S. HRG. 117–386

ADDRESSING NEW VARIANTS: 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

SECOND SESSION

ON

EXAMINING A FEDERAL PERSPECTIVE ON THE COVID-19 RESPONSE, FOCUSING ON ADDRESSING NEW VARIANTS

JANUARY 11, 2022

Printed for the use of the Committee on Health, Education, Labor, and Pensions

Available via the World Wide Web: *http://www.govinfo.gov*

U.S. GOVERNMENT PUBLISHING OFFICE

48–897 PDF WASHINGTON : 2023

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

PATTY MURRAY, Washington, *Chair*

BERNIE SANDERS (I), Vermont
ROBERT P. CASEY, JR., Pennsylvania
TAMMY BALDWIN, Wisconsin
CHRISTOPHER S. MURPHY, Connecticut
TIM KAINE, Virginia
MAGGIE HASSAN, New Hampshire
TINA SMITH, Minnesota
JACKY ROSEN, Nevada
BEN RAY LUJAN, New Mexico
JOHN HICKENLOOPER, Colorado

RICHARD BURR, North Carolina, *Ranking Member*
RAND PAUL, M.D., Kentucky
SUSAN M. COLLINS, Maine
BILL CASSIDY, M.D., Louisiana
LISA MURKOWSKI, Alaska
MIKE BRAUN, Indiana
ROGER MARSHALL, M.D., Kansas
TIM SCOTT, South Carolina
MITT ROMNEY, Utah
TOMMY TUBERVILLE, Alabama
JERRY MORAN, Kansas

EVAN T. SCHATZ, *Staff Director*
DAVID P. CLEARY, *Republican Staff Director*
JOHN RIGHTER, *Deputy Staff Director*

C O N T E N T S

STATEMENTS

TUESDAY, JANUARY 11, 2022

ADDRESSING NEW VARIANTS: A FEDERAL PERSPECTIVE ON THE COVID–19 RESPONSE

Tuesday, January 11, 2022

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

The Committee met, pursuant to notice, at 10:03 a.m., in room G50, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. The Senate Health, Education, Labor and Pensions Committee will please come to order. Today we are holding a hearing with members of the President's COVID–19 response team on the pandemic and our efforts to address new variants like Omicron. After the witnesses give their testimony, Senators will each have 5 minutes for a round of questions. And while we were unable to have this hearing fully opened to the public or media—is my mic working?

While we are 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 you are in need of accommodations, including closed captioning, you can reach out to the Committee or the Office of Congressional Accessibility Services. I want to start this morning by recognizing the difficult moment we are in with this pandemic.

The Omicron variant has caused an unprecedented number of infections across the country over the past month. Thanks to the hard work of so many, we have new tools to address the threat caused by this new variant, including vaccines, boosters, and high quality masks. But the sheer number of infections is inputting an enormous strain on hospitals, health care workers, schools, families, and communities across the country. We all need to do our part to address this new challenge by getting vaccinated and boosted and wearing high quality masks.

That is why we are having this hearing in a larger hearing room where we can be socially distanced, limiting the number of people

who are here in this hearing room, and taking additional measures such as wearing masks. I will be wearing my mask during the entire hearing and would respectfully request others in the room today do the same.

As always, I appreciate the work from the staff of the Sergeant-at-Arms, the Architect of the Capitol, and our Committee Clerk and his staff to make this hearing as safe as possible. Nearly 2 years into this pandemic, people are exhausted after all we have been through, and even as the Delta strain is still circulating, we are all alarmed by how quickly Omicron has spread and anxious about what is next.

People back in my home State of Washington and across the country are frustrated and worried about the course of this pandemic and its persistent challenges, like how hard it still is to get a test. I have heard from so many people who are waiting in long lines and going from pharmacy to pharmacy, trying to find a test, or who are giving up on getting tested because tests are unavailable or cost too much. I have also heard from people who have found the communication about new isolation and quarantine guidance confusing and frustrating. They are trying to keep themselves and their families safe as this pandemic evolves and we continue to learn more.

But I am hearing more and more questions like, what kind of tests should I get? When should I get tested? Why can't I find a test? Do I need to isolate 10 days, 5 days, or even at all? Testing, in particular, is a huge concern for parents who are starting 2022 exhausted from the last 2 years and worried about schools staying open safely this year. I know what a struggle it is for parents scrambling to figure out childcare when they have got to go to work, or how tough it is for kids to keep up with classwork while transitioning back and forth from in-person to online learning.

While most schools are still safely open for in-person learning and we all want to make sure they stay that way, we know schools are struggling with this, especially as Omicron creates new challenges. I am hearing from schools in my States that they are worried they will have to shut down again if they can't get the support for testing they need, or they have staff shortages because of staff who are ill. Nobody wants that.

Based on what we now know about this virus and the tools we have to fight it, schools should be able to stay open safely if they have tests, masks, ventilation, and people are vaccinated. Hospital and health care providers are worried too. They have been stretched too thin after two exhausting years, and now Omicron is causing the worst surge in cases and hospitalizations yet. Because while it may be less severe in most cases, especially for those who are vaccinated and boosted, it is so much more contagious, meaning we are still seeing high rates of hospitalization overall.

We also have to protect children who are too young to get vaccinated and people with health conditions and disabilities that put them at high risk. Back in my State, hospitals are asking our State leaders to declare a crisis for our medical facilities. I have heard from health care providers in Washington who have been well over

their staffed bed capacity for several days and are pausing non-essential procedures.

Families are wondering whether they can get care for non-COVID related conditions and alarmed by how long ER wait times are getting. Health care providers are concerned about how we continue to keep health care workers safe, and also address the fatigue and burnout and mental health challenges that they face. These are not new challenges. I have been raising many of these concerns since the earliest days of the pandemic, so I am frustrated we are still behind on issues as important to families as testing and supporting schools.

That is not to say we have not made progress, it is just clear we haven't made enough. But even though we aren't where we need to be yet, we are not back at the starting line when it comes to COVID–19 either. We have safe and effective vaccines for everyone ages five and up. We have booster shots available for those 12 and up. More and more people are getting their shots each day. The Administration is also working to help get the world vaccinated to end this pandemic and has already pledged over a billion vaccine doses to that effort. We have new life saving therapeutics.

We have additional resources Congress passed in the American Rescue Plan, which can help increase our testing capacity, protect workers, and give schools the support they need to stay safely open. And we have an Administration that is focused on following the science, facing this pandemic head on, and addressing the frustration people are feeling. That is crucial at this moment when the path forward requires steady leadership and clear communication about the challenges we are still facing and the work ahead to tackle them.

President Biden has said plainly that he shares families' frustration around testing, and he wants to make sure schools stay safely open. And he has announced steps to address these challenges by making 500 million tests available free of charge, ordering over 200 million courses of antivirals, expanding manufacturing to be able to make hundreds of millions of tests a month, providing schools with guidance on how to test to stay protocols which can help keep students in the classroom, standing up more testing and vaccinationsites across the country, and providing medical personnel to struggling areas.

I expect to hear more detail on those efforts today, along with what other steps the Administration plans to take, and I will be watching closely as they are implemented. But I also want to be clear, when we talk about these problems, we have to be focused on solutions. You can't just say our schools must stay open if you don't vote to provide additional resources schools need to do so.

You can't just say the latest health guidance is confusing and not call out the blatant misinformation that has come from so many members of the Republican Party. We are not going to get out of this crisis by treating each challenge as a political opportunity. We are going to get through it by being honest about what we are facing and clear about what we are going to do about it. And as we continue working to get through this pandemic, it is important we also look at what we can do to prevent future health crises.

That is exactly why Senator Burr and I have been working in a bipartisan way over the last several months on legislation to learn from and improve on our pandemic response, like strengthening our supply chain for medical products, updating old and incompatible public health data systems, modernizing the process for developing tests, fighting misinformation, addressing root causes of health inequities and more. We will be unveiling a discussion draft soon, and I look forward to working with all of our colleagues to finalize and pass this important package. In the meantime, we will continue working to address the pandemic at hand.

People across the country are worried this will be another year of uncertainty, uncertainty for their work, their schools, and their everyday lives. But there is no reason it should be. People should be able to make plans for the future without fearing that everything they are looking forward to, or even the everyday things they used to take for granted, will be upended by this virus.

We all want that, and we have the tools we need to get us there. We have the tools to get everyone tested quickly, easily, and for free, to keep schools safely open during the Omicron surge and beyond, to keep workers, especially our health care workers, safe and healthy in the workplace. We have the tools to mitigate this virus, to protect those at high risk like seniors or kids who were too young to get vaccinated and people with other health conditions, to get people back to their friends and their lives, and to give families back some certainty and stability.

We can do all this now thanks to the incredibly hard work on the part of health care providers and scientists, parents and teachers, workers, and our witnesses who are here with us today. So what I hope to hear from this Administration at this hearing is what are you doing right now to make sure every American can make use of that progress they have worked so hard for. What can my constituents expect to see improved this week and the week after?

We have come a long way since the start of this pandemic, and I look forward to hearing from each of you today about what you are going to do to build on what we know, bring this virus under control, and bring certainty and stability back to families who are burnt out after 2 years of fighting this pandemic. Thank you. And with that, I will turn it over to Ranking Member Burr for his opening remarks.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Madam Chairman, thank you. And before my opening statement, I hope the Chair will indulge with me for just a second since this is a hearing on preparation. I want to help my good friend, Senator Kaine, as he gets ready for his weekly travels.

I want to make sure that he has got an orange for his car, that he has got a Dr. Pepper, and I provided a Lumbee blanket to make sure that things are three things you have got in your car regardless of what you run into on I–95, and I will have my staff bring them over to you.

The CHAIR. I hope you provide those for everyone has to be used to say to our kids in the classroom, do you have a piece of gum for everyone?

[Laughter.]

Senator BURR. Well, in his particular case, I think he is the only one that makes that trip on a weekly basis. Tim, we are sorry you had to spend 27 hours, but you are now qualified to be the Secretary of Transportation if you are looking for a second job.

[Laughter.]

Senator KAINE. Thank you. It is sad when a career in the Senate's most notable highlight is my long commute, but——

[Laughter.]

Senator BURR. Madam Chairman, thank you for holding this hearing. To our witnesses, welcome back. Today is going to be a tough hearing, but the American people deserve accountability and transparency. I appreciate that all of you have cleared your schedules to allow multiple rounds of questions today. Next week marks 1 year of this Administration. It also marks 2 years since the first COVID case was confirmed. President Biden said in his first, second, and third priorities would be bringing us out of COVID pandemic and that his team would shut down the virus.

This Administration was lucky. It started off on day one with the tools to change the trajectory of COVID response. Operation Warp Speed worked with the private sector to bring us groundbreaking vaccines and treatments in record time.

Although we had a very bumpy start with testing early in the pandemic, we successfully built some strong partnerships with the private sector to support the development and manufacturing of more tests. State and local leaders were rising to the challenge of testing and vaccinating their citizens. There was reason for hope.

Instead, now, a full year later, here is where we are. More than 830,000 deaths caused by COVID, the majority of which occurred under this Administration, despite having many tools and significant resources from Congress, including $80 billion plus for testing. A variant now spreading out of control across the country with places like Washington, DC. seeing a staggering increase in case counts over the holidays, and now my State of North Carolina is following suit with a 319 percent increase as of yesterday.

Over the holidays, when Americans were instructed to do the responsible thing and get tests before they see loved ones, there were no tests on the shelves or online, and hours long lines were the norm at testing sites across the country. The testing situation was worse when many sought tests to safely return to work or to school. And the most vulnerable Americans who contracted the virus could not get the treatments designed to help because they were now in short supply.

This Administration has time and again squandered its opportunities and made worse in the decisions you have made on testing and treatment, and most crucially in communications with the American people. The American people are right to be confused. It seems like you all don't talk among yourself. Some examples. Last August, the President announced that boosters would be available

to all vaxxed by the week of September 20th. The three of you here today signed that statement, but neither the FDA nor the CDC had yet approved boosters when the President made the promise.

When you went to your advisory panels with a predetermined outcome already made, those independent experts pushed back and ultimately had to be overridden to meet the President's goal on boosters. I know the data shows that boosters are necessary. I am boosted. I want everybody to get vaccinated and booster. The facts about the value of vaccines and booster are crystal clear. But the way this Administration rolled out boosters was a disaster. You created skepticism and mass confusion.

Example two, last summer the President dramatically announced that CDC recommendations changed so that vaccinated Americans didn't need to wear a mask indoors, implying that the worst of the pandemic was behind us, even as the Delta variant was exploding in India. Only after Delta hit America did CDC begin to take it seriously and the Administration had to change course.

Example three, last week Dr. Fauci said that the CDC was going to update its guidance on quarantine. He left the American people with the impression that CDC guidance was going to include some testing component to reduce the quarantine to 5 days. But when CDC did update its guidance, there wasn't a testing requirement. Again, I am not questioning the science. I am glad you refrained from testing mandates, but I am questioning your communication strategies.

It is no wonder the American—it is no wonder that the American people are confused. When the President announced on December 21st that 500 million tests were going to be purchased, he left out that the contract wasn't going to be signed for weeks and it would take even longer for those tests to be—to materialize. Immediately, other experts and medical professionals were asking what the value of just 1.5 tests per person was when CDC's own guidance said that you need multiple at home tests to be assured of the results.

Yesterday, the Administration mandated that insurers now cover the 170 million Americans that are covered by private insurance. They must cover up to eight tests per person per month. That would be 16 billion tests. And we have 500 million today that are aspirationally going to be contracted for. It is still unclear when these tests will be available, how to get them, whether any more are on their way.

But it is especially frustrating that the White House press Secretary had previously mocked the very idea of doing what the President later announced in a sarcastic and withering tone when this was first proposed. She had four questions, whether we should just send one to every American, then what happens, how much does it cost, what happens after that? Those are all good questions that remain unanswered by the Administration. My final example, though, there are many to choose from, happened last week too.

The White House press Secretary, a repeat offender in poor communications was asked about boosters. The press Secretary said, and I quote, "they can get boosted now, regardless of what CDC guidance is, whether you just approved for a booster, or you have

been approved for weeks." "Regardless of what CDC guidance is," from the White House podium. And then I was amazed when I got home on Sunday, and I had this letter from the Centers for Medicare and Medicaid Services telling me as a Medicare beneficiary, that I am eligible to get a free vaccine booster.

Five months after the President announced we are going to have boosters, we are—this is the first communication from CMS that I have gotten as a Medicare beneficiary in the 2-years of COVID and all of a sudden I get a request to get a booster. When a Republican Governor, or a Senator, including some on this Committee, suggests concerns about CDC guidance, Twitter and MSNBC can't react fast enough with scorn and anger. So it can't come as a surprise that there is confusion and anger when the White House says to ignore CDC guidance.

I tell my staff, as I have repeatedly said to you all in all previous hearings, to look 30, 60, 90 days ahead. Look 6 months ahead. Look abroad. See what is happening in Asia, Europe, Israel, Africa, UK, and elsewhere around the world. What do we need to anticipate? In our hearing on July 20th, and I warned that Delta would be—would not be our last variant. And I pleaded with each of you to have a plan in place for the next mutation of the virus. So why was the vice President surprised that Omicron came to our shores?

Well, I will say it is very clear—very clearly, so the Administration does not yet again say they are surprised, viruses change, viruses mutate. There will be more variants. They will come to America, period, end of sentence. I don't understand why after tens of billions of Federal dollars being appropriated, this Administration has failed to ensure that the Americans have the tests they need.

I don't understand why suddenly it is okay to take into account the economic and job impact of your guidance and recommendations. You shortened quarantine guidance because too many people would be out of work. Was that because of science or was it because you now know that lockdown, shutdowns, and school closures come with a significant downside impact?

You ask the American people to trust you. Quite frankly, you have lost their trust. Rather than attempting to gain their trust back, the Administration chooses to litigate mandate requirements for employers with over 100 employees. I have asked before, what is the plan? Never gotten a response. Very seldom do I get a letter responded to by this Administration. The Administration has not responded to my letters. Maybe folks at the White House don't think they need to respond to Republican Senators.

I think my record shows, I am approaching all of this as I have for the last 20 years. I am trying to help. I love this country, love its people, and I know we can do better than we have done. I know we have to do better. Maybe I am wrong about this. Maybe you will tell me where I got it wrong. Instead, I am hoping that you will understand that my criticism comes from a place of concern because the communication efforts are a mess and have only made things worse.

Now, I admit it. I am at the end of my rope. I think you will see today that most of my colleagues are as well. I have tried to give

my best advice and share what we hear and what we see because no one is paying attention to the message from this Administration right now. Maybe today you respond to my request to learn what the plan is.

Hopefully, you will take this challenge to rebuild the trust, not just with me, not just with my colleagues, but with the American people we all serve. What do you change in inflection to restore the confidence with the American people that there is a strategy for testing, for treatments, for fixing your communication strategy, because if you don't, things are going to get worse before they get better? Madam Chairman, I yield back.

The CHAIR. Thank you, Senator Burr. We will now introduce today's witnesses. Dr. Rochelle Walensky is the Director of the Centers for Disease Control and Prevention and the Administrator of the Agency for Toxic Substances and Disease Registry.

Dr. Anthony Fauci is the Director of the National Institute of Allergy and Infectious Diseases and the Chief Medical Adviser on President Biden's COVID–19 response team. Dr. Janet Woodcock is the Acting Commissioner of the Food and Drug Administration.

Dawn O'Connell is the Assistant Secretary for Preparedness and Response. And Director Walensky, Director Fauci, Acting Commissioner Woodcock, and Assistant Secretary O'Connell, I want to thank you all for joining us today. We all look forward to your testimony. And we will begin with Dr. Walensky on your opening statement.

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

Dr. WALENSKY. Good morning. Chair Murray, Ranking Member Burr, Members of the Senate HELP Committee, I appreciate the opportunity to join you to provide an update on the COVID–19 pandemic and the impact of the Omicron variant. It has been just over 2 years since we were first alerted to the emergence of SARS-CoV–2 in China.

Since that time, CDC has worked with our partner agencies and you and Congress to make—take remarkable action to protect the health and safety of Americans. Omicron is now the dominant variant in the United States, driving case counts to unprecedented heights here in the United States and around the world.

Despite the increases in cases, there are promising emerging data from South Africa and the United Kingdom that hospitalization rates for people infected with Omicron are lower compared with prior variants. These data seem consistent with what we are seeing so far in the United States.

However, despite a potential decrease in severity, the substantial number of absolute cases is resulting in hospitalization increases across all age groups, including children aged zero to four. The emergence of the Omicron variant again emphasizes the importance of vaccinations and boosters, which decrease the risk of infection, severe disease, and death caused by COVID–19.

Just last week, we made important progress toward increasing booster coverage through key—four key actions. First, we expanded eligibility of booster doses to those 12 to 15 years old. Second, CDC strengthens its booster recommendation for adolescents, now recommending that adolescents aged 12 to 17 years old should receive a booster shot 5 months after their initial Pfizer-BioNTech vaccine series. Third, we recommended that moderately or severely immunocompromised 5 to 11 year olds receive an additional primary dose of vaccine 28 days after their second shot.

Fourth, we shortened the recommended time between a primary mRNA series and a booster dose from 6 months to 5 months. Each action increases access to vaccines and booster doses at a time when protection is critical. As we continue to monitor this rapidly evolving virus, we are working quickly to adapt with it.

Over the holidays, CDC updated our quarantine and isolation guidance, first for health care workers, and then for the general public. I know this update has resulted in numerous questions, so I would like to take a moment to walk through it now.

For people who tested positive for COVID–19, CDC recommends isolation for 5 days. If you are asymptomatic or if your symptoms are resolving, for example, you are without a fever for 24 hours, you no longer need to isolate. However, you should continue to wear a well-fitting mask at all times when around others, including at home and in public for an additional 5 days. We recommend that you avoid activities where you are unable to wear a mask and that you avoid travel for the full 10 days.

In addition, CDC changed the recommended duration of quarantine. And quarantine is what you do after you are exposed. People who are not up to date on recommended COVID–19 vaccines should quarantine for 5 days if they come in contact with someone with COVID–19. People who do not develop symptoms by day five should get tested. If you test positive, you should begin isolation.

People who test negative may end quarantine and should continue to wear a well-fitting mask when around others for an additional 5 days. These recommendations are consistent with over 100 studies collected over the past 2 years, indicating that people are most infectious during their first few days of infection and significantly less infectious 6 to 10 days after infection. A core part of CDC's mission is to translate science into recommendations for best practices and real world circumstances.

Over the holidays, we saw the growing surge of Omicron and took swift science based action to address the very real possibility of staffing shortages in hospitals and in other essential areas of the workforce, including schools, pharmacies, public safety, public labs, grocery stores, and other sites, where shortages could have and have proven to have dire public health consequences. This is the right guidance for what we currently know about transmission and the real world circumstances we currently face.

As we will learn more, we will continue to update accordingly. Omicron is likely not to be the last curveball this virus throws at us, but we have the tools to prevent further spread of this virus. This means for everyone five and older, please get vaccinated. For those 12 and older, get your booster shot.

Please continue to adhere to the multi-layer prevention measures, including masking, and yes, washing your hands. 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 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. Since launching an agency-wide response to the COVID–19 pandemic nearly 2 years ago, CDC has learned more every day about this novel pathogen, how it spreads, and how it affects people and communities. We are committed to continuing to work to provide science-based guidance about how we can best protect ourselves and our communities as the virus and the pandemic evolves.

Update on Omicron

On November 24, 2021, South Africa reported the identification of a new SARS-CoV–2 variant, B.1.1.529 (Omicron), to the World Health Organization (WHO). Omicron was first detected in specimens collected on November 11, 2021, in Botswana and on November 14, 2021, in South Africa. South Africa has since also detected Omicron in specimens collected on November 8, 2021. As of January 4, 2022, Omicron has been detected in 144 countries around the world, including the U.S., where cases have been confirmed in most states and territories. CDC estimates that for the week ending January 8th, the national proportion of lineages designated as Omicron to be 98.3 percent with a 95 percent prediction interval of 96.9–99.1 percent. The national proportion of lineages designated as Delta is predicted to be 1.7 percent with a 95 percent prediction interval of 0.9–3 percent.

Data are emerging on how easily Omicron may spread, the severity of illness it causes, and how well available vaccines and therapeutics work against it. The variant has many concerning spike protein substitutions, some of which are known from other SARS-CoV–2 variants to be associated with reduced effectiveness of available countermeasures, including vaccines and therapeutics. The rapid growth rate in Omicron infections is believed to result from a combination of increased transmissibility and the ability to evade immunity conferred by past infection or vaccination (i.e., immune evasion).

At present, early data suggest Omicron infection might be less severe than infection with prior variants; however, reliable data on clinical severity remain limited. Even if the proportion of infections associated with severe outcomes is lower than with previous variants, given the increase in number of infections, the absolute number of people with severe outcomes could be substantial. In addition, demand for ambulatory care, supportive care for treatment of mild cases, and infection control requirements, including quarantining/isolation of exposed/infected workforce could also stress the healthcare system. These stresses likely will be in addition to the ongoing Delta variant infections and a rising burden of illness caused by other respiratory pathogens, such as influenza, which have begun circulating at greater frequencies.

CDC is working hard with domestic and international partners to better understand how easily Omicron might be transmitted and the effectiveness of currently authorized, cleared, or approved medical countermeasures, such as vaccines and therapeutics, against this variant. In addition, we are working, together with FDA, to ensure that diagnostic tests and variant genomic sequencing accurately measure the spread of Omicron. We continue to monitor and evaluate vaccine effectiveness data from the U.S. Initial data from international partners suggest vaccine effectiveness against infection is significantly reduced; those data also suggest that a booster does provide increased protection against infection, and importantly further decreases the risk of severe disease, including hospitalization, and death from COVID–19. CDC continues to strongly encourage COVID–19 vaccination for everyone 5 years of age and older and boosters for everyone 12 years of age and older. In January 2022, CDC updated its recommendation for when many people can receive a booster shot, shortening the interval from 6 months to 5 months for people who received a Pfizer-BioNTech or Moderna COVID–19 vaccines as their primary series. In addition, CDC recommended that moderately or severely immunocompromised 11-year-olds receive an additional primary dose of vaccine 28 days after their second

shot. Scientists are also working to determine how well existing treatments for COVID–19 work for Omicron infections. Based on the changed genetic make-up of Omicron, some treatments are likely to remain effective, while others may be less effective.

With the growing number of COVID–19 cases from the Omicron variant, and consistent with current understanding of the disease trajectory, on December 23, 2021, CDC released updated guidance for isolation and quarantine for healthcare workers, decreasing their isolation time after infection with COVID–19. Healthcare workers with COVID–19 who are asymptomatic and not immunocompromised can return to work after 7 days with a negative test. If health care personnel test positive at day 5–7, they can return to work 10 days after their initial test, as long as symptoms have improved and at least 24 hours have passed since last fever without the use of fever-reducing medications. Additionally, CDC released an update to guidance for contingency and crisis management in the setting of significant healthcare worker shortages. Healthcare workers who have received all recommended COVID–19 vaccine doses, including a booster, do not need to quarantine at home following high-risk exposures, as long as they remain fully compliant with masking requirements. These updates provide healthcare facilities with the strategies to limit the effects of staff shortages caused by COVID–19 on patient care.

On December 27, 2021, CDC updated and shortened the recommended isolation and quarantine time for the general population. It is important to note that this guidance does not supersede the guidance for health care workers or guidance from state or local public health jurisdictions. CDC shortened the recommended time for isolation from 10 days for people with COVID–19 to 5 days, if asymptomatic or improved and fever-free for at least 24 hours, followed by 5 additional days of wearing a well-fitting mask both at home and in public when around others. The change is motivated by science demonstrating that the majority of SARS-CoV–2 transmission occurs early in the course of illness, generally in the 1–2 days prior to onset of symptoms and the 2–3 days after. Additionally, CDC changed the recommended quarantine period for those exposed to COVID–19. For people who are unvaccinated or are more than 5 months out from their second mRNA dose (or more than 2 months after the J&J vaccine) and not yet boosted, CDC now recommends quarantine for 5 days followed by strict mask use for an additional 5 days. Alternatively, if a 5-day quarantine is not feasible, it is imperative that an exposed person properly wear a well-fitting mask at all times when around others for 10 days after exposure. Individuals who have received their booster shot do not need to quarantine following an exposure, but should properly wear a mask for 10 days after the exposure. For all those exposed, best practice would also include either an antigen test or nucleic acid amplification test (NAAT) for SARS-CoV–2 at day 5 after exposure. If symptoms occur, individuals should immediately quarantine until a negative test confirms symptoms are not attributable to COVID–19.

On January 6, 2022, CDC reduced isolation and quarantine periods in school settings to align with current CDC recommendations for isolation and quarantine. CDC recommends that students, teachers, and staff who are asked to quarantine, including those who are not fully up to date on recommended vaccinations, should not go to school or school events in-person during their quarantine period unless they are participating in a school sponsored "test-to-stay" program.

Schools may consider Test to Stay as an option for keeping asymptomatic school-associated close contacts in the classroom as an alternative to traditional quarantine at home. This includes people who are a school-associated close contact, are not up to date on recommended vaccinations, do not test positive for SARS-CoV–2, and have no symptoms. Test to Stay combines contact tracing and serial testing that is repeated at least twice during the 5-to–7-day period post-exposure to allow asymptomatic school-associated close contacts who are not up to date on recommended vaccinations and do not test positive to continue in-person learning. Outside of the school setting, quarantine recommendations would still apply.

New data about the virologic, epidemiologic, and clinical characteristics of the Omicron variant are rapidly emerging. CDC will continue to actively monitor for and respond to this variant, and we will continue to work diligently with state, local, and global public health officials, and industry partners to learn more, monitor the spread of Omicron, and inform the public.

Testing

On December 2, the White House announced new steps to ensure that Americans have access to no-cost self-testing. CDC is working on multiple fronts to expand access to testing, in support of this aim. CDC has awarded approximately $30 billion

to public health departments to support activities, including testing, through the Epidemiology and Laboratory Capacity cooperative agreement. For schools, CDC has provided $10 billion to states to support COVID–19 screening testing (i.e., testing of asymptomatic persons in order to identify unknown cases of the disease and avoid further transmission) for teachers, staff, and students to assist schools in staying safely open for in-person instruction. More than 23.5 million tests were conducted in schools between April 2021 and November 2021.

CDC also supports Operation Expanded Testing, which provides no-cost screening testing for schools, underserved populations, child care settings, and congregate settings. The program is available to all states and territories and can be tailored to each site's testing needs. Three federally funded contractors (coordination hubs) provide testing materials, supplies, and results reporting at no direct cost to recipients through a hub and spoke model.

The Increased Community Access to Testing (ICATT) program is another testing initiative jointly managed by CDC and other agencies with three primary objectives: working with pharmacies to ensure equitable access to COVID–19 diagnostics, establishing surge testing sites to provide infection control to populations at elevated risk for SARS-CoV–2 transmission, and establishing community testing sites to increase access to COVID–19 testing in under—resourced communities. In October 2021, ICATT reached its goal of establishing 10,000 community testing sites and plans to double that number in 2022 to 20,000 sites.

At the community level, CDC is supporting the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and other agencies with the distribution of tests to Community Health Centers, food banks, and rural clinics that receive grants from the Health Resources and Services Administration (HRSA). Support includes the provision of updated self-testing guidance and materials to accompany test distribution to ensure the public is educated about the use of these tests and how to handle positive results. These materials are publicly available on CDC's website.

Together, these actions will help Americans access the tests they need to help them stop the spread of COVID–19.

Genomic Sequencing and Surveillance

Viruses are constantly changing, and this includes SARS-CoV–2. Currently, the only way to definitively determine if an infection was caused by Omicron is by genomic sequencing. Genomic sequencing allows scientists to identify and monitor how SARS-CoV–2 changes over time, understand how these changes affect the characteristics of the virus, and use this information to better evaluate how it might impact health.

Building on years of investments, CDC has intensified efforts to vastly expand genomic sequencing capacity at both the Federal and state levels over the past year. In addition to direct support to public health laboratories, CDC provides support to academic institutions to conduct genomic surveillance research in collaboration with public health agencies and augments sequencing capacity through contracts with commercial diagnostic laboratories to support the national genomic surveillance system. Collectively, CDC's national genomic surveillance efforts can reliably detect very low levels of variants, even variants that account for as little as 0.1 percent of all COVID–19 cases, circulating in the U.S. with high confidence.

The CDC Advanced Molecular Detection program established the SARS-CoV–2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) to coordinate SARS-CoV–2 sequencing. The SPHERES collaboration includes scientists from clinical and public health laboratories, academic institutions, and the private sector. The SPHERES consortium is led by CDC's Advanced Molecular Detection (AMD) program, which over the past 6 years has invested in Federal, state, and local public health laboratories to expand the use of pathogen genomics and other advanced laboratory technologies to strengthen infectious disease surveillance and outbreak response.

On November 28, 2021, in partnership with U.S. public health laboratories and the Association of Public Health Laboratories, CDC rapidly activated enhanced surveillance for specimens with specific characteristics indicating a possible case of Omicron. The agency requested that public health laboratories send these specimens to CDC as quickly as possible to accelerate the confirmation of Omicron cases and to enable subsequent virological characterization. This led to the rapid identification of the first cases of Omicron in the U.S. CDC began detecting Omicron through its routine baseline genomic surveillance on December 5, 2021. CDC and other Federal

agencies continue to work with international partners to learn more about variants circulating globally and will continue to monitor all data sources closely to identify cases of Omicron in the U.S.

The rapid detection of Omicron in the U.S. reflects the work that CDC and partners have done over the course of the pandemic to build local capacity, enhance communication and information exchange, and advance new technologies. CDC continues to accelerate this work, as it is essential to the Nation's ability to rapidly detect and respond to emerging threats.

Travel Screening

As of December 6, 2021, all air travelers, regardless of citizenship or vaccination status, are required to show a negative pre-departure COVID–19 viral test administered no more than 1 day before travel, or documentation of having recovered from COVID–19 in the past 90 days, before they board their flight to the U.S. CDC continues to recommend that all travelers get a COVID–19 viral test 3–5 days after arrival, and that unvaccinated travelers quarantine for 5 days after travel. CDC's December 2021 amended air travel order strengthens already robust protocols in place for international travel, including requirements for most foreign travelers to be fully vaccinated before travel to the U.S.

This new 1-day testing requirement will help to protect travelers and the health and safety of American communities from COVID–19. In light of concerns and unknowns regarding Omicron, these measures will bring an additional layer of public health security and give us time to ramp up surveillance, continue our messaging about the need for vaccination and boosters, encourage non-pharmaceutical interventions like mask-wearing and distancing, and continue to learn more about this emerging variant and its capabilities. Both the U.S. Government and the airline industry are committed to making this process as seamless as possible for the traveling public.

In addition, CDC is collaborating with commercial partners on SARS-CoV–2 surveillance programs that involve voluntary testing of arriving international travelers at some of the busiest airports in the U.S. Arriving international air travelers are offered pooled testing conducted in the airport and offered at-home kits to be used 3–5 days after arrival. Participants and their respective health departments are notified of positive test results. Some positive samples are sequenced, enabling detection of novel SARS-CoV–2 variants among travelers entering the U.S.

Vaccination Efforts

The recent emergence of the Omicron variant further emphasizes the importance of vaccination, boosters, and prevention efforts needed to protect against COVID–19. As of January 6, 2022, nearly66.3 percent of the U.S. population over the age of 5 have completed a primary vaccination series, and approximately 35.3 percent of the eligible population has received their booster dose, indicating there is still more work to be done. Even as we learn more about the Omicron variant, vaccination remains the best public health measure to protect from disease, slow the spread of SARS-CoV–2, and reduce the likelihood of new variants emerging. Scientists are currently investigating Omicron, including how well vaccinated people will be protected against infection, hospitalization, and death. CDC recommends that everyone 5 years and older protect themselves from COVID–19 by getting vaccinated.

On November 29, CDC strengthened its recommendation on booster doses for individuals who are 18 years and older. Data from clinical trials showed that a booster shot increased immune response in trial participants. With an increased immune response, people have improved protection against COVID–19. For the Pfizer-BioNTech and J&J/Janssen vaccines, clinical trials also showed that a booster shot helped prevent symptomatic COVID–19. CDC recommends that everyone ages 12 years and older should get a booster shot 5 months after vaccination with an initial Pfizer-BioNTech or Moderna series, or 2 months after the J&J/Janssen vaccine. CDC recommends clinical preference for individuals to receive an mRNA COVID–19 vaccine over Johnson & Johnson's COVID–19 vaccine for primary and booster vaccination due to risk of rare, but serious adverse events. In addition, CDC recommends that moderately or severely immunocompromised 5 years of age and older receive an additional primary dose of vaccine 28 days after their second shot.

Global Efforts

CDC works closely with public health authorities around the world, including Ministries of Health. CDC also supports critical multilateral partners, including

WHO, Africa CDC and UNICEF. CDC's support to other nations includes a range of activities to strengthen capacity to prevent, detect, and respond to local COVID–19 cases. These efforts help provide timelier and more accurate data to inform public health decisionmaking, strengthen the public health workforce globally, mitigate COVID–19 transmission across borders, and minimize disruptions to essential health services. CDC's international collaborations and support for special investigations contribute to the scientific understanding of COVID–19 and address crucial unknowns regarding clinical severity, extent and pathways of transmission, and infection.

In addition, CDC is working with global partners and over 50 low-and middle-income countries to support planning, implementation, and evaluation of COVID–19 vaccination programs, including vaccine safety programs. We are currently developing plans to extend additional support to countries that are unable to effectively manage and distribute donated vaccines. CDC is also supporting countries' development of timely, high-quality data on vaccine delivery and safety and providing technical assistance and personnel to Gavi, COVAX, and WHO to assist with the development and implementation of strategies to distribute vaccines and implement vaccine programs.

Of particular importance related to detection of and response to the Omicron variant and in addition to ongoing efforts, CDC is building on a strong foundation of decades of work to augment laboratory capacity in partnership with ministries of health around the world. CDC also has participated in partnerships to develop sequencing capacity in southern Africa.

Conclusion

Although we are still learning about Omicron, we have been fighting COVID–19 for the last 2 years, and we know what people can do to protect themselves. Until we know more about the risks of Omicron, it is especially important to use all tools we have available to protect ourselves and our communities. If you are not yet vaccinated now is the time. If you are eligible, please get your booster. In areas of high and substantial transmission, regardless of vaccination status, wear a mask in indoor public places. Remember, where possible, to stay 6 feet away from people and avoid crowds and poorly ventilated areas. If you are experiencing symptoms or have been exposed to someone with COVID–19, get tested and stay home.

Last, we also must continue to focus on how we can better prepare for the future. Recent investments in public health have increased surveillance and sequencing capabilities that have proven effective to quickly identify Omicron here and around the world. We must make investments now to make sure we maintain and address the long-standing vulnerabilities in our public health system. I am committed to working with Congress to find common ground to support our public health system and make meaningful strides toward achieving health security for all Americans now and into the future.

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. Madam Chair, Ranking Member Burr, Members of the Committee, thank you for giving me the opportunity to discuss with you the role of the National Institute of Allergy and Infectious Diseases in the conduct and support of research addressing our Nation's response to COVID–19. In our most recent hearing before this Committee on November the 4th, I discussed the importance of booster shots to enhance immunity against the Delta variant that wanes over time.

Indeed, booster shots have dramatically reconstituted the waning immunity and has increased protection over and above the original level afforded by the primary vaccine regimen. Today we are faced with a different challenge, a new variant called Omicron that has

rapidly spread throughout the world, including a massive, unprecedented surge in the United States.

This variant possesses a large number of mutations that are associated with an increased efficiency of transmission, immune evasion from certain monoclonal antibodies, convalescent plasma, and antibodies induced by our current vaccines. Thus far, data from our own laboratories at NIAID, as well as from laboratories throughout the world, have indicated that vaccine induced antibodies lose a considerable amount of potency in neutralizing the Omicron variant.

Although this is of obvious concern, the encouraging news is that a third shot boost of an mRNA vaccine significantly reconstitutes and enhances the ability of antibodies from boosted individuals to neutralize the Omicron variant, strongly suggesting that boosters will play a major role in protecting our population, at least from severe disease, in the context of the ongoing massive surge of the Omicron variant that we are currently experiencing, underscoring why it is so important for the unvaccinated to get vaccinated and for those who are already vaccinated to obtain the booster shot.

Therapies in general are an important part of our armamentarium against COVID. In this regard, the NIH has been heavily involved in the development and, or clinical testing of several effective monoclonal antibodies against SARS-CoV–2. However, we have ascertained that certain of the authorized monoclonal antibodies are negatively impacted by the Omicron variant. Direct antiviral therapies also are an extremely important tool in the fight against COVID–19.

Importantly, it appears that the mutations expressed by the Omicron variant do not interfere with the oral antiviral drugs Paxlovid and Molnupiravir that NIH funded investigators played an early role in developing and that have recently received emergency use authorization from the FDA. Nor do they appear to interfere with the FDA fully approved drug remdesivir shown by NIH sponsored studies to be highly effective in preventing severe disease.

Looking ahead in the context of the inevitable continual emergence of new variants, the importance of developing a pan-coronavirus vaccine, namely one that would be effective against all SARS-CoV–2 variants and ultimately against all coronaviruses, becomes even more apparent. My colleagues and I recently published a paper in the New England Journal of Medicine emphasizing the urgent need for such an effort. In this regard, we have made significant progress in that direction.

We have identified antibodies that neutralize multiple different coronaviruses, and in addition, NIAID has issued new awards to fund pan-coronavirus vaccines at four academic institutions. These awards will fund multidisciplinary, collaborative teams to conduct research focused on coronavirus virology, immunology, immunogen design, and innovative vaccine and adjuvant platforms, as well as technologies to discover, design, and develop a pan-coronavirus vaccine candidates.

Finally, I would like to close by looking forward to how we might best enhance our preparedness for what inevitably will be the emergence of future pandemics. The NIAID will play an important

role in the multibillion dollar all of Government plan for pandemic preparedness.

Our mission is the rapid development and implementation of successful countermeasures against several prototype pathogen families of viruses that threaten the health and safety, not only of our Nation, but of the entire world. Thank you for your attention, and I would be happy to answer your questions following the presentations.

[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 once-in-a-lifetime global infectious disease pandemic.

The public health response to COVID–19 has required an unprecedented global public-private research effort. NIAID has played a central and important role in this response. NIAID capitalized on decades of fundamental basic research, including groundbreaking structure-based vaccine design at the NIAID Vaccine Research Center (VRC), to facilitate the rapid development of COVID–19 vaccines. NIAID also initiated clinical trials with creative and adaptive designs, allowing the evaluation of the safety and efficacy of multiple new and existing therapeutics for the treatment of COVID–19, which has helped support authorization of some of these products by the U.S. Food and Drug Administration (FDA). In addition, NIAID has engaged domestic and international clinical research infrastructure and leveraged highly productive partnerships in the public and private sectors to support multiple COVID–19 vaccine candidates to progress in record time from concept to Emergency Use Authorization (EUA) by FDA. Use of these vaccines throughout the world will continue to play a critical role in reducing the threat of COVID–19 in the United States and globally.

One of the most concerning developments of the ongoing pandemic has been the spread of SARS-CoV–2 variants, including the newly described Omicron variant. The Omicron variant is highly transmissible and is now the predominant variant in much of the United States. Early data suggest that the severity of disease caused by infection with the Omicron variant is lower compared to previous variants. However, the increased transmissibility of Omicron and the large number of new infections may lead to substantial numbers of hospitalizations and deaths, particularly among unvaccinated individuals at highest risk. The emergence of the Omicron variant makes it critical that we continue to vaccinate as many people as we can, as quickly as possible, including with booster doses.

The COVID–19 vaccines authorized or approved in the United States appear to remain effective against severe disease for most individuals, despite data showing waning of vaccine-and infection-induced immunity. While antibodies generated by the primary COVID–19 vaccine series do not neutralize the Omicron variant as well as prior variants, laboratory studies show that booster doses of COVID–19 vaccines induce high levels of antibodies against the Omicron variant. Early clinical data also show that booster doses of vaccines restore levels of immunity such that people are, at least initially, well-protected against the Omicron variant, particularly against severe disease. Further research to assess immune protection against Omicron is underway, including studies of the durability of protection offered by COVID–19 vaccination and boosters. NIAID efforts to enhance the protection afforded by COVID–19 vaccines and understand the effects of SARS-CoV–2 variants on immunity will help to address the Omicron variant and any future variants that may emerge.

Responding to Emerging Variants of SARS-CoV–2

NIH, including NIAID, participates in the HHS-established SARS-CoV–2 Interagency Group, along with the Centers for Disease Control and Prevention (CDC), FDA, Biomedical Advanced Research and Development Authority (BARDA), Department of Defense (DOD), and U.S. Department of Agriculture to track variants in real time and address the potential impact of emerging variants on critical SARS-CoV–2 countermeasures including vaccines, therapeutics, and diagnostics. Active monitoring of variants has allowed the U.S. Government to optimally deploy therapeutics to treat COVID–19 patients. NIH, CDC, and DOD are assessing the extent to which vaccine-induced immunity or post-infection immunity prevent infection by variants. NIH, BARDA, and DOD also are assessing the efficacy of authorized and candidate therapeutics against emerging variants in cell lines and animal models.

NIAID and our collaborators have rapidly assessed vaccines, monoclonal antibodies, and antiviral drugs to assess their effectiveness against the Omicron variant. Research suggests that although effectiveness of certain monoclonal antibodies against Omicron has been markedly diminished, one of the three monoclonal antibodies authorized for COVID–19 treatment retains its effectiveness against the Omicron variant. A monoclonal antibody authorized for pre-exposure prophylaxis (prevention) in high-risk people also retains its effectiveness. In addition, antiviral drugs used to treat COVID–19 appear to be effective against the Omicron variant.

NIAID also is supporting the development of next-generation vaccines that could provide protection against emerging SARS-CoV–2 variants by targeting several viral antigens, all of which are highly conserved among viral strains. 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 against conserved viral antigens. NIAID also is conducting early stage research on pan-coronavirus vaccines designed to provide broad protective immunity against multiple coronaviruses, especially SARS-CoV–2 and other viruses with pandemic potential. In 2021, NIAID announced awards to four academic institutions to conduct research to develop vaccines to protect against multiple types of coronaviruses and viral variants.

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. These efforts add to our knowledge about SARS-CoV–2 variants and our ability to combat them.

Developing Vaccines to Prevent COVID–19

Sustained domestic and international research investments by NIAID 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 strategy 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 led to the development of safe and effective COVID–19 vaccine candidates, several now authorized or approved by the FDA, across a range of vaccine platforms.

Six candidate COVID–19 vaccines have been assessed in completed or ongoing large-scale Phase 3 clinical trials in the United States. Clinical trials assessing

COVID–19 vaccine candidates in certain pediatric populations have been completed or are still ongoing. On August 23, 2021, a candidate vaccine developed by Pfizer and BioNTech became the first to be approved by the FDA for the prevention of COVID–19 in individuals 16 years of age and older. The vaccine also is authorized for emergency use and is available under the EUA as a two-dose primary series for individuals 5 years of age and older, as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 12 years of age and older 5 months after completing a primary series of the Pfizer/BioNTech COVID–19 vaccine. The Pfizer/BioNTech COVID–19 vaccine also is authorized for use as a heterologous single booster dose following completion of primary vaccination with a different available COVID–19 vaccine. The Pfizer/BioNTech vaccine is one of six COVID–19 vaccine candidates NIAID has helped advance through support for the fundamental research underlying the vaccine concepts, as well as for clinical testing. Two additional vaccine candidates, from Moderna, Inc., and Johnson & Johnson/Janssen, are available under an FDA EUA.

mRNA–1273 (Moderna)

As part of a longstanding collaboration, the NIAID VRC collaborated 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. After promising results in early clinical trials, NIAID and BARDA began working with Moderna on a Phase 3 clinical trial. NIAID scientists and their collaborators published updated results from this trial indicating that the vaccine had 93.2 percent efficacy in preventing COVID–19 illness, 98.2 percent efficacy in preventing severe disease, and 63 percent efficacy in preventing asymptomatic infection. Importantly, the efficacy of mRNA–1273 in preventing COVID–19 4 months or more after the second dose was maintained at greater than 90 percent. In addition, in observational studies in "real-world" conditions in broader segments of the population, mRNA—based vaccines continue to display high levels of effectiveness.

FDA has authorized mRNA–1273 for emergency use for prevention of COVID–19 in individuals 18 years of age and older as a two-dose primary series, as a third primary series dose for individuals 18 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose in people 18 years of age and older 5 months after completing a primary series of the vaccine. mRNA–1273 also is authorized for use as a heterologous single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different available COVID 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. The vaccine is known as Ad26.COV2.S or JNJ–78436735. NIAID has supported a Phase 3 clinical trial of Ad26.COV2.S 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 efficacious overall at preventing moderate to severe/critical COVID–19 occurring at least 28 days after vaccination and 85 percent efficacious overall in preventing severe/critical COVID–19 in the Phase 3 trial across several geographical regions, including areas where viral variants predominated. In the United States, the efficacy against moderate to severe/critical disease 28 days after vaccination with Ad26.COV2.S was 72 percent. FDA has authorized Ad26.COV2.S for emergency use for prevention of COVID–19 in individuals 18 years of age and older as a single primary vaccination dose and as a single booster dose for individuals 18 years of age and older 2 months after completing primary vaccination with the vaccine.

Ensuring Protection with COVID–19 Vaccine Boosters

FDA-authorized and FDA-approved COVID–19 vaccines have maintained remarkable effectiveness in preventing severe COVID–19. However, protection against mild and moderate disease begins to decrease over time following the primary vaccine series; this effect is seen with both the Delta and Omicron variants circulating in the United States. As noted, the Omicron variant appears to be more transmissible than previous variants and more apt to evade immunity. Individuals who receive a booster dose of a COVID–19 vaccine have markedly higher levels of antibodies against

SARS-CoV–2 variants compared to levels in individuals who received just the primary regimen, and early clinical data still being evaluated suggest these boosted individuals are, at least initially, well-protected against the current Delta and Omicron variants, particularly against severe disease.

FDA amended the EUAs for the Moderna and Johnson & Johnson/Janssen COVID–19 vaccines, respectively, to allow for use of a single booster dose for individuals 18 years of age and older. FDA also amended the EUA for the Pfizer/BioNTech COVID–19 vaccine to allow for the use of a single booster dose for individuals 12 years of age and older. CDC recommends receiving a booster dose of the COVID–19 vaccine at least 5 after completion of the primary series of the Pfizer/BioNTech and Moderna COVID–19 vaccines, and at least 2 months after completion of the single-dose primary regimen of the Johnson & Johnson/Janssen COVID–19 vaccine.

NIAID has initiated several studies to specifically address the Omicron variant and has several more in planning stages. For example, NIAID is testing the impact of a higher dose of the Moderna vaccine as a booster. In addition, the NIAID VRC is conducting preclinical testing of an Omicron-specific booster candidate (mRNA–1273.529) and of mixed (bivalent) booster candidates (mRNA–1273 plus a Beta variant-specific booster) against the Omicron variant. NIAID also plans to examine whether individuals who received boosters—either mRNA–1273 or investigational COVID–19 vaccine boosters designed to incorporate mutations found in emerging variants—generate antibodies that can bind to and neutralize the Omicron variant.

NIAID is leading a study in fully vaccinated individuals to assess the safety and immune responses following boosting with a COVID–19 vaccine different than the one used for the initial vaccination ("mix and match"). This trial includes a booster candidate (mRNA–1273.211) that incorporates several mutations that are present in the Omicron variant. NIAID released early data from this trial demonstrating that administering the Pfizer, Moderna, or Johnson & Johnson/Janssen COVID–19 vaccines at least 12 weeks after individuals received a different vaccine regimen effectively enhanced the immune response to SARS-CoV–2. Additionally, no safety concerns were identified. The results of this trial were made available to FDA during FDA's decisionmaking process to authorize the use of heterologous, or "mix and match," booster dosing in eligible individuals following completion of primary vaccination with a different available COVID–19 vaccine for persons 18 years of age and older.

NIAID is supporting additional preclinical and clinical research to assess the durability of immunity induced by COVID–19 vaccines, as well as the effect of COVID–19 vaccine boosters.

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 decisionmaking about COVID–19 vaccination in people with immune deficiencies and dysregulation conditions. In August 2021, NIAID launched multiple additional studies to assess and enhance the immune response to COVID–19 vaccines in immunocompromised individuals with autoimmune diseases as well as solid organ transplant recipients. This effort features a study with a multicenter, adaptive design to assess the immune responses to an additional dose of the COVID–19 vaccine in immunocompromised individuals. Data from this research will inform future considerations of additional doses of COVID–19 vaccines for these populations. CDC has made a recommendation, after review of the available scientific data, that people with moderately to severely compromised immune systems receive an additional dose of mRNA COVID–19 vaccine at least 28 days after a second dose of Pfizer/BioNTech COVID–19 vaccine or Moderna COVID–19 vaccine.

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 and children. Many pregnant and lactating women already have received the available COVID–19 vaccines. Data from these individuals demonstrate no safety concerns for pregnant women 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. This includes KidCOVE, a Phase 2/3 study launched by Moderna, in collaboration with NIAID and BARDA, to evaluate the safety 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. Pfizer also is evaluating their vaccine candidate in children younger than age 5, including a three-dose primary series. Other vaccine developers have begun, or are planning to begin, trials to test their vaccine candidates in children, adolescents, and other special populations.

Other COVID–19 Vaccine Candidates

NIAID also is supporting Phase 3 clinical trials of COVID–19 vaccine candidates from AstraZeneca (AZD1222) and Novavax (NVX-CoV2373). FDA has not yet authorized either of these vaccine candidates for emergency use.

Understanding the Nature of Immunity to SARS-CoV–2

NIAID is conducting and supporting research to enhance our knowledge of immunity against SARS-CoV–2 and to identify components of the immune response that provide protection against COVID–19. NIAID also is examining the quality and durability of the immune response to SARS-CoV–2, generating information that may be leveraged to develop novel SARS-CoV–2 therapeutics or vaccines and inform public health measures.

Data on infection-induced immunity from natural infection with SARS-CoV–2, including studies by NIAID scientists and NIAID-supported researchers, clearly demonstrate that most individuals generate a protective immune response to COVID–19 after infection. However, uncertainty surrounds several variables that can affect the generation of a protective immune response to SARS-CoV–2 following either infection or vaccination. Variables affecting the immune response include the age of the individual; their immune status; the medical treatments they have received; the impact of SARS-CoV–2 variants; and the impact of the severity of initial infection and time since infection, if applicable. Given that COVID–19 vaccination after infection with SARS-CoV–2 is safe and markedly enhances immune responses, COVID–19 vaccination is recommended for eligible individuals regardless of history of symptomatic or asymptomatic SARS-CoV–2 infection. NIAID continues to support research to understand immune responses to SARS-CoV–2 infection and/or COVID–19 vaccination, including projects investigating the durability of immune responses; whether immunity differs in certain populations; and how SARS-CoV–2 variants may affect immunity.

NIAID also is supporting research to improve understanding of the role of T cells in protection against COVID–19 and COVID–19 disease progression. NIAID supported a collaborative longitudinal study by researchers at Emory University and the Fred Hutchinson Cancer Research Center that demonstrated that SARS-CoV–2-specific T cells were detectable for up to 8 months in patients after mild to moderate COVID–19. NIAID also supported two separate studies examining T cell responses in recovered COVID–19 patients and individuals vaccinated against COVID–19. They found robust immune responses to the original strain as well as multiple variants of SARS-CoV–2 in both groups. Additional work by NIAID researchers and grantees showed that most individuals with existing T cell responses against SARS-CoV–2 should generate a T cell response against the Omicron variant, and that SARS-CoV–2 has thus far not evolved extensive T cell escape mutations. Other work from NIAID-supported investigators has shown that vaccine-induced T cell responses recognize the Omicron variant. 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. However, it is important to note that although we are learning important information about T cell responses in SARS-CoV–2 infected and vaccinated individuals, we still do not know the extent to which T cell responses mediate protection against COVID–19.

To help prepare for future pandemic threats, the NIAID VRC has established the Pandemic Response Repository through Microbial/Immune Surveillance and Epidemiology (PREMISE) program. The program will use data from the measurement of T and B cell immune responses to inform the discovery and development of diagnostic, prophylactic, and therapeutic countermeasures and accelerate the global response to pandemic threats. NIAID anticipates the research conducted by PREMISE

will advance our knowledge of immune response to vaccination and infection and help inform the response to future pandemic threats.

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. COVID–19 therapeutics that inhibit essential viral processes or address the host response to COVID–19 are expected to maintain their effectiveness against emerging variants, such as the Omicron variant. As noted above, some monoclonal antibodies appear to be ineffective against Omicron, while others maintain their activity. NIAID is conducting and supporting additional research to determine how Omicron and other variants impact the effectiveness of monoclonal antibodies and other therapeutics as well as working to develop new drugs.

The Adaptive COVID–19 Treatment Trial

Early in the outbreak, 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. The FDA subsequently revised the EUA for baricitinib to remove the requirement that baricitinib be administered in combination with remdesivir. ACTT–3 evaluated the treatment of hospitalized COVID–19 patients with remdesivir plus interferon beta–1a, which is used to treat individuals with multiple sclerosis, and found no clinical benefit from the addition of interferon beta–1a. ACTT–4 assessed baricitinib plus remdesivir versus the glucocorticoid dexamethasone plus remdesivir in adults hospitalized with COVID–19 and requiring oxygen, showing that these two regimens led to similar outcomes.

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. 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 been expanded and is currently evaluating two investigational therapeutics: SAB–185, a fully human polyclonal antibody produced in cattle, and SNG001, an inhalable beta interferon. After completing the Phase 2 portion of the ACTIV–2 trial, AstraZeneca is independently pursuing a Phase 3 trial of their investigational long-acting monoclonal antibody combination, AZD7442. Brii Biosciences announced a rolling EUA submission for their combination monoclonal antibody therapy, BRII–196 plus BRII–198, based on promising results from ACTIV–2 for the treatment of COVID–19. Among patients at high risk of clinical progression, those receiving BRII–196 plus BRII–198 had 178 percent decreased risk in hospitalization and death. On September 24, 2021, SAB Biotherapeutics announced the graduation of SAB–185 into Phase 3 efficacy studies in ACTIV–2.

ACTIV–3 currently is evaluating the AZD7442 monoclonal antibody combination and PF–07304814, a protease inhibitor, in hospitalized patients. PF–07304814 inhibits a critical part of the replication process of SARS-CoV–2. On April 22, 2021, NIAID and the National Heart, Lung, and Blood Institute (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 to various monoclonal antibodies in its fact sheets for health care providers. NIAID-supported scientists and collaborators are evaluating the potential impact of emerging SARS-CoV–2 variants on the efficacy of monoclonal antibodies. NIAID and BARDA have shared their expertise with FDA as FDA has modified EUAs for monoclonal therapies regarding the testing of these products against variants and the conduct of independent assessments of potency against variants as they emerge.

Additional NIAID-supported Therapeutics Activities

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 therapeutics to a common control arm to identify treatments with relatively large effects as promising candidates for further study in large-scale trials. BET initially evaluated two therapeutics: risankizumab, an immunomodulatory monoclonal antibody developed by Boehringer Ingelheim and AbbVie that is FDA-approved for the treatment of severe plaque psoriasis; and lenzilumab, an investigational immunomodulatory monoclonal antibody developed by Humanigen. Recently, a third therapeutic was added: danicopan, an oral drug that inhibits a key inflammatory pathway and was originally designed to treat a rare but serious disorder called Paroxysmal Nocturnal Hemoglobinuria.

NIAID, in collaboration with the DOD Defense Threat Reduction Agency, supported basic research and product development for the oral antiviral drug molnupiravir. Merck and Ridgeback Biotherapeutics announced clinical data from their Phase 3 trial which showed that molnupiravir reduced the risk of hospitalization or death by approximately 30 percent in at risk, non-hospitalized adult patients with mild-to-moderate COVID–19. In December 2021, FDA authorized the use of molnupiravir for the treatment of mild-to-moderate COVID–19 in adults who are at high risk for progression to severe COVID–19 and for whom alternative COVID–19 treatment options authorized by the FDA are not accessible or clinically appropriate. NIAID also provided support for the development of Paxlovid, an oral antiviral candidate developed by Pfizer. In a Pfizer-supported Phase 2/3 clinical trial, a course of Paxlovid given within the first 3 days of symptoms reduced the risk of COVID–19-related hospitalization or death by 89 percent among non-hospitalized adults with COVID–19 at high risk of progressing to severe illness. In December 2021, FDA authorized the use of Paxlovid for the treatment of mild-to-moderate COVID–19 in adults and pediatric patients 12 years of age and older weighing at least 40 kilograms who are at risk for progressing to severe COVID–19 and/or hospitalization.

NIH has launched the Antiviral Program for Pandemics, an NIH-BARDA collaboration that aims to develop safe and effective antivirals to treat and prevent SARS-CoV–2 infection. The program 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 target coronaviruses and additional RNA viruses with pandemic potential, helping to better prepare the Nation for future viral threats. Oral drug candidates for broad use in outpatient settings are the primary focus of this effort.

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 address considerations for hospitalized and non-hospitalized patients as well as 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 11 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.

Understanding the Incidence 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 also is working with partners to delineate biological and immune pathways responsible for the varied manifestations of COVID–19.

Early in the pandemic, the intramural research programs of NIAID, the National Cancer Institute, 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 may have exceeded the number of cases medically diagnosed by an additional 16.8 million infections through mid-July 2020. Continued analysis of the 1-year follow-up data from the study will be 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 aims to discover genetic factors conferring resistance to SARS-CoV–2 infection or predisposing to severe COVID–19. The consortium identified a subgroup of patients with severe COVID–19 that have ineffective immune responses to SARS-CoV–2, some of whom have mutations in key immune pathways.

NIAID also is engaged in 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 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.

Addressing 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.

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. On June 10, 2021, NIH announced awards to New York University (NYU) to build the RECOVER research consortium, harmonize and coordinate data within the consortium, and develop methods for monitoring protocols; and to Massachusetts General Hospital to provide statistical analyses and coordinate data standardization, access, and sharing among RECOVER projects. On September 15, 2021, NIH announced, through NHLBI and the National Institute of Neurological Disorders and Stroke, awards to NYU to develop the RECOVER Cohort with funding from the American Rescue Plan Act of 2021 (P.L. 117–2). NYU is engaging more than 100 researchers at more than 30 institutions to build a diverse national study population and support large-scale studies on the long-term effects of COVID–19.

NIAID intramural scientists initiated the Longitudinal Study of COVID–19 Sequelae and Immunity to better understand PASC and determine the extent to which people who have recovered from acute SARS-CoV–2 infection develop an immune response 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 1, 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 such as Delta and Omicron, 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. Thank you for the opportunity to testify. FDA's thousands of employees remain steadfast in fighting this pandemic.

Our work continued during the holiday season and led to critical advancements in combating the virus. The agency has been closely monitoring the potential impact of the Omicron variant on the currently available vaccines, diagnostics, and therapeutics. I will provide a brief update and actions the agency has taken in these three areas since I last testified before this Committee.

First, regarding vaccines. The currently authorized and approved vaccines remain highly effective at preventing serious outcomes associated with COVID–19 infection, including hospitalization and death. Additionally, data evaluated by the FDA suggests that an additional booster shot following the completion of primary vaccination series provides further protection against these outcomes.

Following these data, FDA updated the Pfizer-BioNTech and Moderna vaccine EUAs to shorten the time between completion of a primary series and a booster dose to at least 5 months rather than 6 months. FDA also updated the Pfizer-BioNTech EUA, so is now available for a primary series in children 5—ages 5 and older, and for the use of a booster dose in all individuals 12 through 15 years of age after completion of primary vaccination, as you have already heard from Dr. Walensky as the CDC followed up on this.

The agency also authorized the Pfizer vaccine for a third primary series dose for certain immunocompromised children that are 5 through 11. These vaccines have met FDA's rigorous standards, and the bottom line is getting vaccinated or receiving a booster with one of the currently available vaccines is the best thing the public can do right now to protect themselves and those they care about. It is not too late to get vaccinated or get boosted.

Second, diagnostic tests, which are another key line of defense in this pandemic. Increasing access to accurate, rapid at home tests continues to be a priority for FDA. Since I last testified, the agency has authorized four additional over-the-counter at home tests, bringing the total number to 15, and the agency continues to prioritize the review of these type of tests. We also partnered with the NIH to establish ITAP, which streamlines validation and authorization of antigen tests with potential for large scale manufacturing.

We expect shorter review times for such EUA request due to our partnership with ITAP. In fact, the first two tests that participated in this program were authorized in 2 days or less from the time FDA received the final data. So this is a very good model for Government assistance of diagnostic manufacturers. In this new program, ITAP will prioritize new over-the-counter test submissions that could be manufactured at significant scale to accelerate the availability of high quality, accurate, and reliable tests for the public as quickly as possible.

Third, as new variants continue to emerge, it is crucial to expand the country's arsenals of COVID–19 therapeutics, especially for those unable to get vaccinated or who can't respond to vaccination. Since I last testified, three therapeutics have been authorized for use in the treatment of COVID–19 for emergency use. The first of these EUAs, Evusheld, was authorized for the prevention of COVID–19.

The other two therapies, Paxlovid and Molnupiravir, as you heard from Dr. Fauci, are the first authorized treatments for COVID–19 in the form of a pill that can be taken orally, which is a major step in the fight against this global pandemic. These authorizations provide new tools to combat COVID–19 at a crucial time, and it should make antiviral therapy more accessible to people at high risk for progression.

Now, while these are important tools, they are not a substitute for vaccination and people for whom vaccination is recommended, and I continue to urge the public to get vaccinated if eligible. And fourth, we continue our mission of protecting the public from fraudulent medical products.

Since March, we have refused admission of more than 23,000 lines of FDA regulated products that were trying to get into the country illegally. And finally, I want to assure the public the FDA is committed to continue to use every tool in our toolbox to fight this pandemic with the best available diagnostics, lifesaving therapeutics, and vaccines.

Thank you, and I look forward to your questions.

[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, approval, and availability of critical, safe, and effective medical products to address the COVID–19 public health emergency.

I want to note that this testimony is just a snapshot of some of our extensive 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 on COVID–19 response efforts non-stop since the start of the pandemic. I want to commend and recognize their efforts and thank them for their dedication and service. I also want to thank all FDA employees who have continued to work on the myriad issues the Agency is responsible for that do not directly involve COVID–19.

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.

This includes working to quickly address any potential impacts of the new omicron variant. FDA is working as quickly as possible to evaluate the potential impact of this variant on the currently available diagnostics, therapeutics and vaccines. We are closely monitoring the situation and are committed to communicating with the public as we learn more. Just a couple weeks ago we updated the SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests web page to share new information on the omicron variant and its impact on antigen diagnostic tests. FDA is committed to continuing to use every tool in our toolbox to fight this pandemic, including pivoting as the virus adapts, to arm ourselves with the best available diagnostics, and lifesaving therapeutics and vaccines to fight this virus.

At this time, the current vaccines remain highly effective at preventing serious clinical outcomes associated with a COVID–19 infection, including hospitalization and death. Additionally, currently available data from our international partners and vaccine manufacturers that has been evaluated by the Agency, suggests that an additional booster shot following the completion of a primary vaccination provides further protection.

Getting vaccinated or receiving a booster with one of the currently available vaccines is the best thing Americans can do right now, in addition to standard precautions like wearing a mask, to help protect themselves and their families.

Biologics, Including Vaccines

FDA's Center for Biologics Evaluation and Research (CBER) continues to use every tool available to help facilitate the development and availability of vaccines and other biological products to combat the COVID–19 pandemic expeditiously and safely.

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

- Helping to facilitate expedited 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 individual sponsors and through issuance of guidance documents;
- Supporting product development and facilitating the scaling up of manufacturing capacity for high priority products to treat COVID–19 and conducting timely reviews;
- Expediting the review of Emergency Use Authorization (EUA) requests and Biologics License Applications (BLAs) for vaccines and other critical medical products to address COVID–19, including the evaluation of booster doses of COVID–19 vaccines and the use of COVID–19 vaccines in certain pediatric populations;
- Helping to ensure an adequate and safe blood supply; and

- Providing information to healthcare providers and researchers to help them submit expanded access investigational new drug application (IND) requests to permit the use of CBER-regulated investigational products for patients with COVID–19.

CBER's work on COVID–19 vaccines, as discussed below, has made a tremendous difference in addressing the pandemic by facilitating the availability of COVID–19 vaccines, that meet the Agency's rigorous standards, as expeditiously as possible. Through our transparent scientific evaluation process, FDA has issued EUAs for three COVID–19 vaccines and has approved one vaccine for use in individuals 16 years of age and older. In doing so, we have relied upon the Agency's rigorous standards for safety, effectiveness, and manufacturing quality. These COVID–19 vaccines were developed without cutting corners or compromising our regulatory and scientific 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 an EUA, allowing for quicker access to products once FDA reviewed the data and found the products met the Agency's rigorous standards for authorization or approval.

For the approved vaccine, as well as those that have been authorized for emergency use, our process included a thorough evaluation of the data by the Agency's career staff. We also solicited input from independent scientific and public health experts through our public advisory committee meetings for the COVID–19 vaccines that we have authorized. Throughout our scientific and regulatory process, FDA took additional steps to facilitate transparency, such as posting sponsor and FDA briefing documents and key decisional memoranda.

The COVID–19 vaccines that are available in the United States have shown clear and compelling efficacy in large, well-designed phase 3 trials. These vaccines are helping the country in the fight against this pandemic and have met FDA's rigorous standards for safety and effectiveness to support either EUA or approval. All the COVID–19 vaccines that FDA has authorized for emergency use have far surpassed being at least 50 percent more effective than a placebo in preventing COVID–19, which was recommended in our June 2020 guidance document, Development and Licensure of Vaccines to Prevent 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. The vaccines are approved or authorized to prevent COVID–19, and have been shown to significantly reduce the associated serious outcomes, including hospitalization and death.

During this past year, we have continued to make great strides with regard to COVID–19 vaccines. As part of our continued efforts to be transparent and educate the public, we have a wealth of information on our website about the COVID–19 vaccines available for use in the United States. The information includes fact sheets for healthcare providers (vaccination providers) and fact sheets for vaccine recipients and caregivers in multiple languages, with important information such as dosing instructions; information about the benefits and risks of each vaccine; and topical Questions and Answers developed by FDA for the approved vaccine and each authorized vaccine.[2]

It is also important to highlight that, as part of each EUA or approval, manufacturers and vaccination providers are required 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).

COVID–19 vaccine safety is a top priority for the Federal Government, and we take all reports of health problems following COVID–19 vaccination very seriously. FDA and CDC have implemented a coordinated and overlapping approach for continuous safety monitoring of all COVID–19 vaccines using state-of the art technologies. Specifically, the Agency's monitoring following authorization of the COVID–19 vaccines uses a multi-pronged approach including: 1) passive surveillance using VAERS consisting of safety reports submitted by healthcare providers (providers in the CDC COVID–19 Vaccination Program are required to report ad-

[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*

verse events following COVID–19 vaccination to VAERS), patients, parents and other members of the public, combined with 2) active surveillance, using large population-based healthcare datasets. These latter healthcare data systems offer a higher likelihood of detecting rare adverse events because they capture medical data on millions of Americans, cover diverse subpopulations (i.e., pregnant women, elderly, and patients with comorbidities) and can provide a longer duration of follow-up when compared to the prelicensure clinical studies. In addition, COVID–19 vaccine recipients are encouraged to enroll in CDC's v-safe After Vaccination Health Checker smartphone-based tool that uses text messaging and web surveys to check-in with vaccine recipients over time after they receive a COVID–19 vaccine. Through v-safe, they can quickly tell CDC if they have any side effects after getting a COVID–19 vaccine. Together, the passive and active safety surveillance provide a coordinated and overlapping approach to vaccine safety monitoring for COVID–19 vaccines.

On August 23, 2021, FDA announced the first approval of a COVID–19 vaccine. The vaccine previously known as the Pfizer-BioNTech COVID–19 Vaccine was approved and is now marketed as Comirnaty, for the prevention of COVID–19 in individuals 16 years of age and older. Comirnaty has the same formulation as the originally authorized Pfizer-BioNTech COVID–19 Vaccine. Since the approval of Comirnaty, the Pfizer-BioNTech COVID–19 Vaccine has continued to be available under an EUA, including for the two-dose primary series in individuals 12 through 15 years of age and as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromised conditions. While millions of people have already safely received COVID–19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. To be clear, the American public should feel confident in receiving any of the available vaccines.

On September 22, 2021, FDA amended the EUA for the Pfizer-BioNTech COVID–19 Vaccine to allow for use of a single booster dose, to be administered at least 6 months after completion of the primary series in the following groups: individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID–19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure puts them at high risk of serious complications of COVID–19 including severe COVID–19.

On October 20, 2021, FDA further amended the EUA to clarify that a single booster dose of the Pfizer-BioNTech COVID–19 Vaccine may also be administered at least 6 months after completion of the primary series to individuals 18 through 64 years of age with frequent institutional or occupational exposure to severe acute respiratory syndrome coronavirus 2(SARS-CoV–2).

On October 20, 2021, FDA also amended the Moderna COVID–19 Vaccine EUA to include use of a single booster dose at least 6 months after completion of the primary series in the following groups: individuals 65 years of age and older, and those 18–64 years of age at high-risk of severe COVID–19 or with frequent institutional or occupational exposure to SARS-CoV2. The Agency also amended the Janssen EUA to include the use of a single booster dose of the Janssen (Johnson & Johnson) COVID–19 Vaccine, administered at least 2 months after completion of the single-dose primary regimen to individuals 18 years of age and older. As of this announcement, all three COVID–19 vaccines had been authorized for a booster dose, but with varying eligibility.

Additionally, FDA authorized the use of heterologous, or "mix and match," booster dosing in eligible individuals following completion of primary vaccination with a different available COVID–19 vaccine.

On October 29, 2021, the FDA authorized the emergency use of the Pfizer-BioNTech COVID–19 Vaccine for the prevention of COVID–19 to include children 5 through 11 years of age. The authorization was based on the FDA's thorough and transparent evaluation of the data that included input from independent advisory committee experts who overwhelmingly voted in favor of making the vaccine available to children in this age group. We are confident in the safety, effectiveness and manufacturing data behind this authorization. As part of our commitment to transparency around our decisionmaking, which included a public advisory committee meeting, we have posted documents supporting our decision. We hope this information gives parents the confidence they need to have their children vaccinated.

On the same day, FDA also authorized a manufacturing change for the vaccine to include a formulation that uses a different buffer; buffers help maintain a vaccine's pH (a measure of how acidic or alkaline a solution is) and stability. This authorization is for two presentations: one for individuals 12 years of age and older and one for individuals 5 through 11 years of age. This new formulation is more

stable at refrigerated temperatures for longer periods of time, permitting greater flexibility for vaccination providers. The new formulation of the vaccine developed by Pfizer Inc. contains Tris buffer, a commonly used buffer in a variety of other FDA-approved vaccines and other biologics, including products for use in children. FDA evaluated manufacturing data to support the use of Pfizer-BioNTech COVID–19 Vaccine containing Tris buffer and concluded it does not present safety or effectiveness concerns. FDA has since approved this new Tris formulation as part of the Comirnaty BLA.

On November 19, 2021, FDA amended the EUA for both the Moderna and Pfizer-BioNTech COVID–19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older 6 months after completion of primary vaccination with any FDA-authorized or approved COVID–19 vaccine. On December 9, 2021, FDA amended the EUA for the Pfizer-BioNTech COVID–19 Vaccine, authorizing the use of a single booster dose for administration to individuals 16 and 17 years of age at least 6 months after completion of primary vaccination with the Pfizer-BioNTech COVID–19 Vaccine.

On January 3, 2022, FDA amended the EUA for the Pfizer-BioNTech COVID–19 Vaccine to expand the use of a single booster dose to include use in all individuals 12 through 15 years of age after completion of primary vaccination and authorized a third primary series dose for certain immunocompromised children 5 through 11 years of age. Additionally, FDA authorized the shortening of the time between the completion of primary vaccination of the Pfizer-BioNTech COVID–19 Vaccine and a booster dose to at least 5 months. Last Friday, January 7, 2022, FDA also amended the EUA for the Moderna COVID–19 Vaccine to shorten the time between the completion of a primary series of the vaccine and a booster dose to at least 5 months for individuals 18 years of age and older.

At this time FDA is closely monitoring the emergence of the Omicron variant in order to determine what, if anything, needs to be changed in the composition of COVID–19 vaccines moving forward to best protect the population. The Agency has already issued COVID–19 vaccine-specific guidance to address the emergence and potential future emergence of variants of SARS-CoV–2, the virus that causes COVID–19.

Figure 1

This pandemic is dynamic and evolving, with new data continuously emerging about vaccine safety and effectiveness. As we obtain more data about the safety and effectiveness of COVID–19 vaccines, including the use of a booster dose, we will continue to evaluate the rapidly changing science and keep the public informed.

At this time, it is clear that the approved or authorized vaccines reduce the risk of severe illness; however, data are not yet available to make a determination about how long they will provide protection. Additionally, although we do not yet know the full range of SARS-CoV–2 variants that each of the vaccines will protect against, there is evidence that the available 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).

To date, having three authorized vaccines and one approved vaccine that meet FDA's expectations for safety and effectiveness at this point of the COVID–19 pan-

demic is a tremendous achievement and a testament to the dedication of vaccine developers and FDA's career scientists and physicians. We are highly engaged in ensuring that all COVID–19 vaccines meet the high quality that the American public expects and deserves. The Agency is very proud of these efforts, and we believe that the vaccines will help bring this pandemic to an end.

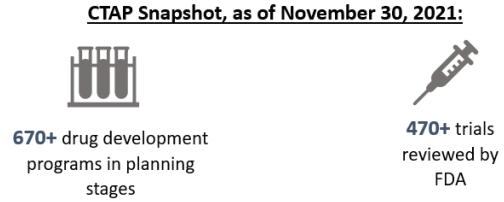
In addition to its work on COVID–19 vaccines, CBER also has been actively involved in reviewing data related to COVID–19 convalescent plasma and on December 28, 2021, the FDA updated the EUA for COVID–19 convalescent plasma. The update limits the authorization to the use of COVID–19 convalescent plasma with high titers of anti-SARS-CoV–2 antibodies for the treatment of COVID–19 in patients with immunosuppressive disease or who are receiving immunosuppressive treatment. These patients may be treated in outpatient or inpatient settings. Additionally, to help assure the manufacture of high titer COVID–19 convalescent plasma, the update to the EUA revises acceptable tests and increases qualifying result cutoffs to be used for manufacturing COVID–19 convalescent plasma with high titers of anti-SARS-CoV–2 antibodies.

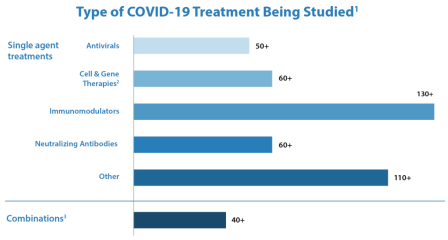
Drug Products

Since the beginning of the COVID–19 pandemic, FDA's Center for Drug Evaluation and Research (CDER) 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 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 and researchers 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 November 30, 2021, there are more than 670 drug development programs in the planning stages and the Agency has reviewed more than 470 trials of potential therapies for COVID–19. These include antivirals, immunomodulators, 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.

Figures 2 & 3

Figures 2 & 3





[1] Corresponds to number of safe to proceed INDs. Excludes INDs related to vaccines
[2] For additional information, please see Cellular & Gene Therapy Products
[3] Includes INDs with more than one product

As of December 31, 2021, FDA has approved one drug to treat COVID–19 and 14 therapeutics are currently authorized for emergency use. On December 8, 2021, FDA issued an EUA for AstraZeneca's Evusheld (tixagevimab co-packaged with cilgavimab and administered together) for the pre-exposure prophylaxis (prevention) of COVID–19 in certain adults and pediatric individuals (12 years of age and older weighing at least 40 kilograms [about 88 pounds]).

On December 22, 2021 FDA issued an EUA for the first oral antiviral, Paxlovid, manufactured by Pfizer. Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) is authorized for the treatment of mild-to-moderate coronavirus disease (COVID–19) in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms or about 88 pounds) with positive results of direct SARS-CoV–2 testing, and who are at high risk for progression to severe COVID–19, including hospitalization or death.

On December 23, 2021, FDA issued an EUA for another oral antiviral, molnupiravir, manufactured by Merck. Molnupiravir is authorized for the treatment of mild-to-moderate coronavirus disease (COVID–19) in adults with positive results of direct SARS-CoV–2 viral testing, and who are at high risk for progression to severe COVID–19, including hospitalization or death, and for whom alternative COVID–19 treatment options authorized by the FDA are not accessible or clinically appropriate.

Both Paxlovid and Molnupiravir are available by prescription only.

In considering EUA requests for therapeutics, we promptly and carefully evaluate the totality of the scientific evidence to determine whether the statutory criteria for issuance under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3) are met. Among other criteria, this evaluation considers whether the product may be effective for its proposed authorized uses, and whether the product's known and potential benefits outweigh its risks.

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 FD&C Act or for recommending that an EUA be revised or revoked. For example, last month, FDA held a meeting of its Antimicrobial Drugs Advisory Committee (AMDAC) to discuss Merck and Ridgeback's request for an EUA for molnupiravir, an investigational antiviral drug to treat COVID–19. The advisory committee discussed the available data supporting the use of molnupiravir to treat mild-to-moderate COVID–19 in adults who have tested positive for COVID–19, and who are at high risk for progression to severe COVID–19, including hospitalization or death. The meeting was scheduled as soon as possible following the submission of the EUA request by the company. FDA thoroughly evaluated the data and information submitted in the EUA request before the meeting and engaged in a robust public discussion with the advisory committee members.

FDA continues to work closely with manufacturers to mitigate and prevent shortages as the COVID–19 pandemic evolves. For example, the Agency has issued four 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 sufficient FDA-approved alternatives to these products were not available 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 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 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

FDA's Center for Devices and Radiological Health's work to support access to medical devices for the COVID–19 pandemic began in January 2020—before the Public Health Emergency (PHE) was declared in the U.S. and 2 months before the pandemic was declared worldwide—due to the immediate need for COVID–19 tests and testing supplies, collection kits, personal protective equipment (PPE), and other devices. The need for medical devices to respond to the COVID–19 pandemic has far exceeded what we experienced in any prior 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. Since January 2020, FDA has received over 7,500 EUA requests and Pre EUA (PEUA) submissions for devices. Further, the emergency use requests included submissions for devices that FDA's Center for Devices and Radiological Health (CDRH) had never received EUA requests for during prior PHEs. This included ventilators and novel devices such as extracorporeal blood purification devices, as well as novel indications for devices such as continuous renal replacement therapy devices. Since the start of the pandemic, FDA has issued EUAs or granted marketing authorization to nearly 2,000 medical devices for COVID–19-related uses. In addition, FDA rigorously monitors safety signals and medical device reports, using the information to publish 23 letters to healthcare providers and 9 safety communications. 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 these work through the EUA review. The EUA process expedites access to appropriately accurate diagnostic tests during emergencies, when information gaps and false results may adversely affect individual patient care and public health decisionmaking. Through this process, molecular diagnostic tests are able 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 employed its EUA authorities to facilitate availability of tests in six previous emergencies. Careful review of tests is critical because false test results can adversely impact the Nation's response. In PHEs, FDA is generally open to receiving and reviewing EUA requests for tests from any developer, including commercial kit manufacturers and laboratories, for tests that address the public health need.

FDA sought to facilitate COVID–19 test evaluation and authorization through the development and availability of templates for EUA requests. 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 an EUA. 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 had as many as ten posted templates and continues to update, add, combine, and remove templates as the science evolves and as necessary to support developers of COVID–19 tests. As of October 8, 2021, these templates have received over 556,635 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 74 weekly virtual town halls for test developers. The Agency has worked with over 1,000 test developers since January 2020.

The Agency prioritizes review of EUA requests for at-home rapid antigen tests and is actively engaging with test developers to increase their availability. The Agency first discussed this prioritization in the Spring of 2020, during one of its weekly virtual Town Halls on COVID–19 tests, due to their potential impact on test accessibility and public health. To further encourage such test development, on July 29, 2020, FDA posted a template for at-home diagnostic tests. This template in-

cludes recommendations for validating over-the-counter (OTC) tests for screening asymptomatic individuals with general performance expectations that are lower than for lab-based tests. The Agency recognizes the benefits of increased availability of OTC tests, and these recommendations have helped to increase OTC screening test availability, particularly rapid antigen tests.

Throughout the pandemic, FDA has also monitored evolving circumstances and growing scientific knowledge and made adjustments when appropriate to help streamline and expedite the path to market for these and other tests as much as possible while assuring they are supported by sound science. In March 2021, FDA obtained results from an NIH-sponsored study that supported further streamlining of FDA's at-home test recommendations. Based on these data, on March 16, 2021, FDA issued an EUA that provides a streamlined path to authorize tests with at least 80 percent sensitivity in symptomatic individuals, with sensitivity falling in a range as low as 70 percent in certain circumstances, for developers to offer their test for OTC serial screening without additional data collection. Multiple tests were authorized under this approach within weeks.

FDA authorized the first at-home test on November 17, 2020. At-home tests, also referred to as self-tests, are those that can be performed by a lay user at home, or in other settings, with a self-collected sample. In Fall 2021, the Agency added home tests from ACON Laboratories, Celltrion Diatrust, iHealth, and InBios International to the growing list of home tests authorized in the U.S. Two of the FDA's recent authorizations alone may result in up to 400 million more at-home tests available monthly to American consumers by early 2022, based on projections by the manufacturers and dependent on Federal subsidies. As of December 31, 2021, FDA has authorized 15 distinct at-home COVID–19 tests.

FDA further streamlined the process for manufacturers developing over-the-counter at-home tests on October 25, 2021, by facilitating at-home single-use testing for symptomatic individuals for tests currently authorized only for serial testing. Developers of certain tests may request authorization to add single-use testing for symptomatic individuals without submitting additional data. For example, right now when people go to a pharmacy to buy an at-home test, they are sold in two-packs. This change would allow tests authorized for single use to be sold in singles, meaning more individual tests for sale potentially at a lower price.

On November 15, 2021, FDA published an update to its Policy for Coronavirus Disease–2019 Tests During the Public Health Emergency that describes our review priorities based on the current needs of the pandemic. Going forward the FDA generally intends to focus its review on EUA requests for the following types of tests:

- At-home and point-of-care (POC) diagnostic tests for use with or without a prescription and that can be manufactured in high volumes;
- Certain high-volume, lab-based molecular diagnostic tests (and home collection kits for use with such tests) that expand testing capacity or accessibility such as through pooling of specimens to increase throughput, testing specimens collected at home and shipped to the lab, screening asymptomatic individuals or detecting multiple different respiratory viruses at once;
- Certain lab-based and POC high volume antibody tests that can measure the amount of antibodies (fully quantitative antibody tests) or the amount of neutralizing antibodies; and
- Tests for which the request is from, or supported by, a U.S. Government stakeholder, such as the Biomedical Advanced Research and Development Authority or the National Institutes of Health's Rapid Acceleration of Diagnostics (RADx) initiative.

These priorities help developers focus their prospective efforts where they are most needed, and reduce inefficient use of developer and FDA time on tests with less public health impact. Ultimately, we anticipate we will receive EUA requests only for those tests identified in the guidance for which the public health need is greatest, and we will be able to focus our attention on the review of such tests.

FDA also worked with NIH to establish an Independent Test Assessment Program (ITAP) to streamline validation and authorization of antigen tests with potential for large-scale manufacturing. This program is an extension of the RADx program which has already supported development of several authorized tests, including the first at-home OTC COVID–19 test. ITAP goes further to conduct studies on over-the-counter tests and work with companies to help them provide complete, high quality submissions for FDA review. ITAP is conducting independent laboratory and clinical evaluations using protocols developed jointly with FDA. FDA uses informa-

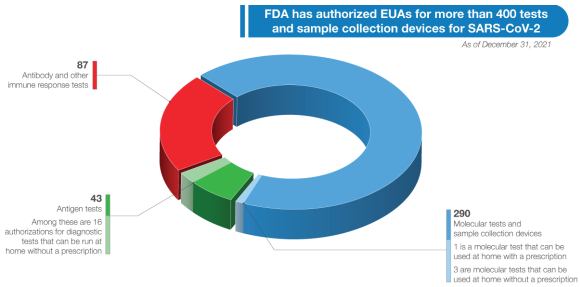
tion from these evaluations in deciding whether to grant EUAs. On December 24, FDA authorized the first at home COVID–19 test where validation data were gathered through ITAP and the second followed shortly after on December 29. We expect to continue shorter review times for such EUA requests due to our partnership with ITAP in establishing the evaluation program to address our regulatory needs.

Going forward, FDA continues to take steps to increase access to reliable, accurate rapid antigen tests. This includes continuing to prioritize review of EUA requests for at-home antigen tests, and increasing staffing on the antigen test review team as resources permit. FDA is actively working to increase the pipeline of at-home tests by engaging with companies to obtain data that can be used to support their EUA, working with developers with authorized POC tests to expand their authorization for at-home use, continuing support of ITAP and engagement with RADx and international regulators, and conducting targeted outreach to manufacturers of home tests in non-U.S. markets.

Because of these various efforts, as of December 31, 2021, FDA has authorized over 400 tests and sample collection devices for SARS-CoV–2. As noted in Figure 4 below, these include 290 molecular tests and sample collection devices, 87 antibody and other immune response tests, and 43 antigen tests. Among these are 16 authorizations for diagnostic tests that can be run at home without a prescription (three molecular and 13 antigen authorizations). We have also authorized 33 tests for serial screening programs (24 antigen and nine molecular). The volume and variety of authorized tests is a testament to FDA's support of innovative test design and our commitment to public health. FDA will continue to adapt to address public health needs and increase access to tests for consumers, including at-home diagnostic tests, adopting an approach that is grounded in sound science.

Figure 4

Figure 4



In addition to these efforts, FDA has been actively monitoring for the possible emergence of SARS-CoV–2 variants since early in the pandemic and has worked with test developers when a new variant (or mutation) emerges that could impact test performance. FDA also works with test developers, who are required to monitor their authorized test for the impact of viral mutations. As the FDA's or the developer's analysis identifies tests whose performance could be impacted by SARS-CoV–2 viral mutations, these tests are added to FDA's SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests webpage. This includes posting the latest information on the omicron variant and testing implications as they become available. FDA also works with other agencies and divisions in HHS, such as NIH, as we monitor tests for potential effects of genetic variation on test performance on an ongoing basis.

Since early 2020, FDA has adopted agile, interactive, and innovative approaches to review EUA requests for all types of devices. For example, FDA developed the umbrella EUA approach to efficiently authorize multiple devices of the same type falling within the scope of authorization and meeting the statutory criteria for issuance. The Agency has also issued 28 guidance documents (including 21 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 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.

Given the magnitude of the COVID–19 PHE, the FDA recognizes that continued flexibility, while still providing necessary oversight, will be appropriate to facilitate an orderly and transparent transition back to the eventual resumption of normal operations. In December 2021, FDA issued draft guidance for public comment to help manufacturers begin to plan a future return to normal operations, including a proposed phased-in transition period and recommendations relating to submitting marketing submissions. The Agency hopes that providing additional transparency on our current thinking now will facilitate advance planning for an orderly transition to normal operations after the public health emergency with fewer supply disruptions for device manufacturers, healthcare providers, and patients.

At the beginning of the pandemic, when there were relatively few diagnostic tests authorized, FDA's priority was to rapidly increase the availability of tests. For medical devices, review times have increased over time as the number of EUA requests and Pre-Emergency Use Authorization (PEUA) submissions for medical devices have increased to unprecedented levels. This is demonstrated in the tables we have provided with review times for IVD EUA requests over time, and submission volume for IVD EUA requests over time (see Figures 5 & 6 below). At the beginning of the pandemic, FDA was authorizing tests and other devices in as little as 1 or 2 days upon receipt of complete data packages. Congress has provided critical, one-time funding that FDA has used to leverage contractors from outside organizations, to provide technical expertise to supplement our review staff in the review of EUA requests and other marketing submissions. These personnel are authorized to work alongside full-time employees, integrated into our internal review teams to help with the massive workload for tests, ventilators, PPE, and other devices, but the workload has continued to greatly exceed capacity even with the additional support.

Figure 5

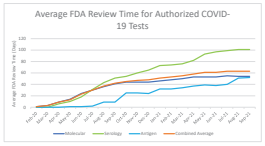
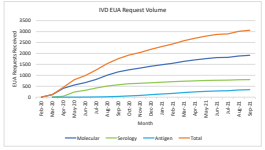


Figure 6

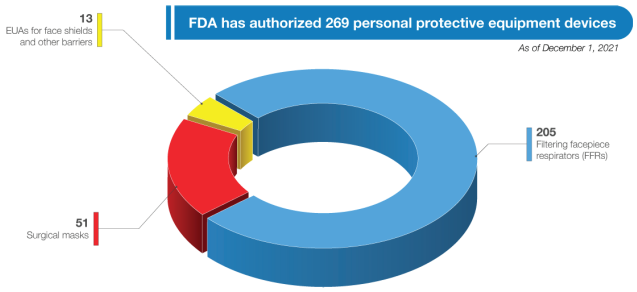


Please note that FDA's actions have reduced the review times for tests from a peak average of 90 days for EUA requests received in September 2020 to approximately 35 days for those received since February 2021.

FDA has authorized a wide variety of other medical devices for use in combating the pandemic, including a wide range of PPE, ventilators, and other therapeutic devices. As of December 31, 2021, FDA has authorized 269 PPE devices, including 51 surgical masks, 205 filtering facepiece respirators (FFRs), and issued 13 EUAs for face shields and other barriers intended to protect the user from bodily fluids, liquid splashes, or potentially infectious materials. See Figure 7. In addition to issuing EUAs, FDA has also cleared, through its premarket notification pathway, over 500 PPE 510(k)'s, which not only support the response to this pandemic but also future PHEs as well.

Figure 7

Figure 7



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 (Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine)

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 there is no evidence to show that SARS-CoV–2 is likely to be transmitted by food, some components of the food system are experiencing challenges and supply chain imbalances. We saw this at the outset of the pandemic with the dramatic shift in where people were eating, and most recently, we are seeing that the broad supply chain issues impacting so many commodities are also impacting food. Overall, food production and manufacturing in the U.S. has been remarkably resilient, but we continue to monitor the food supply chain systems closely to efficiently and promptly identify supply chain challenges and apply mitigation strategies when necessary.

In response to the pandemic, FDA's Foods Program developed 21 Forward, a food supply chain data management tool, to help identify where risks for interruptions in the continuity of the food supply may be greatest. As part of 21 Forward, FDA conducted targeted outreach to the food industry to offer additional resources and technical assistance in addressing challenges.

FDA also recognizes that food supply chain continuity and worker safety are two sides of the same coin. Thus, a robust food supply depends 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 pandemic.

In collaboration with HHS, CDC, Health Resources and Services Administration (HRSA) and U.S. Department of Agriculture (USDA), data from 21 Forward on the estimated numbers and distribution of food and agricultural workers 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. Now, FDA is using the information from 21 Forward to help identify and react to supply chain challenges and elevate as needed to the appropriate agencies or other entities. In addition, FDA has worked with its Federal partners to provide both COVID–19 and flu vaccination encouragement messages for the food industry.

FDA's Coordinated Outbreak Response and Evaluation team has been working throughout the pandemic looking for signs of foodborne illness outbreaks and initiating responses as needed. FDA's Center for Veterinary Medicine is monitoring the animal food supply and initiating needed foodborne illness and natural disaster responses. In terms of inspectional work, FDA's Office of Regulatory Affairs (ORA) investigators continue to conduct mission-critical inspections domestically and abroad, including inspections and investigations in response to foodborne outbreaks, as they have done throughout the pandemic. FDA resumed standard operations for domestic surveillance inspections in July 2021. FDA continues to screen every line of every shipment of imported food entering the U.S. 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 surveillance 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 2020, FDA has conducted approximately 2,982 FSVP inspections, which represents a 95 percent increase in inspections (1,527) over the 18 months prior to the pandemic. Additionally, FDA continues to identify human and animal foods that are unsafe, misbranded, or may cause a serious health concern for the public at the border with over 10,481 lines being refused admission since March 2020.

In July 2020, FDA announced the New Era of Smarter Food Safety Blueprint outlining the Agency's plans over the next decade to create a more digital, traceable, and safer food system. The Agency has learned from its response 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, strengthening food safety infrastructures with regulatory partners, and the safety of foods ordered by consumers online. The number of consumers ordering food online has been steadily increasing over the years, but it has skyrocketed during the COVID–19 pandemic. FDA recently hosted a virtual Summit on E-Commerce to help the Agency improve its understanding of how human and animal foods are sold through e-commerce models and to identify courses of action for addressing potential food safety vulnerabilities, including those that may arise in the "last mile" of delivery.

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 with uninterrupted support from ORA's laboratories. Through continued vigilance, FDA has prevented unsafe and unproven pharmaceuticals and other medical products from entering the country. Since March 2020, with the cooperation of and in coordination with the U.S. Customs and Border Protection (CBP), FDA has received and destroyed almost 85,500 products, totaling over 15,050,242 capsules, tablets, and other dosage forms of unapproved drugs.

Since March 2020, FDA has maintained the same level of screening for imported products as pre-pandemic and refused approximately 121,759 lines of imported violative medical 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 investigators 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, and also assisted with expediting the importation of other compliant vaccine-related shipments as well as other COVID–19 necessities.

Despite generally 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 until we resumed standard inspectional operations for domestic surveillance inspections in July 2021.

On May 5, 2021, FDA issued a report titled, "Resiliency Roadmap for FDA Inspectional Oversight,"[3] outlining the Agency's inspectional activities during the COVID–19 pandemic and its detailed plan to move toward a more consistent state

[3] *https://www.fda.gov/media/148197/download*

of operations, including FDA's priorities related to this work going forward. The report was updated on November 22, 2021.[4]

The report described our oversight work during the pandemic and outlined the inspectional activities that the Agency had postponed 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 outlined 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.

Additionally, the Resiliency Roadmap outlines FDA's continued, successful use of alternative tools and approaches where inspections are not feasible, including remote assessments (e.g. requests to regulated establishments to remotely view records) and remote interactive evaluations that include remote livestreaming video of operations, teleconferences, or screen sharing, and leveraging information from trusted regulatory partners. For example, FDA made over 1,300 requests to human and animal drug and biological product manufacturers to remotely view records, to support on-time regulatory decision actions. Our review of records requested under section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act supported more than 300 approval recommendations for new or abbreviated drug applications, as well as support for authorization decisions for EUA requests, potentially allowing new products to come to market and provide access to lower cost generic drugs to patients more quickly than may have otherwise been possible.

Notably, FDA's bioresearch monitoring program staff have conducted more than 130 remote assessments that were directly used in application decisions.[5] 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 physical onsite inspections, and that there are situations where only an onsite inspection is appropriate, based on risk and history of compliance with FDA regulations.

The Resiliency Roadmap further outlined 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 could not be performed during the pandemic. On July 1, 2021, FDA transitioned to standard operations for domestic surveillance inspections and other prioritized operational work through the end of September 2021. As noted in the updated November 2021 report, FDA has exceeded the goals for completing domestic surveillance inspections that were detailed in the May Resiliency Roadmap. We also exceeded our performance goal related to following up on previous inspections classified as official action indicated (OAI). Additionally, of the more than 13,500 applications for medical product approval or authorization received between March 2020 and September 2021, only 68 applications had been delayed due to the inability to conduct inspections—the vast majority of these applications are not deemed mission-critical. From the time FDA first issued the Resiliency Roadmap in May to September 2021, the FDA has been able to make decisions on nearly half of the 68 applications.

When planning surveillance inspections, the Agency is prioritizing higher-risk establishments. For example, a sterile manufacturing site that has not been previously inspected and is making narrow therapeutic index drugs would likely be deemed a higher risk than a site that had a well know inspectional and compliance history that is making over-the-counter solid oral dosage form drugs. 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 launched a multi-year modernization effort in July 2021 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 includes a review of inspectional approaches using next-generation assessment technologies and improvements. FDA established

---

[4] *https://www.fda.gov/media/154293/download*

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

an Agency-wide Inspectional Affairs Council (FIAC) that provides 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 regulatory oversight responsibilities, while achieving optimal public health outcomes.

Compliance and Enforcement

FDA exercises its regulatory authority by, among other things, issuing warning letters and by pursuing civil and criminal enforcement actions against firms and individuals who do not comply with regulatory requirements, including those distributing 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 the Agency's 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 hundreds of abuse complaints to domain name registrars and internet marketplaces. The Agency also has sent more than 260 warning letters to sellers of unproven products claiming to treat or cure COVID–19. Working with the Department of Justice (DOJ), FDA has sought and obtained preliminary injunctions that require defendants to halt the sale of unproven 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, since the start of the COVID–19 pandemic, FDA has issued 17 warning letters to owners and/or operators of illicit internet pharmacy websites that offer for sale unapproved and misbranded drugs purported to treat COVID–19 to U.S. consumers.

In addition, ORA's Office of Criminal Investigations (OCI), working with other Federal and local law enforcement agencies, has conducted criminal investigations involving unproven COVID–19-related products. In one such example, OCI investigated a physician who attempted to profit from the pandemic by marketing and selling an unproven COVID–19 treatment. The physician marketed and sold treatment kits—which included hydroxychloroquine—as a cure for COVID–19. In July 2021, the physician pleaded guilty to, among other things, trying to smuggle hydroxychloroquine into the United States to sell in his COVID–19 "treatment kits." In another case, OCI investigated an individual who attempted to import approximately 1,000 unlawful COVID–19 test kits from China, which were intercepted at a FedEx facility in Memphis, Tennessee. As a result of OCI's investigation, the individual pleaded guilty in October 2021 to a felony smuggling charge. OCI also has conducted criminal investigations to bring to justice those who tamper with COVID–19 vaccines. For example, OCI investigated a hospital pharmacist who tampered with COVID–19 vaccine doses at a Wisconsin hospital where he worked. On two successive nights, the pharmacist purposefully removed a box of COVID–19 vaccine vials from the hospital's refrigeration unit intending to render the vaccines inert and no longer effective. Before the full extent of his conduct was discovered, 57 people received doses of the vaccine from these vials. In January 2021, the pharmacist pleaded 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 of violative products where appropriate. We protect the supply chain in two equally critical ways: first, we help ensure safe products are coming in; and second, that illegal, dangerous, and fraudulent products do not get into the country. These efforts include partnering with U.S. Customs and Border Protection (CBP) in establishing satellite laboratories at selected International Mail Facilities (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 COVID–19. As a result of this investigation, a British national was charged and arrested for shipping mislabeled and unapproved products. In May 2020, FDA worked with CBP to intercept several shipments of counterfeit facemasks, with the result that they were refused and destroyed before entering U.S. commerce.

FDA also 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. FDA has tested several hundred products using field-based and laboratory-based tools and found more than a hundred violative products. FDA also has taken steps to help ensure that these dangerous or subpotent products do not enter domestic commerce, including coordinating with CBP to identify such products, and we have listed products made by more than 65 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 U.S. 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.[6] We work closely with manufacturers, within our current resources and authorities, 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 (FY) 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.[7]

This is especially important as the COVID–19 pandemic has exposed major vulnerabilities in the supply chain that FDA continues to face as it works to help ensure access to the treatments and devices that patients and healthcare providers need.

In addition to our usual communications 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 problems with access to critical care drugs used to treat COVID–19.

FDA understands the significant impact shortages can have on patient care and we are using our authorities to help prevent and alleviate disruptions. When we identify a shortage, we react swiftly to help mitigate the impact to U.S. patients and health care professionals, and quickly share that information with the public. Restoring and increasing the supply of approved drugs has been the agency's priority. In addition, where necessary, FDA has issued temporary policies during the COVID–19 emergency to respond to reports from hospitals of increased demand and interruptions in supply, some of which have not resulted in a drug shortage but caused concern about continuing access to drugs to support hospitalized patients with COVID–19. 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 for hospitalized patients with COVID–19. The Agency has published guidances to help applicants and manufacturers provide FDA with timely and informative notifications about changes in the production of certain human drugs, including biological products, and certain animal drugs. We urged the timely submission of these notifications, which may assist in our efforts to prevent or mitigate shortages of such products. In addition, section 503B(a)(2)(A) of the FD&C Act permits outsourcing facilities to use bulk drug substances to compound drug products that appear on the drug shortage list in effect under section 506E of the FD&C Act at the time of compounding, distribution, and dispensing, when all conditions of section 503B are met.

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 both the public and private sector collectively have important roles to play in strengthening the domestic medical device supply chain. FDA can play a critical role in identifying and preventing shortages for devices, because the Agency not only reviews and authorizes these products, but has unique, collaborative relationships that allow direct engagement with device manufacturers, patients, distributors, healthcare organizations, and other stakeholders. Even before the pandemic hit the U.S., there were disruptions in the supply chain due to higher demand for devices in other nations where COVID–19 was already prevalent and shutdowns

---

[6] *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply chain-review-report.pdf*

[7] FDA Fiscal Year 2022 Justification of Estimates for Appropriations Committees *(https://www.fda.gov/media/149616/download)*

in locations from which supplies were sourced. As a result, FDA began shortage mitigation activities for medical devices in January 2020 before the PHE was declared in the U.S., and 2 months before a pandemic was declared worldwide. At that time, the Agency did not have any dedicated funding or explicit authority regarding prevention or mitigation of medical device or animal drug shortages. The Agency lacked dedicated staff necessary to mitigate supply chain disruptions and/or shortages. Nevertheless, the Agency took several actions to rapidly respond to supply chain needs, including reassigning over 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. However, because the Agency lacked any explicit shortages authority at this time, only about one-third of facilities that were contacted responded even in part to CDRH requests because response was voluntary. This lack of explicit authority, staff and supply chain information significantly hampered our efforts to mitigate and prevent shortages at the outset of the pandemic.

On March 27, 2020, the CARES Act was signed into law. The CARES Act gave FDA, for the first time, authority related to device shortages (see section 506J of the FD&C Act). The enactment of the CARES Act at the height of the initial pandemic response gave some authority to help prevent or mitigate medical device shortages during the public health emergency. Specifically, section 506J of the FD&C Act requires manufacturers to notify FDA of a permanent discontinuance in or interruptions in the manufacture of certain devices that are likely to lead to a meaningful disruption in supply of that device in the United States during, or in advance of, a public health emergency. Section 506J also requires FDA to maintain a publicly available list of devices the Agency has determined to be in shortage, as well as devices that have been discontinued. The Agency is also directed to, as it deems appropriate, prioritize and expedite inspections and review of premarket submissions to help alleviate the supply chain constraint.

Since receiving this new authority, during the pandemic response, FDA has among other actions:

- issued guidance on submitting notifications to FDA during the COVID–19PHE and updated the guidance to provide better assistance based on stakeholder feedback;
- published a list of device types it has determined to be in shortage at this time, as well as a list of devices for which we have been notified by manufacturers the device has been permanently discontinued;
- created the infrastructure around receiving, processing, and analyzing notifications to determine devices that are in shortage and publicly post a list of the devices that FDA has determined to be in shortage;
- worked with manufacturers to plan for an expedited device premarket submission, which allows us to increase device availability for products that are most needed.

In addition to the implementation of the new device shortages authorities, 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 Q-tip-type 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.

FDA continues to work to implement and operationalize the new device shortage authority and utilizing one time funding from COVID supplementals, stand up a new state-of-the-art Resilient Supply chain and Shortages Prevention Program (RSCSPP). Medical device shortages not only put patients in harm's way but also jeopardize our health care workers on the front lines, during PHEs like the COVID–19 pandemic and every day in our health care system. Moreover, device shortages

disproportionately affect at-risk populations and exacerbate health disparities. For these reasons, FDA continues to do all it can within its current authorities and resources to mitigate shortages and supply chain interruptions for COVID–19 and within the U.S. health care system generally.

Congress has acknowledged the importance of FDA's work on shortages in our health care system and we want to continue working with this Committee and others to make sure FDA has the resources and authorities needed to ensure U.S. patients and health care providers have the medical products they need each day. To ensure the U.S. is properly prepared now, and in the future, we must take action to secure our medical device supply chain, including related materials, parts, and components. The FDA recognizes that this will take resources and expanded authority.

Conclusion

FDA continues to advance its mission to protect and promote public health by helping to ensure 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 help 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, it is an honor to testify before you today on efforts within ASPR to respond to the pandemic since the emergence of the Omicron variant. When Omicron first emerged, as we have done with each new variant, we immediately evaluated its impact on our current vaccines, therapeutics, and diagnostics, and adjusted our response accordingly. Data suggests that our current vaccine doses with a boost confer protection against Omicron.

As a result, we have continued distributing the three authorized and approved vaccines. Over 600 million doses of vaccine have been developed and delivered since the start of the pandemic. We have ample supply of both primary and booster doses, contributing to more than 200 million Americans now being fully vaccinated. However, we have had to make adjustments to our therapeutics supply in light of Omicron.

Two of our workhorse monoclonal therapies, one from Lilly, the other from Regeneron, are not as effective against Omicron. As a result, we have increased our supply of GSK's monoclonal, which is effective. We continue to purchase all that we can from GSK, though this supply is still limited. We are on track to have 250,000 courses available this month. A force monoclonal by AstraZeneca is targeted for immunocompromised individuals at high risk and is taken prior to exposure to prevent infection.

It has retained effectiveness against Omicron, and we will have made nearly half a million courses available through the end of this month. All four monoclonal that are currently available for

States and jurisdictions to order free of charge on a weekly basis to treat either Omicron or Delta infections. Also, we now have antivirals by Pfizer and Merck that are effective against Omicron and are being delivered to States free of charge every other week. We have procured 3.1 million courses of Merck that are now available.

Last week, we doubled our commitment to order 20 million courses of Pfizer's product. We have 265,000 courses available through this month and anticipate delivering the first 10 million courses to States by mid-summer. We remain in frequent communication with States and territorial health officials on the distribution of therapeutic products and continue to focus on ensuring these lifesaving therapies are available to Americans across the country. The dramatic rise in cases due to Omicron has put a significant strain on our testing capacity. Despite significant effort and investment, there is more work to do, and we are working every day and night with manufacturers to increase the availability of tests.

As soon as we saw the dramatic increase in cases in South Africa and Europe, we reached out to test manufacturers to understand their surge capacity and supply chain constraints. We are engaging daily with the lab test providers to mitigate any supply chain constraints with their sub-tier suppliers. We are also working with the commercial and public health labs to prioritize their needs.

We continue to use the Defense Production Act's authorities when needed. To further increase test availability, we are procuring 500 million rapid tests to distribute to American households. As a requirement of this procurement, none of these tests can interfere with what is available in the current commercial market so as not to diminish what consumers are able to access now.

We are currently shipping 2.8 million tests to long term care facilities per week, as we have throughout the pandemic. We continue to work to send 50 million rapid tests to federally qualified health centers and food banks, with 7 million having shipped so far. And we will keep working around the clock with manufacturers and our Government partners to increase and sustain the number of tests available now and in the future.

Finally, in addition to vaccines, therapeutics, and testing, ASPR continues to provide on the ground support to States and communities in need. Since July 40, National Disaster Medical System teams, nearly 880 team members have deployed to 19 separate States and the Commonwealth of the Northern Mariana Islands to support a range of functions, including hospital augmentation and decompression, setting up medical overflow centers for patients, and mortuary support.

We continue to send supplies as requested from the Strategic National Stockpile, including 300 ventilators to six jurisdictions since the emergence of our Omicron. We are grateful for the support from this Committee and Congress, and 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 respond to the current pandemic, restore and strengthen our capabilities, and prepare for future health emergencies. I am grateful for this opportunity to address this Committee and appreciate your continued support.

Update on ASPR's COVID–19 Response Effort

As we enter the third year of the pandemic, we continue to apply a whole of government approach to protect Americans from COVID–19. At the direction of Secretary Becerra and in my role as ASPR, I am responsible for leading HHS' COVID–19 response coordination. In this role, I work closely with my fellow panelists on all facets of the Department's response, however, for the purposes of this testimony, I will focus my update on the work for which the ASPR organization is chiefly responsible.

HHS Coordination Operations and Response Element (HCORE)

The vaccines and therapeutics available to us today are the result of an unprecedented partnership between HHS and the Department of Defense, through the Countermeasures Acceleration Group (CAG), previously known as Operation Warp Speed. Together this team, has helped develop and deliver over 600 million doses of vaccine and 3.9 million treatment courses to protect the American people from COVID–19.

On December 31, 2021, our Memorandum of Understanding with DOD expired and on January 1, 2022, we successfully completed the planned transition of this work to the recently established HHS Coordination Operations and Response Element, or HCORE. HCORE institutionalizes the efforts previously led by the CAG within ASPR. It will allow us to build on the progress to date, retain expertise and skills, and continue providing the necessary tools to the American people to respond to the COVID–19 pandemic.

Since my last appearance before the Committee, HCORE continues to lead, in partnership with CDC, the rollout and distribution of the Pfizer, Moderna, and Johnson & Johnson vaccines and boosters. While the data suggests that primary doses of vaccine confer reduced levels of protection against Omicron, we know that boosters strengthen protection significantly. These vaccines are being administered widely at 90,000 locations around the country, and ample supply is available in the field to meet the needs for both booster and primary series vaccinations. Additionally, the introduction of vaccines for children ages 5 through 11 has resulted in over 6.7 million doses delivered for this population. Significant work with the state, Federal, territorial, and pharmacy partners continues to ensure that there is ample vaccine available at locations where young children are likely to receive their vaccines.

In addition to vaccines HCORE continues to purchase and distribute to states and jurisdictions a wide variety of treatments including monoclonal antibodies and oral antivirals. In total, we have bought nearly 30 million treatment courses for patients with COVID–19.

Some of these therapies may be less effective against Omicron, however. The new variant is predicted to have markedly reduced susceptibility to two of the monoclonal antibody treatments we have purchased (Lilly's bamlanivimab/etesevimab and Regeneron's REGEN-COV). However, two of the monoclonal antibody treatments we have procured are expected to retain activity against Omicron—GSK's Sotrovimab and AstraZeneca's EVUSHELD. We are increasing our supply of the GSK monoclonal to 1 million courses over the next few months and are on track to have more than 250,000 courses available in January. AstraZeneca's monoclonal is a pre-exposure therapy which is targeted for immunocompromised individuals at high risk. We will have more than half a million courses on hand in January.

In addition to these monoclonal antibody treatments, the newly authorized oral antiviral pills developed by Merck and Pfizer are expected to retain activity against Omicron and HCORE is distributing doses to all states and jurisdictions. More than 360,000 courses were delivered to dispensing sites in December—with a total of about 3 million courses of the Merck antiviral and more than 265,000 of the Pfizer antiviral on the way in January. The Administration recently announced plans to double the Pfizer antiviral order from 10 million to 20 million treatment courses.

Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority (BARDA) continues to leverage the supplemental appropriations provided by Congress to support the development of vaccines, therapeutics, and diagnostics to end the COVID–19 pandemic. BARDA has awarded contracts for 78 medical countermeasure projects to aid the COVID–19 response to date. All of these contract awards are listed on medicalcountermeasures.gov in detail and include 16 therapeutics, 55 diagnostics, and seven vaccine candidates. Notably, BARDA has placed 1.5 billion doses of vaccine under contract (including a combination of adult primary, booster, and pediatric doses), distributed over 3.3 million doses of monoclonal antibodies, and shipped more than 182 million diagnostic kits.

BARDA also supports research on expanding eligibility for the current authorized and approved vaccines as well as the continued development of vaccine candidates that have not yet been authorized or approved. This ongoing work on vaccines is critical as we begin to look for next generation vaccines that are easier to store, ship, administer and may prove more durable than the current authorized and approved vaccines.

BARDA's work on therapeutics is critical as we seek to balance the ease of administration with the benefits of the treatment. For example, many of the available monoclonal antibodies are administered by infusion which must be done in clinical settings. BARDA's collaboration with industry on developing oral antivirals offer an important alternative to monoclonal antibodies. As a result, there are now two antivirals available under EUA for the prehospital treatment of patients at high risk for progression to severe COVID–19.

BARDA continues to play an important role in the development of diagnostic tests that expand beyond central labs to point of care and at home solutions. This includes contracts for three molecular and two antigen point of care and home use tests and for two molecular and five antigen point of care only tests. In addition, BARDA has funded six manufacturing capacity expansion efforts to increase domestic testing capacity.

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 multiple domains of medical equipment and supplies. Many vital products and their raw materials are primarily made overseas, and practices like "just in time" inventory management resulted in difficulty accelerating manufacturing when demand surged last spring. This created significant and devastating challenges for States and healthcare systems that required access to 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. Since the beginning of the pandemic, the SNS has deployed more than 250 million items to aid the national response including Personal Protective Equipment (PPE), ventilators, Federal Medical Stations, and pharmaceuticals. In particular, the SNS deployed almost 3,000 ventilators to 17 jurisdictions between July and October 2021, to respond to the Delta variant case surge. The SNS has deployed more than 300 ventilators and High Flow Nasal Cannula to six jurisdictions since Omicron emerged.

I highlighted in my testimony in July that ASPR continues to work to replenish SNS inventory to levels at or above pre-COVID–19 amounts to ensure we are prepared for any subsequent wave of additional cases and to do so to the extent possible with domestically manufactured supplies and equipment. As of December 29, 2021, the SNS has utilized approximately $12 billion from COVID–19 supplemental appropriations provided by Congress to have in its inventory approximately: 747 million N95 respirators (59 times pre-pandemic levels); 274 million surgical and procedure face masks (8.5 times pre-pandemic levels); 19.6 million face shields (two times pre-pandemic levels); 59.6 million gowns and coveralls (12.5 times pre-pandemic levels); 4 billion gloves (240 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels). SNS has also made investments to ensure there is capacity to make these critical supplies.

In addition, to better identify and understand baseline issues during the COVID–19 response and improve future response operations, we supported three meetings with Tribal representatives to determine if changes or updates are needed regarding how federally recognized Tribal governments request SNS support. These listening sessions were in collaboration with the Indian Health Service (IHS), the Centers for

Disease Control and Prevention (CDC)/Division of State and Local Readiness, and the HHS/Office of Intergovernmental and External Affairs (IEA). The SNS team continues to engage other key state and local leaders and organizations as it seeks input on how to improve access to the stockpile.

While replenishing the SNS is essential, it is also critical to address the root cause 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 public health supply chain for medical materials, ingredients, and supplies is critical for any national response to public health emergencies.

Throughout the COVID–19 response, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) to issue 66 priority ratings for U.S. Government (USG) contracts for health resources, eight priority ratings for USG contracts for industrial expansion, three 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—all to ensure private sector partners making life-saving products are able to acquire the raw materials, components, and products requisite to deliver for the response.

Also under the DPA, ASPR is strengthening the industrial base to secure and develop domestic capacity, retool and expand industry machinery, scale production facilities, train workforces, and ultimately infuse the supply chain and marketplace with products the U.S. needs to contain further pandemic waves. ASPR continues to invest in critical funding in expanding domestic manufacturing including investments in manufacturing PPE, testing consumables, vaccine raw material, vaccine vials, at home and point of care tests, and testing raw materials. Each of these domestic manufacturing initiatives meets current, as well as future COVID–19 needs, and seeks to create or sustain high-value domestic jobs.

All of these investments, and the industrial base overall, require dedicated and persistent management and engagement. As such, my intent is to institutionalize this mission in ASPR. I am working to integrate and organize supply chain situational awareness and industrial analysis, domestic industrial base expansion, and supply chain logistics into a new office within ASPR. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains. I ask for your support as we work to address this effort and would be happy to provide future briefings on this effort as needed.

As you are likely aware, several groups outside of ASPR are reviewing the SNS as well as other Federal stockpiles. Specifically, the HHS Inspector General (IG) is completing a 3-year SNS review. The IG began the review when the SNS transitioned from CDC to ASPR in 2018 but shifted the review slightly in 2020 with the onset of the COVID–19 pandemic to review holdings, requirements, and available resources to meet needs.

In addition, the National Academies (NAS) has reviewed at our request the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the interagency group of experts that advise, among other things, what should go into the SNS. The full report is available via the NAS website: *https://www.nap.edu/read/26373/chapter/1*. We are reviewing the findings in the National Academies report to determine how to strengthen both the PHEMCE and the SNS. Restoring and rebuilding the SNS is one of my priorities and I look forward to reviewing both of these reports and incorporating their findings or recommendations into the strategic work we are undertaking to rebuild and restore the stockpile and realign it with the PHEMCE. I would be happy to discuss both of these reports with this Committee once both are released and made public. As chair of the PHEMCE, I plan to incorporate lessons learned from the COVID–19 response into future PHEMCE planning. I'm pleased to report that we will relaunch the PHEMCE next month.

Healthcare System Preparedness

Next, 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 healthcare needs.

Through ASPR's Hospital Preparedness Program (HPP), 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, while leveraging and amplifying technical guidance from the CDC. These components work together to provide a coordinated, national approach to preparing healthcare systems to surge for public health and medical emergencies.

We also continue to support our Regional Disaster Health Response System (RDHRS) demonstrationsites. The goal of the RDHRS is to link together existing health systems to address health care preparedness challenges, establish best practices, expand access to specialty clinical care, and increase medical surge capacity at the regional level. As I mentioned in my November 2021 statement, a fourth RDHRS demonstrationsite was established at Emory University. With this award, we now have demonstrationsites based at Massachusetts General Hospital, Nebraska Medical Center, and Denver Health and Hospital Authority. The ultimate goal of this system is to support a more coordinated, comprehensive, and capable health care disaster response system able to respond to health security threats.

As part of our COVID–19 pandemic response, the National Special Pathogen System 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. Since July 2021, forty National Disaster Medical System teams nearly 880 team members were deployed to support sites in 19 separate states and the Commonwealth of the Northern Mariana Islands (CNMI). There is currently an NDMS team in New York and Missouri. For these deployments, NDMS personnel support a range of functions including hospital augmentation and decompression, setting up medical overflow centers for patients, and mortuary support. As we learn more about Omicron, and if additional needs are identified, we will continue to make resources available to states and communities to respond.

Of note, this critical system requires a renewal of its direct hiring authority, which was set to expire on September 30, but was extended as part of the continuing resolution. NDMS has utilized this authority to bring on additional personnel over 1,000 personnel hired to date and will continue to utilize the expedited authority, if extended by Congress, to continue to enhance the force.

Testing

In addition to the Industrial Base Expansion efforts I mentioned previously, ASPR continues to support COVID–19 testing for the Nation. The HHS Testing and Diagnostics Working Group (TDWG) mission was established early in the pandemic to increase testing capacity through interagency coordination and partnerships with industry and state, tribal, local, and territorial public health agencies. TDWG was created as part of the Federal response to COVID–19 in March 2020, residing with Operation Warp Speed temporarily, and then established under the Office of the Assistant Secretary of Health (OASH) leadership and was located in the Joint Coordination Cell (JCC) run by the U.S. Coast Guard. In March 2021, when the JCC was officially stood down, TDWG's administrative and contracting support were moved to ASPR.

While there is more work to do to increase the supply of rapid tests, we have significantly increased our country's testing capacity over the past several months. In fall 2021, ASPR invested $3 billion to accelerate the production of rapid tests and expand capacity. As a result, we have quadrupled the number of rapid at home-tests available since we made those investments in September. To further increase testing supply, ASPR, is leading the Administration's procurement of 500 million Over-the-Counter (OTC) tests, an investment of over $3 billion, with plans for initial tests to be available this month. ASPR has also shipped over 40 million rapid antigen tests and 2.3 million point-of-care PCR tests to our most vulnerable populations, including nursing homes, federally qualified health centers, and long-term care facilities since May 2021. In addition to the purchase and distribution of these tests, ASPR continues to work with manufacturers, companies, and laboratories to identify and proactively address any supply issues.

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 to all of our witnesses. We will now begin a round of 5 minute questions of our witnesses, and I again ask my colleagues to keep track of your clock and stay within those 5 minutes. As the Omicron variant of COVID–19 continues to spread at an alarming rate, people are looking for clear, straightforward guidance on how to protect themselves and those around them.

It is really critical that we reduce the infection rates so we can relieve pressure on our health care workers, protect people with disabilities and older Americans, young kids and anyone else who has been disproportionately impacted by COVID–19.

However, I have heard from so many people who find the latest CDC isolation and quarantine guidance confusing and hard to interpret. So, Dr. Walensky, can you please clearly explain CDC's latest guidance on what people need to do to protect themselves and others if they are exposed to or contract COVID–19? And let me start with vaccinated people. What is your guidance to them?

Dr. WALENSKY. Thank you, Chair Murray, for the opportunity to clarify. Maybe if I could just rewind the clock to just before the holidays, where we were hearing from hospitals that they were—their staff were going out and that they were in a real crunch in terms of beds. They had plenty of beds, but they didn't have staff to staff them.

ICU beds were starting to close. So immediately we worked toward our updated health care worker guidance, but when we did so, we recognized that we were going to have challenges and that this Omicron surge that we were about to face was threatening many other places of our health care——

The CHAIR. I appreciate the background, but I just want to know straight forward if someone is exposed to or has COVID–19 and they are vaccinated, what do they do?

Dr. WALENSKY. If they are exposed to COVID–19 and they are completely boosted, they should—they do not need to stay home, but they should get a test at day five. If they have COVID, our guidance is—does not distinguish between your vaccination status, and our science has demonstrated that you are maximally infectious 2 days before and two to 3 days after.

By 5 days after your symptoms, if you are feeling better, if your fever is better, if you are cough and sore throat are better, then on day six you can go out, but you have to wear a mask, you have to wear a mask reliably and you should not go to places you can't wear a mask. You probably shouldn't go and visit Grandma. You shouldn't get on an airplane.

The CHAIR. For vaccinated. What about unvaccinated?

Dr. WALENSKY. Same for unvaccinated for isolation. So isolation being those who have had disease—who have disease.

The CHAIR. Well, let me just say, nearly 2 years ago, when this Committee first started having Congressional hearings on COVID–19, the very first thing I asked was where are the tests? And we have made progress since then, and we are now producing 300 mil-

lion rapid at home tests each month, along with ramping up our lab based testing.

But I am disappointed, as I said, by the testing challenges that we are facing. Tests are hard to find. They are costly. People are unable to find the at-home tests in pharmacies, online. They are waiting in long lines, and often after that, waiting days for results. So it is ineffective at the end of the day.

Ms. O'Connell, I want to ask you, what are you doing to address the frustrations and challenges we are hearing about COVID testing?

Ms. O'CONNELL. Chair Murray, thank you so much for this very important question. Testing remains a critical priority for this Administration. When we saw the unprecedented cases of Omicron sweep into South Africa and Europe, we immediately reached out to our manufacturers to understand any supply constraints they had and to evaluate their surge capacity.

We have also met daily with them to make sure that they have what they need from their suppliers and have used the Defense Production Act authorities 12 times throughout this pandemic in support of testing needs. Most recently in the last few weeks for two tests, we were able to unlock supplies and manufacturing capacity. We continue to invest in rapid, over-the-counter tests, which are in high demand.

In the fall we invested $3 billion to increase manufacturing line staffing and to commit to those manufacturing lines for 13 months. As a result, we went from 50—46 million tests, over the counter tests available in October, to the 300 million, Chair Murray, that you just mentioned that are available now. But that is not enough. We are continuing to bring tests to the American people.

As a result, the President has announced, and we are in the process of procuring the 500 million tests, which every American household will be able to order and have shipped directly to their house. We have completed four contracts so far, have secured 50 million tests, and are in the process of securing the additional tests over the next several days.

The U.S. Postal Service has agreed to do the distribution, and the U.S. Digital Services is going to help with the website. We anticipate the first tests going out at the end of this month, with the remaining tests going out over the next 60 days.

The CHAIR. Okay, I am out of time, but I do want to just say this, I am hearing from so many schools that are having trouble staying open. They want to stay open. Part of it is they have staff that are sick. That is understandable. But a big part of it is they don't have access to the safety measures like masks and testing supplies. What do I tell them about where they go to get that?

Ms. O'CONNELL. Chair Murray, thank you. Having—schools having enough supply, testing supplies to stay open as a critical priority for us. We have invested $10 billion of the American Rescue Plan given to States to support and stand up testing programs. We have also invested $60—$650 million in a program called Operation Expanded Testing, which set up regional hubs of labs that schools could contract with to run their testing programs.

But that doesn't work if there aren't tests available, so ASPR is working directly with States to match additional manufacturing capacity with States that need it. Not only that, we are in the process within ASPR of looking at our contracts to see if we have any additional capacity, and we will commit to sending that capacity to the school programs.

The CHAIR. Senator Burr.

Senator BURR. Thank you, Madam Chairman. Let me just cut to the chase. Dr. Fauci, you said CDC was going to update its guidance and include antigen testing or suggested that it would. Dr. Walensky and CDC came out with the guidance that didn't include it. Was that part of the communications plan to start with and they diverted it, or was that something you just chose to inject?

Dr. FAUCI. Thank you for that question, Senator Burr. In discussions about the real gray zone, which Dr. Walensky described about after the 5-days where you have a considerable diminution in the likelihood of being transmitting, we had been in discussions about what the role of antigen testing would be.

As a matter of fact, when Dr. Walensky came out with the final guidelines, they include that if you have a test available, you may take a test. So at the end of the day, we were quite in concordance with our views.

Senator BURR. Well, I think the Chair and I share this, we found it very confusing, and I think the American people found it confusing, and I don't see it lightly when I say not too many people in America listening to what comes out of Washington, whether it is Congress or out of the Administration as it relates to COVID.

The President makes an announcement, Ms. McConnell, of 500 million at home test. Is this the first time that you have thought about purchasing at home test or have you tried to before and it was rejected?

Ms. O'CONNELL. Thank you, Ranking Member Burr. This is the first time the Administration has committed to purchasing tests to send to the American households.

Senator BURR. So is that ASPR or is that DOD? Because of all the notifications of contracts signed, I have seen them from DOD. I haven't seen them from HHS.

Ms. O'CONNELL. Thank you for that question, Ranking Member Burr. We use—we have a relationship with DOD for assisted acquisitions, so ASPR will request that DOD put out a solicitation or manage a contract on our behalf.

They are able to do it extraordinarily quickly. And we have had an MOU in place with DOD for this work that will run through June 2023. We have used this relationship to purchase vaccines and therapeutics, and we are now using it for testing.

Senator BURR. So the best I can find, you mentioned 50 million doses having been contracted. I can identify 27 million out of two companies, Medea and Atlantic Trading. Neither one of them are manufacturers of test, and I believe the third one, Revival, is not a manufacturer of test.

Medea actually came to fame with the importation of vodka and tying cell phones to vodka. And like a lot of other companies, they

got the PPE business in 2020 with some nominal FEMA contracts. Why should we have any confidence in these contracts if in fact we are dealing with companies that don't manufacture anything? And can you assure me that the tests that are coming in are not coming from China?

Ms. O'CONNELL. Thank you, Ranking Member Burr. Absolutely, these tests—what we initially did to be able to access tests for the initial shipments that will go toward the end of January, we worked with warehouses to see where additional tests were stored and assessed that additional capacity and are bringing that capacity to bear for these initial tests that are going out, which is why you are seeing contracts with warehouses and not with test manufacturers.

Senator BURR. So is what you are telling me, they have got 50 million tests in warehouses in the United States, and all we did was access that inventory?

Ms. O'CONNELL. That is my understanding.

Senator BURR. Well, will you confirm your understanding? This is a very, very important piece, when you have got companies that don't manufacture tests and all of a sudden we are giving them $190 million contract for about 14 million home tests and their expertise is importation of vodka.

I encourage you to look through the list of people that we are signing up with. Are you aware that some of the larger test manufacturers in 2021 shut down lines because of the lack of purchases for at home test?

Ms. O'CONNELL. One of the things we did in the fall was a $3 billion investment that we made was to turn lines on and to commit to those lines for 13 months so they wouldn't be turned off again.

Senator BURR. Dr. Woodcock, let me just—last question, Chair. Of the 15 tests that you have currently approved for over the counter, how many detect Omicron?

Dr. WOODCOCK. We are still working on that, but we believe all of them detect Omicron. We simply feel they are somewhat less sensitive than they were to some of the previous variants.

Senator BURR. Of the 50 million tests that the ASPR has contracted for, how many of those tests detect Omicron?

Dr. WOODCOCK. I don't know which tests they are. We can get back to you on that.

Senator BURR. So you haven't consulted with what we are purchasing on the $500 million, and they haven't consulted with FDA to figure out whether the tests they are buying actually detect Omicron.

Dr. WOODCOCK. I believe they have. I simply don't have that list.

Senator BURR. Okay. I think thank the Chair.

The CHAIR. Senator Kaine.

Senator KAINE. Thank you. Thank you, Chair Murray and to the witnesses. Dr Fauci, can you provide us a general breakdown of what percentage of hospitalized individuals are vaccinated versus

unvaccinated, and what percentage of COVID deaths are among vaccinated or unvaccinated individuals?

Dr. FAUCI. Thank you for that question, Senator Kaine. One of the ways to answer that question would be to look at people who are in the hospital and take a look at if you are vaccinated versus unvaccinated.

If you look at vaccinated versus unvaccinated, there is about a 10 times greater chance that you be infected if you were unvaccinated, about a 17 times greater chance that you would be hospitalized if you were unvaccinated, and about a 20 times likelihood that you would be—that you would be dead if you were unvaccinated.

When you look at every parameter, 10 times, 17 times, 20 times infection, hospitalization, death.

Senator KAINE. Thank you, Dr. Fauci. Ms. O'Connell, I want to ask you a question about vaccine—additional vaccine development. The current vaccines against COVID, as was indicated by Dr. Fauci's answer, have been very successful in reducing deaths, severity of illnesses, and hospital admissions.

However, they have had more limited success in preventing forward transmission from vaccinated individuals after breakthrough cases, and the existing vaccines are not as durable as vaccines in other areas, so we need booster shots to continue to protect against the virus.

Is the Administration considering supporting the development of additional vaccines that might be able to address the gaps in the current vaccines' capabilities?

Ms. O'CONNELL. Senator Kaine, thank you so much for that question. Yes, absolutely. I think we all see the need for next generation vaccines. We are also looking for next generation antivirals and therapeutics as well.

We are in the process of working with Dr. Fauci's team to develop a unified NIH, BARDA research agenda and budget to address these issues, to identify candidates that might already be in the pipeline, to help support the research into candidates that are just starting in the pipeline, just so we can accelerate the availability of the next generation vaccines and therapeutics.

Senator KAINE. Thank you for that answer. Dr. Walensky, I would like to ask you a question about access to testing, and in particular, what is the CDC doing to make sure that testing capacity is robust in rural America and also among community health centers in disadvantaged parts of the country?

Dr. WALENSKY. Thank you, Senator Kaine. So we have this program, increased community access to testing, in collaboration with ASPR as well. This is a program that has collaborated with FEMA to increase surge testing just over the holidays.

We have increased testing, Federal testing sites for PCR, 12 Federal testing sites doing thousands of tests over the holiday. We also work with pharmacies in collaboration with pharmacies, and in that stead, we are able to map where the pharmacies are and their social vulnerability index, and we can actually put PCR tests in

areas of High Social Vulnerability Index through all of our pharmacy partners, CVS, Walgreens, Rite Aid, and whatnot.

Then we actually put tests in our community centers as well. So really a broad stretch in order to be able to get access to testing, especially among those most vulnerable. And then, of course, as ASPR O'Connell mentioned, $10 billion for testing supplies to our schools and working closely with our schools in peer to peer support, in technical support, to allow those tests to be used well in those school settings. Thank you.

Senator KAINE. Thank you for that answer. And Dr. Fauci, one more question for you. I ask a version of this question every time we have this panel before us. What is the NIH doing right now, or what is the current status of NIH research to better understand long COVID, to look at symptoms and potential treatments?

Dr. FAUCI. There are several levels of activity going on. Some news since we spoke last. I had mentioned to you, Senator, that in fact, there was a $1.15 billion program for studying long COVID that is now developing cohorts to look at various incidences, prevalence, pathogenesis, and potential interventions.

There have been a number of awards that have been given. Most recently in September, there was an additional $470 million funding supported through the American Rescue Plan, engaging about 100 researchers from 30 institutions to get individuals together.

One of the things that is really interesting that we are seeing right now is that when you look at individuals who have these symptoms that go on, as you know and have experienced yourself, for a considerable period of time, a recent study that is in the preprint stage, so it hasn't been peer reviewed, has some very interesting information that needs to be validated and verified.

It was an autopsy study in people who had varying levels of COVID, from relatively mildly symptomatic to moderately symptomatic individuals who actually died, and when they looked at the spread of what was not necessarily replication competent virus, but was PCRable virus, which means you could have nucleotides that were there, there was, it seems to be a persistence in multiple organ systems, indicating that even if you clear the virus, one of the possibilities.

I have to emphasize possibility because it needs to be validated, is that you don't completely clear the fragments of the virus and you have continual stimulation, not that you are infectious or that you are going to infect anybody else, but that it is still generating perhaps an aberrant response in your immune system.

I underscore again, it is preliminary, it is in the pre-print stage, and it needs to be peer reviewed, but that is some of the information we are starting to gather.

Senator KAINE. Thank you very much for that answer. Thank you, Chair Murray.

The CHAIR. Senator Paul.

Senator PAUL. Dr. Fauci, the idea that a Government official like yourself would claim unilaterally to represent science, that any criticism of you would be considered a criticism of science itself is

quite dangerous. Central planning, whether it be of the economy or of science, is risky because of the fallibility of the planner.

It would not be so catastrophic if the planner were simply one physician in Peoria. Then, the mistakes would only affect that physicians' patients, the people who chose that physician. But when the planner is a Government official like yourself who rules by mandate, the errors are compounded and become much more harmful.

A planner who believes he is the science leads to an arrogance that justifies in his mind using Government resources to smear and to destroy the reputations of other scientists who disagree with him. In an email exchanged with Dr. Collins, you conspired, and I quote here directly from the email, "to create a quick and devastating published takedown of three prominent epidemiologist from Harvard, Oxford and Stanford."

Apparently, there is a lot of fringe epidemiologists at Harvard, Oxford, and Stanford. And you quote in the email that they, or from Dr. Collins and you agree, that they are fringe. And immediately there is this takedown effort. A published takedown, though doesn't exactly conjure up the image of a dispassionate scientist.

Instead of engaging them on the merits, you and Dr. Collins sought to smear them as fringe and take them down, and not in journals, in lay press. This is not only antithetical to the scientific method, it is the epitome of cheap politics, and it is reprehensible, Dr. Fauci. Do you really think it is appropriate to use your $420,000 salary to attack scientists that disagree with you?

Dr. FAUCI. The email you are referring to was an email of Dr. Collins to me. If you look at the email——

Senator PAUL. That you responded to and hurried up and said, I can do it, I can do it, we got something in wire——

Dr. FAUCI. No, no, I think in usual fashion, Senator, you are distorting everything about me.

Senator PAUL. Did you ever object to Dr. Collins's characterization of them as fringe? Did you write back to Dr. Collins, no, they are not fringe, they are esteemed scientists, and it would be beneath me to do that?

Dr. FAUCI. I did not——

Senator PAUL. You responded to him that you would do it, and you immediately got an article and sent it back to him, and said, hey, look, I got him, I nailed him in Wired of all scientific publications.

Dr. FAUCI. That is not what went on. There you go again. You just do the same thing every hearing.

Senator PAUL. That was your response—that was your response? And this wasn't the only time. So your desire to take down people——

Dr. FAUCI [continuing]. you are incorrect—as usual, Senator, you are incorrect with almost everything said——

Senator PAUL. Well, no, you deny, you deny, but the emails tell the truth of this.

Dr. FAUCI. No.

Senator PAUL. This wasn't the only time your desire to take down those who disagree with you didn't stop with Harvard, Oxford, and Stanford. You conspired with Peter Daszak, who you communicated with privately, and other members of the scientific community that wrote opinion pieces for Nature.

Five of them signed a paper for Nature, an opinion piece. 17 signed a paper that called it conspiracy theory, the idea that the virus could have originated in the lab. Do you think words like conspiracy theory should be in a scientific paper?

Dr. FAUCI. Senator, I never used that word when I was referring to it. You are distorting virtually everything——

Senator PAUL. Did you communicate with the five scientists who wrote the opinion piece in Nature, where they were describing, oh, there is no way this could come from the lab?

Dr. FAUCI. That was not me——

Senator PAUL. Did you talk with any of those scientists—?

Dr. FAUCI. See, but you keep distorting the truth. It is stunning how you do that——

Senator PAUL. Did you—talk to any of the scientists privately who wrote the opinion——

Dr. FAUCI. Yes.

Senator PAUL. You did. What were they telling you privately?

Dr. FAUCI. Well, let me explain. You know, you are going back to that original discussion when I brought together a group of people to look at every possibility with an open mind. So not only are you distorting it, you are completely turning it around as much as you usually do.

Senator PAUL. Well, most of the scientists who came to you privately, did they come to you privately and say no way this came from the lab or was their initial impression, Dr. Gary and others that were involved, was their initial impression actually that it looked very suspicious for a virus that came from lab.

Dr. FAUCI. You know, Senator, we are here at a Committee to look at a virus now that has killed almost 900,000 people. And the purpose of the Committee was to try and get things out, how we can help to get the American public. And you keep coming back to personal attacks on me that have absolutely no relevance to reality.

Senator PAUL. Do you think anybody has had more influence on our response to this than you have?

Dr. FAUCI. Madam Chair, can I——

Senator PAUL. Do you think it is a great success what has happened so far? Do you think the lockdowns were good for our kids? Do you think we slowed down the death rate?

More people have died now under President Biden than did under President Trump. You are the one responsible. You are the architect. You are the lead architect for the response from the Government, and now 800,000 people have died.

Dr. FAUCI. Right.

Senator PAUL. Do you think it is a winning success what you have advocated for Government?

Dr. FAUCI. Senator, first of all, if you look at everything that I said, you accuse me of in a monolithic way telling people what they need to do. Everything that I said has been in support of the CDC guidelines, wear a mask, get boosted, get vaccinated——

Senator PAUL. You have advocated to make it coercive and done through force——

Dr. FAUCI. Take everything that I have said——

Senator PAUL. You have advocated it be done by mandate. You have advocated that you are infallible opinion be dictated by law.

Dr. FAUCI. Right. So again, Madam Chair, I would like just a couple of minutes because this happens all the time. You personally attack me and with absolutely not a shred of evidence of anything you say. So I would like to make something clear to the Committee. He is doing this for political reasons. What you need to do is—he said in front of this Committee——

Senator PAUL. Do you think your takedown of three prominent epidemiologists was not political?

Dr. FAUCI. You don't want me to finish——

Senator PAUL. That was my question.

Dr. FAUCI [continuing]. because you know what I am going to say.

Senator PAUL. That was the question.

The CHAIR. Senator——

Senator PAUL [continuing]. were you political in taking down these three prominent epidemiologists?

The CHAIR. Senator Paul, if you would, please, I am going to allow this—Dr. Fauci to respond. We have a number of Senators who would like to ask questions, and I would like him to be able to respond. Please do so.

Dr. FAUCI. The last time we had a Committee or the time before, he was accusing me of being responsible for the death of 5, 4 to 5 million people, which is really irresponsible, and I say, why is he doing that? There are two reasons why that is really bad. The first is it distracts from what we are all trying to do here today, is get our arms around the epidemic and the pandemic that we are dealing with, not something imaginary.

No. 2, what happens when he gets out and accuses me of things that are completely untrue is that all of a sudden that kindles the crazies out there and I have life—threats upon my life, harassment of my family and my children with obscene phone calls because people are lying about me.

Now, I guess you could say, well, that is the way it goes. I can take the hit. Well, it makes a difference because as some of you may know, just about three or 4 weeks ago, on December 21st, a person was arrested who was on their way from Sacramento to Washington, DC. at a speed stop in Iowa, and they asked, the police to ask him where he was going and he was going to Washington, DC to kill Dr. Fauci, and they found in his car an AR–15 and multiple magazines of ammunition because he thinks that maybe I am killing people.

I ask myself, why would the Senator want to do this? So go to Rand Paul website and you see fire Dr. Fauci with a little box that says, contribute here you, can do $5, $10, $20, $100. So you are making a catastrophic epidemic for your political gain. So the only thing——

Senator PAUL. You have politically attacked your colleagues, and in a politically reprehensible way, you have attacked their reputations. You won't defend it. No, going to argue it. You will just simply turn around the attack.

The CHAIR. We are going to continue this hearing. We have a number of questions.

Dr. FAUCI. Just one more minute, if I——

The CHAIR. Dr. Fauci, I really appreciate your response, but we do have a number of questions from Senators, and we do have a second round and I am being asked to make sure that everybody has their time, so thank you.

Dr. FAUCI. Thank you very much for allowing me, Madam Chair.

The CHAIR. We will move to Senator Murphy.

Senator MURPHY. Thank you, Madam Chair. Dr. Fauci, thank you. Thank you, first of all, for what you do. You shouldn't have to put your life at risk. You shouldn't have put your family's life at risk to simply stand up and do your job to try to protect my constituents from a pandemic disease. And thank you for calling out this agenda for what it is, an attempt to score political points, to build a political power base around the denial of science and around personal attacks on you and your family.

On social media I follow many of President Trump's advisers and family members and they make us sport out of attacking you personally in some of the most vicious, hateful, ugly ways that are possible. They do it because it gets clicks. They don't do it because they are legitimately engaged in a honest debate about the science revolving—surrounding COVID. Those people attack you because it gains them political followers.

I appreciate the fact that you are willing to stand up for yourself and for your colleagues who have been dragged into the political muck, not because those that followed President Trump are interested in an honest, science based debate about how to attack COVID, but because they see political opportunity.

Thank you, Dr. Fauci, for your work, for the panel's work, and for sticking up for yourself, which is not always easy. Dr. Walensky, I want to take my time to just do a little bit of an update on best practices for schools. I know we talk about this a lot here, but you know part of what I think is frustrating for a lot of parents is that the guidance they are getting from the schools changes.

I get it, educators are sort of adjusting as the variant changes, as technology changes but what has changed since the last time, has there been any change since the last time you were here about what you were recommending for schools to stay open? And I appreciate what you said in the last hearing is that schools should be the first places to open and the last places to close.

Man, as the parent of two public school kids, I couldn't agree more. The trauma on these kids during this pandemic has been significant, and the data tells us that especially for poor kids and kids of color, distance learning just doesn't work.

I am grateful that I have got a Governor who has gone to extraordinary lengths to make sure that the Federal dollars are used to keep schools open. But anything new that you can share with us about what you are recommending for schools to stay open for the rest of the year?

Dr. WALENSKY. Thank you, Senator Murphy. And in fact, that you took the words right out of my mouth. Schools should be the first places to open and the last places to close. We had a Delta surge in the fall, and 99 percent of our schools were safely open. And one of the things that is majorly different between September 2021 and today is we have pediatric vaccinations.

We have vaccines that are available for every child over the age of five. And the children who are in the hospital now are largely those who are unvaccinated. So first and foremost, one of the most important things that has changed is we should be getting our children and our teenagers vaccinated. And if our teenagers are eligible, we have boosters available for our teenagers as well.

We saw through the Delta surge that we were able to keep our children safely in school before we had vaccines. So now today, what do we have for our children? We have vaccines, of course, that we can use. We have school testing programs.

We have new science that demonstrates tests to say. This is where a child might be exposed in the classroom, but if they are exposed, they don't have to stay home in quarantine. They can test every other day or twice a week and stay in the classroom safely. And what that has demonstrated is hundreds of thousands of person days of children in school rather than at home.

We have new science that has demonstrated the value of masking, 3.5 times increased risk of school outbreaks if you are masking—if you are unmasked in schools versus if you are masking in schools. And just this week we updated our K–12 guidance so that it is consistent with our isolation and quarantine guidance for the general public so that people can come back to school after isolation after 5 days.

Senator MURPHY. Thank you, Dr. Walensky, for that and for your commitment to keeping our schools open. Final quick question for you, Ms. O'Connell. Talking about in-home tests, obviously, a lot of focus on in-home tests today, but these are antigen tests. There are some interesting research going on about the ability to make PCR tests available at home.

There are companies all over the country, including one in Connecticut, that believe that with some additional investment to bring those tests to scale, we could get PCR tests into families hands at home for a cost that is at or below what we are currently charging, or companies are currently charging for antigen tests. Is that a possibility?

Ms. O'CONNELL. Senator Murphy, thank you. We share your interest, of course, in seeing as many tests available for the American

people as quickly as possible. And at BARDA, have worked very closely with several of the manufacturers that you mentioned for these at home PCR tests.

We have contracted with one of them and have reached 5 million per month manufacturing capacity in contract with them and continue to look at the others in ways that we can support them.

I would also like to say NIH colleagues in a program called RADx, the rapid acceleration of diagnostics, are working very closely with many of these companies as well as they go through the development stages. So we remain very committed to the work that these companies are doing and look forward to partnering with them as they begin to bring these products forward.

The CHAIR. Thank you.

Senator Collins.

Senator COLLINS. Thank you. Ms. O'Connell, over the past 2 years, Congress has appropriated $82.6 billion specifically for testing. In addition, we have given the Department flexibility to use other sources of funding.

Yet, as you have heard repeatedly today, our frustrated constituents cannot find rapid tests when they need them. This testing crisis appears to have been entirely preventable, as is evidenced by the availability, the widespread availability of rapid tests in Europe, for example. The fact is that it appears the Administration simply failed to anticipate our testing needs.

As the former Assistant Secretary of Health recently pointed out, a lack of Federal orders for tests between January and September 2021 caused the manufacturers to reduce their lines and lay workers, including at Abbott facilities in the State of Maine where 400 workers were laid off.

As a Member of the Appropriations Committee, I share the concerns that have been expressed by Senators Burr and Blunt. I don't believe that we are in the position that we are in now due to a lack of funding, but rather a lack of planning. My question to you is, has any of this funding, as close to $83 billion that was supposed to be used for testing, been diverted for other purposes?

Ms. O'CONNELL. Senator Collins, thank you for this question. Testing remains a priority for this Administration. And all the work we have done on testing has been to promote the priorities of expanding the number of testing sites available, expanding the type of tests that are available for use in the United States, expanding the supply of tests in the United States, and lowering the cost of tests.

We used the $47 billion that came in the American Rescue Plan. $10 billion of that went to schools through the States to set up the school testing programs. $8.3 billion has gone to community testing sites, including for the uninsured and at the community health centers and the pharmacy program Dr. Walensky mentioned.

$5 billion has gone to procure tests and supplies, and an additional $4.5 billion will go toward this 500 million that we are in the process of procuring. $29 billion has gone directly to States from previous supplementals for them to build and promote testing programs within their jurisdictions. The testing money, as you re-

call, was for testing, contact tracing, and mitigation efforts, and some of that, the funds have been used for mitigation efforts.

For example, when children are crossing the border one of the responsibilities that we have within HHS is to make sure that anyone who has—that the children that are unaccompanied are cared for, and we used some of the funds to test those children and then to separate them from COVID negative children at the border.

Senator COLLINS. Was—I am going to repeat my question because you did not answer it. Has any of that money been used for non-testing related purposes at the border?

Ms. O'CONNELL. For the mitigation purposes as well, which the legislation allowed the funding to be used for.

Senator COLLINS. I will follow-up with you because I don't feel like I am getting an answer. Dr. Fauci, just last week, the President once again said that COVID–19 is a pandemic of the unvaccinated. And let me make very clear that I have been encouraged vaccinations. I believe in them.

But contracting—contradicting the President's statement, in Maine our largest health system reported that absences of vaccinated staff caused by COVID–19 last week was at the highest point since vaccines became available. It has increased by four fold.

Does the message that COVID is a pandemic of the unvaccinated still hold true with the emergence of Omicron? And do you agree with the New York Times, which has twice reported that while the COVID vaccine is critical in preventing hospitalizations and death, it is less effective against the Omicron variant?

Dr. FAUCI. Thank you for that question, Senator. Yes, indeed there is no doubt that the Omicron variant, when you look at the protection against symptomatic disease and asymptomatic infection, it dramatically goes down to about 30 percent.

What maintains itself, it goes up to about 70—it is about 70 percent against severe disease. When you boost, when you boost, what happens is you get a rather significant reconstitution of the protection, particularly against hospitalization. So if you were to say that Omicron or even COVID–19 as it is, is really a pandemic, when you are talking about a pandemic that causes serious disease, there is no doubt that there is an extraordinary divergence of risk between vaccinated and unvaccinated person.

In response to the question just a bit ago when I said that, if you look at vaccinated versus unvaccinated, there is a 17 times greater chance of being hospitalized and a 20 times greater chance of dying if you are unvaccinated versus vaccinated.

The CHAIR. Thank you.

Senator Hassan.

Senator HASSAN. Thank you, Madam Chair and Ranking Member Burr, and thank you to all of our witnesses for being here today and for your ongoing work. I deeply appreciate it. Dr. Fauci, I want to start with a couple of questions for you.

We need to make sure that individuals who become seriously ill with COVID–19 can receive treatment, and that doctors have clear

guidelines on the effectiveness of each treatment for the latest variant.

You touched on this in your opening statement, but I would like you to just expand a little bit on this. In light of Omicron, how is the Administration evaluating new COVID–19 treatments and monitoring the effectiveness of existing treatments?

Dr. FAUCI. Thank you for that question, Senator. There are a number of studies that have been conducted and that are being conducted right now, and they have to do with studies that NIH sponsored, one of which is the adaptive COVID–19 treatment trials, or ACTT, which in fact have been from the very beginning as early as February 2020, was the basis for the FDA approval of the antiviral remdesivir.

Other of those studies, particularly those on monoclonal antibodies, showed several of them in the clinical trials to be effective at first against Delta. We know now that a couple of them, except for one, has now lost some of its effectiveness.

There is another group of studies called Activ and there are six of those, and that stands for accelerating COVID–19 therapeutic interventions and vaccines, and the whole gamut of oral, IV monoclonal antibodies, direct antivirals. And as I mentioned in my opening statement, antivirals like Paxlovid and Molnupiravir, the original research had been done in the early trials by the NIH.

But importantly in direct answer to how we know what to use, the NIH has put together a guidelines panel made up of 48 highly qualified clinicians and individuals with experience in COVID–19 to give a prioritization of what you do if you are infected and with advanced disease in the hospital, as well as what you do as an outpatient, and they have fairly clearly delineated in the guidelines, which is easily accessible by just going to the NIH website and going to nih.gov and then guidelines panel, and people can get a good idea, clinicians throughout the country and the world, of how to use these antivirals. Thank you.

Senator HASSAN. Thank you. I want to follow-up, I am grateful that the Administration heeded my call to send FEMA teams to New Hampshire to help administer COVID–19 treatments.

However, the teams were delayed in arriving and are scheduled to stay only for a short period of time. So, Dr. Fauci, what additional personnel and support is the Administration planning to provide to New Hampshire and other States to help treat COVID–19 patients in the most effective way possible?

Dr. FAUCI. Well, there are several things, perhaps Assistant Secretary O'Connell can answer, but I can start off by saying that there are surge teams right now, at least 60 surge teams that have been deployed to help those areas that have difficulty because of the surge and the fewer volume of cases to be able to handle them with regard to everything from hospitalizations to treatment and other implementations.

Senator HASSAN. I appreciate that Assistant Secretary O'Connell is in a good position to follow-up, and I would like to follow-up after the hearing, but I did want to ask one other question to Dr. Walensky.

We have long had problems with accurate State vaccination data in New Hampshire. It has come to light that the CDC's data on New Hampshire's vaccination rates is also inaccurate. Apparently, the CDC can't consistently distinguish in its data between first doses of the vaccine and boosters, and as a result, the agency incorrectly records boosters as first doses, artificially raising the vaccination rate.

The CDC's data is inaccurate for other States as well. We have been looking at this for other States too. So what steps is the CDC taking to resolve these data inaccuracies, and when will the CDC have accurate data for New Hampshire?

Dr. WALENSKY. Thank you, Senator. This is a really important question. So CDC is the compiler of the data, and we rely on the State immunization services to provide CDC the data at the State level. Now, among the challenges with these accuracy is that if people don't bring in their card, they are counted as a first dose when in fact their card would have been a third dose.

We rely on the States to work to reconcile any differences if a person put in a middle initial on one card, but not on another. And we are working closely with every single State to increase their accuracy.

We are encouraging people to bring their cards because that also increases the accuracy. We recognize this challenge, and we are working State by State, including in New Hampshire, to reconcile these inaccuracies to get them more accurate in our comprehensive reporting of every State.

Senator HASSAN. Well, I appreciate that very much. Thank you, Madam Chair. I will just say that what I am hearing you say to the general public is it is really important to help with the accuracy of data by keeping your car, taking a photo of your card, making sure that you are sharing all your information at the site where you are getting a vaccine or booster shot.

Dr. WALENSKY. Very helpful. Yes. Thank you very much.

Senator HASSAN. Thank you.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. President Biden inherited a vaccine, a distribution plan, trillions of dollars in funding, but unfortunately, this Administration has chosen to put all its eggs in one basket, prioritized unconstitutional vaccine mandates and testing.

Yet comparing 2021 to 2022, COVID infections have increased 72 percent and deaths increased 27 percent. This we know, if you look at this data, your current plan is not working. The current plan is not working, we need therapeutics at warp speed. Ms. O'Connell, who is responsible for this failure?

Ms. O'CONNELL. Senator Marshall, thank you for that question. We are making six therapies available to the American people free of charge.

Senator MARSHALL. Who is responsible for the failure?

Ms. O'CONNELL. Senator Marshall, we continue to make therapies available at warp speed to the American people.

Senator MARSHALL. The Biden administration has allocated over $80 billion for testing and only $15 billion on therapeutics. It is obvious that your plan has failed. We can't keep throwing good money after bad money. This is insanity. We have to admit our mistakes and go a different direction. Ms. O'Connell, would you commit to an Operation Warp Speed for therapeutics?

Ms. O'CONNELL. Senator Marshall, thank you. Therapeutics are part of Operation Warp Speed. And that is how we have the six therapies that we are currently making available to States free of charge.

Senator MARSHALL. They will be available after Delta has already been come and gone and also after, of course, Omicron will be said and done as well. Dr. Fauci, 59 percent of Americans and 81 percent of Republicans do not have a favorable opinion of you. Frankly, honestly, you have lost your reputation.

The American people don't trust the words coming out of your mouth. Every day you appear on TV, you do more damage than good when it comes to educating the public on COVID. Suppose you were leading a team in an effort to try to get people to stop smoking cigarettes, but every time your spokesperson goes on television, over half the Nation goes out and buys a pack of Marlboros, wouldn't you stop that person from appearing on national television?

Dr. FAUCI. Once again, Senator Marshall, I believe that is a real distortion of the reality. If you look at everything that I have said on TV, it is to validate, encourage, and get people to abide by the recommendations of the Centers for Disease Control and Prevention. Look at everything I have ever said——

Senator MARSHALL. Dr. Fauci—but perception is reality. And you are hurting the team right now. You are hurting the team right now. Dr. Fauci, you previously told this Committee under oath that NIH and NIAID have never funded gain of function research with the EcoHealth Alliance. However, a report from the Department of Defense Inspector General released yesterday States that EcoHealth Alliance opposed DARPA in 2018, seeking funding to conduct gain of function research on bat-borne coronaviruses.

This proposal, named Project DEFUSE, was rejected by DARPA because the project didn't address the current researcher's potential to violate the gain of function moratorium. "The proposal does not mention or assess potential risk of gain of function research." That is a direct quote from the DARPA rejection letter.

The same proposal rejected by DARPA for gain of function potential was not rejected by NIAID under your leadership. You funded Project DEFUSE and its research that took place at the Wuhan Institute of Virology. Why did you tell the Committee that your agency has never funded gain of function research?

Why did your agency award this grant, despite it being rejected by DARPA due to its concerns about violating the moratorium that was in place? And finally, will you commit today to release all records fully unredacted by the end of this week so Congress and the American people can know the truth about NIH's role in the origins of COVID–19?

Senator MARSHALL. So again, Senator, it really pains me to have to just point out to the American public how absolutely incorrect you are. What came out last night on Project Veritas was a grant that was submitted to DARPA. Then it distorted and said we funded the grant.

We have never seen that grant and we have never funded that grant. So once again, you are completely and unequivocally incorrect, when you joined the DARPA proposal was a grant that we never saw, and we did not fund. So you are incorrect.

Senator MARSHALL. Our social media will have all the supporting documents and we will be entering into the record as well.

Dr. FAUCI. Senator, you are backing down on this. Why don't we go and look at the very tossed statement? They were talking about a grant that was submitted to DARPA——

Senator MARSHALL. Are you saying this is not—are you saying that this was viral gain of function research?

Dr. FAUCI. I am telling you that you are saying——

Senator MARSHALL. Are you saying that this was not viral gain of function research?

Dr. FAUCI. By the definition that you were very well aware——

Senator MARSHALL. The—definition is just legalese to get away and allow you to do the viral gain of function.

Dr. FAUCI. This is what I am talking about, Senator——

The CHAIR. Senator Marshall, please allow the witness to respond.

Dr. FAUCI. Senator, we know and misinformation that the guide rails for what can be done or not were not established by me, they were established by a 3-year process led by the Office of Science and Technology Policy of the White House——

Senator MARSHALL. And decided by you in a secret meeting at the White House in December 2019.

Dr. FAUCI. Senator, that is incorrect, and this refers exactly to what I was talking about in response to Senator Rand Paul. You are incorrect completely, and every time I try to explain——

Senator MARSHALL. You are saying you are incorrect, but the facts are on my side. So why—would you not commit to sharing everything, open, unredacted with this Congress?

The CHAIR. Senator Marshall——

Dr. FAUCI. So here is an example——

The CHAIR. Dr. Fauci—this hearing is critically important to the American people. There are millions of people infected with the COVID virus. It is impacting every part of our economy. Every family is asking for answers to critical questions.

Both sides of the aisle have asked tough questions, but we are not going to allow this Committee hearing to be another personal attack that undermines our ability to deal with this terrible virus that is impacting so many people. I will then turn to Senator Smith. Thank you.

Dr. FAUCI. Thank you, Senator.

Senator SMITH. Thank you. Thank you, Chair Murray, and well, I will just let that go. So as we move into the third year of the COVID–19 response, it seems to me that our strategy is shifting. We are shifting from a goal of trying to get to zero COVID cases to eradicating the virus. And our goal is really much more about minimizing the damage of this pandemic. You and I have talked about this, Dr. Fauci, as well as with Dr. Walensky. So we need, of course, to minimize hospitalizations and deaths caused by COVID.

We do that through vaccines and through therapies. And we also need to minimize the COVID damage by understanding how to keep kids in school, how to keep businesses open, and how to protect against the damage that is caused by social isolation and burnout and other stresses that injures our mental health.

It seems to me that while—this is happening while COVID continues to seriously stress our health care system, and while we still have people in this country, including sadly, some Members of Congress who continue to spread misinformation and lies about the pandemic. So it seems like we have to be realistic that these cycles of the pandemic, until it becomes endemic, are going to continue. We are going to probably continue to see some unpredictable variants arise.

Madam Chair, I just want to say that I hope that this Committee can find some time to discuss these issues as they relate to global vaccine strategy, because this is going to be crucial to our work to protect Americans' health as we go forward since we are not an island.

But let me ask, I am very interested in how we think about like the data that is important for Americans to keep in their minds as they are trying to measure relative risk. Last week, public health experts published some interesting articles that suggested that we should maybe think about incorporating COVID–19 data into aggregate risk for all respiratory viruses that are circulating, including the flu and RSV, and that maybe this data, if we could look at it in real time from medical facilities and ERs and so forth, testing facilities and private homes even, and would give us a better picture of what is happening.

Let me ask Dr. Walensky and Dr. Fauci, if you could talk a little bit, I want to understand about this—I want to understand how you think about this question of relative risk, how we should be transitioning in what we consider from daily case counts, for example, to looking at other data and particularly how you evaluate this idea of looking at all respiratory illnesses in one basket.

Dr. WALENSKY. Yes, Senator Smith, this is such a critically important question. Thank you for raising this. So we have to do two things simultaneously. Right now, we are dealing with an Omicron surge where we have the most number of cases we have ever had in a day in this country.

We have to get out of this Omicron surge. But in the meantime, we have to look down the field and we have to understand what is this going to look like when we are not in a surge? How do we deal with endemic disease? And what don't we start looking at with regard to endemic disease?

You are absolutely right. We need to think about the severity of that disease because now with 62 percent of Americans vaccinated, some of that disease is not as severe as it was. That is the success of our vaccines. We have to look critically at hospital capacity. What can our hospitals handle, because if people are coming in with COVID or have hospital staff are out with COVID that is a really important measure that we are going to look at. And one of the things we probably still are going to examine, although perhaps with less import, is the actual number of the cases.

Why that is important in general is because it generally foreshadows what is coming into the hospital. So knowing that and understanding what that might mean for the future of hospitalizations, future of severity, future of capacity, and all of those are things that we are looking at right now. But one of the things that you critically mentioned was our efforts in data modernization.

How do we take the efforts that we have had so far with COVID and increase them, continue to keep the pedal to the metal as it were? When we started here, we were not collecting racial and ethnicity data. We didn't have a way to link in a personal—with personal identifiers removed, electronic health records with our testing records. We had 187 hospital systems who could do that.

Now we have 10,000. So what we really need to do is scale up our data modernization efforts and do it, as you say, not just for COVID, but—and not just for other respiratory diseases like flu, RSV, as you note, but for all diseases.

We are looking at doing this for maternal mortality, for sickle cell disease, for opioid injury, for many, many diseases and this is going to be the power of our data modernization efforts and I am really grateful for resources from Congress to be able to leverage those. Thank you.

Senator SMITH. Thank you. Madam Chair, I believe I am out of time, but I will have other questions if we have a second round.

The CHAIR. We will have a second round.

Senator Tuberville.

Senator TUBERVILLE. Thank you, Madam Chair. Thank you for being here today. You know, this Administration has been in charge of the Federal COVID response for a year. I have to say I don't think it has been a job well done. Our Federal Government not only sets the tone and the guidance for how millions of Americans should be handling COVID, we set the standard for the world.

Our information has to be correct. I continue to hear that we need to follow the science and I agree. But we have to yet hear the clarity from this Administration. We are conflicting guidance across the board. In order to be effective, guidance has to be understood and implemented by the average American, but most Americans can't make heads or tails of anything coming out of this Administration.

We are all, all of us, are failing this test. One thing I do know is that when we finally toward the end of this thing, Congress is going to have an investigation. We all know that. We have heard that the FDA and President Biden say 55 years will be needed to share data related to a lot of those decisions. But we will have to

investigate. This group will have to investigate and have the information before 2076.

Heck, most of us won't be here in 2076. This investigation will look into what—who had authority to make decisions. I know there are more people making decisions behind the scenes. So what I would like to know is I am just concerned how badly the response has been. It is handled—President Biden has handled this in his first year. We have heard all the pluses and minuses.

This Administration took office with three successful vaccines and numerous effective therapeutics and basically drove the response into a ditch. At times, it doesn't seem like anyone is in charge. You started the year by dismantling Operation Warp Speed, canceling contracts of monoclonal antibodies, underinvesting in testing, and we spent billions in that, first with Delta now on Omicron, people can't find a test.

I am getting text as we speak sitting here, where do I get a test. We spent billions on this. You know, if we can't find a test and test positive, they can't get treatment. Monoclonal antibodies are rationed. Antiviral pills are months away.

I just got a simple question, of all of you up there and whoever wants to answer this, if you have a problem in your coordinates, who do you go to? Who is the head coach of this virus that you have to go to, whether it is an Administration, whether it is one of you? Dr. Fauci, who do we go to?

Dr. FAUCI. The person who is in charge of that is Jeff Zients——

Senator TUBERVILLE. At the White House?

Dr. FAUCI. At the White House. And we meet very, very regularly, the entire medical team as well as others going over all of the data, going over what the strategies are, going over what the issues are, what the problems are, what we have done right, what we have done wrong. We examine literally continually, sir,.

Senator TUBERVILLE. Has he done a good job?

Dr. FAUCI. You know, I think given the circumstances that we are in right now, I believe he has done a very good job. I really do this. This is an extraordinary virus, the likes of which we have not seen even close to in well over 100 years. It is a very wily virus. It is fooled everybody all the time from the time it first came into Delta to now Omicron. Very unpredictable and we are doing the best we possibly can.

Senator TUBERVILLE. Yes. Dr. Walensky, it has been reported by some virologists and scientists that this year around 170 people have died from taking the regular flu vaccine. The Vaccine Advisory Adverse Reporting System reported that the number of people dying after or following the COVID vaccine is actually in the thousands.

Now this is what I am hearing. I will give you a chance to refute that or confirm it here. You know, is this true? Are we having that many people die after taking one of these vaccines?

Dr. WALENSKY. Senator Tuberville, thank you for that question. The Vaccine Adverse Event Reporting System is a mandatory system of any adverse event that happens after being vaccinated.

If you get hit by a car tragically after getting vaccinated, that gets reported in the vaccine adverse reporting system, VAERS system. So the vaccines are incredibly safe. They protect us against Omicron, they protect us against Delta, they protect us against COVID. They don't protect us against every other form of mortality out there.

Senator TUBERVILLE. Do we keep numbers of people that died following taking a COVID test—from taking this vaccine? Do we have any idea? I am just asking.

Dr. WALENSKY. I am sorry, those who have died after taking a COVID test?

Senator TUBERVILLE. Following taking the vaccine. Is there any number or count? Do we keep records on that from——

Dr. WALENSKY. Absolutely, yes. I couldn't give you the absolutely number off the top of my head, but our staff could absolutely get back in touch with you. We collect this data.

Senator TUBERVILLE. Do you know, Dr. Fauci? Do you have any clue on that?

Dr. FAUCI. About how many died——

Senator TUBERVILLE. 100?

Dr. FAUCI. I don't know the number, but I think it is really important for——

Senator TUBERVILLE. Microphone, microphone.

Dr. FAUCI. I am sorry, I don't have a number, but I think part of the confusion is that when you do a reporting, if you get vaccinated and you walk out and get hit by a car, that is considered a death—I mean, that is the thing that gets confusing, that everything that happens after the vaccination, even if you die of something completely obviously unrelated, it is considered a death. So if I had metastatic cancer, got vaccinated and died 2 weeks later that is a death that gets counted.

Senator TUBERVILLE. I understand that.

Dr. WALENSKY. And every one of those is adjudicated.

Senator TUBERVILLE. Yes. And one quick question before we get through here, I am in rural Alabama, but I get one of these home tests. I test positive. I have—asymptomatic. What do I do? People call—what do I do? I don't have a doctor. What do I do?

Dr. WALENSKY. Thank you. So you are asymptomatic? You are asymptomatic, no symptoms, feel well?

Senator TUBERVILLE. Yes.

Dr. WALENSKY. You stay home for 5 days and the next 5 days, if you continue to be asymptomatic, you can go out, wear a mask. Don't go traveling. Don't go to gyms——

Senator TUBERVILLE. If I get real sick, then what do I do?

Dr. WALENSKY. Then—well, first you go and call your physician. And in fact, I tell you, call your physician regardless, but call your physician, call your provider. If you are continuing to have symptoms, then you stay home until your symptoms are resolved.

Senator TUBERVILLE. No therapeutics?

Dr. WALENSKY. Well, that is where I would say call your physician and see if you are eligible for therapeutics.

Senator TUBERVILLE. A lot of these people don't have physicians. They have got a drug store.

The CHAIR. Senator, we do need to move on.

Senator TUBERVILLE. Thank you.

The CHAIR. Thank you.

Senator Rosen.

Senator ROSEN. Thank you, Madam Chair. Thank you, Ranking Member Burr. This hearing is so very important. I really want to thank all of the witnesses here for testifying today, for your continued work. Thank you so much as we combat this pandemic in real time, in real time.

First, I just want to want to echo the concerns my colleagues have raised about access to testing, both in-person PCR tests and the at home rapid test. We do know that home test kits are scarce. Americans are standing in extremely long lines to get a COVID test, and hospital emergency Departments in my home State of Nevada have seen a significant increase in people coming solely for tests because there just aren't enough alternatives.

This is just really only adding to the stress, as again, I can say speak to Nevada on our health systems. Nevada has been expanding our testing options but increased Federal support on the ground in addition to home testing, we feel is absolutely critical. And in the future, the Federal response must be more proactive in this space.

I am a little bit concerned about the testing keeping up with the variants because we are—this is all happening in real time. COVID is evolving. You don't know which strain may become the dominant strain. And so we want to ensure just in addition to the effectiveness of the vaccines and therapeutics that the testing accuracy must also keep up.

Dr. Fauci, with some recent reports about the current variant settling more in the throat than in the nose for some patients, what are we doing with the development and deployment of rapid at home tests based on saliva versus a nasal swab?

Then, Dr. Woodcock, how rapidly do you think of the over-the-counter testing can be delivered, approved—looked at approved, delivered to the American public to make sure that they are less anxious?

Dr. FAUCI. Thank you for that question, Senator. Yes, there have been recent reports that in fact the sensitivity and the ability to detect in a swab of the throat versus the nose of pharynx, at least with omicron, that is the preliminary report.

I think it needs to be validated and verified. If the data were strong enough, then we—the company, whatever, who makes that will likely go to the FDA to ask to change the indication because the emergency use authorization is for a nasal swab.

If the data, the scientific data indicate that is better to get an oral or other swab, they would present that to the FDA. So I would leave that to Dr. Woodcock to answer the rest of that question.

Senator ROSEN. Thank you.

Dr. WOODCOCK. Certainly. Well, we can act very rapidly. But first, I would like to say people should not use swabs that are designed as nasal swabs and try to swab their throat. They may stab themselves, Okay. That would not be good.

What we need to do is have tests that see whether the throat swab, as Dr. Fauci said, could provide more sensitivity. We do know the tests are picking up omicron, but right now with less sensitivity than they did some of the other variants.

As far as time, as I said, after the ITAP program does the testing at NIH, FDA has been able to approve—authorize within a day or two of getting those data. However, the companies would have to change the test configuration to accommodate the swab, the larger swab that you would use in the throat, and that is probably what would take the most time, as well as seeing whether that was better.

Senator ROSEN. To continue with that point, as we have seen with some of the testing, the reagents or the materials that it really takes to use the test, is there the ability for people to return a test that may no longer work?

Can those agents, any of that be recycled or upcycled if they are returned to the company unopened? Like, how can—how do we not dispose them and not get some recyclability out of that? Is that possible in some way?

Dr. WOODCOCK. We can get back to you on those parameters. Would be happy to do that.

Senator ROSEN. Thank you, I appreciate that. I would like to talk a little bit again, people are talking about the public health data. You know, we are noting about all the daily statistics, noting about some of the statistics about possibly deaths, and so positive or negative, critical—this data is critical even for us to make our decisions as far as what we fund.

Sometimes there is no choice to say that we shouldn't include home testing in the daily statistics because they might not be reliable. So Dr. Walensky, to build on some of that testing and the statistics that you need to do your job, that all of us need to do our job, how is the CDC working with the State, local health, our hospitals to be sure that the voluntary self-reporting guidance, it is going to be accurate and give us the kind of statistics we need going forward?

Dr. WALENSKY. Yes, thank you for that question, Senator. So we are routinely reporting PCR tests. That is what is routinely reported from the State and that is what our updated statistics are. There are—there is passive reporting that occurs with rapid tests, but I also want to—understand, the importance of rapid tests, at home tests for people to be empowered to use these rapid tests to do the right thing.

Regardless of whether we can count them, generally they tend to be people who have milder symptoms. They might have been vaccinated, have a runny nose, and they decide to go and get a rapid test and do the test at home. Less important is counting that case

than it is that person stay home, isolate, do the right thing, and not be forward transmitting.

I think that many of these tests have different purposes. But one of the really important purposes of these rapid tests, even if we don't count them, is to empower the public to do the right thing through this pandemic.

The CHAIR. Thank you.

Senator ROSEN. Thank you very much.

The CHAIR. Senator Romney.

Senator ROMNEY. Thank you. Thank you, Madam Chairman. Just a couple of thoughts. One, it has been 2 hours since we have been here. As one of the people at the low level here—out in the hinterlands. Just a couple of thoughts. One, I think it would be helpful if, and please excuse me for this comment, if the Chair and Ranking Member limited their opening comments to the 5-minutes, just like you expect those folks to limit their comments to 5 minutes.

We didn't get started till 25 minutes after asking these folks their questions. I do want to note also that in this process, as I am sure you who are testifying here today recognize, that some of what we do is performing, and so what we do is to become informed. And I do both from time to time, so I am not just in one camp or the other in that regard, but I do want to point out how much I personally and I believe the great majority of the people in our country respect you individually and professionally for the work that you do. You are scientists, not politicians.

Nevertheless, you are being made subject to the political whims of various political individuals and that comes at a high cost, which unfortunately I fear will lead some to not want to participate in helping our Government make scientific choices. But I very deeply appreciate your commitment to the American people and your desire to do things as well as we possibly know how to do. That doesn't mean they will be done perfectly. That doesn't mean you won't make mistakes. Doesn't mean there won't be changes from time to time.

Sometimes as data comes in that is different than what you had anticipated, and sometimes just because you were wrong. I mean, it is the nature of being a human being. That is where we are. I think unfortunately, the Administration was wrong in not building testing capacity at a time when we all thought COVID was kind of going away.

I remember the summer and the fall, going into a grocery store—excuse me, into a drugstore and seeing two rapid tests on the shelf, and those things stayed there for days. No one was interested in buying a rapid test. And apparently the Administration didn't think that it should be aggressively building rapid tests.

Omicron came along, cut people by surprise, and we were obviously badly mistaken, the Administration was, and we are suffering in part because of that. Let me ask with regards to Paxlovid. Ms. O'Connell, is that being subject to Warp Speed?

My understanding is that Paxlovid is far superior to other oral antivirals. Should we not be much more aggressively producing that and getting that out so that it can be prescribed?

Dr. WALENSKY. Thank you, Senator Romney. We are in active conversations with Pfizer about how to increase their time limits. It is my understanding, and the scientists on the panel can feel free to jump in, is that the process required in order to generate this particular antiviral is months-long. It is a chemical process.

It is one that is very, very hard to accelerate. What we have been able to do is to find additional doses to work with Pfizer to try to unlock additional capacity, where they can find it. And we are continuing to do that actively.

Senator ROMNEY. Thank you. Dr. Walensky, good to see you again. I appreciate the chance we had to speak earlier this week or last week rather. As I have looked on the CDC's COVID tracker report, I note the data goes through November 20th and I remember my days in business, if we didn't have daily information, we couldn't make good decisions.

I wonder, do we need to invest in either developing a new subagency or a task force to get basically immediate data, daily data so we know what is going on. And that is not just for the public that is for those of you who are making those decisions. Do we need do a much better job moving faster getting data?

Dr. WALENSKY. Senator, first of all, let me thank you for your earlier comments. But also to comment on our COVID data tracker, I think you are speaking to the seven—I am sorry, the 27 jurisdictions that we now compile data, that allows those jurisdictions to report together their testing data, their cases data, their immunizations data, their age data, as well as their death data.

It is over two-thirds of the country that we do, and we update that about once a month, and it is about three or 4 weeks in a year. So mid-January, we will be having data through the end of December, and it simply does take that long for our jurisdictions to compile those data.

Of course, our death data are generally lagging. It takes a while for those to get reported and adjudicated. So we are now updating those are about 6 weeks in a year and that is in—we are working hard to keep those in real time.

Senator ROMNEY. Yes, I know retailers like Zara, for instance, they apparently get data and correlate it daily. So I would hope we could find a way to increase the speed with which we get that data. I know my time is up. If I could just going to make a comment, and that is that I think it would be helpful if people knew when they should get tested, when it is called for, because I think a lot of individuals, myself included, get tested when there is no indication that I need to get tested, other than just want to make sure I am not sick.

There is huge demand for tests which are in short supply, in part because of that. And No. 2, when you say when people have been exposed, please let us know what it means to be exposed. We are in a room right now. I am sure someone here has Omicron.

Are we all exposed and therefore need to get tested? What does it mean to be exposed and when do we need to get tested? And I know—I wanted to ask that of Dr. Fauci. I can't do that given my time. Those are topics I would love to have elaborate on that. Thank you.

The CHAIR. Senator Romney, I think that is a question we all want answered, and I will give Dr. Fauci the opportunity to respond to that.

Senator ROMNEY. Dr. Fauci.

Dr. FAUCI. Well, the CDC guidelines make that very clear, and it is if you are exposed to an individual with known—if you are in a period of 15 minutes at a time or a total of 15 minutes over a 24 hour period, in a situation where you come into close contact, perhaps Dr. Walensky could expand on that, but that is the fundamental core of the CDC guidelines.

Dr. WALENSKY. That is exactly right in terms of the definition of exposure. In terms of who should get tested, you should get tested if you have symptoms of COVID–19. If you do a rapid at home test and you continue to have symptoms and that test is negative, you should do another test or get a PCR.

You should get tested within 5 days of your exposure or after 5 days of your exposure with the definition that Dr. Fauci mentioned. And we are testing through tests to stay and other mechanisms as well.

Many reasons to test, but really, most importantly, if you are exposed, if you have symptoms, and also if you are going into a setting where you might be seeing an immunocompromised person, somebody who is vulnerable, not able to be—to take a vaccine.

The CHAIR. Thank you very much.

Senator Casey.

Senator CASEY. Chair Murray, thank you very much for this hearing. And I want to start by commending the public service of all of the members of the panel, Dr. Walensky, Dr. Fauci, Dr. Woodcock, and Assistant Secretary O'Connell. This is difficult work, and we appreciate your public service.

In particular, I want to reiterate statements I think I had to make before in light of Dr. Fauci's commendable public service, not just in the middle of this pandemic, throughout the pandemic, but also for decades. I think I speak for a lot of people back home and across the country that not only have confidence in your integrity, but also your work in public health, and so we are grateful for that. Let me start with a question for Dr. Walensky.

Doctor, I am quoting from a statement you made on Friday on television in the context of a question about COVID–19 deaths. And I will quote two sentences. One is, "the overwhelming number of deaths, over 75 percent occurred in people who had at least four co-morbidities. So really, these are people who were unwell to begin with and, yes, really encouraging the news in the context of Omicron."

Now, this statement, and I know it was part of a broader interview, caused great concern. I know from my work as a Senator for years that you and your team at CDC, whether it is your, the pol-

icy or the work that you do, that policy and that work are both focused on ensuring that all Americans receive the best possible treatment and protection.

This is especially important for older adults and people with disabilities who may need additional supports and protections. So context is important in an interview like this. So please explain what point you were making, that is No. 1, the point you were making. And second, outline CDC's commitment to protecting older adults and people with disabilities as we continue to address the pandemic.

Dr. WALENSKY. Senator Casey, I am really grateful for the opportunity to explain this. And to step back, that interview on Friday, I recently spoke to a study on the high level of protection against vaccines. It was a pre-taped interview and much of it was cut and that phrase was taken out of context, as you note.

The study was a cohort of 1.2 million people who were vaccinated and 36 people passed, demonstrating their remarkable effectiveness of our vaccines. But no less tragic is the 36 people who passed because of COVID–19, and that many of them had comorbidities, comorbidities that I have spent my career taking care of, comorbidities that just prior to coming to the CDC, we saw time and time again disproportionately impacting people with COVID–19 and the hospitals that I cared for patients.

What are we doing at CDC given the critical importance? Well, we have toolkits for COVID–19 for patients with disabilities. We have accessible materials that are available in braille and in American sign language so that people with disabilities, in easier to read and understand language, so that people with disabilities can access our materials. We have improved data collection systems on our COVID data tracker. You can track vaccination status by disability.

We have worked with States to make sure that those are reporting. And the more funding partners in our public health partners to do more for patients with disability. And if anything, this issue on Friday has redoubled our commitment to continuing to make sure that we have access for people with disabilities. Thank you for allowing me to clarify.

Senator CASEY. Well, I appreciate that, and I appreciate the time it took to respond. I would also suggest and maybe even ask you to spend some time meeting with leaders from both the disability and aging communities to walk through what you just walk through and even expand beyond that.

Dr. WALENSKY. We are already planning. Thank you.

Senator CASEY. Thanks very much. I want to turn now to vaccine development for children. The recent setbacks in vaccine trials for children under five is of great concern. So many parents are exhausted from this pandemic.

I know we can't change the outcome of the trials, but we can take steps to reassure parents that their young children will still get vaccinated as soon as possible. Dr. Fauci, Dr. Woodcock, if you could briefly talk about these trials and any—anything you can tell

us about speeding up the development of safe and effective vaccines for children under five.

Dr. FAUCI. Thank you for that question. Senator, I will take a quick shot at it and then pass it over to Dr. Woodcock. The situation that I believe the public needs to understand is that the trials from children from 6 months to 4 years was broken up into two groups. It was 6 months to 24 months, 24 months to 4 years.

In the dosage that was used, the individual, the children, the younger group, the trial met the end point of noninferiority, comparing it to what would be the standard of what would be success. However, for the middle group, the 24 months to 4 year group, they did not meet that standard of noninferiority.

Because of that, it was felt that this likely will be a three dose vaccination for children in that group, so the trials are being done now as quickly as possible to see if they can get that data to have a uniform dose and a uniform regimen. But I will pass it over to Dr. Woodcock.

Dr. WOODCOCK. Yes, well, of course, I can't say a lot, but we are working very closely with the manufacturers of vaccines on accelerating and making sure that vaccines are available for the youngest children.

Senator CASEY. Thank you very much.

The CHAIR. Thank you.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Chairman—Madam Chairman. It says a lot about 2021 when the most appreciated gift under the Christmas tree in our family was COVID kits for everybody. I am still getting thank yous for those. Dr. Walensky, there has been a lot of discussion here today about the—some of the confusion with guidance and just some very clear asks to tell us what that is.

A question that I am going to forward to you from a teacher is, if the teacher is fully vaccinated, boosted, tests positive for COVID, but after they test positive, they feel pretty fine, there is no fever, there is no nothing, after 5 days, can that teacher return to school without testing negative just so long as that individual wears a mask?

Dr. WALENSKY. Yes. Thank you, Senator.

Senator MURKOWSKI. Great. That is exactly what I needed to know. I am going to be having a meeting, a zoom meeting later this afternoon with several different Alaska based companies that have more than 100 employees. They are quite concerned about the mandate that requires testing of unvaccinated employees.

We all know that this is under litigation now, and things may change on that. But right now their real concern is, if this goes into place and we are required to ensure that these unvaccinated individuals receive testing, right now testing all around the State is in limited supply. The front page of the Anchorage Daily News shows the line of cars that are waiting to get there their PCR tests.

You can't find the at home tests available in the stores now. It is becoming harder and harder. And then again, if you really do have a mandate in place, it is going to require this. So I know that

the question has been asked about what more is being done. I know we have heard the extraordinary Federal resources that have gone that way, but the facts on the ground remain that we are in an extraordinarily short supply of testing, whether it is the at home kits or whether it is the ability to get the testing that you need.

It is cold back home right now and my hearts go out to those workers who are working in the outdoor drive in where they have to go out when it is 20 below as it is in Fairbanks. That is more of a statement rather than a question there, but I think it is important for folks to realize that we are still in a very difficult place when it comes to accessibility.

Dr. Walensky, this is a question for you, and you and I have had many conversations last year about the specific impact of conditional sail orders as it relates to the cruise industry. That industry was effectively shut down or all of 2020, and we were able to salvage a bit of it as things relax last year.

But in fairness, the industry itself has undertaken extraordinary precautions as one industry to make sure that people are protected from this virus. So the question to me—to you is, I want to make sure that Alaskan communities and businesses can have a season this coming year. And right now people are making their decisions as to whether or not to book a trip to Alaska for the summer or not.

I understand the conditional sail order is set to expire in a few days in recognition that the companies have practices that adhere to or even exceed the guidance in the orders. So I guess I would like some assurance from you that they can count on that, that this is clear guidance and messaging to those within the industries and to those who are counting on being able to have a season is coming summer.

Dr. WALENSKY. Yes, thank you, Senator. And I think the conditional sails order and the fact that the industry has stepped up and is now interested in doing and exceeding, as you note, the compliance with the sail order without the order even necessarily needing to be in place is a real testimony to how well that has worked and how we work collaboratively with the industry.

What I can say is that just over the last 2 weeks with Omicron, we have seen a 30 fold increase in cases on ships during this season because of Omicron. So while I anticipate that with ships following conditional sail order, we still will continue to follow—do the oversight and watch and do all the technical assistance and support in every single way.

We anticipate that this order will not be renewed and that the cruise ship industries will continue to understand that this is a really safe practice for those industries. What I can't predict is what the summer will bring.

Senator MURKOWSKI. I understand that, but for right now, you expect this guidance to stay in place.

Dr. WALENSKY. That is my anticipation.

Senator MURKOWSKI. Thank you. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Hickenlooper.

Senator HICKENLOOPER. Now it is on. Thank you, Madam Chair and Ranking Member Chair, right. First, I want to reiterate a little bit about what Senator Romney said. You know, I was the odd one out, I was—worked as a scientist for a number of years, then I was a Mayor of a big city and was pretty much the only scientist among all the Mayors. I was a Governor and pretty much the only scientists around Governors. And now I am one of the only scientists among Senators and I recognize from that long list of experience the frustration that you must feel having to put up with the attacks and assaults when you are out there trying to do your job. It is something that each of you have committed to, the service of society.

I just want you to know that I appreciate how difficult science is, it is not perfect, and when you combine that with the complexity of dealing with any large bureaucracy, I am not making apologies, these are just like just like any—well, we are having a war against this virus, and just like in any wartime situation, mistakes have serious consequences, but I appreciate more than I can say how much work you all have done.

I don't think anyone here thinks you are not trying your very best all the time. Really appreciate that. Dr. Fauci, I think one of the problems we haven't gotten far enough on is innovation, and how do we stimulate innovation to go faster and better? How do we increase not just the breadth of our vaccines, but the durability so that as we get the next wave—I am not sure how many letters there are in the Greek alphabet, but I know there is going to be another one?

In that process, because I think we are, this country is known for innovation, it is one of the tools that we have that we know work. I am hoping that you can take the opportunity to be a little bit optimistic and feel that you are not going to be judged and held accountable because I think people want to hear that we are going to come through and begin to look at some of these things successfully.

Dr. FAUCI. Well, thank you very much, Senator, for your original kind comments. And I will answer your question now. As a scientist, that there are fundamental basic issues that are discovery, that once you get the discovery, then you could do the implementation of that discovery—we were very fortunate in that the basic research and clinical research investments that had been made literally for decades prior to the new revelation that we had a very threatening virus among us was the reason why we were able to use new platform technologies as well as immunogen designed to get highly successful and safe vaccines.

That same thing is going on right now. It isn't well known because it isn't front page yet. And as a scientist, when you are doing your basic research, it is only until you get the result that people really understand what you have been doing.

There is a lot of investment not only in improving the vaccines that we have for COVID, for SARS-CoV–2, but a lot of work, as I mentioned in my opening statement, about looking at using the tools of fundamental, basic, and applied science to develop next

generation of vaccines, particularly universal coronavirus vaccines, or at least universal SARS-CoV–2 vaccines, so we won't be chasing after the next variant. That we will be able to have a vaccine that has the capability of responding to every iteration of a variant.

There is a lot of work going on with that right now. But again, when you are doing basic research, as you can appreciate as well more than anyone that usually isn't very well recognized by the public.

Senator HICKENLOOPER. Point made. In terms of testing, a parallel thought, Dr. Woodcock, maybe you can address this, but the testing now by the time it gets the retail is somewhere in the $15 to $20 range, maybe as high as $22 or $23 in some places.

Is there the prospect of—because I keep reading about different approaches to testing, that we might find a way to do—reduce the cost of testing down to service instead of $15 could be $0.15 cents, or at least for the chemical side of it? I realize then you have got a manufacturer and put it in cases and packaging. Maybe you can provide a little optimism on that.

Dr. WOODCOCK. Sure. Well, I believe the RADx program, which Congress provided funding for quite some time ago, is really cutting edge, and they have a sort of a shark tank approach. They are really looking for innovation.

They are—they provide assistance to developers, and I really believe that is promising, that we will come up with additional technologies that are easier to manufacture and actually easier for people to use and cheaper.

Senator HICKENLOOPER. Great. Thank you, and I have obviously more questions, but I will yield the floor back—for now.

The CHAIR. Thank you.

Senator Braun.

Senator BRAUN. Thank you, Madam Chair. Reading the paper last night, lead editorial in The Washington Post, and I about dropped it when I read the first paragraph. In the title of the editorial is, living with COVID. "Quite understandably, the coronavirus pandemic at first was a dire emergency, but it can't be one forever. The crisis will have to shift to a manageable health threat without massive disruption and overwhelming anxiety. President Biden has been fighting the virus as an emergency in his first year, but a shift must come before too long." Never thought I would read anything like that in a place like Washington Post, but I think it reflects where we are at in the journey.

Generally when you wrestle with something of this magnitude where it has dominated the conversation for now 2 years and you are still seeing results similar to, if not worse, from when we started, it would beg the question, do we need to take a different approach? It has been very top-down, been put in place, I think understandably, by the agencies that would be most pertinent.

But when you look at the results, you look at the fact that a third of the country, for whatever reason, is not going to get vaccinated. You got a mandate that now is going to force the hand. And when you get someplace like The Washington Post saying that we have got to take a different approach, I am wondering, do we

have it within our constitution here, when we have been brought in for so long that this is the way it has got to be?

Listening to Senator Casey earlier, made a very good point, everybody talks about data, paying attention to the data, and when this is so ravaged such a small percentage so significantly of a population with comorbidities that are elderly, it just keeps saying, why don't we change the approach?

You don't want to have the legacy of being a country in disruption and full of anxiety. And kind of what I am hearing here today, I am not sensing that we are going to see a real change in approach, and even more so, doubling down on what now for 2 years has arguably not gotten us in a place where we feel better about it, where we are not drowning in anxiety. And I am going to pose the question to Dr. Woodcock.

You have been involved in Federal health care in one way or another for a long time, Acting Commissioner at the FDA. Normally, a Board of Directors, a CEO would be fired as a CEO, No. 1, a Board of Directors would be questioned in terms of how good they are, meaning maybe us here in the Senate, to where you are not directing for something other than what we have had, which in my opinion, would be decentralizing it, providing the information to the American public to make their own best decisions.

Dr. Woodcock, do you think that is sensible? Do you think The Washington Post makes sense? And are you willing to change up there on this panel to reflect accordingly?

Dr. WOODCOCK. Well, I think that we are talking about a natural disaster, and you can fire your Board of Directors because your factory was devastated by a hurricane or tornado or a wildfire, but I don't know whether that would improve this situation. I think right now we need to focus on continuity of operations for hospitals and other essential services as this variant sweeps through the population.

I don't think that will last a really long time, but that is what—where I think we are right now. So I don't think prior approaches reflect what is going on right now. I think it is hard to process what is actually happening right now, which is most people are going to get COVID, alright.

What we need to do is make sure that hospitals can still function, transportation other essential services are not disrupted while this happens. I think after that will be a good time to reassess how we are approaching this pandemic.

Senator BRAUN. I am out of time, but I think if you want to regain the trust of the American public, you probably need to look at a total revamp on what we do in terms of how we contend with it over the next year or so, or I think you are going to get more forceful editorials from places that you would never imagine. If you keep doing the same thing, generating the same results, that isn't the formula for success in any endeavor.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you, Madam Chair. And I want to thank all of our witnesses today. And I also want to just under-

score the preface that our colleague, Senator Romney, gave to his questioning. I like the way he described it, sometimes we come to perform, sometimes we come to be informed.

I guess I would just speculate a little bit beyond that if there were to be a true tit for tat on the performance angle, there is any number of areas we could go. I reflect on proposals for ultraviolet light and drinking bleach and drinking hydroxychloroquine. We could go there, but it is not constructive.

I am going to be constructive in my questions, and I just urge my colleagues to do that. We are all in this together, and we have a duty to act responsibly in that fashion. And again, thank you to our witnesses. Dr. Walensky, I am going to start with you on a topic that I bring up frequently when you are in our presence, and that is the tools we have now to sequence, do genomic sequences to better understand variants, to better track variants.

I know that there has been much investment in that. I would like to hear what tools that we have in place now that we didn't before and what you see the future of this genomic sequencing is, especially as this Committee looks at pandemic preparation for future potential pandemics.

Dr. WALENSKY. Thank you, Senator Baldwin, and for your championing our ability to ramp up our genomic sequencing efforts and the resources from the American Rescue Plan. Once that $1.7 billion really did allow us to detect Omicron swiftly.

Maybe I will just tell you the story of what happened with Omicron, and that as we heard about this variant that was coming from South Africa and we didn't know if it was here yet, but we did know it had this unique footprint of the S-gene target failure on PCR.

What we did immediately after hearing about this is to enhance surveillance for this footprint and do enhanced sequencing so that any sequence that had this footprint—I shouldn't say any. Many sequences that had this footprint, we were specifically looking for this Omicron variant.

Within days, we found it. So within 3 days, I think that we started doing this enhanced surveillance, and then within days we had tens, forties. By about 4 days later, by December 5th is when we started detecting it in our background genomic sequencing. So that background genomic sequencing now does tens of thousands of sequences a week. It is a collaboration with academic partners, industry commercial labs, CDC labs, public health partners to do tens of thousands of sequences a week.

What we do is we look at the number of cases that are out there, and our goal is to detect a variant that is present at 0.1 percent with 99 percent confidence, so that we see the menu of variants that are out there. We are enthusiastic about this program.

We are intending to ramp up this program for potentially other viruses with the potential to do so there, for other foodborne outbreaks, as well as for wastewater investigation. We have the capacity to do that there as well. So again, thank you for championing this effort, which truly did allow us to detect Omicron in real record speed. Thank you.

Senator BALDWIN. Thank you. Next, Assistant Secretary O'Connell, when we last met in this Committee, I asked you for a commitment that a significant portion of the $10 billion for the Defense Production Act funding that I helped secure as part of the American Rescue Plan be invested in the raw materials needed to make N95 masks here in America.

The alarming spread of Omicron has made the need for N95 even more clear, and yet ASPR has not spent any of this American Rescue Plan funding on the raw material needed to make N95s in America, while it has invested $3.1 billion on other priorities, primarily using prior supplemental funding.

The FDA reports now that 60 percent of the KN95 masks that are being imported from China are fake, and Americans still can't go to a local pharmacy and purchase an American made N95. So President Biden has now personally urged Americans to upgrade the quality of the masks they wear.

I want to know when the American people will be able to buy an American made N95 mask that they know will protect them, and when we can expect ASPR to invest the American Rescue Plan funding into the raw materials necessary.

Ms. O'CONNELL. Senator Baldwin, thank you for that question. You can buy an N95 mask manufactured in America now. We have 737 millions of those in the Strategic National Stockpile. We are also in the process, this month, we hope, to award—or next month as contracts go, to award an agreement for warm based manufacturing of N95 masks.

What we are asking the vendors to return to us as part of the proposal is their ability to manage 141 million masks a month at a surge capacity and to be able to maintain that manufacturing at a 20 to 30 percent rate in times where demand is not as high.

We are very invested in N95 masks being made available, and we will continue to look, and I appreciate your support in getting us the American Rescue Plan dollars that we are currently investing. And we will continue to look at the right ways to invest that and have really appreciated the conversations you and I have had around that.

The CHAIR. Thank you very much. I appreciate the witnesses have been here well over two and a half hours. We are going to have a second round of questions. So I am going to recess for 10 minutes to allow a break for our witnesses. We will reconvene at 12.45 p.m.

[Recess.]

The CHAIR. This Committee will reconvene. And before I start, I do want to make clear that this Committee will conduct itself with decorum and respect, and if I do hear personal attacks, I will gavel, and we will move on to the next questions. And I want to thank the Committee Members and witnesses.

I also am going to be very strict with the 5-minute rule as we have moved way past our time here and we need to move on. So with that, I look forward to the next round of questions so we can get to the essential work of addressing this pandemic, which has

upended so many lives and that continues to threaten the public health. And we will begin with Senator Baldwin.

Senator BALDWIN. Thank you, Madam Chair. Dr. Walensky, during our last hearing, we discussed the critical need for my Bio-Preparedness Workforce Act legislation that I introduced with Senators Collins, Rosen, and Murkowski to strengthen our outbreak response workforce so that we can better prepare for the next pandemic.

This legislation would address the serious workforce shortages and recruitment challenges that you mentioned by establishing a new loan repayment program focused on encouraging students to pursue careers as clinicians and bio preparedness health professionals.

As this Committee assembles a package of policies to respond to the next pandemic, it is important to remember that without people, there is no preparedness. In the midst of the Omicron surge, it has never been clearer that we need a robust and capable workforce to fully respond to public health emergencies.

The Bio Preparedness Workforce Act would go a long way toward that goal. So Dr. Walensky, as an infectious disease physician and public health leader, can you share more about how a strong clinical and public health workforce is key to responding to outbreaks, and how legislation like the Bio Preparedness Workforce Act is important to prepare for the future—for future public health emergencies?

Dr. WALENSKY. Yes. Thank you, Senator. There is so much here. So first, let me just say there has been a recent study that had demonstrated that our public health workforce is now down about 80,000 jobs. So just to give you a sense of massive public health workforce—that is not physicians who are actually doing the work on the ground, right, in the hospitals. This is a public health workforce down 80,000 jobs.

We saw through this pandemic the challenges in sort of the volume of people who are doing public health work, but also where they were located and their experience. We need an up skilled public health workforce.

For example, we need people to do those genomic sequences. We need genomic epidemiologists. We need people who are diverse, as diverse as the communities they serve. We also need to make sure that they are compensated and have the right salaries, and as you say, have loan repayment for their work.

To give folks a sense, the infectious disease physicians are among the lowest paying physicians in hospitals. They don't do procedures. And by virtue of not doing procedures, there is not a large incentive from a financial standpoint to continue to go into infectious diseases, which are the bread and butter of what outbreak investigation and clinical does.

There have been many resources that we are moving forward to expand our public health workforce. Public Health AmeriCorps is a big piece of that. And that is something that we are working on and really grateful to resources from Congress to be able to do so.

But there is a vital need now to expand our public health workforce in laboratory capacity, in genomic surveillance, in disease outbreak investigation, and a workforce that is upskilled and as diverse as the communities we serve. Thank you.

Senator BALDWIN. Thank you. We all know that vaccines remain the best way to protect yourself against existing variants of COVID–19. And I have been encouraged by the FDA's work to authorize vaccines for the public.

But parents continue to be concerned that we don't have a vaccine for their kids as Omicron surges. Dr. Woodcock, can you provide an update on where we are in examination of the authorization of COVID–19 vaccines for children under five?

Dr. WOODCOCK. Certainly. As Dr. Fauci said earlier, there were—one of the companies, Pfizer had done trials. There were other trials going on. There were probably complications with the dose in the slightly older of the younger children, perhaps indicating that a third dose, as Dr. Fauci said, might be needed to the primary regimen.

FDA is working with the company very closely. Trials are ongoing. I too have heard from many, many parents of the youngest children. They have other children in school. They may have immunocompromised individuals in their household, and there are people who really want to get this vaccine, so—one of the vaccines and get the children vaccinated.

We are working very intensely on this right now, and we are working, of course, with NIH and with the companies.

Senator BALDWIN. Thank you. I yield back.

The CHAIR. Thank you.

Senator Paul.

Senator PAUL. Dr. Fauci, it is disappointing for you to suggest that people who dare to question you are responsible somehow for violent threats. Realize that by attacking me you are attacking the one Member who actually has suffered from violent attacks. I was at the ballfield the day Steve Scalise almost died.

I was 10 feet away from a staffer who was shot in the leg. We had over 160 rounds of semiautomatic weapons fired at us, ammunition. So for you to somehow suggest that somehow I or people who dare to oppose you are responsible for a threat that is insulting. The person who shot at us and almost killed Steve Scalise was a rabid supporter of Bernie Sanders.

But the one thing you will find if you look at the record is not one of us accused Bernie Sanders of being responsible for that. So this is the kind of ignorant sort of personal attacks that you have engaged in.

You engaged in these attacks with fellow scientists. Not only was it three scientists from Harvard, Oxford, and Stanford that you chose to malign, 50,000 scientists and medical doctors signed this petition. And what they wanted was something that most Americans think is pretty reasonable, is a different kind of approach. Instead of saying that everyone is the same and everyone should get the same treatment, and everybody ought to just get vaccinated,

what it did is it said that the death rate for this disease is extraordinary in the risk being different according to ages.

If you look at an 80 year old, it is at least a thousand times greater death rate than it is for a 10 year old. So wouldn't we want to say that well, we are going to assess the risks of each individual and have the treatment according to that? Or would we just simply say everyone should be vaccinated? The death rate for kids under 18 is about one in a million, a little bit less than the chance of being struck by lightning.

We don't yet know fully whether or not kids who have already had COVID might be at risk for some of the side effects of the vaccine. It still needs to be explored. But for a kid under 18 who has already had COVID, the death rate of about one in a million, even if you haven't had a disease, even if you haven't had COVID, it is about one in a million.

It is extraordinarily uncommon for a child to die. If you have already had the disease, it is probably a great deal less than that. Many Americans wonder why you steadfastly refused and worked with others to try to hide any kind of knowledge of natural immunity and how it would affect our decisionmaking.

For example you have a 10 year old kid and his mom comes up, and all of a sudden he gets myocarditis from the vaccine and dies. Admittedly, a rare complication. But what are you going to tell her when she says, well, he had COVID 3 months ago, I mean, why would you force me to vaccinate my kid? Why would you force me to vaccinate my kid without even checking to see whether he is already immune?

Now, the idea of natural immunity is the idea upon which vaccines are based. We have believed in, and all of medicine is based on the idea of acquiring natural immunity. People often respond and say, but you don't know how long it will last. Well, we don't know how long vaccines will last and that doesn't make us antivaccine. We do know that the vaccines are waning very quickly in potency.

We do know that the vaccine against Omicron really isn't preventing transmission. You have noticed that the debate has shifted, and the debate is now talking about trying to prevent hospitalizations and death. And I agree with those statistics. I think it is a good idea if you are at risk to be vaccinated. I have always been pro-vaccine. I am just simply against authoritarianism and against mandates.

The anger that has developed with you, Dr. Fauci, is that you don't want to give us advice, you want to tell us what to do. You think you are the science and that anybody responds to you, how dare you, how dare you criticize science, as if you somehow our science. That kind of arrogance, that hubris is really—that is where the anger is coming toward you.

If you were one doctor among hundreds of doctors in the Government who gave advice, I don't think anybody—people might object to your advice, but there wouldn't be such a degree of anger. But you are so certain that you are right, they are not willing to hear anyone else.

Three epidemiologists, of which you are not even an epidemiologist, but three epidemiologists prominent in their field, Oxford, Stanford, and Harvard, you maligned them. You spoke openly with Dr. Collins, and you did not disagree that let's paint them as fringe. You went after them and said, we will do a public takedown, not in science or Nature, or Lancet, in Wired, in the Nation, a left wing publication.

You have engaged in base politics. You will wonder why there is so much anger? You are not an objective scientist. You have lost that long ago. And so many of the things that people want, it is like, they say they want to know why you are forcing their children to be vaccinated when 95 percent of people at risk have been vaccinated.

Over 95 percent of people over 65, it is huge voluntary success. And yet you won't rest until you force every child to get this. So yes, there is a great deal of dissatisfaction with you and many people want you to go, but nobody wishes you violence.

The CHAIR. Senator Paul, your time has expired. I will use one time of my remaining 5 minutes to allow Senator Fauci to respond.

Dr. FAUCI. Thank you very much——

The CHAIR. Dr. Fauci.

Senator PAUL. Thank you, Dr. Murray——

[Laughter.]

The CHAIR. No, no.

Dr. FAUCI. So first of all, Senator, again, at a hearing such as this, where there are almost 900,000 people in this country have died from this outbreak, you have chosen to just personal attacks on me that go back to multiple hearings.

Again, just for the record, for people to check, I have never said take people down in that email. It was an email that was sent to me see, and again——

Senator PAUL. You agreed with Dr. Collins in the email.

The CHAIR. Senator Paul, this is my time.

Dr. FAUCI. You know, you personally attacked me and the things that you do are incorrect and proven incorrect. You have publicly accused me at a hearing of being responsible for the deaths of 5 million people when there is not a single, single shred of evidence that anything that was done with the NIH had anything to do with COVID–19. You talk about things like gain of function——

The CHAIR. Dr. Fauci, I am going to let you respond continually, but I think you have responded, and I appreciate——

Dr. FAUCI. Okay, I appreciate the time. Thank you very much, Madam Chair. But I just want to say I am actually stunned by the amount of misinformation. The only thing I have ever done, and this will take 20 seconds. If you look at the things I have said, they have been to support the recommendations of the CDC, of their advisory committees, and of the FDA.

I have told people that it is important to get vaccinated, to get boosted, to wear a mask, and to be prudent. That is the only thing I said. I haven't dictated anything that is only a monolith with me.

It is always public health practices. And anybody goes back over any record of me, they know that.

The CHAIR. Thank you and I will retain the balance of my time. Thank you very much.

Senator Casey.

Senator CASEY. Thank you, Chair Murray. I want to start with Dr. Walensky. Doctor, as the CDC has been working with my staff on an outstanding nursing home vaccine data request. I would appreciate it if you and your team would continue to work with me and with our team at the Aging Committee to resolve this matter.

Dr. WALENSKY. Yes, thank you, Senator, I am aware of that matter, and we are committed to continuing to that work with you. Thank you.

Senator CASEY. Thank you. Let me turn to a matter for Health and Human Services. Assistant Secretary O'Connell, you know that our Nation's long term care facilities were ground zero during the first year of COVID–19. 200,000 residents and workers, when we add up the number of residents plus the number of workers who died, it gets to 200,000 over these 2 years.

However, nursing home deaths have declined, declined dramatically thanks to the safety and effectiveness of the vaccines. It is a credit to the Administration that 90 percent of nursing home residents and 80 percent of workers have been vaccinated. We know that infections are on the rise right now, though, in nursing homes, raising safety concerns and putting additional pressures on workers who have been stretched thin.

For instance, we know the pandemic has worsened existing staffing shortages and turnover issues. So we also know at the same time that the rescue plan the Democrats passed in March helped to fill the staffing gap with a $500 million initiative for strike teams based upon legislation that I was leading recently.

These strike teams provide medical personnel and other supports that help nursing homes get through the surges like the one that we are seeing right now. On the 22d of December of last year, I along with three of my colleagues sent a letter to Secretary Becerra asking how Health and Human Services was protecting nursing home residents and workers in the current COVID–19 surge, including the distribution of booster shots.

What is HHS doing to ensure nursing homes have the support they need to protect residents and workers who care for those residents?

Ms. O'CONNELL. Senator Casey, thank you so much for your question. We share your concern for nursing home staff and long term care facility residents and have continued to do all we can to make sure they have access to boosts.

We have worked with pharmacies to bring in vaccination clinics, bring those to the long term care facilities and skilled nursing facilities so that vaccines are available on the ground and the residents don't have to travel or access the vaccines on their own.

In addition, ASPR has been sending since the beginning of the pandemic or since the beginning that these tests were available, 2.8 million tests per week to long term care facilities across the

country. We know how important it is that they are able to surveil any disease in their facilities and having access to these tests is one of the ways they can stay on top of where they are.

We share your concern, and we will look forward to responding to your letter.

Senator CASEY. Thanks very much.

The CHAIR. Senator Burr.

Senator BURR. Thank you, Madam Chairman. Ms. Woodcock, I know you said a while ago that you are excited about what RADx accomplished, and I think we all are. But FDA issued revised guidance stating that it would focus its review efforts on at home testing and point of care COVID test applications from developers, with the capacity to manufacture more than 500,000 tests per week within 3 months of being authorized.

Why did the FDA move the goalpost at this particular time and suggest to companies that can't ramp up to that manufacturing that they are not going to get an accelerated EUA pathway?

Dr. WOODCOCK. Well, because of what some of the Members have been discussing over the last several hours that we have an urgent need for high volume, home based tests, and we have a queue—we have done, moved heaven and earth to get as many done as possible.

We have approved, authorized over 400 different kinds of tasks or test collection devices during this pandemic. But as far as what the queue is a priority, we are prioritizing the highest volume and just putting them to the front so that we can get home test kits into the hands of people.

Senator BURR. I get what you are doing. My question is this, what does this say to the innovative company that is out there that doesn't have the manufacturing capacity, and without us marrying them to a large manufacturing capacity, it is basically saying don't innovate because you are not going to get consideration under the EUA if you don't have a manufacturing capacity 500,000 tests a week.

Dr. WOODCOCK. It says these are prioritized. It doesn't say we won't get to the others.

Senator BURR. Well, get to the others. I mean this there is all—a sense of urgency here. I just think that might have been thought of before we did this. Let me go to you, Ms. O'Connell. I am really challenged on this procurement of 500 million tests, as you can tell.

I don't understand why there has not been a release that came out of ASPR or BARDA publicly announcing here is how many we have contracted, that I have got to find it somewhere in a DOD contract that a very limited amount of people go to, certainly not one that I regularly looked at.

But based on what of your contracts, we have got 13.6 million tests costing $190 million. I think that is from the vodka distributor. When I break that down, that is about $14 a test. Now, CMS just put out a new rule that mandated that insurers must cover up to eight tests per person per week—per month for a family of four, that is 32 tests, and that they can reimburse at $12.

Now, if I am a manufacturer and I am under a $12 reimbursement or I can go over here and I can sell directly to the Federal Government and get $14, I am probably going to sell to the Federal Government to get $14. Where am I wrong?

Ms. O'CONNELL. Thank you, Senator Burr. We continue to work to access the tests that will be distributed as part of the 500 million and the tests that you are referring to.

First of all, DOD by tradition has put out, whenever we have done and assisted acquisitions with them, they put out within the first 24 hours of that contract going out an announcement that the contract has gone out.

That is what you are seeing and that has been the rigor. It has been what—the way DOD has approached us through our entire relationship. We are continuing to——

Senator BURR. Why would ASPR not putting out a similar public statement?

Ms. O'CONNELL. We would be happy to and thank you, Senator. I will go back and talk to the communications team and see if there is a companion press release that makes sense for us to put out.

Senator BURR. Well, I am not sure you addressed my concern, which is it is more profitable to sell to the Federal Government than it is to put it on retail based on the reimbursements that this Administration has now required of insurers. I hope you will think about that. This is alarming to me.

As we have all displayed, there are no tests out there. There are no tests on the shelves of Walgreens, CVS that people can go in, buy, and take home, and do it. So it makes it even more confusing CDC's policy that if you want to take a test, go ahead and take it. It is not required, but you can take it. You can't get it.

Dr. Fauci, just very quickly. South African data suggests that Omicron may have an ability to build immunity to Delta. Delta does not have an immunity—it does not build an immunity to Omicron. Have you got any comments on that? Cyprus announced a Deltacron variant. Are you worried about that?

We have been about 3 weeks behind Israel throughout this whole thing. And even though we have seen South African data go up and go back down very quickly, Israel epidemiologists just this week said they expect that for the next 2 weeks, they will see a doubling of the infections in Israel, meaning they are not following the same timeline that we saw in South Africa. How should we interpret that for the U.S.?

Dr. FAUCI. Okay, thank you very much for those questions, Senator. With regard to the cross-protection, I think it is too early to tell because you are dealing with multiple population demography of people who have been previously infected, vaccinated, or what have you.

It seems pretty clear that if you get infected with Omicron, you are going to get good protection against Omicron, but also good protection against some of the other spillover. So we really yet to have seen, and I think the basis of your question is a reasonable one. If we wind up getting infected with Omicron at a very, very low

level of pathogenicity, is that going to be sort of almost like a live attenuated vaccine?

I don't think we can say that right now. We really have to see how things spread out when we see how that affairs in the next variant. So there will be invariably another variant. We are going to have to take a look at whether or not there is going to be any protection there. That is the first thing. With regard to the Deltacron, this new variant, right now, even though it has got a bunch of mutations that people look at, it is not something that at least the WHO has looked at this carefully, feels that has to be something that is of great concern, but we always keep our eye on it to make sure.

When you say it is not of a great concern now—the one encouraging thing about it is that it has been around for a while. It isn't something that just popped up, and yet Omicron completely outstripped it, as did Delta. So it doesn't look like it has the capability of being transmissible enough to be a problem.

Nonetheless, we still keep an eye out on it. With regard to Israel, I mean, I am not—I am sorry. I forgot your question about Israel. Could you repeat it?

The CHAIR. We are way over time here.

Senator BURR. They are on about 3 weeks in front of us but yet their experience is not up and down drastically. Like South Africa, data begins to show, they went up, and now it looks like over the next 2 week, their epidemiologists say it is going to double and maybe double again before they hope it comes down. What should we expect?

Dr. FAUCI. Yes, I think it is a bit—that is a great question, Senator. But what it really reflects is that when you have an outbreak of a particular variant, how high it goes up, when it peaks and comes down is a reflection of what the status is in your country.

Because if you look at what you saw in South Africa, they were almost free of Delta when they got Omicron. So Omicron—so it had the unfettered capability of going way up and way down. When you talk about what happened in Israel that is a different population. It is a mostly vaccinated population, so they are likely going to see breakthrough infections.

In the United States, we have such a large country with such differences in vaccinations versus infections, etcetera, that we believe we will see it peak, and we will see it come down. But it is very difficult to predict whether it is going to be a sharp decrease or whether it is going to do this.

Our own feeling, and I believe that Dr. Walensky feels the same way as I do, that it is going to vary depending upon where in the country you are, how much infection you had previously, what at the level of vaccination is. So we may see a peak up and down in some regions of the country and a pickup and doing this in other regions of the country. Thank you.

The CHAIR. Thank you very much.

Senator Smith.

Senator SMITH. Thank you, Madam Chair. I would like to ask a question of Dr. Walensky, if I could. I think we all know that

Americans need better access to rapid testing, and this is a big deal for us in terms of trying to figure out what are our health risks, how do we protect ourselves, and how do we also go about our lives?

I think that we are making headway here, that we have a long way to go. Dr. Walensky, I would like you to talk about this issue of how we should be or not collecting and analyzing the data from rapid home tests. Should we be incorporating this data into like should be trying to capture that data? Is this important for local communities as they are trying to make decisions about masking and other public health strategies that they want to deploy?

Should we be thinking of the data from rapid tests as a tool for individual risk assessment or as an important tool for population level understanding of what is happening? How do you see that?

Dr. WALENSKY. Yes, thank you so much, Senator Smith. So we have been using the PCR test, not the rapid tests, the lab tests, the molecular tests to really capture our case counts and really get a good view of where we are in terms of the epidemiology, anticipating what was going to be coming into the hospitals. But the tests are a really important valuable tool for people to empower themselves, their own health, to not expose themselves to other people, to get some information about their own health.

If an individual were to test positive, if they are feeling unwell, they should certainly consult with a health care provider, consult with a pharmacist, and your health Department. But if you are feeling well, then use that rapid test to say, okay, my test was positive, I need to stay home and isolate, protect myself from the community, protect myself or the community from me, and protect me—my loved ones so that they don't get infected themselves.

I think that it is less about the absolute case count of understanding whether you have asymptomatic infection, or a runny nose and your rapid test was positive, than it is really about empowering you to do the right thing and not be forward transmitting.

Senator SMITH. Could you talk a little bit about what other countries are doing. Are other countries in trying to incorporate this rapid testing data into their population metrics—how is that working in other places around the world?

Dr. WALENSKY. Some countries are, and some countries aren't. London and UK have been doing more reporting of rapid testing, but they too are saying that they are missing I think somewhere around 40 percent, I would have to confirm that number, but they too, well they capture more than we have tried to. They also agree that they are missing some as well.

Senator SMITH. Okay. Thank you very much. Madam Chair, I am going to cede back the rest of my time. I just want to acknowledge something I think has been going on here today that I think just deserves being called out.

Dr. Fauci has been the target of a concerted and coordinated campaign of disinformation and distortion and personal attacks, and then he is being blamed for all of this hatred and anger that has been generated against him.

I think we just need to be honest here that this is being done by some members of the Republican Party that are using it for fundraising. I am not saying that is happening by members of this—I am just saying that is happening. It was just pointed out to me that somebody sent out earlier in 2021, a Fauci for prison email.

I just think it is important that we—I have to call this out, and I think it is important that we see it and we have to try to rise above this kind of behavior. Our Committee here should be focusing on these kinds of nitty gritty policy questions, and we are not always going to agree.

I have never heard Dr. Fauci, or Dr. Walensky, for that matter, declare themselves to be invincible. I certainly am not. But that should not mean that an individual's career, public servants are subjected to this kind of abuse. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Collins.

Senator COLLINS. Ms. O'Connell, I want to follow-up on my previous questions to you because I don't feel, frankly, that I got answers. I asked you specifically how much money was diverted from the testing budget to deal with the surge of people, including unaccompanied minors, illegally crossing the Southern border, and how much money was diverted out of the funds allocated for the strategic stockpile?

Ms. O'CONNELL. Thank you, Senator Collins. Again, all of the funds, as they were appropriated to the American Rescue Plan, were for testing, contact tracing, and mitigation efforts.

Of those funds, funds were used to test unaccompanied children at the border and then to mitigate the COVID positive cases so they wouldn't enter the community and spread COVID, which was a use of the funds that was allowed under the testing, contact tracing, and mitigation requirements.

Senator COLLINS. Well, you are still not answering my question on the amount of money that was used to deal with the crisis at the Southern border, so I will tell you that our staff's investigation found that $850 million out of the testing budget and another $850 million out of the allocation for the stockpile were instead used to deal with the crisis at the Southern border. Do those numbers sound right to you?

Ms. O'CONNELL. Senator, I will be happy to take that back and discuss that with our finance team to make sure that those numbers are the same numbers that they are tracking.

Senator COLLINS. Well, I have to say that it is interesting to me that you knew all of the numbers, and I commend you for this, that we are going to community programs, to schools, etcetera, but you can't tell me how much was reallocated to deal with the crisis at the Southern border, a crisis that we are it right under control, we would have these funds for the purposes that they were intended. Let me ask you further, what do you mean when you say mitigation as applied to the Southern border and the surge, the unprecedented surge of people crossing?

Ms. O'CONNELL. Thank you. One of the important things that we needed to do when we identified a COVID positive unaccompanied child was to make sure, for example, they didn't ride on the same bus to a shelter with a COVID negative child. So there were additional costs for transportation to keep the children separate to mitigate spread as the statute allowed us to spend those funds.

In addition, within the shelters, it was necessary to set up a separate room where COVID positive unaccompanied children would reside so they wouldn't interact with their COVID negative children. And that required additional resources in those shelters in order to keep them separate.

When the children entered the community with their sponsors, they were not bringing COVID into the communities.

Senator COLLINS. Well, I will tell you, having visited the Southern border in late March, testing was being done, but people had been there for weeks at a time with no testing, and there were people, adults who were released into the community with no testing.

The fact remains that if we had the Southern border under control, we would be using the $850 million designated for testing to buy more rapid tests. We would be using the money out of the stockpile, the $850 million for the purposes for which it was intended.

I think that this is a problem that has contributed to the shortage of testing, the uncontrolled crisis at the border, and I also am perplexed by the lack of Federal orders for tests between January and September 2021, which I know from my experience in Maine caused the major manufacturer, Abbott, to lay off 400 workers that were producing those tests because it lacked the Federal orders. That makes no sense to me and seems very shortsighted. Thank you.

The CHAIR. Thank you, Senator.

Senator Hickenlooper.

Senator HICKENLOOPER. Great. Thank you, Madam Chair. Again, thank each of you for your public service. Dr. Walensky, I wanted to talk to you just for a moment about genomic sequencing. Even before COVID–19 appeared, Colorado made a genomic sequencing of diseases a high priority, and we are now, I think, one of the leading States in detecting changes as they evolve and COVID–19.

We test about 15 percent of all positive COVID tests. I think that is still one of the highest rates in the country. And we also monitor wastewater for community detection. So, Dr. Walensky, how would we or how can we expand genomics surveillance and expand those capabilities in order to try to stay ahead of existing but also future threats, COVID–19 or otherwise? How do we close the gap between the states that are heavily sequencing and following this and those that aren't?

Dr. WALENSKY. Yes. Thank you for that and for your leadership in Colorado in genomic sequencing. As I have mentioned we need to have both numbers and breadth and geographic distribution in order to get a real good view of what is happening genomic—in genomic sequencing.

We need to sample from State labs, so we get samples from every single lab. We also get samples from commercial labs, which gives us a lot of volume. We have partnerships now with 19, I believe, academic medical centers in order to do so. And what we do and power our genomic sequencing is so that we are able to detect a sequence that is present in less than 0.1 percent.

We scale up and based on the number of cases that we have, we scale up or scale down our genomic sequencing so we can detect it. And what we were able to do with Omicron is when we saw the footprint of the S-gene target failure in PCR, a similar footprint as Alpha, we were able to do targeted enhanced surveillance of sequences that actually had that initial footprint and able to identify sequences even before they reach that 0.1 percent threshold.

As you said, we can scale this up in wastewater. We are able to potentially scale it up for purposes of antimicrobial resistance, for foodborne outbreaks, and many other things, which we are really looking forward to doing now that we have established this incredible capacity.

Senator HICKENLOOPER. Right. Great. Perfect. Ms. O'Connell, I want to ask you a question in terms of the, we have talked a lot about the distribution of tests and whether it is schools or workplaces, hospitals, and we have talked about how at this moment we don't have enough tests out there and we are not getting results quickly enough.

In terms of the distribution of tests on a national level, we are still obviously working on a system, I know the Administration is hard at work on this, but some States like Colorado already have systems in place where tests are being mailed directly to people in their home.

I guess, I am not—I don't know, is the Federal Government working with States like Colorado and trying to look at those systems already in place, and how do we integrate the Federal system with those States?

Ms. O'CONNELL. Absolutely. Thank you, Senator. That is terrific what Colorado is doing. We have invested $29 billion with the State so they could set up such testing programs however they saw fit. And we are seeing States like Colorado use those funds to be able to do exactly what we are hoping to do on a national level. We are in the process, as we have talked about today, setting this up, working with the U.S. Postal Service.

As the Federal Government, we will allow American households to order and have them delivered to their house as well. I imagine that we will—these will be in addition to what Colorado is able to provide. And we want to have as many tests, of course, available to all Americans as possible.

If Colorado is already doing it that is terrific. I am sure we will learn some lessons from the experiences you have had in your State and apply those to this national initiative.

Senator HICKENLOOPER. Great. Thank you on that. And then just real quickly, Dr. Fauci, we have heard from Dr. Walensky, who was just talking about how you integrate the aggregation of large amounts of data, and we have had a discussion about Israel versus

South Africa, and it really is a question of how do we take—my question is, is how do we take information from global sources and learn from those countries who are ahead of us on the curve, make sure that we are learning from their experiences. And I think how can we do a better job working with our international partners to make sure that we are prepared for the next Greek letter?

Dr. FAUCI. Yes. Well, thank you very much. Excellent question, and we are just actually doing that. Every week to 10 days, I have a long phone call with Chris Whitty and Patrick Vallance, who are the two leading medical and scientific advisers to the Prime Minister of England to get a feel of what is going on there. We have regular phone calls with our Israeli colleagues.

Every Saturday or Sunday morning, depending upon what it is, Dr. Walensky and I and others are on the phone with our South African colleagues. So we are in literally constant communication with them.

Senator HICKENLOOPER. Great. Thank you. I yield back.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. The American people my family, all of our families, are struggling as this pandemic continues to drag on with no end in sight. The words I hear every day, multiple times each day, continue to resonate and echo in my mind as I said here, words like I am tired, confused, burnout, scared, and frustrated. The list goes on.

What is making the situation worse are the officials leading our Nation's COVID response going on national television and contradicting each other. And of course, some Supreme Court justices are spreading misinformation as well.

Dr. Walensky, this past week, you recommended asymptomatic people be able to return to work after 5 days. But Dr. Fauci ambiguously corrected you on national television and suggested folks needed a test before return.

How does that make you feel when Dr. Fauci or someone like Justice Sotomayor upstages a previous statement or policies of yours, blatantly contradicts and undermined your guidance, or offers false claims that cause more confusion for the American people?

Dr. WALENSKY. Thank you, Senator. I have the great honor of leading the agency of 12,000 public health servants in this country, and we work collaboratively with tens of thousands of public health officials around the country to provide guidance.

I also get to work with a COVID–19 task force that is full of a multidisciplinary group of people with diverse expertise, from immunology to drug regulation to epidemiology. This science is moving really quickly, and I know you will appreciate that it is moving fast, and it is changing. And our responsibility——

Senator MARSHALL. Right. You are not answering my question.

Dr. WALENSKY [continuing]. is to convey that science.

Senator MARSHALL. I will move on. The FDA has recently set up protocols for monoclonal antibodies and antiviral pharmaceuticals

to be prioritized based upon race. Dr. Woodcock has the CDC or FDA getting multiple regression analysis on race to see if indeed it is an independent factor for increased morbidity and mortality. And if it has, don't you think zip code would actually be more predictive?

Wouldn't it make sense to prioritize these antivirals and testing, for that matter, to senior citizens and those with significant comorbidities regardless of race, especially if the multiple regression analysis proves my opinion? Dr. Woodcock.

Dr. WOODCOCK. What FDA did was to recommend if, you know that people at high risk would be candidates for these products.

Senator MARSHALL. Did you do a multiple regression analysis on this independent factor?

Dr. WOODCOCK. We did not.

Senator MARSHALL. Okay.

Dr. WOODCOCK. We did not. We don't make those kind of recommendations. We make——

Senator MARSHALL. But you can do studies, right? The FDA and CDC can do studies to see if it is truly an independent factor, or if not truly that the issue should be about your comorbidities and your age. So Dr. Fauci, according to Forbes, you have an annual salary in 2020 was $430,000.

You oversee over $5 billion in Federal research grants. As the highest paid employee in the entire Federal Government, yes or no, would you be willing to submit to Congress and the public a financial disclosure that includes your past and current investments?

After all, your colleague, Dr. Walensky, and every Member of Congress submits a financial disclosure that includes their investments.

[Technical problems.]

Dr. FAUCI. I don't understand why you are asking me that question. My financial disclosure is public knowledge and has been so for the last 37 years or so, 35 years——

Senator MARSHALL. The big tech giants are doing an incredible job of keeping it from being public. We will continue to look for it. Where would we find it?

Dr. FAUCI. All you have to do is ask for it. You are so misinformed, it is extraordinary.

Senator MARSHALL. Why am I misinformed? This is a huge issue. Wouldn't you agree with me that you have a—you see things before Members of Congress would see them, so that there is an air of appearance that maybe some shenanigans are going on. You know, I don't think that is—I assume that is not the case.

Dr. FAUCI [continuing]. are you talking about the case? My financial disclosures are public knowledge and have been so. You are getting amazingly wrong information.

Senator MARSHALL. So what—I cannot find them. Our office cannot find them. Where would they be if they are public knowledge, where?

Dr. FAUCI. It is totally accessible to you if you want it.

Senator MARSHALL. For the public, is it accessible for the public?

Dr. FAUCI. Through the public to the public. You are totally incorrect.

Senator MARSHALL. Well, we look forward to reviewing it.

The CHAIR. Senator Marshall, Dr. Fauci has answered you it is public information, and he is happy to give it to you if you were to ask.

Senator Moran.

Senator MORAN. Chairwoman, thank you. I know this has been talked about, I have watched a bit of the hearing from my office this morning and into this afternoon, but would you highlight for me—I suppose this is for Dr. Woodcock. Lots of funding. I think adequate funding. Certainly knowledge about winter months would bring an increase in cases. What is the challenge in not being better prepared for access to testing, in home and elsewhere? And how soon will that change?

Dr. WOODCOCK. I don't think that is—I think that is a question for Assistant Secretary O'Connell. But I would tell you, FDA has approved or authorized over 400 tests or collection systems just for COVID. We have approved, authorized 15 over-the-counter tests, but it is capacity that we are talking about here, production capacity.

Senator MORAN. So there is no—what you were telling me, Dr. Woodcock, is there is no problem with the FDA approval of tests, it is the manufacturing process and the supply chain?

Dr. WOODCOCK. We could do more with more resources. We have authorized over 2,000 different device products, including the 400 test related products in 2 years. So that is an incredible increase in the workload, and we really appreciate the funding that Congress has provided.

However, the test manufacturers, many of them give us incomplete results. We have to go back and forth with them. The ITAP program that we are doing with NIH for home testing, I think we will improve that tremendously. That is a big advance forward. But there is also the matter of production capacity with this huge surge and so many more people becoming infected.

Senator MORAN. Is there a separate FDA results process in which the test is read and determine positive or negative, there is no challenges there in that process?

Dr. WOODCOCK. That is what the ITAP program over—NIH is doing. They are actually doing the laboratory and clinical testing for the manufacturers, and then they send us the data. And so it is standardized, and it is a panel and that really accelerates our ability to get these authorized very quickly.

As I said earlier, we have authorized them within 2 days of getting the data from the ITAP program. So it is that—that is a tremendous set up that I think is really beneficial where we have standardized testing by scientists in the Government and that enables the manufacturers to get their products through very fast.

Senator MORAN. Thank you.

Ms. O'Connell.

Ms. O'CONNELL. Thank you, Senator. And just to pick up where Dr. Woodcock left off, once those tests are authorized, ASPR reaches out to the manufacturers to make sure that we are optimizing the manufacturing capability.

That part is sort of a seamless process that we have. But all of the work we are doing and testing in this Administration is in service of four priorities. One, to expand the number of testing sites that are available.

Two, to expand the number of tests that are available, that is the part that I am working on, to increase capacity. Three, the kinds of tests that are available. That is the part Dr. Woodcock just discussed. And then to help lower the cost of tests.

Senator MORAN. Is there is there a problem—I don't know whether the testing devices are manufactured domestically. Do we have another challenge of the importation of tests, as we did with masks, gowns, and gloves?

Ms. O'CONNELL. We continue to look for tests wherever we can find them, and we have encouraged actually some test manufacturers that are approved in Europe to apply for FDA approval here in the United States. So I do anticipate we will have some importation of tests at some point. But we have used the Defense Production Act authorities 12 times to support the domestic manufacture of tests and to priority rate those orders so we can increase the supplies and manufacturing capacity here in the U.S..

Senator MORAN. In the third of a minute that I have left, we have changed, I think, our view on masks recently and we are emphasizing N95s. Is there any intentions to—is there a plan to manufacture additional 95 masks so there are more available? Is there a way to make them more comfortable? I will leave that—that is the crux of my question.

Ms. O'CONNELL. We continue to support the manufacture of N95 masks. We have 737 million in the Strategic National Stockpile, all sourced from 12 domestic manufacturers. So we are continuing to support that. We are also in the process of putting out an agreement for warm based manufacturing.

We are able to keep this capacity that we currently have going even when demand diminishes. So that is all underway right now. As far as fit and style and how they work, I am sure colleagues at the table are probably have various pieces of their programs that might be participating to that effort and consulting with the manufacturers on how that will work. Thank you.

The CHAIR. Thank you.

Senator Tuberville.

Senator TUBERVILLE. Thank you very much. Just very quickly I know there is plenty of misinformation on both sides when it comes to COVID but I would say the fear mongering on the left is and I will give you a couple of questions here about this, has made matters much worse.

Dr. Fauci, I just want to ask you this from my constituents back in Alabama. Ivermectin. Forty year drug. Now my constituents read this, they hear about it. This 40 year drug, they call it a won-

der drug. It is about a nickel of tablet. It has done wonders, supposedly in India and several other places.

Then you have this new antiviral pill that were coming out and my constituents think, this thing is going to cost about $500, $600, $700 each. Could you give me a rundown on the difference in those two, what you think about them?

Get it on record here, so I can tell my people back home, this is what Dr. Fauci says.

Dr. FAUCI. Yes. So Paxlovid, the drug from Pfizer has shown in a randomized, placebo controlled trial to be highly effective to the point of 89 percent, almost 90 percent.

Senator TUBERVILLE. What is it called?

Dr. FAUCI. Paxlovid.

Senator TUBERVILLE. Okay.

Dr. FAUCI. It is made by Pfizer and has been shown in a very well controlled, randomized, placebo controlled trial that if you take that drug compared to the placebo within the first three to 5 days within the first 3 days, you have about an 89 percent chance of preventing you from going to the hospital or dying. There were no deaths in the Paxlovid group, and there were several deaths in the placebo group. That is Paxlovid.

Ivermectin has had non-controlled trials suggesting that it might be effective, mostly anecdotal. The CDC—excuse me, the NIH guidelines panel have looked at that data and felt is not sufficient evidence to say that it works, or it doesn't. The WHO recommends strongly against it and suggests that it might actually be harmful.

The NIH active studies are doing a whole bunch of studies with ivermectin, as well as others to try and settle it once and for all, to prevent people from taking it if it doesn't work, because it could be toxic. So there is a world of difference between ivermectin and Paxlovid.

Senator TUBERVILLE. But this is a 40 year drug. And we are talking about one that is just now coming on the market. So we actually know that much about this Pfizer drug. I wish they would come up with a lot easier names——

Dr. FAUCI. Yes, they always do that. They fool me too with the names, coach. But it is what it is. The fact is, I think it is kind of a mis comparison to say one is a 40 year drug and one is a drug that was just discovered.

It was just discovered, but it was shown in a very well controlled clinical trial to be highly effective. Even though ivermectin is a good drug for some parasites, it has not been shown in a well-controlled, placebo controlled trial to be effective in COVID.

Senator TUBERVILLE. Okay. Thank you. Dr. Walensky, I don't know if anybody has asked this question. I just want to get cleared up. Our Supreme Court justice last week, looking into the situation with the mandate, Justice Sotomayor said there is 100,000 children that are sick as we speak with Omicron, and a lot of them are serious and in the hospital. Is that true or false?

Dr. WALENSKY. I don't have the number of children in the hospital right now. It is likely less than 100,000.

Senator TUBERVILLE. Yes. And Justice Breyer said that if we continue to delay this ruling, that we are going to have 750,000 more that are not vaccinated infected a day. I mean, does that make sense to you?

Dr. WALENSKY. What I can't tell you is our children between the ages of zero and four, one of the only places where our hospitalization rates are currently rising, and that children who are in the hospital are generally unvaccinated, not uniformly, but generally unvaccinated. And that is true for not just our 0 to 4 who are obviously ineligible, but also true for 5 to 11 year olds, as well as our 12 to 17 year olds.

Senator TUBERVILLE. Thank you. Well, thank you all for being here today. Thank you very much. Thank you, Madam Chair.

The CHAIR. Thank you so much. I have one final question for Ms. O'Connell and Dr. Walensky, and that is regarding education. In the past, we have seen school districts that serve a significant number of students of color or those in low income or rural areas that are facing great challenges in accessing resources they need to serve our students.

How is the Federal Government working now to make sure that States are equitably distributing tests and necessary resources like masks to all school districts, particularly those that serve predominantly students from families with low income, students of color, or rural students? And Ms. O'Connell, I will start with you.

Ms. O'CONNELL. Thank you, Chair Murray. Equity is woven into all of the work that we are doing in this response. It is something that we remain focused on, including making sure that schools across all States are able to access the tools and resources that they need. We gave $10 billion, as you know, from the American Rescue Plan, for schools to be able to set up their funding programs—we are also—testing programs.

We have also made it possible through Operation Expanded Testing, which Dr. Walensky can talk more about, where we have regional hubs, where schools can contract directly with labs to run their programs for them. That was designed for schools that might not otherwise have resources to be able to manage a testing program on their own. In addition, we are making tests available through the federally qualified health centers and rural health centers. And we have done that with masks as well earlier in the year.

The CHAIR. Thank you.

Dr. Walensky.

Dr. WALENSKY. Yes, and maybe I will just pick up exactly where ASPR O'Connell has put down. So our ICATT program, our increase community access to testing program, does place tests in pharmacies in socially vulnerable—social vulnerability indices that are high. That is by design.

Tests in federally qualified health care centers and community centers, just as the Assistant Secretary mentioned. We also continue to support screening tests at no cost to childcare centers, K–12 schools, and congregate settings through exactly the program that the ASPR mentioned, Operation Expanded Testing.

We prioritized high schools that have and all schools that have high social vulnerability, and we have own website now that is active where you can enroll.

The CHAIR. Okay, thank you. Senator Burr, I understand you have two additional questions.

Senator BURR [continuing]. questions, if I could, Madam Chair. This is for Dr. Woodcock and Ms. O'Connell. It is my understanding that prior to Omicron, BARDA informed some therapeutic manufacturers that they would no longer be supporting additional work on new therapies because there is no longer an unmet need which may impact whether and how FDA prioritizes reviewing such therapies. Did BARDA and FDA change course on this policy once the Omicron variant was discovered in November?

Ms. O'CONNELL. BARDA's decision to put that notification out was in light of the fact that the therapeutics development was moved over to Operation Warp Speed and BARDA was supporting the therapies that were being developed through the Warp Speed effort. So it was a way of combining the funding that was available to be able to move the therapies through faster. BARDA never stopped supporting therapy work. But I will let Dr. Woodcock——

Dr. WOODCOCK. Yes, there is—we still regard, there is an extreme unmet medical need for therapeutics at most stages of the disease, particularly the late stages where we still don't have interventions and so people are dying in the late stage of disease, getting into the ICU, going on the ventilator.

Of course, we have had have 670 INDs that we have been—clinical protocols that are ongoing, to my knowledge. So robust development is still ongoing in the therapeutic area.

Senator BURR. So how much—how much funding has BARDA allocated to therapeutics this year and how much is left to spend?

Ms. O'CONNELL. I will have to go back and check that. On the actual development, we have spent a lot of funds this year on the procurement of the therapeutics that have already been developed but would be more than happy to bring that number to you and your staff.

Senator BURR. And this is, I am talking about the development end of it. There is a firm belief out there that BARDA went to the industry and said, we are not supporting this anymore. They didn't say this got moved over to Operation Warp Speed, which by the way doesn't exist anymore.

But they said, BARDA said we are not supporting therapeutics because there is not an unmet need. That is what the industry heard. I would love for you to clarify that for me. Last thing, Dr. Woodcock, since we did discuss the point of care and at home testing. I just had them come up with the chart that FDA put out not long ago. So let me just, and you are probably familiar with it, one is molecular, one is antigen, and one is serology.

For the molecular and the antigen point, if you test yes for point of care or at home, that kicks you to the right. The next box is high manufacturing capacity. If your answer is no there, it kicks you down to an FDA intends to decline box. There is no option. So if you are not a high manufacturing test, then FDA is going to de-

cline to review. Boy, I got to tell you, I think this is a huge mistake.

Now if you tell me that you have got a couple of hundred tests that fall into the high manufacturing capacity right now at the FDA, where you have got the luxury of being able to kick out new innovative companies that haven't solved their manufacturing yet, by all means, tell me that is the case, that there are a couple hundred.

Right now, Ms. O' Connell was struggling to buy 500 million test, where 47, maybe 50 million there, that leaves another 450 million to purchase. And we are going to distributors trying to buy their inventory, not to manufacturers trying to buy their capacity. Something is not right here, guys, on testing. And I will tell you, the current Administration's Chief of Staff got it right in 2020 March, and he said testing is broken, testing is broken, testing is broken. I just say to all of you right now, testing is broken.

Ms. O'Connell, I think the responsibility falls to the ASPR. I wrote the law. If—in the case of CDC, they were the delay to begin with, but to acquire testing, that falls in your lane. And I, for the life of me can't figure out after $82 billion, except for somebody sitting down and saying, well, we just don't need those tests, we don't need to buy them, how you could let Abbott close two lines because there wasn't any business.

These are some of the most premier manufacturers in the world that we have let get out of the mass manufacturing of home test business. If I am wrong, tell me I am. I respect all four of you in a huge way. But I also express my disapproval very quickly and that is what I am doing today. Anything you want to add to that? Ms. O'Connell.

Ms. O'CONNELL. Please. Thank you, Ranking Member Burr. Let me just clarify, of course, that the initial contracts you are speaking of toward the 500 million were the available inventory that these distributors had. These the distributor contracts.

The manufacturer contracts are currently being worked. You will see that capacity come on quickly. We just haven't been able to land the contracts, to draft the contracts as quickly as the distributors, but they are coming.

Senator BURR. My suggestion in the future is that when you guys huddle inside the COVID team, try to get the Administration to refrain from making these proclamations until we have got the product, until we know who we are negotiating with. We are now 3 weeks since the President said we are going to buy 500 million test.

We have 50 million currently contracted. I don't know how long it is going to take to get the rest of the contracts. This is not dissimilar to when we went out and said we are going to booster everybody in America, yet we rolled it out with just people over 60 to start with and then we started moving down. And now we are begging people to get boosted, which is where we should have been on day one because we had the product available.

But listen, you guys have a tough job. And I don't know of anything else Congress can do than try to create the statutory frame-

work that you can work in to do your job, which exists, or provide the funding to allow you to acquire. Those are the only two things we can do other than bitch and gripe when it doesn't happen as quickly as we would like. But Tony, I really respect you and I am sorry you and your family went through what you are going through.

But please understand, we go through that every time we go home with millions of people in North Carolina, millions that believe the bad information that is out there, millions of people that have a loved one in the hospital but there is no monoclonal form to take, millions of people who are unvaccinated, probably wish today they had gotten vaccinated, probably wish they had gotten boosted. But they are now in the ICU and their wife or husband, or daughter is calling us and saying, what do I do?

We are here to support. What you need, tell us. But don't think that we are just going to sit here and print money without a full accountability of where it has gone. And I hope the Secretary is listening to that conversation today. Senator Blunt and I said give us a full audited accounting of the $82 billion and will entertain additional funding for testing. That was 10 days ago.

I am not sure when we are going to get it or if we are going to get it, but it is conditional, and this is the most powerful person on the other side of the Appropriations, and I think she knows I am serious on this one.

There has got to be accountability on the money and the way it is spent. Thank you for being here. Thank you, Madam Chair.

The CHAIR. Thank you. I want to thank, truly thank all of our witnesses today, Dr. Walensky. Dr. Fauci, Dr. Woodcock, Assistant Secretary O'Connell. We all know this is a very difficult, challenging, changing time and you have all been through it for a long time. I think you do understand the frustration.

I am sure you all have it as well as where we are. We all want to find solutions and we stand at your back to be able to provide those. But thank you so much for answering all our questions. This is a really important conversation about the threat of the new COVID variant, or whatever the next one is, and about the path forward for our pandemic response, and we really do appreciate all the work you and all the people in your agencies do.

For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, January 26 at 5.00 p.m.

With that, the Committee does stand adjourned.

QUESTIONS AND ANSWERS

RESPONSE BY ROCHELLE WALENSKY TO QUESTIONS OF SENATOR CASEY, SENATOR HASSAN, SENATOR LUJÀN, SENATOR CASSIDY, SENATOR BRAUN, SENATOR SCOTT, AND SENATOR TUBERVILLE

SENATOR CASEY

Question 1. At the hearing, I asked how the Federal Government is working with vaccine manufacturers to speed the development of a safe and effective vaccine for children under age five. Under-

standing that the Pfizer trial for children 24 months to 5 years old did not meet its endpoint, my follow-up questions are, how did we get here and what's next? Please describe, generally, the following——

Question 1(a). How vaccine developers make decisions about dose size, quantity and spacing in age deescalation trials;

Answer 1. CDC defers to FDA.

Question 2. What type of indicators a vaccine manufacturer might consider when determining whether and how to change the dose size, quantity or spacing if primary endpoints are not met; and

Answer 2. CDC defers to FDA.

Question 3. Whether the emergence of a viral variant could affect the efficacy of a vaccine in children differently than it would affect the efficacy of the same vaccine in adults.

Answer 3. CDC defers to FDA.

Question 4. Furthermore, could you please provide an update on current Federal goals and investments relating to the development of vaccines to protect children under age five from COVID–19, including grants, contracts or other funding awarded to vaccine developers; and what information is currently being provided to vaccine developers regarding current or planned opportunities for collaboration between the Federal Government and vaccine developers, including the extent to which BARDA will conduct TechWatch/CoronaWatch meetings and the extent to which FDA will accept applications for emergency use authorization.

Answer 4. CDC defers to FDA and ASPR.

Question 5. Finally, could you describe current thinking across your agencies regarding the circumstances under which your efforts would expand to include the development of additional or next generation vaccines and therapeutics for COVID–19?

Answer 5. CDC defers to NIH and ASPR.

SENATOR HASSAN

Question 1. Individuals with autoimmune diseases are at higher risk of severe COVID–19 symptoms and death. Additionally, some of the medicines these patients may take can alter vaccine effectiveness. Does the CDC plan to put out guidance regarding the interaction between COVID–19 vaccines and treatments and immunosuppressant medications to help patients with autoimmune diseases and their providers?

Answer 1. Some people with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID–19. CDC's Interim Clinical Considerations for Use of COVID–19 Vaccines includes information for healthcare providers regarding COVID–19 vaccination in moderately or severely immunocompromised people. Immunocompromised people ages 5 years and older should receive a primary COVID–19 vaccine series as soon as possible; for those 18 years and older, mRNA COVID–19 vaccines are preferred over the Janssen COVID–19 Vaccine. The current Food and Drug Administration (FDA) approved or FDA authorized COVID–19 vac-

cines are not live vaccines and therefore can be safely administered to immunocompromised people. Moderately or severely immunocompromised people may not mount a protective immune response after initial vaccination and, furthermore, their protection by primary vaccination may wane over time making them susceptible to severe SARS-CoV–2 infection. The Advisory Committee on Immunization Practices (ACIP) and CDC have made age-specific recommendations for an additional primary dose and a booster dose for this population. Evusheld is a combination of two long-acting monoclonal antibodies that is authorized for emergency use as pre-exposure prophylaxis for persons who are moderately to severely immunocompromised or unable to get vaccinated.

SENATOR LUJÀN

Question 1. Americans are confused about how to best protect themselves and their communities from the spread of COVID. In New Mexico, trusted health messengers such as hospitals are struggling to convey updated guidance to the patients they serve. As new guidance comes out, the burden falls on providers to disseminate this information in a way that reflects the diversity of racial and ethnic, regional, and political identities present in the state of New Mexico. Hospitals, already stretched thin, still have non-urgent, non-symptomatic people showing up because these patients simply do not know where to turn. The American people need clear guidance, presented in a format that leave no doubt as to the official recommendations. What can you do in your role as a public health official to ensure that public health guidance is communicated clearly and effectively?

Answer 1. CDC recognizes that we can always make improvements as an agency and are committed to ensuring that our public health messaging and communication efforts are effective and accessible to providers and patients alike. As the science and our understanding of COVID–19 evolves, we are actively working to disseminate the latest public health data and guidance as quickly as possible. CDC continues to reach out to healthcare providers and has hosted over 50 Clinician Outreach and Communication Activity (COCA) calls and sent over 20 Health Alert Network notices. CDC has connected with numerous partner organizations, working with them to better understand the needs of the people they serve, including organizations serving people at increased risk of serious illness or death from COVID–19. These audience-specific outreach efforts are in addition to providing accessible information via the web, social media, and news media briefings and interviews. Since the emergence of the virus, CDC has worked very closely with state, tribal, local, and territorial (STLT) health departments and public health partner organizations. We have heard that people want to hear from us directly, to that end we have instituted CDC briefings with CDC scientists and subject matter experts in order to convey the latest recommendations to the public. In addition, I have personally conducted over 80 White House press briefings on COVID–19 in just this past year, as part of our engagement efforts.

CDC is working to ensure the agency is communicating across government, the scientific community, and the medical community

in order to provide real-time updates and guidance that are both feasible and realistic to implement. As we strive to move us forward on this path out of the pandemic, we see it as our mission to restore public trust in science.

Question 2. We know that this virus mutates and presents new challenges, that our understanding of the virus continues to grow, and that sometimes new information can alter recommendations or even change the public's understanding of the virus in terms of public health messaging. What lessons have you learned from the most recent guidance change? How can the CDC improve?

Answer 2. Our scientific understanding has changed frequently during this pandemic it has evolved and even with 2 years of data, research, and experience, there are things we do not know or do not understand completely. Despite this, we continue to work to communicate what we know, what we recommend based on what we know, and what steps we are taking to learn more.

Because science is continually evolving, we are committed to bringing that information to the public in real time. That means we must update our guidance to ensure that recommendations are understandable and actionable so that people can implement them.

When we communicate guidance during a dynamic, evolving public health situation, we need to be clear that our guidance is based on our best understanding at the time and that, as we learn more, our recommendations may change.

Question 3. Studies have found that minds are most changed during personal conversations with trusted sources like clinicians or loved ones. Among the CDC's recommended strategies are developing a corps of vaccine Ambassadors. How do we scale up our ability to engage in conversations in a supportive, empathetic, and non-judgmental way?

Answer 3. Vaccinate with Confidence is the strategic framework of the CDC to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. Strong confidence in COVID–19 vaccines within communities leads to more adults, adolescents, and children getting vaccinated. High vaccine coverage rates reduce the number of COVID–19 illnesses, hospitalizations, and deaths. One of CDC's strategies within the Vaccinate with Confidence framework focuses on engaging communities and individuals in a sustainable, equitable, and inclusive way—using two-way communication to listen, build trust, and increase collaboration. CDC works with health departments and national partners to engage communities around vaccine confidence and service delivery strategies to meet community needs. Also, CDC collaborates with trusted messengers within the community to tailor and share culturally relevant messages and materials. CDC provides information on how to tailor COVID–19 vaccine information to help those, including vaccine Ambassadors, understand their audience and create messages that resonate.

Question 4. How can a corps of vaccine Ambassadors combat public health misinformation that proliferates on social media?

Answer 4. Vaccine Ambassadors play a key role for public health in validating the credibility of messages and effectively delivering

messages and strategies within their community. They can address mis-and disinformation by working with jurisdictional communications staff to take questions on social media, share accurate information, and post shareable graphics and content. Many of the tools are available on CDC and HHS websites.

Question 5. How can we be prepared to counteract misinformation and vaccine hesitancy early in future pandemics or other public health emergencies that require vaccinations?

Answer 5. Monitoring misinformation through social listening is a key strategy to quickly identify and address misinformation about COVID–19 vaccines. This includes identifying trending inaccurate information, which, if not addressed, can lead to the spread of misinformation.

Catching misinformation early can help develop and get out accurate information to address concerns and questions ahead of time and close information gaps before they are filled with inaccurate information.

CDC created the Insights Unit to use an evidence-based approach, leverage socio-behavioral and epidemiological insights, and execute a plan to reduce and prevent the spread and harm of misinformation and promote accurate, credible information. Limited tools exist to address misinformation and traditional risk communication and social media outreach approaches are not sufficient because they are inherently reactive approaches.

Identifying misinformation before it spreads and developing programmatic and communications approaches to address it is critical to prevent and manage misinformation in future pandemics and public health emergencies.

The Insights Unit generates the COVID–19 State of Vaccine Confidence Insights Reports which identify the public's questions, concerns, frustrations and circulating misinformation. The results are used to identify how CDC and partners can take action against the information gaps and misinformation.

Misinformation is not unique to COVID–19, and as technology makes communication easier, misinformation will continue to be a problem. The lessons learned from the COVID–19 pandemic can be expanded to other disease areas of vaccine hesitancy.

Question 6. In thinking about education and messaging, what changes would you all advise for these same leaders on the media platforms to use to make vaccination messages resonate with those who may still be hesitant about taking the COVID–19 vaccine?

Answer 6. Vaccinate with Confidence is the strategic framework of the CDC to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. Strong confidence in COVID–19 vaccines within communities leads to more adults, adolescents, and children getting vaccinated—which leads to fewer COVID–19 illnesses, hospitalizations, and deaths.

CDC's Vaccinate with Confidence strategy is built on three pillars:

Answer 1. Build trust: Share clear, complete, and accurate messages about COVID–19 vaccines, and take visible actions to build trust in the vaccine, the vaccinator, and the vaccination system.

Answer 2. Empower healthcare personnel: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients.

Answer 3. Engage communities and individuals: Engage communities in a sustainable, equitable, and inclusive way-using two-way communication to listen, build trust, and increase collaboration.

Answer 4. CDC is working in coordination with national, state, and local governmental and non-governmental partners using strategies to build trust in the vaccine, the vaccinator, and the vaccination system.

SENATOR CASSIDY

Question 1. The U.S. is in the middle of flu season, which has the potential to add additional burden to already-stressed health care systems due to the ongoing pandemic.

- What steps is HHS taking to ensure the availability of appropriate diagnostics and treatment options to address the potential dual threats of COVID and influenza, including through shoring up the Strategic National Stockpile?

Answer 1. CDC defers to ASPR.

- Beyond testing and preventative steps like vaccination, what steps has HHS taken to proactively treat vulnerable populations like the elderly or others who may be at risk for and are likely to spread communicable diseases like COVID and the flu?

Answer 1(a) The COVID–19 pandemic has reinforced the importance of healthcare infection prevention and control in keeping Americans-especially our most vulnerable populations in nursing homes and hospitals safe and healthy. CDC has worked with the Healthcare Infection Control Practices Advisory Committee (HICPAC), a Federal advisory committee appointed to provide advice and guidance to HHS and CDC regarding the practice of infection prevention and control (IPC) and strategies for surveillance, prevention, and control of healthcare-associated infections, antimicrobial resistance and related events in United States healthcare settings, to develop general guidelines for preventing transmission of infectious diseases, including respiratory diseases like influenza.

In addition to those guidelines developed with HICPAC, CDC works closely with the Centers for Medicare & Medicaid Services and the long-term care (LTC) community to support implementation of best practices and provides tools and resources to protect residents and staff from infectious diseases, including COVID–19 and influenza. In order to monitor and track infections including healthcare-associated infections (HAI) and COVID–19 activities in LTC settings, CDC has utilized the National Healthcare Safety Network (NHSN) LTC Facilities Component (LTCFC) to track infections and infection prevention process measures and also to identify problems and improve care. This includes tracking healthcare personnel (HCP) influenza vaccination status, COVID–19 vaccination status for both residents and HCP. Additionally, CDC funds state HAI programs that work directly with LTC facili-

ties to keep residents and staff safe. It was the relationships that these programs had built over many years that allowed for quick responses and support to many outbreaks in LTCFs.

CDC has also developed educational materials for LTCFs, including trainings such as the National Nursing Home Training Series and the Nursing Home Infection Preventionist Training Course. While the use of CDC's Infection Control Assessment and Response Program (ICAR) infection control assessment tools has been recently used mostly to improve IPC activities as part of the COVID–19 response, these tools were developed for use in assessing IPC programs at healthcare facilities for any infectious disease. CDC has developed setting specific guidance and assessment tools, including for long term care facilities, in both English and Spanish.

CDC is using American Rescue Plan (ARP) funding to expand efforts that protect Americans from COVID–19 infections and other emerging infectious diseases across healthcare settings, specifically long-term care facilities and nursing homes. For example, over the next 3 years, CDC will issue awards totaling $1.25 billion to 64 state, local, and territorial health departments to support this work. Initial awards totaling $885 million were made in October 2021 to 64 health department jurisdictions, including $500 million to support state-based COVID–19 nursing home and other long-term care strike teams. The state-based nursing home and other long-term care strike teams will allow state, local, and territorial jurisdictions to provide surge capacity to facilities for clinical services; address staffing shortages at facilities; and strengthen infection prevention and control activities to prevent, detect, and contain outbreaks of COVID–19, including support for COVID–19 vaccine boosters. This builds on previous CDC investments in health departments to improve patient safety through the Antibiotic Resistance (AR) Solutions Initiative and Prevention and Public Health Fund established by the Patient Protection and Affordable Care Act of 2010 (ACA).

HHS is working with other Federal agencies, health departments, healthcare providers, professional organizations, and public health partners to increase vaccine uptake and promote the use of boosters in residents and staff in LTCFs. The Federal Government is committed to ensuring that residents and staff in these facilities have access to COVID–19 vaccines to receive primary series and booster shots. All LTC settings that request assistance accessing COVID–19 vaccines for their residents and staff will receive the support they need. Many LTC providers have already identified strategies and partnerships to obtain and administer COVID–19 vaccines for residents and staff. These include working with established LTC partners and retail pharmacy partners and coordinating with state and local health departments.

Question 2. Health systems in Louisiana have been overwhelmed by successive waves of COVID variants. These health systems could have been better prepared for these growing variant trends if they had access to better national and regional dashboards monitoring variants of concern. What are you all at the CDC, FDA, NIH, and HHS doing to make sure health providers are armed with the best data to respond appropriately to the next COVID var-

iant or pandemic? Second, how are you all harnessing the speed and innovation of the private sector to help predict, prevent, and mitigate future COVID–19 variants or other pathogens of concern?

Answer 2. CDC is building on lessons learned from responding to COVID–19 variants to determine how to gather and report data on variants of concern, particularly the application of genomic sequencing. CDC is evaluating sources from the data pipeline to determine which prove most useful in responding to an emerging variant of concern. These findings will inform response to future variants.

National SARS-CoV–2 Strain Surveillance (NS3) is implemented in partnership with state and local public health laboratories and the Association of Public Health Laboratories (APHL). State public health laboratories provide to CDC, on a weekly basis, confirmed, de-identified, diagnostic specimens that, ideally, represent a variety of demographic and clinical characteristics and geographic locations. The program provides a comprehensive and population-based surveillance system for national monitoring to track virus evolution over time and identify emerging variants that may affect the performance of diagnostics, therapeutics, or vaccines, or that impact the transmissibility of SARS-CoV–2 or severity of COVID–19.

In addition to the NS3 program, CDC contracted with large commercial diagnostic laboratories to sequence specimens from across the United States. These contracts provide consistent access to SARS-CoV–2 sequence data across the country to supplement existing public health sequencing efforts. The proportion of variants in a population are calculated nationally, by HHS region, and by jurisdiction and are available on CDC's COVID Data Tracker.

SENATOR BRAUN

Question 1. Over 62 percent of Americans are fully vaccinated against COVID–19. Yet, the rate of positive COVID–19 cases reported in the U.S. has increased six fold from early December to early January. The spike in cases is likely due to the contagious nature of the variant.

- Why is the CDC not tracking the number of individuals who have been diagnosed with a breakthrough infections after having received a COVID–19 vaccine?

Answer 1. As part of ongoing efforts to understand how COVID–19 vaccines are working, CDC monitors rates of COVID–19 cases, hospitalizations, and deaths in vaccinated (breakthroughs) and unvaccinated persons. CDC now monitors rates of COVID–19 cases and deaths using data from jurisdictions that routinely link case surveillance data with records from immunization information systems (IIS) to identify the vaccination status of all reported COVID–19 cases. This approach provides more complete information on breakthrough cases and a better understanding of the impact of vaccines than was available previously. These data are updated monthly on the COVID Data Tracker.

As of December 2021, 27 jurisdictions, representing all 10 HHS regions and more than 50 percent of the United States, can link their case, death, and vaccine data and are voluntarily sharing

these data with CDC. Jurisdictions report these breakthrough data to CDC in multiple ways. Interoperable information systems that enable linkage of data is a core goal of CDC's Data Modernization Initiative.

CDC uses COVID-NET, a population-based surveillance system of COVID–19-associated hospitalizations from a network of 250 acute-care hospitals in 14 states, to monitor rates of COVID–19-associated hospitalizations by vaccination status. These data are also updated monthly and shared with the public on the COVID Data Tracker. Previous data on breakthrough cases were reported in an MMWR that summarized data from January—April, 2021. Follow-up analysis of breakthrough surveillance data on hospitalizations and deaths reported during January-September 2021 has shown that characteristics of people with severe COVID–19 following vaccination were similar to people at risk for severe COVID–19 in general, including older age. Notably, historical breakthrough data were reported as case counts which was useful during initial vaccine introduction, but challenging to interpret because of limited completeness and representativeness, as well as a lack of denominator data for calculating rates and making direct comparisons with unvaccinated persons to contextualize trends.

Additionally of note, the Federal Government lacks the authority to compel reporting of key hospital and case data elements, including vaccination status. While robust systems have been set up to capture and analyze voluntary reporting of breakthrough cases as described above, significant gaps remain in the data that is needed to detect adverse events and monitor vaccine effectiveness for COVID–19. This has been particularly challenging for real-world observational vaccine effectiveness studies because it is not possible to identify a cohort of individuals that we know are unvaccinated. It is challenging to directly compare vaccinated individuals and unvaccinated individuals. Therefore, Federal authority to require reporting of public health data, such as vaccination status associated with case and hospital data, would provide a more complete national picture of the COVID–19 outbreak and allow for better tracking of breakthrough infections. A Federal public health authority would benefit all levels of public health and provide better data to inform decisionmakers.

SENATOR SCOTT

Omicron Status

Question 1. Dr. Walensky—Of omicron hospitalizations, what percentage are ICU cases and what percentage are on ventilators? How do those percentages compare to the previous 2 variants?

Answer 1. CDC is currently working to determine this information and expects to publish an upcoming paper in CDC's Morbidity and Mortality Weekly Report.

Question 1(a). Doesn't this and other available data suggest that the omicron variant is less severe than the previous 2 variants?

Answer 1(a) Omicron infection generally causes less severe disease than infection with prior variants. Preliminary data suggest that Omicron may cause more mild disease, although some people

may still have severe disease, need hospitalization, and could die from the infection with this variant. Even if only a small percentage of people with Omicron infection need hospitalization, the large volume of cases could overwhelm the healthcare system.

Question 2. Dr. Walensky—What is the difference between someone hospitalized with COVID and someone hospitalized because of COVID?

Answer 2. Some data sources of hospitalization allow us to distinguish when patients are hospitalized with COVID, and when they are hospitalized for (or because) of COVID. However, making this distinction with the data may not always be clear. We are currently exploring the available data, including primary and secondary diagnoses codes, as well as data on medications such as remdesivir and dexamethasone, to determine how to make this distinction.

In the Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET), we have the ability to examine primary reason for admission on a sample of hospitalized cases. In an analysis (on a preprint server and not yet peer-reviewed) among adults aged 18 years who were hospitalized with laboratory-confirmed SARS-CoV–2 infection from January-July 2021, 716 (11.7 percent) of 6,115 hospitalizations had a primary reason for admission other than COVID–19 related illness. In a recent study of children aged 18 years hospitalized with laboratory-confirmed SARS-CoV–2 infection during July 1-December 1, 2021, 81.3 percent of 1,703 COVID–19-associated hospitalizations in children were likely related to COVID–19. This proportion is similar to a prior published analysis using the same data source that found children aged 18 years hospitalized with laboratory-confirmed SARS-CoV–2 infection during March 2020-May 2021, approximately 718 (23 percent) of 3,106 had a primary reason for admission of Ob/labor and delivery, inpatient surgery or procedures, psychiatric admission needing acute medical care, trauma or had "other" reason for admission with no symptoms of COVID–19 on admission. The remaining 77 percent had a primary reason for admission likely related to COVID–19.

We have historically avoided making strong claims that these hospitalizations are not related to COVID–19, as COVID-NET was designed to conduct rapid surveillance of COVID–19-associated hospitalizations and not to carefully adjudicate the reason for admission for each hospitalization. Determining the primary reason for admission to a hospital can be complex, and multiple factors can influence the decision to seek care or be admitted, including COVID–19 status. Levels of community incidence of COVID–19 and population vaccination coverage can also have an impact. Additionally, patients who test positive for SARS-CoV–2 infection may develop symptomatic illness after admission, which may influence the course of their hospitalization, and this would not necessarily be captured in the patient's primary reason for admission.

Question 2(a)1. Is the data currently being collected sophisticated enough to differentiate?

Answer 2(a) CDC Response: Data used to examine this question do not include distinguishing details needed to differentiate be-

tween patients being hospitalized with COVID–19 or because of COVID–19. To examine this question other accompanying information from the discharge, claim or electronic health record must be leveraged. CDC continues to examine data from multiple hospitalization data sources, to better understand trends in COVID–19 related hospitalizations.

Question 2(b)1. How long does it take to publish this differential?

Answer 2(b) CDC Response: Data available for hospitalizations come from multiple sources; some of which cannot distinguish "with" and "for". Analysis of the various datasets is ongoing.

The process of identifying claims where hospitalization occurred "with" COVID–19 is not readily available or apparent through query of available data. Data are reported by the process of utilizing electronic health record data to identify an incidental COVID–19 case is complex.

Question 2(c). Given continuous updates to guidance, is this lag in reporting problematic when crafting guidance that is commensurate with the actual risk posed by a variant of concern?

Answer 2(c) CDC Response: CDC guidance is based on the best available data at the time. CDC uses a combination of available sources including hospital data and epidemiological studies to inform guidance during fluctuating conditions of a response. Prevalent Hospitalizations of Patients with Confirmed COVID–19 are published on COVID Data Tracker within a 2–3-day lag. CDC has also published Disease Severity Among Hospitalized Patients on COVID Data Tracker. The disease severity metrics are the percentage of hospitalized COVID–19 patients who were admitted to the intensive care unit (ICU), received invasive mechanical ventilation (IMV), or died. These data, from three healthcare data sources, show downward trends in ICU admission, invasive mechanical ventilation, and mortality among hospitalized patients over the course of the pandemic.

Testing

Question 1. Dr. Walensky—Can T-cell testing be used to measure the U.S.' progress toward herd immunity?

Answer 1. CDC defers to FDA.

- Can T-cell testing complement antibody testing to inform efforts against COVID–19 variants that might evade vaccines or allow for reinfection?

Answer 1(a) CDC defers to FDA.

- If so, how can we ensure physicians have access to tools-like T-cell testing-they need to make appropriate clinical decisions in treating patients?

Answer 1(b) CDC defers to FDA.

Vaccinations & Treatments

Question 1. Dr. Walensky—Can monoclonal antibody treatments be used to prevent COVID infection?

Answer 1. CDC Response: Anti-SARS-CoV–2 monoclonal antibodies (mAbs) have shown evidence of clinical benefit in treating

SARS-CoV–2 infection, however, some have reduced effectiveness against Omicron. Some anti-SARS-CoV–2 mAbs have shown evidence of clinical benefit as post-exposure prophylaxis after a potential exposure to SARS-CoV–2, like in a household setting or during SARS-CoV–2 outbreaks in skilled nursing or other long term care facilities. Other anti-SARS-CoV–2 mAbs have shown evidence of reducing the risk of infection when used as pre-exposure prophylaxis. The FDA has issued an emergency use authorization for tixagevimab plus cilgavimab (Evusheld), an investigational medicine used in adults and children ages 12 years and older. Evusheld consists of 2 monoclonal antibodies provided together to help prevent infection with the virus that causes COVID–19. A healthcare provider gives Evusheld as two separate consecutive intramuscular (IM) injections at a doctor's office or healthcare facility. If an individual is moderately or severely immunocompromised or severely allergic to COVID–19 vaccines, they may be eligible for Evusheld.

School Closures

Question 1. When discussing children and the omicron case surge on MSNBC, President Biden's chief medical advisor, Dr. Fauci, pointed out that pediatric hospitalizations are much lower on a percentage basis than adults, especially when compared with the elderly. He went on to state: "But the other important thing is that if you look at the children who are hospitalized, many of them are hospitalized with COVID as opposed to because of COVID. And what we mean by that—if a child goes into the hospital, they automatically get tested for COVID and they get counted as a COVID-hospitalized individual when, in fact, they may go in for a broken leg or appendicitis or something like that. So it's over-counting the number of children who are, quote, 'hospitalized with COVID,' as opposed to because of COVID."

Question 1(a). Dr. Walensky—Do you agree with Dr. Fauci's assessment?

Answer 1. In the Coronavirus Disease 2019-Associated Hospitalization Surveillance Network (COVID-NET), we have the ability to examine primary reason for admission on a sample of hospitalized cases.

In an analysis (on a preprint server and not yet peer-reviewed) among adults aged 18 years who were hospitalized with laboratory-confirmed SARS-CoV–2 infection from January-July 2021, 716 (11.7 percent) of 6,115 hospitalizations had a primary reason for admission other than COVID–19 related illness. In a recent study of children aged 18 years hospitalized with laboratory-confirmed SARS-CoV–2 infection during July 1-December 1, 2021, 81.3 percent of 1,703 COVID–19-associated hospitalizations in children were likely related to COVID–19. This proportion is similar to a prior published analysis using the same data source that found children aged 18 years hospitalized with laboratory-confirmed SARS-CoV–2 infection during March 2020-May 2021, approximately 718 (23 percent) of 3,106 had a primary reason for admission of Ob/labor and delivery, inpatient surgery or procedures, psychiatric admission needing acute medical care, trauma or had "other" reason for admission with no symptoms of COVID–19 on

admission. The remaining 77 percent had a primary reason for admission likely related to COVID–19.

We have historically avoided making strong claims that these hospitalizations are not related to COVID–19, as COVID-NET was designed to conduct rapid surveillance of COVID–19-associated hospitalizations and not to carefully adjudicate the reason for admission for each hospitalization. Determining the primary reason for admission to a hospital can be complex, and multiple factors can influence the decision to seek care or be admitted, including COVID–19 status. Levels of community incidence of COVID–19 and population vaccination coverage can also have an impact. Additionally, patients who test positive for SARS-CoV–2 infection may develop symptomatic illness after admission, which may influence the course of their hospitalization, and this would not necessarily be captured in the patient's primary reason for admission.

Question 2. CDC published in its March 19, 2021 Morbidity and Mortality Weekly Report that "changes in modes of instruction have presented psychosocial stressors to children and parents that can increase risks to mental health and well-being and might exacerbate educational and health disparities."

Question 2(a). Dr. Walensky—Does virtual learning present more risks than in-person learning related to child and parental mental and emotional health in addition to healthy behaviors like physical activity which can impact individuals over a lifespan?

Answer 2. Findings from a nationwide study of 1,290 parents of children ages 5–12 conducted from October 8-November 13, 2020 and published in March 19, 2021 MMWR "Association of Children's Mode of School Instruction with Child and Parent Experiences and Well-Being During the COVID–19 Pandemic—COVID Experiences Survey, United States, October 8-November 13, 2020", suggest children not receiving full-time, in-person instruction and their parents might experience increased risk for negative mental/emotional and physical health outcomes.

Specifically:

- Parents of children receiving virtual-only or combined instruction more frequently reported that their child's mental/emotional health worsened during the pandemic and that their time outside, time in-person with friends, and physical activity decreased.
- Parents of children receiving virtual-only instruction more frequently reported their own distress, difficulty sleeping, loss of work, concern about job stability, conflict between work and providing childcare, and childcare challenges than did parents whose children were receiving in-person only instruction.
- Children receiving in-person instruction and their parents reported the lowest prevalence of negative indicators of child and parent well-being.
- Parents whose children attended school in-person only were less likely to report challenges with employment and childcare.

Answer 1. CDC recognizes the need for a comprehensive, coordinated, multidisciplinary approach to promoting student mental health and well-being, especially given the potentially broad impact of school closures on student mental health.

Schools have the infrastructure to provide critical support to youth and families, including opportunities to engage in academic, social, mental health, and physical health services, and mental health promotion activities, all of which can buffer stress and lessen negative outcomes. Many students and staff have been adversely impacted by the pandemic. While mental health services are necessary, this alone is not sufficient to promote mental health and well-being.

Question 2. We have witnessed the damaging impacts school closures have had on student achievement, mental health, and even physical health. I believe parents, in consultation with their child's doctor, not teachers' unions know what's best for their child.

- Dr. Walensky—Should teachers' unions have a role in crafting health guidance?

Question 2(a). Should teachers' unions be pushing policies that directly contradict CDC guidance on in-person learning and have damaging impacts on child development?

Answer 2. When developing guidance and recommendations, CDC often engages with organizations and groups that are impacted. The agency does so to ensure recommendations are comprehensive, address the stakeholder needs and concerns, and are feasible to implement. These informative and helpful interactions result in beneficial feedback for final revisions to promote clarity, completeness, and usability.

For the development of the school guidance, CDC had close engagement with the U.S. Department of Education and sought input from a variety of organizations and stakeholders-including public health and education organizations to discuss experiences, challenges, and lessons learned in implementing prevention strategies for infectious diseases in K–12 schools

CDC Guidance

Question 1. The CDC in 2018 published a Crisis and Emergency Risk Communications pamphlet which stresses the need to "be first, be right, be credible." Unfortunately, we've seen anything but. We've seen statements made anonymously or on background. We've seen pronouncements made in anger and frustration regarding factors outside of the Administration's control. We need timely, accurate, clear guidance instead of mixed messages and paternalistic attitudes.

- Dr. Walensky—How is CDC working to restore and broaden public trust?

Answer 1. CDC's mission is to protect the American public from threats to their health. The American public should know that CDC is comprised of dedicated and compassionate scientific professionals who are working long hours every day to serve and protect them. At CDC, we are striving to advance science and communicate

our findings and recommendations in the least confusing and most effective manner.

The dedicated experts at CDC have been responding to this pandemic since the early days of 2020 and have done their best to communicate with the American people openly and clearly about this public health emergency. When we haven't met our own standards for clear and open communication, we've worked to provide additional information quickly. And when we have heard from scientific colleagues, policymakers, and the public that we can do better, we have listened and made changes. President Biden's commitment to leading with science and truth and treating each other with respect and kindness can help CDC regain its reputation and credibility, but we have a lot of ground to make up and restoring public trust is going to take time.

The virus that causes COVID–19 has challenged and humbled us, teaching us even more about modern threats to the public's health-like global interconnectedness and the spread of misinformation. These threats compound the risks posed by novel infectious diseases. And while everyone has worked as hard as they can with the best of intentions, there have been missteps and the spotlight has been shone on the weaknesses in our country's public health system. CDC alone cannot strengthen this system, prepare for future emergencies, and rebuild trust in public health. Our success in doing these things-which are critical to our health and safety as a nation-depends on state and local public health, governments, businesses, communities, and many others working together.

Question 2T1. What is the Agency doing to address a process that has, so far, produced confusing and sometimes conflicting guidance that appears to be consistently behind the curve instead of ahead of it?

Answer 2. As the science and our understanding of COVID–19 evolves, CDC is actively working to disseminate the latest public health data and guidance as quickly as possible. To provide unified guidance, CDC is collaborating across government and across the scientific and medical community to stay ahead of the virus, stop the spread of infection, keep people out of the hospital, and save as many lives as possible.

SENATOR TUBERVILLE

COVID and Vaccinations

Question 1. In March 2021, you stated "vaccinated people do not carry the virus, don't get sick." Do you stand by this statement?

Answer 1. The immunity provided by vaccine and prior infection are both high but not complete. Multiple studies have shown that antibody titers correlate with protection at a population level, but protective titers at the individual level remain unknown. As described in greater detail in CDC's COVID–19 Vaccine and Vaccination Science Brief, studies have demonstrated waning of both antibody titers and vaccine effectiveness against infection over time, especially among older populations. Decreased vaccine effectiveness may reflect a combination of waning antibody titers and decreased

neutralizing capacity in the setting of widespread circulation of variants with partial immune escape.

Question 2. In July 2021, you stated "99.5 percent of deaths from COVID–19 in the United States were in unvaccinated people" and Dr. Fauci also stated 99.2 percent of deaths in June were unvaccinated. Is this still accurate?

Answer 2. As part of ongoing efforts to understand how COVID–19 vaccines are working, CDC monitors rates of COVID–19 cases, hospitalizations, and deaths in vaccinated (breakthroughs) and unvaccinated persons. CDC monitors rates of COVID–19 cases and deaths using data from 30 jurisdictions representing all 10 HHS regions and 70 percent of the U.S. population that routinely link case surveillance data with records from immunization information systems (IIS) and vital registration to identify the vaccination status of all reported COVID–19 cases and deaths. This approach provides more complete information on breakthrough cases and deaths and a better understanding of the impact of vaccines than was available previously. These data are updated monthly on the COVID Data Tracker.

CDC also uses COVID-NET, a population-based surveillance system of COVID–19-associated hospitalizations from a network of 250 acute-care hospitals in 14 states, to monitor rates of COVID–19-associated hospitalizations by vaccination status. These data are also updated monthly and shared with the public on the COVID Data Tracker.

While people had become accustomed to following counts of breakthrough infections, the public health impact of case counts is difficult to interpret without knowing the underlying burden of community transmission or the proportion of the population that has been vaccinated. Reporting rates based on comprehensive capture of information on vaccination status provides more accurate information about breakthrough infections, including patterns over time and across age groups, vaccine types, and receipt of booster doses and direct comparisons with unvaccinated persons to contextualize trends.

An MMWR published in September 2021 demonstrated that incidence rate ratios are more stable and directly related to vaccine effectiveness (VE), while the percentage of vaccinated people among COVID–19 cases rises with either increasing vaccination coverage or decreasing VE, complicating interpretation of this metric. Interpretation of the proportion of vaccinated people among hospitalized and fatal cases may be further complicated by older people and people with comorbidities having higher risks of severe COVID–19 outcomes and higher vaccination coverage.

Question 3. Dr. Walensky, you have stated this is a pandemic of the unvaccinated. Is that still accurate?

Answer 3. Vaccines greatly reduce the risk of the most severe outcomes for those who are sickened with COVID–19, including the risk of severe illness and death among people who are fully vaccinated. Vaccine effectiveness against hospitalizations has remained relatively high over time, although it tends to be slightly lower for der adults d for people with weakened immune systems.

Question 4. Many countries as well as cities like San Francisco and New York City have high vaccination rates and mask and vaccine mandates but have recorded some of the highest levels of COVID–19 infections ever in December 2021 and January 2022.

Question 4(a). Why are these cities experiencing COVID–19 outbreaks?

Answer 4. The Omicron variant was first clinically identified in the United States on December 1, 2021 and spread rapidly. By late December, it became the predominant strain, and by mid-January it represented 99.5 percent of sequenced specimens in the United States (1). The Omicron variant has been shown to be more transmissible and less virulent than previously circulating variants.

Question 4(b). Please provide data to confirm that mask and vaccine mandates are effective at reducing the spread of COVID–19.

Answer 4(b) COVID–19 vaccination helps protect adults and children ages 5 years and older from getting sick or severely ill with COVID–19 and helps protect those around them. CDC tracks state-issued vaccination requirements by requirement type (e.g., a vaccination requirement with no test-out option versus those that allow recurring testing in lieu of vaccination), exemption types allowed, documentation required to apply for an exemption, and groups to which the vaccination requirement applies (e.g., school workers, government workers, healthcare workers, as well as others).

Vaccination requirements have increased vaccination rates by 20+ percentage points to over 90 percent in many organizations. An analysis of health care systems, educational institutions, public-sector agencies, and private businesses shows that organizations with vaccination requirements have seen their vaccination rates increase by more than 20 percent and have routinely seen their share of fully vaccinated workers rise above 90 percent. That is substantially higher than broader working-age vaccination rates for Americans aged 18 to 64.

Question 5. What percentage of Americans have had COVID–19?

Answer 5. As of January 11, 2022, more than 62.6 million cases of COVID–19 have been reported in the U.S. However, case surveillance data do not represent the true burden of COVID–19 in the United States. The number of cases also includes reinfections and therefore does not equal the number of people who have had COVID–19. Many people infected, even if symptomatic, do not seek medical care or get tested. In these situations, data cannot be extracted from medical records. Data can also be limited if people are unavailable or unwilling to provide information.

Most of the case reports captured by health departments are based on laboratory reports that might contain limited patient information. Because of the volume of cases, most health departments are unable to obtain additional information on every case. As a result, many case reports are missing data on patient demographics, symptoms, underlying health conditions, characteristics of hospitalizations such as ventilator use, and other factors such as

travel history. Because of missing data, analyses of these data elements are likely an underestimate of the true occurrence.

Question 6. What percentage of children under 18 have had COVID–19?

Answer 6. As of January 11, 2022, there are 8,968,092 cumulative COVID–19 cases among children aged 0–17 years, as shown on the CDC COVID Data Tracker Note that this number does not represent the number of unique individuals with infection as it also includes reinfections. Case based surveillance of SARS-COV–2 also likely underestimates the prevalence of infections.

Question 7. For the most recent week, what percentage of COVID–19 infections are breakthrough cases in vaccinated and boosted individuals?

Answer 7. As part of ongoing efforts to understand how COVID–19 vaccines are working, CDC monitors rates of COVID–19 cases, hospitalizations, and deaths in unvaccinated and vaccinated persons, including people who received booster doses. Data are published monthly on CDC's COVID Data Tracker. Unvaccinated adults had 5 times the risk of testing positive for COVID–19 in December 2021, compared to fully vaccinated adults with additional or booster doses. Although changes occurred in December related to the emergence of the Omicron variant, monthly rate ratios are more stable than weekly and are therefore preferred for monitoring.

Question 8. For the most recent week, what percentage of hospitalizations and deaths are vaccinated/boosted individuals?

Answer 8. As part of ongoing efforts to understand how COVID–19 vaccines are working, CDC monitors rates of COVID–19 cases, hospitalizations, and deaths in unvaccinated and vaccinated persons, including people who received booster doses. On a monthly basis, CDC publishes rates of hospitalizations and deaths by vaccination status on COVID Data Tracker. During December 2021, unvaccinated adults had 41 times the risk of dying from COVID–19-associated death compared to fully vaccinated persons with additional or booster doses. COVID–19-associated hospitalizations were 45 times higher in unvaccinated adults ages 50–64 years and 51 time higher in unvaccinated adults ages 65 years and older, compared with fully vaccinated persons with additional or booster doses in each age group during December 2021.

Question 9. Has the Federal response to COVID–19 been successful?

- (a) Please explain.
- (b) If not, please explain what should have been done differently.

Answer 9. As of January 2022, more than 900,000 people have died in this country alone from COVID–19. Others have been sickened, lost time with their family and loved ones, missed work and school, and developed post-COVID conditions. These losses are an incalculable tragedy, for every person who has personally experienced them and for our country and our world.

The entire Federal Government is committed to preventing as many deaths as we can while minimizing the negative effects COVID–19 has on the health and well-being of our society. We have developed safe, effective vaccines and administered more than 545 million doses as of January 2022. The Federal response has developed treatments for COVID–19 and are working to ensure everyone, particularly those at highest risk of severe illness, has access to these treatments. We have enhanced existing public health data and surveillance systems and stood up new ones to monitor the spread of this virus, so that we can more quickly detect and respond to case surges, increased healthcare system burden, and the emergence of new variants. We've worked to reopen schools safely and to keep them open because schools are so critical to the well-being of children, families, and communities. Most recently, we have further scaled up testing capacity, making millions of at-home self-tests available to America households free of charge, and we've worked with pharmacy and health center partners to distribute free masks across the country.

Question 10. Will you commit to doing a cost-benefit analysis of the COVID–19 response?

Answer 10. An effective public health response requires global, Federal, state, territorial, tribal, and local public health partners to be independently strong, yet closely coordinated. This pandemic has continued to reinforce how interconnected we all are and why it is critical to support surveillance and response capacity abroad, as we make public health investments at home.

I will continue to prioritize support for the improvement of core public health capabilities across public health partners through flexible and consistent funding to support surveillance capabilities, data modernization, laboratory capacity, and workforce development.

Question 11. Please provide specific examples where your agency has utilized real world evidence in regards to COVID–19 or treatments for COVID–19.

Answer 11. The clinical spectrum of SARS-CoV–2 infection includes asymptomatic or pre-symptomatic infection and mild, moderate, severe, and critical illness. CDC provides considerations for healthcare providers regarding the clinical management and treatment of COVID–19 stratified by whether the patient has mild or moderate illness that often can be managed in the outpatient setting, or severe or critical illness that requires hospitalization. CDC recommends clinicians refer to the recommendations in the National Institutes of Health (NIH) COVID–19 Treatment Guidelines, recommendations and information contained within FDA websites and EUAs for treatment, and the Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID–19. These recommendations and those from CDC are based on scientific evidence and expert opinion and are regularly updated as more data become available. CDC defers additional questions on treatments available to FDA and NIH.

Question 12. Do you believe schools and universities should be requiring students to be vaccinated and boosted in order to be enrolled or attend school?

Answer 12. Ensuring students can safely attend school in-person is a priority and being up to date on vaccines is the most effective way to do so. CDC is working with state public health partners to reach school districts and universities across the country to continue to demonstrate the importance of implementing layered prevention strategies in schools, including vaccination and screening testing.

Vaccine Adverse Event Reporting System (VAERS)

Question 1. It's been reported by some virologists and scientists that this year, around 170 people died from taking the flu vaccine. The Vaccine Adverse Event Reporting System (VAERS) reports that the number of people dying after taking the COVID vaccine is actually in the thousands—maybe as many as 20,000 people. I understand that VAERS reports deaths "after taking" the vaccine as opposed to "from" the vaccine, however, these numbers are startling.

Question 1(a) What do we know about how many people might have died as a direct relation to taking the COVID vaccine?

Answer 1. CDC scientists have conducted detailed reviews of Thrombosis with thrombocytopenia syndrome (TTS) cases following receipt of the J&J/Janssen COVID–19 vaccine and have identified nine deaths causally associated with J&J/Janssen COVID–19 vaccination. CDC and FDA continue to review deaths following COVID–19 vaccination reported to VAERS—including death certificates, autopsy reports, and available medical records—and provide updated information to healthcare providers and the public as it becomes available. With the exception of the nine deaths from TTS following the J&J Janssen COVID–19 vaccine, there is no evidence to suggest that COVID–19 vaccines are causing or contributing to deaths. In fact, CDC published an analysis that showed that during December 2020-July 2021, COVID–19 vaccine recipients had lower rates of non-COVID–19 mortality than did unvaccinated persons after adjusting for age, sex, race and ethnicity, and study site: *(https://www.cdc.gov/mmwr/volumes/70/wr/mm7043e2.htm)*.

Reports of death after COVID–19 vaccination are rare. FDA requires healthcare providers to report any death after COVID–19 vaccination to VAERS, even if it is unclear whether the vaccine was the cause. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. More than 539 million doses of COVID–19 vaccines were administered in the United States from December 14, 2020, through December 14, 2021. During this time, VAERS received 10,688 preliminary reports of death (0.0022 percent) among people who received a COVID–19 vaccine.

Question 1(b) Why does VAERS report data this way?

Answer 1(b) CDC Response: VAERS serves as the Nation's early warning system to monitor vaccine adverse events and detect potential safety problems. As a passive surveillance system, it relies on individuals to send in reports of their experiences to CDC and FDA. CDC accepts all reports of adverse events after vaccination

from healthcare providers and individuals to assess possible safety concerns related to vaccines, including COVID–19 vaccines. FDA also requires vaccine manufacturers to submit reports for any adverse events following vaccinations to VAERS. These data are especially useful for quickly detecting unusual or unexpected patterns of adverse event reporting that might indicate a possible safety concern (or "signal") with a vaccine.

When VAERS reports are received, they are reviewed, processed, and coded. To better understand the circumstances around a particular adverse event, VAERS staff from CDC and FDA request follow-up medical records for reports that are classified as "serious." This includes adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect. FDA requires all healthcare providers to report any death following COVID–19 vaccination to VAERS and all reports of deaths are reviewed by CDC and FDA. All adverse events reported in VAERS are then publicly posted to the CDC WONDER data base, except for in very rare and specific instances.

Question 1. Where can Americans find data about the actual number of deaths from the COVID vaccine, as opposed to "after taking" it?

Answer 1. This information is reported publicly on CDC's website at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.*

SENATOR HASSAN

Question 1. Children under age five are still not eligible for a COVID–19 vaccine. Moderna reported earlier this month that it expects to report trial data on its COVID–19 vaccine in children ages 2 to 5 by March.

Question 1(a). Meanwhile, the number of children with COVID–19 is surging in New Hampshire and across the country. As of January 1, the hospitalization rate for children under age 5 reached 4 in 100,000 children–3 times higher than the same time last year.

Question 1(b). What guidance are you providing to parents of young children to keep them safe in the interim?

Answer 1. CDC recommends that all family members above the age of 5 years old be vaccinated to help protect younger children who are not yet eligible to be vaccinated. In addition, CDC recommends the following strategies on our website to help protect yourself and others from getting sick with COVID–19: *https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html*

SENATOR TUBERVILLE

Question 1. Does science still support a 90-day period after an infection during which a person should be exempt from testing requirements?

Answer 1. CDC continues to recommend that people who have had a laboratory-confirmed SARS-CoV–2 infection within the past 90 days who have subsequently recovered and no longer have

COVID–19 symptoms do not need to quarantine following an exposure. In addition, CDC continues to recommend that people who develop symptoms consistent with COVID–19 isolate immediately and get tested.

Currently, there are not enough data to support a change in this recommendation. CDC will continue to monitor relevant data and update public health recommendations and guidance on quarantine and isolation for the general population as more information becomes available.

Question 2. Why does our Federal Government not currently recognize natural immunity, as other countries do?

Answer 2. Available evidence shows that fully vaccinated individuals and those previously infected with SARS-CoV–2 each have a low risk of subsequent infection for at least 6 months. Data are presently insufficient to determine an antibody titer threshold that indicates when an individual is protected from infection. At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.

Multiple studies have shown that antibody titers correlate with protection at a population level, but protective titers at the individual level remain unknown. Whereas there is a wide range in antibody titers in response to infection with SARS-CoV–2, vaccination typically leads to a more consistent and higher-titer initial antibody response. Substantial immunologic evidence and a growing body of epidemiologic evidence indicate that vaccination after infection significantly enhances protection and further reduces risk of reinfection, which lays the foundation for CDC recommendations.

Response by Anthony Fauci to Questions of Senator Casey, Senator Hassan, Senator Luján, Senator Paul, Senator Cassidy, Senator Braun, Senator Scott, and Senator Tuberville

SENATOR CASEY

Question 1. At the hearing, I asked how the Federal Government is working with vaccine manufacturers to speed the development of a safe and effective vaccine for children under age five. Understanding that the Pfizer trial for children 24 months to 5 years old did not meet its endpoint, my follow-up questions are, how did we get here and what's next? Please describe, generally, the following:

Question 1(a). How vaccine developers make decisions about dose size, quantity and spacing in age de-escalation trials;

Question 1(b). What type of indicators a vaccine manufacturer might consider when determining whether and how to change the dose size, quantity or spacing if primary endpoints are not met; and

Question 1(c). Whether the emergence of a viral variant could affect the efficacy of a vaccine in children differently than it would affect the efficacy of the same vaccine in adults.

Answer 1(a)(b)(c). NIAID defers to FDA and ASPR on the above questions.

Question 1(d). Furthermore, could you please provide an update on current Federal goals and investments relating to the development of vaccines to protect children under age five from COVID–19, including grants, contracts or other funding awarded to vaccine developers; and what information is currently being provided to vaccine developers regarding current or planned opportunities for collaboration between the Federal Government and vaccine developers, including the extent to which BARDA will conduct TechWatch/CoronaWatch meetings and the extent to which FDA will accept applications for emergency use authorization.

Answer 1(d). NIAID currently is supporting the evaluation of existing coronavirus disease 2019 (COVID–19) vaccines and novel COVID–19 vaccine approaches for potential use in young children. Researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID), in collaboration with the Biomedical Advanced Research and Development Authority (BARDA) and Moderna, Inc., are evaluating the mRNA–1273 vaccine in children 6 months to less than 12 years of age in a Phase 2/3 clinical trial called KidCOVE. There are multiple trial sites at the NIAID-supported Vaccine and Treatment Evaluation Units (VTEUs). Moderna has indicated that it expects to report data in March 2022 for children 2 years of age to less than 6 years of age. In addition to the clinical evaluation of mRNA–1273, NIAID intramural scientists are conducting early stage research on an intranasal live-attenuated parainfluenza virus-vectored severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) vaccine approach, which is designed to protect infants and young children against both human parainfluenza virus 3 and SARS-CoV–2. NIAID also is supporting a study to identify adjuvants that improve vaccine efficacy in very young children.

NIAID notes that the Pfizer-BioNTech COVID–19 Vaccine also is being evaluated in children under 5 years of age; however, NIAID is not involved in the trial. NIAID would defer to the vaccine manufacturer to provide an update on the status of the trial.

Question 1(e). Finally, could you describe current thinking across your agencies regarding the circumstances under which your efforts would expand to include the development of additional or next-generation vaccines and therapeutics for COVID–19?

Answer 1(e). NIAID is supporting research on next-generation COVID–19 vaccines. 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. In addition, NIAID is pursuing the development of mucosal vaccine approaches that may stimulate greater immunity in the upper respiratory tract. These candidates could result in a much lower rate of breakthrough infection, broader and more durable protection, and stronger reduction in disease transmission than that observed with currently available COVID–19 vaccines. One of these mucosal vaccine approaches is an Adenovirus type 4 (Ad4)-based intranasal SARS-CoV–2 vaccine candidate developed by NIAID researchers that currently is undergoing preclinical testing.

Current COVID–19 vaccines approved or authorized by the U.S. Food and Drug Administration (FDA) elicit robust immune responses to the spike protein of SARS-CoV–2. NIAID Vaccine Research Center investigators have created a nanoparticle-based pan-coronavirus vaccine candidate designed to elicit antibodies targeted to the spike protein of multiple different coronaviruses. This mosaic nanoparticle-based approach—based on the universal influenza vaccine concept known as FluMos—is currently undergoing preclinical testing in an animal model. NIAID-supported scientists also provided proof of principle that self-assembling mosaic nanoparticles displaying receptor binding domains of multiple coronaviruses in the Sarbecovirus subgroup (including SARS-CoV–2) can induce protection in mice when challenged with another Sarbecovirus. In addition, NIAID intramural investigators are evaluating inactivated whole virus vaccine candidates for a broadly protective beta-coronavirus vaccine based on related efforts to develop a universal influenza vaccine. NIAID also is supporting studies through its vaccine adjuvant program to compare different classes of adjuvants and identify the most efficacious vaccine formulations. The identification of vaccine adjuvants that promote cross-protective and durable immunity in vulnerable populations would complement ongoing efforts to develop next-generation coronavirus vaccines.

In late 2021, NIAID announced four awards to fund multidisciplinary, collaborative teams that had submitted highly meritorious applications to conduct research on universal coronavirus vaccine candidates and help accelerate pan-coronavirus vaccine development. The teams will incorporate advances in coronavirus biology and immunology; immunogen design; and innovative vaccine and adjuvant technologies to discover, design, and develop vaccine candidates to protect against multiple types of coronaviruses and viral variants. The four awards are funded under the auspices of the Emergency Awards Notice of Special Interest (NOSI) on Pan-Coronavirus Vaccine Development Program Projects. A key goal of this NIAID initiative is to develop multivalent vaccine platforms and strategies suitable for use in vulnerable populations and to understand vaccine-induced immune responses and efficacy related to a person's age or sex. NIAID currently expects additional awards will be issued in 2022 to highly meritorious applications to support pan-coronavirus vaccine research from additional institutions submitted in response to the NOSI.

The National Institutes of Health (NIH) also is supporting research to identify and develop additional COVID–19 therapeutics.

The NIH Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership coordinates research strategies for prioritizing and speeding development of the most promising treatments. The ACTIV public-private partnership has evaluated hundreds of available therapeutic agents with potential application for COVID–19, prioritized the most promising candidates, designed and harmonized adaptive master protocols for ACTIV clinical trials, and selected numerous NIH-supported networks to launch these clinical trials to test prioritized therapeutic candidates.

On a particular note, NIAID 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 therapeutics to a common control arm to identify treatments with relatively large effects as promising candidates for further study in large-scale trials. In addition, NIH has launched the Antiviral Program for Pandemics, an NIH-BARDA collaboration that aims to develop safe and effective antivirals to treat and prevent SARS-CoV–2 infection. The program 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 target coronaviruses and additional RNA viruses with pandemic potential, helping to better prepare the Nation for future viral threats. Oral drug candidates for broad use in outpatient settings are the primary focus of this effort.

NIAID will continue to conduct and support research to identify and develop next-generation COVID–19 vaccines and therapeutics. These efforts will improve our response to the current pandemic and bolster our preparedness for the next viral disease outbreak.

SENATOR HASSAN

Question 1. Children under age five are still not eligible for a COVID–19 vaccine. Moderna reported earlier this month that it expects to report trial data on its COVID–19 vaccine in children ages 2 to 5 by March.

Meanwhile, the number of children with COVID–19 is surging in New Hampshire and across the country. As of January 1, the hospitalization rate for children under age 5 reached 4 in 100,000 children—3 times higher than the same time last year.

Question 1. At this point, when do you expect that vaccinations will be available to children under age 5?

Answer 1. NIH defers to FDA.

Question 2. What guidance are you providing to parents of young children to keep them safe in the interim?

Answer 2. NIH defers to CDC.

SENATOR LUJÀN

Question 1. You stated recently in an interview that, "scientists tend to talk in a different language than regular people can understand. It's kind of a mismatch between those who communicate and those who want to be communicated with not talking the same language." What is the consequence of scientists and regular people not speaking the same language? How do you overcome that?

Answer 1. NIAID notes that the statements in Question 1 were not made by Dr. Fauci. The BuzzFeed News article containing these quotes appears to cite a "prominent scientist who spoke with BuzzFeed News—but asked to remain anonymous due to the sensitive nature of the questions". NIAID does appreciate the opportunity to reaffirm the importance of conveying complex and rapidly evolving public health information and research findings in a manner that is accessible to non-scientists. The NIAID Director frequently answers questions from non-scientists and has the opportunity to assess where there may be confusion around the latest research on COVID–19. One effort to overcome such confusion is through the White House COVID-19 Response Team's public briefings in which Administration officials help translate and contextualize the latest research advances for non-scientists.

Question 2. There are differences between PCR and antigen testing and the appropriate use for both. How has the public been educated about the differences and appropriate uses? How can it be done better?

Answer 2. The Centers for Disease Control and Prevention (CDC) would be the most appropriate agency to elaborate upon efforts to educate the public about COVID–19 testing.

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) at the NIH has overseen the Rapid Acceleration of Diagnostics (RADx) Tech and Advanced Technology Platforms programs, part of the overall RADx initiative. These programs have supported development of technologies to increase lab capacity for PCR tests, development of test supplies, and development of new lab, point-of-care, and over-the-counter test devices, including both PCR and antigen technologies. NIBIB's focus is on the research and development of testing technologies and information about the different types of tests in development has been provided through the NIBIB website. This includes descriptions of the tests and a list of tests authorized for use by the FDA organized by type of test.

NIBIB also supported development of the When to Test website to help guide individuals and families on COVID–19 testing. The Testing Impact Calculator also includes tools to help organizations plan for and develop testing strategies. This site includes additional resources on testing strategies and obtaining supplies.

Additionally, NIBIB has issued press releases about the awarding of contracts for development of tests and the NIBIB Director has participated in numerous media interviews about this project and the tests that were developed. Press releases are listed on the news section of the NIBIB website.

NIBIB uses social media and e-newsletters to disseminate this information to the public.

Question 3. Given the increased demand for N95 and KN95 masks, we have seen an increase in costs to the consumer. New Mexicans hoping to protect themselves face costs as steep as $6 per mask—a cost that is simply out of reach for some of our most vulnerable populations. What barriers are preventing the Federal Government from providing N95 or KN95 masks to the public free of charge?

Answer 1. NIH defers to ASPR.

SENATOR PAUL

Question 1. Did the NIH award a grant (available at *https://reporter.nih.gov/search/6Io2KK8sZEefzzm WqkIOyg/project-details/8674931*) on bat SARS-related coronaviruses to EcoHealth Alliance with a subcontract to the Wuhan Institute of Virology? Please answer yes or no.

Answer 1. Yes, the NIH award to EcoHealth Alliance (EHA) included funds for a subaward to the Wuhan Institute of Virology (WIV) and EHA then entered into an agreement with WIV.

Question 2. Was the NIH informed in a grant progress report submitted in 2016 that the researchers constructed new SARS-related coronaviruses (so-called "chimeric SARS-related coronaviruses") that combined the spike gene of one SARS-related coronavirus with the rest of the genetic information of another SARS-related coronavirus, and that the resulting new viruses infected human cells? Please answer yes or no.

Answer 2. No, NIH received a progress report in 2017 describing research testing whether spike proteins from naturally occurring bat coronaviruses in China were capable of binding to cultured human cells (HeLa) genetically engineered to express the human ACE2 receptor. The presence of the human receptor alone is not sufficient to drive human infection.

Question 3. Did the NlH inform EcoHealth Alliance in a letter dated May 28, 2016, that "[a]s per the funding pause announcement, new USG funding may not be released for Gain of Function (GoF) research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS, viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route" and that the grant "appears to involve research covered under the pause"? Please answer yes or no.

Answer 3. While the NIH did send a letter to EHA dated May 28, 2016; the language quoted above in Question 3 differs from the language in the letter.

The relevant section from the May 28, 2016, letter is included below. In particular, please note the letter to EHA states "new USG funding will not be released" while Question 3 states "new USG funding may not be released"

"Based upon information in the most recent progress report, NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the U.S. Government funding pause (*http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The fol-*

lowing specific aims appear to involve research covered under the pause:

Aim 3: Testing predictions of CoV inter-species transmission

As per the funding pause announcement, new USG funding will not be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.".

In addition, the letter clearly states that such a determination of whether the research included projects subject to the funding pause had not yet been made: "Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below."

Question 4. Did the NIH inform EcoHealth in 2016, under "Special Terms and Conditions" for continuation of the grant, that "should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log [10 times] over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information"? Please answer yes or no.

Answer 4. Yes, in an abundance of caution and as an appropriate biosafety measure, additional language was included in the terms and conditions of the grant award to EHA. The Special Terms and Conditions of the award state:

"No funds are provided and no funds can be used to support gain-of-function research covered under the October 17, 2014 White House Announcement (NIH Guide Notice NOT-OD–15–011). Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes."

These measures would prompt a secondary review to determine whether the research aims should be re-evaluated to determine whether new biosafety measures should be enacted.

Question 5. Was the NIH informed in a progress report submitted in 2018 that the researchers had found that their novel, laboratory-generated chimeric SARS-related coronaviruses exhibited increased pathogenicity and greater than 4-log (greater than 10,000 times) enhanced viral growth in lungs of so-called "humanized mice" (i.e., mice engineered to display human receptors on lung cells)? Please answer yes or no.

Answer 5. NIH received a progress report in 2018 that showed a figure presenting transient differences in weight loss and viral load within the lungs of transgenic mice infected with chimeric bat severe acute respiratory syndrome-related coronaviruses (SARSr-

CoVs). Note, however, that these findings were not reported to be statistically significant in comparison to mice infected with the parental backbone virus.

Question 6. Did the NIH continue to fund the grant, despite the violation of the terms and conditions outlined on page S of the 2016 grant Notice of Award (specifically, for failing immediately to "stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist. .. with the relevant data and information")? Please answer yes or no.

Answer 6. NIH did not conclude that there was non-compliance with the Special Terms and Conditions of the award based on the figures presented in the 2018 progress report.

Question 7. Did the NIH award another 5-year grant in 2019 to EcoHealth Alliance with a subcontract to the Wuhan Institute of Virology (available at *https://reporter.nih.gov/search/6lo2KK8sZEefzzmWqkIOyg/project-details/9819304*) for research on bat SARS-related coronaviruses, which proposed to continue and expand the construction of new chimeric SARS-related coronaviruses? Please answer yes or no.

Answer 7. NIH renewed the EHA grant in 2019 after the renewal application underwent peer review and was found to be highly meritorious. EHA has reported that no subcontract or subaward agreement was reached with WIV under the renewal award and EHA has reported that no funds from the renewal award were sent to WIV.

Question 8. Did the NIH award the second 5-year grant despite the fact that the 2018 grant proposal disclosed the greater-than-I 0,000-times enhanced viral growth and enhanced viral pathogenicity of the laboratory-generated chimeric SARS-related coronaviruses? Please answer yes or no.

Answer 8. Please see answers to Questions 5 through 7.

Question 9. Did the NIH award the second 5-year grant despite not having forwarded the grant proposal to the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) Committee for risk-benefit review? Please answer yes or no.

Answer 9. NIAID awarded the grant after reviewing it in accordance with the U.S. Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens (HHS P3CO Framework). Only proposed research being considered for funding and that has been determined by the funding agency as reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (ePPPs) is subject to additional HHS department-level review.

Question 10. Did Sections I and II of the HHS P3CO Framework (available at https://*www.phe.gov/s3/dualuse/documents/p3co.pdf) require that NIH forward grant proposals to the HHS Potential Pandemic Pathogen Care and Oversight (P3CO) Committee for risk-benefit review whenever "proposed research is reasonably anticipated to create, transfer, or use enhanced PPPs," where "enhanced PPP is defined as a PPP resulting from the enhancement of the*

transmissibility and/or virulence of a pathogen"? Please answer yes or no.

Answer 10. Yes, Section II of the HHS P3CO Framework states that "proposed intramural and extramural life sciences research that is being considered for funding and that has been determined by the funding agency as reasonably anticipated to create, transfer, or use enhanced PPPs is subject to additional HHS department-level review." The HHS P3CO Framework defines a PPP as:

> "a pathogen that satisfies both of the following: 1. It is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and 2. It is likely highly virulent and likely to cause significant morbidity and/or mortality in humans."

NIAID, as the funding agency, reviewed the EHA grant in accordance with the HHS P3CO Framework and determined that the experiments to generate SARS-like or MERS-like chimeric coronaviruses were not reasonably anticipated to create, transfer, or use ePPPs and, therefore, were not subject to additional HHS department-level review as delineated in the HHS P3CO Framework.

Question 11. If you answered yes to any of the questions above, are you prepared to retract your previous false testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions?

Answer 11. None of the responses to Questions 1 through 10 contradict testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions.

SENATOR CASSIDY

Question 1. The U.S. is in the middle of flu season, which has the potential to add additional burden to already-stressed health care systems due to the ongoing pandemic.

> *Question 1(a)*. What steps is HHS taking to ensure the availability of appropriate diagnostics and treatment options to address the potential dual threats of COVID and influenza, including through shoring up the Strategic National Stockpile?
>
> *Question 1(b)*. Beyond testing and preventative steps like vaccination, what steps has HHS taken to proactively treat vulnerable populations like the elderly or others who may be at risk for and are likely to spread communicable diseases like COVID and the flu?
>
> Answer 1. NIH defers to CDC.

Question 2. Health systems in Louisiana have been overwhelmed by successive waves of COVID variants. These health systems could have been better prepared for these growing variant trends if they had access to better national and regional dashboards monitoring variants of concern.

> *Question 2(a)*. What are you all at the CDC, FDA, NIH, and HHS doing to make sure health providers are armed

with the best data to respond appropriately to the next COVID variant or pandemic?

Answer 2. NIH defers to CDC.

Question 2(b). Second, how are you all harnessing the speed and innovation of the private sector to help predict, prevent, and mitigate future COVID–19 variants or other pathogens of concern?

Answer 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 or COVID–19 therapeutics. In addition, NIAID-supported scientists are collaborating with vaccine manufacturers to assess the impact of new variants of concern on their products and to design and test new vaccines to help protect against variant viruses. These efforts add to our knowledge about SARS-CoV–2 variants and our ability to combat them.

Question 3. Dr. Fauci: Many experts have expressed optimism regarding how the Omicron variant might leave behind extremely high levels of immunity, and the prospect of an end to this pandemic is encouraging. However, with each new variant that emerges, any gaps in population-level data on how our immune systems respond—not just antibodies but also T-cells—limit our ability to inform the policies on which public health experts, public officials, providers, and patients depend.

Question 3(a). Given that questions about efficacy of COVID–19 vaccines and the need for boosters can only be answered by understanding both T-cells AND antibodies, how do we ensure that T-cell analysis is fully included in research decisions for vaccines and boosters going forward?

Question 3(b). How can NIH ensure T-cell data is incorporated into its ongoing research to combat the pandemic, including the effectiveness of vaccines and prior infection against new variants, including Omicron and what might come next?

Answer 3(a)(b). NIAID continues to conduct and support research to improve understanding of the role of T cells in protection against COVID–19 and COVID–19 disease progression. NIAID supported a collaborative longitudinal study by researchers at Emory University and the Fred Hutchinson Cancer Research Center that demonstrated that SARS-CoV–2-specific T cells were detectable for up to

8 months in patients after mild to moderate COVID–19. NIAID also supported two separate studies examining T cell responses in recovered COVID–19 patients and individuals vaccinated against COVID–19. They found robust immune responses to the original strain as well as multiple variants of SARS-CoV–2 in both groups. Additional work by NIAID researchers and grantees showed that most individuals with existing T cell responses against SARS-CoV–2 should generate a T cell response against the Omicron variant, and that SARS-CoV–2 has thus far not evolved extensive T cell escape mutations. Other work from NIAID-supported investigators has shown that vaccine-induced T cell responses recognize the Omicron variant. In another NIH-supported study, researchers uncovered features of T cells that distinguish fatal from non-fatal cases of severe COVID–19, which could help harness knowledge of T cells to inform new potential treatments for this disease.

Question 3(c). How can NIH ensure T-cell data is fully integrated into its RECOVER research initiative for those suffering from prolonged symptoms following a COVID infection?

Answer 3(c). Assessment of T-cell function after SARS-CoV–2 infection may provide important clues to disease mechanisms, diagnosis, and treatment of post-acute sequelae of SARS-CoV–2 infection (PASC), including Long COVID. In recognition of this, the NIH Researching COVID to Enhance Recovery (RECOVER) Initiative includes studies of the pathobiologic mechanisms underlying PASC, including studies characterizing the cellular immune response to SARS-CoV–2. Importantly, RECOVER also includes collection, analysis, and biobanking of serum and peripheral blood mononuclear cells (PBMC), including T cells, from adult and pediatric study participants during the course of the project. A RECOVER Consortium group of experts is monitoring the state of the science regarding immunologic responses to SARS-CoV–2 infection and the best technical approaches for characterizing those responses as well as evaluating optimal approaches for cell-based assays for the RECOVER serum and PBMC samples. RECOVER core immunophenotyping laboratories will conduct the recommended T-cell function assays utilizing the biobanked specimens. These analyses will provide a unique resource for correlation of PASC clinical symptoms with deep clinical phenotyping in the RECOVER cohorts as well as for studies by the broader research community.

Question 3(d). How can NIH support efforts to integrate T-cell data into vaccine, booster, and other public health decisions at FDA and CDC?

Answer 3(d). NIAID investigators will continue to integrate T cell data into vaccine and booster research, including in clinical studies and pre-clinical challenge studies for COVID–19 vaccine candidates. For example, NIAID is sup-

porting a Phase 1 clinical trial in healthy adults to assess the safety and immunogenicity of COVID–19 vaccine candidates developed by Gritstone Oncology, Inc., that utilize a strategy aimed at inducing both neutralizing antibodies and T cell responses to elicit a broad immune response against conserved viral antigens. In addition, the NIAID Vaccine Research Center has established the Pandemic Response Repository through Microbial/Immune Surveillance and Epidemiology (PREMISE) program. The program will use data from the measurement of T and B cell immune responses to inform the discovery and development of diagnostic, prophylactic, and therapeutic countermeasures and accelerate the global response to pandemic threats. NIAID anticipates the research conducted by PREMISE will advance our knowledge of immune response to vaccination and infection and help inform the response to future pandemic threats.

NIAID also is leading a study in fully vaccinated individuals to assess the safety and immune responses (including T cell responses) following boosting with a COVID–19 vaccine different than the one used for the initial vaccination ("mix and match"). NIAID released early data from this trial demonstrating that administering the Pfizer, Moderna, or Johnson & Johnson/Janssen COVID–19 vaccines at least 12 weeks after individuals received a different vaccine regimen effectively enhanced the immune response to SARS-CoV–2. The results of this trial were made available to FDA during FDA's decisionmaking process to authorize the use of heterologous, or "mix and match," booster dosing in eligible individuals following completion of primary vaccination with a different available COVID–19 vaccine for persons 18 years of age and older.

SENATOR BRAUN

Question 1. Your administration is explaining to the American public that COVID tests will be "free" to everyone covered by private insurance. Is this true? Will employer and individual premiums be impacted by the cost of these tests?

Question 2. Over the past 2 years, businesses of all sizes have faced innumerable challenges and significant disruptions. To add to this, inflation is at its highest level since the 1980's and is having a significant impact on business operations. How will adding significant costs to employers' healthcare bills through the over-the-counter (OTC) testing coverage requirement help bring down the costs of these tests and help employers address their workforce and inflation concerns?

Question 3. How does the new OTC testing coverage requirement policy solve for the problem of the limited supply of tests in the country, particularly with your administration seemingly purchasing most of the current supply?

Answer 1,2,3. Thank you for your questions, these are best addressed by the Centers for Medicare & Medicaid Services.

Question 4. Senior caregivers working across assisted living and memory care communities have been instrumental in successfully mitigating the spread of COVID–19 among the most vulnerable populations in congregate care settings. Without the Federal relief that other long-term care options, like nursing homes, have received, nearly two-thirds of assisted living communities have not experienced a single COVID–19 death due to the outstanding efforts of frontline caregivers. However, emerging variants mean that seniors in assisted living and memory care remain extremely vulnerable despite high vaccination rates.

T3Question 4(a). Dr. Fauci, as new Federal data shows that 85 percent of reported breakthrough deaths were of those 65 and older, and 80 percent of all COVID–19 deaths are individuals over age 65, should these assisted living and memory care communities be prioritized in the distribution of rapid tests, PPE, and additional boosters?

Answer 4. Access to both rapid tests and personal protective equipment is critical for assisted living and memory care communities to carry out infection prevention and control programs and remain vigilant against COVID–19 among residents and staff. Older adults are at high risk of developing severe COVID–19 disease and remaining up-to-date with all recommended COVID–19 vaccine doses is essential to protect both staff and residents against developing severe COVID–19. It also is important for any visitors to these facilities remain up to date with all recommended COVID–19 vaccine doses. I continue to urge everyone, especially those who are most vulnerable, to protect themselves by getting vaccinated and boosted.

SENATOR SCOTT

Omicron Status

Question 1. Dr. Fauci, should we be employing a "COVID zero" strategy or should our strategy be to minimize mortality and social harm until we reach herd immunity?

Answer 1. I agree that our strategy should minimize mortality and social harm by sustaining and building on the progress we have made so far. As therapeutics to prevent progression to severe COVID–19 are becoming more widely available and a higher percentage of the population is vaccinated and boosted, we should be able to return to some degree of normality. It is important to note that the emergence of new variants capable of evading currently available therapeutics and/or vaccines is possible. Therefore, NIAID will continue to conduct and support research to develop next-generation COVID–19 vaccines and therapeutics in order to help protect against novel SARS-CoV–2 variants.

SENATOR TUBERVILLE

Omicron Infection

Question 1. What information does the administration have about the potential for someone to be reinfected with the Omicron variant?

Answer 1. Reinfections with the Omicron variant in individuals who already have recovered from an Omicron variant infection are rare. If someone mounts a good immune response to the initial infection, it is unlikely that they will be re-infected with the same variant. Most reinfections occur in people who have been infected with one variant, such as Delta variant, and then are subsequently re-infected with a different variant, such as Omicron variant. We also have to be prepared for the possibility of another variant emerging that is so different from existing variants that it eludes any protection that individuals have acquired from vaccinations and/or prior infections. NIAID will continue to conduct and support research to develop next-generation COVID–19 vaccines and therapeutics in order to help protect against novel SARS-CoV–2 variants.

Question 2. Does science still support a 90-day period after an infection during which a person should be exempt from testing requirements?

Answer 2. NIH defers to CDC.

Question 3. In a CNN appearance on January 11, 2022, you said "What the CDC has said and it gets misinterpreted they're saying wearing any mask is better than no mask at all." Can you provide the data that informed these remarks?

Answer 3. According to the CDC, loosely woven cloth products provide the least protection compared to other types of masks, layered finely woven products offer more protection, well-fitting disposable surgical masks and KN95s offer even more protection, and well-fitting NIOSH-approved respirators (including N95s) offer the highest level of protection. For additional information on studies informing CDC's public health messaging on masks, please see the CDC's Science Brief: Community Use of Masks to Control the Spread of SARS-CoV–2 (*https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html).*

COVID and Vaccinations

Question 4. On May 16, 2021, you stated "So even though there are breakthrough questions with vaccinated people, almost always the people are asymptomatic and the level of virus is much lower in their nasopharynx, the top part of their throat that lies behind the nose, than it is in someone who is unvaccinated. When you get vaccinated, you not only protect your own health and that of the family but also you contribute to the community health by preventing the spread of the virus throughout the community. In other words, you become a dead end to the virus." Do you still agree with this statement?

Answer 4. The statement was accurate at the time it was made. Since then, we have seen the emergence of SARS-CoV–2 variants—such Omicron—that remain highly transmissible even in communities with a high level of vaccination. It is important to note that COVID–19 vaccines and boosters protect against severe disease, hospitalization, and death from known variants of concern.

Question 5. In June 2021, President Biden stated "[y]ou're not going to get COVID if you have these vaccinations," and "[i]f you're vaccinated, you're not going to be hospitalized, you're not going to

be in the ICU unit, and you're not going to die." Do you agree with this statement?

Answer 5. Most individuals who are vaccinated and boosted remain asymptomatic or have only mild symptoms following SARS-CoV–2 infection. Booster doses remain remarkably effective against the Omicron variant. COVID–19 vaccines and booster shots can keep you out of the hospital and certainly can save your life.

Question 6. In July 2021, Dr. Walensky stated "99.5 percent of deaths from COVID–19 in the United States were in unvaccinated people" and you also stated 99.2 percent of deaths in June were unvaccinated. Is this still accurate?

Answer 5,6. The statements were accurate at the time they were made. NIAID would defer to the CDC to provide the most recent data on the percentage of deaths from COVID–19 in the United States that were unvaccinated people.

Question 7. In July 2021, former NIH Director Collins stated 99 percent of people in a hospital were unvaccinated. Is this still accurate?

Answer 7. Dr. Collins' statement was accurate at the time it was made. NIAID would defer to the CDC to provide the most recent data on the percentage of COVID–19 hospitalizations who were unvaccinated.

Question 8. In August you stated that "vaccines prevent getting infected, prevent getting sick, prevent your hospitalization." Is that statement still accurate?

Answer 8. COVID–19 vaccines and boosters protect against severe disease, hospitalization, and death from known variants of concern; however, vaccines may not be as effective in preventing asymptomatic or mild infection with SARS-CoV–2 variants.

Question 9. Has the Federal response to COVID–19 been successful?

Question 9(a). Please explain.

Answer 9,9(a). The public health response to COVID–19 has required an unprecedented global public-private research effort. NIAID has played a central and important role in this response. NIAID capitalized on decades of fundamental basic research, including groundbreaking structure-based vaccine design at the NIAID Vaccine Research Center, to facilitate the rapid development of COVID–19 vaccines. NIAID also initiated clinical trials with creative and adaptive designs, allowing the evaluation of the safety and efficacy of multiple new and existing therapeutics for the treatment of COVID–19, which has helped support authorization of some of these products by FDA. In addition, NIAID has engaged domestic and international clinical research infrastructure and leveraged highly productive partnerships in the public and private sectors to support multiple COVID–19 vaccine candidates to progress in record time from concept to Emergency Use Authorization by FDA. Use of these vaccines throughout the world will continue to play a critical role in reducing the threat of COVID–19 in the United States and globally.

Question 9(b)4. Please explain what should have been done differently.

Answer 9(b). The emergence of novel SARS-CoV–2 variants, namely Delta and Omicron, has highlighted the importance of vaccinating the rest of the world. The United States is a world leader in these efforts; however, we should continue to look at ways to buildupon existing efforts to address global vaccine disparities. Improving global COVID–19 vaccination rates is one way that the Federal Government could help limit the impact of additional SARS-CoV–2 variants.

Question 10. Please provide specific examples where your agency has utilized real world evidence in regards to COVID–19 or treatments for COVID–19.

Answer 10. Randomized controlled clinical trials are the gold standard and continue to be used to determine the safety and efficacy of candidate COVID–19 vaccines and therapeutics. Real-world evidence also continues to play an important role in the public health response to COVID–19. Specifically, real-world evidence from observational studies was used—when available—to help prioritize which repurposed agents to evaluate in the ACTIV–6 trial. Real-world evidence also has helped inform recommendations of the NIH COVID–19 Treatment Guidelines Panel, which aim to provide clinicians with evidence-based recommendations on the management of COVID–19. In addition, real-world evidence of vaccine effectiveness has shown that COVID–19 booster doses reconstitute the waning immune protection of the initial vaccine series. Booster doses are especially effective in protecting against severe COVID–19 disease, hospitalization, and death. NIAID will continue to use real-world evidence to help inform research on COVID–19 medical countermeasures.

Question 11. A recent Kaiser study found increased myocarditis risk in men 18–24 years old who have taken the COVID–19 vaccine and some physicians have raised alarm over recent sudden deaths in young athletes worldwide, particularly soccer players. Yet, the Biden administration is pushing booster shots amongst this and younger age groups. Are you concerned that this administration's policy could be increasing the risk of adverse events like myocarditis in individuals that have minimal risk from COVID–19, many of whom are fully vaccinated and have protection from a prior COVID infection?

Answer 11. Reports of myocarditis and pericarditis in adolescents and young adults following COVID–19 vaccination are rare. Unvaccinated adolescents and young adults are at higher risk of developing myocarditis from SARS-CoV–2 infection itself. The benefits of COVID–19 vaccination outweigh the possible risk of myocarditis or pericarditis as most patients who receive care respond well and feel better quickly. Patients can usually return to their normal daily activities after their symptoms improve. Vaccines and boosters continue to be the best way protect individuals from severe COVID–19 disease.

Question 12. Do you believe schools and universities should be requiring students to be vaccinated and boosted in order to be enrolled or attend school?

Answer 12. The decision to require COVID–19 vaccines and boosters (and other vaccines) to attend schools and universities is made at the local level. I will continue to encourage everyone who is eligible to protect themselves from COVID–19 by getting vaccinated and boosted.

Natural Immunity

Question 13. In September 2021, when asked whether natural immunity provided similar protection as a vaccine, you stated you did not have a firm answer on that but needed to discuss the durability of the response. In the roughly 4 months since you made those comments, have you developed a firm answer?

Answer 13. Available evidence shows that vaccinated and boosted individuals are at much lower risk of hospitalization and death from COVID–19. Individuals previously infected with SARS-CoV–2 are believed to have a low risk of subsequent infection for at least 6 months. At this time, there is no FDA-authorized or—approved test that health care providers or the public can use to reliably determine whether a previously infected person is protected from SARS-CoV–2 infection at any given time. It also is important to note that the level of protection from prior infections may not be the same for all viral variants or in all individuals. Further, we now know that vaccination enhances the protective immune response in previously infected individuals.

Question 14. Why does our Federal Government not currently recognize natural immunity, as other countries do?

Answer 14. NIH defers to CDC.

Early Treatments for COVID–19

Question 15. Please provide a complete list and funding amount of studies funded by the Federal Government that have examined early treatments for COVID–19.

Answer 15. NIH is only able to provide information about projects funded by the NIH. You may wish to consult with HHS or other agencies for information on studies not funded by NIH.

NIH sponsored a wide range of research activities during Fiscal Year (FY) 2020 and fiscal year 2021 that related to investigation of potential early treatments for coronavirus disease 2019 (COVID–19) spanning both inpatient and outpatient settings as well as early stage research where the modality was not yet tested in humans. A total of 201 projects were funded, representing a trans-NIH initiative involving multiple Institutes, Centers and Offices (ICOs), led by NIAID. The portfolio of NIH-funded COVID–19 early treatment projects included a diverse range of research.

Through fiscal year 2021, $389 million in COVID–19 emergency supplemental and annual appropriations supported grants, contracts, and other research agreements related to early treatment research projects.

Funding IC	FY 2020 Obligations	FY 2021 Obligations	Total FY 2020 & FY 2021 Obligations	No. of Projects
NIAID	$193,394,653	$81,080,280	$274,474,933	110
NHLBI	$35,890,868	$10,684,487	$46,575,355	7
NCATS	$9,921,728	$24,330,995	$34,252,723	28
NCI	$13,596,274	$4,231,135	$17,827,409	31
NIEHS	$3,206,576	$5,152,543	$8,359,120	7
NIBIB	$1,366,290	$2,388,843	$3,755,133	8
OD	$2,070,470	$521,426	$2,591,896	6
NICHD	$1,079,400		$1,079,400	4
Total	**$260,526,259**	**$128,389,709**	**$388,915969**	**201**

The COVID–19 early treatment-targeted projects examined the full spectrum of research opportunities for suppression of infection symptoms and improved health outcomes in both inpatient and outpatient settings as well as early stage research where the modality was not yet tested in humans. These projects included investigation of a broad range of therapeutic approaches, such as antiviral treatments, anti-inflammatory medications, immunotherapeutics, convalescent plasma, dietary supplements or vitamins, and repurposed drugs. Other projects investigated the use of advanced technologies, such as nanobodies.

Topic	FY 2020 Obligations	FY 2021 Obligations	Total FY 2020 & FY 2021 Obligations	No. of Projects
Chloroquine and Hydroxychloroquine	$8,083,110	$1,848,182	$9,931,292	7
Other Investigational Products	$149,945,138	$78,958,425	$228,903,564	147
Remdesivir	$1,703,830	$760,184	$2,464,014	5
Vitamins and Other Repuposed Drugs	$32,928,856	$11,868,302	$44,797,158	27
Monoclonall Antibody/Biologic	$67,019,048	$30,488,737	$97,507,785	10
Multiple	$846,277	$4,465,879	$5,312,156	5
Total	**$260,526,259**	**$128,389,709**	**$388,915969**	**201**

Projects in the Multiple category displayed in the table above include grants for projects in which more than one medication or therapeutic was evaluated for treatment effectiveness, such as chloroquine, hydroxychloroquine and remdesivir.

Projects in the Other Investigational Products category encompassed different lines of inquiry, including the use of high throughput screening (HTS) to identify whether metabolic changes induced by COVID–19 could be blocked or reversed. Other sample efforts include projects that supported development of novel therapeutics that target the COVID–19 virus spike protein or replication ma-

chinery. For example, one project examined modified mRNA (modRNA) drugs to target COVID–19. Another project identified potential drugs that could target the virus spike protein through an approach called protein-catalyzed capture (PCCs).

The projects funded within the Vitamins & Other Repurposed Drugs research category involved varied approaches to discover existing drugs or vitamins that could effectively block the cellular mechanisms required for viral infection or block the cellular response to infection that causes disease. One project investigated the efficacy and use of dietary supplements sold for weight loss, energy, sports performance, and immune function in treating COVID–19 infection. For example, a prevention study in health care workers evaluated the efficacy of low versus moderate to high doses of Vitamin D.

Question 16. Why does the NIH-funded trial of ivermectin not conclude until 2023?

Answer 16. Ivermectin is being studied in a clinical trial known as ACTIV–6 (Accelerating COVID–19 Therapeutic Interventions and Vaccines master protocol number 6), which began recruiting participants on June 11, 2021. ACTIV–6 is a clinical trial to test up to seven existing medications, at varying doses, for adults with COVID–19 who have mild-to-moderate symptoms. The ACTIV–6 study completion date of March 2023 listed on clinicaltrials.gov reflects when enrollment for all ACTIV–6 drugs is anticipated to be complete. The 'study completion date' on clinicaltrials.gov does not reflect completion dates for individual drugs/dosages tested. An independent Data Safety and Monitoring Board is responsible for periodic assessment of ACTIV–6 data and makes recommendations related to the study protocol, individual drugs/dosages, and continuation of the trial to the study team and trial sponsors to maintain the safety of ACTIV–6 participants.

Ivermectin is being tested at two different dosages within ACTIV–6. A study testing a lower dosage of ivermectin opened for enrollment on June 11, 2021, and will close in February 2022, having met its enrollment goal. Results from the lower dose ivermectin study are anticipated later this year, after a period of participant follow-up and data analysis. All results from ACTIV–6 will be made available to the public and also for review by treatment guidelines committees, which span the Federal Government, and public health organizations, for potential development into guidelines and recommendations for healthcare providers. A higher dose ivermectin study is anticipated to start in February 2022 and will continue to enroll participants over the next six to 8 months until enrollment goals are met, with results expected in early 2023.

RESPONSE BY JANET WOODCOCK TO QUESTIONS OF SENATOR CASEY, SENATOR SMITH, SENATOR BURR, SENATOR CASSIDY, SENATOR BRAUN, SENATOR SCOTT, SENATOR TUBERVILLE, AND SENATOR HASSAN

SENATOR CASEY

Question 1. At the hearing, I asked how the Federal Government is working with vaccine manufacturers to speed the development of a safe and effective vaccine for children under age five. Understanding that the Pfizer trial for children 24 months to 5 years old did not meet its endpoint, my follow-up questions are, how did we get here and what's next? Please describe, generally, the following:

Question 1(a). How vaccine developers make decisions about dose size, quantity and spacing in age de-escalation trials;

Question 1(b). What type of indicators a vaccine manufacturer might consider when determining whether and how to change the dose size, quantity or spacing if primary endpoints are not met; and

Question 1(c). Whether the emergence of a viral variant could affect the efficacy of a vaccine in children differently than it would affect the efficacy of the same vaccine in adults.

Question 2. Furthermore, could you please provide an update on current Federal goals and investments relating to the development of vaccines to protect children under age five from COVID–19, including grants, contracts or other funding awarded to vaccine developers; and what information is currently being provided to vaccine developers regarding current or planned opportunities for collaboration between the Federal Government and vaccine developers, including the extent to which BARDA will conduct TechWatch/CoronaWatch meetings and the extent to which FDA will accept applications for emergency use authorization.

Question 3. Finally, could you describe current thinking across your agencies regarding the circumstances under which your efforts would expand to include the development of additional or next-generation vaccines and therapeutics for COVID–19?

Answer 1. As with all vaccines, the FDA requires that COVID–19 vaccine developers provide sufficient data to the Agency to evaluate the safety and effectiveness of the vaccine for its intended use and population. Having a safe and effective COVID–19 vaccine available for younger children is a priority for FDA. The Agency will ensure the data support effectiveness and safety before authorizing or approving a COVID–19 vaccine for use in younger pediatric populations.

As background, dose finding studies are a part of vaccine development where various dosages are tested in people in randomized-controlled studies. These studies also provide some initial safety information on common short-term side effects and risks, the safety profile at the different dose levels, and examine the relationship between the dose administered and the immune response and the ability of a vaccine to generate an immune response.

For some vaccines, including COVID–19 vaccines, age de-escalation is a step-wise approach that is undertaken for vaccine development in pediatric populations. With an age-de-escalation approach in the pediatric population, clinical trials may begin in adults and/or adolescents and proceed downward in age, in a stepwise manner, as safety and effectiveness data are accrued, sometimes including from post-marketing use in a much larger number of children than evaluated in clinical trials. COVID–19 vaccines may be authorized for emergency use in pediatric populations, depending on the available safety and effectiveness data and benefit/risk considerations, which may be different for various age groups.

Conducting clinical trials to determine an appropriate vaccine dose in younger pediatric populations requires additional investigation and study over that done in the clinical trials for adults, including the evaluation of different dosages to ensure that the vaccine dosage and the schedule chosen for younger pediatric populations is optimal before larger clinical studies in pediatric populations to evaluate safety and effectiveness.

Acknowledging that COVID–19 affects all age groups, but that the epidemiology and pathogenesis of COVID–19, and the safety and effectiveness of COVID–19 vaccines, may be different in children compared with adults, FDA generally expects that pediatric trials would be initiated in specific age groups as soon as available data support that the vaccine would confer a prospect of direct benefit and acceptable risk to trial participants (21 CFR 50.52).

This determination will be made in the context of specific vaccine development programs and following discussion of study design elements that ensure participant safety and compliance with 21 CFR Part 50 Subpart D regulations providing additional safeguards for children in clinical investigations. The development of COVID–19 vaccines for pediatric populations is addressed in our June 2020 Guidance for Industry, Development and Licensure of Vaccines to Prevent COVID–19, which reflects the advice FDA has been providing to vaccine developers since the onset of the pandemic.

In June 2021, FDA convened its Vaccines and Related Biological Products Advisory Committee (VRBPAC) to discuss licensure and emergency use authorization of vaccines to prevent COVID–19 for use in pediatric populations and specifically to discuss approaches to evaluating safety and effectiveness to help FDA advise COVID–19 vaccine manufacturers to ensure that pediatric trials will be adequately designed to support vaccine licensure (or emergency use authorization, when relevant statutory criteria are met) in various age groups.

FDA has been working closely with vaccine manufacturers to provide advice as data accrue about safety and effectiveness, the latter of which may be comprised of immune response data or the number of COVID–19 cases that occur, or a combination of both, for their respective COVID–19 clinical trials in pediatric populations. These data are accruing as the United States experiences SARS-CoV–2 variant surges, such as Delta and Omicron.

For the FDA-authorized COVID–19 vaccines and the populations authorized for use, at this time, the available evidence supports the effectiveness of the current vaccines, including a single booster

dose, in preventing COVID–19 and serious outcomes that can occur, including hospitalization and death.

With respect to the circumstances that would warrant next-generation COVID–19 vaccines, the FDA has anticipated the emergence of SARS-CoV–2 variants. FDA is prepared to work closely with vaccine manufacturers to provide feedback in the clinical development and, if applicable, the licensure or EUA of vaccines that are tailored to a specific SARS-CoV–2 variant. With respect to therapeutics, FDA is committed to working with companies to evaluate and expeditiously address the potential impact of emerging variants on existing therapies and facilitate the development and availability of new therapies that retain activity against such variants.

SENATOR SMITH

Question 1. Given the importance of ensuring we have sufficient supply of accurate COVID–19 tests, can you explain the Administration's plans to develop and increase access to broad spectrum diagnostic tests, including molecular tests, to increase our ability to detect current and future COVID–19 variants?

Answer 1. Since the start of the pandemic, the FDA has adapted its regulatory approach to address the public's testing needs and has been working closely with test developers to adjust as those needs have changed. These efforts have helped increase testing capacity and broaden public access to all types of COVID–19 tests, including laboratory-based, point-of-care, and over the counter (OTC) tests.

FDA sought to facilitate COVID–19 test evaluation and authorization through the development and availability of templates for EUA requests. 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 an EUA. 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 had as many as ten posted templates and continues to update, add, combine, and remove templates as the science evolves and as necessary to support developers of COVID–19 tests.

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 78 weekly virtual town halls for test developers. The Agency has worked with over 1,000 test developers since January 2020.

Since its inception in April 2020, FDA has worked closely with NIH on the Rapid Acceleration of Diagnostics (RADx) initiative, which aims to speed the development, validation, and commercialization of innovative point-of-care and home-based tests, as well as improve clinical laboratory tests, that can directly detect the virus. FDA meets regularly with RADx Tech program staff and test developers to answer questions and provide feedback on validation plans.

Additionally, in October 2021, the Administration launched and invested in a program called the Independent Test Assessment Program (ITAP), an innovative partnership between the NIH and FDA, funded with resources from the American Rescue Plan to further accelerate new products to market.

This initiative leverages the clinical and scientific expertise of the FDA and the NIH to develop validation protocols and the resources of the NIH to perform validation testing to establish test performance, which enables FDA to accelerate test manufacturers through the FDA review process based on data provided by trusted partners through the NIH. The first two successful candidates to come through this process were authorized by FDA in the last week of 2021, which was weeks, if not months, ahead of schedule. The ITAP program and the FDA continue to prioritize new OTC test candidates which have the potential for large-scale production capacity.

FDA prioritizes review of tests with the greatest public health impact, including those that can be run in high volumes, at the point-of-care, and at home. The Administration has also proactively reached out to manufacturers with self-tests on the international market (e.g., in the United Kingdom or Germany) and asked them to submit their tests for FDA review.

To date, the FDA has authorized over 420 tests and sample collection devices that provide a wide array of test options. This includes POC tests, rapid at-home tests, multi-analyte tests that detect both COVID–19 and flu, antigen, molecular, and serology tests as well as tests for pooling, screening, and serial screening.

FDA has been monitoring for viral mutations and their impact on authorized molecular and antigen diagnostic tests throughout the pandemic. FDA tracks the part of the viral genome targeted by each authorized molecular test in a data base, monitors global data bases for emerging variants, and conducts in silico analyses to evaluate whether any of the authorized test probes target a part of the viral genome that has mutated.

If FDA identifies a potential impact on test performance, FDA contacts the test developer and communicates with the public. The first such communication took place on January 8, 2021, not long after variants began to emerge. FDA issued a safety alert and Letter to Health Care Providers to caution that the presence of viral genetic mutations in a patient sample can potentially change the performance of a diagnostic test.

At that time, FDA identified three authorized molecular tests that may be impacted by genetic variants of SARS-CoV–2, though the impact did not appear to be significant. FDA also provided recommendations to address possible false negative results for clinical laboratory staff and health care providers who use molecular tests for the detection of SARS-CoV–2.

In January 2021, the RADx program established a Variant Task Force (VTF) to monitor for emerging variants and study the performance of COVID–19 tests with different variants. Most recently, the VTF has been evaluating the performance of antigen tests with patient samples that have the omicron variant.

On February 22, 2021, FDA issued a guidance to provide test developers information on evaluating the potential impact of emerging and future viral genetic mutations on COVID–19 tests. (See "Policy for Evaluating Impact of Viral Mutations on COVID–19 Tests".) The guidance describes the FDA's activities and provides recommendations to test developers, such as considering the potential for future viral genetic mutations when designing their test, and conducting their own routine monitoring to evaluate the potential impact of new and emerging viral genetic mutations, which may be the basis of viral variants, on the performance of their tests.

In March 2021, FDA launched a website with information regarding the impact of viral mutations on COVID–19 tests. (Please see SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests (FDA.) The website includes a list of tests that are impacted by viral mutations and provides test-specific analyses of the impact on performance as well as recommendations for clinical laboratory staff and health care providers using the test. The website is updated regularly as new information becomes available.

In September 2021, FDA revised EUAs for most tests to add Conditions of Authorization requiring test developers to conduct their own monitoring of their test in addition to the monitoring done by FDA. These Conditions require test developers to notify FDA if any viral mutations are found to affect the performance of the test, perform and provide any additional analyses requested by the FDA, and update labeling with any risk mitigations identified by FDA regarding the impact of viral mutations on test performance.

Question 2. Looking long-term, what steps should Congress and the Administration take to improve development and supply of broad spectrum diagnostics for future pandemics?

Answer 2. Ensuring the rapid development of diagnostic tests in response to future public health emergencies (PHEs) will require a coordinated national response across several Federal agencies, as well as dedicated funding. FDA will play an important role in these efforts so that it can help to ensure tests used in emergencies are appropriately accurate and reliable. Based on the Agency's experience, FDA has identified the following Federal Government goals:

Establish More Effective Mechanisms for Sample Sharing During Outbreaks to Facilitate Test Development/Validation

Access to clinical specimens is critical for the validation of accurate and reliable tests. At the beginning of the COVID–19 outbreak, clinical specimens were not available to the U.S. Government or laboratories. Although developers could design tests based on the published sequence of the virus, the lack of clinical specimens made it challenging to validate these tests.

For example, the developers could use contrived specimens—including synthetic contrived specimens—for validation, but these contrived specimens may not have accurately characterized the performance of the test if the test was not done properly. Fifty-nine molecular tests for SARS-CoV–2 were authorized based on validations with contrived transcripts before clinical specimens or viral

RNA were readily available. Of note, FDA later found that validation with synthetic transcripts had not accurately shown test performance. Looking forward, the U.S. Government should work with international partners to establish a plan for sharing clinical specimens as soon as a public health threat emerges. This effort could be aided by having appropriate international agreements in place in advance.

Establish Contracts to Pre-Position a Handful of Commercial Developers Ready to Respond in an Outbreak

Following the MERS outbreak, South Korea established public and private partnerships and invested approximately $25 million in infectious disease diagnostic technology. As a result of these investments and the expectations created through these partnerships, a subset of South Korean commercial manufacturers were well positioned to develop and manufacture tests quickly.

For example, two commercial manufacturers began developing COVID–19 tests several weeks prior to the South Korean government's request to do so. In the United States, there was no such pre-positioning of test developers and manufacturers for immediate response. In fact, hesitancy from some U.S. commercial manufacturers was expressed based on unfavorable experiences with prior outbreaks in which some test manufacturers had significantly invested in tests that were not ultimately needed.

Furthermore, the test platform installation base in laboratories across the United States is heterogeneous, which adds a layer of complexity to a rollout of widespread testing. For example, molecular diagnostic tests are validated for use only on specific polymerase chain reaction (PCR) machines from specific vendors and are generally not interchangeable. The laboratories therefore had to wait for an authorized test that could be used on the platform they had available. The installation base of any given platform is proprietary to the vendor, which made it difficult for the U.S. Government to ensure laboratories had access to tests they could run.

FDA reviewed EUA requests from all comers and was soon flooded by thousands of requests. With tests for SARS-CoV–2, the virus that causes COVID–19, FDA ultimately had to implement a triage and prioritization process. In the fall of 2020, FDA began to prioritize review of the tests that could either increase testing accessibility (e.g., POC tests, home collection tests, at-home tests) or significantly increase testing capacity (e.g., tests that would reduce reliance on test supplies, high throughput tests, widely distributed tests). Looking forward, we believe the U.S. Government could establish contracts to preposition a handful of commercial developers to be ready to respond in an outbreak.

Ideal candidates would have a good track record with test development and be capable of working fast and scaling manufacturing operations quickly. These contracts should consider the availability of platforms in laboratories across the United States and ensure that tests will be available to all the laboratories that need them. The government may wish to develop test designs that could be implemented by preset contract manufacturers, commercial manufacturers, and laboratories performing the tests.

This pre-positioning of commercial developers and commercial contract manufacturers would enable the country to achieve a greater overall testing capacity with a smaller number of tests. In a situation where these contracts were prepositioned, FDA would have the enhanced capacity to ensure these tests are accurate and reliable before they are used.

De-Risk Test and Incentivize Product Development, as was Done for Covid–19 Vaccines

To encourage the development of diagnostic tests by commercial manufacturers, the South Korean government guaranteed both purchasing of minimum quantities of tests and reimbursement once the tests were authorized for emergency use by the MFDS, which is FDA's South Korean counterpart. This process eliminated the risk that a test developer might lose revenue from shifting manufacturing lines to tests for SARS CoV–2. These types of steps to de-risk and incentivize product development, although later taken for vaccine development, were not taken early on by the U.S. Government for test development. Instead, to incentivize development of tests, FDA issued policies regarding developers offering certain tests prior to an EUA while an EUA request was pending (and for certain serology tests, without an EUA or submission of an EUA request). These policies had tradeoffs; for example, FDA later found that some poorly performing tests were being used. Of particular note, FDA's experience with serology tests underscores the importance of FDA reviewing tests used in a PHE prior to such products entering the market based on sound science. In the future, the government should consider de-risking the financial investment needed to produce accurate and reliable tests at scale. This effort could be focused on the developers who are pre-positioned to produce tests at scale when needed.

Establish a Centralized Clinical Validation Program

To complement the flexible policies that FDA put in place for serology tests, FDA collaborated with the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) to establish a government capability to evaluate the performance of serology tests. This was the first time the Federal Government created a capability to evaluate tests itself to inform regulatory decisions.

This was valuable in helping FDA deal with poorly performing tests and ultimately for making decisions on EUA requests. FDA's research into South Korea's response found that the Korea Disease Control and Prevention Agency established a testing capability in selected laboratories to conduct a clinical evaluation of all molecular tests for which the manufacturer sought an EUA. As a result, test developers in South Korea did not have to find their own clinical specimens or viral material to evaluate their tests, which likely shortened the length of time needed to complete validation studies to support EUA applications and increased the government's confidence in each test's accuracy.

With respect to molecular tests, the traditional approach of test developers conducting their own clinical evaluation of their tests continued, as no independent testing capability existed in the

United States. Establishing the capacity within or on behalf of the Federal Government to evaluate test performance before outbreaks occur would permit an independent evaluation to be quickly performed during an outbreak. This established capacity would minimize the need for developers to find patient specimens or other clinical samples to validate their tests and would conserve specimens for validation. By centralizing validation materials and providing this evaluation for developers, the government could expedite the validation and authorization of tests while increasing confidence in test performance. The Federal Government should also consider the utility of this approach for technologies used outside an outbreak.

Collaborate With Laboratories and Commercial Developers on a Framework for How to Conduct Appropriate Validations

FDA received thousands of pre-EUA and EUA requests for tests for SARS-CoV–2, many of which came from developers without prior experience with appropriate test validation. FDA created templates to facilitate test validations and EUA submissions; however, FDA encountered many cases of poor validation and poor-quality submissions, which required the Agency to expend even more resources. For example, in an analysis of 125 EUA requests from laboratories for molecular tests, FDA found that 79 requests had issues with the validation. FDA saw similar problems with EUA requests from commercial manufacturers, particularly those with less experience in test development.

Going forward, FDA intends to work collaboratively with the community on best practices and common approaches to validating test design and performance. FDA could proactively create validation protocols in collaboration with the test developer community for commonly anticipated pathogens and sample types before an outbreak; the Agency could then modify them as necessary after an outbreak occurs. This proactive approach would facilitate appropriate and faster validation. Additionally, FDA believes a modern legislative framework for all tests, regardless of who makes them, would facilitate a more common understanding of validation prior to an outbreak and would enhance the developer community's collaboration with FDA during an outbreak.

Stockpile Testing Supplies

There were no testing supplies in the Strategic National Stockpile, and by March 2020, laboratories were experiencing shortages of supplies ranging from extraction reagents, to swabs, to transport media. FDA worked to develop shortage mitigation measures by seeking alternative products that could adequately perform so that end users did not experience a depletion of materials. For example, FDA proactively reached out to platform developers with PCR instruments, which are used to detect and amplify RNA and DNA sequences. FDA requested that these developers validate the use of CDC's assay on their PCR instruments, leveraging data from a prior authorization of CDC's influenza panel to support the use of additional PCR instruments and extraction kits.

In addition, FDA supported manufacturers who do not typically produce medical supplies as part of their business operations in al-

tering their manufacturing to create products usable for U.S. testing. 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 Q-tip-type swab for testing. FDA also collaborated with laboratories and clinical investigators validating potential alternative sources of control materials, transport media, and swabs, later posting the results of these collaborations on the Agency's website. Similarly, as individual developers validated alternative components, FDA requested their permission to share their findings publicly, on the Agency's website, so that others could benefit. In this way, FDA shared scientific information that the entire community could leverage to mitigate shortages and increase testing capacity. Going forward, the Federal Government should either maintain a stockpile of basic testing supplies so that it does not need to seek out and validate so many alternatives or use less optimal alternatives in a future outbreak.

Provide Continuing Education on the Appropriate Use of Tests as the Situation and Scientific Knowledge Evolve

During COVID–19, FDA saw examples of when the clinical community relied on tests for uses that were outside their authorization and not supported by science. For example, many members of the community relied on serology tests for diagnosis, or as measures of immunity, despite the lack of evidence correlating an immune response to immunity from infection. In another example, lower sensitivity tests were used to screen asymptomatic individuals in whom infection may have been harder to detect, if present at all. All members of the clinical community should have an understanding of test performance and how to use that information in patient care.

Tests should be accompanied by clear, standardized, and comprehensible information on performance for clinicians and patients. Training and continuing education can enhance physicians' understanding of test performance, selection, interpretation, and clinical usefulness. Ongoing education is paramount in any PHE response as scientific knowledge evolves, particularly given the misuse of serology tests for diagnosis, the potential for false positive results when a single test is used in populations with a low rate of infection, and the perception of immunity. The national approach to testing needs to be consistently updated and guided by sound science.

Invest in Novel Poc and At-Home Technologies

As the pandemic evolved, FDA saw a growing demand for tests that could be performed outside of a traditional laboratory, such as at the POC, in homes, in schools, and at other non-healthcare settings. FDA developed templates for and authorized tests that could be performed in these settings; however, most such authorizations came many months into the pandemic. The Federal Government should invest in the development of truly novel technologies that can be used at the POC and in homes and for multiple conditions—including potential advances such as sequencing to provide mutation detection, breath analyzers, and light-based devices—as long as they are accurate.

In fact, the first POC COVID–19 tests authorized by FDA came from developers applying technologies that had already been developed prior to COVID–19. Although it may be difficult to predict diagnostic needs, it is generally easier to add a new, specific target of analysis to an existing platform than it is to create, validate, and manufacture an entirely new test and testing platform. This especially applies to POC and at-home tests as they often go through additional validation to demonstrate accuracy and reliability in the hands of untrained users. The Federal Government could use several mechanisms, including competitions with prize awards and grants. FDA believes that the establishment NIH's Independent Test Assessment Program (ITAP) is critical for supporting these efforts.

The goal of this program is to accelerate the availability of more high-quality, accurate, and reliable OTC tests to the public, as quickly as possible. If we invest in POC and at-home testing technologies now, when a public health threat warrants large-scale testing, the government would be able to move swiftly to financially support modifications to detect the target pathogen, ramp up large-scale production, and provide guaranteed reimbursement for use of applicable and already FDA-approved tests

SENATOR BURR

Question 1. On November 15, FDA issued revised guidance stating it would focus its review efforts on at-home and point-of-care COVID test applications from developers with the capacity to manufacture more than 500,000 tests per week within 3 months of being authorized.

> *Question 1(a).* How many test developers are able to scale up to manufacture more than 100,000, but less than 500,000 tests per week?
>
> *Question 1(b).* Will FDA review their test under the EUA pathway? If not, why not?
>
> *Question 1(c).* Is FDA denying applications that cannot meet the 500,000 tests per week manufacturing capacity requirement?
>
> *Question 1(d).* How does this policy account for manufacturers developing tests at risk who have the near term potential to reach the 500,000 capacity but cannot scale up without authorization?

Answer 1. FDA has received over 5,000 EUA and PEUA requests for IVDs since January 2020, and continues to receive over 100 EUA requests a month, mostly for IVDs. It is therefore critical that we focus limited resources on those tests that will have the greatest impact on the public health. There remains a public health need for increased access to testing. This can best be addressed by prioritizing review of tests such as at-home and point-of-care diagnostic tests that can be produced in high volumes.

The priorities outlined in our guidance of November 15, 2021 are based on our experience working with test developers to respond to the pandemic for over 2 years. We took into account both our review capacity as well as what we have seen developers accomplish

with respect to ease of use and manufacturing capacity. When considering manufacturing capacity, we generally consider the developer's projected capabilities within 3 months of authorization. This allows manufacturing scale up to take place post-authorization rather than prior to authorization. FDA also reviews any EUA requests for tests from or supported by a US government stakeholder, regardless of the developer's manufacturing capacity. This helps to ensure that tests that are part of a coordinated response, such as the school and community testing programs, are prioritized for review.

FDA does not have information on the number of test developers able to scale up to manufacture more than 100,000, but less than 500,000 tests per week. However, any developers of tests that have not been prioritized by the Agency for EUA may seek marketing authorization through traditional device review pathways such as 510(k) notification or De Novo classification.

Question 2. FDA has authorized over 400 COVID tests, and has stated that some of these tests may not be as sensitive to the Omicron variant. The more this virus shifts and drifts from its original strain, the more difficult it may be for our tests to detect. What is the FDA doing to work with manufacturers to address the challenge that will come along with diagnosing and detecting new variants of COVID–19?

Answer 2. FDA has been monitoring for viral mutations and their impact on authorized molecular and antigen diagnostic tests throughout the pandemic. FDA tracks the part of the viral genome targeted by each authorized molecular test in a data base, monitors global data bases for emerging variants, and conducts in silico analyses to evaluate whether any of the authorized test probes target a part of the viral genome that has mutated. If FDA identifies a potential impact on test performance, FDA contacts the test developer and communicates with the public.

The first such communication took place on January 8, 2021, not long after variants began to emerge. FDA issued a safety alert and Letter to Health Care Providers to caution that the presence of viral genetic mutations in a patient sample can potentially change the performance of a diagnostic test. At that time, FDA identified three authorized molecular tests that may be impacted by genetic variants of SARS-CoV–2, though the impact did not appear to be significant. FDA also provided recommendations to address possible false negative results for clinical laboratory staff and health care providers who use molecular tests for the detection of SARS-CoV–2.

In January 2021, the RADx program established a Variant Task Force (VTF) to monitor for emerging variants and study the performance of COVID–19 tests with different variants. Most recently, the VTF has been evaluating the performance of antigen tests with patient samples that have the omicron variant.

On February 22, 2021, FDA issued a guidance to provide test developers information on evaluating the potential impact of emerging and future viral genetic mutations on COVID–19 tests. (See "Policy for Evaluating Impact of Viral Mutations on COVID–19 Tests".) The guidance describes the FDA's activities and provides

recommendations to test developers, such as considering the potential for future viral genetic mutations when designing their test, and conducting their own routine monitoring to evaluate the potential impact of new and emerging viral genetic mutations, which may be the basis of viral variants, on the performance of their tests.

In March 2021, FDA launched a website with information regarding the impact of viral mutations on COVID–19 tests. (Please see SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests (FDA.) The website includes a list of tests that are impacted by viral mutations and provides test-specific analyses of the impact on performance as well as recommendations for clinical laboratory staff and health care providers using the test. The website is updated regularly as new information becomes available.

In September 2021, FDA revised EUAs for most tests to add Conditions of Authorization requiring test developers to conduct their own monitoring of their test in addition to the monitoring done by FDA. These Conditions require test developers to notify FDA if any viral mutations are found to affect the performance of the test, perform and provide any additional analyses requested by the FDA, and update labeling with any risk mitigations identified by FDA regarding the impact of viral mutations on test performance.

Question 3. What is the latest science on boosters for recipients of the J&J vaccine? When will you have answers for the millions of Americans that received this shot who are interested in ensuring they continue to be protected against Omicron and future variants?

Answer 3. FDA has authorized a single-dose primary vaccination regimen for the Janssen COVID–19 Vaccine for individuals 18 years of age and older. FDA has also authorized a single Janssen COVID–19 Vaccine booster dose that may be administered at least 2 months after primary vaccination with the Janssen COVID–19 Vaccine. Additionally, FDA has authorized use of either the Pfizer BioNTech COVID–19 Vaccine or the Moderna COVID–19 Vaccine as a heterologous booster dose for individuals who have received primary vaccination with the Janssen COVID–19 Vaccine. The booster dose of either of the mRNA vaccines may be administered at least 2 months after completion of primary vaccination with the Janssen COVID–19 Vaccine.

Data published in a Morbidity and Mortality Weekly Report by the CDC are reassuring in that for the mRNA COVID–19 vaccines, two doses and one booster dose, and for the Janssen COVID–19 Vaccine, one dose and a booster dose, continue to provide protection against severe COVID–19 and hospitalization and death. Rates of COVID–19 cases were lowest among fully vaccinated persons who had received a booster dose, compared with fully vaccinated persons who had not received a booster dose, and much lower than rates among unvaccinated persons during October/November and also December 2021, when the Omicron variant was circulating.

In addition, during December, unvaccinated people had approximately 5 times the risk for developing COVID–19 compared to vaccinated people who had received a booster dose of a COVID–19 vaccine. A similar increase in risk was seen among unvaccinated peo-

ple compared to people who had received a booster dose, irrespective of what vaccine people received for primary vaccination.

Question 4. FDA has authorized vaccines for COVID–19 for individuals and children ages 5 and up. When does FDA expect that a vaccine for ages 2–4 will be available? What challenges exist for clinical trials conducted for the 2–4 year old age group, and how is FDA working to help address such challenges?

Answer 4. FDA recognizes the need for a safe and effective vaccine for younger children, particularly given the rapid spread of the Omicron variant, the notable rise in the number of hospitalizations in young children with severe disease, and the possibility that future variants could cause severe disease in those who are unvaccinated.

It is important that the public recognize that, because children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are undertaken to evaluate the safety and effectiveness of a COVID–19 vaccine in pediatric populations. Children are not small adults and issues that may be addressed in pediatric vaccine clinical trials can include the appropriate dose and administration schedule of vaccines already used for adults.

Conducting clinical trials to determine an appropriate vaccine dose in younger pediatric populations requires additional investigation and study over that done in the clinical trials for adults including ensuring that the vaccine dosage is safe and effective. FDA has been working closely with vaccine manufacturers to provide advice as data accrue about safety and effectiveness, the latter of which may be comprised of immune response data or the number of COVID–19 cases that occur, or a combination of both, for their respective COVID–19 clinical trials in pediatric populations. Once adequate data are available, we plan to convene a meeting of our Vaccines and Related Biological Products Advisory Committee to publicly discuss the data.

SENATOR CASSIDY

Question 1. Second, how are you all harnessing the speed and innovation of the private sector to help predict, prevent, and mitigate future COVID–19 variants or other pathogens of concern?

Answer 1. FDA continues to work with companies that are developing additional medical products, researchers, and manufacturers to help expedite the development and availability of medical products such as additional vaccines,'monoclonal antibodies, and other drugs to prevent or treat COVID–19?

SENATOR BRAUN

Question 1. Dr. Woodcock, we understand that, through the National Institutes of Health Rapid Acceleration of Diagnostics' Independent Test Assessment Program, companies worked closely with the FDA to obtain Emergency Use Authorization for rapid antigen tests. Diagnostic manufacturers are producing millions of much-needed rapid antigen tests for the American people. Can you discuss the future of this program?

Answer 1. The Independent Test Assessment Program (ITAP) will continue to be critical to streamlining validation and authorization of antigen tests with potential for large-scale manufacturing. FDA has already authorized three new OTC, at-home COVID–19 tests that participated in this program one manufactured by SD Biosensor and distributed by Roche, one manufactured by Siemens (please see the following release for more details: Two New Over-the-Counter At-Home COVID–19 Tests Brought to U.S. Market Quickly by Biden-Harris administration (*HHS.gov*), and a third manufactured by Maxim Biomedical.

This program is an extension of the RADx program which has already supported development of dozens of authorized tests, including the first over-the-counter COVID–19 test. Organizations applying to ITAP will be evaluated for participation based on several criteria.[1] Prior to EUA submission, ITAP supports independent laboratory and clinical evaluations using protocols developed jointly with FDA.

We plan to continue to use the information from ITAP to grant emergency use authorization when the science supports doing so. We are already seeing shorter review times for such EUA requests due to our partnership with ITAP in establishing the evaluation program to address our regulatory needs. The average FDA review time for a test evaluated under ITAP is less than a week, and can be as short as 1 day.

This solution is based on our lessons learned earlier in the pandemic. Namely, developers unfamiliar with the regulatory process often provide incomplete or poor validation data that is insufficient to support authorization. FDA interacts with such developers to guide them in appropriate validation, but this is inefficient for both parties and stretches out review times. The establishment of ITAP is a targeted solution that will continue to assist developers and streamline the FDA review process, and ultimately accelerate the availability of more high-quality, accurate and reliable over-the-counter tests to the public.

Our experience with ITAP illustrates the value of an independent government testing capability in bringing accurate and reliable tests to market quickly. South Korea took this approach with molecular diagnostics at the beginning of the COVID–19 outbreak and was able to scale their national testing capacity very quickly. In the Spring of 2020, we established an evaluation program with NCI for serology tests which provided valuable data to inform our regulatory decisions. As we have noted in our perspective on lessons learned published in NEJM, we should establish the capacity within or on behalf of the Federal Government to evaluate test performance before outbreaks occur so that independent evaluation can be performed quickly during an outbreak.

SENATOR SCOTT

Treatments

Question 1. Dr. Woodcock what is the status of in-patient therapeutics? Do we have effective treatments for those in the ICU to

[1] https://www.poctrn.org/itap

prevent ventilator intubation or post-intubation to accelerate recovery

Question 1(a). Are repurposed drugs being considered and approved?

Answer 1. Currently, the following products are approved or authorized for certain patients who are hospitalized:

- Oral Paxlovid (ritonavir-boosted nirmatrelvir) is authorized for the treatment of COVID–19 among persons with mild to moderate symptoms who are at high-risk for disease progression. In a clinical trial, Paxlovid reduced the risk of hospitalization and death by 89 percent in unvaccinated outpatients with COVID–19 at higher risk of severe disease. Serious adverse events are uncommon with Paxlovid treatment. Paxlovid is given twice daily for 5 days, starting as soon as possible and within 5 days of symptom onset, and is approved for use in adult and pediatric patients (12 years of age and older weighing at least 40kg).
- Veklury (remdesivir) is an approved drug product that is indicated for the treatment of coronavirus disease 2019 (COVID–19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV–2) viral testing, who are:
  - Hospitalized, or
  - Not hospitalized and have mild-to-moderate COVID–19, and are at high risk for progression to severe COVID–19, including hospitalization or death;
- Actemra (tocilizumab) is authorized for emergency use for the treatment of COVID–19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO);
- Olumiant (baricitinib) is authorized for emergency use to treat COVID–19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO;
- COVID–19 convalescent plasma with high titers of anti-SARS-CoV–2 antibodies is authorized for emergency use for the treatment of COVID–19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting.

Since early in the COVID–19 public health emergency, FDA recognized the increased demand for certain products and prioritized the review of generic drug applications for potential treatments and supportive therapies for patients with COVID–19, such as for heparin and dexamethasone.

With respect to additional products, including repurposed drugs, being considered for emergency use authorization or approval, we note that, consistent with Federal statutes and FDA's implementing regulations concerning the confidentiality of commercial information, and to protect the integrity of the review process, FDA generally cannot disclose information about unapproved products. FDA is committed to quickly and thoroughly reviewing all submitted applications, including requests for emergency use authorization, to speed patient access to medicines to prevent or treat COVID–19 provided they meet the agency's rigorous standards. Through the Coronavirus Treatment Acceleration Program (CTAP), we continue to support research and clinical trials that are testing new treatments for COVID–19, including therapies intended to treat severe forms of the disease, so that we gain valuable knowledge about their safety and effectiveness.

SENATOR TUBERVILLE

Antibody Testing & Treatments

Question 1. On May 19, 2021, the FDA recommended against antibody testing to determine a person's level of immunity.

a. How should people be aware of their level of antibodies or need for a booster?

b. Do you believe people are receiving a booster when they already have adequate protection from COVID–19?

Answer 1. The currently authorized SARS-CoV–2 antibody tests should not be used to evaluate a person's level of immunity or protection from COVID–19 at any time, including after the person received a COVID–19 vaccine. Currently authorized SARS-CoV–2 antibody tests have not been evaluated to determine whether they can predict if a person is protected against COVID–19. Furthermore, there is no specific level of a particular antibody which has been shown to be associated with protection against disease. The available data from the COVID–19 clinical trials and ongoing assessment of the effectiveness of the vaccines provides confidence that the vaccines protect against COVID–19, including serious consequences that can occur such as hospitalization and death.

Based on HHS's assessment of currently available data, including during the surge of the circulation of Delta and Omicron variants, a single booster dose of the currently authorized vaccines after completion of primary vaccination is recommended to provide protection against COVID–19. With this in mind, individuals ages 12 years and older who have completed primary vaccination may receive a single booster dose.

The FDA amended the emergency use authorization for the Pfizer-BioNTech COVID–19 Vaccine to allow for a single booster dose for people ages 12 years of age and older at least 5 months after completion of a primary series with the Pfizer-BioNTech COVID–19 Vaccine or Comirnaty (COVID–19 Vaccine, mRNA). Individuals 12 through 17 years of age should receive only the Pfizer-BioNTech COVID–19 Vaccine or Comirnaty (COVID–19 Vaccine, mRNA) as their booster dose.

Individuals 18 years of age and older who completed a primary series with the Pfizer-BioNTech COVID–19 Vaccine, Comirnaty (COVID–19 Vaccine, mRNA), or the Moderna COVID–19 Vaccine, at least 5 months ago, may receive a single booster dose of any of the currently authorized or approved COVID–19 vaccines. Individuals 18 years of age and older who completed their primary vaccination with Janssen COVID–19 Vaccine at least 2 months ago, may receive a single booster dose of any of the currently authorized or approved COVID–19 vaccines.

Question 2. Please provide specific examples where your agency has utilized real world evidence in regards to COVID–19 or treatments for COVID–19.

Answer 2. The following is an example of when FDA has utilized real world evidence for a COVID–19 vaccine. FDA has determined that the known and potential benefits of a single booster dose of the Pfizer-BioNTech COVID–19 Vaccine to provide continued protection against COVID–19 and the associated serious consequences that can occur including hospitalization and death, outweigh the known and potential risks in individuals 12 through 15 years of age when given at least 5 months following primary series.

FDA reviewed real-world data from Israel, including safety data from more than 6,300 individuals 12 through 15 years of age who received a booster dose of the vaccine at least 5 months following completion of the primary two-dose vaccination series. These additional data enabled the FDA to reassess the benefits and risks of the use of a single booster dose in this age group in the setting of the January 2022 surge in COVID–19 cases. The data showed that there were no new safety concerns following a booster in this population, and in particular, that no new cases of myocarditis or pericarditis were reported in these individuals.

(Moved from the NIH set of QFRs)

SENATOR HASSAN

Children under age five are still not eligible for a COVID–19 vaccine. Moderna reported earlier this month that it expects to report trial data on its COVID–19 vaccine in children ages 2 to 5 by March.

Meanwhile, the number of children with COVID–19 is surging in New Hampshire and across the country. As of January 1, the hospitalization rate for children under age 5 reached 4 in 100,000 children—3 times higher than the same time last year.

Question 1. At this point, when do you expect that vaccinations will be available to children under age 5?

Answer 1. FDA recognizes the need for a safe and effective vaccine for younger children, particularly given the rapid spread of the Omicron variant, the notable rise in the number of hospitalizations in young children with severe disease, and the possibility that future variants could cause severe disease in those who are unvaccinated.

It is important that the public recognize that, because children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are undertaken to evaluate the

safety and effectiveness of a COVID–19 vaccine in pediatric populations. Children are not small adults and issues that may be addressed in pediatric vaccine clinical trials can include the appropriate dose and administration schedule of vaccines already used for adults.

Conducting clinical trials to determine an appropriate vaccine dose in younger pediatric populations requires additional investigation and study over that done in the clinical trials for adults including ensuring that the vaccine dosage is safe and effective. FDA has been working closely with vaccine manufacturers to provide advice as data accrue about safety and effectiveness, the latter of which may be comprised of immune response data or the number of COVID–19 cases that occur, or a combination of both, for their respective COVID–19 clinical trials in pediatric populations.

Once adequate data are available, we plan to convene a meeting of our Vaccines and Related Biological Products Advisory Committee to publicly discuss the data. For the Pfizer-BioNTech COVID–19 Vaccine, we will provide an update on timing for the advisory committee meeting once we receive and evaluate additional data on the results of three doses administered to children 6 months through 4 years of age from the company's ongoing clinical trial.

RESPONSE BY DAWN O'CONNELL TO QUESTIONS OF SENATOR CASEY, SENATOR BALDWIN, SENATOR HASSAN, SENATOR SMITH, SENATOR LUJÀN, SENATOR BURR, SENATOR CASSIDY, SENATOR SCOTT, AND SENATOR TUBERVILLE

SENATOR CASEY

Question 1. At the hearing, I asked how the Federal Government is working with vaccine manufacturers to speed the development of a safe and effective vaccine for children under age five. Understanding that the Pfizer trial for children 24 months to 5 years old did not meet its endpoint, my follow-up questions are, how did we get here and what's next? Please describe, generally, the following:

Question 1(a). How vaccine developers make decisions about dose size, quantity and spacing in age de-escalation trials;

Answer 1,1(a). In general, vaccine developers typically do a small, carefully planned 'dose ranging' study for each new age range. Based on the adult and non-clinical data, developers may select a number of different dose levels to test. Typically, the spacing between doses and number of doses is the same as in the adult trials, at least initially, to allow for bridging between the two populations. The safety and immunogenicity data from these small trials is analyzed, including comparing immunogenicity results with immunogenicity results from the adult population, and based on the data, one or two different dose levels may be selected for the larger, confirmatory trials. If results from the small trial do not identify a dose with a proper safety and immunogenicity profile, a second small study might be conducted before moving to larger trials. This follow-on study could include looking at additional dosing regimens or looking at lower or higher dose levels.

Question 1(b). What type of indicators a vaccine manufacturer might consider when determining whether and how to change the dose size, quantity or spacing if primary endpoints are not met; and

Answer 1(b). As mentioned above, vaccine developers typically do a small, carefully planned 'dose ranging' study for each new age range. Based on the adult and non-clinical data, developers may select a number of different dose levels to test. Typically, the spacing between doses and number of doses is the same as in the adult trials, at least initially, to allow for bridging between the two populations. The safety and immunogenicity data from these small trials is analyzed, including comparing immunogenicity results with immunogenicity results from the adult population, and based on the data, one or two different dose levels may be selected for the larger, confirmatory trials. If results from the small trial do not identify a dose with a proper safety and immunogenicity profile, a second small study might be conducted before moving to larger trials. This follow-on study could include looking at additional dosing regimens or looking at lower or higher dose levels.

Question 1(c). Whether the emergence of a viral variant could affect the efficacy of a vaccine in children differently than it would affect the efficacy of the same vaccine in adults.

Answer 1(c). Emergence of a variant can potentially impact vaccine effectiveness, and a vaccine may not work as well to protect against disease caused by the variant for all. In addition, it is not uncommon for a vaccine to have a different level of efficacy for certain ages/populations as many factors can play into this, including decreased immune response to some vaccines as individuals age, the health status of the individual, and the endpoint being assessed.

Question 2. Furthermore, could you please provide an update on current Federal goals and investments relating to the development of vaccines to protect children under age five from COVID–19, including grants, contracts or other funding awarded to vaccine developers; and what information is currently being provided to vaccine developers regarding current or planned opportunities for collaboration between the Federal Government and vaccine developers, including the extent to which BARDA will conduct TechWatch/CoronaWatch meetings and the extent to which FDA will accept applications for emergency use authorization.

Answer 2. From the beginning of the COVID–19 response, ASPR has been committed to developing safe and effective vaccines for all age ranges. When BARDA awarded the initial COVID–19 vaccine development contracts to Janssen and Moderna in the early spring of 2020, funds were included to conduct trials in all age ranges down to the youngest populations. Subsequent product development and procurement contracts to Novavax, Sanofi/GSK, and AstraZeneca included scope and funds to support pediatric clinical trials. Similarly, advanced purchase agreements with Pfizer included procurement of pediatric doses. Over the last 2 years, ASPR/BARDA has and will continue to work closely with each product developer to support development of their vaccines for pediatric indications as early as is appropriate (for example, once efficacy in

adults has been shown). This includes funding the majority of the Moderna pediatric trial that just announced Phase III results, as well as advanced purchase agreement of Pfizer pediatric vaccine to support their pediatric development efforts, including advanced purchase of the Pfizer-BioNTech COVID–19 Vaccine for children ages 5 through 11 years that is currently authorized under EUA and being widely distributed.

BARDA's TechWatch program remains open to all threat areas, including COVID–19. Industry partners, including those developing COVID–19 vaccines, are encouraged to request a TechWatch meeting. This program continues to serve as a central location for industry to engage interagency government partners with potential funding opportunities. At this time, ASPR/BARDA does not have sufficient funding to initiate development of additional or next generation COVID–19 vaccines. Several promising potential candidates and technologies for investment have been identified and will be pursued if funding is provided, with plans to develop vaccines with broader and/or more durable protection.

Question 3. Finally, could you describe current thinking across your agencies regarding the circumstances under which your efforts would expand to include the development of additional or next-generation vaccines and therapeutics for COVID–19?

Answer 3. BARDA's TechWatch program remains open to all threat areas, including COVID–19. Industry partners, including those developing COVID–19 vaccines, are encouraged to request a TechWatch meeting. This program continues to serve as a central location for industry to engage interagency government partners with potential funding opportunities. At this time, ASPR/BARDA does not have sufficient funding to initiate development of additional or next generation COVID–19 vaccines. Several promising potential candidates and technologies for investment have been identified and will be pursued if funding is provided, with plans to develop vaccines with broader and/or more durable protection.

Regarding therapeutics, the oral antivirals are recent authorizations and allow for much easier administration and improved patient access. One of the benefits of the oral antivirals Paxlovid and molnupiravir is that they have much broader activity against SARS-CoV–2 and its variants. In fact, both Paxlovid and molnupiravir have activity against all SARS-CoV–2 variants tested as of January 2022. Looking to the future and the President's Pandemic Preparedness Plan, focusing on broad acting antivirals with activity against many viruses, as well as focusing on host-targeted therapeutics that are virus-agnostic will be high priorities.

SENATOR BALDWIN

Question 1. The Omicron variant has made clear the critical need for higher quality masks, such as N95. Further, I applaud the Administration's efforts to begin distributing N95 masks to the public.

Question 1(a). Masks that are currently being distributed to the public came from the Strategic National Stockpile (SNS). How is ASPR working to make sure that masks purchased to replenish the stockpile following this distribution are made in the United States, using raw materials from American manufacturers?

Answer 1,1(a). The Administration is committed to procuring domestically manufactured PPE in accordance with the Infrastructure Investment and Jobs Act (IIJA). The Department has relied on COVID–19 supplemental resources to support the COVID–19 response. ASPR is currently validating COVID–19 PPE stockpiling goals and assessing priorities to ensure the best use of remaining supplemental funds, possibly including investments geared toward creating or expanding domestic capabilities to manufacture the raw materials and intermediates needed for final manufacture of N95 masks.

Question 1(b). Please describe how ASPR intends to support small domestic manufacturers in the process of replenishing the SNS.

Answer 1(b). The SNS adheres to small business procurement regulations. If a small business can meet the requirements of the solicitation and is the best offeror for the requirement, they will be selected.

Question 1(c). What is ASPR's plan to invest in domestic manufacturers of the raw materials needed to make high-quality PPE, including N95s, here in the United States?

Answer 1(c). ASPR is utilizing funding appropriated by Congress via various COVID–19 supplemental appropriations to invest in domestic manufacturing of PPE when possible. ASPR has stood up an industrial-based expansion office and is working to hire staff with specific expertise in this field to award contracts to ensure preparedness for future public health incidents.

Question 1(d). How will ASPR work to ensure that any contracts for warm-base manufacturing capacity of PPE and its raw materials support small businesses?

Answer 1(d). HHS adheres to small business procurement regulations. If a small business can meet the requirements of the solicitation and is the best offeror for the requirement, they will be selected.

Question 1(e). Please provide an update on the status of the RFI for medical-grade meltblown production.

Answer 1(e). The U.S. produces approximately 2 percent of the man-made fiber (MMF) needed for PPE and other products used domestically. During the ongoing COVID–19 response, we have invested approximately $20.7 million in meltblown material capacity expansion for use in N95 masks, surgical masks, and ventilator filters. The chart below captures these investments.

Vendor	City	State	Award Date	Award Amount	Capacity Increase	Full Prod Date	Source Account
Hollingsworth & Vose	Floyd	VA	5/19/2020	$1.9M	Meltblown 3.1M N95s/mo 27.5M Vent/mo	20-Dec	DPA Title III
Lydall	Strafford	NH	6/19/2020	$13.5M	Meltblown 100M N95s/mo or 192M surgical masks/mo	21-May	HHS CARES

Vendor	City	State	Award Date	Award Amount	Capacity Increase	Full Prod Date	Source Account
FyterTech Nonwovens	Green Bay	WI	7/24/2020	$2.75M	Meltblown 60M N95s/mo or 170M surgical masks/mo	Jan 2022	HHS CARES
Hollingsworth & Vose	Floyd	VA	12/2/2020	$2.5M	Meltblown 8.3M N95s/mo	22-Jan	HHS CARES

We currently have a solicitation (*https://sam.gov/opp/0e037509432b491a80d789e5a4f34380/view*) and are currently reviewing offerors for MMF capacity and research and development to support gown manufacturing.

SENATOR HASSAN

I'm grateful that the administration heeded my call to send FEMA teams to New Hampshire to help administer COVID–19 treatments, as this assistance was essential to keeping our health system functioning. However, there were delays in the teams' arrival and limits to how long they were able to remain in the state.

Question 1. What additional personnel and support is the administration planning to provide to New Hampshire and other states to help providers overwhelmed by the pandemic?

Answer 1. The Secretary of HHS, and by delegation the ASPR, serves as the lead for Emergency Support Function No. 8 (ESF–8) under the National Incident Response Framework. Utilizing an established resource request process through the ASPR and FEMA Regional Offices, state, local, tribal, and territorial requests for Federal medical support for healthcare facilities and needs related to the COVID–19 pandemic are evaluated and resourced under that construct, to include deployment of personnel for medical surge, vaccination, monoclonal antibody administration, testing sites, and technical support. To support the review of such requests, HHS conducts a call as required with the other Federal partners supporting elements of the medical response. On this ESF–8 Partner Call, the Federal partners including NDMS, DoD, the VA, PHS Commissioned Corps, and CDC, gather to discuss, coordinate, and determine resourcing support decisions based on requests received from states, tribes, and territories. As COVID–19 case counts and other considerations change, the requests are reviewed in real-time to determine the best allocation possible given limited Federal resources. We will use this established process to determine any additional support the Administration can offer to New Hampshire and other states overwhelmed by the pandemic.

SENATOR SMITH

Question 1. Given the importance of ensuring we have sufficient supply of accurate COVID–19 tests, can you explain the Administration's plans to develop and increase access to broad spectrum diagnostic tests, including molecular tests, to increase our ability to detect current and future COVID–19 variants?

Answer 1. The Administration has been focused on testing since day one and has four priority areas:

Answer 1(a). Increasing the number of testing sites and programs for getting tested in the U.S., for example, through the Increasing Community Access to Testing (ICATT) program and federally Qualified Health Centers (FQHCs);

Answer 1(b). Increasing the types of tests authorized for use in the U.S., working closely with FDA;

Answer 1(c). Increasing the overall supply of tests; and

Answer 1(d). Lowering or eliminating the costs of testing, in coordination with CDC and CMS.

Advancing equity in access and use of tests is woven throughout each of these key goals—from selecting the location of Federal, free testing sites to the provision of free tests to the uninsured to expanding lower-cost testing options more generally. We continue to do everything we can to advance our four priority areas, as quickly as we can.

FDA, in collaboration with other offices in HHS (CDC, BARDA, NIBIB), is working to ensure that authorized tests can detect all circulating SARS-CoV–2 variants. Most tests can detect all high prevalence variants, but several tests have had issues detecting specific circulating variants. In those cases, FDA works with the manufacturers so that the manufacturers can improve their tests quickly or remove them from the market.

Antigen tests are relatively low cost, are now widely available to detect SARS-CoV–2 infections, and are essential to ending the ongoing pandemic. However, molecular tests are generally much higher performing and can be developed and deployed for a new emerging disease much more rapidly than antigen tests. Molecular tests can be developed that are specific enough to differentiate a particular disease variant from other circulating variants. New molecular testing technologies that overcome some of the challenges associated with centralized laboratory molecular testing have been in development over the past 5 or so years and have become available for use, with significant Federal investment, during the COVID–19 pandemic. These new tests may be appropriate for use in non-laboratory settings including doctors' offices and nursing homes, and even as self-tests for some diseases like COVID–19.

Question 2. Looking long-term, what steps should Congress and the Administration take to improve development and supply of broad spectrum diagnostics for the current and future pandemics?

Answer 2. The Administration is working to support efforts to make testing available more quickly, both for new emerging diseases and emerging SARS-CoV–2 variants. Due to the shorter development time for molecular test technologies, the Administration is also supporting efforts to support investment in domestic capabilities to manufacture newly emerging molecular tests that are appropriate for use in non-laboratory settings, including homes, making them much more widely available. The Administration is also working on a revised National Biodefense Strategy that will include broad objectives and plans for future investments in this

space. There is no timeline for release of the revised NBS at this time.

SENATOR LUJÀN

Question 1. Throughout the pandemic, state and Federal policymakers have asked pharmacists to provide clinical services to patients. Every state now authorizes licensed pharmacists to order and administer vaccines, tests for COVID–19 and other infectious diseases, and therapeutics to treat COVID–19, but pharmacists' ability to perform these services will expire with the public health emergency expiration. The Secretary of Health and Human Services even used their authority under the Public Readiness and Emergency Preparedness (PREP) Act to ensure that all Americans could access these services from their pharmacist. At least 38 states have expanded their Medicaid coverage of clinical services provided by pharmacists during the pandemic, and many commercial payers cover clinical services provided by pharmacists. But I understand that the Medicare program cannot cover clinical services that Medicare beneficiaries want to receive from their pharmacist. When Medicare beneficiaries need clinical services from their pharmacist, does the Medicare program have the authority it needs to pay for those services? If not, what legislative change is necessary to ensure Medicare beneficiaries have access to clinical services that their pharmacist is licensed to provide?

Answer 1. This response is best addressed by the Centers for Medicare & Medicaid Services.

SENATOR BURR

Question 1. The development of the first successful mRNA vaccines is a clear success story from the COVID–19 pandemic. However, this virus has, and likely will, continue to mutate, which means that we must continue to support the development of a variety of medical countermeasures, including those that utilize different platforms or mechanisms of action. Operation Warp Speed recognized this need and supported multiple vaccine platforms and therapeutic candidates. In response to Omicron and the continued threat of COVID–19, how is ASPR ensuring that there are funding opportunities for innovators who have products that might work better against the next SARS-CoV–2 variant or emerging infectious disease than the countermeasures we have now?

Answer 1. Some of the vaccine technologies BARDA has invested in during the COVID–19 response are considered readily adaptable technologies which means they can be updated easily. For example, a change in the sequence of an mRNA vaccine can produce a vaccine targeted to a SARS-CoV–2 variant. All the investments in the vaccine industrial base capacity expansion support not only the current COVID–19 response efforts, but also responses to variants as well as other future pandemic response and preparedness efforts.

With respect to therapeutics, one of the benefits of the oral antivirals Paxlovid and molnupiravir is that they have much broader activity against SARS-CoV–2 and its variants. In fact, both

Paxlovid and molnupiravir have activity against all SARS-CoV–2 variants tested as of January 2022.

Looking to the future and the American Pandemic Preparedness Plan, focusing on broad acting antivirals with activity against many viruses as well as focusing on host-targeted therapeutics that are virus-agnostic will be high priorities.

SENATOR CASSIDY

Question 1. The U.S. is in the middle of flu season, which has the potential to add additional burden to already-stressed health care systems due to the ongoing pandemic.

Question 1(a). What steps is HHS taking to ensure the availability of appropriate diagnostics and treatment options to address the potential dual threats of COVID and influenza, including through shoring up the Strategic National Stockpile?

Answer 1,1(a) There are four FDA-approved influenza antivirals drugs recommended by CDC for use against recently circulating influenza viruses: oseltamivir, baloxavir-marboxil, peramivir and zanamivir. Oseltamivir is the most widely used oral antiviral for the treatment of influenza and is also widely available in generic form with at least 10 different manufacturers approved by FDA to provide drug on the U.S. market. The broad manufacturing capacity ensures that even large waves of influenza infections can be sufficiently covered by the commercial market. In the event that demand for influenza antivirals exceeds commercial capacity, HHS could activate influenza antivirals that are stored in the SNS.

Early in the COVID–19 outbreak, ASPR/BARDA recognized the negative impact that needing influenza testing would have on national COVID–19 testing capacity during flu season. As such, we began supporting the development of multiplexed panels to test for both diseases in one testing operation. BARDA is supporting the development and submission for review for 17 test panels for use in laboratory and limited testing resource settings such as homes, nursing facilities, tribal clinics, doctors' offices and temporary testing centers. Four of these panels have received EUAs so far, with the remaining 13 awaiting FDA review of their submissions or finalizing test development. BARDA is supporting most of these test panel developments through the FDA's 510(k) clearance process.

Question 1(b). Beyond testing and preventative steps like vaccination, what steps has HHS taken to proactively treat vulnerable populations like the elderly or others who may be at risk for and are likely to spread communicable diseases like COVID and the flu?

Answer 1(b). ASPR proactively works with Federal and state, local, tribal, and territorial (SLTT) partners to address the access and functional needs of at-risk populations, including older adults and others who may be more adversely affected by or susceptible to infectious diseases such COVID–19 or flu through developing tools, guidance, training, and programs to support public health emergency preparedness and response activities and engaging with Federal and proactively engaging with stakeholders to disseminate and implement critical information and best practices.

ASPR's At-Risk Individuals Program continues to monitor emerging issues, oversee development of curriculum, and disseminate and update promising practices including developing a series of web-based trainings and capacity-building guidance that address all-hazards planning including infectious disease outbreaks. In addition, the HHS emPOWER Program is a mission-critical partnership between ASPR and CMS. It provides Federal data, mapping, and artificial intelligence tools, as well as training and resources, to help communities nationwide protect the health of at-risk Medicare beneficiaries, including 4.4 million individuals who live independently and rely on electricity-dependent durable medical and assistive equipment and devices, and or essential health care services. The HHS emPOWER Program continues to grow and innovate, including leveraging the program to develop the restricted HHS emPOWER Program: COVID–19 At-Risk Medicare Populations suite of datasets, geographic information systems, and dashboards tools for SLTT partners to use in response and community mitigation efforts.

Question 2. Health systems in Louisiana have been overwhelmed by successive waves of COVID variants. These health systems could have been better prepared for these growing variant trends if they had access to better national and regional dashboards monitoring variants of concern. What are you all at the CDC, FDA, NIH, and HHS doing to make sure health providers are armed with the best data to respond appropriately to the next COVID variant or pandemic? Second, how are you all harnessing the speed and innovation of the private sector to help predict, prevent, and mitigate future COVID–19 variants or other pathogens of concern?

Answer 2. ASPR has supported internal development data governance strategies, building out modernized IT systems for data sharing (HHS Protect, Tiberius and ASPR Ready), and has coordinated closely with CDC and the Office of the National Coordinator for Health Information Technology (ONC). Overall, the engagement at the state/local level with healthcare providers is through CDC.

SENATOR SCOTT

Question 1. Ms. O'Connell—How much COVID funding is still left for testing and what is the plan for its investment?

Answer 1. As of the hearing date, the Federal Government has invested $10 billion to support school testing; $8.3 billion on free community testing, testing for the uninsured, rural clinics and hospitals; and $5 billion on test procurement, distribution, and materials. As of the hearing date, $4.4 billion remains available for future testing efforts.

On efforts related to test procurement and distribution, we have quadrupled the amount of at-home tests available since the fall and have worked with test manufacturers and FDA to help expedite development and review of at-home tests, which will directly result in even more tests being available. In the near-future, we will announce an initiative in which households can place orders for tests, free of charge, and test kits will be delivered via USPS. More information will be provided to Congress as this initiative goes live.

We have also supported free testing sites at over 10,000 pharmacies throughout the country, over 10,000 state-and locally run community sites offering free testing generally with FEMA or CDC support—for a total of over 20,000 free testing sites across the country today. As of the hearing date, we are setting up surge testing sites in states to further increase access. There are 17 sites up and running in New York City, New Jersey, Pennsylvania and Washington, DC, with plans for sites in more than a dozen additional states in the coming couple of weeks.

Question 1(a). How many tests does the Federal Government currently have and what is the distribution plan?

Answer 1(a). As of the date of this hearing, the Federal Government had begun contracting for the tests to be provided to the general public at no cost. As of the date of this hearing, over 50 million tests were secured through four initial letter contracts, and we will continue to award more in the days ahead to get us to a goal of having 1 billion tests available. Under the distribution plan, the tests would be distributed through the U.S. Postal Service to households who place orders in the system. As of the hearing date, final plans were being set for the website as well as an automated help number.

Question 1(b). How is distribution determined?

Answer 1(b). In the near-future, we will announce an initiative in which households can place orders for tests, free of charge. Under the distribution plan, the tests would be distributed through the U.S. Postal Service to households who place orders in the system.

Question 1(c). Given concerns regarding limited accuracy and inability to detect early infection with antigen tests, what action has the Administration taken to support increased production and procurement of rapid, at-home molecular tests? If none, why not and does the Administration plan to do so?

Answer 1(c). Testing continues to be a vital part of our response. We've made significant progress in increasing testing supply, availability, and affordability. As of the hearing date, we went from zero over-the-counter tests in January 2021 to supporting the manufacturing of approximately 375 million tests per month. We invested $3 billion to accelerate production of rapid tests and expanded capacity, including necessary components such as pipette tips and vials. We're also standing up an office within ASPR to focus on making sure we have the right mix of products, suppliers, and partnerships to respond to public health emergencies and strengthen the Nation's overall preparedness.

In January, President Biden announced a plan to make 1 billion free at-home tests available to the American people and mail them directly to their homes via *COVIDTests.gov*.

Question 2. Ms. O'Connell—Recently, President Biden mentioned that there is no Federal solution to defeating COVID–19 and later said Americans need to adjust and prepare for COVID to be a part of everyday life.

Question 2(a). How does the Administration view the role of the Federal Government moving forward?

Answer 2,2(a). The President has been clear that we're moving toward a time when COVID won't disrupt our daily lives—a time when COVID won't be a constant crisis. Rather, it will be something we can easily prevent and treat. In doing so, we will rely on the powerful tools we've used to protect the public from COVID–19—vaccines, treatments, and testing. As we move toward that time, we're working closely with state Governors, local public health officials, and other subject matter experts on steps we should be taking to keep the country moving forward.

Question 2(b). What are the protocols for hospitals regarding overloading: what does the trigger look like regarding National Guard or other supports?

Answer 2(b). The Secretary of HHS, and by delegation the ASPR, serve as the lead for Emergency Support Function #8 (ESF–8) under the Incident Response Framework. Requests for medical support are evaluated and resourced under that construct. To support the review of requests, HHS supports a daily call where the other Federal partners supporting elements of the medical response, including DoD, the VA, PHS Commissioned Corps, and CDC, gather to discuss, coordinate, and determine resourcing assignment decisions. As case counts and other considerations change, the requests are reviewed in real-time to determine the best allocation possible. Using this process, this team will decide when to deploy a National Disaster Medical Services team or DOD clinical response team to decompress an overwhelmed hospital-factors for consideration include the number of cases, the available beds, and the available staff in the hospital setting.

Question 3. One of the things that we've learned in this pandemic is that we have the best biopharma industry in the world. It has been a truly unbelievable feat that America's biopharmaceutical companies have been able to respond to an unprecedented and evolving pandemic by delivering safe and effective vaccines in essentially less than a year's time. Additionally, we are seeing continued innovation in the COVID space—antivirals, new medications designed to keep people off ventilators, as well as continued promising research on existing medications, all which will help us to continue to expand our COVID-fighting capabilities. As a long term champion for the strategic national stockpile and the advanced research and preparation conducted by BARDA, I do worry that we may be falling behind in our efforts to maintain the most up-to-date and innovative repository to respond to the current and future pandemics.

Question 3(a). Ms. O'Connell—What can be done to improve partnerships with industry to allow for public-private partnerships to manage and to provide certainty for production needs and distribution of essential medical countermeasures?

Answer 3,3(a). HHS is committed to supporting our industry partners, providing value-added services, expertise, and funding to develop, manufacture and deliver medical countermeasures that protect health and save lives in public health emergencies. To help the country build manufacturing capabilities needed to produce population-scale vaccines and therapeutics, we issued a Request for Information (RFI) and held a virtual Industry Day as part of our

market research into the capabilities needed, how those capabilities could be sustained over time, and how best to build consortia that engage more industry partners with large-scale manufacturing experience. In addition, BARDA issued an RFI on domestic vaccine manufacturing capabilities utilizing mRNA technology. We will leverage all of the legislative authorities at our disposal and available funding to build not just the capacity but also the capability that the Nation needs. We look forward to working with industry on this critical issue for national security.

SENATOR TUBERVILLE

Question 1. The administration's declaration on December 21, 2021 that they would make 500 million test kits available to be shipped to people's homes has made it more difficult for companies to get shipments to help keep workplaces safe, as there have been fewer tests available for private purchase.

Question 1(a). Can you provide a high-level roadmap to an increase in EUA antigen test production?

Answer 1,1(a). Testing continues to be a vital part of our response. We've made significant progress in increasing testing supply, availability, and affordability. As of the hearing date, we went from zero over-the-counter tests in January 2021 to supporting the manufacturing of approximately 375 million tests per month. We invested $3 billion to accelerate production of rapid tests and expanded capacity, including necessary components such as pipette tips and vials. We're also standing up an office within ASPR to focus on making sure we have the right mix of products, suppliers, and partnerships to respond to public health emergencies and strengthen the Nation's overall preparedness.

In January, President Biden announced a plan to make 1 billion free at-home tests available to the American people and mail them directly to their homes via *COVIDTests.gov*.

Question 1(b). Specifically, how much are vendors increasing test manufacturing? In what quantity and by what date?

Answer 1(b). In early 2021, we saw a decline in demand for tests following the rollout of COVID vaccines and domestic manufacturing capacity for rapid antigen tests significantly exceeds current demand. Our industry partners have reached out to us with concerns that active manufacturing lines risk being shut down without orders from the Federal Government to partially offset this imbalance. ASPR recognizes the importance of keeping this critical infrastructure active given the large supply/demand shifts created by the spread of recent—and potentially subsequent—variants. As such, we are working in tight coordination with our industry partners as we continue to invest in procurement of tests to build a stockpile that will be at the ready to respond to rapid demand surges and continue to explore ways that we can "warm base" existing manufacturing capacity so that tests are available if needed.

Question 2. Across the country, members of the health care workforce have been fired for refusing to comply with COVID–19 vaccine mandates. Do you believe that these mandates have contributed to labor shortages in hospitals and other health care facilities?

Answer 2. The Office of the Assistant Secretary for Preparedness and Response has worked tirelessly to support the development and manufacturing of safe and effective COVID–19 vaccines. ASPR is committed to ending the pandemic and ensuring Americans can live safe and healthy lives. ASPR can provide resources, such as personnel from the National Disaster Medical System (NDMS), to augment care if and when a medical system or systems is in need of additional staff augmentation. The issue of labor shortages is something outside of ASPR's role and responsibility, but we stand by to support requests if and when needed and have done so throughout the ongoing response.

Question 3. One of the things we've learned during this pandemic is that America has the best biopharma industry in the world. It was an almost unbelievable feat that America's biopharmaceutical companies were able to respond to an unprecedented and evolving pandemic by delivering safe and effective vaccines in essentially less than a year's time. We've also seen continued innovation in the COVID space-antivirals, new medications designed to keep people off ventilators, as well as promising research on existing medications. All of these things will help us to further expand our COVID-fighting capabilities for all variants. As a supporter of the Strategic National Stockpile and the advanced research and preparation conducted by BARDA, I worry that we may be falling behind in our efforts to maintain the most up-to-date and innovative repository to respond to the current and future pandemics.

Question 3(a). What can be done to improve partnerships with industry to allow public-private partnerships to manage and to provide certainty for production needs and distribution of essential medical countermeasures?

Answer 3,3(a). HHS is committed to supporting our industry partners, providing value-added services, expertise, and funding to develop, manufacture and deliver medical countermeasures that protect health and save lives in public health emergencies. To help the country build manufacturing capabilities needed to produce population-scale vaccines and therapeutics, we issued a Request for Information (RFI) and held a virtual Industry Day as part of our market research into the capabilities needed, how those capabilities could be sustained over time, and how best to build consortia that engage more industry partners with large-scale manufacturing experience. In addition, BARDA issued an RFI on domestic vaccine manufacturing capabilities utilizing mRNA technology. We will leverage all of the legislative authorities at our disposal and available funding to build not just the capacity but also the capability that the Nation needs. We look forward to working with industry on this critical issue for national security.

(Moved from NIH QFRs)

SENATOR LUJÀN

Question 1. Given the increased demand for N95 and KN95 masks, we have seen an increase in costs to the consumer. New Mexicans hoping to protect themselves face costs as steep as $6 per mask-a cost that is simply out of reach for some of our most vulnerable populations. What barriers are preventing the Federal Govern-

ment from providing N95 or KN95 masks to the public free of charge?

Answer 1. In January, 2022, just before we testified before this Committee, the Biden administration announced a plan to deploy more than 400 million American-made, high-quality N95 masks from the Strategic National Stockpile (SNS) to retail pharmacies and federally qualified health centers (FQHCs) across the country. This effort represents the largest deployment by the SNS to date, and it is also the largest deployment of personal protective equipment (PPE) in U.S. history. It will help ensure that Americans have access to high-quality masks. Please note these masks were N95s as those are the masks manufactured in the U.S.

[Whereupon, at 1:55 p.m., the hearing was adjourned.]

○