechnology company Moderna to develop a vaccine candidate designated mRNA–1273, which uses a messenger RNA (mRNA) vaccine platform to express the stabilized SARS-CoV–2 spike protein. Early clinical trials demonstrated that mRNA–1273 was generally well tolerated and induced robust immune responses in healthy adults. NIAID and BARDA then began working with Moderna on a Phase 3 clinical trial through the CoVPN that showed that mRNA–1273 was 94.1 percent efficacious in preventing symptomatic COVID–19. On December 18, 2020, after a thorough review of comprehensive data on mRNA–1273, the FDA issued an EUA for the mRNA–1273 vaccine for prevention of COVID–19 in individuals 18 years of age and older. In subsequent observational studies under "real-world" conditions in broader segments of the population, mRNA-based vaccines continue to display high levels of effectiveness. For example, in an article published in *Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention (CDC) researchers and their collaborators showed that among health care personnel, first responders, and other essential workers, the mRNA–1273 and the Pfizer-BioNTech mRNA vaccine were 90 percent effective against SARS-CoV–2 infections 14 or more days after receiving a second dose. Other MMWR articles reported that these vaccines were 94 percent effective at preventing symptomatic COVID–19 among health care personnel and reduced the risk of COVID–19 hospitalization by 94 percent among people 65 years of age and older. Recently, NIAID scientists and their collaborators demonstrated that anti-SARS-CoV–2 antibodies persist for at least 6 months after the second dose of mRNA–1273. On June 26, 2021, FDA updated the EUAs for the Moderna and Pfizer COVID–19 vaccines to include information on the potential risks of myocarditis and pericarditis, particularly following the second dose. According to CDC, reports of myocarditis and pericarditis following vaccination with mRNA COVID–19 vaccines are rare. Most patients who received care have responded well to treatment and rest, and patients usually can return to their normal daily activities after their symptoms improve. Given the significant potential health risk of COVID–19, the CDC continues to recommend that individuals ages 12 and older be vaccinated with the relevant FDA-authorized COVID–19 vaccine.

Ad26.COV2.S (Johnson & Johnson/Janssen)

Decades of NIAID support for basic, preclinical, and clinical research on adenovirus (Ad)-based HIV vaccines underpin the development by Johnson & Johnson/Janssen of a coronavirus vaccine candidate based on the Ad26-vector, known as Ad26.COV2.S or JNJ–78436735. NIAID is supporting a Phase 3 clinical trial of Ad26.COV2.S through the CoVPN and has provided immunological testing of the candidate using NIAID-funded core laboratory infrastructure. As reported in the *New England Journal of Medicine*, the one-dose vaccine candidate was 66 percent effective overall at preventing moderate to severe/critical COVID–19 occurring at least 28 days after vaccination and 85 percent effective overall in preventing severe/critical COVID–19 in the Phase 3 trial across several geographical regions, including areas where emerging viral variants predominate. In the United States, the efficacy against moderate to severe/critical disease 28 days after vaccination with Ad26.COV2.S was 72 percent. On February 27, 2021, the FDA issued an EUA for Ad26.COV2.S for prevention of COVID–19 in individuals 18 years of age and older. On April 13, 2021, out of an abundance of caution, the FDA and CDC released a joint statement recommending a pause in the use of Ad26.COV2.S in order to review extremely rare case reports of blood clots in combination with low blood platelets after vaccine administration. Medical and scientific teams at the FDA and CDC found that available data suggest that the chance of this serious adverse event occurring is very low. Following their thorough safety review—and in accordance with recommendations from the CDC's Advisory Committee on Immunization Practices—the FDA and CDC lifted the recommended pause on the use of Ad26.COV2.S on April 23, 2021. On July 12, 2021, FDA announced revisions to the vaccine recipient and caregivers and vaccination providers fact sheets for the Johnson & Johnson/Janssen COVID–19 vaccine regarding a suggested increased risk of Guillain-Barré syndrome during the 42 days following vaccination. The chance of this occurring following vaccination appears to be very low.

Other COVID–19 Vaccine Candidates

NIAID, through the CoVPN, is supporting Phase 3 clinical trials of COVID–19 vaccine candidates from AstraZeneca (AZD1222) and Novavax (NVX-CoV2373). AstraZeneca's AZD1222 COVID–19 vaccine candidate uses a chimpanzee adenovirus-vectored vaccine approach developed by researchers at the University of Oxford in collaboration with scientists at NIAID's Rocky Mountain Laboratories. On March 25, 2021, AstraZeneca announced an updated interim analysis of AZD1222 reporting that the vaccine candidate was 76 percent effective at preventing symptomatic COVID–19, including 85 percent effective in participants aged 65 years and over. Importantly, the efficacy of AZD1222 against severe COVID–19 disease was reported to be 100 percent. Novavax's NVX-CoV2373 COVID–19 vaccine candidate uses a protein nanoparticle vaccine approach. On June 14, 2021, Novavax announced that NVX-CoV2373 demonstrated 90.4 percent efficacy in preventing symptomatic COVID–19 and 100 percent protection against moderate and severe disease. In addition, the company reported that NVX-CoV2373 showed 91 percent efficacy in preventing symptomatic COVID–19 in people 65 years or older, as well as those with certain comorbidities or those who were identified as being likely to experience regular exposure to SARS-CoV–2. FDA has not yet authorized either of these vaccine candidates.

Clinical Trials of COVID–19 Vaccine Candidates in Special Populations

To effectively end the COVID–19 pandemic, it will be important to vaccinate as many people as possible, including those in special populations, such as pregnant and lactating women, children, and people with immune deficiencies. More than 130,000 pregnant and lactating women already have received the COVID–19 vaccines under FDA EUAs, and early data are promising. These data do not demonstrate any safety concerns for women who are pregnant or their babies. In addition, protective antibodies against SARS-CoV–2 have been detected in babies born to pregnant women who received mRNA COVID–19 vaccines. On June 23, 2021, NIAID launched an observational study, MOMI-VAX, to evaluate the immune responses generated by COVID–19 vaccines administered to individuals during pregnancy or up to 2 months postpartum. The study also will assess vaccine safety and evaluate the transfer of vaccine-induced antibodies to infants across the placenta and through breast milk.

Efforts to evaluate COVID–19 vaccines in pediatric and other special populations are ongoing. On March 16, 2021, Moderna, in collaboration with NIAID and BARDA, announced the launch of KidCOVE, a Phase 2/3 study to evaluate the safe-

ty and efficacy of mRNA–1273 in children ages 6 months to less than 12 years. This study is in addition to Moderna's ongoing TeenCOVE study of mRNA–1273 in adolescents between the ages of 12 and 17. On May 10, 2021, the FDA expanded the EUA for Pfizer's COVID–19 vaccine to include adolescents ages 12 to 15 years of age, and Pfizer also is evaluating their vaccine candidate in younger individuals. Other vaccine developers also have begun, or are planning to begin, trials to test their vaccine candidates in children, adolescents, and other special populations. On April 23, 2021, NIAID launched an observational study at the NIH Clinical Center assessing how people with immune system deficiencies or dysregulations respond to COVID–19 vaccination. NIAID investigators also will gather information about COVID–19 illness in these individuals. This study will inform decision-making about COVID–19 vaccination in people with immune deficiencies and dysregulation conditions.

Monoclonal Antibodies to Prevent COVID–19

NIAID, collaborating with Regeneron Pharmaceuticals and Eli Lilly and Company, also initiated two Phase 3 clinical trials to evaluate whether their investigational monoclonal antibodies, REGEN-COV and bamlanivimab respectively, can prevent infection or symptomatic disease in people at high risk of exposure due to their living or working conditions. Regeneron reported in a preprint publication that REGEN-COV prevented symptomatic and asymptomatic infection in household contacts of individuals who had recently tested positive for SARS-CoV–2. Bamlanivimab also was reported to prevent symptomatic and asymptomatic infection in residents and staff of skilled nursing and assisted living facilities, and these findings were published in the *Journal of the American Medical Association*. FDA has not yet authorized the use of either of these drugs for prevention of COVID–19. Clinical trials to test the safety and efficacy of monoclonal antibody therapies for the treatment of COVID–19 are being tested through the ACTIV partnership, and these are discussed below.

Identifying Therapeutics to Treat COVID–19

Safe and effective therapeutics are urgently needed to treat patients with COVID–19. NIAID has worked quickly from the earliest days of the pandemic to evaluate promising therapeutics for COVID–19 in rigorous, randomized, controlled clinical trials.

The Adaptive COVID–19 Treatment Trial

NIAID launched a multicenter, randomized placebo-controlled clinical trial, the Adaptive COVID–19 Treatment Trial (ACTT), to evaluate the safety and efficacy of multiple investigational therapeutics for COVID–19. ACTT–1 examined the antiviral drug remdesivir for treatment of severe COVID–19 in hospitalized adults. Based on positive data from ACTT–1, the FDA approved the use of remdesivir for treatment in adults and children 12 years of age and older and weighing at least 40 kg hospitalized due to COVID–19. ACTT–2 evaluated the anti-inflammatory drug baricitinib in combination with remdesivir, and based on favorable data from ACTT–2, the FDA issued an EUA for the use of baricitinib in combination with remdesivir for treatment of adults and children older than 2 years hospitalized with COVID–19 and requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation. ACTT–3 currently is evaluating treatment of hospitalized COVID–19 patients with remdesivir plus interferon beta–1a, which is used to treat individuals with multiple sclerosis. ACTT–4, a study assessing baricitinib plus remdesivir versus the glucocorticoid dexamethasone plus remdesivir in adults hospitalized with COVID–19, has closed to enrollment because the study met pre-defined futility criteria.

The ACTIV Public-Private Partnership

NIAID, in collaboration with other NIH Institutes, also launched two clinical trials as part of the ACTIV partnership, which utilizes master protocols allowing the addition of other investigational therapeutics as the trials continue. The two studies, ACTIV–2 and ACTIV–3, initially evaluated the use of the monoclonal antibody bamlanivimab to treat COVID–19 in outpatient and inpatient settings, respectively. ACTIV–2, which is focused on outpatients, has since been expanded to evaluate two combination monoclonal antibody therapies—BRII–196 plus BRII–198 and BMS–986414 plus BMS–986413—as well as four additional investigational therapeutics: SAB–185, a fully human polyclonal antibody produced in cattle; SNG001, an

inhalable beta interferon; and AZD7442, an investigational long-acting monoclonal antibody combination. Camostat mesilate, an orally administered drug that may block SARS-CoV–2 from entering cells, was evaluated but ultimately not included in ACTIV–2 efficacy studies, as it failed to induce early changes in viral shedding or improvement in symptoms. ACTIV–3 currently is evaluating the AZD7442 monoclonal antibody combination, as well as the small molecule ensovibep, in hospitalized patients. Ensovibep binds to several sites on the SARS-CoV–2 spike protein, which may inhibit the virus's ability to infect human cells. On April 22, 2021, NIAID and NHLBI launched a new trial, known as ACTIV–3 Critical Care, to test Zyesami and remdesivir (alone and in combination), for their safety and efficacy in hospitalized COVID–19 patients who are experiencing acute respiratory distress syndrome, a life-threatening condition. Zyesami is a synthetic version of vasoactive intestinal peptide, which is made naturally in the human body and appears to have lung-protective antiviral and anti-inflammatory effects.

Three monoclonal antibody therapies currently have FDA EUAs for the treatment of COVID–19 in outpatients. Due to concerns of variant resistance to monoclonal antibody therapies, the FDA now includes information on the susceptibility of SARS-CoV–2 variants in its fact sheets for health care providers for each of these therapies. NIAID-supported scientists and collaborators are evaluating the potential impact of emerging SARS-CoV–2 variants on the efficacy of monoclonal antibodies.

Additional NIAID-Supported Therapeutics Activities

On April 13, 2021, NIAID announced the launch of the COVID–19 anti-CD14 Treatment Trial (CaTT) to evaluate the use of a monoclonal antibody known as IC14 in adults hospitalized with COVID–19. IC14 works by binding to and blocking a human protein called CD14 that is associated with the development of severe inflammatory reactions in some COVID–19 patients. In addition, NIAID completed a Phase 3 trial called, "Inpatient Treatment with Anti-Coronavirus Immunoglobulin," or ITAC, to evaluate hyperimmune intravenous immunoglobulin (hIVIG) for treatment of COVID–19 in hospitalized adults. The study demonstrated that hIVIG plus remdesivir was not superior to remdesivir alone.

NIAID also launched the ACTIV–5/Big Effect Trial (BET), which is designed to streamline the identification of experimental COVID–19 therapeutics that demonstrate the most promise. BET, an adaptive Phase 2 clinical trial, compares different investigational therapies to a common control arm to identify treatments with relatively large effects as promising candidates for further study in large-scale trials. BET initially is evaluating two therapeutics: risankizumab, an immunomodulatory monoclonal antibody developed by Boehringer Ingelheim and AbbVie, which is FDA-approved for the treatment of severe plaque psoriasis; and lenzilumab, an investigational immunomodulatory monoclonal antibody developed by Humanigen.

NIH recently launched the Antiviral Program for Pandemics, a collaboration between NIH and BARDA that aims to develop safe and effective antivirals to treat and prevent SARS-CoV–2 infection. The program also will build sustainable platforms for targeted drug discovery and development of antivirals directly targeting viruses with pandemic potential. As part of this effort, NIAID will establish Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern. These multidisciplinary research centers will create platforms that will initially target coronaviruses, and then could be expanded to other viruses with pandemic potential—helping to better prepare the Nation for future viral threats.

The NIH also has established the COVID–19 Treatment Guidelines Panel to provide recommendations to health care providers regarding specific COVID–19 treatments based on the best available science. The Guidelines also address considerations for special populations, including pregnant women and children. Each Treatment Guidelines section is developed by a working group of Panel members with expertise in the area addressed in the specific section; these members conduct systematic, comprehensive reviews of relevant information and scientific literature. The Panel comprises representatives of NIH and five other Federal agencies along with representatives of nine professional organizations, academic experts, and treating physicians including providers from high COVID–19 incidence areas, and community representatives. The Panel meets regularly to evaluate possible treatment options for COVID–19 and update the Treatment Guidelines as new clinical evidence emerges.

Responding to Emerging Variants of SARS-CoV–2

NIAID is fully engaged in efforts to mitigate the potential impact of emerging variants of SARS-CoV–2. NIH, including NIAID, participates in the HHS-established SARS-CoV–2 Interagency Group, along with CDC, FDA, BARDA, the Department of Defense (DOD), and the U.S. Department of Agriculture to address the potential impact of emerging variants on critical SARS-CoV–2 countermeasures. NIH, CDC, and DOD are assessing whether vaccine-induced immunity, or natural immunity from prior infection, can be effective in combating the variants. NIH, BARDA, and DOD also are determining the efficacy of certain authorized therapeutics against emerging variants in cell lines *in vitro* and in animal models.

NIAID is collaborating with vaccine manufacturers on key areas of research to investigate whether vaccines designed for the original strain of SARS-CoV–2 can maintain efficacy against emerging variants. NIAID also is conducting and supporting comprehensive studies to understand the ability of vaccine-induced antibodies to neutralize the variant viruses. NIAID researchers have analyzed the immune responses of individuals who recovered from COVID–19 prior to the emergence of variants and demonstrated that their T cells—a key component of the immune response to SARS-CoV–2—also were capable of recognizing the three most widespread SARS-CoV–2 variants at the time, Alpha (also known as B.1.1.7), Beta (B.1.351), and Gamma (P1). These findings, published in *Open Forum Infectious Diseases*, shed new light on the role of T cells in the development of immunity to SARS-CoV–2 and suggest that these cells also may help protect against emerging variants of concern. On March 25, 2021, NIAID launched a Phase 1 clinical trial in healthy adults to assess the safety and immunogenicity of second-generation COVID–19 vaccine candidates developed by Gritstone Oncology, Inc. Gritstone's COVID–19 vaccine candidates utilize a strategy aimed at inducing both neutralizing antibodies and T cell responses to elicit a broad immune response. This approach could provide protection against emerging SARS-CoV–2 variants by targeting several viral antigens, all of which are highly conserved among viral strains.

NIAID also plans to test new vaccine formulations that may protect against certain variants that show early indications of reduced sensitivity to existing countermeasures. On March 31, 2021, NIAID launched a Phase 1 clinical trial of an investigational Moderna vaccine based on its FDA-authorized COVID–19 vaccine, designed specifically to target the Beta (B.1.351) SARS-CoV–2 variant first detected in South Africa. NIAID and Moderna are evaluating this vaccine candidate as a precautionary measure as we gain more data to confirm that current vaccines provide an adequate degree of protection against currently circulating SARS-CoV–2 variants. In addition, NIAID is leading a study in fully vaccinated individuals to determine the safety and efficacy of boosting with a COVID–19 vaccine different than the one used for the initial vaccination. The results of this trial are intended to inform public health policy decisions on the potential use of mixed vaccine schedules should booster doses be needed.

NIAID, the National Human Genome Research Institute, and the National Library of Medicine are participating in the SARS-CoV–2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) initiative. SPHERES is a national genomics consortium led by CDC that helps to coordinate SARS-CoV–2 sequencing across the United States. NIAID is working with partners to identify, monitor, and calculate the frequency of current variations in the SARS-CoV–2 genome to help predict emerging variants. NIAID also facilitates the use of cutting-edge modeling and structural biology tools to understand how variants might affect interactions between the virus and the immune system or COVID–19 therapeutics. NIAID scientists are helping to inform our understanding of transmissibility of the variants by studying their stability in the environment of infected individuals and their ability to grow in human lung cells. These efforts add to a growing body of knowledge about SARS-CoV–2 variants and our ability to combat them.

Understanding the Immunology and Pathogenesis of COVID–19

NIH is supporting studies to understand the incidence of SARS-CoV–2 infection in specific populations, including children, as well as certain aspects of the clinical course of infection, including thromboses, strokes, heart attacks, and other sequelae of infection. NIAID is working with partners to delineate biological and immune pathways responsible for the varied manifestations of COVID–19. NIAID also will examine the quality and durability of the immune response to SARS-CoV–2; this information may be leveraged to develop novel SARS-CoV–2 therapeutics or vaccines and inform public health measures.

NIAID, along with FDA, is supporting a National Cancer Institute (NCI) effort to determine the sensitivity and specificity of certain SARS-CoV–2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV–2. NCI and NIAID also are working to establish a collaborative network to increase national capacity for high-quality serological testing with rapid return-of-results to subjects. These efforts include the use of serological testing to support clinical trials of convalescent serum and the establishment of registries for seroprotection studies.

Early in the pandemic, the intramural research programs of NIAID, NCI, the National Center for Advancing Translational Sciences, and the National Institute of Biomedical Imaging and Bioengineering partnered to rapidly deploy the SARS-CoV–2 Pandemic Serosurvey. The study investigated whether adults in the United States without a confirmed history of SARS-CoV–2 infection have antibodies to the virus, thus indicating prior infection. Findings from the first time point of this longitudinal study suggest that the prevalence of COVID–19 in the United States during the spring and summer of 2020 may have far exceeded the number of cases medically diagnosed. Extrapolating from analyses of blood samples from people who did not have a previously diagnosed SARS-CoV–2 infection, along with socioeconomic, health, and demographic data, the researchers estimate that there may have been an additional 16.8 million undiagnosed SARS-CoV–2 infections through mid-July 2020. Continued analysis of the one-year follow-up data from the study will be very important in better understanding mortality rates, prevalence of immunity, and the impact SARS-CoV–2 has had on various communities in the United States.

NIAID scientists are participating in leadership of the COVID Human Genetic Effort, an international consortium of hospitals and genetic sequencing hubs that aim to discover genetic factors conferring resistance to SARS-CoV–2 infection or predisposing to severe COVID–19 disease. The consortium has identified a subgroup of patients with severe COVID–19 that have ineffective immune responses to SARS-CoV–2, some of whom have identifiable mutations in key immune pathways. NIAID also supports efforts to understand the rare, but extremely serious, multisystem inflammatory syndrome in children (MIS-C) that has been associated with SARS-CoV–2 infection in children and adolescents. NIAID hosted a virtual workshop on MIS-C with scientists and clinicians from academia, NIH, FDA, and industry, and a report of the workshop recommendations was published on November 2, 2020. NIAID also supports the Pediatric Research Immune Network on SARS-CoV–2 and MIS-C (PRISM) to evaluate acute and long-term clinical and immunological effects of MIS-C and SARS-CoV–2 infection in children. In addition, NIAID is collaborating with Children's National Medical Center to follow 1,000 children with a history of SARS-CoV–2 infection, including those with MIS-C, to determine long-term effects of the illness. NIAID is participating in a trans-NIH effort to coordinate MIS-C research led by NHLBI and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. This centralized effort, the Collaboration to Assess Risk and Identify Long-term Outcomes for Children with COVID (CARING for Children with COVID), will permit data to be shared across studies to determine the spectrum of illness and predict long-term consequences of infection.

Monitoring the Long-Term Effects of COVID–19

Many people who have had COVID–19 experience continued symptoms or other sequelae as they transition from the acute to post-acute phases of the disease, and we continue to learn more about the duration and manifestations of COVID–19 as we hear from these patients. In December 2020, NIAID hosted a Workshop on Post-Acute Sequelae of COVID–19 with clinicians, immunologists, virologists, and members of the patient community to present existing data, identify key knowledge gaps, and explore different perspectives on this heterogeneous condition. A report from this workshop highlighting the key scientific questions and knowledge gaps regarding PASC was recently published in the *Annals of Internal Medicine*. NIH has announced the Researching COVID to Enhance Recovery (RECOVER) Initiative, a trans-NIH effort to address PASC, including targeted funding for research in this critical area. The NIH RECOVER Initiative will complement ongoing NIAID studies to better understand the various post-acute manifestations of COVID–19 in various populations.

NIAID intramural scientists initiated the Longitudinal Study of COVID–19 Sequelae and Immunity to better understand PASC and determine whether people who have recovered from acute SARS-CoV–2 infection develop an immune response to SARS-CoV–2 that provides protection against reinfection. NIAID-supported investigators also have established the Immunophenotyping Assessment in a COVID–19 Cohort (IMPACC) to determine how immunological markers correspond to, or may

even predict, the clinical severity of COVID–19. Since May 1st, 2020, IMPACC researchers have collected detailed clinical data along with blood and respiratory samples from more than 1,200 hospitalized COVID–19 patients of diverse race and ethnicity at approximately 20 hospitals nationwide. The cohort will be followed during hospitalization and up to 1 year after discharge to assess their functional and immunologic recovery.

Conclusion

NIAID continues to expand efforts to elucidate the biology, pathogenesis, and clinical manifestations of SARS-CoV–2 infection, including emerging variants, and to employ this knowledge to develop safe and effective interventions to diagnose, treat, and prevent SARS-CoV–2 infection and COVID–19. NIAID is focused on developing safe and effective SARS-CoV–2 vaccines and therapeutics and sensitive, specific, rapid point-of-care molecular diagnostic and serological tests. NIAID also is conducting early stage research on candidate vaccines that could protect against multiple strains of coronaviruses. All these efforts will improve our response to the current pandemic and bolster our preparedness for the next, inevitable viral disease outbreak.

The CHAIR. Thank you.
Dr. Woodcock.

STATEMENT OF JANET WOODCOCK, M.D., ACTING COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. WOODCOCK. Good morning, Chair Murray, Ranking Member Burr and Members of the Committee. Thanks for the opportunity to be here today. I am going to provide a brief update of what the agency has been doing in our COVID–19 response. But first, I want to start by recognizing the thousands of FDA employees who have really been working nonstop for the past year and a half. I really commend their efforts and thank them for their service to the country. It has been extraordinary.

From the earliest days of this public health emergency, there was a need for reliable diagnostics, as we all know. We began gauging developers in early January 2020. And as of last week, FDA has authorized nearly 400 tests and sample collection devices that provide a wide range of options for testing beyond diagnostics. We have evaluated emergency use requests for ventilators and novel devices such as continuous renal replacement therapy products. We continue to review additional submissions for COVID medical devices and rigorously monitor safety signals and reports, including their performance against variance for the products on the market.

This is in addition to addressing numerous device shortages that occurred during the pandemic and working with our Government partners to prevent counterfeit and substandard PPE and other products from entering the United States because, of course, people take opportunities to try to get substandard products into the country. FDA has also supported development and availability of COVID therapeutics as expeditiously as possible. On March 31st, we announced the creation of an emergency review and development program, the Coronavirus Treatment Acceleration Program. We reassigned staff from other areas to review the hundreds and hundreds of requests from companies, scientists, and doctors who are working to develop treatments as of June 30th.

We have reviewed more than 460 trials for potential COVID therapies. These include antivirals, neutralizing antibodies, cell

and gene therapies, and combinations of these products. The diversity of therapeutic approaches that are being investigated is really critical to increasing our knowledge of this disease in its different stages. And these efforts have led to one approved drug therapy to treat COVID–19 and 10 therapeutics currently authorized for emergency use.

In addition, FDA issued EUA, as you know, for three COVID–19 vaccines. These vaccines were authorized without cutting corners or sacrificing our rigorous standards. Intensive interactions between FDA and manufacturers minimize the time between different ordinary phases of the clinical development process and allowed for seamless movement through development, manufacturing, and our rigorous scientific review.

Throughout the vaccine authorization process, we took steps to facilitate transparency and trust by posting trial data, putting out guidances on what our standards would be, key decisional memoranda, and we held public advisory committee meetings. These vaccines have met the standards and quality to support an EUA and are helping, as you have heard, in our fight against the pandemic. Our work did not end with the authorization of these vaccines, though we have to share as much information as we can with the public to help with trust and transparency. We are also deeply involved with CDC on the safety surveillance for the vaccines as they go into millions of healthy people to understand what adverse events might be related. And we continue to find that the known and potential benefits of these vaccines far outweigh the known risks, even as additional rare risks have been discovered.

All this is in addition to the critical work we do to protect the Nation's food supply, which also came into some jeopardy during this, and to interdict substandard medical products at our ports of entry, courier facilities, and international mail facilities. Since March 2020, with coordination with Customs and Border Protection colleagues, we have intercepted and destroyed almost 60,000 illegal and unapproved medical products that were attempting to get into the country.

FDA has also played a major role in investigating the numerous shortages of medical products that have occurred during the pandemic. Partnering with our sister agencies represented here and far beyond, we have responded quickly and decisively while maintaining our commitment to protecting the health of the American people. We look forward to working with the Committee to address further issues. Thank you.

[The prepared statement of Dr. Woodcock follows:]

PREPARED STATEMENT OF JANET WOODCOCK

Introduction

Chair Murray, Ranking Member Burr, distinguished Members of the Committee, I am Dr. Janet Woodcock, Acting Commissioner of the U.S. Food and Drug Administration (FDA or the Agency). Thank you for the opportunity to testify before you today to describe FDA's coronavirus disease 2019 (COVID–19) response efforts. All of our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the Federal Government, to help ensure the development, authorization, licensure, and availability of critical, safe, and effective medical products to address the COVID–19 public health emergency.

I want to note at the outset that this is just a snapshot of some of our recent work and is in the context of efforts across the Agency to address this pandemic. There are thousands of FDA employees who have been working non-stop for the past year-and-a-half. I want to commend and recognize their efforts and thank them for their service.

From the beginning of this public health emergency, FDA has taken an active leadership role in the all-of-government response to the COVID–19 pandemic, inspired by the resiliency of the American people and our great innovators. FDA stood up an internal cross-agency group that continues to ensure we are doing everything possible to protect the American public, help ensure the safety, efficacy, and quality of FDA-regulated medical products, and provide the industries we regulate with the guidance and tools to do the same. We continue to focus on facilitating the development and availability of medical countermeasures to diagnose, treat, and prevent COVID–19, surveilling the medical product and food supply chains for potential shortages or disruptions, and helping to mitigate such impacts, as necessary to protect the public health.

Biologics and Vaccines

FDA's Center for Biologics Evaluation and Research (CBER) uses every tool available to help patients access promising biological products while facilitating research to evaluate their safety and efficacy as well as manufacturing efforts.

CBER is working on multiple fronts to address the COVID–19 pandemic, including:

- Expediting clinical trials for vaccines and certain therapeutic biological products that hold promise to prevent or treat COVID–19 by providing timely interactions, scientific advice, and recommendations for specific sponsors, and generally through guidance documents;
- Supporting product development and facilitating the scaling up of manufacturing capacity for high priority products to treat COVID–19;
- Expediting the review of Emergency Use Authorization (EUA) requests and Biologics License Applications (BLAs) for critical medical products to address COVID–19;
- Helping to ensure an adequate and safe blood supply; and
- Providing information to healthcare providers and researchers to help them submit expanded access IND requests to permit the use of investigational products for patients with COVID–19.

Through our transparent scientific review process, FDA has issued EUAs for three COVID–19 vaccines. In doing so, we have relied upon the Agency's rigorous standards for safety, effectiveness, and manufacturing quality. Development of a vaccine generally proceeds sequentially through the various stages of clinical development; ordinarily this process minimizes scientific and financial risk for the manufacturer. Manufacturing scale-up only takes place when the data support the safety and effectiveness of a vaccine and it is on track for regulatory approval. These three COVID–19 vaccines were developed without cutting corners or sacrificing our standards. Intensive interactions between FDA and manufacturers minimized the time between different studies in the clinical development process; allowed seamless movement throughout the different phases of clinical trials; and simultaneously facilitated manufacturers proceeding with manufacturing scale-up before it was clear whether the safety and effectiveness data for a vaccine would support EUA.

For the three vaccines authorized to date, our EUA process not only included a thorough evaluation of the data by the Agency's career staff, but also included input from independent scientific and public health experts through our public advisory committee meetings. Throughout this process, FDA took additional steps to facilitate transparency, such as posting sponsor and FDA briefing documents and key decisional memoranda.

The three authorizations make available COVID–19 vaccines in the United States that have shown clear and compelling efficacy in large, well-designed phase 3 trials. These vaccines have met rigorous standards for safety and effectiveness to support EUA and are helping us in the fight against this pandemic. All the COVID–19 vaccines that FDA has authorized for emergency use are at least 50 percent effective compared to placebo in preventing COVID–19, which is the expectation we conveyed in our June 2020 guidance document, *Development and Licensure of Vaccines to Pre-*

vent COVID–19.[1] A vaccine with at least 50 percent efficacy, we noted, would have a significant impact on disease, both at the individual and societal level.

As part of our continued efforts to be transparent and educate the public, we have a wealth of information on our website about the authorized COVID–19 vaccines. The information includes fact sheets for healthcare providers (vaccination providers) and vaccine recipients and caregivers, with important information such as dosing instructions; information about the benefits and risks of each authorized vaccine; and topical Questions and Answers developed by FDA for each authorized vaccine.[2]

It is also important to highlight that, as part of each EUA, we are requiring the manufacturers and vaccination providers to report serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS), and cases of COVID–19 that result in hospitalization or death to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety surveillance program jointly run by FDA and the Centers for Disease Control and Prevention (CDC).

These surveillance efforts have led the Agency to take steps to proactively address emerging safety signals. In April, out of an abundance of caution, FDA and CDC recommended a pause in the use of the Janssen COVID–19 vaccine while we investigated reports of thrombosis with thrombocytopenia syndrome. Later that month, after careful evaluation of the data, FDA announced revisions to the vaccine recipient fact sheet to include information about the risk of thrombosis with thrombocytopenia, and the vaccination provider fact sheet to include a warning about the risk of thrombosis with thrombocytopenia syndrome. We concluded that the available data suggest that the chance of this serious adverse event occurring is very low. FDA and CDC determined that the recommended pause regarding the use of the Janssen COVID–19 vaccine in the U.S. should be lifted and use of the vaccine should resume. As with all of the COVID–19 vaccines, we continue to closely monitor the safety of the Janssen COVID–19 Vaccine.

On June 25, FDA announced revisions to the vaccine recipient and caregivers and vaccination provider fact sheets for the Moderna and Pfizer-BioNTech COVID–19 vaccines regarding the suggested increased risks of myocarditis and pericarditis following vaccination. The chance of these adverse events occurring following administration of either the Moderna or Pfizer-BioNTech COVID–19 vaccine appears to be very low, but the level of potential risk due to vaccination is still under investigation. FDA and CDC are monitoring the reports, collecting more information, and will follow-up to assess longer-term outcomes over several months.

On July 12, FDA announced revisions to the vaccine recipient and caregivers and vaccination providers fact sheets for the Janssen COVID–19 vaccine regarding a suggested increased risk of Guillain-Barré syndrome during the 42 days following vaccination. The chance of this occurring following vaccination appears to be very low.

At this time, data are not yet available to make a determination about how long these authorized vaccines will provide protection, nor are we certain that the vaccines prevent transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) from person to person. Additionally, although we do not yet know the full range of SARS-CoV–2 variants that each of the authorized vaccines will protect against, there is evidence that the current vaccines protect against disease caused by variants circulating in the United States.

Finally, manufacturers whose COVID–19 vaccines have been authorized for emergency use are expected to continue their clinical trials in order to obtain additional safety and effectiveness information and pursue licensure (approval).

Having three vaccines authorized to date that meet FDA's expectations for safety and effectiveness only 1 year after the declaration of the COVID–19 pandemic is a tremendous achievement and a testament to the dedication of developers and FDA's career scientists and physicians. We are highly engaged in ensuring that all COVID–19 vaccines meet the high quality that Americans expect and deserve and are also actively engaged in ensuring the safety of these vaccines following deployment. FDA is also working with international partners as part of multinational efforts to end this global pandemic. We have provided guidance and technical assistance, and continue to share information as we evaluate and release vaccine doses for use in other countries. The Agency is very proud of these efforts, and we believe that the vaccines will help bring this pandemic to an end.

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[1] *https://www.fda.gov/media/139638/download.*

[2] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently asked-questions.*

Therapeutics

Since the beginning of the COVID–19 pandemic, FDA has been working tirelessly to facilitate the development and availability of therapeutics for use by patients, physicians, and health systems as expeditiously and safely as possible. FDA has also accelerated the development and publication of guidance and other information for industry and researchers on developing COVID–19-related treatments. Further, on March 31, 2020, FDA announced the creation of an emergency review and development program for possible therapies for COVID–19, the Coronavirus Treatment Acceleration Program, or "CTAP." The primary goal of CTAP is to help accelerate the development of therapeutics for patients and consumers. The Agency has supported the program by reassigning staff and working continuously to review requests from companies, scientists, and doctors who are working to develop therapies. Under CTAP, FDA is using every available authority and regulatory flexibility to facilitate the development of safe and effective products to treat patients with COVID–19. As of June 30, 2021, there are more than 630 drug development programs in planning stages and the Agency has reviewed more than 460 trials of potential therapies for COVID–19. These include antivirals, immunodulators, neutralizing antibodies, cell and gene therapies, and combinations of these products. The diversity of therapeutic approaches being investigated is important because it rapidly expands our understanding of the effect of different categories of potential treatments.

FDA has approved one drug to treat COVID–19 and eleven therapeutics are currently authorized for emergency use. Our goal is to be as transparent as possible about the scientific basis for recommending that a drug or biological product be authorized for emergency use under section 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb–3) or for recommending that an EUA be revised or revoked.

FDA also continues to work closely with manufacturers to mitigate and prevent shortages as the COVID–19 pandemic evolves. For example, the Agency has issued three EUAs to authorize the emergency use of certain therapeutic products intended to treat serious or life-threatening diseases or conditions (e.g., Acute Kidney Injury, Acute Respiratory Distress Syndrome) caused by COVID–19 after determining that the FDA-approved alternatives to these products were not available in sufficient quantities to fully meet the emergency need. This has helped to alleviate shortages of some therapies that are essential for the care of critically ill COVID–19 patients. FDA is also working with manufacturers to increase supplies to meet current demand by expediting review of applications. In addition, the Agency has prioritized the review of generic drug applications for potential treatments and supportive therapies for patients with COVID–19, such as antibiotics, sedatives used in ventilated patients, anticoagulants, and pulmonary medications. In June 2021, FDA reached a milestone of approving 1,000 original and supplemental generic drug applications since the start of the pandemic to help in the treatment of patients with COVID–19. This supports FDA's everyday mission of improving access to safe, effective, high-quality treatment options, especially during the COVID–19 pandemic.

Medical Devices

The need for medical devices to respond to the COVID–19 pandemic has far exceeded what we experienced in any prior Public Health Emergency (PHE). The first EUAs issued for the COVID–19 PHE were for medical devices, and the volume of EUA requests quickly surpassed (by two orders of magnitude) that of any prior PHE or other situation. Further, the emergency use requests included submissions for devices that CDRH had never received EUA requests for during prior PHEs. This included ventilators and novel devices such as continuous renal replacement therapy devices. Since the start of the pandemic, FDA has issued EUAs or granted full marketing authorization to almost 1,500 medical devices for COVID–19-related uses. In addition, FDA rigorously monitored safety signals and medical device reports using the information to publish 21 letters to healthcare providers and seven safety communications, and FDA completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID–19.

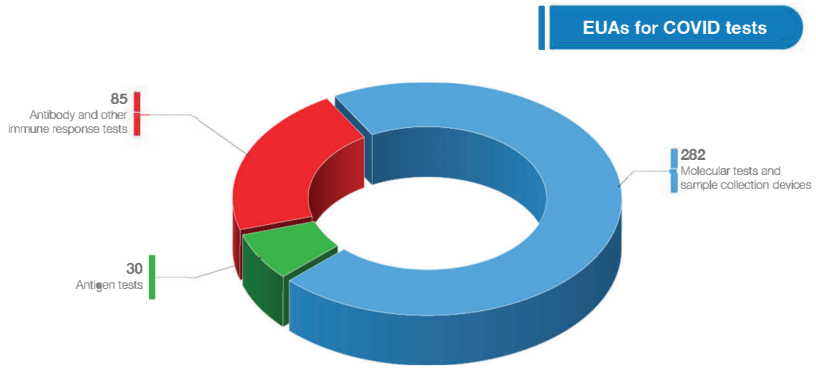
Diagnostic tests are the first line of defense in an outbreak, and FDA plays an important role to ensure they work through EUA review. The EUA pathway expedites access to accurate diagnostic tests during emergencies, when information gaps and false results may adversely affect individual patient care and public health decision-making. EUAs enable molecular diagnostic tests to be developed, validated, authorized, and deployed within weeks rather than several months to over a year, as is typical for test development and traditional premarket submissions. The Agency has employed its EUA authorities to facilitate availability of tests in each PHE or

threat situation since 2009, when the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics. In PHEs, FDA is generally open to receiving and reviewing EUA request for tests from any developer, including commercial kit manufacturers and laboratories.

FDA sought to facilitate COVID–19 test evaluation and authorization through the development and availability of templates. The templates provide recommendations for test validation and a fill-in-the-blank form to streamline the paperwork and make it easier for developers to provide information in support of a request for emergency use authorization. Since providing the first template in January 2020, FDA has been in daily contact with test developers to answer questions and help them through the EUA process. This has proved to be a helpful tool for many. FDA has now made nine templates available for a variety of test types. As of July 13, 2021, these nine templates have received 510,725 hits from those visiting FDA's website. FDA also supported test developers through establishment of a dedicated mailbox, 24–7 toll-free hotline that ran until July 2020, the posting of over 100 frequently asked questions on our website, and by hosting weekly virtual town halls for test developers. The Agency has worked with over 1,000 test developers since January 2020.

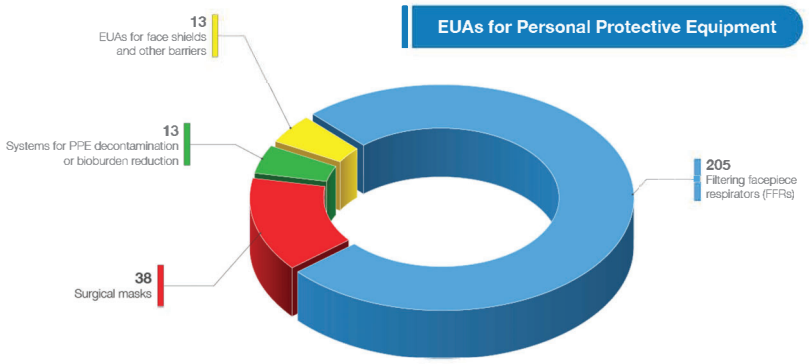
Since early 2020, FDA has adopted agile, interactive, and innovative approaches to EUA review for all types of devices. For example, FDA developed the umbrella EUA approach to efficiently authorize multiple devices of the same type meeting the same criteria. The Agency has also issued 28 guidance documents (including 17 revisions) outlining policies to help expand the availability of medical devices needed in response to COVID–19. For example, developers of certain tests offered their tests, upon validation and notification to FDA prior, to issuance of an EUA during Agency review of the EUA request. Further, FDA made several improvements to our EUA review processes to make the most efficient use of our resources, including establishing a front-end triage process to identify devices that would have the greatest impact on the public health. These improvements incorporate the latest information on device availability and shortages, prioritizing novel or critical devices not yet available on the market or those that would address significant device shortages.

As of July 13, 2021, FDA has authorized 397 tests and sample collection devices for SARS-CoV–2. As noted in the graphic below, these include 282 molecular tests and sample collection devices, 85 antibody and other immune response tests, and 30 antigen tests. Among these are 11 diagnostic tests that can be run at home (three molecular and eight antigen tests), seven of which do not require a prescription. We have also authorized 18 tests for serial screening programs (11 antigen and seven molecular). The volume and variety of available tests is a testament to FDA's support of innovative test design and our commitment to public health.



FDA has authorized a wide variety of other medical devices for use in combating the pandemic, including a wide range of personal protective equipment (PPE), ventilators, and other therapeutic devices. As of July 13, 2021, FDA has authorized 270 PPE devices including 39 surgical masks, and has authorized 205 filtering facepiece respirators (FFRs), 13 systems for PPE decontamination or bioburden reduction at

the time there was a need for these types of devices due to PPE shortages,[3] and 13 EUAs for face shields and other barriers intended to protect the user from bodily fluids, liquid splashes, or potentially infectious materials (see related graphic below). In addition to granting EUAs, FDA has also cleared, through its premarket notification pathway, over 250 PPE 510(k)s.



FDA recognizes that medical devices, particularly tests, will continue to play an important role in the next phase of the pandemic response. The Agency is continuing to monitor its policies, the marketplace, and national needs, and will continue to adapt as the circumstances of the evolving pandemic warrant.

Human and Animal Food

Food security is national security. Thus, throughout the pandemic, FDA has worked with Federal, state, and local partners, as well as industry, to help ensure a safe and adequate food supply for both people and animals.

While SARS-CoV–2 is not transmitted by food, some components of the food system experienced challenges and supply chain imbalances, particularly at the outset of the pandemic. Overall, food production and manufacturing in the U.S. has remained resilient. We continue to monitor the food supply chain systems closely to efficiently and promptly identify mitigation strategies when necessary. Early on, the pandemic caused a significant shift in where consumers were buying food. We took steps to provide temporary guidance to provide flexibility in packaging and labeling requirements to help industry redirect products manufactured for food service and institutional use to retail grocery stores, or if needed to the animal food industry so the food does not go to waste.

FDA also recognizes that food supply chain continuity and worker safety are two sides of the same coin. Thus, a robust food supply is dependent on the safety and health of the Nation's food and agricultural workforce. Along with our federal, state and local partners, we have provided best practices for food and agricultural workers, industry, and consumers on how to stay safe, and help ensure the continuity of operations in the food and agriculture critical infrastructure sector during the

[3] *https://www.fda.gov/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems.*

pandemic and now as restaurants and other retail establishments resume regular operations.

In response to the pandemic, FDA's Office of Food Policy and Response, Center for Food Safety and Applied Nutrition, Office of Regulatory Affairs, and Center for Veterinary Medicine developed *21 Forward*, a food supply chain data management tool, to help identify where risks for interruptions in the continuity of the food supply due to COVID–19 transmission among workers may be greatest. As part of *21 Forward*, FDA also conducted targeted outreach to the food industry to offer additional resources and technical assistance in addressing challenges.

In collaboration with HHS, CDC, and US Department of Agriculture (USDA), data from *21 Forward* have been made available to assist states with their vaccine distribution efforts for workers in the food and agriculture sectors, including migratory and seasonal agricultural workers.

FDA's Coordinated Outbreak Response and Evaluation team has been working throughout the pandemic, is fully staffed, and on the job looking for signs of foodborne illness outbreaks and initiating responses as needed. FDA's Center for Veterinary Medicine is also monitoring the animal food supply and initiating needed responses, working closely with other veterinary diagnostic laboratories in its Veterinary Laboratory Investigation and Response Network (VET-LIRN). In terms of inspectional work, FDA investigators continue to conduct mission-critical inspections domestically and abroad, including inspections and investigations in response to foodborne outbreaks during the pandemic. FDA transitioned to standard operations for domestic surveillance inspections in July 2021. Additionally, our import investigators and laboratory analysts continue to work on-site by:

- Staffing our ports of entry, helping to ensure the efficient distribution and safety of the Nation's imported food supply; and
- Conducting examinations, sample collections, and laboratory analyses of imported and domestic food to ensure the safety of our Nation's food supply.

FDA continues to screen every line of every shipment of imported food entering the United States utilizing our Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) tool. We adjusted the algorithm in PREDICT to place increased scrutiny on shipments from facilities where foreign inspections have been postponed. FDA has made greater use of our Foreign Supplier Verification Program (FSVP) regulation to oversee compliance with FDA Food Safety Modernization Act (FSMA) requirements. The shift to remote FSVP inspections, along with other tools utilized by the foods program, has been critical to ensuring the safety of human and animal food from foreign suppliers during the COVID–19 pandemic. Since March 26, 2020, FDA has conducted 1,888 FSVP inspections. Since March 2020, FDA has refused approximately 8,469 lines of imported food products. FDA will continue to target and refuse human and animal foods that are unsafe, misbranded, or may cause a serious health concern for the public.

FDA continues to closely monitor the overall safety of the Nation's food supply, in collaboration with CDC, USDA, U.S. Customs and Border Protection (CBP) and our state and local partners, to protect consumers from foods contaminated with pathogens.

One year ago, FDA announced the New Era of Smarter Food Safety Blueprint outlining the Agency's plans over the next decade to create a more digital, traceable, and safer food system. We have learned from our response as an Agency to the pandemic that there is an accelerated need for certain goals in this blueprint, especially those involving supply chain continuity and resilience, modernized inspectional approaches, and strengthening food safety infrastructures with regulatory partners.

Inspections, Compliance, and Protecting the Medical Supply Chain

Similar to their work protecting the food supply, import investigators have been onsite protecting the medical supply chain at our ports of entry, courier facilities, and the international mail facilities (IMFs) throughout the pandemic. Through continued vigilance, FDA has prevented unsafe and unauthorized pharmaceuticals and other medical products from entering the country. Since March 2020, with the cooperation of and in coordination with CBP, FDA has received and destroyed almost 60,000 products, totaling over 11,093,868 capsules, pieces, and tablets of illegal or unapproved drugs.

Since March 2020, FDA has refused approximately 94,725 lines of imported violative medical products. We have maintained the same level of pre-pandemic screen-

ing for imported products. However, FDA has focused examinations on COVID–19 relief supplies to ensure compliant products are expedited while maintaining our commitment to refusing imported medical products that are unsafe, misbranded, unapproved, counterfeit, or may cause serious illness or injury to the public. In fact, our import and domestic officers have evaluated donations of shipments destined for the Federal Emergency Management Agency (FEMA) and met the first vaccines (Pfizer Belgium) on their arrival into the United States in December 2020 to ensure proper transport, storage, and reconciliation of products. Our officers also assisted with expediting the importation of other compliant vaccine-related shipments.

Despite pausing domestic and foreign surveillance inspections in March 2020 to safeguard the health and well-being of our staff, as well as employees at facilities we inspect, our investigators continued to conduct mission-critical inspections both domestically and abroad to ensure FDA-regulated industries were meeting applicable FDA requirements. In July 2020, FDA resumed prioritized domestic inspections. To arm our investigators with the most reliable and accurate information, FDA developed a rating system to assist in determining when and where it was safest to conduct prioritized domestic inspections.

On May 5, 2021, FDA issued a report titled, "Resiliency Roadmap for FDA Inspectional Oversight," outlining the Agency's inspectional activities during the COVID–19 pandemic and its detailed plan to move toward a more consistent state of operations, including FDA's priorities related to this work going forward.

The report outlines inspections that the Agency was unable to complete during the past year due to travel restrictions or inability to ensure the safety of our workforce or the workforces within the industries the Agency regulates. The report also outlines the number of mission-critical inspections FDA completed during that time, such as inspections of facilities for which there was a drug shortage, inspections needed for the approval of novel drugs or drugs related to the potential treatment of COVID–19, support of pre-market and pre-license applications, and response to foodborne disease outbreaks or other food safety risks such as food contaminated with pathogens.

Of note:

- From March 2020 through March 2021, FDA conducted a total of 821 mission-critical inspections, including 29 in foreign countries.
- Additionally, the Agency conducted a total of 777 prioritized domestic inspections since resumption of that work in July 2020.
- Of the more than 13,500 applications for medical product approval or authorization received since March 2020, only approximately 68 applications have been delayed due to the inability to conduct inspections—and a majority of these applications are not deemed mission-critical.

Additionally, the Resiliency Roadmap Report outlines FDA's continued, successful use of alternative tools and approaches where inspections were or are not currently feasible, including remote interactive evaluations (e.g., remote livestreaming video of operations, teleconferences, or screen sharing), making record requests to regulated establishments, and leveraging information from trusted regulatory partners. For example, FDA made over 1,300 record requests to human and animal drug and biological product manufacturers, to support on-time regulatory decision actions. In addition, since March 2020, FDA has added products from 18 firms to import alerts as subject to detention without physical examination, based on records requests in advance or in lieu of inspection that FDA submitted pursuant to section 704(a)(4) of the FD&C Act.

Notably, FDA's bioresearch monitoring program staff have conducted more than 130 remote interactive evaluations that were directly used for application decisions.[4] The new tool was incentivized for and supported by industry and continues to provide the Agency with valuable information to assist with risk-based targeting for inspections. FDA recognizes that remote approaches do not replace inspections, and that there are situations where only an inspection is appropriate based on risk and history of compliance with FDA regulations.

The Resiliency Roadmap Report further outlines the ongoing steps the Agency is taking to resume standard operational levels of inspection activities, including how it intends to prioritize domestic and foreign inspections that were not performed during the pandemic. The plan highlights a variety of possible scenarios given the continued uncertainty of the trajectory of the ongoing COVID–19 pandemic. On July

[4] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/remote-interactive-evaluations-drug-manufacturing-and-bioresearch-monitoring-facilities-during-covid.*

1, FDA activated the base-case scenario (COVID response continues on current trend) to transition to standard operations for domestic inspections and other operational work, as detailed in the report. Inspections considered critical to FDA's mission will remain the primary focus. When planning routine surveillance inspections, the Agency will prioritize higher-risk establishments. This means that postponed inspections will be prioritized based on risk and conducted over a longer period of time, ultimately increasing the amount of time between inspections of certain lower-risk facilities in order to focus on products that present the greatest risk to public health.

The Agency will also soon begin a multi-year modernization effort to further transform our data enterprise platforms and cross-program interoperability infrastructure to better support innovation related to its regulatory oversight role. This includes adopting technology to support regulatory assessments to improve our remote receipt, review, and analysis of industry data and records, and improve remote interactions with industry entities to be easier, more efficient, more consistent, and more secure. This modernization effort will include a review of inspectional approaches using next-generation assessment technologies and improvements. FDA is also establishing an Agency-wide Inspectional Affairs Council that will provide for coordination of inspection approaches and assessment processes. The Agency intends to share more information on these efforts as this work progresses. FDA will continue to leverage and maximize every available tool and resource to meet its inspectional responsibilities, while achieving optimal public health outcomes.

Compliance and Enforcement

FDA exercises its regulatory authority by, among other things, issuing warning letters and pursuing civil and criminal actions against firms and individuals who do not comply with regulatory requirements, including those selling unapproved products with false or misleading claims that the products prevent, treat, mitigate, diagnose, or cure COVID–19. In March 2020, FDA launched Operation Quack Hack, which leverages Agency expertise and advanced analytics to protect consumers from fraudulent medical products, including unproven cures, illegitimate test kits, and substandard or counterfeit respirators. FDA has sent thousands of abuse complaints to domain name registrars and internet marketplaces. The Agency also has sent more than 241 warning letters to sellers of unproven COVID–19 products. Working with the Department of Justice (DOJ), FDA has sought and obtained preliminary injunctions that require defendants to halt the sale of fraudulent products claiming to treat or prevent COVID–19, including one product, "Miracle Mineral Solution," that, when used as directed, is equivalent to industrial bleach.

In addition, FDA's Office of Criminal Investigations (OCI), working with other Federal and local law enforcement agencies, investigated a hospital pharmacist who tampered with COVID–19 vaccine doses at a Wisconsin hospital where he worked. On two successive overnight shifts at the hospital in late December 2020, the pharmacist purposefully removed a box of COVID–19 vaccine vials manufactured by Moderna—which must be stored at specific temperatures for specific time periods to remain viable—from the hospital's refrigeration unit intending to render the vaccines inert and no longer effective. The pharmacist acknowledged that after leaving the vaccines out for several hours each night, he returned them to the refrigerator to be used in the hospital's vaccine clinic the following day. Before the full extent of his conduct was discovered, 57 people received doses of the vaccine from these vials. In January 2021, the pharmacist pled guilty to two counts of attempting to tamper with consumer products with reckless disregard for the risk that another person will be placed in danger of death or bodily injury. He has been sentenced to 3 years imprisonment, followed by 3 years of supervised release, and he must pay approximately $83,800 in restitution to the hospital.

In addition, FDA investigators remain on the front lines at ports of entry, quickly examining, reviewing, and sampling import entries, and refusing admission where appropriate. We protect the supply chain in two equally critical ways, by helping to ensure that (1) safe products are coming in; and (2) illegal, dangerous, and fraudulent products do not get into the country. These efforts include partnering with CBP in establishing satellite laboratories at selected IMFs with scientists using state-of-the-art screening tools to rapidly identify unapproved, counterfeit and illicit products.

In March 2020, OCI, with the help of domestic law enforcement partners and foreign counterparts in the United Kingdom, led the investigation of fraudulent COVID–19 "treatment kits" that were falsely declared as "water treatment." Import examination of these shipments found misbranded "kits" intended to treat SARS-

CoV–2. As a result of this investigation, a British national was charged and arrested for shipping mislabeled and unapproved products. Subsequently, in April 2020, FDA intercepted a bulk shipment of hydroxychloroquine coming from China going to a physician in California. The physician was thereafter charged with mail fraud and making a false statement stemming from the allegations that he smuggled hydroxychloroquine from China to make his own pills and concealed the shipment from CBP by mis-declaring it as yam extract. In May 2020, FDA worked with CBP to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before getting into U.S. commerce.

More recently, FDA has taken steps to address hand sanitizer products that pose safety concerns, such as products that do not meet the required ethanol or isopropanol levels, or that contain or may contain toxic ingredients like methanol or 1-propanol. Regarding the latter, substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Ingesting 1-propanol can cause central nervous system depression, which can result in death. FDA has tested several hundred products using field-based and laboratory-based tools, found more than a hundred violative products, issued warnings to consumers not to use contaminated hand sanitizers, and has taken steps to help ensure that these dangerous or subpotent products do not enter domestic commerce. FDA has coordinated with CBP to identify such products, and we have listed products made by more than 40 manufacturers on import alert. FDA also placed all alcohol-based hand sanitizers from Mexico on a countrywide import alert to help stop products from entering the United States that appear to be in violation until the Agency is able to review the products. That action marked the first time the FDA has issued a countrywide import alert for any category of drug product.

Medical Product Supply Chain

FDA monitors and responds to worldwide demand and supply chain disruptions for medical products caused by the COVID–19 pandemic. We work closely with manufacturers to help ensure they continue to notify the Agency of any permanent discontinuance or interruption of drug (human and animal), biological product, and device manufacturing in a timely manner and, as noted in FDA's fiscal year 2022 budget, we are working to better position the Agency and our health care system to assure a strong domestic supply chain in future emergencies. [5]

In addition to our usual communication with drug manufacturers, we work closely with healthcare and pharmacy systems, hospitals, providers, and others on the frontlines of COVID–19 patient care to identify current or emerging regional shortages of critical care drugs used to treat COVID–19.

FDA understands the significant impact shortages can have on patient care and is doing everything within our authorities to help prevent and alleviate disruptions. When we identify a shortage, we react swiftly to mitigate the impact to U.S. patients and health care professionals, and quickly share that information with the public. For example, we issued temporary policies for outsourcing facilities registered with FDA and pharmacists in state-licensed pharmacies or Federal facilities, regarding the compounding of certain drugs used to treat hospitalized patients with COVID–19 when approved drugs are not available. The Agency has also published guidance to help applicants and manufacturers provide FDA with timely and informative notifications about changes in the production of certain drugs (including animal drugs) and human biological products, and urging the submission of these notifications, which may assist in our efforts to prevent or mitigate shortages of such products.

The Agency quickly identified the need to help ensure widespread access to hand sanitizers as demand spiked, while also continuing our mission to ensure these products are not contaminated by removing adulterated products from the market. FDA has published and continues to update three guidance documents designed to help facilitate the production of alcohol-based hand sanitizer in non-traditional settings such as pharmacies or distilleries. The Agency has launched several enforcement initiatives and import alerts to help stop adulterated and subpotent hand sanitizer products from getting into U.S. distribution channels.

Our experience with COVID–19 demonstrates that a strong domestic supply chain depends on a resilient supply chain for medical devices as well. Indeed, multiple entities across the public and private sector have important parts to play in strengthening the domestic medical device supply chain. FDA can play a critical role in iden-

[5] *https://www.fda.gov/media/149616/download*.

tifying and preventing shortages for devices, because the Agency not only reviews and authorizes these products, but also has unique, collaborative relationships that allow direct engagement with device manufacturers, patients, distributors, healthcare organizations and other stakeholders. Even before the pandemic hit the United States, there were already problems in the supply chain due to demand for devices in other nations where COVID–19 was already prevalent. As a result, FDA began shortage mitigation activities for medical devices in January 2020 before the PHE was declared in the U.S., and months before a pandemic was declared worldwide. The Agency took several actions to rapidly respond to supply chain needs, including reassigning 130 staff to perform shortages work across CDRH and contacting over 1,000 manufacturing facilities in 12 countries in just a few weeks' time to get as much information as possible about critical devices.

In addition, FDA has conducted horizon scanning to assess demand for devices needed to respond to the pandemic, including PPE, ventilators, diagnostic supplies, infusion pumps, and non-contact infrared thermometers; and established a rapid response team, working with field personnel to address fraudulent imports. The Agency has likewise worked to prevent and mitigate shortages of testing supplies. For example, FDA collaborated with U.S. Cotton, one of the world's largest manufacturers of cotton swabs, to develop and produce a polyester-based swab for testing. FDA also collaborated with laboratories and clinical investigators validating potential alternative sources of control materials, transport media, and swabs. As individual developers validated these alternative components, FDA requested their permission to share their findings publicly so that others could benefit, and we posted these alternatives on our website. In this way, FDA has been serving as a clearinghouse for scientific information that the entire community can leverage to mitigate shortages and increase testing capacity. FDA continues to post this information on a rolling basis on an FAQ website so that labs have access to the latest information regarding alternative controls, transport media, extraction, instruments, and swabs.

Congress has acknowledged the importance of this work to our health care system, and we want to continue working with this Committee and others to ensure FDA has the resources and authorities needed to ensure U.S. patients and health care providers have the products they need each day, and especially during public health emergencies.

Conclusion

FDA continues to advance its mission to protect and promote public health by ensuring the safety of human and animal food, and the safety and effectiveness of medical products. We take our public health mandate very seriously and will continue to work each day to end this pandemic. We continue to communicate with the American public and make regulatory decisions based on data and sound science. I look forward to continuing to work with the Committee on these efforts and thank you again for the opportunity to testify today.

The CHAIR. Thank you.

Assistant Secretary O'Connell.

STATEMENT OF DAWN O'CONNELL, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Ms. O'CONNELL. Chair Murray, Ranking Member Burr, and distinguished Members of the Committee, I am honored to testify before you today regarding efforts within the Office of the Assistant Secretary for Preparedness and Response to support the ongoing response to COVID–19. First, let me thank you for your support of my confirmation. It was just 6 weeks ago that I was before you as a nominee, and it has been just over 3 weeks since I was confirmed as the ASPER.

I am honored that you have entrusted me with this important role, and I pledge to do everything I can to maintain your trust and confidence in my abilities to lead this Office with vision, precision,

and transparency. While I continue to assess ASPER's work, one thing is abundantly clear. The ASPER team is working tirelessly to end this pandemic, and I am pleased to share some examples of the work that they are leading. As you know, the Strategic National Stockpile, or SNS, worked to backstop states' medical supply needs when the pandemic strained global supply chains.

The SNS has deployed more than 200 million items including personal protective equipment or PPE, ventilators, Federal medical stations, and pharmaceuticals. ASPER has invested approximately $10 billion from COVID–19 supplementals to replenish the SNS to levels at or above pre-COVID–19 amounts. A new mission ASPER has taken on over the course of the pandemic is securing the medical supply chain. This work is complex and challenging and has forced our organization to stretch in new ways. A secure and resilient medical supply chain is not only necessary for our current COVID–19 response but will be critical for any nationwide response that follows.

ASPER is investing in industrial base expansion efforts to reduce supply chain vulnerabilities and generate a domestic warm base for manufacturing that can be leveraged in a crisis. So far, ASPER has supported efforts for domestic manufacturing of PPE, active pharmaceutical ingredients, COVID–19 tests and supplies such as reagents and resins.

In support of this work, ASPER is also leveraging the authorities delegated to the secretary under the Defense Production Act to ensure that private sector partners making life saving products have the materials they need to deliver their product. So far, ASPER has priority rated 55 contracts to directly and indirectly support the COVID–19 response effort.

ASPER will continue to leverage all of the tools we have at our disposal to ensure the supply chain is secure and that we are never again in this situation we found ourselves in last year. The national disaster medical system has completed nearly 5,400 mission assignments. The teams have brought surge capacity to ICU and emergency rooms, established medical overflow centers, provided mortuary support in places like New York City, established sites to deliver therapeutics, and operated Federal vaccination sites. They are currently standing by to participate in surge teams being stood up by the Administration to respond to recent hotspots.

The ASPER's Biomedical Advanced Research and Development Authority, or BARDA, has supported over 65 medical countermeasure projects for the COVID–19 response. Most notably, BARDA led the vaccine development work for what was then known as Operation Warp Speed and is now known as the Countermeasures Acceleration Group and advanced the development of the three vaccines currently authorized by the FDA.

This was done, as you know, at historic speed with less than a year between the identification of the virus in the authorization of the first vaccine. ASPER is also working with HHS leadership and the Department of Defense to transition the Countermeasures Acceleration Group to a long term sustainable management structure within HHS. Dr. Robert Johnson, a senior leader at BARDA, recently assumed the responsibilities as the Chief Operating Officer of the mission.

I look forward to using this transition planning period as an opportunity to evaluate gaps and bring in the additional logistical capacity needed at ASPER and HHS to sustain the enduring mission for as long as it is required. As we move forward, I would like to build on this foundation to accelerate and recalibrate the work where needed and continue to do all we can to bring an end to the pandemic as quickly as possible.

Thank you again for inviting me to testify and allowing me to share these examples of the work ASPER is leading on behalf of the Administration wide COVID–19 response effort. I look forward to answering your questions.

[The prepared statement of Ms. O'Connell follows:]

PREPARED STATEMENT OF DAWN O'CONNELL

Chair Murray, Ranking Member Burr, and distinguished Members of the Committee, it is an honor to testify before you today on efforts within the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) to support the ongoing response to COVID–19. I am grateful for this opportunity to address this Committee and appreciate your continued support for the ongoing response efforts.

When I first appeared before the Committee in early June as the ASPR nominee, I shared my top three priorities for the office, which are reflected in the Fiscal Year 2022 Budget request:

> First, I wanted to ensure that ASPR has the resources and support necessary to continue its critical COVID response work, and help the Nation emerge quickly from the current pandemic. This critical work is in addition to our normal preparedness and response efforts for natural disasters, chemical, biological, radiological, and nuclear incidents, and pandemic influenza PI events.
>
> Second, I wanted to restore and strengthen capacities that have become strained during the COVID–19 pandemic. Specifically, I wanted to ensure the Strategic National Stockpile (SNS) is appropriately resourced, replenished, and ready to respond to future challenges, and that the medical supply chain is resilient and can support our country's needs.
>
> Finally, I wanted the organization to increase readiness for future public health emergencies by working with our colleagues both inside the Department and across the interagency to prepare for whatever manmade or naturally occurring threats may come next.

A month into the job, these remain my top priorities. Every passing day I am awed by the hard work and dedication of the ASPR team. It is clear to me that they are working as hard now to end the pandemic as they did when the outbreak first began. Today, I am pleased to share with you an update on the tireless work they have been doing to respond to COVID–19.

Update on ASPR's COVID–19 Response Effort

Countermeasures Acceleration Group

The response to the COVID–19 pandemic has required an unprecedented whole of government approach. As you are familiar, HHS and the Department of Defense (DoD) forged a partnership formerly called Operation Warp Speed (OWS) that is now known as the Countermeasures Acceleration Group (CAG). This partnership brought together the two Departments to develop, manufacture, and deliver safe and effective vaccines and therapeutics to the American people. ASPR has played a significant leadership and coordination role on behalf of HHS in the effort. This endeavor has delivered nearly 390 million vaccine doses and over a million therapeutic doses to protect the American people from COVID–19.

In addition, the President has committed to sharing 580 million doses of vaccine with the world. This includes half-a-billion Pfizer doses the United States will purchase and donate to 100 countries in need—the largest-ever donation of COVID–19 vaccines by a single country, and a commitment to share 80 million doses of our

own surplus U.S. supply. The CAG has delivered nearly 40 million vaccines to 25 countries, with millions more en route.

Now, work is underway to transition DoD's role in the CAG to HHS for long term sustainability and management. Dr. Robert Johnson, the Director of the Influenza and Emerging Infectious Diseases Division of ASPR's Biomedical Advanced Research and Development Authority (BARDA), assumed the responsibilities as the Chief Operating Officer of the CAG earlier this month. Under Dr. Johnson's leadership, ASPR's role in the response is more apparent than ever.

Biomedical Advanced Research and Development Authority

ASPR's BARDA has supported over 65 medical countermeasure projects for the COVID–19 response. All of these contract awards are listed on *medicalcountermeasures.gov* in detail and include 14 therapeutics, 48 diagnostics, and seven vaccine candidates. Notably, BARDA, as part of the then-Operation Warp Speed, accelerated the availability of three vaccines—Moderna, Pfizer, and Johnson & Johnson. This was done at historic speed, with the novel virus identified and the first vaccine authorized in under a year.

Looking forward, BARDA will leverage the supplemental appropriations provided by Congress to continue its work as part of the CAG to support the development of additional vaccines and therapeutics to end the COVID–19 pandemic. There are still populations—like children under the age of 12—that cannot yet receive the vaccine as we complete careful clinical testing. It is critical that the work continue to develop vaccines and to establish successful treatments for those who do become infected. I look forward to working with this Committee on specific plans toward this effort.

Strategic National Stockpile and Medical Supply Chain

The pandemic has severely strained our public health and medical supply chains. As this Committee is well aware, the medical supply chain ecosystem is complex, with different private sector players and market dynamics across categories of medical equipment and supplies. Many vital products are primarily made overseas, and practices like "just in time" inventory management resulted in difficulty surging manufacturing when demand surged last spring. This created significant and devastating challenges for states and healthcare systems that needed these key supplies.

Over the course of the COVID–19 response, the SNS has worked to backstop States' medical supply needs at an accelerated pace. As of June 15, 2021, the SNS deployed more than 200 million items to aid the national response including Personal Protective Equipment (PPE), ventilators, Federal Medical Stations, and pharmaceuticals. Now, ASPR is working to replenish the SNS to levels at or above pre-COVID–19 amounts, so it is prepared for any subsequent wave of additional cases.

As of July 9, 2021, the SNS has utilized approximately $10 billion from COVID–19 supplemental appropriations provided by Congress to inventory approximately: 517 million N95 respirators (35 times pre-pandemic levels); 272.5 million surgical and procedure face masks (eight times pre-pandemic levels); 11.9 million face shields (two times pre-pandemic levels); 22 million gowns and coveralls (five times pre-pandemic levels); 524.7 million gloves (17 times pre-pandemic levels); and 167,000 ventilators (10 times pre-pandemic levels).

While replenishing the SNS is essential, it is also critical to address the root-causes of why supply chains were so strained in the first place. ASPR is taking on this work as well since ensuring a safe and consistent supply chain for medical materials, ingredients, and supplies is critical for any national response to public health emergencies.

To start, ASPR is leveraging the authorities delegated to the Secretary under the Defense Production Act (DPA) to ensure that private sector partners making life-saving products are able to acquire raw materials, retool their machinery, scale their production facilities, train their workforces, and ultimately deliver their product. Throughout the COVID–19 response, ASPR has used the DPA authority to issue 46 priority ratings for U.S. Government (USG) contracts for health resources, eight priority ratings for USG contracts for industrial expansion, 3 priority ratings for non-USG contracts to support the production of resins for both diagnostics and infusion pumps, and the manufacture of closed suction catheters for treatment of patients with COVID–19. Going forward, ASPR will continue to build capacity and partnerships with private industry toward the shared goal of ending the COVID–19 pandemic.

In addition, ASPR is working to steward Congress's investment in expanding the domestic industrial base. These industrial base expansion (IBx) efforts seek to reduce supply chain vulnerabilities and generate a domestic "warm-base" for manufacturing that can be leveraged in a crisis. So far, ASPR has supported domestic manufacturing of PPE; active pharmaceutical ingredient manufacturing capacity; and COVID–19 testing, including swabs, tests and kits, and supplies such as reagents and resins. Each of these domestic manufacturing initatives meet current, as well as future COVID–19 needs, and seek to create or sustain high-value domestic jobs.

Healthcare System Preparedness

Finally, I want to share more about ASPR's work to prepare our healthcare system to surge to meet the demands of those being treated for COVID–19, without compromising day-to-day health care needs.

Through ASPR's Hospital Preparedness Program (HPP), the only Federal program that supports preparedness efforts within the healthcare system, ASPR has invested $350 million from supplemental appropriations in the National Special Pathogen System (NSPS). These investments span the 62 HPP funding recipients, their associated 55 Special Pathogen Treatment Center sub-recipients, 10 Regional Ebola and Special Pathogen Treatment Centers (RESPTC) recipients, the National Ebola Training and Education Center (NETEC) (a consortium of three academic medical centers), and 53 hospital associations, and helped leverage and amplify technical guidance from the Centers for Disease Control and Prevention (CDC). These components work together to provide a coordinated, national approach to preparing health care systems to surge for public health and medical emergencies.

During the COVID–19 pandemic, the NSPS coordinated national expertise, regional capabilities, and state and local healthcare capacities across the public and private sectors to support an effective pandemic response. Looking ahead, I look forward to examining ways to strengthen investments like these in preparedness to ensure the healthcare system is ready to surge for future public health and medical incidents.

Further, if a public health or healthcare system becomes overwhelmed with patients, states can request National Disaster Medical System (NDMS) personnel to provide additional support. During the COVID–19 response, NDMS has completed nearly 5,400 mission assignments so far, and counting. For these deployments, NDMS personnel supported hospital augmentation including emergency room support; hospital decompression; setting up medical overflow centers for patients and mortuary support; establishing monoclonal antibody therapy sites; ICU augmentation; and, operating Federal vaccine sites. With the aid of NDMS personnel and resources, communities were able to continue to provide care to those in need of medical assistance and treatment. NDMS will continue to support such requests.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the COVID–19 response. I look forward to answering your questions and working with my team at ASPR and our colleagues across HHS to end the COVID–19 pandemic.

The CHAIR. Thank you very much to all of our panelists today. We will now begin a round of 5 minute questions of our witnesses. I ask all of my colleagues, please keep track of your clock. Stay within those 5 minutes. We do have votes starting at 11:30 a.m. and we have many Members in attendance today. My first question is for the whole panel.

We are at a pivotal point in this pandemic, and after weeks of declining rates of cases and deaths, we are now seeing a resurgence of COVID–19 in part due, as you mentioned, to the circulation of variants. Vaccination rates are plateauing and COVID fatigue is setting in around the country. So I want to ask each of you, what is the one thing everyone can do to help keep us from returning to the early days of this pandemic?

Dr. Walensky.

Dr. WALENSKY. Get vaccinated and get your neighbors vaccinated.

Dr. FAUCI.

[Technical problems.]

The CHAIR. Dr. Woodcock.

Dr. WOODCOCK. Couldn't say it better.

The CHAIR. Ms. O'Connell.

Ms. O'CONNELL. Get vaccinated.

The CHAIR. Thank you to all of you and I hope everyone heard that. Dr. Fauci, the quick development of effective COVID vaccines has been a real success story during this pandemic. People are getting vaccinated. It is really key to everyone's ability to return to normal lives. With the spread of variants, as we all talked about, driving and increases in cases and deaths now, I am encouraged to see public health experts and vaccine developers are now considering the possible need for boosters. You mentioned this a bit in your opening remarks, but I want to ask you, how do you assess the duration of vaccine efficacy and the impact of variants on that efficacy?

Dr. FAUCI. Thank you very much, Madam Chair. There are two ways that are actively being used now to assess the answer to your question. One is there are correlates of immunity which have been established. In other words, you have a level of measurable laboratory, for example, neutralizing antibody, which is the easiest to measure. There are also areas of immunity that are more difficult to measure, like T-cell responses. But the one that seems to be very well correlated is the antibody level.

We know from studies, from the clinical trials, as well as from animal studies that there is a baseline level below which you go, you are much more vulnerable to getting a breakthrough infection. So the first is laboratory data. The second is watching and following cohorts of people to see if you have an increase in breakthrough infections. We know, according to the clinical trial, take for an example, the mRNA, they are 93 to 94 percent effective in preventing clinically recognizable disease.

If you see a fall below that into the 80's or even unfortunately hope it never happens into the 70's, then you reached the point where the durability needs a boost. Those studies are ongoing right now.

The CHAIR. We don't have any data about whether or not we are seeing that?

Dr. FAUCI. No, we don't. There are some preliminary data that we have heard about from Pfizer, which studies that they did in Israel and in their own studies, which seem to indicate that there is waning immunity. We have a lot of cohorts that we are following. The CDC is following at least 20 cohorts that will be able to amplify on that data and give us much more of a basis of making a decision.

The CHAIR. How will the Administration determine if booster shots are needed?

Dr. FAUCI. Just by those very studies. Just by the following the cohort studies and we are waiting. We will be maybe—perhaps Dr. Walensky would like to comment because she has in her domain of the CDC a number of cohort studies that will inform us. In the

meantime, we at NIH are doing studies now to determine when you give a booster, how high up do you get it and what kind of a cushion do you get for antibody responses?

The CHAIR. Okay.

Dr. Walensky.

Dr. WALENSKY. Yes. Thank you, Senator. We have numerous cohort studies. They represent tens of thousands of people, and they are represented across the United States. These include data from 14,000 nursing home facilities, long term care facilities. We have a heroes cohort that is essential workers of over 5,000 people that are actually getting weekly PCR testing. We have health care worker cohorts.

We have cohorts across the country where we are following these data and really looking at it every several weeks to understand what the vaccine efficacy is. And it is among that, and the laboratory data will be the decisions that we use. Fortunately, we are anticipating that this will wane and not plummet. So as we see that waning, that will be our time for action.

The CHAIR. Okay, thank you very much. We really appreciate it. We will stay in touch on that. I will reserve the balance of my time because there are many Members here.

Senator Burr.

Senator BURR. Thank you, Madam Chair. I have got to say, the last exchange was, oh, my god, we haven't learned anything. Let me just make this point. I remember early on in this when the question of testing came up, the CDC said we do testing. And CDC demanded to do the test and we lost weeks. And I am not here to evaluate data. Tony, that is your job and Rochelle and others. But to say we are going to make this decision based upon the research we have got going on at CDC, based upon the information that we have put out and only our research counts, and to basically ignore the Israeli data or the Pfizer data—and I am not suggesting that we are totally doing that.

I guess my question would be, is Israel giving us transparency into their data? If you still lived in a world when we didn't accept foreign data for applications, which FDA has had the authority to do since 1996 when I changed the law, but it took COVID to actually make that happen. So I realized that we want accuracy. But do we really have to wait for CDC to complete the data? Do you think you are going to come to a different conclusion than Israel did? Share with me.

Dr. WALENSKY. Thank you for that question, Senator. Absolutely not. We have to have collaboration across the globe because this is a global problem. So we have already had two conversations with Israel. We have data sharing from our collaboration—from our cohorts as well as from theirs. We have also been in discussions with the UK to see what data they have because, of course, they are several weeks ahead of us in the delta variants. So we intend to leverage all of the data we have around the world to share liberally with other countries and the hopes that they will share with us so that we can make the proper decisions here in this country and around the world.

Senator BURR. Is there a reason to believe that the Israeli data is flawed?

Dr. WALENSKY. I am sorry?

Senator BURR. Is there reason to believe the Israeli data is flawed?

Dr. WALENSKY. Flawed, we are in discussions, epidemiologic discussions. There are numerous cohorts in Israel, those in the Ministry of Health, those in their health care systems. And we have seen some of their data. They are actually continuing to analyze the data. And so where we are in those active epidemiologic conversations.

Senator BURR. My point is they have made a decision to do booster's based upon their data. And we are saying we are still going to work out through our research to determine. And that is where you begin to lose the trust of the American people in our health care experts. In April, the Biden administration announced a $1 billion commitment for sequencing at CDC. To date, only 844 cases from North Carolina have been sequenced, according to CDC website. We had over a million cases. It seems there is a major problem again at CDC. Let me just ask you, in CDC's recent updated mask guidance for schools, says community should use local outbreak data to make decisions.

Yet I would challenge you that if only 844 cases have been sequenced, those local people don't have the data they need to make that determination as to what the policies are going to be at a local level. Would you agree?

Dr. WALENSKY. That discussion is based on cases, not based on variance. So we are actually getting data from around the country based on variance as well, based from the local health departments within North Carolina and with all of the states, as well as academic centers, and commercial labs. And the recommendations for schools was based on test positivity and positive cases, not necessarily based on variance.

Senator BURR. But shouldn't transparency by the local health department about the variant in their community be important to their decision as to what they do in the schools?

Dr. WALENSKY. Absolutely. And we have data by region for variants that are posted on our website. They have been updated this morning with 83 percent. So not only are we looking at test positivity actually down to the county level, but variants that come in as well from each of the individual states, from the academic partners, from the labs.

Senator BURR. Dawn, I know you have only been there 3 weeks. What are your plans to address the pressure that the flu is going to cause on the system?

Ms. O'CONNELL. Ranking Member, thank you for that question. That has been something that we have been—the ASPER team has been considering and planning for over the last several months. There is now an interagency process set up by the White House Supply Chain Coordinator that ASPER has been actively participating in, working with manufacturers of both flu vaccines and COVID vaccines to make sure that the supplies are there so we have access to both vaccines as we head into the fall.

But it is something that we will continue to monitor and recalibrate if needed so we are sure that we can do both at the same

time. At this point, our planning assumption suggests that we can, but I will continue to monitor that.

Senator BURR. Thank you. Thank you, Chair.

The CHAIR. Senator Kaine.

Senator KAINE. Thank you, Chair Murray and Ranking Member. Thank you to the witnesses. I want to say a word about disinformation and then have some questions. Former President Trump was on television this weekend and he said one of the reasons people won't get vaccinated is because, "they don't trust the election results." And when I heard that, I sort of chuckled at that. I thought that was odd to be connecting a big lie about the election to refusal to get vaccinated. But it caused me to do something that I hadn't done, which is look at the vaccination rates in all 51 states, including the District of Columbia.

The CDC data from yesterday morning shows the following. The 21 jurisdictions with the highest vaccination rates all vote for Joe Biden. 25 of the 30 jurisdictions with the lowest vaccination rates voted for Donald Trump. There is a difference between causation and correlation. But possibly what the President said on television on Sunday, there may be something to it that repeated disinformation about the election is now connecting in people's minds with this information about willingness to take the vaccine.

It didn't have to be this way because one of the great things about President Trump and the Trump administration working with partners and funded by Congress was setting a world record in terms of developing really super effective vaccines in record time. President Trump had COVID in October. He decided to get vaccinated in January. He didn't tout the vaccination. It came out months later. But he could still tout it, he could still say this is a Trump accomplishment and encourage people in these states who are lagging behind the national average to get vaccinated.

That won't solve all of the problem because there are many reasons people don't get vaccinated. But I am now convinced, I just came back from Latin America. In Latin America, they are so thrilled at the U.S. donation of vaccines, and they view our vaccines as state-of-the-art compared to the China and Russia vaccines. And they appreciate that we are donating them rather than charging them, which China and Russia are doing. So around the world, people are beating a door down to try to get to U.S. vaccines if they can. And here we have near universal availability.

Again, I thought it was sort of comical, the President's comments this past weekend. But as I look at the CDC data, maybe it is not so comical, but it is incredibly serious. Dr. Walensky, I wanted to ask you this question. I think you stated in your opening testimony that the overwhelming majority of deaths now are people who are not vaccinated. Now, when you say overwhelming majority, are you talking about 60 percent, 80 percent, 95 percent, 99 percent? What is the statistic?

Ms. O'CONNELL. In a five-month study from January to May and numerous states, five or six states, it was 99.5 percent.

Senator KAINE. Now, obviously, before the vaccine started, it was 100 percent. 100 percent of people who died before we were vaccinating were unvaccinated by definition. And since the vaccine has begun to be deployed, 99.5 percent of people who died are people

who are unvaccinated. Those are very, very powerful statistics. As the Administration has begun to say this is now a pandemic of the unvaccinated. Dr. Walensky, I am very concerned with a CDC press release, I guess, from last week about overdose deaths in the last calendar year. A 29 percent increase in overdose deaths.

It appears to be connected to the isolation. Substance use disorders is often a disorder of isolation. It appears to be connected to the intense isolation of the last year. Can you tell us what CDC and other partners are doing to look at this and work together with us to try to combat the resurgence of a scourge which we had seen some positive movement on in the last few years?

Dr. WALENSKY. Yes, thank you, Senator. You know, there have been two things in the last decades that have decreased life expectancy in this country. One is COVID–19 and the second is overdose. And so we are now seeing a collision of those two things happening at the same time. And in fact, as you noted, the report demonstrated a 29 percent increase in overdose deaths a year over year.

We are actively working to not only study this issue and not only study the overdose deaths, but the overdose hospitalizations, to look at surveillance, to look at the infectious diseases associated with injection drug use, to promote certain services programs, naloxone programs, as well as to provide services and toolkits around the country for not just substance use disorders, but for mental health, Hear Her Now campaigns—Hear Her Now campaigns for maternal mortality, toolkits for suicide prevention for youth. Parental toolkits.

We are actively not only doing the surveillance and the studying of this, but also the—in the communities for the toolkits on the prevention side.

Senator KAINE. Right, thank you. I yield back, Chair Murray.

The CHAIR. Thank you.

Senator Paul.

Senator PAUL. Dr. Fauci, as you are aware, it is a crime to lie to Congress. Section 1001 of the U.S. Criminal Code creates a felony and a five-year penalty for lying to Congress. On your last trip to our Committee on May 11, you stated that the NIH has not ever and does not now fund gain of function research in the U.S. Institute of Virology. And yet gain of function research was done entirely in the Wuhan Institute by Dr. Xi and was funded by the NIH.

I would like to ask unanimous consent to insert into the record the human virology paper entitled, Discovery of A Rich Gene Pool of Bats SARS Related Coronaviruses. Please deliver a copy of the Journal article to Dr. Fauci. In this paper, Dr. Xi credits the NIH and lists the actual number of the grant that she was given by the NIH. In this paper she took two bat coronavirus genes, spiked genes, and combined them with a SARS related backbone to create new viruses that are not found in nature.

These lab created viruses were then shown to replicate in humans. These experiments combine genetic information from different coronaviruses that infect animals but not humans to create novel artificial viruses able to infect human cells. Viruses that in

nature only infect animals were manipulated in the Wuhan Lab to gain the function of infecting humans.

This research fits the definition of the research that the NIH said was subject to the pause in 2014 to 2017, a pause in funding on gain of function. But the NIH failed to recognize this defines in a way, and it never came under any scrutiny. Dr. Richard Ebright, a molecular biologist from Rutgers, described this research in Wuhan as, "the Wuhan lab used NIH funding to construct novel chimeric SARS related coronaviruses able to infect human cells and laboratory animals.

This is high risk research that creates new potential pandemic pathogens—potential pandemic pathogens that exist only in the lab, not in nature. This research matches," these are Dr. Ebright's words, "this research matches, indeed epitomizes the definition of gain of function research done entirely in Wuhan," for which there was supposed to be a Federal pause.

Dr. Fauci, knowing that it is a crime to lie to Congress, do you wish to retract your statement of May 11th where you claimed that the NIH never funded gain of function research in Wuhan?

Dr. FAUCI. Senator Paul, I have never lied—.

Senator BURR. Microphone.

The CHAIR. The Microphone.

Dr. FAUCI. Senator Paul, I have never lied before the Congress, and I do not retract that statement. This paper that you were referring to was judged by qualified staff up and down the chain as not being gain of function.

Senator PAUL. What does—.

Dr. FAUCI. Let me finish——

Senator PAUL. You take an animal virus, and you increase its transmissibility to humans. You are saying that is not gain of function?

Dr. FAUCI. That is correct. And Senator Paul, you do not know what you are talking about, quite frankly. And I want to say that officially. You do not know what you are talking about. Okay, you get one person—can I answer your question?

Senator PAUL. From the NIH definition of gain of function—this is your definition that you guys wrote. It says that scientific research that increases the transmissibility among mammals is a gain of function. They took animal viruses that only occur in animals, and they increased their transmissibility to humans. How you can say that is not gain of function.

Dr. FAUCI. It is not.

Senator PAUL. It is a dance, and you are dancing around this because you are trying to obscure responsibility for 4 million people dying around the world from a pandemic.

The CHAIR. Let's let—Dr. Fauci.

Dr. FAUCI. I have to—well, now you are getting into something. If the point that you were making is that the grant that was funded as a sub-award from Eco Health to Wuhan created SARS-CoV–2, that is where you are getting. Let me finish.

Senator PAUL. We don't know. We don't know if it did—but all the evidence is pointing that it came from the lab, and there will be responsibility for those who funded the lab, including yourself.

Dr. FAUCI. I totally resent—.

The CHAIR. This Committee will allow the witness to respond.

Dr. FAUCI. I totally resent the lie that you are now propagating, Senator, because if you look at the viruses that were used in the experiments, that were given in the annual reports that were published in the literature, it is molecularly impossible—.

Senator PAUL. No one is saying those viruses caused it.

Dr. FAUCI. It is molecularly—.

Senator PAUL. No one is alleging that those viruses caused the pandemic. What we are alleging is the gain of function research was going on in that lab and NIH funded it.

Dr. FAUCI. That is not——

Senator PAUL. You can't get away from it. It meets your definition, and you are obfuscating the truth.

Dr. FAUCI. I am not obfuscating the truth, you are the one.

The CHAIR. Senator Paul, your time has expired, but I will allow the witness to——

Dr. FAUCI. Let me just finish. I want everyone to understand that if you look at those viruses, and that is judged by qualified virologists and evolutionary biologists, those viruses are molecularly impossible to result in SARS-CoV–2.

Senator PAUL. No one is saying they are. No one is saying those viruses caused the pandemic. We are saying they are going to function viruses—.

Dr. FAUCI. They are not—.

Senator PAUL. Because they are animal viruses that became more transmissible in human, and you funded it. Why won't you admit the truth?

Dr. FAUCI. You are implying——

The CHAIR. Senator Paul, your time has expired, and I will allow witnesses who come before this Committee to respond.

Dr. FAUCI. You are implying that what we did was responsible for the deaths of individual—I totally resent that—.

Senator PAUL. It could have.

Dr. FAUCI. If anybody is lying here, Senator, it is you.

The CHAIR. Senator Smith.

Senator SMITH. Thank you, Dr. Fauci. And thanks to all of our panelists for being here today. And thank you, Chair Murray and Ranking Member Burr. I just want to say, Dr. Fauci, is there anything more that you would like to say to counteract these attacks on your integrity that we have all just witnessed?

Dr. FAUCI. Well, Senator, thank you. I don't think I have anything further to say. This is a pattern that Senator Paul has been doing now at multiple hearings based on no reality. He is talking about gain of function. This has been evaluated multiple times by qualified people to not fall under the gain of function definition. I have not lied before Congress. I have never lied, certainly not before Congress. Case closed.

Senator SMITH. Thank you. So we are 6 months into this pandemic, and I think we are at a critical moment. Two-thirds of adults have received at least one dose of the vaccine. And at the same time, we are seeing cases rising to about 41,000 a day. As Dr. Walensky has said, we have an epidemic here of the unvaccinated. And—but, of course, this continues to affect every single one of us. So it seems to me that our actions and messages in this moment

are going to make a huge difference in whether we move forward or backward, not only here in the United States, but everywhere in the world.

Today, as I was walking into this Committee hearing, for the first time in months, I saw a line of people waiting outside of a pharmacy for testing and vaccines. And it made me wonder whether the recent surge of the delta variant is getting people's attention and moving them from indecision to action. What a terrible way for this to happen. But—so I have a few questions just I hope clear up some of the misinformation and misunderstandings. Dr. Fauci, the COVID–19 vaccine protects against the delta variant, is that correct?

Dr. FAUCI. It protects against the clinically apparent disease, and it protects extremely well against hospitalization and death.

Senator SMITH. Right. So if you are not vaccinated, given how contagious the delta variant is, I mean, it is—would it be fair to say you are almost—you are very likely to get this variant. To get the COVID–19 variant, would you say?

Dr. FAUCI. Well, certainly when you look at the capability of this virus to transmit from people to people. I mean, obviously you have to be in an environment in which the virus is present. So if you are in it, for example—and I believe Dr. Walensky mentioned that in her remarks. If you are in an area, be it a state, a city, a county or what have you, well, you have a high level of infection in the community and a very low level of vaccinated people, the chances in that environment of getting infected are reasonably high.

Senator SMITH. Right. And how do you compare, how do you think about the risks—the side effect risks of the COVID–19 vaccine compared to the risks of not being vaccinated? Because this is, I think, what people are struggling with.

Dr. FAUCI. Right. It refers to the risk benefit ratio of getting a vaccination. And every time this has been evaluated, not only with this vaccine, but with so many other vaccines, there is no intervention that is without some time getting an adverse event. I mean, I don't think I can think of one that hasn't.

When you have that situation, you balance the rarity or the uncommonness of a particular adverse event with the advantage that you would get from protecting yourself against the actual disease against which you are vaccinated. And thus far, whenever this has come up about an adverse event, it has been evaluated, perhaps even a warning has been given, but it is always weighed on the part of saying that the benefit of the protection of the vaccine outweighs the risk of the adverse event.

Senator SMITH. Thank you. Dr. Walensky I talk with public—I have spoken with a lot of public health experts in Minnesota who tell me that they are still challenged getting especially younger adults who are eligible to be vaccinated, getting them vaccinated. And part of it is the challenge, this perception that COVID is just not that big a deal for younger people, people who consider themselves healthy and have got a strong immune system and so forth. So let me ask you this. Are there a larger number of younger people getting hospitalized today versus a year ago or 6 months ago?

Dr. WALENSKY. We have seen hospitalizations go up for every age bracket recently as cases go up. Proportionally because there

are more cases now among younger people, we are seeing more of those people in the hospital. They still get hospitalized at a less frequent rate given unvaccinated than elderly patients. But in fact, because there are more of them now that we are seeing more of them in the hospital.

Senator SMITH. Okay. So another good piece of advice there to have, being aware of the risk, even if you are—even if you see yourself as young and healthy.

Dr. WALENSKY. Absolutely.

Senator SMITH. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Moran.

Senator MORAN. Madam Chair, thank you. Thank you and Senator Burr for today's hearing. Thank you for the witnesses for being here. Let me start with Dr. Walensky, please. Doctor, in May, the CDC announced new guidance for fully vaccinated individuals, that they could resume activities without wearing a mask or staying socially six feet apart.

At that time, the CDC further said that they would continue to update guidance for travel as the science was developing and they would need to collaborate with other agencies regarding a face mask requirement. A month later, a number—me and a number of my colleagues sent a letter to the CDC and the TSA asking for an update regarding the mask requirement during travel.

While we had a response from TSA, we have not had it yet, a response from CDC. And I wondered if you would tell me where the CDC is in the process of updating the mask requirement for fully vaccinated individuals while traveling.

Dr. WALENSKY. Thank you for that question, Senator. Obviously, as you know, the discussion about masking on Federal aviation and ships is an interagency process, not simply with CDC. I will say a lot has changed since May 13th. As you heard from Dr. Fauci, we now have a variant circulating in this country that is at the time was less than 3 percent and is now 83 percent and much more transmissible.

We are continuing those conversations, working toward a letter back to you. Thank you for your patience. And we will continue to revisit that as we learn more about vaccine efficacy, as we learn more about transmission in the context of vaccination, and as we understand more about the delta variant.

Senator MORAN. Are you expecting a change in the expiration date of that continued requirement?

Dr. WALENSKY. I think we still have more looking to do with that.

Senator MORAN. Let me turn to Ms. O'Connell. Ms. O'Connell, you are not the perfect witness from HHS for my statements or questions, but you are my only witness from HHS for my statements. It is a bit about the future, which you are fully engaged in. We need a better response to public health emergencies. And I want to talk about—in that regard, I want to talk about the parameters of the provider relief fund. HHS, in my view, is terribly slow in their release of guidance and on how the funds could be utilized.

There has been a lot of confusion by health care providers. They have been reluctant to spend the money. It is—we are incapable of

solving problems if the resources that we provide to those who are in the health care field, they are not utilized because they are fearful that they don't know what the guidance is and therefore, if they make a mistake, they have penalties at a later date.

I guess the question that could be for you, what is the plan to get HHS to perform better or more quickly so that providers have the necessary information and comfort level to take the steps necessary to prevent the spread of the virus and to care for the health care of Americans and others?

The part that doesn't necessarily involve you, but in hopes that HHS is otherwise listening, there is about $24 billion left unspent in the Provider Relief Fund and we have been anxiously awaiting always with the answer that it is in the works about assistance and care for facilities that care for our senior populations. And there is still no answer in that regard.

I don't know that you have a comment necessarily on that part of my commentary, but again, I would utilize this as an opportunity to try to get more certainty at HHS on the spending of those dollars.

Ms. O'CONNELL. Senator Moran, thank you for your question, for both parts of it, and I certainly appreciate how frustrating it has probably been not to have the clarity that you and your constituents have been seeking.

We will take the comments that you have made today and bring them back to the secretary and other parts of HHS senior leadership to make sure that we understand how important it is that this money is moving quickly, and that the guidance comes out expeditiously and that we can do all we can to support. I mean, we really want to do all we can to support your constituents.

It is helpful to know that this has been a problem, and I look forward to working with you and your staff on it.

Senator MORAN. If you can accomplish that, the purpose of my comment will be satisfied. I would particularly ask that someone from HHS respond to us about the provider relief fund as it relates to senior care living circumstances.

Dr. Fauci, in the 24 seconds I have left, I will just ask a quick question. What are the necessary steps—you have talked about mental health. What are the necessary steps to mitigate a mental health and drug overdose crisis? What should Congress and American institutions be doing today for a future pandemic?

Dr. FAUCI. Well, first of all, I think the lesson that we have learned from this, and we would hope in good preparation for what will inevitably be another challenge in the future, can't predict when, is to realize the important mental health impact that this outbreak has had, not only in the suffering from the disease itself, but from the extraordinary disruption of our society, which I think we are going to have to realize, that even when we get this under control, the mental health effects of this are going to be following this for months if not years afterwards.

We can't forget that. When the outbreak is over, the mental health effects are not going to be over. They are going to linger. And that is what we really need to address.

The CHAIR. Thank you.

Senator Rosen.

Senator ROSEN. Thank you, Chair Murray, Ranking Member Burr, for holding this vitally important hearing today. And I really want to thank all of the witnesses for helping to get our Country vaccinated. It is so important to every person that we know and love in our community and our personal lives that we do everything we can to save them and protect them, and I appreciate your hard work in this regard.

I just want to speak a little bit about vaccine outreach, because our Country—we have made tremendous progress over the past several months in making the vaccine available to most individuals, to getting shots and arms. I have had the honor of going to some of the vaccine sites, of course, clinics in my home State of Nevada. Our health care heroes, they are pillars of strength in our communities, showing up day after day to be sure that everybody that wants a vaccine can get one.

We just can't lose ground. But unfortunately, Nevada is—our cases are growing, and we seem to be getting to the top of the list nobody wants to be in, in the cases of the delta variant. I am extremely concerned about the lag in vaccination rates. In fact, last week, especially a nursing home, Senator Cortez Masto and I sent a letter to Secretary Basara to raise concerns about the low reported vaccination rates in Nevada's nursing homes. And we have to find a solution to protect those most vulnerable who can't go out to a site and even their loved ones couldn't take them.

Dr. Walensky, are there any plans for the CDC or in coordination with other agencies to restart the pharmacy partner program that sent teams directly to every nursing home, perhaps, or every facility with less than a 90 percent vaccination rate for residents and staff and I might even say families of staff who they go home to?

Dr. WALENSKY. Thank you for that question, Senator Rosen. And we recognize this challenge, and we are with you. And that, in fact, we have 10 CDC people deployed to Nevada right now working to assist. You know, part of the long term plan in terms of working to vaccinate our long term care facilities, not necessarily these staccato partnerships with the pharmacies, but to have a longitudinal plan, because, in fact, especially in our long term care facilities, there is quite a bit of turnover of the patients.

We want to make sure that there is always vaccine available. Many of these long term care facilities have access to pharmacies, and we want to make sure that there is a vaccine actually active in the pharmacies so that they can do vaccination when patients come in. I agree with you and in fact we need to work to get our staff vaccinated as well. In fact, staff in some of these long term care facilities are 20 percent less coverage than the facility members themselves—the residents themselves.

We are working on confidence in those areas, but specifically strike teams in with a long term care facilities to assist in getting vaccine to those places that is not reliant on a one time mass vaccination, but really has a longitudinal plan to make sure vaccine can be available in the long term.

Senator ROSEN. Yes, and I would hope that you would include the families of the staff, because oftentimes they have a high turnover, too. They go home to their community and are just going to keep putting out that fire over and over. But I would like to switch

now and talk a little bit about the research in vaccines, because obviously we are discovering more about COVID every single day.

I think for years to come, we are going to continue to learn. And so now is the time to take those additional steps to say—to see we don't look back and find gaps in data that could have been prevented, those gaps could have been prevented if we had acted sooner, speaking of longitudinal. And so data like this could save lives. That is why I introduced the Ensuring Understanding of COVID–19 to Protect Public Health Act. And it is bipartisan legislation that requires long term those longitudinal studies on a variety of COVID patient population with regular public reporting.

For example, some of the recent research is showing that COVID–19 vaccine may actually improve symptoms for some patients with long haul COVID. So, Dr. Fauci, how do we—what do we know about this so far and how common is the vaccine to be a strong prevention tool, but also to work therapeutically in this case? And what else should we be studying?

Dr. FAUCI. Very good point, Senator. And there has been anecdotal reports of people who have been infected, have developed long COVID, and their symptoms have been improved upon getting the SARS-CoV–2 vaccine. That has not been proven under the scrutiny of a clinical trial.

Right now, we are looking at individuals who actually have recovered and seeing if, in fact, vaccination does improve. Right now, although the anecdotal cases suggest that I don't think we can say anything definitively from a scientific standpoint, but that is something that is being looked at.

Senator ROSEN. Thank you. I see my time is up. Thank you.

The CHAIR. Thank you.

Senator Romney.

Senator ROMNEY. Thank you, Madam Chair. And thank you to the members of our panel today for being here responding to our questions. Thank you also to the teams of people that you work with. Their tireless work over the last year and a half is something which many of us feel a great deal of gratitude for, for that effort. As we try and understand vaccine hesitancy, I am sure some of that is due to spurious conspiracy theories.

Perhaps and I don't know this, but social media may be populated in part by enemies of our Country that are putting out theories to try and get people not to take vaccines. But there is also, I believe, another reason why some people who are not prone to believe those conspiracies don't get vaccinated, and that is because they don't know what the data really suggests. And they wonder, Okay, is this really a good thing for my 16 year old?

What are, the serious side effects of this vaccine for a 16 year old versus the probability of them getting very ill? And I wonder, do we provide or is there a place where people can go to find out what the data show for the side effects of vaccines by age group and how many serious complications there are for people of different ages and then compare that perhaps with the serious implications of getting COVID? And I will ask first, Dr. Walensky.

Dr. WALENSKY. Yes. Thank you very much, Senator Romney. In fact, that is exactly what we are doing. So, one of the things I think that is so important to understand is that when people don't want

to be vaccinated it's for a whole host of reasons. And until you start talking to them about what is their reason, is it, I can't take off work tomorrow and I may feel unwell, is it because I don't understand these potential side effects for my 6 year old?

We and CDC have what we call vaccine confidence consults. So we have state departments, local health departments who can call into us and say, these are the things that we are hearing on the ground. What is the real data so that we can have trusted messengers for providing that real data in real time to people and making sure that their answers are—their questions are answered and that we can empower the people who are the trusted messengers on the ground with exactly those data.

Senator ROMNEY. Is that information being collected? Are doctors and hospitals actually collecting the data that shows how many people are getting side effects by age group? Are you getting accurate information that people can rely upon? Because, again, I see on social media and some broadcasters a sense that somehow this is being hidden, that the side effects are being underplayed, that you have an incentive not to let people know what the kind of side effects might be and the seriousness of those side effects.

Dr. WALENSKY. The answer is absolutely. We have numerous large scale mechanisms by which to collect these data. We have the first ever V-safe monitoring program where people are—given their vaccine, how did they do today? How are they doing in a week? We have the Vaccine Adverse Event Reporting System. That is a passive reporting system.

Everything gets reported, is supposed to get reported but we recognize it is passive. Things may get missed. And then we actually also have the vaccine safety data link, which is a link of nine academic centers that were able to get real vaccine data as well as their denominators, which is hard to get in passive reporting so we can check numerators and denominators there and give us real estimates. We are doing—we are covering the gamut.

Senator ROMNEY. The talk that Senator Burr described with regards to getting a booster, the suggestion from Israel is it makes sense. There are a number of us that would get in line to get a booster. How long is it going to take before we are able to get sufficient information to allow Americans who want to get an additional vaccination to be able to do so? Are we talking weeks, are we talking months? I mean, I guess given the fact that this is being done overseas, can we not use the data that has come from those places to allow people in this country to get a third shot if they want to?

Dr. WOODCOCK. The agencies represented here are all monitoring this extremely carefully. As you have heard, 95–99.5 percent of all people are being hospitalized now are unvaccinated. So at the moment, the people that are getting sick are the people who haven't been vaccinated.

Senator ROMNEY. I understand but I am looking at the data that is coming from Israel, and people who have double vaccinations are still susceptible to the delta variant for serious disease and death. And they are showing that if they get a booster, that dramatically is reduced. Why should we not allow people who are elderly or have other compromised conditions to be able to get that booster?

Dr. WOODCOCK. Certainly. We are looking at all that. Remember this vaccine right now, the vaccines that are under emergency use authorization require an additional authorization for a booster.

Senator ROMNEY. How long is that going to take? That is a question. We have people who want to get that booster, and I am hearing that from people who are at risk and concerned. They want to take that booster. They are willing to take the additional risk of something that has not been—they have already had two shots of it. They are saying, give me the third, because I got this over a year ago. I got the vaccination over a year ago. I want to get that protection. Why can't they? And if—I understand, you won't let them yet. But when will you let them?

Dr. WOODCOCK. Well, Pfizer, at least has announced that it is going to submit to their EUA data, both Pfizer data and Senator Burr's early point, other Israelis—other data that they have available to potentially make the case for a booster. So the FDA will be looking at that.

Senator ROMNEY. I am sure you will. I don't like the timeframe, frankly, given the fact that this is being done elsewhere. My time is up so I will turn back to you, Chair.

The CHAIR. Dr. Woodcock, for clarification, Pfizer has not requested FDA to approve a booster?

Dr. WOODCOCK. Well, of course, I can't talk about that, but Pfizer has publicly announced that they are going to submit an amendment to their EUA to request—for a booster dose.

The CHAIR. Thank you.

Senator Hassan.

Senator HASSAN. Well, thank you, Chair Murray and Ranking Member Burr. And thank you to all of our witnesses today for the work you do. I want to just start to talk about a recent news item. It is a deeply disturbing report detailing dangerous inequities that USA Paralympians are facing at this year's Tokyo Paralympics. Becca Myers is a six time Paralympic medalist who won three golds in Rio 5 years ago. She is deaf, blind, but in the past, that hasn't stopped her from competing and winning at the highest levels.

This year, though, she and other athletes from Team USA who experienced disabilities are being denied adequate access to personal care assistants, reportedly due to COVID–19 restrictions. Individuals who experience disabilities should not be forced to navigate the Tokyo Olympics without the support that they need in the midst of a global pandemic. Becca announced on Sunday that she is quitting the team because she is being denied a, and this is her quote, "reasonable and essential accommodation" that would enable her to compete.

This is an outrage and a preventable situation that should never have gotten to this point. So I want the U.S. Olympic and Paralympic Committee to work immediately to address this issue, and I want them to ensure that all of our athletes are able to compete safely at this summer's game, including by providing them the basic supports that they need just to navigate the world. So I do have a question though, Director Walensky, because over the last year and a half, the CDC has provided guidance on how to mitigate

the risk of COVID–19 in various activities, as well as special events, including sports.

I have a question that you all could answer in writing. You can comment on it now if you would like. But what I am interested in is your best guidance regarding COVID–19 mitigation, taking into account the needs of people with disabilities. So if you would like to comment now you can or we can just do it in writing.

Dr. WALENSKY. Maybe I will just comment and say I share your concern. We have dedicated resources specifically to disabled communities, especially those who are unable to come out and get vaccinated. I think probably the details of individual sports, which we can do by writing, but I just want to echo your concerns.

Senator HASSAN. I just want to be clear that for some people with disabilities, the accommodation, the aid they need is another human being. And it really needs to be seen as the same kind of accommodations we would make in other situations. So I appreciate having an ongoing discussion with you about it.

Now, I would like to turn to you, Ms. O'Connell. Last year, many states, hospitals, and First Responders struggled to acquire personal protective equipment, and the Federal stockpile did not contain the supplies needed to fulfill their requests for help. The stockpile also contained many expired and unusable products, which further limited its effectiveness.

I recently introduced bipartisan legislation with Senator Cassidy that would improve transparency into the stockpile, authorized transfers of expiring products, and assist states in establishing and maintaining their own stockpiles in order to help avoid the kinds of challenges that we faced last year.

What steps are you taking to improve the stockpile, and will you continue to work with us on this bipartisan legislation to make further improvements?

Ms. O'CONNELL. Senator Hassan, thank you so much for your question. This is a place where I intend to spend a lot of time in my new role. I am pleased to report that ASPER has spent and invested over $10 billion in supplemental funds to restock the stockpile.

We currently have 35 times the number of N95 respirators we had at the beginning of the pandemic. We have 17 times the number of gloves, 8 times the number of masks, and of the N95 masks, all 12 contracts are with domestic manufacturers. So we are beginning to see some progress.

Senator HASSAN. Will you work with us on the bipartisan legislation that Senator Cassidy and I have introduced?

Ms. O'CONNELL. I would look forward to. Thank you, Senator.

Senator HASSAN. Thank you. Dr. Fauci, I have a question for you about pediatric vaccines. Many parents and family members are understandably eager for updates on the potential availability of COVID–19 vaccine authorized for use for children under 12. I am encouraged that clinical trials for young children are underway, and I am hopeful that we will see the same safety and efficacy that we have seen from previously authorized COVID–19 vaccines. Doctor, when do you believe parents and families can expect trials to yield the type of data needed to pursue authorization for use in children under 12?

Dr. FAUCI. Thank you for that question, Senator. From the standpoint of the data that would be required to make a decision, that very likely when you do the age de-escalation studies, so we have gone from 12 to 9, 9 to 6, 6 to 2, and then 6 months to 2 years, likely by late fall, early winter, we will have enough data. But that doesn't mean that then it is all of a sudden going to be allowed to happen. That will be a regulatory decision that the FDA will have to make.

Senator HASSAN. Well, thank you. And I see that I am out of time. I will follow-up with you in writing because I am also interested in what you think we could do now to help boost confidence and uptake for the pediatric population once the approval is authorized.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. Thank you, Madam Chair. My first question for Dr. Walensky. As a physician, we always want to be able to know and discuss the benefits and risk of anything that we are prescribing, including a vaccine. It is estimated that 40, maybe 50 percent of children have already had the COVID virus. What are the additional benefits to the vaccine to a child who has already had the virus?

Dr. WALENSKY. I think it very much depends on what that variant that child might have had, whether they could potentially be infected or reinfected. And one thing I just want to note with the children is I think we fall into this flawed thinking of saying that only 400 of these 600,000 deaths from COVID–19 have been in children. Children are not supposed to die. And so 400 is a huge amount for a respiratory season.

Senator MARSHALL. Thank you. Dr. Woodcock, how many children under the age of 18 without a preexisting condition, a significant health condition, have died from COVID in this country?

Dr. WOODCOCK. I don't—I don't have that at my fingertips. I am sorry.

Senator MARSHALL. Dr. Walensky.

Dr. WALENSKY. Over 400

Senator MARSHALL. Without a pre-existing——

Dr. WALENSKY. That, I don't know.

Senator MARSHALL. The answer is probably zero. So I think if you take a deep dive, most of the children that have died had some type of underlying health condition. Dr. Fauci, in my hand is a three dimensional printing of the COVID spike, something that is certainly a scientific—just baffles me in so many ways.

It is composed of two units, as you know. There is an S2 subunit and an S1. And I would like for you to talk about the S2 subunit for a second. Can you explain the significance of the furin cleavage side, the double arginine CGG codon, if you would, and how that works clinically for us?

Dr. FAUCI. Yes. Thank you for that question, Senator. The furin cleavage site is a site of a set of amino acids, which is at the point where the enzyme furin can cleave it so that the virus can then bind to the receptor cell and then enter the cell. So what is seen on a number of viruses, it has been seen on the SARD-CoV–2 and it is also seen on other beta coronaviruses. You asked also about

the double CGG codon that is a codon again, that is unusual, but it is also seen on a number of beta coronaviruses. It is not a very common codon for the amino acid in question, but it is seen in coronaviruses.

Senator MARSHALL. Dr. David Baltimore, a Nobel Laureate, I will quote him here, "when I first saw the furin cleavage side in the viral sequence with this arginine codon I said to my wife, it was the smoking gun for the origin of the virus. These features make a powerful challenge to the idea of a natural origin for SARS–2." And again, this is Nobel Laureate, Dr. David Baltimore saying this. Would you agree or disagree with Dr. Baltimore?

Dr. FAUCI. Well, Dr. Baltimore, who is an extraordinarily accomplished scientist, has backtracked on that statement, and says, I wish I had not used the word smoking gun when it was pointed out to him that actually this is seen in a number of coronaviruses, including one of the common cold coronaviruses. So I believe, if you would ask—.

Senator MARSHALL. You disagree with him?

Dr. FAUCI. Well, I agree with his second statement where he backtracked and said he wished he had not—.

Senator MARSHALL. You disagree with his first statement though?

Dr. FAUCI. He disagrees with his first statement.

Senator MARSHALL. Okay, not going to answer the question. We also have the S1 subunit, and I refer to the timeline behind me here that there was a moratorium placed for viral gain of function in 2014. And I think you will agree with me that the NIH funded research that led to this, an S1 spike that looks very similar, if not exactly to what is on the COVID–19 spike.

Dr. FAUCI. What are you referring to, Senator? Can you please be more specific?

Senator MARSHALL. Yes. So I am talking about the S1 subunit of the current COVID–19 spike.

Dr. FAUCI. What about it? I mean, are you talking about an experiment or are you talking about a paper that was published?

Senator MARSHALL. I am talking about viral research that was done using NIH funding with the North Carolina lab and Dr. Xi developed this S1 subunit spike that looks exactly like what we have on the current COVID–19 spike. Is that not true?

Dr. FAUCI. No, I am not sure exactly what you are referring to. Are you referring to the paper of Baric and Xi in Nature Immunology? Is that what you are referring—I need to know specifically.

Senator MARSHALL. Yes, Dr. Baric and Xi printed studies on this S1 unit that was basically the development of the key to the door that was—specifically took the original SARS virus and made it so it would bind to the human lung cells.

Dr. FAUCI. No, there was gain—if you are referring, Senator, to gain of function by the definition.

Senator MARSHALL. That is not my question. Would you agree that the spike that was developed there is was also on the current—

Dr. FAUCI. Yes, but that is irrelevant to anything until you have a context in which you are putting it. You are talking about an S1

and a spike in what context? If you are talking about a paper that was written by them.

Senator MARSHALL. But would you agree or disagree that it is the same spike?

Dr. FAUCI. I am not sure what you are talking about, Senator. I am really not sure what you are talking about.

Senator MARSHALL. Okay, thank you.

Dr. FAUCI. Alright.

The CHAIR. Thank you.

Senator Casey.

Senator CASEY. Thank you, Chair Murray. And I want to thank the panel for being here today and for your public service. A challenging time for the country. I just wanted to make a couple of statements at the top. Assistant Secretary O'Connell, I was—I want to ask you a question, but just wanted to note on page four and five of your testimony about the information about the inventory that you have built up. We are happy to read that. I won't go through it all.

Also the statement you made about ensuring, "ensuring a safe and consistent supply chain for medical materials, ingredients and supplies is critical for any national response to public health emergencies." I couldn't—we couldn't be, I should say, more pleased with that kind of a focus, because we are going to need that in the future. Dr. Walensky, there was an earlier question, I think, by Senator Hassan talking about nursing homes and nursing home workers in particular.

I want to ask you a question, because I have got a separate question. But the lower vaccination rate for nursing home workers is of concern. We are told by Federal data that there are still 13 states with less than half, less than half of nursing home workers have been vaccinated. So the message about vaccinations couldn't be more important.

Last thing I would say, Dr. Fauci, in reference to the questions by Senator Paul today and the accusation, I think it is a widely shared view in both houses, in both parties that the integrity that you bring to your work and the knowledge you bring to your work on behalf of the Nation, that I think that sentiment is a broad and deep reservoir, and it is very, very much bipartisan. I want to ask you to comment on that.

But I wanted to—I have a question for Dr. Fauci and Dr. Walensky about breakthrough infections. We know that even with any—even with the great success of the vaccines, there is no 100 percent effectiveness. So I wanted to ask you about breakthrough infections. I haven't seen, maybe it is available, but I haven't seen information about either breakthrough infections or enough information about cases of long COVID, because—I assume because of a lack of data.

Dr. Walensky, I would ask you, what types of data is CDC collecting to track breakthrough infections? And how are both CDC and the National Institute of Allergy and Infectious Diseases, Dr. Fauci, using data to monitor outcomes in patients with breakthrough infections?

Dr. WALENSKY. Thank you, Senator. So there are different ways that we are capturing these data. And I think all of them fit to-

gether in a puzzle. One is passive surveillance where folks give us data when they break through, the hospital systems provide us data. They know that somebody is hospitalized and has a history of vaccination. We want to know about those cases to the extent possible. We would like to have a sample of the virus so that we can understand the viral load, so that we can sequence it, we can understand their symptoms and their risks that potentially put them in that situation.

However, that is actually limited because it actually doesn't give us the denominator. We don't know who else would have been reporting or who we missed in that process. And in order to do real effectiveness studies, we need to have both the numerator of the cases as well as the denominator. So we are doing many of those studies across the Nation. We do have them geographically sampled. We have a long term care facility study where we are getting data from over 14,000 long term care facilities. We have a health worker study.

We have an essential worker study. That is 5,000 essential workers that are being tested by PCR every single week. And we have numerous other cohorts in 19 academic medical centers, 187 hospitals to monitor both the numerator, how many people are breaking through, how serious is their infection, as well as the denominator, how many people overall were vaccinated, so we can get a really good window as to the breakthrough—the percentage of people who are breaking through.

Senator CASEY. Thank you.

Dr. Fauci.

Dr. FAUCI. Well, thank you very much for your prior comment, Senator. That is much appreciated. With regard to your question, I think people need to appreciate when you talk about breakthrough infections, that the original data from the clinical trial, the efficacy data, was based on preventing clinically apparent disease, not preventing infection such as asymptomatic infection.

When you hear about a breakthrough infection, that doesn't necessarily mean the vaccine is failing because it is still holding true, particularly with regard to protection against severe disease, leading to hospitalization and deaths.

As per your question, what are we doing? We will be following for two-years the people who are in the clinical trials, the 30,000 and 44,000 people, to be able to determine just what percent now in the context of the delta variant are actually breaking through, to determine if it is more than that original that we saw or in the context of delta, if it is actually much more.

Senator CASEY. Thank you, Doctor. Thank you, Chair Murray.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. Thank you all. I will ask—if I cut you off, it is not—I am not being rude, I just got 5 minutes. Got to hustle. Ms. O'Connell to follow-up on what Senator Hassan said, thank you for replenishing the strategic national stockpile. The one thing that troubled us is that there was no first in, first out. There was no rotation of material before it expired which was just dumped. What—just yes or no, have inventory management systems been implemented to minimize the wastage?

Ms. O'CONNELL. Thank you, Senator. Yes, we are looking at that.

Senator CASSIDY. Looking is a very vague term. If you are one of my medical students on rounds, I would say, what does that mean?

Ms. O'CONNELL. Well, one of the things we are pursuing is the model of the vendor manage.

Senator CASSIDY. Wonderful. Thank you. Second, related to that, I am told there is a lot of vaccine that is about to expire. So it is 6 months from being expired in a state which is not completely using it. Unfortunately, my state, is among those.

Ideally, from my perspective, we rotate that vaccine out to the border for those who are coming across as undocumented or down to Central America and Mexico, which is having these COVID outbreaks. I am told there is contractual issues with that. But is there any effort to rotate out soon to expire vaccine that doesn't appear as if it is going to be used into a set in which it could be used quite rapidly?

Dr. WOODCOCK. We have been working on this, and what we have been advising the states is where they have repositories to hold on to that vaccine because unlike most medical products you are used to, we are making these stability determinations on the fly.

Senator CASSIDY. Dr. Woodcock, that is the news. You are telling me that even if it goes beyond the expiration date, that the vaccine can still be used?

Dr. WOODCOCK. No, I am saying we are telling people to hold on to it, because when the additional stability—because we are doing stability—the companies are doing stability on the fly because we—

Senator CASSIDY. I understand.

Dr. WOODCOCK. Yes, so we have extended the date once already for one of the vaccines. We may be able to keep extending as more stability—as there is longer stability observed.

Senator CASSIDY. But it still seems to me inevitably, sooner or later, you are going to decide you have got to toss it. Now, just an inventory management system. It seems wise to be rotating that to a place where it would be taken up quickly as opposed to a place where it is being taken up quite slowly. Agree, disagree, and if you agree, any thoughts regarding that?

Dr. WOODCOCK. Well, that is really for probably ASPER to talk about——

Senator CASSIDY. Maybe for State Department.

Dr. WOODCOCK. Yes.

Senator CASSIDY. Are there other contractual obstacles to doing that? Because someone told me that the contracts with the drug companies would not allow the transfer of the product to another setting. We couldn't give it to Mexico, for example, because it just has to be tossed. Do you know about that?

Dr. WOODCOCK. Well, they aren't FDA's contract so my understanding is that it is possible under EUA to do exports and that could be possible. So that—but we can get back to you on that, because it really isn't an FDA issue.

Senator CASSIDY. Sounds great. Next, as regards Dr. Fauci, Walensky, it does seem to me this issue of Dr. Woodcock, of whether or not we need a booster would be ascertainable by whether or

not we can see a response of antibody to re-challenge within the window period is what, 4 days for the virus between exposure and an onset of infection if the antibodies after exposure to vaccine, if you will, mimicking an infection, shoot up rapidly, we have got protection. Are any studies taking place along these lines?

Dr. WOODCOCK. Yes, absolutely, both within the Government and within the companies. And we certainly are—the Government as a whole, the agencies involved are monitoring this very carefully and we are sharing all the data. And we have heard from——

Senator CASSIDY. Now these are very simply done in very short—and don't have a lot of timeframe. Obviously, the window period is only 4 days. So, and I have asked about this before, but it doesn't seem as if there are any answers. What is the delay in knowing this? Because that would answer Senator Romney's question as regards whether or not a booster is required.

Dr. WOODCOCK. Well as Dr. Fauci said, there are two things going on here. One is, when does immunity wane to the point that you need to give a booster? Our populace is not just going to—we can't just boost them all the time, right. We need to boost them when it is appropriate.

Senator CASSIDY. But isn't there a subset of people whom you are following longitudinally that have negative antibodies? Their antibodies are initially positive and now they have gone on either very low or zero.

Dr. WOODCOCK. They are waning. I wouldn't say they are negative. Obviously, Senator, Dr. Cassidy, there are going to be people who don't respond to vaccination primarily because of some immunocompromise. However, what is being followed is the waning of humoral immunity, as Dr. Fauci described, over time. But it is waning. It isn't vanished. And that is clear because everybody who is getting hospitalized is unvaccinated and they are being exposed to the delta variant. So the vaccination is holding right now in the U.S.

Senator CASSIDY. Good. I thank you all.

The CHAIR. Thank you.

Senator Lujan.

Senator LUJAN. Thank you so much, Chair Murray, for this important hearing, and to all of our witnesses for being here today. While I am encouraged that data shows vaccine rates are increasing across America, still less than half of Hispanics have been vaccinated despite data showing that it is the least vaccine hesitant group. Dr. Walensky, Federal investment in community health centers increased Hispanic vaccination rates. Yes or no, did this investment in this community save lives?

Dr. WALENSKY. I am grateful for your collaboration with HRSA and the Federal qualified health centers, and I absolutely think that being able to reach out to these communities has saved their lives, some of their lives.

Senator LUJAN. Dr. Walensky, additionally, when Hispanic communities has received outreach in Spanish, it increased vaccination rates. What is the plan to build on the success of using culturally appropriate outreach and messaging to boost Hispanic vaccination rates?

Dr. WALENSKY. I think we need to use culturally appropriate messaging in all of our vaccination efforts. And not just in our vaccination efforts, in all of our health care efforts. We have—our vaccination toolkits are available in more than 20 languages. So it has to work within the vaccination of the Hispanic community, but also many of our other harder to reach communities.

Yes, we are continuing to do outreach by trusted messengers in their own language and culturally sensitive ways. And in fact, we are seeing that is working. We had a recent NWR in North Carolina that demonstrated when we did this outreach, we were able to reach Hispanic communities, increasing vaccination rates from 8 to 19 percent.

Senator LUJAN. Dr. Walensky, the next question I have is along those lines. The Administration has enlisted Black owned barbershops and beauty salons, as well as faith based community outreach to promote the shots and even serve as vaccination sites to increase Black vaccine rates. Which is important and I applaud. Does the Administration have plans to employ similar targeted outreach to the Hispanic community?

Dr. WALENSKY. The Administration is working to reach people where they are and to understand the community by community, what is it that community needs, to understand—to have trusted messengers, whether it is in barbershops, whether it is in faith based organizations, whether it is in grocery stores, that is what we are working to do.

Senator LUJAN. I would be interested if you could submit to me or get to me what those plans are for outreach into the Hispanic community, similar to the plans I just described. I wish I could ask the panel similar questions about Native American vaccination rates. IHS is not sharing the data, with the exception of the good work that is happening in Alaska, where Alaska is not depending on IHS to get vaccination rates.

We do not have state specific IHS data. Many officials have told me they are going to fix this. It has not been fixed. Please fix it. Let's get IHS on board. Let me ask each of you a yes or no question, has disinformation on tech platforms negatively impacted the response to the pandemic, Dr. Walensky?

Dr. WALENSKY. Yes. And in fact, it has propagated 70 percent more often.

Senator LUJAN. Dr. Fauci.

Dr. FAUCI. Yes, it has.

Senator LUJAN. Dr. Woodcock.

Dr. WOODCOCK. Yes, absolutely.

Senator LUJAN. Ms. O'Connell.

Ms. O'CONNELL. Yes, it has.

Senator LUJAN. Assistant Secretary O'Connell, viruses don't respect international borders, and for interconnected border states like New Mexico, our physical and economic health depends on international cooperation. I very much appreciate the line of questioning from Dr. Cassidy. We need to do better in this space and look for every available tool that exists to make sure we are helping get vaccine out, especially into neighboring countries across the Americas. What can the Federal Government do to decrease COVID infections in border communities?

Ms. O'CONNELL. Thank you, Senator, for that question. And, I did want to follow-up on what Senator Cassidy asked and Dr. Woodcock was responding to. It is a question of liability, which is one of the things that we work through in these contracts that need to be worked through when vaccines are shared with other countries.

That is the contracting issue that can be an impediment. But it is important, I think, that we offer tests and vaccines where we can to prevent the spread of COVID in the border communities.

Senator LUJAN. I recently joined a CODEL to Latin America, and one of the countries we visited in Ecuador, where I found out that some of the vaccine formularies and samples have not been made available to local regulators to approve the vaccine anticipating if the United States can donate more vaccine or there is more vaccine purchased.

Dr. Walensky and Dr. Woodcock—and I know my time is about to expire. Maybe submit this into the record. How can the Federal Government better coordinate internationally to ensure that foreign regulatory bodies have the data and vaccine supply so they can be approved locally? If you want to give me a quick response so then I can follow-up into the record.

Dr. WOODCOCK. We have—we have collaborations with regulators around the world through EKRA, which is the International Medicines Group, Medicine Regulator Group, as well as other ways. So we are actively reaching out to other foreign regulatory authorities to give them information about what we have done to review vaccines and what we know about them.

Senator LUJAN. Thank you. And I want to thank this trusted panel. I certainly hope that we can stop the spread of misinformation, that we can listen to the experts, and save more people across America. Thank you for your commitment to saving lives. I yield back.

The CHAIR. Thank you.

Senator Braun.

Senator BRAUN. Thank you, Madam Chair. Questions for Dr. Fauci. I am a strong believer in First Amendment protections, and we have obviously seen coming from the business world as well, the tech industry carries so much clout. They are monopolies as ones are defined. And when you have markets that you control over 70, 80 percent, that is so much not only economic power, but it is a lot of other power that goes along with it. When you have any case where the Federal Government gets in cahoots in any way with big companies like that, that is almost unheard of.

Generally the Government would try to do something about that. In February, Facebook included new criteria for removing misinformation, and part of it was about the origination of the COVID virus, which now has gone from what they were declaring is misinformation to maybe the way we think it actually occurred.

Facebook has said that they have made consultations with leading health organizations. Was your organization, NIAID, one of the leading health organizations Facebook consulted with when deciding what speech to filter through?

Dr. FAUCI. To my knowledge, Senator, that is not the case. When you say consulting with my agency regarding what speech to filter

through, I don't ever recall or have ever heard of any discussion about filtering speech.

Senator BRAUN. Did they consult with you on any topics, not necessarily whether you would filter through it or not? Have you been in contact with them to give them your personal opinion on this or that?

Dr. FAUCI. I don't know what you mean by this or that. There was one communication or two perhaps with Mark Zuckerberg in which he emailed me and wanted to know if there is anything that he could do that I believe it was promoting vaccination or making sure people do the right thing, wear a mask. But it was mostly propagating a public health message. It had nothing to do with the origins of the virus at all.

Senator BRAUN. Then do you, on a very frequent basis, consult with him, either via email or do you have his cell phone number, for instance?

Dr. FAUCI. I have exchanged a few emails. You probably know that because you are asking the question. About 10,000 pages of my email have been FOIA'd. And in fact, there is an email exchange or two between myself and Mr. Zuckerberg. I don't recall—I can look it up right now and see if I have a cell phone number. I am not sure I do.

Senator BRAUN. Well, you can get back to me on that. I am guessing you might. My point is an entity like that, and we have got 190 million users here in the U.S. and they are getting into the fray on so many things. And they are the classic example where there is too much concentration within one entity. And in years past, we have done something about that, not just let it kind of run its course. And we have never had any of the big monopolies get involved with filtering or censoring speech to boot.

Another question related to the White House, has recently said that they are wanting to flag problematic posts. And working for the President, would you be one that would try to come up with whatever posts that are out there that need to be flagged as misinformation?

Dr. FAUCI. No, I have not at all been involved, even indirectly, in that.

Senator BRAUN. Do you think there is a risk, even though you haven't been involved, to the White House wanting to flag stuff that they think is problematic, and then have that same type of communication with entities like Facebook? Just your opinion on that?

Dr. FAUCI. No, actually, this is beyond my area of expertise. I developed vaccines to save people's lives. I don't get involved in flagging things, Senator. So, I am sorry.

Senator BRAUN. Let's then pivot to speaking of vaccines.

Dr. FAUCI. Yes.

Senator BRAUN. When you entered grade school, there are many vaccines that are mandated, and I think accepted over time. Would you, and I would like Dr. Walensky to ask or answer this as well, would you be for mandating ever a vaccine for COVID–19 or any other variants as mandatory for getting into grade school?

Dr. WALENSKY. I think first we need to see the data. I hope they are efficacious. But first we need to see the data. Understand the risk benefit. So I think that is premature at this point.

Senator BRAUN. What data would you need beyond what we have got to go to that next step of making that a mandate, along with some of the others that have been so for a long time?

Senator BRAUN. We don't have—we don't have clinical trial data in the grade school age population yet.

Senator BRAUN. I think that means for you that you might considering further down.

Dr. WALENSKY. I think we need to see what the clinical trial data to see the risk benefit and see the long term data.

Senator BRAUN. Dr. Fauci?

Dr. FAUCI. I think the same thing. You have to make decisions based on data. We don't have that data right now. When we do, then we could address that decision.

Senator BRAUN. Thank you.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Madam Chair. So I have been encouraged by this Administration's use of the Defense Production Act to produce more pandemic supplies in the U.S. And I was proud to be a part of the effort to secure $10 billion in the American Rescue Plan to increase the domestic supply of PPP and other medical supplies. In 2020, the U.S. was overly dependent on China, and we did not have sufficient domestic sources of very critical PPE, which was exacerbated by a shortage of raw materials.

When the pandemic hit, there was a bottleneck in the global production of medical grade meltblown material that is essential for N95 masks. Today, Wisconsin manufacturers have the ability to provide the meltblowns to provide surge capacity required to produce billions of N95 respirator masks. This type of American manufacturing is exactly what we need to be supporting.

Ms. O'Connell, I know that ASPER has used significant funding to increase its inventory of supplies, but I am concerned that if we don't focus some of our expenditures on raw materials, we may remain dependent on China and other countries. How is ASPER working to secure supplies of raw materials like meltblown to make us better prepared for the future?

Ms. O'CONNELL. Senator Baldwin, thank you so much for that question and thank you for the work that you did to get that $10 billion in the American Rescue Plan. We just recently had released by OMB $2 billion of that $10, which is going to go to, among other things, expanding manufacturing for raw materials for vaccines. So that is one of the first efforts that is going to—that money will be used for. It will also go to make sure that we have enough fill-finish capacity, needles and syringes, and it is just the start.

We are, of course, very anxious to get these contracts awarded and moving. But it is the beginning of that $10 billion going to exactly what you had hoped it would go to. Of course, that is not enough. We have got more to go. But I just wanted to share with you, that is where we are right now. We have also spent, as I mentioned earlier, other supplemental funds on producing, and in the U.S., gowns and other PPE.

We are continuing to do that domestic manufacturing. But we do have this industrial base expansion for vaccine manufacturing capacity right now.

Senator BALDWIN. Okay, thank you. During this Committee's last COVID–19 hearing, I asked about the Administration's approach to reducing waste and better targeting vaccines, including by reducing the number of doses in each vial and the number of vials in each package. Experts believe that both of these steps would significantly aid vaccination efforts as doctors' offices and community organizations could more easily give interested patient shots without worrying about spoiling additional doses.

In that hearing, Dr. Kessler expressed the Administration's strong desire and efforts to move forward on both of those goals. But recent reporting suggests that this might no longer be the case. Dr. Fauci, can you assure me that the Administration is doing all it can to encourage the production of smaller vials and smaller batches as soon as possible? And what steps are being taken and what is your anticipated timeline for changes like this?

Dr. FAUCI. Well, thank you for that question, Senator. That is not really in my area of activity. I believe that is more of an FDA question.

Senator BALDWIN. Well, Dr. Woodcock, please.

Dr. WOODCOCK. Certainly. And between ASPER and FDA, right. Basically, to do that, we need to get the manufacturers to change how they are manufacturing the drug and what the storage conditions might be and things like that. And I think heroic efforts are being made to try and get a vaccine—get vaccines that don't require deep freezing storage conditions and that could be then broken up into smaller groups and stored in, say, a pediatrician's office refrigerator.

I mean, that is the idea here, that—so that pediatricians and others could—primary care, at the pharmacy, at the nursing home pharmacy, whatever, as new people come in, they could vaccinate them without wasting large amounts of vaccine or having to break into something in the deep freeze.

Those efforts are arduously going on. They are highly technical, though, and they aren't simple. And I think the Government and the manufacturers are both united in realizing this is necessary.

Senator BALDWIN. Thank you.

The CHAIR. Thank you.

Senator Tuberville.

Senator TUBERVILLE. Thank you very much. Thank you for being here today, testifying. Dr. Walensky, you have been in your current post since January. You are in the top position, and you surely have heard critiques of the job the CDC has done so far in each—this Administration, even the last, you usually learn from some things that happened in the past. What would you say to those who look to the CDC and say that change is needed, that perhaps the agency needs a bit of restructuring?

Dr. WALENSKY. Thank you for that question. Certainly during—

Senator TUBERVILLE. What would you do different?

Dr. WALENSKY. What would I do differently? You know, certainly during the times of pandemic, I came in on January 20th. We had our pedal to the metal, shall we say, moving forward to try and do

everything that we could to get us out of the pandemic. We have made a lot of progress. We have had to be humble about what this virus can do. And a lot has changed just in the last 6 months. We need a public health infrastructure in this country that allows CDC and our state and local health departments to be prepared for a pandemic.

In that process of restructuring, we need long term disease diagnostic funding that isn't like a roller coaster that comes with one pandemic and, or one infectious disease threat and disappears when that threat is gone. We are going to be dealing with this—when, God willing, everybody is vaccinated and people are well and the pandemic is largely behind us, we have long COVID, we will have boosters to be thinking about, we will be dealing with mental health issues for a very long time to come and we need the public health infrastructure to do so. That would be my biggest—my biggest task and change.

Senator TUBERVILLE. Thank you. Dr. Woodcock, FDA currently has emergency use authorization for three COVID vaccines, but they have not yet received the full FDA seal of approval. What would you say to the vaccine hesitant people who don't feel comfortable taking a vaccine that hasn't been fully FDA approved?

Dr. WALENSKY. Well, first of all, I would say we did not cut any corners in these 30,000 patient trials and these 44,000 patient trials and all the surveillance you have been hearing about of potential rare side effects. So compared to other vaccines they would be looking at, these have really gotten the full court press as far as evaluation and study.

They have gone through the FDA process, and they have gone to the ACIP, the CDC's advisory committee, and strongly recommended that people take them. That said, it is public that one of the companies put a marketing application before us and we are going to do everything we can to review that in a timely manner. But, of course, I can't say anything more about that.

Senator TUBERVILLE. What kind of timeline, do you think, that we will have full approval?

Dr. WALENSKY. That is the kind of thing I can't talk about. Thank you.

Senator TUBERVILLE. Thank you. Dr. Fauci, we have made this way too political—this has been tough on the American people. We all know that. Everybody has worked hard to try to get through this. Politics has played a huge role in this. We have all watched it from close and afar.

But I think people need a unifying message from all of us. Because in my State of Alabama, we don't have everybody taking a vaccine and we are having outbreaks as we speak. We have had Operation Warp Speed General Perna here in a committee hearing—not in this Committee, but in other committee. He took a beating saying how poorly a job he did. And the American people saw that.

A lot of people voted for Donald Trump and a lot of people in the South, a lot of people in my state, and we have to have a unified message. We can't be blaming this or that. We have got to go North with this. We can't go South. We can't go the other direction.

Dr. Fauci, can you understand unless this Administration acknowledges the efforts of the last one, a large part of Americans, they are going to continue to feel like nothing is positive. They are not going to take the vaccine. You understand what I am saying?

Dr. FAUCI. I understand exactly what you are saying, Senator. And thank you. That is a very appropriate question that I would be pleased to answer. Having been present through the last year, which was the year when COVID began, the last year of the former Administration, I can tell you that no doubt that the former Administration deserves a considerable amount of credit for the effort that was put into Operation Warp Speed that was able to allow not only the rapid development and testing, but also the implementation of the vaccine.

There is no doubt in my mind, as someone who has been on both sides of the fence, to say that is the case. But with regard to a unifying message, if I might, sir, I think what we need to appreciate is that we are dealing with a common enemy and the common enemy is the virus. The virus doesn't know if you are a Republican, Democrat or Independent. The virus just knows that it makes people ill and it kills people.

We have an extraordinarily efficient tool against that common enemy. And what I would hope the message would be, the unifying message is let's all pull together and utilize that tool, which is vaccination, to really crush that common enemy. I think we have it within our capability to do it. And I would hope that would be the message.

Senator TUBERVILLE. Positive attitude plus effort equals performance. And if we keep that positive attitude, we can get through this thing. We just need to quit fighting in the media and get everybody believing in the same thing. We are all on the same team. Thank you very much.

The CHAIR. Thank you.

Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Madam Chair and Ranking Member. Thank you, Coach. I appreciate that. The belief in the positive attitude. As someone who was a part of many scientific debates back in my salad days, it just—it makes—it increases my respect beyond what I can say in words of how well you have gone through the intense debate, because these are life and death decisions you have to make oftentimes where there was conflict among the science, and we were trying to get the facts assembled and sorted and prioritized as quickly as we could.

Before I even ask any questions, just let me say that my questions are always toward a unified future. But I want to make sure I recognized how well you have each served your Country under very difficult circumstances. So, and I don't know, Dr. Fauci, how many of these types of hearings have you been in so far?

Dr. FAUCI.

[Technical problems.]

Senator HICKENLOOPER. Yes. So just to look at the intensity by which you focus on the answers is remarkably impressive and I want to express my gratitude and our gratitude. I guess first with Dr. Walensky and Dr. Fauci together, we saw yesterday the Pediat-

rics Academy talk about kids older than two wearing masks. We know that kids 12 and older should be getting vaccinated.

Well, just quickly, just to give you a platform to talk about that unified message, what should schools be thinking about and who should they be talking to get ready? Obviously, the more kids we can get that are over 12 and older, the more we get them vaccinated, there can be—they will be fully protected by the time they get to school in the fall, if we start now.

What does that message look like—would be a couple of—Dr. Walensky why don't you start then Dr. Fauci can fill in.

Dr. WALENSKY. Thank you for that question, Senator. First of all, I want to lean in and say I think it is critically important that our schools be open for full in-person learning in the fall. We have learned enough over the last year to understand what we need to do to keep our children safe. And we believe based on the science, that we can keep them safe in those settings. How are we going to keep them safe?

The first and foremost is the best thing would be to have everybody vaccinated who can be vaccinated. Surround unvaccinated children who are no longer—who are not yet eligible, with people who are vaccinated to protect them. So that is the highest and most important thing. For those children who are not able to be vaccinated, they can and should wear a mask in those school settings. And we have said that in our guidance.

I want to also comment on one other thing, and that is that I think is critically important in the school year coming ahead and that is the role of testing. Senator Burr has talked about the importance of other viral syndromes, flu, influenza. We are going to see upper respiratory infections in these schools in the fall. These kids have not been in school.

They have not been with each other. And I am worried about the upper respiratory infections. And we are going to have to understand what is COVID and what is a simple cold among children. So those are among the things that I am thinking about. Thank you.

Senator HICKENLOOPER. Great. Thank you. Nothing to add?

Dr. FAUCI. Nothing to add. That was a very good explanation.

Senator HICKENLOOPER. You have become a good—an admirable team. Dr. Woodcock, some of the FDA reports on—is it pronounced Adulhelm? Biogen's new Alzheimer's drug I think are very concerning. Last week, there was an expert panel convened by the Institute for Clinical and Economic Review unanimously concluded that it wasn't—it wasn't efficacious, it didn't provide a benefit for patients with Alzheimer's and certainly wasn't worth the price tag. And I know that I saw a couple—I was researching or reading my briefs from my remarkable staff last night that it could have been handled differently. How specifically differently should the FDA have looked at this?

Dr. WOODCOCK. Well, a lot of the confusion is in some of the controversy is simply what you said, this is an accelerated approval. That means it was approved on a surrogate endpoint that we believe is reasonably likely to predict clinical benefit. So the conclusion that you just referred to is not surprising, Okay, because they haven't definitively shown benefit.

Now, Congress has urged us to use the accelerated approval pathway for life threatening diseases that don't have any effective therapy. Alzheimer's is one. I think part of the issue was that it was brought to an advisory committee and proposed for traditional approval, not on a surrogate endpoint. The advisory committee more or less conclusively shut that down. And so the agency went back and looked at all the data on the surrogate endpoint, which is clearing out the Alzheimer's plaque, the amyloid plaque from the brain.

They found that correlated with benefit, benefit meaning slowing a decline of deterioration of thinking, right. And so with Malta looking at other programs with other antibodies to do the same thing, they concluded that this clearing out of a plaque was reasonably likely to predict clinical benefit, right. But not—doesn't definitively mean that there is a clinical benefit. So I think with such a prevalence—it is very common in cancer. It is well accepted.

That is how we approved HIV drugs from the very beginning, alright. And that was a very big success story. That is how we approve many drugs for rare diseases. But this is a common disease and almost everyone probably in this room has had a relative—.

The CHAIR. Dr. Woodcock, thank you. We do have votes called and we have got to finish our hearing. So I appreciate the response.

Dr. WOODCOCK. I am sorry.

The CHAIR. Thank you.

Senator Burr.

Senator BURR. Thank you, Madam Chair. Let me say, Dr. Woodcock, I think the decision that FDA made relative to surrogate endpoints is exactly that forward leaning approach that we envision when we created that expedited pathway. And I applaud the decision. I look back at HIV, who Tony Fauci was very involved in, and had we not done similar things then, we wouldn't have found the keys that unlock doors that we needed.

I want to turn to Dr. Walensky for just a second. I just want to ask a quick follow-up on breakthrough. And Dr. Fauci, I understood what you said about the NIH following the clinical trials over a two-year period as it relates to breakthrough. That is important. It is not important from a standpoint of today and the decisions that we make. It is my understanding that CDC is only tracking breakthroughs that result in hospitalization. Is that accurate?

Dr. WALENSKY. No, it is not. So that is in passive surveillance, which is, as I mentioned earlier, not the best way to track these breakthroughs and one of the limitations of our passive surveillance system, which is why we are collecting longitudinal data in tens of thousands of people, some of whom are getting PCRs so that we can check each test for asymptomatic breakthroughs as well.

Senator BURR. Okay. I think it is extremely important that we be as specific on breakthrough exposures. One of the last tools that we have is, yes, you may get vaccinated, but you may become infected, and you are going to have to prove the data that says you probably won't go to the hospital, and you certainly won't die. So without that data, you are in a very weak situation. So I would encourage you to build that data base. I am going to take a couple

of minutes to make an editorial, and it really gets to the heart of supply chain.

Ms. O'Connell, this is going to fall in your lap. And this is something that the Chair and I and the Committee are going to deal with. You talked about a warm base. I know the target for what we want in the strategic national stockpile. Here is the reality. Federal purchases are 4 percent of PPE. And for us to set up a sustainable supply chain, it means that you have to compete with dumping practices of China on N95 masks. You have to compete with competition from around the world.

I think, I know Janet and Tony understand that the memory span of a Member of Congress is about 18 to 36 months. After that, we sort of forget about the last incident that we went through and where we look at it and say, well, why are we funding to keep the lights on in this N95 mask facility. We don't need any more N95 masks. And the problem is that the 96 percent of the purchasers providers across the country have now turned to the lowest cost competitor, which is probably not the warm base facilities that we have got. We have got to come up with a solution to this, and I want to work with you.

I want to work with the White House. Because I have gotten to a point through a process of elimination as to what won't work, faced with the realities of Congress's inability to continue to fund indefinitely things that don't produce something tangible. We have had to put BARDA on life support three different times because members didn't see a need for it. Thank God we were able to keep it resuscitated.

I am not sure that there is a way to do this without creating an America's trading bloc, where we incorporate North and South America together, where we incorporate the low cost, low labor areas of Central America, where textile companies already have a presence, where companies could move automatic N95 masks, and not just warm base them, but actually let them compete with China in the open marketplace and sell to the rest of the world, and invite the EU and invite Australia and invite Africa and India to be part of the America's trading bloc where we can expand.

As Janet knows, we have had problems with Brazilians on knocking off pharmaceutical manufacturing down there for years. Let's turn them into a part of our inventory of assets where we can turn to vaccine production down there, pharmaceutical production down there, raw materials of South America.

If not, then show me something that is sustainable without the condition of Congress coming in and funding at the tune of hundreds of billions of dollars on an annual basis to keep that supply chain for us as a purchaser of only 4 percent. Somehow we have got to—we have got to present to the other 96 percent a domestic manufacturing capability that makes them competitive against China even with China's dumping practices.

I sort of lay that on the table. It won't be the first time Tony has looked at me and said, you come up with something crazy, but I am in the business of trying to find solutions that are sustainable. And it will only happen if we think outside the box on this. We thought outside the box with surrogate endpoints and Janet, well down the road people don't die of HIV. They extend their lives.

Maybe the keys we find are actually cures in the future, mRNA technology platform, Tony. We may be curing cancer off of that platform two, three, four years down the road. I wonder what the person who didn't like mRNA for the vaccine for COVID think when they have got prostate cancer and they have got a cure on an mRNA platform? I think they are going to take it.

Everything is going in our favor, but this is absolutely crucial to our assurance to the American people and to the American economy and manufacturers that we are going to put them somewhere, in a system that is sustainable for the future. I thank you for listening to me and I thank the Chair. I yield back.

The CHAIR. Thank you, Senator Burr. Appreciate that. That will end our hearing for today. And I want to thank all of our colleagues, our witnesses, Dr. Walensky, Dr. Fauci, Dr. Woodcock, Ms. O'Connell, Assistant Secretary O'Connell, for such a thoughtful discussion about our ongoing response to this pandemic and the path forward.

With that, for any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, August 3rd at 5 p.m. The hearing record will also remain open until then for Members who wish to submit additional material for the record.

The Committee will next meet tomorrow, July 21st, for an executive session to consider the Family Violence Prevention and Services Improvement Act of 2021 and the nominations of Catherine Lhamon to be Assistant Secretary for Civil Rights at the Department of Education, Lisa Brown to be General Counsel of the Department of Education, Roberto Rodriguez be Assistant Secretary for Planning, Evaluation and Policy Development at the Department of Education, David Weil to serve as Administrator of the Wage and Hour Division at the Department of Labor, and Gwynne Wilcox and David Prouty to serve as members of the National Labor Relations Board.

Again, thank you to all of our witnesses today. With that, this Committee does stand adjourned.

QUESTIONS AND ANSWERS

RESPONSE BY DR. ROCHELLE WALENSKY TO QUESTIONS OF SENATOR CASEY, SENATOR BALDWIN, SENATOR HASSAN, SENATOR BURR, SENATOR BRAUN, AND SENATOR TUBERVILLE

Responses to the QFRs are accurate as of the date of the hearing.

SENATOR CASEY

Question 1. Even as the vaccination campaign continues—whether it is reaching people who thus far have been reluctant to get vaccinated, or hopefully expanding the campaign soon to include younger children—testing remains an important tool in our fight against COVID–19. Especially given that younger children are not yet eligible for vaccination, and with the rise of the Delta variant, testing continues to be a pressing need to ensure that cases are caught early to break the chain of transmission—or to rule out COVID–19 when someone is showing symptoms that are common to different illnesses. How is CDC working with local public health officials, health care providers, employers and schools to support robust testing regimes, and what do those recommendations look like currently?

Answer 1. CDC is actively engaging with our state, tribal, local and territorial public health partners and with K–12 schools to support implementation of robust

testing programs. CDC guidance on testing can be found here: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html*.

CDC has provided specific technical assistance (TA) on testing and/or deployed teams to jurisdictions and school districts who have requested assistance. Support is provided through technical assistance calls, sharing of resources, and creating connections with their state or local school testing teams at the health department or referrals to other opportunities for Federal testing support, such as the HHS Testing and Diagnostics Work Group.

CDC is also partnering with jurisdictions interested in exploring various ways to expand access to testing and incentives to test in populations they have identified as likely to benefit from additional testing. This includes factors such as current proximity to testing sites, area percent test positivity or case burden, and other factors such as social vulnerability index scores. Pilot activities have explored expanding testing in high density workplaces, using pop-up testing in retail sites in the communities, and event-based testing where testing is offered in conjunction with previously scheduled or well-known events or gatherings. As an example, the Race to End COVID project at the Talladega Superspeedway, sponsored by Talladega Superspeedway, the Alabama National Guard, the U.S. Department of Health and Human Services, the CDC Foundation, and the Alabama Department of Public Health, offered an incentive to drive two laps around the track behind a pace car to all participants who were tested or vaccinated at the pop-up site hosted by the track. The lessons learned from these pilots will be disseminated to inform other jurisdictions who are seeking ways to expand testing availability and desirability within their populations.

Starting in mid-May, one-on-one TA calls were held with 46 health departments to discuss their testing plans for summer schools and summer camps as well as their plans to offer screening testing to K–12 schools in their jurisdiction using CDC Epidemiology and Laboratory Capacity (ELC) Reopening Schools cooperative agreement funds.

Question 2. Earlier this year, I sent a letter with Senator Wyden, Senator Tim Scott, and Senator Crapo, calling on CDC to publicly release data that have been provided to the Federal Government by CVS and Walgreens in relation to the Long-Term Care Partnership (LTC Partnership). The LTC Partnership data is the only real time accounting of the COVID–19 vaccine rollout from the beginning, and experts have testified to Congress that it is critical to understanding how the distribution of vaccines proceeded, as well as the racial, economic and geographic equity of the COVID–19 vaccine distribution. As the bipartisan letter noted, releasing such information retrospectively will help researchers and policymakers analyze issues such as the speed and equity of vaccine distribution, and the vaccine's role in reducing disease and death in nursing homes. One need look no further than your agency for proof of the data's usefulness—CDC shared the LTC Partnership data with states, and used the data for its own public-facing research. Please provide me with all facility-level vaccination data that has been transmitted to CDC by the LTC Partnership since December 2020. Please provide these data no later than August 20, 2021.

Answer 2. CDC has been in communication with your staff regarding this data request.

Question 3. There is concern that cases of influenza this coming winter season will be significantly higher than last year. Is there an opportunity to encourage increased uptake of both flu and COVID–19 vaccines in the coming months, and what would need to occur to make that happen, in terms of patient and provider education, vaccine distribution plans, etc.?

Answer 3. This influenza (flu) season, CDC will expand education efforts to promote flu vaccination, including among groups of people for whom vaccination is especially important, such as people with underlying health conditions, pregnant women, children under 3, and people within racial and ethnic minority groups, which typically have lower vaccine uptake. CDC is investing an additional $150 million to continue to build community engagement around COVID–19 and flu vaccination among racial and ethnic minority groups.

In addition, CDC has planned outreach through social media, press conferences, web page spotlights, radio media tours, op-eds, and other publications. A digital campaign will launch to educate the public and people who are at increased risk from influenza and COVID–19 complications about the importance of vaccination. Finally, CDC will support a special campaign to inform the general population, with a focus on Black/African American and Hispanic/Latino audiences, about the importance of flu vaccination.

SENATOR BALDWIN

Question 1. The CDC is updating its variant tracker once every 2 weeks. Please provide additional information regarding CDC's plan to increase the frequency of this reporting, improve the granularity of data provided, and work with state and local health departments to enhance sequencing efforts on the ground.

Answer 1. CDC reports variant proportion data on two-week time intervals with plans to increase frequency in the coming weeks. CDC developed guidance for state and local public health laboratories to "tag" sequences submitted to public data bases that were generated through state-level baseline genomic surveillance efforts. By tagging these sequences, CDC can incorporate these sequence data into the national analysis of variants. Integration of surveillance across the U.S. maximizes the sequencing capacity, expertise, and available data across the U.S. that is available to inform public health decision-making.

To improve the detection, monitoring, and mitigation of COVID–19 variants, the American Rescue Plan invested $1.7 billion to help the CDC, states, and other jurisdictions more effectively detect and track variants by scaling genomic sequencing efforts. This one-time funding is supporting CDC and state and local public health to increase the use of sequencing in the U.S. public health system. The information from sequencing allows CDC and state and local public health leaders to respond to emerging infectious threats more effectively. Sequencing technology is used not only to help in the detection and prevention of COVID–19, but also with most other infectious disease threats. The CDC Advanced Molecular Detection (AMD) program was established in 2014 and has been funded by Congress at $30 million per year, to incorporate sequencing and relevant technologies into public health and has been applied to food safety, emerging infections, biosecurity, antimicrobial resistance, and many other pathogens. CDC has also funded 29 universities to conduct genomic surveillance research in collaboration with public health agencies. The studies are meant to provide deeper insights into viral genomics and molecular epidemiology within the various regions across the country.

SENATOR HASSAN

Recently, deeply disturbing reports have been published detailing dangerous inequities that USA Paralympians are facing at this year's Tokyo Paralympics.

Becca Meyers is a six-time Paralympic medalist who won three golds in Rio 5 years ago. She is deaf and blind, but in the past that hasn't stopped her from competing—and winning—at the highest levels.

This year, though, she and other athletes from Team USA who experience disabilities are being denied adequate access to personal care assistants, reportedly due to COVID–19 restrictions.

Individuals who experience disabilities should not be forced to navigate the Tokyo Olympics without the support they need in the midst of a global pandemic.

Becca announced on Sunday that she is quitting the team because she is being denied a, "reasonable and essential accommodation" that would enable her to compete.

This is an outrage—and an entirely preventable situation.

The US Olympic & Paralympic Committee must work immediately to address this issue, and ensure that all of our athletes are able to compete safely at this summer's games—including by providing them the basic supports they need to navigate the world.

Question 1. Director Walensky, over the last year and a half, the CDC has provided guidance on how to mitigate the risk of COVID–19 in various activities, as well as special events—including sports. Understanding that the CDC does not have jurisdiction over specific safety measures taken by the US Olympic & Paralympic Committee, can you please explain how COVID–19 mitigation efforts take into account the needs of people who experience disabilities?

Answer 1. We know that most people with disabilities are not more likely to become infected with or have severe illness from COVID–19. However, some people with disabilities might be more likely to get infected or have severe illness because of underlying medical conditions, residing in congregate living settings, or systemic health and social inequities.

CDC is currently providing $93 million to the Administration for Community Living (ACL) within HHS to administer grants to aging and disability networks in every state and territory. These funds are providing assistance to older adults and people with disabilities for scheduling vaccine appointments, transportation to vac-

cine sites, direct support services needed to attend vaccine appointments, connection to in-home vaccination options, and education about the importance of receiving the vaccine to older adults and people with disabilities. This partnership is also providing an additional $5 million in funding to stand-up and maintain a new Disability Information and Access Line (DIAL) to help people with disabilities find vaccination locations in their communities, assist callers with making vaccination appointments, and connect callers to local services.

CDC partners with state, territorial, local, tribal partners, and community-serving organizations to support communities at higher risk for COVID–19. For example, CDC is partnering with FEMA, CDC Foundation, Georgia Tech Center for Inclusive Design and Innovation, University of North Carolina Center for Literacy and Disability Studies, DeafLink, and National Association of State Directors of Developmental Disabilities Services, to provide COVID–19 guidance and resources for people with disabilities and care providers. There is a need for guidance and resources that are tailored for people with disabilities and their care providers. This project aims to compile and develop guidance and tools to help people with disabilities and those who provide services or care for them make decisions, protect their health, and communicate with their communities. The tools and guidance developed in this project reflect what CDC has learned about the needs of people with disabilities and care providers from partners and listening sessions, projects, and research efforts. Following the launch of the CDC Toolkit for People with Disabilities web page (*https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/people-with-disabilities.html*), we gathered feedback from partners indicating a need for more information geared toward people with disabilities related to vaccine access, accessible vaccination sites, and accessible communications products/web resources to develop web content, fact sheets and one-pagers, scheduling language, and a promising practices document on vaccination access for people who have challenges leaving their home. As a result, we began the integration of information related to people with disabilities as well as social media and web-based graphics that reflect varying disabilities throughout the CDC sites instead of just on disability-related webpages.

Another collaborative project involving CDC Foundation and Georgia Tech Center for Inclusive Design and Innovation is developing accessible materials and culturally relevant messages for people with disabilities. The project focuses on people with disabilities, as well as caregivers of people with disabilities, and organizations serving people with disabilities to deliver essential COVID–19 information. The project helps to ensure that COVID–19 guidance is not only accessible to people with disabilities, but also that it is culturally appropriate and relevant to the challenges people with disabilities face during emergency response situations such as COVID–19.

SENATOR BURR

Question 1. Is CDC tracking the number of individuals who got vaccinated that were previously infected with COVID–19?

Answer 1. CDC uses seroprevalence surveys to estimate the proportion of the population that has antibodies as a result of vaccination, infection, or both. Both vaccination and infection result in production of antibodies. By using a combination of antibody tests and vaccine history, we can distinguish if someone has been infected, vaccinated, or both.

CDC is working with national blood collection organizations to estimate the number of vaccinated persons that were previously infected based on vaccine history and antibody testing. We are analyzing these data and working to publish soon.

CDC is modifying its national commercial laboratory survey to capture similar information and hopes to implement this during the upcoming months.

Question 2. If not, how is CDC estimating the actual level of immunity—both natural immunity from having COVID–19 and the immunity provided by vaccination—to get a full picture of the road ahead to protect our communities?

Answer 2. CDC is currently estimating the level of immunity through the seroprevalence studies described above. The type of antibodies detected can determine if the person has antibodies because of past infection or due to vaccination alone. In addition, CDC currently has a manuscript in production that assessed SARS-CoV–2 seroprevalence related to infection and vaccination in the US population.

Question 3. Is CDC tracking reinfection rates for those that have been previously infected with COVID–19?

Answer 3. CDC is using several data sources to understand reinfections including cohort studies, review of big data from electronic health record systems, and by working with local jurisdictions as they link cases over time. In terms of surveillance, CDC is working closely with public health jurisdictions and the Council of State and Territorial Epidemiologists (CSTE) to update the national surveillance case definition of COVID–19 and enable states to count repeat infections in the same individuals over time. This information will be included in the approved position statement 21-ID–01 titled "Update to the standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID–19)." The rate of reinfections depends on both the level of protection by previous infection, for which there is increasing evidence, and the general rate of infections in the population, which is highly variable. Unlike ascertaining vaccine status, ascertaining prior infection status relies on data systems linking multiple episodes in local jurisdictions or on widespread sequencing.

Question 4. Can T-cell testing be used to gain better insight in to how COVID–19 variants interact with immunity from previous infection or vaccine?

Answer 4. SARS-CoV–2 T cell assays are very complex, and therefore are not widely available. Individuals cannot obtain these tests from health care providers. T cell studies can be performed in a research setting. However, we do know that T cells contribute to immunity. Preliminary studies indicate that vaccines generate T-cell immunity, and it is maintained against variants. Ongoing studies are being performed to understand T-cell immunity better.

Question 5. According to CDC, 74 percent of hospitalized or fatal breakthrough infections occurred in individuals 65 and older. Is CDC tracking how many of these individuals have other conditions that may make them more susceptible to severe illness from COVID–19?

Answer 5. The best data for this come from the Coronavirus Disease 2019 (COVID–19)-Associated Hospitalization Surveillance Network (COVID-NET), because it has more comprehensive and complete information on underlying medical conditions among hospitalized patients.

COVID-NET is a population-based surveillance system that collects data on laboratory-confirmed COVID–19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states covering approximately 10 percent of the U.S. population. Preliminary data from COVID-NET show, among all COVID–19-associated hospitalizations, approximately 29 percent of all vaccinated cases are immunocompromised compared to 11 percent of all unvaccinated cases. Additionally, approximately 68 percent of vaccinated hospitalized cases have 3 or more underlying medical conditions compared to 52 percent of unvaccinated cases. For adults ages 65 years, 32 percent of all vaccinated hospitalized cases are immunocompromised compared to 13 percent of unvaccinated hospitalized cases. For adults ages 65 years, the proportion of vaccinated hospitalized cases (74 percent) is not significantly different from the proportion seen in unvaccinated cases (69 percent).

For national surveillance, 7,525 vaccine breakthrough infections among people who were hospitalized or died were reported as of August 2, 2021. Of those, 2,895 (38 percent) had one or more of the following conditions noted: pregnant, diabetes, renal disease, liver disease, autoimmune disease, immunocompromised, or immunosuppressive medication. However, another 3,352 (45 percent) were missing data regarding one or more of these underlying conditions. In addition, national vaccine breakthrough surveillance does not collect information on other underlying medical conditions (e.g., obesity, cardiovascular disease, or pulmonary disease) that have been associated with more severe COVID–19 disease but are not presumed risk factors for a vaccine breakthrough infection.

Of note, of the 7,525 reported vaccine breakthrough infections among people who were hospitalized or died, 5,557 (74 percent) were aged 65 years, including 3,704 (49 percent) who were aged 75 years. Therefore, a large majority likely have one or more underlying medical conditions that might reduce their response to vaccination and/or increase their risk for severe COVID–19 disease.

The number of COVID–19 vaccine breakthrough infections reported to CDC through national surveillance likely are an undercount of all SARS-CoV–2 infections among fully vaccinated persons. National surveillance relies on passive and voluntary reporting, and data might not be complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases.

Question 6. CDC stated that children who are eligible for the COVID–19 vaccine can get their routine vaccinations at the same time as their COVID–19 vaccine.

Looking to the fall and a potential need for boosters, can a person receive the flu shot and the COVID–19 shot at the same time?

Answer 6. COVID–19 vaccine and other vaccines may be administered on the same day, as well as any interval without respect to timing (*https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf*). However, some additional guidance related to co-administration of COVID–19 vaccines and influenza vaccines specifically is under consideration for the upcoming Prevention and Control of Seasonal Influenza With Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP)—United States, 2021–2022 Influenza Season. CDC will provide a further update when available.

SENATOR BRAUN

Question 1. Can you please provide specific updates on your plans to ensure that nursing home staff and residents have sufficient point of care molecular diagnostics and access to the most appropriate prophylactics and treatments?

Answer 1. Long-term care facilities (LTCF), such as nursing homes, are high-risk settings for residents, staff, volunteers, and visitors. Case and death rates for LTCF staff and residents have declined sharply since mid-December 2020 when vaccine rollout began. Recent outbreaks, including those linked to variants and/or breakthrough cases, further stress the need to vaccinate residents and staff, including vaccinating new residents and staff given relatively high turnover in both categories, and continue to implement appropriate infection prevention and control (IPC) practices effectively and consistently.

More than 80 CDC teams have deployed to LTCFs to investigate outbreaks, assess staff and supply shortages, and recommend IPC measures. Additionally, CDC maintains guidance specifically for nursing homes and long-term care facilities around IPC practices and the appropriate use of testing which are both essential to quickly detect, identify, and prevent the spread of SARS-CoV–2 infections in LTCFs.

CDC continues to provide resources and information on our website and for patients and healthcare providers regarding the availability of monoclonal antibody treatments and other COVID–19 therapeutics for certain patients at high risk of disease progression.

CDC is working to rapidly characterize emerging variants to understand the potential impacts on critical SARS-CoV–2 medical countermeasures (e.g., vaccines, therapeutics, and diagnostics). CDC provides updated information on variant classifications and definitions as well as the national prevalence of variants of interest and concern. These data and other clinical considerations are being used by the Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS and other Federal and state partners to inform decisions regarding distribution and allocation of testing supplies, therapeutics (i.e., monoclonal antibodies), and personal protective equipment (PPE) supplies to help jurisdictions and their nursing homes. CDC continues to update its information and resources as new science becomes available. CDC also continues to work closely with the Centers for Medicare & Medicaid Services (CMS) within HHS and jurisdictions to provide technical assistance and support to nursing home facilities across the U.S. through current CDC programs and those stood up as part of the ongoing COVID–19 response. This also includes hosting webinars, Clinician Outreach and Communication Activity (COCA) calls, and engaging LTCF partners to provide the latest information.

Question 2. Due to mandatory lockdowns, limited doctor office, clinics and emergency room visits, there has been a rapid decline in routine health screenings such as HIV/AIDS. Your agency found that at just one commercial laboratory system, comparing a six-month period in 2019 to 2020, they reported nearly 700,000 fewer HIV screening tests completed and about 5,000 fewer confirmed HIV diagnoses. This is reflective of what has happened across the country: HIV testing is greatly reduced due to patients not accessing healthcare and health departments moving resources to COVID.

Question 2(a). This is especially troublesome because as we know, early detection and getting patients on a treatment plan is critical to limiting the spread of HIV/AIDS. Will you commit to keeping this Committee updated on HIV screening levels? Will you commit to developing a plan to encourage Americans to visit their local healthcare provider for routine screenings?

Answer 2. Yes, and thank you for asking this important question. After an initial interruption of key HIV prevention activities due to the pandemic, jurisdictions rapidly prioritized surveillance activities and many scaled up self-testing and mobile

HIV testing activities. These innovations could help overcome longstanding barriers to prevention by providing testing in locations beyond traditional testing venues. Although overall HIV testing declined in 2020, 2021 HIV testing year-to-date is back on track.

Answer 2(a). CDC will keep the Committee updated on progress related to HIV screening and testing in the U.S. Through CDC's core HIV programs and our role in the Department of Health and Human Services-wide initiative, Ending the HIV Epidemic in the U.S., CDC is committed to making testing accessible, convenient, and routine by scaling-up self-testing, making HIV screening a regular part of health care, and increasing testing in non-traditional settings, such as correctional facilities and syringe services programs.

Question 3. Congress has provided a substantial amount of funding for COVID testing—nearly $50 billion in the American Rescue Plan alone, plus tens of billions of dollars more last year. A significant amount of testing money appears to be unspent. This is concerning, given that we are hitting a vaccine wall and cases are on the rise due to the delta variant. We need to ensure that our capacity for testing remains high going into the fall and winter.

Question 3(a). How much money remains for COVID testing from the American Rescue Plan?

Question 3(b). How much money remains for COVID testing appropriated in 2020?

Question 3(c). What is the Administration's plan for the remainder of the COVID testing funds? How and when will this money be spent?

Answer 3(a), 3(b), 3(c). As of the end of July 2021, of the approximately $95 billion identified by Congress across all COVID supplemental appropriations for testing-related activities, all but $17.5 billion had been allocated to support testing, contact tracing and mitigation activities across HHS. HHS is in the process of allocating the remaining balance for priority activities such as increasing community access to testing and supporting domestic manufacturing capacity of tests and enhancing testing capacity in congregate settings.

In particular, as of the end of July 2021, the Centers for Disease Control and Prevention awarded approximately $40 billion of the COVID supplemental funding appropriated to HHS for broad testing, mitigation and related activities, support for school testing and to address testing-related health disparities in high-risk and underserved communities to state, local, and territorial health departments. In addition, CDC had plans in place for additional awards to targeted settings. These funds support a range of activities, including: enhancing testing and mitigation in targeted settings such as correctional facilities, and among homeless populations; expanding the Nation's disease intervention specialists; supporting infection prevention and control; expanding the Nation's wastewater surveillance system; and improving laboratory data and capacity.

SENATOR TUBERVILLE

Question 1. What would you say to those who look at the CDC and say that change is needed, that perhaps the agency needs restructuring?

Question 2. What areas or offices specifically do you think could be restructured?

Answer 1 & 2. Thank you for the questions. The ability to respond to a public health emergency requires a strong day-to-day public health system, supported by infrastructure that is not highly segmented by disease, condition, or activity. In addition to the COVID–19 pandemic, over the past 24 months, CDC has also responded to diverse public health threats from E-cigarette or Vaping Product Use-Associated Lung Injuries (EVALI), Ebola, complex multi-state food-borne disease outbreaks, wildfires, and hurricanes. Responding to the unique characteristics of each of these public health emergencies has required deep scientific expertise to deploy a specialized approach and called for a robust public health system with world-class infrastructure nationwide to stop disease at its source. Unfortunately, this recent history has revealed the effects of an inadequate public health infrastructure. Ongoing health disparities made us as a nation more vulnerable to outbreaks, large-scale public health emergencies, and pandemics as well as burdening large segments of our population with chronic public health concerns. Additional investments in both domestic and global public health and health security infrastructure are needed.

With investments requested in the fiscal year 2022 Budget, CDC will begin to address mission-critical gaps in public health infrastructure and capacity nationwide. Transitioning from sporadic influxes of supplemental funding tied to a specific emergency to flexible funding that can prevent another crisis will strengthen the current

public health system. Flexible, sustainable investments in infrastructure and capacity are critical for saving lives and averting economic losses caused by public health emergencies and chronic public health problems. In fiscal year 2022, CDC will prioritize funding to rebuild the most critical public health infrastructure needed to safeguard the Nation's health and economic security.

Question 3. Isn't it important for CDC to track cases in order to determine the effectiveness of the vaccine against COVID?

Answer 3. CDC has multiple surveillance systems and ongoing research studies to monitor the performance of vaccines in preventing infection, disease, hospitalization, and death. CDC also collects data on breakthrough infections through outbreak investigations. Examples of CDC's systems for monitoring performance of vaccines include: The National Healthcare Safety Network (NHSN), HEROES/RECOVER, Influenza and Other Viruses in the Acutely Ill (IVY), and the Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET).

Question 4. Do you consider it misinformation for individuals to share their stories of adverse events following vaccination?

Answer 4. Millions of people in the United States have received COVID–19 vaccines under the most intense safety monitoring in U.S. history. Communicating timely and transparent information to public health officials, healthcare providers, and the public about the safety of vaccines, including possible adverse events following vaccination, continues to be a top priority for CDC. CDC's communication effort will always be based on the scientific evidence and data that we have gathered to-date through different sources, including analyzing our vaccine safety monitoring data and vaccine safety clinical research.

CDC recommends that individuals who may have experienced an adverse event following vaccination speak to their healthcare providers. CDC also encourages anyone experiencing any possible adverse events following vaccination to share this information through CDC and FDA's vaccine safety monitoring system, Vaccine Adverse Event Reporting System (VAERS). When individuals are administered COVID–19 vaccines, they are also given information about the opportunity to register with CDC's after-vaccination health checker service, called v-safe. Through v-safe, vaccine recipients can quickly tell CDC if they have any side effects after getting a COVID–19 vaccine.

Question 5. Can you provide the estimated number of reinfections in COVID-recovered individuals, to the best of the CDC's understanding?

Answer 5. CDC is using several data sources to understand reinfections including cohort studies, review of big data from electronic health record systems, and by working with local jurisdictions as they link cases over time. In terms of surveillance, CDC is working closely with public health jurisdictions and the Council of State and Territorial Epidemiologists (CSTE) to update the national surveillance case definition of COVID–19 and enable states to count repeat infections in the same individuals over time. This information will be included in the approved position statement 21-ID–01 titled "Update to the standardized surveillance case definition and national notification for 2019 novel coronavirus disease (COVID–19)." The rate of reinfections depends on both the level of protection by previous infection, for which there is increasing evidence, and the general rate of infections in the population, which is highly variable. Unlike ascertaining vaccine status, ascertaining prior infection status relies on data systems linking multiple episodes in local jurisdictions or on widespread sequencing.

Question 6. Can you explain the scientific differences between CDC and WHO recommendations for masking children under 5 years old?

Answer 6. Out of an abundance of caution, CDC recommends masks for children older than age two, carefully weighing the risks and benefits of masking this age demographic. Conversely, most children older than 2 years old do not have any anatomic, physiologic, or developmental limitations that should preclude them from wearing a mask safely and effectively. Masks have been shown to be safe in children older than age two. A cohort study among infants and young children in Italy found that the use of facial masks was not associated with respiratory distress or significant changes in oxygen saturation, including among children age 24 months and younger. In addition, studies suggest that masks are not likely to impact social development in children.

Additional research emerged during the ongoing COVID–19 pandemic with strong and consistent evidence demonstrating the effectiveness of mask use among children age 2 years and older in preventing SARS-CoV–2 transmission, especially when it is combined with multiple prevention strategies.

Question 7. Can you provide the most recent estimate of the number of COVID infections in children under 18 years old?

Answer 7. There were 3,757,699 cases aged 0–17 years during the period, January 21, 2020—August 17, 2021, based on the aggregate case surveillance system counts, accessed August 18, 2021.

Question 8. Are you aware of any ongoing studies into the effectiveness of masking in children under 12 years old?

Answer 8. CDC regularly scans the published and pre-print literature as well as other sources for research on this topic. CDC uses this information to assess current guidance and whether any amendments are warranted based on that new science. There are data from studies of children, including children under 12 years old, that demonstrate masking provides an additional layer of protection against spread of infection in schools. These data are reviewed in this document: *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission-k-12-schools.html*.

Question 9. Funds in part from NIH/NIAID helped build the 12 Regional Biocontainment Laboratories (RBLs) and 2 National Biocontainment Laboratories (NBL) to support high consequence infectious disease research after 9/11 and the anthrax scares in 2001. However, unlike the NBL facilities, the RBL facilities received no further direct support until last year when Congress provided enhanced investment through NIH/NIAID, targeted specifically to RBL facilities, one of which is at the University of Alabama at Birmingham (UAB) in my state. Nevertheless, it seems as though the RBL infrastructure, most importantly the highly trained staff these facilities maintain and produce is something that falls within the purview of the HHS ASPR, considering among other things the UAB RBL has had collaborations with Altimmune and ImmunityBio for COVID19 vaccine development, and supported BARDA contractors. This type of work strongly aligns with numerous ASPR Strategic Goals, such as Fostering Strong Leadership, and Sustaining Robust and Reliable Public Health Security Capabilities. The RBL infrastructure and personnel is expensive to maintain and operate, and perhaps should not solely rest on either the shoulders of the host University or the NIH/NIAID.

Question 9(a). Therefore, is support from Assistant Secretary for Preparedness and Response (ASPR) something under consideration?

Question 9(b). If not, why not, and if so what is needed to facilitate that conversation?

Answer 9(a) & 9(b). CDC defers to our HHS colleagues from NIH and ASPR.

RESPONSE BY DR. ANTHONY FAUCI TO QUESTIONS OF SENATOR BURR, SENATOR BRAUN, AND SENATOR TUBERVILLE

Responses to the QFRs are accurate as of the date of the hearing.

SENATOR BURR

Question 1. Recent reports from the Administration have indicated that, while we don't need a booster for the COVID–19 vaccine just yet, we will likely need one in the near future.

Question 1(a). What does the data show us so far about the durability of all three authorized vaccines, particularly against circulating variants, such as Delta?

Answer 1(a). At this time, data indicate that all currently authorized COVID–19 vaccines remain effective at preventing severe disease and death from COVID–19, including from the Delta variant of SARS-CoV–2 (also known as B.1.617.2). The National Institute of Allergy and Infectious Diseases (NIAID) is supporting research to assess the duration of protection provided by current COVID–19 vaccination regimens and further quantify the protective effect of these vaccines against variants of SARS-CoV–2. Moderna and Pfizer/BioNTech recently reported that immune responses to their respective COVID–19 vaccines remained robust 6 months following vaccination. Johnson & Johnson/Janssen also reported that the durability of immune response from vaccination with their COVID–19 vaccine lasts at least 8 months and that the average neutralizing antibody levels were greater at 8 months than at 29 days post-vaccination. In addition, data from both lab studies and clinical effectiveness studies show the effectiveness of all three authorized COVID–19 vaccines against the Delta variant, particularly against hospitalization.

Question 1(b). What factors should be considered in determining if or when a booster is needed? Should certain populations be considered for a booster before others?

Answer 1(b). The National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and U.S. Food and Drug Administration (FDA) continue to engage in a science-based, rigorous process to help evaluate whether the durability of immune protection from currently authorized COVID–19 vaccines is waning and whether a booster may become necessary. Current data indicate that all currently authorized COVID–19 vaccines remain highly effective at preventing severe disease and death from COVID–19, including against the Delta variant, and as of the date of the hearing, the CDC and FDA have stated that fully vaccinated people do not need a booster shot at this time.

Whether a booster is needed in the future will depend on multiple factors, including the durability of immune protection, the emergence of a SARS-CoV–2 variant that evades protection from currently authorized vaccines, and the strength of immune responses elicited by the initial vaccine regimen in certain populations. For example, data indicate that some immunocompromised individuals, including solid organ transplant recipients and individuals with cancer, have a weak response to the standard vaccine regimen. Emerging data suggest that some of these individuals are able to generate immune responses to an additional dose of COVID–19 mRNA vaccines. Given these data, immunocompromised individuals are likely to be considered for additional doses of the COVID–19 vaccine before other populations.

NIH is conducting and planning studies to measure and enhance the immune response to COVID–19 vaccines in immunocompromised individuals. In April 2021, NIH scientists began two clinical trials to assess how adults and adolescents with certain cancers or immune system deficiencies respond to COVID–19 vaccination. These studies will provide valuable information about the immune responses to COVID–19 vaccines in these individuals. NIAID also plans to launch two additional trials in August 2021 that will assess immune responses to an additional dose of a COVID–19 vaccine in patients taking immunosuppressive medications. One of these trials will enroll participants with one of five autoimmune diseases, and the other will enroll kidney transplant recipients. Each study will enroll participants who have absent or weak antibody responses after an initial course of COVID–19 vaccination. NIAID also plans to launch an additional study that will enroll other solid organ transplant recipients who are receiving immunosuppressive medications. Results from these studies will help us to better understand the immune response to vaccination in immunocompromised individuals and identify approaches to safely enhance their responses to vaccination. These studies may also lead to evidence-based guidelines for safely enhancing responses to COVID–19 vaccination in immunocompromised individuals.

Question 1(c). What is the status of studies looking at using different types of vaccines together, such as administering doses of both Moderna and Pfizer to someone or using an mRNA vaccine as a potential booster for Johnson & Johnson?

Answer 1(c). It is possible that the use of mixed vaccine regimens—in which an individual receives doses of more than one vaccine type—may induce a broader immune response, resulting in improved protection against COVID–19. NIAID currently is supporting research to determine the effect of mixed vaccine regimens and on June 1, 2021, launched a study to determine the safety and efficacy of boosting with a COVID–19 vaccine different than the one used for the initial vaccination, such as the Johnson & Johnson/Janssen vaccine followed by one dose of the Moderna COVID–19 vaccine. The study also will evaluate immune responses against SARS-CoV–2 variants. Initial results from this trial are expected in late summer 2021 and may inform public health policy decisions on the potential use of mixed vaccine schedules, should booster doses be needed.

NIH is committed to supporting further research into the use of mixed vaccine regimens. NIAID also is studying the currently available COVID–19 vaccines—which were designed to target the original strain of SARS-CoV–2—to assess the durability of protection they provide against SARS-CoV–2 variants.

Question 2. Given all of the work that we have put into identifying and tracking these new variants as they emerge, once a new variant is detected, how quickly can we determine—in days or weeks—whether our vaccines will continue to protect us from severe illness due to COVID–19?

Answer 2. As mentioned in the response to question 1, data indicate that all currently authorized COVID–19 vaccines remain effective at preventing severe disease and death from COVID–19, including against known variants of SARS-CoV–2. Once a new SARS-CoV–2 variant of interest or of concern is detected and scientists obtain a sample of the variant or the genetic sequence of the variant, they can assess whether antibodies from individuals who have recovered from COVID–19, or who received a COVID–19 vaccine, can neutralize the variant virus. These experiments,

which provide an early indication of vaccine efficacy against a new variant, can be performed in a matter of days. However, the process of definitively determining the impact of a variant can take months and can vary based on several factors, including how widespread, transmissible, and/or pathogenic the variant is. NIAID is fully engaged in efforts to rapidly mitigate the potential impact of emerging variants of SARS-CoV–2.

NIAID, the National Human Genome Research Institute, and the National Library of Medicine are participating in the SARS-CoV–2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) initiative. SPHERES is a national genomics consortium led by CDC that helps to coordinate SARS-CoV–2 sequencing across the United States. NIAID is working with partners to identify, monitor, and calculate the frequency of current variations in the SARS-CoV–2 genome to help predict emerging variants. NIAID also facilitates the use of cutting-edge modeling and structural biology tools to understand how variants might affect interactions between the virus and the immune system. NIAID scientists are helping to inform our understanding of transmissibility of the variants by studying their stability in the environment and their ability to grow in human lung cells. These efforts add to a growing body of knowledge about SARS-CoV–2 variants and our ability to combat them.

As part of the ongoing COVID–19 response, NIAID is collaborating with vaccine manufacturers on key areas of research to investigate whether vaccines designed for the original strain of SARS-CoV–2 maintain efficacy against emerging variants. NIAID is conducting and supporting comprehensive studies to understand the ability of vaccine-induced antibodies to neutralize the variant viruses. In addition, NIAID is supporting the development of additional COVID–19 candidate vaccines that seek to induce a broader immune response. On March 25, 2021, NIAID launched a Phase 1 clinical trial in healthy adults to assess the safety and immunogenicity of second-generation COVID–19 vaccine candidates developed by Gritstone Oncology, Inc. Gritstone's COVID–19 vaccine candidates utilize a strategy aimed at inducing both neutralizing antibodies and T cell responses to elicit a broad immune response. This approach could provide protection against emerging SARS-CoV–2 variants by targeting several viral antigens, all of which are highly conserved among known viral strains.

Question 3. The Regional and National Biocontainment Laboratories were designed to facilitate NIAID-funded research to address biothreats, including emerging infectious diseases. As you know, Duke University is home to one of these regional biocontainment laboratories, and you have previously highlighted some of their promising research, including a pan-coronavirus vaccine candidate that could potentially provide increased protection against SARS-CoV–2 and a variety of other coronavirus infections.

Question 3(a). Could you expand on the role of the Regional and National Biocontainment Laboratories in the development of medical countermeasures for COVID–19 and other threats?

Answer 3(a). NIAID established the U.S. National Biocontainment Laboratories (NBLs) and Regional Biocontainment Laboratories (RBLs) to conduct research on biodefense and emerging infectious disease agents and to be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism or infectious disease emergency. Biocontainment laboratories, including the NBLs and RBLs, are essential for the development of medical countermeasures for emerging and re-emerging infectious diseases.

The NBLs and RBLs offer unique resources for the research community, including animal models, imaging services, and specialized equipment. In the case of COVID–19, research that involves the use of live SARS-CoV–2 is required to take place in high biocontainment laboratories, such as the BSL–3 laboratories within the NBLs and RBLs. The NBLs and RBLs were able to utilize their unique BSL–3 capacity to assist with basic, translational, and clinical research on SARS-CoV–2 and COVID–19.

Over the past year, the NBLs and RBLs played a critical role in helping to address the COVID–19 pandemic and have been utilized to conduct research with clinical samples containing live SARS-CoV–2 to advance the development of COVID–19 medical countermeasures. The NBLs and RBLs also have been involved in a variety of pre-clinical research activities to test novel vaccines and therapeutics for COVID–19 and to explore the pathogenesis of, and immune responses to, SARS-CoV–2. This research includes the development of new animal models for COVID–19 research and the analysis of SARS-CoV–2 variants of concern.

Question 3(b). How can these biocontainment laboratories be used in future preparedness and response efforts?

Answer 3(b). As noted in the response to question 3(a), the NBLs and RBLs facilitate the conduct of research that aims to prevent, prepare for, and respond to emerging and re-emerging infectious diseases. NIAID recently published a funding opportunity for facility and building system upgrades for the RBLs, which will facilitate future research efforts in these laboratories. NIAID will continue to support highly meritorious biomedical research in biocontainment laboratories, including at the NBLs and RBLs, to prepare for and respond to future infectious disease threats.

SENATOR BRAUN

Question 1. Dr. Fauci, what steps are your agency taking to prepare for the increased exposure to flu, COVID variants, and other communicable diseases in nursing homes?

Answer 1. Older adults, and specifically those in nursing homes and long-term care facilities, are often at higher risk for severe outcomes from infectious diseases, and the Administration is committed to the development and testing of medical countermeasures for this vulnerable population. The Centers for Disease Control and Prevention (CDC), the lead agency for public health, has released guidance on the prevention and management of transmissible diseases in long-term care facilities, including nursing homes. This includes specific detailed guidance for COVID-19, influenza, and other communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports basic, translational, and clinical research into infectious diseases, including research into the prevention of infectious diseases. This research encompasses studies in vulnerable populations, such as older adults and individuals living in nursing homes.

Vaccines are the most effective public health tools for preventing infectious diseases, and COVID–19 vaccines currently authorized by the U.S. Food and Drug Administration (FDA) are well tolerated and effective at preventing severe disease and death, including in older adults. NIAID has played an integral role in the evaluation of COVID–19 vaccines. Early in the pandemic, NIAID supported a Phase 1 clinical trial of Moderna, Inc.'s COVID–19 vaccine, mRNA–1273, which was developed through a collaboration between scientists at the NIAID Vaccine Research Center and Moderna. NIAID included individuals aged 55 and over in this trial to assess the safety and efficacy of mRNA–1273 in older adults. The data from this trial facilitated progression of mRNA–1273 into more advanced clinical trials that ultimately led to the emergency use authorization (EUA) of this vaccine by the FDA.

New viral threats will continue to emerge, and the development of universal influenza vaccines and pan-coronavirus vaccines, which would protect vaccinated individuals against multiple viruses in one shot, can help us be better prepared for future infectious disease threats. NIAID is leading efforts to develop universal influenza vaccines to protect against multiple strains of seasonal and pandemic influenza viruses. NIAID also is conducting early stage research on the development of pan-coronavirus vaccines designed to provide broad protective immunity against multiple coronaviruses, especially SARS-CoV–2 and other viruses with pandemic potential. These vaccines ultimately would be evaluated for use across the age spectrum, including in older adults. NIAID also is investigating the use of therapeutics for prevention of COVID–19 in older adults. In collaboration with Eli Lilly and Company, NIAID initiated a Phase 3 clinical trial that demonstrated that the investigational monoclonal antibody, bamlanivimab, could prevent symptomatic and asymptomatic infection in residents and staff of skilled nursing and assisted living facilities. In addition, NIAID is supporting the development of broad-spectrum therapeutics, including antivirals and antimicrobials, that can be used to treat infections, including in older adults.

NIAID also conducts and supports research into understanding how the immune system changes as we age. On October 21, 2020, NIAID announced a new funding opportunity announcement (FOA), "Cohort Studies To Improve Our Understanding of Influenza Immunity, Vaccine Response and Effectiveness in Older Adults." This FOA will support research to increase understanding of (1) factors that correlate with protection against influenza in older individuals, (2) the impact of influenza exposure and vaccination history on protective immune responses, and (3) immunological mechanisms associated with vaccine failure, including potential intra-seasonal waning of protection. Moreover, this research may lead to the identification of risk factors for severe outcomes associated with influenza infection. Ultimately, this work will inform efforts to develop durable, broadly protective influenza vaccines across the age spectrum of adults.

Question 2. COVID vaccines do not appear to be working as well in immunocompromised individuals or individuals taking immunosuppressants. Could antibody tests be used to greater effect in this population to identify individuals who may need an additional vaccine dose?

Answer 2. Immunocompromised individuals are at an increased risk for poor clinical outcomes from COVID–19. While data indicate that some immunocompromised individuals have a weak response to the COVID–19 vaccines available under FDA EUAs, vaccines remain the most effective tool that we have for preventing COVID–19. As of the date of the hearing, the FDA does not recommend using currently authorized SARS-CoV–2 antibody tests to evaluate a person's level of immunity or protection from COVID–19, including whether an individual may need an additional dose of the COVID–19 vaccine. Antibody tests have not been evaluated to assess the level of protection provided by immune responses to COVID–19 vaccination, including in immunocompromised individuals.

NIH is conducting and planning studies to assess and enhance the immune responses to COVID–19 vaccines in immunocompromised individuals. In April 2021, NIH scientists began two clinical trials to assess how adults and adolescents with certain cancers or immune system deficiencies respond to COVID–19 vaccination. These studies will provide valuable information about the immune responses to COVID–19 vaccines in these individuals. NIAID also plans to launch two additional trials in August 2021 that will assess immune responses to an additional dose of a COVID–19 vaccine in patients taking immunosuppressive medications. One of the trials will enroll participants with one of five autoimmune diseases, and the other will enroll kidney transplant recipients. Each study will enroll participants who have absent or weak antibody responses after an initial course of COVID–19 vaccination. NIAID also plans to launch an additional study that will enroll other solid organ transplant recipients who are receiving immunosuppressive medications. Results from these studies will help us to better understand the immune responses to vaccination in immunocompromised individuals and identify approaches to safely enhance their immune responses to vaccination. These studies may lead to evidence-based guidelines for safely enhancing responses to COVID–19 vaccination in immunocompromised individuals.

Results from these studies will help us to better understand the immune responses to vaccination in immunocompromised individuals and may better inform the development of meaningful antibody tests or other assessments of immune response to vaccination for this population.

SENATOR TUBERVILLE

Vaccination of Children/Parental Consent

Question 1. Last November, the District of Columbia passed a bill allowing children 11 years and older to get vaccinated without their parents' consent. It's been proven that this virus has an insignificant impact on children under the age of 15 or 16.

Question 1(a). Do you think minor children should be vaccinated without the consent of their parents?

Answer 1 & 1(a). I cannot comment on legislation passed at the local level. While it is true that young children and adolescents are less likely to experience severe symptoms from COVID–19, a portion of these individuals will still experience severe disease and hospitalization. Additionally, children and adolescents who are infected with SARS-CoV–2 can experience a rare, but extremely serious, multisystem inflammatory syndrome in children (MIS-C). As the Delta variant (also known as B.1.617.2), which appears to be more transmissible, has become the dominant strain of SARS-CoV–2 in the United States, it is critical that as many people as possible are vaccinated against COVID–19. The U.S. Food and Drug Administration (FDA) has authorized the Pfizer/BioNTech COVID–19 vaccine for use in individuals 12 years old and older, and I would encourage everyone who is eligible to receive the vaccine to do so as soon as they can.

COVID–19 Origins

Question 2. Did you have knowledge of safety concerns at the Wuhan lab?

Question 2(a). If so, when did you become aware of those concerns?

Question 2(b). Was it before or after you said in May 2020 that the virus was more likely to have emerged naturally?

Answer 2(a) & (b). NIAID was aware of interest on the part of the Wuhan Institute of Virology (WIV) to obtain additional information and trained staff as they prepared to begin research in a new biocontainment level 4 (BSL–4) facility.

My own view, based on the studies I have reviewed and my prior experience, is that it is most likely that SARS-CoV–2 infections in people resulted from zoonotic transmission from animals to humans, based on what occurred with two other coronaviruses—Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS)—and many other emerging diseases, as well as what is known about the molecular makeup of SARS-CoV–2. The available scientific evidence, including information about the sequence of the virus, does not support the assertion that SARS-CoV–2 was engineered. This view is consistent with an emerging consensus from world-renowned experts in virology, genetics, and evolutionary biology based on currently available data. However, as I have publicly stated, the possibility of a laboratory accident exists. A laboratory accident could include scenarios where a naturally occurring virus was unintentionally released during research activities such as collection of animal samples or examination of virus in a laboratory. I am in favor of a full investigation into the origins of SARS-CoV–2, and I look forward to the findings of the experts in the various disciplines relevant to this discussion.

Question 3. What is your awareness of Dr. Baric's collaboration with researchers at the Wuhan lab?

Answer 3. I am aware of collaborations between Dr. Ralph Baric from the University of North Carolina and the WIV. Dr. Baric was listed as a collaborator on a 2014 grant "Understanding Risk of Bat Coronavirus Emergence" submitted by EcoHealth Alliance and also was listed as a co-investigator on the corresponding 2019 grant renewal application. Prior to the renewal, this grant had included subawards to the WIV. Based on results published in peer-reviewed papers that include authors from Dr. Baric's lab and the WIV, I also am aware that Dr. Baric has collaborated with investigators from the WIV on basic coronavirus research.

Question 4. At what point did you realize that more investigation is necessary to determine the origins of the virus?

Answer 4. Since the beginning of the pandemic, I have been supportive of a full investigation into the origins of SARS-CoV–2 by qualified experts in the relevant fields.

Question 5. In May, President Biden asked the Intelligence Community to review the origins of Covid–19. Biden also asked that this effort include work by our National Labs and other agencies of our government to augment the Intelligence Community's efforts. Have you participated in this review?

Answer 5. The National Institutes of Health (NIH) is supporting and cooperating with the President's call for a U.S. Intelligence Community (IC) investigation and would refer you to the IC for additional information about their review.

NIH Grants

Question 6. The HHS Office of Inspector General (OIG) is conducting a review of NIH grants.

Question 6(a). Have you provided documentation to the OIG?

Question 6(b). Have you been interviewed as part of this review?

Answer 6(a) & (b). I am unable to specifically comment on any ongoing oversight engagements; however, I will note that the NIH is fully cooperating with the Department of Health and Human Services (HHS) Office of Inspector General.

COVID–19 Vaccine Clinical Trials

Question 7. Members of your staff served as co-investigators on the COVID–19 Vaccine clinical trials.

Question 7(a). Have they investigated every report of an adverse event by a trial participant?

Question 7(b). If so, what does that investigation entail?

Question 7(c). Do they evaluate each participant reporting an adverse event?

Answer 7(a), (b) & (c). Vaccine clinical trials are designed, in part, to assess the safety of candidate vaccines, and all reported adverse events are investigated by the trial sponsor. The National Institute of Allergy and Infectious Diseases (NIAID) was the trial sponsor for the Phase 1 clinical trial for the Moderna vaccine candidate, and the study recorded all adverse events among the 120 enrollees, including cap-

turing any symptoms, new medical conditions, and laboratory abnormalities. While NIAID is supporting the underlying critical infrastructure for other clinical trials for COVID–19 vaccines through the COVID–19 Prevention Network (CoVPN), NIAID is not the trial sponsor.

Clinical trial protocols include information surrounding the definition and handling of adverse events. NIAID would note that most of the trial sponsors for the Phase 3 clinical trials of the COVID–19 vaccines tested through the CoVPN have made the protocols for these trials available online, including for Moderna's COVE trial, Johnson & Johnson/Janssen's ENSEMLE trial, and Novavax's PREVENT–19 trial. The protocol for Pfizer/BioNTech's Phase 3 clinical trial also is available online. NIAID recommends contacting the trial sponsors for further information on COVID–19 vaccine clinical trials.

Misinformation

Question 8. Are you involved in the administrations recently revealed efforts to flag "misinformation" about COVID–19 for removal by social media companies?

Answer 8. No, I am not involved in the described efforts.

Question 9. Do you consider it misinformation for individuals to share their stories of adverse events following vaccination?

Answer 9. No. I encourage anyone who has experienced an adverse event following vaccination to report it to the Centers for Disease Control and Prevention and FDA Vaccine Adverse Event Reporting System (VAERS), a national early warning system to detect possible safety issues in vaccines.

Question 10. Funds in part from NIH/NIAID helped build the 12 Regional Biocontainment Laboratories (RBLs) and 2 National Biocontainment Laboratories (NBL) to support high consequence infectious disease research after 9/11 and the anthrax scares in 2001. However, unlike the NBL facilities, the RBL facilities received no further direct support until last year when Congress provided enhanced investment through NIH/NIAID, targeted specifically to RBL facilities, one of which is at the University of Alabama at Birmingham (UAB) in my state. Nevertheless, it seems as though the RBL infrastructure, most importantly the highly trained staff these facilities maintain and produce is something that falls within the purview of the HHS ASPR, considering among other things the UAB RBL has had collaborations with Altimmune and ImmunityBio for COVID19 vaccine development, and supported BARDA contractors. This type of work strongly aligns with numerous ASPR Strategic Goals, such as Fostering Strong Leadership, and Sustaining Robust and Reliable Public Health Security Capabilities. The RBL infrastructure and personnel is expensive to maintain and operate, and perhaps should not solely rest on either the shoulders of the host University or the NIH/NIAID.

Question 10(a). Therefore, is support from Assistant Secretary for Preparedness and Response (ASPR) something under consideration?

Question 10(b). If not, why not, and if so what is needed to facilitate that conversation?

Answer 10(a) & (b). NIAID defers to the HHS Office of the Assistant Secretary for Preparedness and Response to respond to this question.

RESPONSE BY DR. JANET WOODCOCK TO QUESTIONS OF SENATOR BURR, SENATOR BRAUN, SENATOR SCOTT AND SENATOR TUBERVILLE

Responses to the QFRs are accurate as of the date of the hearing.

SENATOR BURR

Question 1. Pfizer and Moderna have both submitted or begun to submit applications for full, standard approval of their vaccines. Given FDA's extensive knowledge and understanding of the vaccine data, are the agency's review timelines going to be faster than a traditional application? If not, why not?

Answer 1. FDA's review of a Biologics License Application (BLA) is among the most comprehensive in the world. When a BLA is submitted, the Agency evaluates the information supporting safety and effectiveness as well as manufacturing data. FDA also inspects the facilities that are involved in the manufacturing of the product to ensure that the vaccines that are distributed meet rigorous quality standards.

FDA scientists are working around the clock and reviewing the applications, which include hundreds of thousands of pages of data and other information, as expeditiously as possible, in a thorough and science-based manner.

Having safe and effective approved COVID–19 vaccines is a top priority for HHS and FDA. We firmly believe that those eligible to receive a vaccine under the existing EUAs should get their COVID–19 vaccine now.

As you know, FDA first issued an EUA for the use of the Pfizer-BioNTech COVID–19 Vaccine in individuals 16 years of age and older on December 11, 2020. Additionally, two other vaccines are currently available under EUA for the prevention of COVID–19. On December 18, 2020, FDA issued an EUA for the use of the Moderna COVID–19 Vaccine, and on February 27, 2021, FDA issued an EUA for the use of the Janssen COVID–19 Vaccine. The Moderna and Janssen COVID–19 vaccines are authorized for use in individuals 18 and older. For additional information on COVID vaccines, please visit: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines*.

Question 2. FDA has made great strides in supporting innovative clinical trial designs. How do you plan to continue to advance innovative clinical trial designs to expedite the development of novel products, using the creativity and flexibilities exercised during the pandemic response as a roadmap?

Answer 2. FDA has a long-standing commitment to supporting innovation in clinical development programs to help bring safe and effective drugs to patients more efficiently. Although the COVID–19 pandemic accelerated the use of innovative trial designs, FDA's policy development in this area long preceded the current public health emergency. FDA recognizes that there are emerging shifts in how diseases are diagnosed, prevented, and treated, and in the development of therapeutics. FDA is working on multiple fronts to provide guidance on innovative approaches to drug development, such as complex, innovative trial designs, master protocols, decentralized trials, trials utilizing real world data and evidence (RWD/RWE), modelling, and simulation. Our engagements with stakeholders have supported innovative trial designs as part of the COVID–19 pandemic response. These designs improve clinical trial efficiency and may optimize product development.

FDA continues to promote innovation in clinical trial design and conduct, and to encourage the utilization of advanced technologies. The agency is already working in many ways to facilitate pharmaceutical development and improve the overall clinical trial enterprise. We are also leveraging strong national and global partnerships in collectively advancing scientific knowledge to ultimately benefit patients. We are invested in advancing innovations, such as decentralized clinical trials and the use of digital health tools that have the potential of making clinical trials more efficient and may allow for wider inclusivity of diverse populations. Further, recognizing the value of innovative designs, FDA is committed to continuing the Complex Innovative Designs Meeting Program, which provides applicants accepted into the program with additional meetings with FDA to discuss proposed innovative designs.

Question 3. What has FDA learned from its review of products made using platform technologies, such as the mRNA and viral vector-based platforms, during the response? How will FDA support the development of products for other disease areas that leverage platform technologies?

Answer 3. FDA recognizes that, when scientifically appropriate, certain products have begun sharing manufacturing platform technologies, allowing certain information from one product to be applicable to future products with similar production strategies. The Agency is interested in finding ways to streamline the development and review of such innovative technologies. Toward this end, FDA hopes to find ways to best leverage knowledge gained from approved products that rely on certain platform technologies and associated manufacturing methods to be applied to subsequent products that a sponsor may develop. As this is a novel area, FDA continues to work to determine how to best leverage such platform technologies and looks forward to working with Congress in this area.

Question 4. On July 8th, the FDA and CDC said that Americans who have been fully vaccinated do not need boosters at this time. Pfizer announced it would file for authorization of a booster with the FDA, and the ACIP has stated that they cannot recommend booster shots for specific groups of individuals without FDA action. What is the timeline for determining whether to authorize a proposed booster, either for certain populations or the general public?

Answer 4. At the time of the hearing, FDA was closely monitoring data as it became available from studies administering a booster dose of the authorized COVID–19 vaccines to immunocompromised individuals. The Agency is collaborating with the Centers for Disease Control and Prevention and continues to evaluate all poten-

tial solutions to this growing question in the medical community. For more information and updates, please see: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines*.

FDA understands the potential importance of booster vaccine doses for control of this pandemic and will promptly review any data submitted to the Agency regarding their use in a thorough and science-based manner. Due to legal and regulatory restrictions, FDA generally cannot discuss product submissions that may be under review, including the timing of any potential FDA action to authorize or approve the use of additional doses of COVID–19 vaccines. Please contact the vaccine manufacturers directly regarding their plans to submit data for their individual vaccines and the timing of such submissions.

SENATOR BRAUN

Question 1. FDA has authorized large numbers of COVID tests and other products using emergency use authorizations. Without further action from FDA, when the public health emergency comes to an end these products will no longer be available for use.

Question 1(a). How does the FDA plan to transition products to full approval or clearance? What will happen if the public health emergency ends, and critical products have not received approval or clearance from FDA?

Answer 1 & 1(a). On February 4, 2020, the Secretary of the Department of Health and Human Services (HHS) determined, pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act, [1] that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID–19. Pursuant to Section 564 of the FD&C Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of COVID–19 (February 4, 2020), personal respiratory protective devices (March 2, 2020), other medical devices (March 24, 2020) for use during the COVID–19 outbreak, and drugs and biological products during the COVID–19 pandemic (March 27, 2020). (Please note that a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020, and subsequently renewed, is insufficient to enable FDA to issue EUAs.)

The declarations under section 564 have enabled FDA to authorize unapproved products and unapproved uses of approved or cleared products when, based on the totality of the scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the disease or condition and the known and potential benefits of the product's use outweigh the known and potential risks, taking into consideration the material threat posed by an emergency situation. Irrespective of the status of the public health emergency declaration under section 319 of the Public Health Service Act, FDA is empowered to authorize such uses until the Secretary terminates the declaration of emergency or threat justifying emergency use under section 564(b), the criteria for EUA issuance are no longer met, or revocation is otherwise appropriate to protect the public health. It may be the case that once the public health emergency declaration under section 319 of the Public Health Service Act expires, the benefit-risk justification for issuance of any particular EUA are no longer met or revoking such use is otherwise appropriate. In some instances, manufacturers of certain devices, especially non-conventional manufacturers, may no longer wish to market or distribute these products. In other instances, manufacturers may desire to transition to full approval or clearance and the statute directs FDA to communicate with manufacturers regarding such transition.

The Agency is required to periodically review the authorizations made under section 564 of the FD&C Act. As part of that review, FDA reviews the progress made toward approval, licensure, or clearance of the products authorized. See section 564(g) of the FD&C Act and FDA's guidance on Emergency Use of Medical Products and Related Authorities. [2] As outlined in FDA's guidance, Emergency Use Authorization for Vaccines to Prevent COVID–19, it is FDA's expectation that, following submission of an EUA request and issuance of an EUA, a sponsor would continue to collect placebo-controlled data in any ongoing trials for as long as feasible and

[1] *https://www.fda.gov/regulatory-information/laws-enforced-fda/Federal-food-drug-and-cosmetic-act-fdc-act*.

[2] *https://www.fda.gov/media/97321/download*.

would also work toward submission of a Biologics License Application (BLA) as soon as possible. FDA's recommendations regarding the safety and effectiveness data and information are essential to ensure that clinical development of a COVID–19 vaccine has progressed far enough that issuance of an EUA for the vaccine would not interfere with the ability of an ongoing Phase 3 trial to demonstrate effectiveness of the vaccine to support licensure and to continue safety assessments, including investigating the potential for vaccine-associated enhanced respiratory disease (ERD). The ability of a sponsor to accrue this information about a COVID–19 vaccine is critical to ongoing assessment of its benefits and risks.

FDA is working on a transition plan for devices that have been authorized under EUAs[3] or that fall within enforcement policies[4] issued during the COVID–19 public health emergency. FDA's intention is to issue guidance in draft form and request public comment before finalization and implementation. Transition plan draft guidance is on CDRH's Fiscal Year 2021 "A List,"[5] meaning that this is a prioritized policy that FDA seeks to publish in a timely fashion. FDA recognizes that it will take time for device manufacturers, healthcare facilities, healthcare providers, patients, consumers, and FDA to adapt and adjust from policies adopted and operations implemented during the public health emergency to normal operations. One of the goals of developing guidance on this topic is to have an orderly transition process and to provide transparency around FDA's approach to that transition. In addition, FDA is engaging in discussions with individual companies that are interested in obtaining marketing clearance or approval for their devices, and we encourage companies to initiate those discussions. Note that this proactive engagement is an integral part of FDA's transition plan. As we shift more resources toward working with sponsors pursuing full marketing status and as more devices achieve this status, there will be a smoother transition away from reliance on products authorized for emergency use or that fall within enforcement policies issued during the COVID–19 public health emergency.

SENATOR SCOTT

Question 1. Dr. Woodcock, the COVID–19 pandemic has had a disproportionate and devastating impact on communities of color. Drivers of this disparate impact correlate directly to social determinants of health, such as health and financial literacy, transportation, housing conditions, employment, safety, and education. I have expressed concerns at a number of hearings on the prevalence of vaccine hesitancy among Black Americans, with a 2020 survey suggesting that only 25 percent of Black adults planned to get vaccinated in the event of a COVID–19 vaccine approval. The pandemic has exposed several disparities that exist within the U.S. healthcare system. One such area is the under-representation of communities of color in clinical trials. Improving the diversity of participants in clinical trials continues to be a challenge due to a number of obstacles, including a lack of racial diversity in clinical trial investigators, community mistrust and skepticism due to historic abuses of racial minorities used as test subjects, as well as a lack of convenient and affordable transportation to clinical trial sites. To improve health outcomes for those most at risk, we must diversify our pool of participants. Our goal should be to include participants from diverse ethnic backgrounds and income levels. It is also imperative investigators make devices and software available to participants in addition to allowing enrollees to participate from diverse settings such as their home, local clinics, and, potentially, skilled nursing facilities.

Question 1(a). Dr. Woodcock—You have praised the success of the innovations made within clinical trial designs. What is your vision to expand access to clinical trials and how do we get there?

Answer 1 & 1(a). Modernizing clinical trials is a priority for FDA and the subject of significant policy work in which we are currently engaged. We view modernizing clinical trial designs and conduct and utilizing innovative technologies as an essential area to improve efficiencies and to facilitate the development of drugs, biological products, and devices.

Prior to the pandemic, the Agency was working on these areas, and the current public health emergency further catalyzed these efforts. There is a wide range of designs, tools, and methods that can be utilized in this area. For example, decentral-

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[3] *https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices.*

[4] *https://www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid19-and-medical-devices#guidance.*

[5] *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2021-fy-2021.*

ized clinical trials, hybrid trials, trials embedded in healthcare settings, trials that allow for seamless transition between phases, the use of digital health technologies, and supporting efficient, risk-based, approaches to trial conduct are all areas that FDA is currently working on or is planning on addressing. We have recently announced that the Agency will be issuing a draft guidance on the use of digital health technologies in clinical investigations and another draft guidance on decentralized clinical trial designs.

Question 1(i). What was done during the pandemic to ensure COVID–19 treatment and vaccine trials were clinically diverse?

Answer 1(i). FDA published guidance [6] to encourage diversity in clinical trials and make recommendations on how to help increase diversity in trials.

Sponsors who have requested an Emergency Use Authorization have provided numbers, including enrollment numbers about the diverse populations, in the package submitted to FDA for consideration for potential Emergency Use Authorization (EUA). We continue to strongly encourage the companies to improve their enrollment diversity and we provide recommendations on how to do so by leveraging messaging in local communities, site selection, and other strategies to raise the proportion of minorities being enrolled.

With regard to COVID–19 vaccines, in the June 2020 guidance, *Development and Licensure of Vaccines to Prevent COVID–19*, the Agency encourages the inclusion of diverse populations, including those most affected by COVID–19, in all phases of vaccine clinical development.

For the three vaccines that FDA has authorized for emergency use, all clinical trials included members of racial or ethnic groups at greater risk from COVID–19.

FDA, vaccine manufacturers, and other scientists are currently working to try to understand how long the authorized vaccines will provide protection for the prevention of COVID–19. Many studies are well underway to evaluate how long protection from a COVID–19 vaccine lasts and whether there is any variability based on age, race or ethnicity, or comorbidities that disproportionately impact underserved communities. These studies are currently being conducted by government agencies, academia, and industry partners. Specifically, these studies are longitudinal patient follow-up studies, which usually entail measuring antibody titers in a cohort of individuals before and at multiple times after vaccination, and identifying an association between antibody responses below a certain antibody level threshold and vaccine failure/infection. These studies may be designed to demonstrate differences in various groups based on age, race and ethnicity, or comorbidities.

Question 1. If successful, how can we implement these changes post-pandemic?

Answer 1. Advancing innovative and inclusive clinical trials is a key part of FDA's ongoing efforts that started prior to the pandemic and will continue post-pandemic. FDA will continue to encourage the inclusion of diverse populations in clinical trials and is committed to continue to work on ensuring that best practices for enhancing diversity in COVID–19 treatment and vaccine trials are sustained beyond the pandemic. Because clinical trials provide a crucial base of evidence for evaluating whether a medical product is safe and effective, enrollment in clinical trials should reflect the diversity of the population that will ultimately use the product. The opportunity to participate in clinical research should be available to all eligible patients who are impacted by the disease.

In November 2020, FDA issued a final guidance for industry titled, *Enhancing the Diversity of Clinical Trial Populations; Eligibility Criteria, Enrollment Practices, and Trial Designs.* [7] This guidance recommends approaches that sponsors of clinical trials to support a new drug application or a biologics license application can take to broaden eligibility criteria, when scientifically and clinically appropriate, and to increase enrollment of underrepresented populations in their clinical trials. FDA has also published several additional guidances supporting clinical trial diversity, including, *Collection of Race and Ethnicities in Clinical Trials (2016); Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials (2018); Clinical Lactation Studies: Considerations for Study Design (2019); Postapproval Pregnancy Safety Studies (2019); and Older Participants-ICH E7.*

FDA remains committed to increasing the participation of racial and ethnic minorities and other underrepresented populations in clinical trials that test new medical products for all diseases and conditions through issuing guidance, developing

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[6] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversityclinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial.*

[7] *https://www.fda.gov/media/127712/download.*

tools, and encouraging the use of innovative trial designs. In addition, FDA is working on policies pertaining to the use of decentralized trial designs and digital health technologies. Decentralized clinical trials have the potential to increase diversity of research participants by incorporating, telemedicine and mobile/digital technologies to increase access to under-represented populations and/or communities—rural or remote—that may not have access to major medical and research centers.

Moving forward, FDA will apply lessons learned from COVID–19 to help support the participation of people in racial, ethnic, and other minority groups in the clinical trials that test new medical products through hosting public meetings, developing tools, and issuing guidance documents.

Question 1(ii). What are some of the benefits to providing technology to clinical trial participants? For example, mobile glucose monitors or tablets and phones equipped with software to transmit information back to clinical trial investigators.

Answer 1(ii). Digital health technologies are among the most promising tools we have for advancing clinical trial innovation and promoting diversity and inclusion. Including digital health technologies in clinical trials may make trial participation less burdensome for participants and expand access to trials by enabling remote data collection and monitoring from the participant's home instead of traveling to a clinical site. Additionally, providing digital health technologies to participants may enhance a participant's experience in a clinical trial by promoting engagement and more seamless information sharing between trial participants and clinical investigators. Some of these digital health technologies allow continuous collection of data from trial participants, which could allow round-the-clock monitoring of drug effects. This may improve our ability to understand the safety and efficacy of new drugs in ways that were not previously possible.

When digital health technologies are included in clinical trials, however, FDA recognizes the crucial importance of maintaining both the safety of trial participants and clinical trial integrity. To promote both, the Agency promptly provided guidance during the COVID–19 pandemic titled *Conduct of Clinical Trials of Medical Products during COVID–19 Pandemic*[8] that included recommendations regarding the remote collection of data in clinical trials.

In this guidance, FDA explains that sponsors planning to use remote electronic assessments as part of a clinical investigation should use appropriate technology and develop procedures for provision of technology and technical support to trial participants, investigators, and/or other trial personnel to facilitate those assessments. For example, sponsors could develop a plan to accommodate trial participants who are either already enrolled in a trial or may be enrolled in a trial in the future, but who do not have access to appropriate communication technology (e.g., cell phones or Internet), by providing trial participants with these services.

FDA encourages the use of digital health technologies in clinical trials that are beneficial to study participants. The Agency issued final guidance in November 2020, entitled *Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry*.[9] This guidance encourages sponsors to think about reducing visit frequency, when appropriate, in addition to considering whether flexibility in visit windows is possible and whether electronic communications, such as phone, email, social media platforms, or other digital health technology tools, can replace site visits and provide investigators with real-time data.

In the above-referenced guidances, FDA provides a few examples of potential approaches, and encourages the development of other approaches that can make trial participation less burdensome for participants and foster retention and inclusiveness.

Question 1. What statutes need to be changed to allow for this exchange?

Answer 1. At this time, FDA has not identified statutory changes that are necessary to facilitate the use of digital health technologies in clinical trials. The Federal Food, Drug, and Cosmetic Act and the Public Health Service Act provide sufficient flexibility to enable use of a broad spectrum of technologies when appropriate to a particular development program. Sponsors are already utilizing digital health technologies in clinical development programs, and FDA is working with sponsors to help facilitate such use consistent with applicable regulatory requirements.

Question 2. The role of the Food and Drug Administration (FDA) in combatting the COVID–19 pandemic has been critical, and I'd like to thank you for the agency's

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[8] *http://wcms-internet.fda.gov/media/136238/download*.
[9] *https://www.fda.gov/media/127712/download*.

vital work to support the successful delivery of three vaccines to the American people. You have testified in the past before this Committee that no corners were cut in FDA's evaluation of COVID–19 vaccines in authorizing them under Emergency Use Authorization (EUA), meaning that the FDA's gold standard review for evaluating the safety and efficacy of COVID–19 vaccines was met or surpassed for the vaccines authorized in the United States. Looking to future pandemic preparedness efforts and other biological threats, whether naturally occurring, deliberate, or accidental, I would like to better understand the EUA process—not just for vaccines, but also for vaccine manufacturing. Vaccine manufacturers moved at unprecedented speed to develop a product and its manufacturing process while simultaneously scaling-up manufacturing capacity—all at a record-breaking pace. These efforts took place in the middle of a pandemic in an environment with serious supply chain constraints. While not unexpected given the circumstances, our understanding is that there have been a number of challenges with COVID vaccine and therapeutic manufacturers—with media reports focused on a range of companies, including some of the largest pharmaceutical companies in the world (Merck, Lilly) and some smaller contract manufacturers (Emergent, Texas A&M/Fujifilm DioSynth, Catalent). So, I think explaining the EUA standard for the authorization of the product and the manufacturing process will serve to assure the American public and the world that any product authorized during a public health emergency by the FDA is appropriate—both for the current pandemic and in preparation for the next.

Question 2(a). Dr. Woodcock—Can you please briefly explain the standards for granting an EUA for a vaccine candidate?

Answer 2 & 2(a). FDA may issue an EUA after FDA has determined that the product that is the subject of an EUA request meets the statutory requirements under section 564 of the FD&C Act. In determining whether to issue an EUA for a vaccine, FDA evaluates the available evidence to determine, among other things, whether it is reasonable to believe that the vaccine may be effective in preventing COVID–19 and whether the known and potential benefits of the vaccine, when used to prevent COVID–19, outweigh any known and potential risks of the vaccine. Once a manufacturer submits an EUA request for a COVID–19 vaccine, FDA evaluates the request and determines whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to the Agency. The FDA guidance, *Emergency Use Authorization for Vaccines to Prevent COVID–19* [10] provides more information about FDA's current recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act for an investigational vaccine to prevent COVID–19, including chemistry, manufacturing, and controls information; nonclinical data and information; and clinical data and information, as well as administrative and regulatory information. [11]

Question 2(i). Can you please explain the standards for authorizing a bulk drug substance manufacturing facility as part of a product EUA in a public health emergency?

Answer 2(i). As stated in FDA's Guidance for Industry, *Emergency Use Authorization for Vaccines to Prevent COVID–19*, FDA assesses current good manufacturing practice (CGMP) compliance for each manufacturing site using all available tools and information. FDA expects manufacturers to submit sufficient data to ensure the quality and consistency of their product, and FDA evaluates the chemistry, manufacturing, and controls and facility information for the product. FDA uses all available tools and information, including reviews, site visits, inspections, EUA investigations, and previous compliance history, and has utilized the authority under section 704(a)(4) of the FD&C Act to request records and other information from foreign and domestic establishments to assess compliance with CGMP requirements of facilities that are intended to manufacture vaccines to prevent COVID–19 under an EUA. FDA has also used establishment inspection information from capable foreign regulatory authorities under the Pharmaceutical Annex to the U.S. and European Union Mutual Recognition Agreement (MRA), and the Pharmaceutical Annex to the U.S. and United Kingdom MRA, as well as other confidentiality agreements and commitments.

FDA takes its responsibility for helping to ensure the quality of manufacturing of vaccines and other medical products for use during this pandemic very seriously. As outlined above, the Agency is using a variety of tools to help ensure that prod-

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[10] *https://www.fda.gov/media/142749/download*.

[11] *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions#biologics*.

ucts being produced in different facilities meet the high-quality standards that Americans have come to expect. It is important to note that even when companies use contract manufacturing organizations, it is ultimately the responsibility of the company that holds the EUA to ensure that the required quality standards are met. No product can be distributed by manufacturers until FDA authorizes its distribution from the facility that is manufacturing it. FDA will continue to work with companies to ensure that the quality standards it expects for products distributed under an EUA are met, and will continue to work diligently to help bring needed medical products in a timely manner to Americans during this public health emergency.

Question 2(ii). Can you please explain the standards for authorizing a fill/finish manufacturing facility as part of a product EUA in a public health emergency?

Answer 2(ii). Please see the response to "i" above.

Question 3. Current data suggests high efficacy rates among the vaccines for which Emergency Use Authorization was approved, good news for the 85.7 percent of South Carolinian seniors who have received at least one dose and the 77 percent of whom are fully vaccinated. However, as the Delta variant remains extremely contagious and the World Health Organization labeling the Lambda version a "variant of interest," the U.S. cannot remain idle as we work to return students back into the classroom and more adults come back to work. Recently, Pfizer announced it planned to submit COVID–19 booster shot data to the FDA by mid-August 2021. American seniors, their families and caregivers, and stakeholders remain interested in knowing what the Federal Government plans to do regarding the possible authorization and distribution of booster vaccines. This information is especially timely since the first Americans, including South Carolinian long-term facilities residents, received their initial vaccines in December 2020.

Question 3(a). Dr. Woodcock—What collaborations are occurring between the Federal Government, vaccine developers, the states, long-term care facilities, the senior community, and other interested stakeholders regarding information about booster vaccines? When will this information be made public?

Answer 3 & 3(a). The COVID–19 vaccines authorized in the United States continue to be remarkably effective in reducing risk of severe disease, hospitalization, and death, even against the widely circulating Delta variant. Recognizing that many vaccines are associated with a reduction in protection over time, and acknowledging that additional vaccine doses could be needed to provide long lasting protection, we have been analyzing the scientific data closely from the United States and around the world to understand how long this protection will last and how we might maximize it.

FDA understands the potential importance of booster vaccine doses for control of this pandemic and will promptly review any data submitted to the Agency regarding their use in a thorough and science-based manner. Due to legal and regulatory restrictions, FDA cannot discuss product submissions that may be under review, including the timing of any potential FDA action to authorize the use of booster doses of COVID–19 vaccines. Please contact the vaccine manufacturers directly regarding their plans to submit data for their individual vaccines and the timing of such submissions.

SENATOR TUBERVILLE

Question 1. Funds in part from NIH/NIAID helped build the 12 Regional Biocontainment Laboratories (RBLs) and 2 National Biocontainment Laboratories (NBL) to support high consequence infectious disease research after 9/11 and the anthrax scares in 2001. However, unlike the NBL facilities, the RBL facilities received no further direct support until last year when Congress provided enhanced investment through NIH/NIAID, targeted specifically to RBL facilities, one of which is at the University of Alabama at Birmingham (UAB) in my state. Nevertheless, it seems as though the RBL infrastructure, most importantly the highly trained staff these facilities maintain and produce is something that falls within the purview of the HHS ASPR, considering among other things the UAB RBL has had collaborations with Altimmune and ImmunityBio for COVID19 vaccine development, and supported BARDA contractors. This type of work strongly aligns with numerous ASPR Strategic Goals, such as Fostering Strong Leadership, and Sustaining Robust and Reliable Public Health Security Capabilities. The RBL infrastructure and personnel is expensive to maintain and operate, and perhaps should not solely rest on either the shoulders of the host University or the NIH/NIAID.

Question 1(a). Therefore, is support from Assistant Secretary for Preparedness and Response (ASPR) something under consideration?

Question 1(b). If not, why not, and if so what is needed to facilitate that conversation?

Answer 1(a) & (b). FDA defers to ASPR to respond to these questions.

RESPONSE BY DAWN O'CONNELL TO QUESTIONS OF SENATOR BALDWIN, SENATOR BURR, SENATOR BRAUN, AND SENATOR TUBERVILLE

Responses to the QFRs are accurate as of the date of the hearing.

SENATOR BALDWIN

Question 1. I was encouraged to hear Assistant Secretary O'Connell's announcement that $2 billion of the $10 billion that I secured in the American Rescue Plan for domestic manufacturing and utilization of the DPA would be used to support vaccine industrial base expansion for raw materials, consumables, fill/finish capacity, needles, vials, and syringes. Please provide additional details on the recipients of this funding, as well as any information that can be shared regarding future obligations.

Answer 1. With $10 billion received for industrial base expansion, ASPR has been establishing and maintaining domestic capacity for vaccine production and administration, in addition to a number of other efforts for PPE and pharmaceutical manufacturing. Specifically, ASPR is executing an acquisition strategy to expand the capacities and surge capabilities for high-speed, reliable sterile filling/packaging operations, domestic conversion of bulk biological drug substance into drug product for distribution, and investments in manufacturing capacities to better avail raw materials and consumables that are commonly used across the commercial sterile biologic products industry for production, delivery and administration (e.g., nucleoside triphosphates (NTPs), enzymes, resins, lipids, and needle and syringe sets).

Question 2. How is the Administration utilizing this funding to ensure that American companies that shifted and significantly expanded production of raw materials to aid in our pandemic response receive support? How is the Administration working to build on our pandemic response to develop a public health industrial base with the capacity to respond to crises and make us less reliant on China?

Answer 2. ASPR is leveraging the authorities delegated to the Secretary under the Defense Production Act (DPA) to ensure that private sector partners making life-saving products are able to acquire raw materials, retool their machinery, scale their production facilities, train their workforces, and ultimately deliver their product. Throughout the COVID–19 response, ASPR has used the DPA authority to issue 46 priority ratings for U.S. Government (USG) contracts for health resources, 8 priority ratings for USG contracts for industrial expansion, and 3 priority ratings of specific purchase orders for companies manufacturing critical lifesaving health resources that have been impacted by COVID–19 response demands. ASPR is also continuing to build capacity and partnerships with private industry toward the shared goal of ending the COVID–19 pandemic. ASPR is also working to support efforts in expanding the domestic industrial base. These industrial base expansion (IBx) efforts seek to reduce supply chain vulnerabilities and generate a domestic "warm-base" for manufacturing that can be leveraged in a crisis.

Supporting domestic vaccine development and manufacturing efforts, BARDA has invested $1.256B in the advanced research and development of Moderna's mRNA–1273 vaccine candidate, supporting clinical trials and manufacturing scale up and validation. The investments in a mRNA vaccine will support new vaccine production platforms in the future that will improve the efficiency and reduce the timeline to develop vaccines for other biodefense threats and emerging infectious diseases. Platform technologies, such as the mRNA approach, can provide flexible and rapid response and have many advantages with potential to revolutionize the way vaccines and therapeutics are produced for known and newly emerging threats.

Question 3. Will the Administration commit to using some of this funding for the raw materials, including medical-grade meltblown, needed to produce N95 and N99 masks so that we are not dependent on countries like China for this material?

Answer 3. ASPR has invested over $20.5 million in several companies to increase and sustain melt-blown fiber production in the U.S., producing enough raw material to manufacture the equivalent of approximately 171 million N95 or 400 million surgical masks a month. In addition, utilizing the $10 billion received via the American Rescue Plan Act to support industrial base expansion, ASPR has been working to establish and maintain domestic capacities for N95 manufacturing.

SENATOR BURR

Question 1. As we saw during the early stages of the COVID–19 response, quickly identifying and containing the spread of a new pathogen is a significant challenge. In preparing for the next public health threat, how is HHS taking into account additional capacity for testing in health care facilities as a result of health systems' investments in high throughput instruments during the COVID–19 response?

Answer 1. HHS monitors the testing supply chain through collaboration with diagnostic manufacturers. Ten of the major manufacturers send shipment data, install base data, and supply projections on a regular basis. HHS integrates this data into HHS Protect, a platform that overlays epidemiological data, hospital clinical data, COVID–19 testing data, and other public health metrics. Of the three main data reports, the install base data gives HHS visibility into the locations and quantity and utilization of all the high-throughput machines for a specific company. This information allows HHS to monitor how additional capacity for testing has increased since the beginning of the pandemic.

Question 2. T-cell testing adds a critical dimension to how we measure immune response. How can these tests be used to inform both individual clinical decisions and a population-based, public health response, and what steps is HHS taking to include T-cell testing in planning for future public health threats?

Answer 2. T cells are an important component of the immune response to viruses, including SARS-CoV–2, the virus that causes COVID–19. Existing T cell testing technologies available for widespread use can be used to aid in identifying individuals with an adaptive T cell immune response to a virus, indicating recent or prior infection. For example, the T-Detect COVID Test, which was developed by Adaptive Biotechnologies and received an emergency use authorization (EUA) from the FDA, can help determine if a person previously had COVID–19. This test may be useful for people who have exhibited symptoms previously but have not tested positive for COVID–19 using a molecular or antigen diagnostic test. At this time, the test has only been authorized to detect prior infection by SARS-CoV–2, and cannot be used to indicate the degree of protection induced by COVID–19 vaccination or infection.

It is important to note that antibody or serum-based commercial assays are readily available to the public and are easier and less expensive to perform than T cell assays. Antibody or serum-based tests also are generally sufficient to indicate current or previous infection/vaccination. Techniques to examine T cells are labor intensive, relatively expensive, and require specialized equipment and sample collection. Laboratories that perform the T-Detect test for commercial purposes also must be specifically designated by the company and have obtained specialized certification. For these reasons, monitoring of T cell responses to COVID–19—or other infectious disease threats—is only possible on a small scale at this time. Nonetheless, scientific studies of T cells can provide important insights into COVID–19 progression, protection against SARS-CoV–2 variants, and durability of immunity. HHS, through the National Institute of Allergy and Infectious Diseases (NIAID), is supporting research to improve understanding of the role of T cells in protecting against COVID–19 as well as in COVID–19 progression. These efforts may lead to improved T cell tests and help support the public health response to COVID–19.

NIAID also conducts and supports basic and clinical immune research, including on T cell responses, to improve understanding of SARS-CoV–2. NIAID supported a collaborative longitudinal study by researchers at Emory University and the Fred Hutchinson Cancer Research Center that demonstrated that T cells were detectable for up to 8 months in patients after mild to moderate COVID–19. NIAID also supported two separate studies—one led by researchers from NIAID and Johns Hopkins Hospital and another by scientists from the La Jolla Institute—that examined the T cell responses in recovered COVID–19 patients and individuals vaccinated against COVID–19 and found robust immune responses to the original strain—as well as multiple variants—of SARS-CoV–2 in both groups. In another NIH-supported study, researchers uncovered features of T cells that distinguish fatal from non-fatal cases of severe COVID–19, which could lead to new treatments for this disease.

NIAID also is funding a number of basic research studies that will inform how T-cell based approaches could be incorporated into future countermeasures. This includes assays that measure the magnitude of T cell responses in individuals who receive the currently authorized COVID–19 vaccines. Understanding how T cells respond to SARS-CoV–2 infection and vaccination may help improve protection afforded by future vaccines. Additional monitoring of T cell responses to SARS-CoV–2 may also improve our understanding of the extent and longevity of immunological protection against SARS-CoV–2.

Question 3. Health systems have experienced a spike in cyber-attacks during the pandemic. For example, Universal Health Services, Inc. experienced a cybersecurity attack in September 2020, which forced hospital systems offline for weeks. Pursuant to the 2020 National Defense Authorization Act Section 9002, the ASPR was designated as the sector risk management agency for the health care and public health sector.

Question 3(a). What work does ASPR perform as the sector risk management agency? Of this work, what proportion is specific to cybersecurity?

Answer 3 & 3(a). This past year has been full of challenges, and HHS has found ourselves responding to increased quantities and new types of cyber-attacks against the Healthcare and Public Health Sector. In ASPR, the Division of Critical Infrastructure Protection (CIP) serves as the hub for HHS as the sector-specific agency. Based on authorities included in the 2021 National Defense Authorization Act (NDAA), CIP is now the focal point for HHS as the sector risk management agency. The goal of sector risk management agencies is to look at the entire sector—in this case, health care and public health—for all hazards. CIP works closely with government and private sector partners through the structure of the Critical Infrastructure Partnership Advisory Council to identify and address risks across the sector—working with hospitals, pharmacies, manufacturers, distributors, health IT providers, insurance plans, and mass fatality managers. Over the past 5 years, CIP has been focused on four main areas of risks management:

1. Identifying risks at facilities across the sector in an objective data driven manner through our Risk Identification and Site Criticality Tool (RISC), currently in development of an enhanced, web-based version. The RISC tool identifies cyber risks alongside natural hazard and other manmade risks, unlike many other tools used in the sector, thus promoting conversation between IT security staff and emergency managers. The tool was released 2 years ago and has been downloaded in all 50 states and utilized by at least 1,400 individuals.

2. Monitoring supply chain challenges in the health sector, including dependence on foreign sourcing and challenges of just-in-time-distribution;

3. Overall mitigation of risks before, during, and after disasters—with a focus on planning for and communicating during responses, including Hurricane Maria and the WannaCry and Petya/notPetya cyber incidents of 2017, wildfires, hurricanes, and the COVID–19 pandemic; and

4. Coordinating with the White House, DHS, and the FBI to enhance HHS' ability to identify and share cyber hygiene best practices; promote sharing of cyber incident information; engage in discussion and coordination with the private sector on priority education, policy, and communications activities; and exercise existing and new cyber plans among government and private sector partners.

As cybersecurity is such a threat to the Healthcare and Public Health Sector, CIP makes sure to incorporate that risk into a majority of projects to both raise awareness and encourage all those involved in the partnership to recognize their potential role in preventing or responding to cyber incidents.

Question 3(b). How has ASPR been executing its cybersecurity responsibilities as part of this role and/or how does ASPR plan to execute these responsibilities? If the latter, what is ASPR's timeline for putting into place this plan?

Answer 3(b). ASPR led the development of a "strategy for public health preparedness and response to address cybersecurity threats" that was required by section 703(a)(1) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019. This strategy was delivered to the HELP Committee on August 2, 2021 by Secretary Becerra. This strategy identifies duties, functions, preparedness and response goals for which HHS is responsible for the Healthcare and Public Health (HPH) Sector. It also includes strategies to address identified gaps and strengthen public health emergency preparedness and response capabilities.

ASPR will direct and monitor implementation of this strategy through the CIP Division, relying on expertise and activity from many HHS Operating and Staff Divisions, including the FDA for medical devices, OCR for privacy and security, ONC for health IT, and OCIO for the HC3 and 405d programs. ASPR also manages the Critical Infrastructure Partnership Advisory Council Joint Cybersecurity Working Group, with hundreds of members. The group bases its work on the recommendations of the 2018 Healthcare Industry Cybersecurity Task Force and is currently developing CY2022 joint priorities.

ASPR CIP has led the development of the HPH sector Incident Response plan, which will be appended as an annex to the all hazard plan. The plan describes the full spectrum of the USG response to HPH cyber incidents, including coordination of tactical activities among HHS, FBI and CISA; development of an assessment of the effect of cyber incidents on delivery of care, on supply chains, and on system integrity; engagement of ESF–8 as necessary; and development of post-incident reporting and of after-action plans.

Question 3(c). How many FTEs and resources are dedicated to cybersecurity at ASPR?

Answer 3(c). For the management of the Sector Risk management Agencies (SRMA) role for external HPH Sector Cybersecurity (which excludes internal HHS/ASPR IT security), ASPR has one dedicated staff member supporting cybersecurity preparedness across the health care and public health (HPH) sector, partial time of a second staffer and two contractor positions currently waiting to be filled. In addition, ASPR staff greatly leverage external resources of HHS, DHS, and the private sector to ensure comprehensive risk management for the HPH Sector. Specific activities include:

- Co-chairing the Joint Cybersecurity Working Group comprised of 15 subject-specific Task Groups and over 300 organizations represented;
- Leading efforts of Federal, state, local, tribal and territorial entities to develop and disseminate Sector-wide recommendations and guidance to prepare and better secure the sector from Cyber threats, to identify risks from cyber threats, lead response efforts to HPH-wide cyber events, and promote mitigation and resiliency strategies;
- Collaborating with private sector and Federal, state, local, territorial, and tribal partners to establish and lead work groups to address recommendations made by the Healthcare Industry Cybersecurity Task Force Report for improving healthcare cybersecurity, released in June 2017;
- Leading collaborative interagency and other HPH sector efforts to identify emerging cyber risks in HPH, including risks associated with emerging technologies such as artificial intelligence and machine learning-based tools, as well as risks associated with new care delivery models such as telehealth;
- Leading tracking and assessment efforts during the Federal response to Cyber Incidents;
- Developing and implementing mitigation strategies as well as incident and after action reports to inform and advise on future response operations; and,
- Creating a bi-weekly bulletin on cybersecurity topics that reaches approximately 3,000 subscribers. Topics discussed in the bulletin include information pertinent to understanding and mitigating cybersecurity risks across all critical infrastructure sectors, identification and analysis of trends in cyberattacks and vulnerabilities, best practices for general cyberhygiene, and specific recommendations for addressing significant cyber threats.

Question 3(d). How does ASPR coordinate with the Cybersecurity and Infrastructure Security Agency and the Federal Bureau of Investigations?

Response: One of the ways ASPR collaborates with CISA is by promoting their tools and resources and sharing info that could help our sector partners. ASPR serves as a conduit between the Healthcare and Public Health (HPH) Sector and CISA. Confronting cybersecurity threats requires contributions from across the Federal Government, including CISA, the FBI's National Cyber Investigative Joint Task Force, and other stakeholders. ASPR participates in weekly calls with CISA colleagues and our health sector partners. ASPR also works closely with CISA through the Federal Senior Leadership Council Roles and Responsibilities work, through which we have negotiated mechanisms of sharing information between SRMAs, CISA, and the FBI.

Question 3(e). Please describe ASPR's coordination with the health care and public health sector specifically related to cybersecurity.

Answer 3(e). As described above, ASPR holds weekly calls with sector partners to discuss cybersecurity threats. During these calls, ASPR is able to provide both the specialized knowledge regarding cybersecurity as well as sector-specific knowledge to assist partners in preventing and responding to incidents like a ransomware

attack. ASPR is also able to create private sector partnerships that have a Federal Advisory Committee Act (FACA) exemption so that we can meet with the same private sector partners and request consensus advice and recommendations from them in a closed setting. Last, ASPR holds joint sector working groups with private sector and government sector partners to identify topics to work on, analyze best practices, and develop products to release to the private sector.

SENATOR BRAUN

Question 1. Can you please provide specific updates on your plans to ensure that nursing home staff and residents have sufficient point of care molecular diagnostics and access to the most appropriate prophylactics and treatments?

Answer 1. You should be aware that HHS has and continues to distribute approximately 3 million point of care tests to long term care facilities on a weekly basis. In addition, HHS monitors the testing supply chain through collaboration with diagnostic manufacturers. Ten of the major manufacturers send shipment data, install base data, and supply projections on a regular basis. HHS integrates this data into HHS Protect, a platform that overlays epidemiological data, hospital data, testing data, and other public health metrics. Of the three main data reports, the install base data gives HHS visibility into the locations and quantity of all the high-throughput machines for a specific company. This information allows HHS to monitor how additional capacity for testing has increased since the beginning of the pandemic.

SENATOR TUBERVILLE

Question 1. Funds in part from NIH/NIAID helped build the 12 Regional Biocontainment Laboratories (RBLs) and 2 National Biocontainment Laboratories (NBL) to support high consequence infectious disease research after 9/11 and the anthrax scares in 2001. However, unlike the NBL facilities, the RBL facilities received no further direct support until last year when Congress provided enhanced investment through NIH/NIAID, targeted specifically to RBL facilities, one of which is at the University of Alabama at Birmingham (UAB) in my state. Nevertheless, it seems as though the RBL infrastructure, most importantly the highly trained staff these facilities maintain and produce is something that falls within the purview of the HHS ASPR, considering among other things the UAB RBL has had collaborations with Altimmune and ImmunityBio for COVID19 vaccine development, and supported BARDA contractors. This type of work strongly aligns with numerous ASPR Strategic Goals, such as Fostering Strong Leadership, and Sustaining Robust and Reliable Public Health Security Capabilities. The RBL infrastructure and personnel is expensive to maintain and operate, and perhaps should not solely rest on either the shoulders of the host University or the NIH/NIAID.

Question 1(a). Therefore, is support from Assistant Secretary for Preparedness and Response (ASPR) something under consideration?

Answer 1(a). NIAID provided funding in 2003 and 2005 for the construction of National Biocontainment Laboratories (NBLs) and Regional Biocontainment Laboratories (RBLs). The NBLs and RBLs are designed to complement and support the research activities of NIAID-funded biodefense and emerging infectious diseases research as well as assist national, state, and local public health efforts. The NBLs and RBLs achieve this mission by providing safe and secure state-of-the-art BSL–3/4 laboratory space to the scientific community to advance research on biodefense pathogens and emerging infectious diseases. NIAID's mission to support the development of medical products to counter bioterrorism and emerging and reemerging infectious diseases is part of a larger national strategy that involves many agencies.

The majority of Federal oversight of U.S. BSL3/4 labs is done on those conducting select agent research, and falls under the purview of CDC and USDA through the Select Agent Program. Additional certification and oversight responsibilities for BSL3/4 labs is handled at the level of the institution. As such, NIH and ASPR oversight is generally limited to oversight of funded research.

Question 1(b). If not, why not, and if so what is needed to facilitate that conversation?

Answer 1(b). See response to 1(a).

[Whereupon, at 12:24 p.m., the hearing was adjourned.]

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