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AN UPDATE ON THE ONGOING FEDERAL RESPONSE TO COVID–19: CURRENT STATUS AND FUTURE PLANNING

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING AN UPDATE ON THE ONGOING FEDERAL RESPONSE TO COVID-19, FOCUSING ON CURRENT STATUS AND FUTURE PLANNING

JUNE 16, 2022

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C O N T E N T S

STATEMENTS

THURSDAY, JUNE 16, 2022

AN UPDATE ON THE ONGOING FEDERAL RESPONSE TO COVID–19: CURRENT STATUS AND FUTURE PLANNING

Thursday, June 16, 2022

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

The Committee met, pursuant to notice, at 9:32 a.m., in room 106, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Sanders, Casey, Baldwin, Kaine, Hassan, Rosen, Lujàn, Hickenlooper [presiding], Smith, Burr, Paul, Collins, Cassidy, Braun, Marshall, and Romney.

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 having a hearing on the ongoing Federal response to the COVID–19 pandemic. I will have an opening statement followed by Ranking Member Burr, and then we will introduce our witnesses.

After they give their testimony, Senators will each have 5 minutes for a round of questions. Today, we will be having one of our witnesses, Dr. Fauci, testify remotely by video following a positive COVID test.

I appreciate the work of our Committee staff to make it possible for us to accommodate this so that we can hear from Dr. Fauci while he isolates and recovers. 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*.

If anyone needs accommodations including closed captioning, please reach out to the Committee or the Office of Congressional Accessibility Services. Before we do get started on this hearing, there is another issue we are all extremely focused on, the formula crisis. Dr. Califf, I understand flooding from the storms has forced Abbott's infant formula manufacturing facility in Sturgis offline once again.

Ranking Member Burr and I agreed, and I would like to give you a moment before we begin to update the Committee on the latest with the plant. I hope you can speak directly to the families in Washington State and across the country about what happened, and how you are taking action to get them formula and making

sure this doesn't worsen the crisis or delay our work to get formula back on the shelves as soon as possible.

Dr. Califf, I want to return to you for that before we begin the rest of the hearing.

Dr. CALIFF. There we go. Thanks, Senator Murray and Senator Burr for giving me a minute to speak about this. You know, we have twice daily intensive calls about all the work streams working on the infant formula issue.

At the end of the call yesterday, I commented it was one of the first days that we hadn't had any surprises, 20 minutes later the email came across about the flood in Sturgis, which has forced the facility to temporarily shut down. This is an unfortunate setback and a reminder that natural weather events can cause unforeseen disruptions in supply chains. I had a call with the CEO last night.

He is sharing our desire to get the facility up and running again as quickly as possible. Abbott is working to assess damage today and we will be talking daily, and we have our people in the facility to help get it up as quickly as we possibly can.

To your main question, which I know is of utmost importance and we are all, certainly all of us are very concerned about parents trying to get a formula for their infants, I do want to reassure parents and caregivers that the all the Government work to increase supply means will have more than enough product to meet current demand and FDA is committed to working closely with Abbott so that Sturgis can restart producing safe and quality formula products quickly.

Thanks to the collaboration of all of the players in the market, we now for the first time are getting production numbers from them about how much formula each company is producing, including Abbott, which has ramped up its other plants and is currently meeting the supply production quotas that they were using before the shutdown.

All the other manufacturers have increased their production and of course we have flying formula in full swing now. I have good numbers to indicate there will be adequate supply. We had hoped to have a super supply so that we get the shelves completely restocked.

The estimate is perhaps 2 weeks, but it is too early to give an exact estimate of what the delay will be in the Sturgis plant.

The CHAIR. Well, thank you, Dr. Califf. I assure you that this Committee and all Americans will be following this very closely. We want to be kept updated and apprized as closely as possible as you learn the facts and make sure that parents across this country are getting what they need.

Dr. CALIFF. I understand. Thank you.

The CHAIR. Thank you. With that, we will turn to the hearing at hand. And let me just begin by saying that we have made a lot of progress in the fight against this pandemic. It is much easier to get tests. Schools have safely return to in-person learning. Businesses have reopened.

There are new life saving treatments for people with COVID, and multiple safe, effective vaccines. And there is encouraging news to

suggest vaccines for kids under age five will be available soon. Something I know that parents across my state and the country are eagerly awaiting.

Across the country, we have gotten over half a billion shots in arms. Three in four people have gotten their first COVID vaccination. Two-thirds of people are fully vaccinated. This is really remarkable progress,. But we have to remember the hardships of this pandemic, especially the early days and the hard work it took us to get to where we are today. COVID–19 has killed over 1 million people in our Country.

That is an unthinkable loss. It closed businesses, shifted schools online, and as we all know a lot more. We cannot afford to get caught off guard by this virus again. We cannot afford to go back. That is why I am shocked I still have to remind my colleagues the progress we have made so far was not guaranteed. It was accomplished through congressional action and through robust investments.

What happens next is not a given either. It is up to us to stay the course in our support and investments if we are going to protect our families and communities from whatever this pandemic throws at us next. That is why passing emergency funding to continue our response has to be a top priority for every single one of us.

Because make no mistake, it is not a matter of if this pandemic will throw us another curveball, it is a matter of when. That is why emergency COVID funding is not something that would be nice to have.

It is something that we desperately need. Because if we wait until there is already a new dangerous variant, or until we are in the middle of a fall or winter surge, which some experts are predicting will happen, we will have missed the boat. We need to be doing everything we can now to get ready. That is what people back in Washington State and across the country are depending on Congress to do.

It is why I want to hear more about—that is what I want to hear more about from all of our witnesses today, what do we need to do right now so we are not caught off guard later? Because one thing we already know is when it comes to pandemics, when it comes to public health, an ounce of prevention is worth a pound of cure.

We need to be investing in prevention now. We need to be ordering the treatments we need for a fall surge now, especially when it can take 6 months, by the way, to manufacture paxlovid. We need to be ordering the vaccines we will need now. We need to be combating misinformation that is already far too prevalent and damaging now.

We need to be getting the testing, PPE we will need lined up, especially for our schools and health care facilities, now. And let's be clear, we can't just keep buying the same tests, treatments, and vaccines, especially when this virus is getting more effective at evading them.

As important as they continue to be to our progress, we cannot continue acting as though the vaccines and therapeutics we have

now are the end all, be all. We have got to support the next generation, keep several irons in the fire, and avoid getting caught in a situation where our tools or options are limited to just a few companies.

After all, we know this virus will not play favorites. That is why it is critical we invest in the research and development of the next generation tests, vaccines, and treatments that are more effective or easier to store or transport or administer.

Because once there is a variant that cannot be detected by our current tests, that does not respond to current treatments, that is not stopped by our current vaccines, we have got to be ready. And the research and development of these critical tools can take time. And let's be clear, none of that would be unprecedented, in fact, it is to be expected.

When it happens, time is of the essence to save lives, and families are counting on us right now to act like it. The reality is we are already running out of resources to prepare for the fall, and we are running out of time to fix that.

Democrats have been hammering this home for months. We have been yelling from the rooftops, warning what is at risk if we do not get this done. I am at a loss as to how I can possibly make the urgency of this moment more clear to all of our Republican colleagues. The fact that the Administration has had to resort to allocating resources from our long term needs to keep our short term response afloat, that is not a solution.

That is a stopgap, and it should be a clear sign of how urgent it is that Congress take action. We need to continue to support a full, robust response. This is simply too important to scramble again on short notice or shortchange our communities.

In addition to more resources, we need to make sure we are getting our communities the guidance and technical assistance they need to get ready as well. This is especially critical for our schools.

School officials and educators want to do everything they can to keep our students safely in the classroom. In fact, everyone wants that. But we can't leave them waiting until back to school season if we are going to make it happen. Schools back in my state want to know what they can be doing right now to get ready for the next school year.

How can they best position themselves to make sure if we have a fall surge, they have the resources and a plan in place that protects students and educators and keeps them safely in the classroom. I want to hear more from our witnesses about how they are working with the Department of Education to get schools the support they need.

Of course, in addition to making sure we prepare for what is next in the course of this pandemic, we need to make sure we are ready for whatever public health threat we face next, period. That means making sustained annual investments in our public health system like I have proposed, so we can end the cycle of crisis and complacency.

It means making bold investments in pandemic preparedness. It means strengthening our Federal policies and processes like Sen-

ator Burr and I are working to do in our bipartisan Prevent Pandemics Act. I know I have said it already, but I will say it again and again until we get this done.

It means passing the emergency COVID funding. We need to make sure our communities are able to continue getting back to normal, not back to the darkest days of this pandemic, when we couldn't get tests, when we didn't have effective treatments, when we didn't have vaccines.

After everything we have been through, it should be clear this is not the time to settle for doing too little or acting too late. I can tell you that it is clear to me, and it is certainly clear to the families I am hearing from back in Washington State. I am going to keep pressing for us to get emergency funding passed as soon as possible and get our communities everything they need to keep people safe.

I am asking my Republican colleagues to please consider the cost of inaction. Consider what it means for our doctors, for our nurses, our small business owners, our high risk families and friends, including seniors and immunocompromised people, our educators, our students, if we let COVID get the better of us because we failed to make a modest investment right now.

I hope we can work together and find a path forward here. Senator Burr, I will turn it over to you.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chairman. I welcome our guest. Tony, I hope you are having a mild case. To our witnesses, thank you for coming back to the HELP Committee. When we were last together in January, the country was in the throes of the original Omicron surge.

At that time, I asked you one basic question, what is the plan? I hope in your opening statements or maybe when I ask this question in the question around somebody or give me an answer. The Chair just did a fabulous job of painting Republicans into the obstacle for there not being enough emergency funding.

I remind my colleagues, we spent $1.9 billion just on COVID a year ago. Where is that money gone? How is it being spent? Where is it obligated? No plan has been presented, but on multiple occasions, the Chair has been in the room when I have said, here is a condition, present us a plan.

Now in early May, this plan went out. It just tells me what you would buy if you got $10 million and what you would buy if you got $17.5 billion. And it says confidential. This isn't a plan. When is somebody going to share with the American people the destination we are trying to get to and how we are going to get to that destination?

We are still in crisis management, and we are two and a half years into this. I am really sympathetic of Dr. Fauci's position, because Tony, more than anybody understands, we are dealing with a virus that continues to evolve and change. But since the time we last got together, we have seen Omicron subvariants take hold.

Right now, cases of BA.4 and BA.5 are creeping up around the country. In January, I asked yet again how this Administration was looking to other countries that have already experienced new surges so that we can prepare for the impacts of new variants in the U.S. and inform our response.

BA.4 and BA.5, for example, caused a new wave of infections in countries where they are dominant, like South Africa and Portugal. 22 percent of the cases in the United States are currently BA.4 or BA.5, a number that continues to increase daily. We are learning from other countries and regions that are ahead of us, like Israel and Europe.

What do we need to be doing today to ensure that we are prepared for what we face in the weeks and the months to come? I have asked you repeatedly about studies out of Israel and other countries. I have been frustrated by the lack of detail about what you are learning from other countries and how it informs our COVID response.

Quite frankly, I sent my staff to Israel over the Memorial Day recess. It is my understanding that we meet regularly, either by phone or in person, with our Israeli counterparts. During these meetings, they share the latest COVID trends in Israel and any updated data on the vaccine clinical trials and studies. If you are getting the information regularly, why is it taking so long for us to act on it?

In January, Israel became the first country to offer a fourth vaccine dose to individuals over 6,0 and health care workers that were at least 4 months past their first dose—their third dose. Israeli health ministers announced new data at the end of January, demonstrating additional protections from a fourth vaccine dose for those 60 and over.

It took CDC 3 months to take similar steps. I will say it again, 3 months. Israel has also taken steps to appropriately target the use of limited COVID–19 countermeasures. Israel targeted its supply of oral antivirals to treat those with the greatest risk of severe illness to keep them out of the hospital and to keep them alive.

Meanwhile, the Biden administration developed a new plan, Test and Treat, a strategy to provide therapeutics to anybody who presented infected and came up positive. The terms of the emergency use authorization are that Pfizer drugs should be given to high risk patients, not everyone who tests positive. There is the Israeli data influence.

But the way we have applied the EUA instructions from FDA is hand it out to anybody who walks in and tests positive. Tests positive, get an antiviral. The terms of the emergency use authorization, I said, but I will quote this, people can—this was the President, "people can get tested at a pharmacy and if they are positive, receive anti-viral pills on the spot at no cost."

Either the President was confused about his own announcement, or you are deliberately giving these pills to too many patients, violating the terms of the EUA, putting people at risk, and wasting treatments and taxpayer dollars. I am puzzled by the wide gap in

our approaches when so much data is regularly being shared between health leaders in both countries.

Before you say our countries are of different sizes, I will remind you that we can approve drugs and devices based on samples of just a few thousand patients. The virus is the same in Israel and in the United States. And we have seen Israel get hit by new variants every—between six and 8 weeks before the United States.

Israel's quick and decisive actions in early December delayed the onset of the Omicron wave by 5 weeks. They had a clear path and clear leadership. Meanwhile, we have discarded over 82 million COVID vaccine doses in the United States, and this Administration assumes that at least 50 percent of booster doses we purchase this fall will go to waste.

My God, folks, let's figure out a different plan for inoculating these people. Why don't we keep falling further behind? Why aren't we trying to do better? Why aren't we learning from our mistakes? It doesn't seem like we are striving for anything other than mediocrity. Have we given up? Let me highlight just a few of the more glaring inconsistencies.

In April, CDC released data indicating that nearly 60 percent of the Americans and about 75 percent of American people and 75 percent of children had at least one COVID–19 infection by the end of February. Though more recent data has not been released, I imagine the infection rate is even higher today given the recent spikes in cases.

We know the majority of Americans aged five and over are vaccinated. So the majority of Americans have some degree of protection against the virus, yet we only removed our pre-departure testing requirements for travelers entering the United States legally this past Sunday. Many EU countries lifted their pre-entry testing requirements for fully vaccinated travelers in February and March.

Canada followed suit in April. This is not an isolated example of where we lag behind because we either don't believe the data that they are providing, or it doesn't fit with the narrative that we are trying to carry out. In response to a letter I wrote about my concerns with CDC termination of Title 42 order, you wrote, "the COVID–19 risk for U.S. communities is greatly reduced for most people compared to earlier in the pandemic."

Why are we still in an urgent state of emergency and taking months to remove restrictions that other countries have been removing since February? American people are fed up with confusing messaging and inconsistent response.

Let me ask again, what is the plan? More than 2 years ago—two years into this pandemic, the American people are going back to work in person, attending weddings, events, traveling for work and leisure, and Government still allows its employees even at the FDA, CDC, and within HHS platform to work remotely.

Individuals who are at higher risk of severe illness or those who live in communities with higher levels of circulating virus know the precautions they need to take to keep themselves and their family safe. And if they get sick, we have tests and treatments to help them recover. We know more now than we did 2 years ago.

We have more tools today to save more lives. Do we know everything? No. It is past time to think about the future. I have asked you in over and over and over again for a plan. The plan for gaining back the trust of the American people and moving our Country forward. Six months later, I still haven't received an adequate response to what plan—the plan actually is.

Since I am having trouble getting a response to my initial question, let me end with asking each of you a slightly different one. Every good plan is crafted around an intended outcome. I hope all of you can answer this. What is your endgame? Maybe I will respond differently to the Chair about the attacks that we are standing, Republicans in the way of funding emergency money.

But CDC says it is not an emergency anymore. That is why they are ending Title 42. I can go through a litany of things that suggest this has transformed to somewhere. We are in a period that there needs to be an accountability for how we spent the $1.9 trillion devoted to COVID. I think any country in the world laughs at the way we are spending our money relative to this crisis and this virus.

I will continue to ask you for a plan until we get one, and I will continue to be a roadblock for those who believe that we can blindly just appropriate emergency money, borrow it from the Chinese, and spend it on something that none of us have a clue as to what the plan is. I thank the Chair. I yield back.

The CHAIR. Thank you, Senator Burr. I 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 in President Biden's COVID–19 response team. Dr. Fauci, we do appreciate you joining us virtually following your positive COVID test. And of course, we all do wish you a very speedy recovery.

Dr. Robert Califf is the Commissioner of the Food and Drug Administration. Dawn O'Connell is the Assistant Secretary for Preparedness and Response. Director Walensky, Director Fauci, Commissioner Califf, Assistant Secretary O'Connell, thank you all so much for joining us today. We look forward to your testimony. We will begin with Dr. Walensky.

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

Dr. WALENSKY. Chair Murray, Ranking Member Burr, Members of the Senate HELP Committee, I appreciate the opportunity to join you once again to provide an update on the COVID–19 pandemic and the work CDC continues to do to help Americans live safer, healthier lives. It was just over a month ago that we surpassed 1 million COVID deaths in the United States.

To many, that numbers seemed unthinkable when the pandemic began, but it is a sobering reality that so many of us have experienced great loss over the past 2 years. We recently experienced an-

other increase in COVID cases, which was accompanied by an increase in hospitalizations and deaths.

Through this, we continue to see that immunity through vaccination and infection has resulted in fewer hospitalizations and deaths from COVID surges prior to Omicron. At this time, 67 percent of our population live in counties at medium or high COVID community levels, twice as many as people 1 month ago.

CDC's COVID community levels have been an important tool to empower localities and jurisdictions to decide where and when to use proven prevention strategies to limit the impact of COVID–19. Our ability to manage this virus today is in large part due to the tools we have, vaccines, tests, treatments, and masks.

We continue to work hard to increase access to these important tools every day so that Americans can better protect themselves. For example, we have recently expanded the eligibility of COVID vaccine boosters for children ages 5 to 11. And just this week, we are coordinating with our colleagues at FDA to consider recommendations for those 6 months to 4 years to receive their first COVID shots.

Since the start of this pandemic, nearly 8 million children, 11 and younger, have been diagnosed with COVID. Over 50,000 have been hospitalized and over 600 have died. I know that many parents are anxiously waiting to vaccinate their children under five, and we are committed to carefully reviewing the data so that these vaccines are recommended only if they have both safe and effective profiles.

As I look toward the future of CDC's COVID response, thanks to congressional support, CDC will be awarding $3 billion to your states to recruit, hire, and train public health workers to face current and emerging public health threats.

While this is an exciting opportunity to help address a long standing gap, I am deeply concerned that a lack of additional funding for other response activities will end or substantially scale back critical COVID response work. Congress and the American people expect that CDC will continue nationwide studies to evaluate immunity, to conduct long term surveillance on COVID, including on post COVID conditions, and to support future vaccination efforts both globally and domestically.

We need additional funding to do this work. As we continue to support our COVID–19 response effort, we must not forget that this will not be our last public health challenge and we continue to face future public health threats. Just this past month, we have seen outbreaks of monkeypox in non-endemic countries, including here in the United States.

CDC's swift action has supported testing and case identification. However, as threats like monkeypox emerge, we run the risk of again being constrained by incomplete data from our fragmented public health data reporting system. We need to work together to support new authority for CDC to receive timely, standardized, and uniform data.

This pandemic has highlighted the need for disease agnostic investments to address the long standing vulnerabilities in our public

health system. The Fiscal Year 2023 budget request proposes $28 billion for CDC over 5 years to enhance early warning and situational awareness capabilities, to support workforce programs, to bolster public health infrastructure, to invest in data modernization, and to prioritize global health security initiatives.

The budget also proposes a vaccine for adults program modeled on the successful vaccine for children's program. This program highlights my and the Administration's commitment to health equity by creating a mandatory funding stream through which uninsured adults would have increased access to vaccinations, sustaining the infrastructure built during the COVID pandemic. Congressional support for these initiatives, accompanied by additional authorities to collect and coordinate public health data, will strengthen our Nation's ability to prepare for and respond to emerging public health and biosecurity threats.

I am committed to working with each and every one of you to find common ground, to support public health and make meaningful strides toward achieving health security for all Americans, both now and into the future. Thank you, and I look forward to your questions.

[The prepared statement of Dr. Walensky follows:]

PREPARED STATEMENT OF ROCHELLE P. 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 over 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 our work to provide science-based guidance about how we can best protect ourselves and our communities as the virus and the pandemic evolve.

State of the Pandemic

Last month, we reached a tragic milestone: 1 million reported deaths from COVID–19 in the United States, a heartbreaking reminder that COVID–19 is still with us. While we mourn the overwhelming loss that these numbers represent, and we honor each of the individuals who have passed, there are many reasons for hope. We have learned an incredible amount about this virus in a short period of time. We have increased access to the tools we need to protect ourselves and those around us.

Over the past 2 months we have seen increases in cases and hospitalizations on the national level. Cases are beginning to level off on the national level, although we continue to see increases in some regions of the country. And, while the 7-day average of daily deaths continues to decrease, there are still tragically too many deaths each day from this disease. Although COVID–19 continues to circulate, we now have vaccines, tests, and treatments that work to prevent severe disease and death. Most Americans have some immunity due to receipt of vaccines, past infection, or both. In February, CDC transitioned to using COVID–19 Community Levels, leveraging community level data to offer guidance to local jurisdictions and to empower them to decide when and where to implement prevention measures. CDC looks at the combination of three metrics—new COVID–19 admissions per 100,000 population in the past 7 days, the percent of staffed inpatient beds occupied by COVID–19 patients, and total new COVID–19 cases per 100,000 population in the past 7 days—to determine the COVID–19 community level. New COVID–19 admissions and the percent of staffed inpatient beds occupied represent the current potential for strain on the health system. Data on new cases acts as an early warning indicator of potential increases in health system strain in the event of a COVID–19 surge. Jurisdictions can use these data to prioritize efforts to minimize the impact COVID–19 has on our health, our healthcare systems, and our society, while

focusing efforts on protecting those who are most at risk of severe illness. As of June 9, 2022, nearly 78 percent of the U.S. population is in a location with low or medium COVID–19 Community Level.

The pandemic is not over, and we must continue to do all we can to decrease severe disease and death. Despite widespread availability of vaccines, including booster doses, we know that some parts of the country continue to see their healthcare systems stretched thin by the pandemic. In addition, there are many Americans who have a compromised immune system, one or more disabilities, other serious medical conditions, or who continue to be at elevated risk because of their age or other factors. We must continue to use the prevention tools in our toolbox to limit the impact COVID–19 has on those who are most vulnerable and our communities.

Genomic Sequencing and Surveillance

CDC continuously monitors and analyzes the evolution of SARS-CoV–2 and the emergence of variants domestically and internationally, and our national genomic surveillance system can reliably detect variants, including those circulating at low levels. CDC's National Genomic Surveillance System employs critically important and comprehensive strategies to detect and track variants.

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. CDC also augments sequencing capacity through contracts with commercial diagnostic laboratories to support the national genomic surveillance system and the sequencing of thousands of specimens per week.

The rapid detection of emerging variants, including Omicron and its subvariants, 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. In addition, CDC and other Federal agencies continue to work with international partners to learn more about variants circulating globally; CDC will continue to monitor all data sources closely to identify cases of COVID–19 from emerging variants across the world.

As the pandemic and the virus evolve, we at CDC are working quickly to adapt with it, including identifying new strategies to understand what is happening in real time to better inform our decisionmaking and guidance. For example, in early February 2022, CDC unveiled new National Wastewater Surveillance data. We are tracking more than 995 testing sites nationwide, covering over 110 million Americans. Of these, 773 sites are currently represented on COVID Data Tracker. This empowers local and state officials to detect increases in SARS-CoV–2 infection 4–6 days before traditional sentinel signals like test positivity, case counts, and hospitalizations.

Vaccination Efforts

Since December 2020, more than 591 million doses of COVID–19 vaccine have been administered in the U.S. Overall, as of June 13, 2022, over 221 million people in the U.S. have received their primary vaccine series and over 104 million people have received at least one booster dose. Approximately 71 percent of the U.S. population 5 years of age and above have completed a primary vaccination series and 48.8 percent of the population 12 years of age and above have received their booster dose. While progress is being made, these numbers indicate there is still more work to be done. Vaccination remains the best public health measure to protect from severe disease. CDC recommends that everyone who is eligible protect themselves from COVID–19 by getting vaccinated and staying up to date on their vaccinations. This includes CDC's recommendation for boosters for anyone 5 years and older and a second booster of an mRNA vaccine for adults ages 50 years and older and for people aged 12 and older who are moderately or severely immunocompromised.

Strong confidence in COVID–19 vaccines within communities leads to more adults, adolescents, and children getting vaccinated, which in turn can lead to fewer SARS-CoV–2 related hospitalizations and deaths. CDC is employing a variety of approaches to improve vaccine uptake, including developing training materials for healthcare providers, funding a number of on-the-ground social mobilization efforts, offering communication materials to the public, and distributing the COVID–19 State of Vaccine Confidence Insights Reports, which identify the public's questions,

concerns, frustrations, and misinformation they are encountering while providing readers ways they can act on the findings.

Furthermore, the Federal Retail Pharmacy Program continues to be an important component in our commitment to address the disproportionate and severe impact of COVID–19 on communities of color and other underserved populations. CDC partnered with 21 national pharmacy organizations and independent pharmacy networks that represent over 41,000 locations nationwide—to ensure that the public has access to COVID–19 vaccines in a familiar setting. Almost 90 percent of Americans live within five miles of a retail pharmacy. As of June 8, 2022, more than 254 million doses have been administered and reported by retail pharmacies across programs in the U.S., which includes approximately 8 million doses administered onsite in long-term care facilities in the early days of the vaccination program. As of June 8, 2022, 42 percent of the cumulative doses administered through these pharmacy programs have gone to a person from a racial or ethnic minority group. CDC continues to identify and engage in opportunities that align with the guiding principles of the CDC COVID–19 Response Health Equity Strategy, and CDC works to accelerate and strengthen efforts to reduce the disproportionate burden of the pandemic on communities of color and other populations of focus.

Global Efforts

CDC global health experts have worked tirelessly with partners and public health officials globally to respond to the COVID–19 pandemic, leveraging and adapting our global health investments, systems, and programs for the global COVID–19 response. CDC has worked hand-in-hand with Ministries of Health in dozens of countries to provide critical support during the COVID–19 pandemic. CDC's ability to leverage core public health capacities overseas for the global COVID–19 response is built on longstanding investments in surveillance, laboratory networks, emergency management, and workforce development. For example, CDC has supported the development and strengthening of over 30 national Emergency Operations Centers worldwide, and CDC's PEPFAR-supported investments in laboratory networks and systems have been critical to COVID–19 diagnosis and surveillance, with 73 percent of PEPFAR-supported centralized labs implementing SARS-CoV–2 testing.

Just as in all our work at CDC, advancing health equity is a core tenet of CDC's global health work. CDC supports over 70 countries to receive and administer COVID–19 vaccines.

Around the world, CDC is committed to widespread and equitable access to safe and effective COVID–19 vaccines, while continuing to build capacity for essential immunization systems. CDC's approach to global health prioritizes host country ownership, investment in local partnerships, development of sustainable capabilities, and sharing of technical expertise. CDC works to identify, partner with, and reach underserved populations around the globe.

Looking Ahead

When looking ahead, the fiscal year 2023 Budget Request for CDC and ATSDR, provides an important framework to establish future investments in public health. This includes $10.7 billion in program funding for ongoing and expanded efforts to support our mission—protecting America from health, safety, and security threats, at home and abroad. The fiscal year 2023 Budget also outlines transformative mandatory proposals, building upon the lessons learned through our experience with COVID–19 and emphasizing recovery and revitalization of the Nation's public health system. The proposed new Vaccines for Adults program highlights my and the Administration's commitment to health equity by creating a structure and mandatory funding stream through which uninsured adults would have access to all vaccines that have been recommended by CDC's Advisory Committee on Immunization Practices and CDC. In addition, that program will help sustain the adult vaccine infrastructure built with investments during the COVID–19 pandemic, and it will be a critical step toward being prepared for the next pandemic. The Budget also proposes $81.7 billion for pandemic preparedness at the Department of Health and Human Services, of which $28 billion would be allocated to CDC. This will provide early warning and situational awareness, strengthen core capabilities, and strengthen public health systems including workforce and global health security.

Congressional support for these initiatives, accompanied by additional authorities to collect public health data, will make the Nation better prepared for future pandemics, but there are still additional COVID–19 problems to solve here at home and abroad. To continue essential COVID–19 response activities, as delineated in the Administration's $22.5 billion supplemental request to Congress on March 2,

2022, CDC needs additional funds to support infrastructure for surveillance and laboratory capacity, as well as to support ongoing global response needs, including to accelerate vaccine uptake through the U.S. Initiative for Global Vaccine Access, to limit the spread of variants and protect lives here and globally.

In April 2022, CDC announced the launch of the new Center for Forecasting and Outbreak Analytics (CFA). CFA seeks to enhance the Nation's ability to use data, models, and analytics to enable timely, effective decisionmaking in response to public health threats for CDC and its public health partners. CFA's work will focus on three main goals: to predict, inform, and innovate. CFA has begun to build a world-class outbreak analytics team with experts across several disciplines to develop faster, richer evidence to predict trends and guide decisionmaking during emergencies. CFA will also continue to advance the state of the science of outbreak data, models and analytics to improve the Nation's ability to respond to health emergencies.

Conclusion

While we have come a long way since the beginning of the pandemic, there is still much work to be done, and we all have a role to play. I continue to encourage everyone who is eligible to get vaccinated and boosted to protect both themselves and their fellow community members from COVID–19. We must bolster our public health infrastructure by supporting new authorities to enable us to be better prepared, and resources like those in the fiscal year 2023 President's Budget to support pandemic preparedness, data modernization, public health laboratories, domestic and global disease surveillance, and state, territorial, and local public health partners. We must also continue to make investments now to make sure we address the long-standing vulnerabilities in our public health system. I am committed to working with Congress to find common ground to equitably support our public health system and make meaningful strides toward achieving health security for all Americans now and into the future.

Thank you, and I look forward to your questions.

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 conducting and supporting research addressing our Nation's response to COVID–19.

In a prior hearing before this Committee on January the 11th, I discussed the research efforts by NIH to address the Omicron variant. This variant has evolved with multiple mutations that are associated with an increased efficiency of transmission and immune evasion.

Fortunately, our current vaccines have maintained their effectiveness in preventing severe COVID–19. However, individuals who have received only their primary vaccine regimen have a greater likelihood of getting infected with the Omicron variant than with previous variants.

Importantly, booster shots have been shown to significantly reconstitute and enhance the level of antibodies that neutralize the Omicron variant and its sub-lineages. Since I last appeared before this Committee, NIAID launched the COVAIL trial to learn whether various fourth dose booster regimens can further increase the breadth and the durability of immune responses in adults who have received a primary COVID–19 vaccination plus a single boost.

We remain concerned that most children eligible to receive a COVID–19 vaccine have not been vaccinated. NIAID and BARDA have collaborated with Moderna on the KidCOVE study to evaluate the safety and efficacy of Moderna's mRNA vaccine in children, including those under 5 years of age.

Initial results from the KidCOVE study have helped inform the FDA's VRBPAC Advisory Committee and their recommendations to the FDA concerning potential emergency use authorization for their vaccine in this population, and also ultimately to inform the CDC in their recommendations.

Looking ahead to the anticipated emergence of new variants, the importance of developing the next generation of coronavirus vaccines is paramount. I referred to a vaccine that would be effective against all SARS-CoV–2 variants and ultimately run effective against all coronaviruses.

NIAID has issued new awards to fund research focused on designing and developing such pan-coronavirus vaccines. NIAID and other involved entities also have made significant progress in the development of COVID–19 therapeutics. We now have the toolkit, the therapeutics that remain effective against the Omicron variant, and its currently circulating sub-lineage variants.

These therapeutics include the oral antiviral drugs paxlovid and molnupiravir, as well as remdesivir and the monoclonal antibody bebtelovimab, all of which have NIAID fingerprints on their development.

In addition, NIAID is funding nine antiviral drug discovery centers for pathogens of pandemic concern that will develop oral antivirals for use in outpatient settings that target SARS-CoV–2 and other viruses with high potential to cause a pandemic.

We know that even after people recover from an infection with SARS-CoV–2, some will experience ongoing symptoms or other negative health effects after the acute infection has resolved. The NIH Recovery Initiative complements ongoing NIAID studies to better understand the various post-acute manifestations of COVID–19.

The recovered team is building a diverse national study cohort and supporting large scale studies on the long term effects of COVID–19. NIAID also is participating in caring for children with COVID, a trans NIH effort to better understand the rare but extremely serious multisystem inflammatory syndrome or MIS-C that has been associated with SARS-CoV–2 infection in children and adolescents.

NIAID will play an important role in the all of Government plan for pandemic preparedness that aims to develop and implement a range of countermeasures against important prototype pathogen families of viruses that threaten the health and safety not only of our Nation, but the entire world.

Thank you for your attention. I would be happy to answer your questions following the presentations of my colleagues.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY S. 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 research addressing this once-in-a-lifetime infectious disease pandemic.

The public health response to COVID–19 has required an unprecedented global public-private research effort. NIAID has played a central role in this response by capitalizing on decades of basic, clinical, and applied research to facilitate the rapid development of COVID–19 vaccines, which continue to be important tools to reduce the threat of COVID–19 in the United States and worldwide. NIAID also initiated clinical trials with creative and adaptive designs to evaluate multiple new and existing therapeutics for the treatment of COVID–19.

Responding to Emerging Variants of SARS-CoV–2

The emergence of SARS-CoV–2 variants—some of which demonstrate increased transmissibility and an ability to partially evade the immune response from previous infection and/or vaccination—makes it critical that all eligible individuals remain up to date on their COVID–19 vaccines, including recommended booster doses, to ensure the highest possible level of protection. NIAID has launched collaborative research to rapidly assess the effectiveness of vaccines, monoclonal antibodies, and antiviral drugs against SARS-CoV–2 variants. NIAID also is exploring ways to enhance protection afforded by COVID–19 vaccines and supports and conducts research to understand the impact of SARS-CoV–2 variants on infection-and vaccine-induced immunity. NIH, including NIAID, participates in the HHS-established SARS-CoV–2 Interagency Group (SIG) along with the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority (BARDA), Department of Defense (DOD), and U.S. Department of Agriculture. The SIG tracks variants in real time to address the potential impact of emerging variants on critical SARS-CoV–2 countermeasures.

NIAID also facilitates the use of cutting-edge tools such as disease modeling and structural biology to understand how SARS-CoV–2 variants may potentially evade the immune system and/or COVID–19 therapeutics. In addition, NIAID supports the development of next-generation COVID–19 vaccines that could provide protection against disease caused by emerging SARS-CoV–2 variants. Strategies for next-generation COVID–19 vaccines include targeting viral antigens that are highly conserved among SARS-CoV–2 strains and utilizing alternative routes of inoculation, such as intranasal vaccine approaches. NIAID also is conducting research on pan-coronavirus vaccines designed to provide broad protective immunity against emerging SARS-CoV–2 variants and other coronaviruses with pandemic potential. In 2021, NIAID announced awards to four academic institutions to conduct research to develop pan-coronavirus vaccines.

Developing Vaccines to Prevent COVID–19

Sustained research investments by NIAID over decades prior to the emergence of SARS-CoV–2 allowed the unprecedented pace of COVID–19 vaccine development. Longstanding NIAID support enabled the development of versatile vaccine platforms and the use of structural biology tools including cryo-electron microscopy to design specific proteins—called immunogens—that powerfully stimulate the immune system. Prior to the COVID–19 pandemic, scientists at the NIAID Vaccine Research Center (VRC) and their collaborators made the critical scientific discovery of how to mutationally stabilize—in a highly immunogenic form—viral proteins that SARS-CoV–2 uses to infect human cells. This strategy facilitated the design of vaccine candidates that generate robust protective immune responses. As soon as the sequence of SARS-CoV–2 was made available in early January 2020, NIAID 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 of which are now authorized or approved by the FDA, built upon across a range of vaccine platforms including the highly successful mRNA platform.

Through sustained support for fundamental research underlying the vaccine concepts and the establishment and utilization of an extensive clinical trials network,

NIAID helped advance the development of six candidate COVID–19 vaccines. NIAID supported the Phase 3 clinical trials for two vaccines that are currently available for use in the United States: the mRNA–1273 vaccine, developed through a collaboration between the NIAID VRC and Moderna, Inc., and the Ad26.COV2.S vaccine candidate from Johnson & Johnson/Janssen. NIAID also is supporting Phase 3 clinical trials of investigational COVID–19 vaccine candidates from AstraZeneca (AZD1222), Novavax (NVX-CoV2373), and Sanofi/GSK (SARS-CoV–2 adjuvanted recombinant protein vaccine).

In addition, NIAID supports research on COVID–19 vaccines in special populations, such as children and individuals who are pregnant or lactating. NIAID and BARDA are collaborating with Moderna on the Phase 2/3 KidCOVE study to evaluate the safety and efficacy of mRNA–1273 in children ages 6 months to less than 12 years. KidCOVE investigators recently reported positive initial results, and Moderna has submitted to FDA a request for an Emergency Use Authorization of the vaccine in this population. NIAID will continue to explore opportunities to support additional trials to test vaccine candidates in children, adolescents, and other special populations.

Ensuring Protection by the use of COVID–19 Vaccine Boosters

FDA-authorized and FDA-approved COVID–19 vaccines have maintained their effectiveness in preventing severe COVID–19. However, we have seen with both the Delta and Omicron variants that protection against mild and moderate disease begins to decrease over time following the primary vaccine series. NIAID quickly established that boosting with the same vaccine that was used for the primary vaccine series could significantly increase levels of antibodies against all current variants, compared to levels in individuals who received the primary regimen alone. This "homologous" boosting has translated into increased protection against severe disease as well as mild infection. In addition, an NIAID-led study showed that boosting with a COVID–19 vaccine different than the one used for the primary vaccine series ("mix and match") was safe and prompted a robust immune response. Data from this study were evaluated by FDA in their decisionmaking to authorize the use of a "mix and match" approach to boosters for FDA-authorized or approved COVID–19 vaccines.

As SARS-CoV–2 variants have emerged, NIAID moved rapidly to investigate the potential of targeted boosters to enhance immune responses to emerging variants. Shortly after the Omicron variant was first described, the NIAID VRC began conducting preclinical testing of an Omicron-specific booster candidate. NIAID scientists showed in animals that boosting with either the existing mRNA–1273 vaccine or an Omicron-specific vaccine enhanced antibodies against Omicron and increased protection following challenge with the Omicron variant. NIAID now will examine whether people who received boosters—either mRNA–1273 or variant-specific COVID–19 boosters—generate antibodies that can bind to and neutralize the Omicron variant and its sublineages.

NIAID also 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. In 2021, NIAID launched multiple trials assessing the response to COVID–19 vaccination in people with immune systems weakened due to a variety of diseases or organ transplantation. Additionally, NIAID recently launched the Phase 2 COVID–19 Variant Immunologic Landscape (COVAIL) trial to learn whether different vaccine booster regimens can broaden and increase the durability of immune responses in adults who already have received a primary vaccination series and a first booster shot.

Identifying Therapeutics to Treat COVID–19

Additional 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.

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. Data from ACTT were critical for FDA approval of the antiviral drug remdesivir and the anti-inflammatory drug baricitinib for treatment of COVID–19. NIAID, in collaboration with other NIH Institutes, also launched the Accelerating COVID–19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, which is focused on late-stage clinical trials investigating candidate drugs for outpatient and

inpatient settings. ACTIV uses flexible master protocols for clinical trials, allowing the inclusion of additional investigational therapeutics as the trials continue.

The widespread availability of highly effective oral antivirals that can be taken at home early in the course of infection could help prevent SARS-CoV–2 transmission, mitigate overwhelming surges in hospitalizations, and save lives. In collaboration with the DOD Defense Threat Reduction Agency, NIAID supported basic research and product development for the oral antiviral drug molnupiravir (Lagevrio), which the FDA authorized for the treatment of mild-to-moderate COVID–19 in certain populations and situations. NIAID also provided expert advice for clinical trials of Pfizer's oral antiviral Paxlovid, which the FDA authorized for the treatment of mild-to-moderate COVID–19 in certain populations. Paxlovid is now the leading antiviral drug for the treatment of COVID–19, with an almost 90 percent efficacy in preventing severe disease resulting in hospitalization if administered early in the course of infection.

NIH has prioritized and accelerated the development of oral antivirals against potential pandemic pathogens by collaborating with BARDA to launch the Antiviral Program for Pandemics (APP). APP aims to develop safe and effective oral antivirals for broad use in outpatient settings to treat and prevent infection with RNA viruses of pandemic potential. The program will build sustainable approaches for targeted antiviral discovery and development. As part of APP, NIAID recently established nine multidisciplinary Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern with the goal of creating platforms that will target RNA viruses with pandemic potential, helping to better prepare the Nation for future viral threats.

NIAID also conducts and supports research to determine the impact of SARS-CoV–2 variants on the effectiveness of monoclonal antibodies and other therapeutics. For example, research suggests that although effectiveness of certain monoclonal antibodies against Omicron is markedly diminished, the monoclonal antibody bebtelovimab, discovered by AbCellera in collaboration with the NIAID VRC, is active in vitro against all circulating Omicron subvariants. In addition, NIAID is working to develop new drugs, including therapeutics that inhibit essential processes in the virus replication cycle or that address the host response to COVID–19, with an eye toward agents that maintain their effectiveness against emerging variants.

NIH also 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. Each Treatment Guidelines section consists of recommendations 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 meets regularly to evaluate possible treatment options for COVID–19 and update the Treatment Guidelines as new clinical evidence emerges.

Understanding COVID–19 Immunity and Pathogenesis

Data on immunity induced by infection with SARS-CoV–2, including studies by NIAID scientists and NIAID-supported researchers, clearly demonstrate that following infection most people generate a protective immune response. NIAID continues to support research to understand immune responses to SARS-CoV–2 infection and COVID–19 vaccination, including projects investigating the durability of immune responses; whether immunity differs in certain populations; and how SARS-CoV–2 variants may evade immunity. These studies include research across the range of immune components, including the role of memory T and B cell responses in preventing progression of disease during SARS-CoV–2 infection.

In addition, NIAID 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 is supporting multiple studies to evaluate acute and long-term clinical and immunological aspects of MIS-C and SARS-CoV–2 infection in children. NIAID also is participating in a trans-NIH effort to coordinate MIS-C research, the Collaboration to Assess Risk and Identify Long-term Outcomes for Children with COVID (CARING for Children with COVID). This effort supports data sharing across studies funded by multiple NIH Institutes to determine the spectrum of illness and predict long-term consequences of infection in children.

Addressing the Long-term Effects of COVID–19

While most people recover quickly and fully from infection with SARS-CoV–2, some experience ongoing or new symptoms or other health effects after the acute infection has resolved; this syndrome is referred to as post-acute sequelae of SARS-CoV–2 infection (PASC). NIH supports research to inform estimates of PASC prevalence as well as to understand the pathogenic mechanisms underlying the wide range of observed symptoms and the risk factors for developing PASC. NIH also launched the Researching COVID to Enhance Recovery (RECOVER) Initiative, a trans-NIH effort that includes targeted funding for research in this critical area. The NIH RECOVER Initiative complements ongoing NIAID studies to better understand the various post-acute manifestations of COVID–19 and will engage 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.

Conclusion

NIAID continues to expand efforts to elucidate the biology, pathogenesis, and clinical manifestations of SARS-CoV–2 infection, including with variants of concern such as Delta and Omicron, and to apply this knowledge to develop safe and effective interventions to diagnose, treat, and prevent SARS-CoV–2 infection and/or COVID–19. NIAID also supports early stage research on candidate vaccines that could protect against multiple strains of coronaviruses. These efforts will improve our response to the current pandemic and bolster our preparedness for the next inevitable emerging infectious disease outbreak.

The CHAIR. Thank you, Dr. Fauci.

Dr. Califf.

STATEMENT OF ROBERT CALIFF, M.D., COMMISSIONER, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. CALIFF. Chair Murray, Ranking Member Burr, and Members of the Committee, thanks for the opportunity to provide an update on FDA's ongoing work related to the COVID–19 pandemic.

FDA's thousands of employees remain steadfast in their commitment to fighting the pandemic, and we will continue to use every tool in our toolbox to arm ourselves with the best available diagnostics, lifesaving therapeutics, and vaccines to fight the virus.

Since our last update to this Committee, FDA has approved a second vaccine, the Moderna vaccine, for individuals 18 and older, authorized a second booster dose of Pfizer-BioNTech and Moderna vaccines for older people and certain immunocompromised individuals, and expanded eligibility for the Pfizer-BioNTech vaccine booster dose to children 5 to 11 years.

We have also held advisory committee meetings this month related to the emergency use requests for the Novavax vaccine to prevent COVID–19 in individuals 18 years of age and older, for the Moderna vaccine for 6 years to 17 years of age, and just yesterday, for both the Moderna vaccine for 6 months through 5 years of age and the Pfizer-BioNTech vaccine for 6 months through 4 years of age.

In each case, without a dissenting vote, the committee agreed that the benefits outweigh the risks in the intended population. The agency is working diligently to complete our evaluation of the data for these submissions, including taking into account the advisory committee's recommendations and we will make a determination as quickly as we can. Authorizing a vaccine with adequate evi-

dence for safety and efficacy for young children in particular remains a top agency priority.

In addition, on June 28, the Advisory Committee will meet to discuss whether the strain composition of COVID–19 vaccines should be modified, and which strains should be selected for the fall. We also continue to employ our Iowa authorities to facilitate availability of tests, including at home diagnostic tests, molecular antigen and serology tests.

For treatments, as of May 31st, 2022, there are more than 700 drug development programs in the planning stages, and we have reviewed more than 460 trials for potential COVID–19 therapies. These include antivirals, immunomodulators, neutralizing antibodies, and combinations of these products, as well as cell and gene therapies.

Regarding treatments for COVID–19, in February, FDA issued an EUA for bebtelovimab for the treatment of mild to moderate COVID–19 in certain adults and pediatric patients. And in May approved olumiant, baricitinib for treatment of COVID–19 in certain hospitalized adults. I am a cardiologist.

I am accustomed to dealing directly with life and death. The best way to avoid dying or getting critically ill requiring hospitalization from COVID is to be up to date on your vaccinations. And if you then get infected and you are high risk, these new therapies offer additional protection against being dead or in the hospital.

Just like heart attack patients who die without proper treatment to open the blocked artery, a person who dies of COVID without appropriate vaccination and treatment is an unnecessary loss of life. I have evaluated therapies for four decades now, and this is among the most robust data for saving lives that I have ever seen. It is not too late to get vaccinated or boosted so that you are up to date with your vaccinations.

More than 2 years into this pandemic, we continue to work around the clock while not compromising our scientific standards. We also continue to monitor changes in the pandemic. Using our finite resources, we are supporting the expansion of the country's arsenal of safe and effective vaccines and treatments and accurate and reliable tests that will protect the American people as the virus continues to evolve.

We continue to face challenges, particularly in the area of access to the data we need to make the best decisions. It is imperative that we have access to complete data in order to prevent shortages, track adverse events, and evaluate the safety and effectiveness of medical products that are critical to our response efforts, particularly since the virus continues to change, leading to ongoing questions about the pertinence of initial data that leads to the EUA.

We are constantly working to get the data we need together with our partners in a very collaborative ecosystem. But the fragmentation of our health system makes it difficult for us to access the complete data needed to monitor key parameters, so we can do better.

I hope we can continue to work together to address issues like these and learn from the COVID–19 response efforts. Thank you, and I look forward to your questions.

[The prepared statement of Dr. Califf follows:]

PREPARED STATEMENT OF ROBERT M. CALIFF

Introduction

Chair Murray, Ranking Member Burr, distinguished Members of the Committee, thank you for the opportunity to testify before you today to describe the Food and Drug Administration's (FDA's or the Agency'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 intra-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 new variants. FDA continues to evaluate the potential impact of new variants on the currently available diagnostics, therapeutics and vaccines. We are closely monitoring changes to the virus and are committed to communicating with the public as we learn more. In response to the omicron variant, we updated the SARS-CoV–2 Viral Mutations: Impact on COVID–19 Tests web page [1] to share new information on the variants and their 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, life-saving 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. Data also suggest a second booster dose of either the Pfizer-BioNTech Vaccine or Moderna COVID–19 Vaccine could help increase protection levels for certain higher-risk individuals.

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.

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[1] *https://www.fda.gov/medical-devices/coronavirus-covid—19-and-medical-devices/sars-cov–2-viral-mutations-impact-covid—19-tests*

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: the Pfizer-BioNTech COVID–19 Vaccine for use in individuals 5 years of age and older; the Moderna COVID–19 Vaccine for use in individuals 18 years of age and older; and the Janssen COVID–19 Vaccine for use in certain individuals 18 years of age and older.

FDA has also approved Comirnaty (known as Pfizer-BioNTech COVID–19 Vaccine under the EUA) for use in individuals 16 years of age and older and Spikevax (known as the Moderna COVID–19 Vaccine under the EUA) for use in individuals 18 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 vaccines, 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. 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.

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; in-

formation about the benefits and risks of each vaccine; and topical Questions and Answers developed by FDA for the approved vaccines 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, [3] 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 marketed as Comirnaty for the prevention of COVID–19 in individuals 16 years of age and older. The Pfizer-BioNTech COVID–19 Vaccine has continued to be available under an EUA and is currently authorized as a:

- Two-dose primary series for individuals 5 years of age and older; third primary series dose for individuals 5 years of age and older with certain immunocompromising conditions;
- homologous first booster dose (matching the primary vaccination) administered at least 5 months after completion of primary vaccination to individuals 5 years of age and older;
- heterologous first booster dose (not matching the primary vaccination) administered after completion of primary vaccination to individuals 18 years of age and older (the dosing interval is the same as that authorized for a booster dose of the vaccine used for primary vaccination);
- homologous second booster dose administered at least 4 months after a first booster dose to individuals 50 years of age and older and individuals 12 years of age and older with certain immunocompromising conditions; and
- heterologous second booster dose administered at least 4 months after a first booster dose to individuals 50 years of age and older and individuals 18 years of age and older with certain immunocompromising conditions.

On January 31, 2022, FDA approved a second COVID–19 vaccine. The vaccine has been known as the Moderna COVID–19 Vaccine; the approved vaccine is marketed as Spikevax for the prevention of COVID–19 in individuals 18 years of age and older. The Moderna COVID–19 Vaccine has continued to be available under an EUA and is currently authorized as a:

- Two-dose primary series for individuals 18 years of age and older;

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

[3] Providers in the CDC COVID–19 Vaccination Program are required to report certain adverse events following COVID–19 vaccination to VAERS

- third primary series dose for individuals 18 years of age and older with certain immunocompromising conditions;
- homologous or heterologous first booster dose administered after completion of primary vaccination to individuals 18 years of age and older (the authorized dosing interval for a homologous booster is at least 5 months after completion of a primary series, and the authorized interval for a heterologous booster is the same as that authorized for a booster dose of the vaccine used for primary vaccination); and
- a homologous or heterologous second booster dose administered at least 4 months after the first booster dose to individuals 50 years of age and older and individuals 18 years of age and older with certain immunocompromising conditions.

The Janssen COVID–19 Vaccine was originally authorized on February 27, 2021. On May 5, 2022, FDA limited the authorized use of the Janssen COVID–19 Vaccine to individuals 18 years of age and older for whom other authorized or approved COVID–19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID–19 Vaccine because they would otherwise not receive a COVID–19 vaccine.

At this time FDA is closely monitoring the emergence of new variants 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. [4]

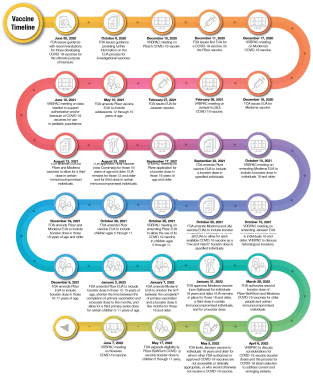
FDA recently held the following virtual meetings of its Vaccines and Related Biological Products Advisory Committee (VRBPAC) related to emergency use requests that have been publicly announced by COVID–19 vaccine manufacturers.

- On June 7, FDA convened VRBPAC to discuss an EUA request for a COVID–19 vaccine manufactured by Novavax to prevent COVID–19 in individuals 18 years of age and older.
- On June 14, FDA and its advisory committee of external experts met to discuss Moderna's EUA request for 6 years through 17 years of age.
- On June 15, FDA and its advisory committee of external experts met to discuss the Moderna EUA request for 6 months through 5 years of age and the Pfizer-BioNTech EUA request for 6 months through 4 years of age.

On June 28, FDA plans to convene the VRBPAC to discuss whether the SARS-CoV–2 strain composition of COVID–19 vaccines should be modified, and if so, which strain(s) should be selected for Fall 2022. This meeting is a follow-up to the April 6 VRBPAC meeting that discussed general considerations for future COVID–19 vaccine booster doses and the strain composition of COVID–19 vaccines to further meet public health needs.

[4] Emergency Use Authorization for Vaccines to Prevent COVID–19, updated March 31, 2022: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-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 booster doses, 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 severe disease caused by variants circulating in the United States.

To date, having three authorized vaccines and two approved vaccines that meet FDA's expectations for safety and effectiveness at this point of the COVID–19 pandemic 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, 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.

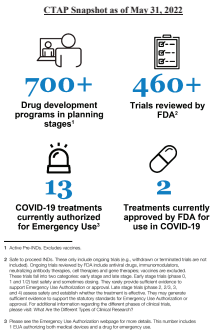
Drug Products

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, FDA created an emergency review and development program for possible therapies for COVID–19, the Coronavirus Treatment Acceleration Program, or "CTAP." 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 May 31, 2022, there are more than 700 drug development programs in the planning stages and the Agency has reviewed more than 460 trials of potential therapies for COVID–19. These therapies include antivirals, immunomodulators, neutralizing antibodies, and combinations of these products, as

well as cell and gene therapies regulated by CBER. The diversity of therapeutic approaches being investigated is important because it rapidly expands our understanding of the effect of different categories of potential treatments.

Figure 2



As of May 31, 2022, FDA has approved two drugs to treat COVID–19 and currently there are 13 authorized therapeutics 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. In the large clinical trial that was conducted among high-risk patients, Paxlovid reduced the risk of hospitalization or death by nearly 90 percent compared to placebo.

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 FDA are not accessible or clinically appropriate.

On February 11, 2022, FDA issued an EUA for bebtelovimab, manufactured by Eli Lilly and Company. Bebtelovimab 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 kg or about 88 pounds) 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.

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 when used as proposed outweigh the known and potential risks of such product.

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. [6]

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 work to support access to devices for the COVID–19 response began in January 2020—before the public health emergency 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), ventilators, and other devices. The need for medical devices to respond to the COVID–19 pandemic has far exceeded what we experienced in any prior public health emergency. The first EUAs issued for the COVID–19 public health emergency were for medical devices, and the volume of EUA requests quickly surpassed (by two orders of magnitude) that of any prior public health emergency or other situation. To help combat the COVID–19 pandemic, FDA and the staff of the Center for Devices and Radiological Health (CDRH) have continued to go well beyond normal operating procedures to help ensure the availability of appropriately safe and effective COVID–19-related devices as quickly as possible.

From early in the pandemic, CDRH has actively reached out to and engaged other government agencies, medical device developers and international regulatory agencies, among other stakeholders. CDRH continues to hold weekly virtual town halls with industry to address COVID–19 test development and validation, as well as additional webinars and town halls addressing other policies and questions including PPE, 3D-printed swabs and manufacturing disruptions during the public health emergency.

CDRH staff have also interacted frequently with test developers and manufacturers through the Pre-Emergency Use Authorization (pre-EUA) process, including rolling reviews of information that helped to further expedite EUA of critical medical devices for patients and health care professionals on the front lines. Since January 2020, FDA has received more than 8,000 EUA requests and Pre-EUA submissions for devices (including more than 1,000 so far in fiscal year 2022).

The emergency use requests included submissions for devices that CDRH had never received EUA requests for during prior public health emergencies. 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. CDRH continues to receive nearly 120 EUA requests and pre-EUA submissions each month, the majority for in vitro diagnostic (IVD) tests, and has begun receiving conventional submissions from firms intending to transition their products beyond emergency use.

Since the start of the pandemic, FDA has issued EUAs or granted marketing authorization to nearly 2,300 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 14 safety communications. FDA completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID–19.

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[6] *https://www.fda.gov/news-events/press-announcements/covid–19-update-fdas-ongoing-commitment-transparency-covid–19-euas*

Diagnostic tests are the first line of defense in an outbreak, and FDA plays an important role to ensure these tests work through the EUA review. The EUA process expedites access to appropriately accurate diagnostic tests during emergencies, when, without such access, information gaps and false results could 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 public health emergencies, 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 April 13, 2022, these templates have received over 618,543 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 86 virtual town halls for test developers.

FDA has prioritized review of EUA requests for at-home tests since Spring 2020—almost a year before other countries pursued expansive use of home tests—and has consistently actively engaged with test developers to support their development. To date, FDA has authorized 19 distinct over-the-counter (OTC) COVID–19 tests, 11 of which were authorized in 4 weeks or less, with five authorized within a week.

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 includes recommendations for validating 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 a National Institutes of Health (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. As of June 1, 2022, the 19 authorized OTC at-home tests have a combined manufacturing capacity of hundreds of millions of tests per month based on data provided to FDA by the manufacturers, and we understand many have scaled beyond their initial estimated capacity with additional government support.

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. 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. In that update, FDA stated that going forward, the Agency generally intends to focus its review on EUA requests for the following types of tests:

- At-home and point-of-care (POC) diagnostic tests 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 NIH'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 partnered with the NIH to establish the Independent Test Assessment Program (ITAP),[7] which streamlines validation and authorization of at-home antigen tests with potential for large-scale manufacturing. This program is an extension of the NIH RADx program which has already supported development of several authorized tests, including the first OTC COVID–19 test. ITAP also supports studies on OTC tests and works with companies to provide complete, high-quality submissions for FDA review. 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. FDA has authorized five OTC, at-home COVID–19 tests that participated in this program through this accelerated pathway—one manufactured by SD Biosensor and distributed by Roche, one manufactured by Siemens, a third manufactured by Maxim Biomedical, a fourth manufactured by Osang, LLC, and a fifth manufactured by Xiamen Boson Biotech Co., Ltd.[8] We are already seeing shorter review times for such EUA requests due to our partnership with ITAP in establishing the evaluation program that provides high quality data. The average FDA review time for a test evaluated under ITAP is just over a week, and can be as short as 1 day, after receipt of a complete data package.

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.

To date, FDA has engaged with over 1,000 developers and authorized more than 475 tests and sample collection devices that provide a wide array of test options. In addition to at-home diagnostic tests, these include other types of molecular and antigen tests, as well as serology tests; POC tests, home collection tests, multi-analyte tests that can detect both COVID–19 and flu; tests using various sample types, including saliva tests; and tests for pooling, screening, and serial testing.[9] Most recently, FDA issued an EUA for the first COVID–19 diagnostic test that de-

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[7] *https://www.hhs.gov/about/news/2021/10/25/new-hhs-actions-add-biden-administration-efforts-increase-access-easy-use-over-counter-covid—19-tests.html*

[8] *https://www.nibib.nih.gov/covid—19/radx-tech-program/ITAP*

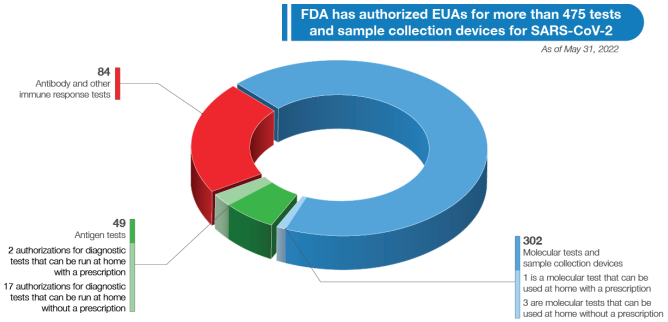
[9] *https://www.fda.gov/medical-devices/coronavirus-disease–2019-covid—19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas*

tects chemical compounds in breath samples associated with a SARS-CoV–2 infection. [10]

As noted in Figure 3 below, as part of this effort, FDA has authorized 302 molecular tests and sample collection devices, 84 antibody and other immune response tests, and 49 antigen tests. We have also authorized 34 tests for serial screening programs (27 antigen and seven 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 3



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 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. [11] 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.

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 May 31, 2022, FDA authorized 274 PPE devices, including 56 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 4*. In addition to issuing EUAs, CDRH has reviewed 510(k)'s for and cleared over 1,400 devices that can be used for COVID–19 and certain similar diseases, including in future pandemics, with over 500 devices in fiscal year 2022 to date.

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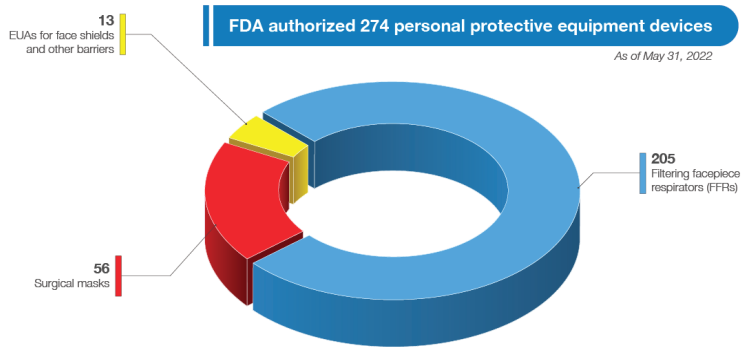
[10] *https://www.fda.gov/news-events/press-announcements/coronavirus-covid—19-update-fda-authorizes-first-covid—19-diagnostic-test-using-breath-samples*

[11] *https://www.fda.gov/medical-devices/coronavirus-covid–19-and-medical-devices/sars-cov—2-viral-mutations-impact-covid—19-tests*

Figure 4



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 outlining policies to help expand the availability of medical devices needed in response to COVID–19.

For example, to help quickly increase availability of tests in the early stages of the pandemic, FDA outlined a policy for developers of certain tests who offered their tests, upon validation and notification to FDA, while Agency review of the EUA request was pending. Additionally, FDA outlined flexible approaches for manufacturers of certain cleared and approved devices (e.g., remote monitoring systems, ventilators, infusion pumps) regarding certain limited modifications made to devices without submitting a premarket submission.

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.

For medical devices, review times have increased over time as the number of EUA requests and Pre-EUA 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

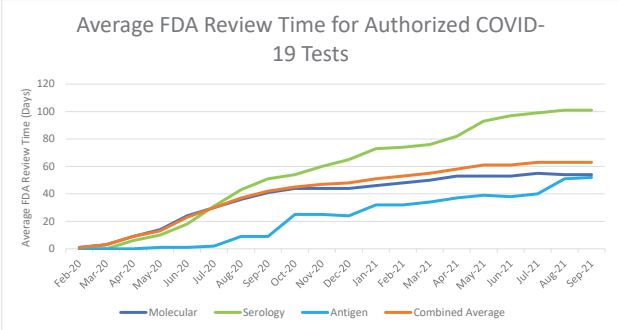
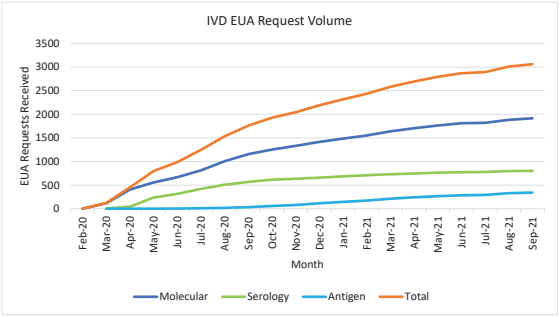


Figure 6



FDA has significantly improved IVD EUA review times. The average total time to decision (TTD) for Original IVD EUAs received in CY 2021 is 54 days, with 91 percent of the 2021 submissions closed.

Given the magnitude of the COVID–19 public health emergency, 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 return to normal operations, including a proposed phased-in transition period and recommendations relating to submitting marketing submissions.

As proposed, FDA would announce the Advance Notice of Termination (ANT) in the Federal Register, which would give manufacturers 180 days to come into compliance with regulatory requirements and submit a conventional marketing submission (e.g., 510(k) or PMA). Provided that the submission is accepted by FDA by this time (180 days after the ANT), FDA does not intend to object to these devices to continue to be distributed and used while the submission is pending review.

FDA is working to address stakeholder feedback and timely finalize this guidance and a companion guidance for devices that fall within COVID–19-related enforcement policies. The transition plan for device EUAs and other actions FDA is undertaking are intended to provide transparency to our stakeholders and to avoid market disruptions and shortages as the Agency and broader device ecosystem transition back to normal operations.

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, Center for Veterinary Medicine, and the Office of Food Policy and Response)

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 humans 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 and apply mitigation strategies for products for which availability has been impacted in part by pandemic-related issues.

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.

As highlighted in the U.S. Department of Agriculture's (USDA's) Agri-Food Supply Chain Assessment report, developed in response to Executive Order 14017 on America's Supply Chains with input from FDA, a dynamic, interconnected, supply chain monitoring platform and robust data sets are necessary to be most effective in monitoring food supply chains, managing risks, and identifying and quickly addressing supply chain disruptions to reduce impacts on consumers.

FDA also recognizes that food supply chain stability and workers' safety are two sides of the same coin. Thus, a stable and 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 to workers in the food and agriculture sectors, including migratory and seasonal agricultural workers. 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 (CVM) 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 continued to conduct mission-critical inspections domestically and abroad, including inspections and investigations in response to foodborne outbreaks, throughout the pandemic. FDA resumed standard operations for domestic surveillance inspections in July 2021, and since March 2022 has been conducting prioritized foreign inspectional work, including surveillance and other inspections. FDA continues to screen every line of every imported food shipment entering the U.S. utilizing our Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT) tool.

We continually adjust 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 review importer records for information showing that foreign suppliers are using processes and procedures consistent with FDA Food Safety Modernization Act (FSMA) requirements. The shift to remote FSVP inspections, along

with other tools utilized by the foods program, was 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 3,423 FSVP inspections. 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 15,324 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. Last year, FDA 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.

Imports, 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 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 refused and destroyed more than 119,000 products, totaling over 21,232,063 capsules, tablets, and other dosage forms of violative drugs shipped via international mail.

Since March 2020, FDA has maintained the same level of screening for products offered for import as pre-pandemic and refused approximately 160,464 lines violative medical products offered for import. FDA has focused examinations on COVID–19 relief supplies to ensure that reviews of compliant products are expedited while maintaining our commitment to refusing medical products that appear to be unsafe, misbranded, unapproved, counterfeit, or may cause serious illness or injury to the public. Import investigators have evaluated donations of shipments destined for the Federal Emergency Management Agency (FEMA) and have been instrumental in expediting the importation of vaccines and related shipments and other COVID–19 necessities starting with the first vaccines (Pfizer Belgium) shipped into the United States in December 2020.

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 and to do other prioritized domestic inspectional work when possible, to ensure FDA-regulated industries were meeting applicable FDA requirements. 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,"[12] outlining the Agency's inspectional activities during the COVID–19 pandemic and its detailed plan to move toward a more consistent state of operations, including FDA's priorities related to this work going forward. The report was updated on November 22, 2021.[13]

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

[12] *https://www.fda.gov/media/148197/download*
[13] *https://www.fda.gov/media/154293/download*

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 as well as remote interactive evaluations that include remote livestreaming video of operations), teleconferences, or screen sharing, and leveraging information from trusted regulatory partners.

For example, ORA made over 2,100 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 350 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 200 remote assessments that were directly used in application decisions.[14] The new tool was incentivized for and supported by industry and continues to provide the Agency with valuable information to assist with risk-based targeting for inspections. FDA recognizes that remote approaches do not replace inspections, and that there are situations where only an inspection is appropriate, based on risk and history of compliance with FDA regulations.

The Resiliency Roadmap further outlined the ongoing steps the Agency is taking to resume standard operational levels of inspection activities, including how it intended to prioritize domestic and foreign inspections that could not be performed during the pandemic. FDA began to transition back to standard operations for domestic surveillance inspections and other prioritized operational work on July 1, 2021, and exceeded the goals 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).

Since October 1, 2021, FDA has been performing domestic inspections at normal operational levels and recently began to conduct foreign facility inspections, including surveillance and other inspectional work, as well. As FDA works through the inventory of postponed 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-known inspectional and compliance history that is making 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 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 pursuing civil and criminal enforcement actions against firms and individuals who do not comply with regulatory requirements, including those distrib-

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

uting 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 treatments, 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 285 warning letters to sellers of unproven products claiming to treat, prevent, or cure COVID–19.

Working with the Department of Justice (DOJ), FDA has sought and obtained preliminary and permanent 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 22 warning letters to owners and/or operators of illicit internet pharmacy websites that offer unapproved and misbranded drugs purporting to treat COVID–19 for sale 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 May 2022, the physician was sentenced to 30 days' imprisonment and 1 year of home confinement after pleading 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 was fined and sentenced to 36 months of probation in October 2021 after pleading 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, we help prevent illegal, dangerous, and fraudulent products from getting 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 sentenced to 10 months of confinement after pleading guilty to 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 70 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.

In addition to the use of compliance and enforcement tools, FDA also used targeted communication to alert the public and address misinformation about the efficacy of products purported to treat COVID.

Medical Product Supply Chain

FDA monitors and responds to worldwide demand and supply chain disruptions for medical products caused by the COVID–19 pandemic.[15] 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 we are working to better position the Agency and our health care system to assure a strong domestic supply chain in future emergencies.

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.

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), signed into law on March 27, 2020, included authorities intended to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA's visibility into drug supply chains. The CARES Act expanded the requirement for manufacturers of certain drugs to provide information on permanent discontinuances and interruptions in manufacturing that may lead to a meaningful disruption in supply to FDA, and required FDA to prioritize and expedite, as appropriate, the review of certain applications and inspections that could help mitigate or prevent a shortage of a drug covered by section 506C(a) of the FD&C Act.

Our experience with COVID–19 only reemphasized that a strong domestic supply chain depends on a resilient supply chain for medical devices. Even before the pandemic hit the U.S., there were disruptions in the medical device supply chain due

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

to higher demand for devices in other nations where COVID–19 was already prevalent and shutdowns in locations from which supplies were sourced.

As a result, FDA began shortage mitigation activities for medical devices in January 2020 before the public health emergency 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 medical device 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.

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.[16] Throughout COVID, FDA has dealt with hundreds of thousands of device units that have been in shortage. FDA used the information it received from its CARES Act authorities to prevent or mitigate shortages including diagnostic testing supplies such as swabs and viral transport media; blood collection tubes; PPE (respirators, surgical masks, gowns, gloves); ventilators; pediatric trach tubes; dialysis products; infusion pumps and accessories; saline flush syringes, sharps containers, needles and syringes.

Specifically, FDA uses the information it receives from the CARES Act to:

- Expedite review of devices and changes to devices;
- Allow/expedite importation;
- Grant enforcement discretion, including outlining flexible approaches for manufacturers of certain cleared and approved devices (e.g., remote monitoring systems, ventilators, infusion pumps) regarding certain limited modifications made to devices without submitting a premarket submission;
- Provide clinical impact assessments to the Assistant Secretary for Preparedness and Response (ASPR) and the White House supply chain coordinator to support informed decisionmaking regarding shortages;
- Authorize EUAs;
- Communicate with healthcare providers about devices in shortage;
- Inform conservation strategies; and
- Provide assessments that allow for informed decisionmaking on medical device shortages across the U.S. Government.

FDA is using this information to develop shortage assessments that inform potential mitigations. This work has helped to protect patients and health care providers around the Nation from critical shortages of devices.

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 and other critical medical devices. For example, FDA collaborated with U.S. Cotton, one of the world's largest manufacturers of cotton swabs, to develop and produce a polyester-based swab for testing. FDA also collaborated with laboratories

[16] 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.

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 has also worked across the medical device ecosystem to address systemic challenges to our supply chain due to sterilization issues and resin shortages. The impacts of supply chain disruptions caused by a natural disaster (Texas Winter Storms) have significantly impacted our most vulnerable populations. Most recently, devices used to compound total parental nutrition for critically ill neonates were impacted by the lack of availability of resins. FDA has worked with manufacturers and suppliers to help mitigate this disruption.

FDA continues to work to implement and operationalize the new device shortage authority, as well as utilize one time funding from COVID supplementals and $5 million in the first annual appropriations it received in fiscal year 2022 to stand up a new state-of-the-art Resilient Supply chain Program (RSCP). Medical device shortages not only put patients in harm's way but also jeopardize our health care workers on the front lines, during public health emergencies 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, and why the Agency has requested additional authorities and funding in fiscal year 2023 to improve our device supply chain readiness going forward 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. FDA recognizes that this will take resources and expanded authority. The pandemic has demonstrated that by the time a public health emergency is declared, it is often too late to effectively prevent or mitigate device shortages.

Moreover, there are situations that occur frequently that do not rise to the level of a public health emergency—such as cybersecurity attacks, natural disasters, recalls and spot shortages that may impact one region of the country or one particular hospital system, but for which device shortages could significantly impact patient care. After the COVID–19 emergency ends, these authorities remain tied to a public health emergency—that is, during or in advance of a public health emergency.

This limits FDA's ability to identify supply chain vulnerabilities and work with the industry to respond to early signs of supply constraints or a potential shortage situation. One need only look at the ongoing resin supply chain issue, noted above, to see the wide-spread impacts that have lasted for over a year and resulted in shortages of multiple devices to include pediatric trach tubes, blood collection tubes, diagnostic tests, and catheters.

Most recently, a critical device component was impacted by this shortage which resulted in an inability to delivery total parental nutrition for neonates [17] Unfortunately, FDA will be very limited in our ability to proactively identify and address device shortages after the COVID–19 emergency ends while its device shortages authorities remain tied to a public health emergency—that is, during or in advance of a public health emergency.

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

[17] *https://www.childrenshospitals.org/content/public-policy/letter/critical-shortages-fda-letter*

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 COVID–19 pandemic.

The Administration continues to apply a whole of Government approach to protecting Americans from COVID–19, and ASPR leads the operational response with responsibilities for procuring and distributing many of the tools needed to fight the virus, including vaccines, therapeutics, and tests.

Thanks to the collaboration across HHS and with partners at DOD and with private industry, ASPR has delivered more than 750 million doses of safe, effective, and free vaccine to 90,000 vaccinationsites around the country, contributing to 221 million people being fully vaccinated.

We continue to allocate vaccine and boosters to sites nationwide. We are now preparing to support the distribution of vaccine for kids under five, should FDA authorize, and CDC recommend a vaccine for that population. We have made 10 million doses available to states, pharmacies, community health centers, and Federal entities to order initially with more doses becoming available soon after.

We are also preparing for the distribution of Novavax's protein based vaccine should it receive authorization and recommendation. This would provide those who are allergic to mRNA vaccine or prefer a non-MRA vaccine, the option to get vaccinated.

While vaccines remain the best way to prevent severe illness caused by COVID–19, we continue to have therapeutics available to prevent and treat infection. Today, ASPR allocates four different products, two oral antivirals, one monoclonal antibody for treatment, and one monoclonal antibody for pre-exposure prophylaxis for immunocompromised people.

We remain focused on making sure that providers and patients know these products are available, that they are free, and they can be found at approximately 50,000 locations nationwide. Testing continues to be an important part of our COVID response.

We have made significant progress in increasing testing supply availability and affordability over the past year. In fact, we went from zero over-the-counter tests in January 2021 to approximately 300 million tests available this winter.

ASPR has secured more than 900 million at home tests for distribution for free to American households through the U.S. Postal

Service. So far, we have delivered nearly 500 million tests to more than 70 million American households via the covidtest.gov program. And we have just opened our third round of ordering.

Since May 2021, ASPR has also shipped over 149 rapid antigen tests and 8.1 million point of care PCR tests to our most vulnerable populations, including nursing homes, federally qualified health centers, and long term care facilities. 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.

ASPR continues to stock the Strategic National Stockpile, or SNS inventory to at or above pre-covid–19 levels to ensure that we are prepared for the next wave of cases. We are doing so to the extent possible with domestically manufactured supplies and equipment.

The SNS currently has 42 times the number of N95 respirators, 8.5 times the number of surgical and procedural face masks, 12.5 times the number of gowns and coveralls, 272 times the number of gloves, and 10 times the number of ventilators than we had prior to the start of the pandemic.

While COVID has been anything but predictable today, we are in a much better position to respond than we were a year ago. A big reason is because Congress, on a bipartisan basis, provided the resources needed to make sure Americans had these free and widely available tools to protect themselves.

Unfortunately, without additional funding, our ability to prepare for whatever comes next is severely limited. Last week, the Administration notified Congress that in the absence of new funding, it was repurposing $10.2 billion in COVID supplemental funding, taking it from critical programs in order to secure more of our most important tools, lifesaving vaccines and therapeutics.

The difficult decision was made to divert funds from our testing program and the SNS at a time when both programs are finally better positioned and better prepared than they have been at any point in this response, and they require funding to be maintained and strengthened in order to stay that way.

Without additional supplemental funds, we are at a point where each spending decision comes with the difficult tradeoff, tradeoffs that none of us want to make. I look forward to working with you on these difficult funding decisions as we continue to respond to COVID and prepare the country for whatever this virus might bring next.

Thank you for your support 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 751.4 million doses of vaccine and 11.3 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 vaccines and boosters. 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 10.3 million first doses delivered for this population. We are also preparing to support the distribution of vaccine for kids under five, if and when FDA authorizes, and CDC recommends, a vaccine for that population. We have plenty of supply of both Pfizer and Moderna vaccines appropriate for this population, and we are making 10 million doses available to states, pharmacies, community health centers, and Federal entities to order initially. Meanwhile, we are also preparing for the potential emergency use authorization of Novavax's protein-based vaccine that, if authorized, would provide those who are allergic to mRNA vaccine or prefer non-mRNA an option to get vaccinated.

In addition to vaccines, HCORE continues to purchase and distribute to states and jurisdictions a variety of treatments including monoclonal antibodies and oral antivirals.

Today we allocate four different products—two oral antivirals, Pfizer's Paxlovid and Merck's Lagevrio; the monoclonal antibody treatment Bebtelovimab from Eli Lilly; and AstraZeneca's Evusheld for pre-exposure prophylaxis for immunocompromised people. We are focused on making sure that providers and patients know these products are available, that they're free and that they are available at approximately 50,000 locations nationwide.

In March, we launched the Test-to-Treat initiative that gives individuals an opportunity to rapidly access free treatments at approximately 2,600 pharmacy-based clinics, federally qualified health centers, and community-based sites. Under this program, people are able to get tested and if they are positive and treatments are recommended for them, receive a prescription from a health care provider (either onsite or via telehealth) and have their prescriptions filled all in one location. In coordination with FEMA, we have also added a federally supported Test to Treat initiative which allows us to partner with states and territories to support additional Test to Treat sites around the country. We currently have sites in Rhode Island and Minnesota and are evaluating additional proposals from several states.

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 81 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 18 therapeutics, 56 diagnostics, and seven vaccine candidates. Notably, BARDA has placed 1.5 billion doses of vac-

cine under contract (including a combination of adult primary, booster, and pediatric doses), distributed over 11.1 million treatment courses of monoclonal antibodies and antivirals, and shipped more than 243 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, monoclonal antibodies are administered by infusion, which must be done in clinical settings, placing a high burden on patients and healthcare staff. BARDA's collaboration with industry on developing oral antivirals offers an important therapeutic option other than monoclonal antibodies. As a result, there are now two oral antivirals available under EUA for the prehospital treatment of patients at high risk for progression to severe COVID–19. In fact, the administration of oral antivirals has increased sixfold in recent weeks.

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 tests for use in both point-of-care and home use settings and for two molecular and five antigen tests for use specifically in point-of-care settings. BARDA has also expanded its portfolio to include development of respiratory panel tests that, at a minimum, can detect SARS-CoV–2 (the virus that causes COVID–19) plus Influenza, but often can detect for other respiratory viruses. BARDA is funding development of an Omicron-specific molecular test for use in informing monoclonal antibody therapy. Last, 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 in the spring of 2021. 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 610 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 January that ASPR continues to work to replenish SNS inventory to levels at or above pre-COVID–19 amounts to ensure that 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 June 2, 2022, the SNS has utilized approximately $12 billion from COVID–19 supplemental appropriations provided by Congress to have in its inventory approximately: 541 million N95 respirators (42 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); 4.8 billion gloves (272 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels). SNS has also made investments to ensure that there is capacity to make these critical supplies.

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.

In response to the COVID–19 pandemic, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) to issue 70 priority ratings. Priority ratings were issued on 54 U.S. Government (USG) contracts to support the development, production, and/or procurement of critical COVID–19 countermeasures such as vaccines, therapeutics, diagnostics, personal protective equipment, ventilators, and ancillary medical supplies. Additionally, priority ratings were issued on 10 USG contracts to support manufacturing expansion for vaccines, diagnostics, N95s, and glass vials as well as for vaccine distribution. In six circumstances, the HHS Secretary authorized a private sector partner to apply priority ratings on select purchase orders to ensure continued production of medical devices that were essential in the COVID–19 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.

Testing

In addition to the Industrial Base Expansion efforts I mentioned previously, ASPR continues to support COVID–19 testing for the Nation. We've made significant progress in increasing testing supply, availability, and affordability over the past year. We went from zero over-the-counter tests in January 2021 to approximately 300 million tests available for use in December 2021. HHS has invested billions of dollars in domestic testing manufacturers to accelerate production of rapid tests and expand manufacturing capacity. At ASPR, we know partnership with industry is critical to ensuring that success continues, which is why I visited an Abbott BinaxNOW manufacturing facility in Illinois to meet with company leadership, visit with the employees on the production floor, and see the manufacturing process up-close. The advances we have made in testing are reflective of a broader effort within ASPR to bolster our industrial base expansion and supply chain efforts.

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. In partnership with the U.S. Postal Service, we have delivered hundreds of millions of tests, and recently opened up a third round of ordering. We are also creating a Federal stockpile of COVID–19 tests to rapidly distribute in the event of a surge.

Since May 2021, ASPR has also shipped over 149 million rapid antigen tests and 8.1 million point-of-care PCR tests to our most vulnerable populations, including nursing homes, federally qualified health centers, and long-term care facilities. 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 this morning. We will now begin a round of 5 minute questions. I ask my colleagues, please keep track of your clock and stay within the 5-minutes.

We are quickly running out of resources to prepare for another COVID surge. I am talking about vaccines that can keep us safe from the new COVID variants, more accurate tests, new treatments that work against new variants to prevent serious illness and death.

Developing those products is essential, but it takes funding, and it takes time. If we don't provide more funding now, the vaccines and treatments we need in the fall may not be available. I don't want to be in a situation again where schools and childcare centers are closed, or hospitals and health care workers are overwhelmed. I want to make sure everyone who wants a vaccine gets one in the fall.

I want to ask each one of you individually this morning, why are additional investments in our COVID response needed now, and how will our ability to prepare for and respond to COVID change if we do not provide additional support? Dr. Walensky, I will begin with you.

Dr. WALENSKY. Thank you, Chair Murray. We have numerous ongoing studies that will not be able to continue, studies that I believe the American people are interested in and need to see, including two nationwide seroprevalence studies that need to end in December 2022. These include the national burden and incidence of infections, immunity and correlates of protection.

We are unable to continue our long term surveillance and that includes comprehensive monitoring of post-COVID conditions. We will be unable to continue our mother to baby surveillance, and that includes mothers with COVID. We have learned a lot about how the impact—they impact on their babies, as well as the vaccine impact of pregnant women and on their babies.

But we won't be able to do those studies for things like paxlovid and other therapeutics, including monoclonal antibodies. And then finally, CDC will not be able to continue its global vaccine efforts and in the future, its domestic vaccine efforts support as well. Thank you.

The CHAIR. Dr. Califf.

Dr. CALIFF. To me, the most important thing that will happen is people will die or be hospitalized or experience long COVID for days to months to maybe a lifetime unnecessarily if they don't have access to the latest vaccines and antivirals. Within the FDA, we have to keep track of all this and adapt to this rapidly changing virus and the environment that it is in.

I want to add one more component we haven't talked about, the supply chains of all of this. I have learned a lot about the food supply chain in the last few months, and it is not just infant formula. We have multiple areas of agricultural supply that are tenuous if workers get sick and can't—and we all remember the early days of the pandemic in that regard.

The CHAIR. Ms. O'Connell.

Ms. O'CONNELL. Thank you. Without additional funds, we have already seen that we are going to be limited in our ability to maintain domestic manufacturing of tests. We have been able to support that over the last several months and keep it ramped up to meet

the demand the American people have had for over the counter tests. We are now having to divert funds away from that.

We are also not going to be able to expand our domestic manufacturing of mRNA vaccines. This was one of the things that we think is important for our current response and future preparedness.

In addition, the Strategic National Stockpile is not going to be able to purchase domestically manufactured surgical gowns as we anticipated being able to do and will struggle to be able to maintain the current PPA—PPE levels that I just walked through. We also are unable to invest in the research and advanced research and development for next generation vaccines and therapeutics.

The CHAIR. Dr. Fauci.

Dr. FAUCI. Yes, Madam Chair. As you know, the role of the NIH is to do the basic clinical and translational research, to develop the countermeasures that we have so successfully been part of that process, to get us the vaccines, therapeutics, and diagnostics.

As you mentioned in your opening statement, this virus is changing, and we need to keep up with it. In order to do that, we have got to do better with new vaccine platforms such as nanoparticle vaccines. We cannot proceed with that unless we get additional funding. Importantly, we need to both prevent infection and transmission.

We know that we cannot do that unless we get a highly effective, mucosal or intranasal vaccine. We have a number of projects that will not be able to be funded unless we do get new resources to continue this funding. These are challenges that we have that I believe we will be letting the American people down if we do not use our scientific capabilities to meet the next challenge of this ever changing virus. Thank you.

The CHAIR. Thank you. You know, COVID–19 vaccines have done incredible job keeping people from getting severely ill. COVID treatments have, as we know, saved thousands of lives. However, we only have a limited number of treatments and vaccines, and they are produced by a small number of companies.

I think everyone in this room is worried we are over reliant on current products and not doing enough to get ahead with the next generation vaccines or treatments or tests. I am worried we are not investing in that research and development of products that we will need this winter.

In our conversations, Dr. Fauci and Ms. O'Connell, it is clear that NIH and ASPR do not have sufficient resources to invest in that necessary research and development work. Dr. Fauci, you alluded to this a little bit, but talk about what you are doing to ensure this next generation research is the top priority for NIH.

What can NIH due to bring these products further along in the process with its existing funding?

Dr. FAUCI. Thank you, Madam Chair. Two examples of what we are doing with regard to therapeutics is the antiviral program for pandemics, where we are using both development and discovery very similar to the paradigm that was used for the highly successful development and discovery of drugs for HIV, namely the

antiviral drugs. We will absolutely need more resources to get that done effectively.

In addition, we have just awarded nine centers that are centers for it is called AViDD, the Antiviral Drug Discovery Centers. We have very good investigators throughout this country. We could fund many more and that would hasten the capability that we have of developing new drugs.

How we can continue to further that is to do what we have been doing all along, is to partner with our industrial partners, to be able to do the fundamental, basic concept development. And then together with BARDA, which we have been very successful with in that partnership, to continue to develop these new drugs as well as diagnostics.

The CHAIR. Thank you. Senator Burr.

Senator BURR. I will turn to each of you for a yes or no answer. You have just described programs that you said would be devastating if emergency funding was not made available. Did the Administration request funding in their '23 budget for the programs you just listed?

Dr. Walensky.

Dr. WALENSKY. I would have to get back with you and——

Senator BURR. Dr. Califf.

Dr. CALIFF. I am certain that parts of it were requested, but not the full amount.

Senator BURR. Ms. O'Connell.

Ms. O'CONNELL. We are beginning the process of figuring out how to absorb these costs into our annual budgets moving forward.

Senator BURR. I asked, did they make a request? You came with the very specific things that are not or are going to be disastrous if emergency spending is not—now we are doing the '23 budget, the budget request coming from the Administration. Did they request these things?

Ms. O'CONNELL. It has been over a year since we have received COVID specific funding. A lot has changed——

Senator BURR. In fact, Administration just took money from the Strategic National Stockpile. They didn't ask for more. They took it. They asked for less. Dr. Fauci, are all the things that you just listed, are they in the '23 budget Administration request of Congress to fund?

Dr. FAUCI. Some of them are, Senator, but not all of them, because at the time that we put in that request, the opportunities to do some of the things we done were not absolutely apparent to us. So the direct answer to your question is not all of it is in the request.

Senator BURR. Are you beginning to see the pattern as to why a plan is important? This has been a well-orchestrated event up to this point. It has done you damage. It really has. Dr. Califf, we have hit the point in public health response where there is a commercial market for COVID vaccines, treatments, and diagnostics, yet FDA is still limiting who can purchase vaccines and treatment under the EUA.

Limit and nothing in the law requires that the purchaser of an authorized or EUA vaccine or treatment must be Government. Does FDA have a plan to allow states or health care providers, including payers, to purchase vaccines and treatments to help put purchasing decisions back in the hands of Americans rather than Government?

Dr. CALIFF. Senator Burr, each of our major product areas, drugs, devices, biologics is working with the industry to be transitioning. A number of them already have transitioned to full——

Senator BURR. You understood what I read in the statement was, you actually write into the EUA, only Government can purchase these.

Dr. CALIFF. That is correct.

Senator BURR. The law does not restrict anybody else from purchasing under an EUA. It is the limitation you put in the EUA, correct?

Dr. CALIFF. Yes, that is correct.

Senator BURR. All right. Let's talk about EUAs a little bit further. The EUA on antivirals. Did I misstate anything that the antiviral EUA states that it should only be prescribed to individuals that are at risk?

Dr. CALIFF. Right. Pfizer did a robust clinical trial and that included people at risk, at higher risk by certain factors. We looked at the data. The data were compelling. That was the basis for the EUA.

Senator BURR. The in the EUA says to be prescribed to individuals at risk?

Dr. CALIFF. Those at high risk. Yes.

Senator BURR. So does Test and Treat violate the restrictions in the EUA if individuals who show up are not at risk, test positive, or are given an antiviral?

Dr. CALIFF. My interpretation of Test and Treat is it is still prescribing paxlovid that is still within the EUA. And so only those who meet the risk criteria would be prescribed it.

Senator BURR. Anybody that does not reach the risk criteria would be in violation of the EUA?

Dr. CALIFF. I think prescribing, as you know, is a complicated area of medical practice. So when you say in violation, I am not sure what the legal meaning of that in the context of medical practice. But people who are low risk, like a 25 year old with COVID and no co-morbidities, would not be expected to get benefited and so it wouldn't make sense to prescribe it.

Senator BURR. Was the vice President high risk when she took the antiviral?

Dr. CALIFF. I am not aware of the vice President's clinical status, and as a physician, I wouldn't discuss a person's medical history.

Senator BURR. Ms. O'Connell, just last week, HHS announced that it had found $10 billion in the couch. Out of those funds previously provided for COVID responses, I was surprised and frus-

trated to hear that these funds were overwhelmingly repurposed from within ASPR, including the stockpile.

It is my understanding that over $1 billion will be taken from the Strategic National Stockpile. What are we giving up in the stockpile so that that $1 billion can be spread across the rest of the response?

Ms. O'CONNELL. Thank you, Senator. Without additional funding, we have been forced to make very difficult decisions, make trade-offs that none of us want to make. And that included finding an additional $1 billion from the Strategic National Stockpile. That funding would have gone to securing the purchase of domestically manufactured surgical gowns in order to meet the requirement that the national stockpile has for surgical gowns, so we are going to be short there. We also are jeopardizing our ability to maintain the PPE at the levels that we currently are. Every piece of equipment we have is warehoused. The warehousing costs money.

Senator BURR. Ms. O'Connell, you are the ASPR, and by statute, you are supposed to lead a pandemic. I am going to turn to you. Tell me what the plan is.

Ms. O'CONNELL. Well, the Administration put forward a plan on March 3rd with how it would spend the additional funds that it was repurposing——

Senator BURR. I understand how you would spend it. Tell me what the plan is to get to some endgame in COVID.

Ms. O'CONNELL. Our plan involves short term, providing, making sure all Americans have access to the critical tools needed to protect themselves. Medium term, making sure that we have access to supplies moving forward. Investing in domestic manufacturing so we are not caught short footed like we were in March 2020.

Then long term, this research and development that we have talked about to get us to the next generation of vaccines that won't require multiple boosts, to get us to therapies that can be prescribed for everybody. That is where we need to go.

Senator BURR. If you can take the outline you just presented to me and get somebody from the Administration to fill in in between the action steps that are going to be taken, you might have a plan. Thank you, Madam Chair.

The CHAIR. Senator Paul.

Senator PAUL. Dr. Fauci, the Government recommends everybody take a booster over age five. Are you aware of any studies that show a reduction in hospitalization or death for children who take a booster?

Dr. FAUCI. Right now, there is not enough data that has been accumulated, Senator Paul, to indicate that that is the case. The—I believe that the recommendation that was made was based on the assumption that if you look at the morbidity and mortality of children within each of the age groups, 0 to 5, 5 to 11——

Senator PAUL. Right. So there are no studies, and Americans should all know this, there are no studies on children showing a reduction in hospitalization or death with taking a booster. The only studies that were permitted, the only studies that were presented were antibody studies.

They say if we give you a booster, you make antibodies. Now, a lot of scientists would question whether or not that is proof of efficacy of a vaccine. If I give you 10 or if I give a patient 10 mRNA vaccines and they make protein each time or they make antibody each time, is that proves that we should give ten boosters, Dr. Fauci?

Dr. FAUCI. No, I think that is somewhat of an absurd exaggeration, Senator Paul.

Senator PAUL. Well that is the proof that you use. Your committees use that. That is the only proof you have to tell children to take a booster so that they make antibodies. So it is not an absurdity. You are already at like five boosters for people. You have had two or three boosters. It is like, where is the proof?

Now, I think there is probably some indication for older folks that have some risk factors. For younger folks, there is not. But here is the other thing. There are some risk factors for the vaccine. So the risk of myocarditis with a second dose for adolescent boys, 12 to 24, is about 80 and 1 million.

This is both from the CDC and from the Israeli study. It is also in the VAERS study, remarkably similar, for boys, much higher from boys than girls, and much higher than the background. The background is about 2 per 1 million. So there is risk and there are risk. And you are telling everybody in America just blindly go out there because we made antibodies. So it is not an absurd corollary to say if you have 10.

In fact, you probably make antibodies if you get a 100 boosters, all right. That is not science. That is conjecture. And we should not be making public policy on it.

Dr. FAUCI. So, Senator Paul, if I might respond to that, we just heard in his opening statement, Ranking Member Burr talk about his staff who went to Israel. And if you look at the data from Israel, the boosts, both the third shot boost and the fourth shot boost, was associated with a clear cut clinical effect, mostly in elderly people, but also as they gathered more data, even in people in the 40's and the 50's. So there is clinical data——

Senator PAUL. But not in children. Well, see, here is the thing is, you are not willing to be honest with the American people. So, for example, 75 percent of kids have had the disease. Why is the CDC not including this in the data? You can ask the question. You can do laboratory tests to find out who has had it and who hasn't had the disease.

What is the incidence of hospitalization and death for children who have been infected with COVID subsequently going to the hospital and dying? What is the possibility if your kid has had COVID, which is 75 percent of the country has had COVID, what is the chance that my child is going to the hospital or dying?

Dr. FAUCI. If you look at the number of deaths in pediatrics, Senator, you can see that there are more deaths——

Senator PAUL. Of people who have had it—of people who have had the disease.

Dr. FAUCI. Senator, we also know from other studies that the optimal degree of protection when you get infection is to get vac-

cinated after infection. And in fact, showing reinfection in the era of Omicron and the sub-lineages, that vaccinated——

Senator PAUL. But you can't answer the question I asked. The question I asked is how many kids are dying and how many kids are going to the hospital who have already had COVID? The answer may be zero, but you are not even giving us the data because you have so much wanted to protect everybody from all the data because we are not smart enough to look at the data.

When you released data earlier, when the CDC released the data, they left out the category of 18 to 49 on whether or not there was a health benefit for adults 18 to 49. Why was it left out? When critics finally complained, it was finally included because there was no health benefit from taking a booster between the 18 to 49 in the CDC study. Another question for you.

The NIH continues to refuse to voluntarily divulge the names of scientists who receive royalties and from which companies. Over the period of time, from 2010 to 2016, 27,000 royalty payments were paid to 1,800 NIH employees. We know that not because you told us, but because we forced you to tell us through the Freedom of Information Act.

Over $193 million was given to these 1,800 employees. Can you tell me that you have not received a royalty from any entity that you ever oversaw the distribution of money in research grants?

Dr. FAUCI. Well, first of all, let's talk about royalties.

Senator PAUL. That is the question. No, that is the question. Have you ever overseen or received a royalty payment from a company that you later oversaw money going to that company?

Dr. FAUCI. You know, I don't know as a fact, but I doubt it.

Senator PAUL. Well, here is the thing is, why don't you let us know? Why don't you reveal how much you have gotten and from what entities? The NIH refuses. We ask them. We ask them. The NIH—we ask them whether or not who got it and how much. They refused to tell us. They send it redacted. Here is what I want to know. It is not just about you.

Everybody on the vaccine committee. Have any of them ever received money from the people who make vaccines? Can you tell me? Can you tell me if anybody on the vaccine approval committees ever received any money—vaccines—?

Dr. FAUCI. Are you going to let me answer the question? Sound bite No. 1. Are you going to let me answer a question? Okay. So let me give you some information. First of all, according to the regulations, people who receive royalties are not required to divulge them even on their financial statement, according to the Bayh-Dole Act.

Let me give you some example. From 2015 to 2020, I—the only royalties I have was my lab and I made a monoclonal antibody for use in vitro reagent that had nothing to do with patients. And during that period of time, my royalties ranged from $21 a year to $17,700 a year, and the average per year was $191.46.

Senator PAUL. It is all redacted, and you can't get any information on the NIH——

The CHAIR. Senator Paul, your time——

Senator PAUL. We want to know whether or not people got money from the people who made the manufacturing——

The CHAIR. Senator Paul, your time is long over expired. I gave you an additional two and a half minutes. The witness has responded. We are going to move on.

Senator Sanders.

Senator SANDERS. Thank you all very much for being here. One of the concerns that I have in terms of where we are now and where we might be in the future, is that the American people do not have ready access to the information they need as to how they can receive the best treatment available of a COVID.

An example of a 60 year old gentleman wakes up in the morning, has bad symptoms, tests positive for COVID. I worry that that person and millions of them may not even know that there are therapeutics out there that can help them, that they may have 5 days, only five—that they have to take it within the first 5 days of symptoms.

Or can you tell us, Dr. Walensky, what we can do to make it easier for people to get the therapeutics that they need?

Dr. WALENSKY. Thank you, Senator Sanders. This is key in terms of our distributing and equitably distributing not only our therapeutics, but in fact, even before therapeutics, communities and at risk people need to understand to do a test because that is the gateway into getting these therapeutics.

We need to have testing available, accessible. A lot of what the ASPR has done in distributing home tests. We need to have therapeutics available in at risk communities across the country and then we need to do public health campaigns so that people understand that a test should be done and that they have access to these therapeutics.

Senator SANDERS. But the concern is that in some of them, at least, you should take the drug within five—the first 5 days. Are you confident that we have a system that if somebody wakes up, they are going to have to get a prescription from a doctor, do they have a doctor that they can get a prescription from within the first few days? Do they know where to get the drug, or—and do they have the money to pay for that drug?

Dr. WALENSKY. The drugs are free. The tests are free. But I am not sure that everybody knows that. And we have expanded our rollout and accessibility of paxlovid. But I will also say that just like early in our vaccine work, we have seen inequities in how that paxlovid has been used.

We will have more data forthcoming from the CDC soon on that. But we have a lot of work to do in the equitable distribution of paxlovid and to getting the education to the communities, to community health centers, to physicians in rural areas.

Senator SANDERS. Should our goal be, it seems to me, to make it nice and simple that if somebody is feeling ill, if somebody has COVID, they can dial a 1–800 number and get the drug as quickly as possible. Is that the goal that we striving for?

Dr. WALENSKY. Yes, we need to do that under the EUA and with the caveat that there are some things like renal insufficiency or drug interactions that need to be assessed. We need to make sure that those assessments are complete as well.

Senator SANDERS. Okay. I want to change course a little bit here and touch on a subject that I don't think we talk about enough as a Nation, and that is that we have a significant shortage of doctors, nurses, pharmacists, dentists, other health care providers.

That shortage has only been exacerbated as a result of burnout related to COVID. I know that is not necessarily within your jurisdiction, but you can give us—can you give us some thoughts about how serious that shortage of medical personnel is and what we might want to do to address it?

Dr. WALENSKY. Yes, I think it is key. Not only medical personnel, but public health personnel. The Beaumont Foundation surveyed demonstrated that we are about 80,000 public health workers in deficit right now and that we need to not only retain the ones who have stepped up to the plate during the COVID–19 pandemic, but we need to foster and invest in future public health workers as well as health care workers.

That includes loan repayment and includes investing in the time and making sure we are competitive from salary standpoint so that we can retain the best of the best in these fields.

Senator SANDERS. Okay. Let me ask Dr. Califf a question. Senator Paul raised the issue about money and so forth. I look at it, his questions are valid, but I look at it a slightly different way. I am concerned, and you correct me if I am wrong here, Moderna, who helped create one of the important vaccines that is saving lives, received, as I recall, about $2.5 billion, I think, during the Trump administration.

My understanding, and you correct me if I am wrong, is that the gentleman who is the head or was the head of Moderna recently received a golden parachute of some $800 million, $2.5 billion of Federal funding to develop the drug, Moderna makes huge amounts of money, this guy receives $800 million a golden parachute. Am I right about that?

Dr. CALIFF. I am not aware of that. It is not something I would keep up with, particularly in this job.

Senator SANDERS. Not something you would keep up with. The Head of the Food and Drug Administration, you would not be concerned that a guy—when we are producing and trying to get vaccines out to people, it was—I am corrected, it is $926 million golden parachute. If that is true, if the Federal Government gives a company $2.5 billion and a short time later the head of the company gets a $900 million golden parachute, that is not a concern to you?

Dr. CALIFF. No, I didn't say it was not a concern. I said it is not something I keep up with in daily life. What I am very concerned about is the equitable distribution of vaccines that save lives and antivirals that save lives. we are not reaching the goals that we need.

Senator SANDERS. Well, maybe, I think we need, I would hope everybody agrees that we need the financial resources to make sure

that everybody has the vaccines. But if one guy ends up with $900 million, rather than using that money to get out the medicine we need, the vaccines we need, out to the people, doesn't make a whole lot of sense to me. Thank you very much, Madam Chair.

The CHAIR. Senator Romney.

Senator ROMNEY. Thank you, Madam Chair. Senator Sanders, I am one of those that doesn't understand why golden parachutes are provided by boards ever. Doesn't make any sense to me to pay someone to leave a ton of money. Not that you change the law. I am just saying I can't figure out why a board would do such a thing. Worth looking into.

I appreciate the work that each of you do and the effort that you make to help the people of our Country have healthier lives and have long lives. I realize that science is not all knowing. And from time to time, there are mistakes. That is the nature of humankind. But I appreciate very much the work that you do and want to express my appreciation personally for that.

I do have an issue that is tangentially related to what you do but related to the Administration of which you are you are part of. And that is that back in March, I had a number of other Members of this Committee sent a letter to the Administration asking for an accounting of how the prior COVID relief money had been spent, and then also how new money that was being requested for emergency supplemental would be spent.

As part of that response to that letter, the Administration released a statement regarding the lack of potential funding for—going forward. I want to read a couple of excerpts from that letter. One is, "the Federal Government is unable to purchase additional lifesaving monoclonal antibody treatments and will run out of supply to send to states as soon as late May.

The Federal Government cannot purchase sufficient quantities of treatments for immunocompromised individuals, and the Federal Government will be unable to sustain the testing capacity we built over the last 14 months." And then continuing, "ending the purchase of monoclonal antibody treatment, scaling back state and territorial allocations, inability to purchase additional oral antiviral pills, inability to purchase new antivirals, scaling back planned purchases of preventative treatments."

Again, what the Administration provided to us in Congress in response to our letter was that the Administration would be unable to purchase therapeutics and monoclonal antibodies, unable to purchase. Madam Chair, I would ask unanimous consent that this release from the Administration be entered into the record.

The CHAIR. Without objection, so ordered.

[The following information can be found on page 81 in the Additional Material:]

Senator ROMNEY. Now, in good faith, I and a number of other people worked over a number of months with Members of this party and across the aisle to develop a supplemental bill providing that $10 billion to address this inability to purchase these things without the $10 billion.

But you can imagine my surprise when I find out that on June 8th, the Federal Government did, in fact prioritize $5 billion for the purchase of additional vaccines, $4.9 billion for therapeutics, and $300 million for additional monoclonal antibodies. But it choose not to do so in February, March, April, or May, again saying they had inability to do so. So the Administration has recklessly and unilaterally spent taxpayers' money. We have runaway inflation.

But instead of taking a real inventory of funds they had at their disposal, they said, hey, we need more money. Now, Washington operates on a relationship of trust between the respective parties, the Administration, and Congress. For the Administration to provide information to us that was patently false is something which dramatically attacks that trust, which I have, Members of my party have, Members of both parties have.

I hope that there is an appreciation that for the Administration to say they could not purchase these things and then after several months divert some funds and then purchase them is unacceptable and makes our ability to work together and have confidence in what we are being told very much shaken to the core.

I would ask this question. If the Administration knew in March that it was feasible to buy these things, do you know why they waited to actually do so? Any one of you can respond. Dr. Fauci, you are on the hot seat on the camera, so we will give it to you. I hope you feel better, by the way.

Dr. FAUCI. Yes. Thank you very much. Senator. I think that question is probably best given to the Assistant Secretary Dawn O'Connell.

Ms. O'CONNELL. Thank you, Dr. Fauci. Thank you, Senator Romney. And thank you for your support in trying to get additional funds freed for us to manage the COVID response.

Senator ROMNEY. Yes, I didn't realize that they weren't needed. I wouldn't have worked as hard with Leader Schumer and with others over many weeks and intensive negotiations and gone to my colleagues and told them these moneys were necessary had I been told that, in fact, they weren't necessary.

It is—and I know money is—you are going to tell me that, hey, we needed to spend money and other things, we had to divert it, but that we could have been told. But we weren't told that. We were told, we could not purchase therapeutics or monoclonal antibodies. And now you have.

Ms. O'CONNELL. We had to do so with significant tradeoffs. Tradeoffs that we—none of us wanted to make as——

Senator ROMNEY. But we should have been—we are part of Congress. When you are asking us for $10 billion, we should be apprised of what those tradeoffs are and have that discussion and help make that decision together. You shouldn't be able to say, hey, we are looking at tradeoffs, we are not going to tell you about them, just give us some more money. Isn't that not unacceptable in a relationship between the Administration and Congress?

Ms. O'CONNELL. We have worked hard to be transparent with our funding needs. And again, I have appreciated the support you have given us in trying to unlock additional funds. Making the de-

cision to spend this money, taking it away from critical programs is absolutely difficult, and it is something we didn't think was acceptable. We are now at a point, because Congress has not given us additional funding, that we have had to do these things that are unacceptable.

Senator ROMNEY. Well we—my time is up. I will just say we agreed on one word and that is, unacceptable. Thank you.

Madam Chair.

The CHAIR. Senator Lujàn.

Senator LUJÀN. Thank you, Madam Chair. Now, as New Mexico continues to battle the COVID–19 pandemic, we are now also battling the largest wildfires the state has ever seen. Wildfires that were started as a controlled burn by the Federal Government and two fires that got out of control.

While I very much respect that people keep telling me 99.8 percent of control burns are always under control, I am more interested in the 0.2 percent that destroyed our state. These dual crises have stretched the resources of the state to the breaking point.

As New Mexicans flee natural disaster, in many cases taking only the belongings they can carry, they face increased exposure to COVID–19 virus, which has run rampant in the congregate settings being used to house evacuees. Assistant Secretary O'Connell, how are you coordinating to support New Mexico's COVID–19 response in light of the wildfires?

Ms. O'CONNELL. Thank you, Senator Lujàn. And we continue to keep the people of New Mexico who are currently experiencing these two tragedies in our minds. The Secretary on May 9th, realizing the extent of what was happening in New Mexico, declared a public health emergency, and that public health emergency freed up flexibilities for the health care system there in order to respond in the emergent condition, including providing telehealth for Medicare beneficiaries, freezing the Medicaid rolls so no one would be—would lose insurance during this time of tragedy.

At ASPR, we continue to support through our hospital preparedness program, New Mexico's Coalition, a healthcare coalition, which was responsible for evacuating many of the hospitals and long term care facilities, nursing homes. And so we continue to work closely with our colleagues there to make sure that everybody is safe and accounted for. We also run the Medical Reserve Corps, and the Medical Reserve Corps in New Mexico has been activated in order to respond to the wildfires.

We continue to support our colleagues out there through that effort. And we have been in close contact with FEMA. We have offered virtual support to FEMA out in New Mexico. And wherever we can be helpful, we are trying to be. And we have not stopped our COVID response. We are continuing to make vaccines and therapeutics and tests available to those in New Mexico that need them.

Senator LUJÀN. Assistant Secretary O'Connell, this is a follow-up to the solid answer with programs that have been made available. The follow-up is, how is HHS ensuring that these resources are being communicated to those impacted, especially given the current

lack of cellular and broadband service in many regions of the state, which is nonexistent in these communities?

Ms. O'CONNELL. Thank you, Senator. We continue to have boots on the ground in New Mexico. We have got regional emergency coordinators in the state that continue to communicate with city and local leaders. We also have our CMS representatives who are making sure that the Medicare and Medicaid provisions are being well communicated to those beneficiaries, and everything we can. We have got several regional representatives leading this effort for us in New Mexico and continue to rely on their ability to communicate on the ground.

Senator LUJÀN. Now, I said earlier that many families were forced to evacuate. They were living in congregate settings. But they were not eligible for the fourth COVID–19 vaccine. Dr. Walensky, will you commit to reconsidering CDC guidelines for the fourth COVID–19 shot to account for the risks of people fleeing from natural disasters who are forced into compact living conditions?

Dr. WALENSKY. Thank you, Senator Lujàn. And let me add my support and strength to the people of New Mexico who are experiencing these natural disasters. Maybe if I could just back up and let you know some of the things that CDC has been doing in including drafting recommendations and documents like wildfire smoke and COVID–19, public health strategies to reduce exposure to wildfire smoke during the COVID–19 pandemic.

Going to a public health—a public disaster shelter during COVID–19. We have documents. We are providing technical assistance on the ground, as well as public health communication, exposure, assessment, and epidemiologic data in order to support the efforts ongoing there. And we have been working in our National Center for Environmental Health over the last decade to support health Departments to prepare for, respond to, and recover from wildfire disasters.

Specifically to your question about booster shots for this population, CDC is committed to continuously reviewing the data on the safety and efficacy and need for booster shots. We do so all the time. We did—we strengthened our recommendation for those—for fourths shots for those over the age of 50.

Should we see a need, safety and efficacy, we will continue to expand, but we certainly want to follow the data as we do so.

Senator LUJÀN. I appreciate that, Dr. Walensky. Madam Chair, as my time expires, I have a couple of questions also made into the record. But I am hoping that that is a long way of saying yes definitively to making these changes. Not all of us are over 50. There were a lot of—and I just turned 50 so I can say—there are a lot of young families and children and grandchildren who are in these settings above the age of five, where we had them all in one place.

When we would get scares of spread or those that are tested positive, it is a perfect place to help provide additional support in a community where it is hard to get to and we don't always have the availability.

This is an area that I will continue to push, and I am hopeful we can find a positive remedy here because New Mexico is not going to be the only state facing natural disasters.

We are in that season right now. I am hopeful that there will be some positive direction in how we can take care of more people. I thank you very much. Madam Chair, yield back.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Thank you all for being here. Thank you for your efforts on part of our Country. And, of course, what we are hearing is that there has to be more money appropriated and dire consequences if not allocated. But that begs the question of the stewardship of the current dollars being allocated. Now, and so I personally think, and I think others agree that physically showing up to work is important. So, Ms. O'Connell, how many days in the last month were you physically in your office?

Ms. O'CONNELL. The vast majority of those days.

Senator CASSIDY. Can you give me a number? I mean, it is so frustrating. I have never been able to get a straight answer from one of you as to how many days you are in the office and what is the return to work policy. So just give me—how many days is past week? And if it is five, I am pleased. How many days in the last week?

Ms. O'CONNELL. The HHS has continued its return to work starting in April. We are bringing everybody back.

Senator CASSIDY. No. How many days have you personally been in your office this last week?

Ms. O'CONNELL. Multiple days, of course.

Senator CASSIDY. Okay, this is not hard to remember. It is only 5 days. And if you dissemble, it makes me think that you have not been in the office, and you don't want to give me a straight answer. I am speaking on behalf of the American people who are paying taxes and a lot of salaries, and they think people aren't showing up to work. How many days in the last five were you physically in your office?

Ms. O'CONNELL. We continue to work——

Senator CASSIDY. Okay, Dr. Califf. How many days in the last five were you physically in your office?

Dr. CALIFF. I was down in North Carolina Monday and Tuesday because the 18 year olds that you met at my confirmation are graduating from high school——

Senator CASSIDY [continuing]. give me 5 days. When there wasn't a family issue, did you go the previous week?

Dr. CALIFF. I—five, every day. When I have been in Washington and not on business travel, I go into the office at White Oak.

Senator CASSIDY. Okay, I get that. Every day you are in Washington does not mean that when you are—that you are here. So are you either doing business travel as part of FDA, and but if not, you are physically in your office?

Dr. CALIFF. Yes. Except for family events like——

Senator CASSIDY. Dr. Walensky, how many days in the last five were you physically in your office?

Dr. WALENSKY. I am not in my office today, but I feel like I am working on——

Senator CASSIDY. No, no, not feel like, how many——

Dr. WALENSKY. I am working onsite. I have been in—I have been traveling, so I have been in my office two, and I have been traveling for two. One of them I was, in fact, in your——

Senator CASSIDY. So, in the last month, do you typically work out of Washington, or do you work out of your home in the Northeast?

Dr. WALENSKY. We are an agency at CDC——

Senator CASSIDY. Boy, it is really hard to get a straight answer.

Dr. WALENSKY [continuing]. work—on the job work. And in fact, some of our work is in your state when you ask us to deploy.

Senator CASSIDY. I get that. I get that. But let me read something from Elon Musk, who is asking Tesla workers to go back to 40 hours a week. "The more senior you are, the more visible you must be. That is why I have lived in the factory. There are companies that don't require this. When was the last time they shipped a great product? You don't ship great products by phoning it in."

There is a perception that your agencies are underperforming. Now, if you are underperforming and you are not showing up, that is not good stewardship. Now, let me ask, because I understand that HHS has a policy which is allowing people to come back every 2 weeks for 8 hours a day.

Now, do any of you have a policy in your agency which is different than this pilot program of only requesting 8 hours in the office every 2 weeks? Ms. O'Connell, yes, no.

Ms. O'CONNELL. We require more than that in the office. Thank you.

Senator CASSIDY. Dr. Califf.

Dr. CALIFF. Yes. I mean, we have talked a lot—we have a pilot program, which adjusts every individual to the optimal working situation for them to be productive.

Senator CASSIDY. Yes, so that tells me that it is really up to the individual to decide——

Dr. CALIFF. No. It is up to the individual, their supervisor——

Senator CASSIDY. In your laboratories, does every laboratory worker show up every day physically? Because in a laboratory you got to be there.

Dr. CALIFF. Well, Senator Cassidy, we are both doctors. You know, everyone who has a job to do in the laboratory that requires them to be there is there every day. But you also know that when you analyze data——

Senator CASSIDY. Analyze data. If you have got a lab tech, the lab tech has to be there.

Dr. CALIFF. Absolutely.

Senator CASSIDY. Is the lab tech there every day?

Dr. CALIFF. Yes.

Senator CASSIDY. I am sorry to be insistent, but it is hard to get an answer.

Dr. Walensky.

Dr. WALENSKY. Yes. Laboratory. The people who need to be in our labs are working in our labs. But I will also say that——

Senator CASSIDY. Are they are working full time, 40 hours a week?

Dr. WALENSKY. When I have a data need at midnight on a Saturday night, people are working. There are not necessarily in the workplace, but they are working.

Senator CASSIDY. I get that. But as a lab employee who is only productive if they are in a lab, are they working 40 hours a week?

Dr. WALENSKY. People who need to be onsite in the lab or onsite in the lab, people who are deployed to the field, deployed nationally, they are working outside the workplace.

Senator CASSIDY. Yes, but I think there is a lot—I have got 18,000 employees and I can't believe they are all deployed. You know, I want to finish with this. You are asking for more money. Ms. O'Connell, you suggested that there is tough tradeoffs that have to be made.

That, by golly, if you don't give us the money, something is going to be sacrificed. I suspect you haven't laid off a single person. I also know that you have the ability to monitor the at homework history as to whether or not they are actually logging on. I would be interested in seeing that data.

But you have got maintenance people who haven't been employed for two and a half years, and I suspect they have not been laid off. But you are asking for more taxpayer dollars, asking tough choices for that family at home trying to make their balance work, and yet it seems as if there is not a tight ship being run. I am over. I apologize. I yield.

The CHAIR. Senator Hassan.

Senator HASSAN. Thank you, Madam Chair, and Ranking Member Burr, for this hearing. And thank you to all of our witnesses today for being here and for your service. Dr. Califf, I want to start with a question to you about the infant formula shortage. I want to follow-up on comments that you made at start of today's hearing.

When you testified in front of this Committee 3 weeks ago, you told me that within 2 months we should be, "beyond normal and with a plethora" of infant formula. Then, as Chair Murray noted, Abbott announced last night that its formula production plant in Sturgis, Michigan, had flooded, which will, "likely delay production and distribution of new product for a few weeks."

But despite that setback, as I understood your answer to Chair Murray earlier, you still hope to have a "super-supply" of baby formula on shelves in the next 2 to 3 weeks, which I take to mean more formula available than was typical prior to the Sturgis plant shutting down. So is that correct?

If so, how do you expect to achieve that goal with Abbott saying that the Sturgis plant will remain shut down for another few weeks?

Dr. CALIFF. Yes, that is correct, with two assumptions. One is that the company stuck to the production data that they have given us, which they have already demonstrated they can do. The second

is there is no other natural disaster like the unexpected one last night.

But we have—one thing that has happened is we now get production data from all the companies involved. It adds up to a surplus relative to the needs that are demonstrated by the number of babies using formula over the last several years. So we should be over that number easily, and that doesn't count the fly formula coming in.

Senator HASSAN. What you are indicating to me is that other producers have been increasing their production.

Dr. CALIFF. Absolutely. All of the manufacturers in the U.S.—remember there were only four, which is another issue. They have all stepped up and are running their plants 24 by 7 and the numbers show it.

Senator HASSAN. Okay. During the last hearing, you indicated that an interagency committee has developed a comprehensive plan to get this super supply on the shelves. Will you provide that written comprehensive plan to my office after this hearing?

Dr. CALIFF. Well, we will provide our plan, yes.

Senator HASSAN. Thank you. And will your—and once we have looked at the plan, we may want to follow-up with you all for a brief. That work for you.

Dr. CALIFF. I understand.

Senator HASSAN. Okay. Second question is to Dr. Fauci and Assistant Secretary O'Connell. Dr. Fauci, for nearly 2 years I have been asking you when a COVID–19 vaccine for children under age five would be ready and they are now nearly there.

While vaccines have been available for older individuals for quite some time, the infant and toddler vaccine has been much slower, leaving many families with young children in a precarious position as they try to keep their kids safe.

Do you anticipate that children ages 6 months to 5 years will be able to get their first dose by the end of this month?

Dr. FAUCI. Well, again, Senator, thank you for that question. But I do not want to get ahead of the advisory committee. You heard from my opening statement and that of Commissioner Califf that in fact, the VRBPAC, which is the advisory committee to the FDA, made a recommendation, a positive recommendation for an emergency use authorization.

The next step would be the CDC, in which Dr. Walensky's advisory committee will likely—in fact, likely, I am sure they will, look at the data and make a recommendation. And then at the end of the day, it will be the Director of the CDC's obligation and duty to make a recommendation. I hope it does.

But we never want to get ahead of the data. The data looked very, very good, Senator. I mean, as you heard from Commissioner Califf, the data looked really quite good. I anticipate that that is going to happen, but it would not be appropriate for me to get ahead of my CDC colleagues.

Senator HASSAN. Got it. And just briefly, Dr. Walensky, what does the timeline look like for that review?

Dr. WALENSKY. We are going to review tomorrow and working on Saturday as well, because we understand the urgency of this for American parents and recognize that even on a holiday weekend, we need to be doing this to get it to American parents.

Senator HASSAN. Right. Thank you. Assistant Secretary O'Connell, how will the Administration work to educate parents on the safety of this vaccine and help as many families as possible to get their youngest children vaccinated?

Ms. O'CONNELL. Absolutely. Assuming that the decisions come through, as we may expect the approval and recommendation, we have made available 10 million doses for states to order, and the vast majority of them have placed those orders that will allow us to ship out as soon as an EUA, should it come, comes with the expectation that parents can begin getting their children vaccinated next week. That is our intention.

Senator HASSAN. Thank you very much. Thank you, Chair Murray.

The CHAIR. Senator Collins.

Senator COLLINS. Thank you. Dr. Califf, we know that the baby formula crisis was exacerbated by the fact that people weren't working in the mailroom and that inspectors were not working a normal schedule in the baby formula plants. In response to a question from Dr. Cassidy, you referred to a return to work pilot program.

How many FDA employees are part of that pilot program as opposed to working full time right now in the office or in the field?

Dr. CALIFF. Well, of course, as you allude to, they are all working full time. I will have to get back to you on the exact number. But it is a majority are in the pilot program in one way or another. The goal is to adjust to the maximum productivity and job satisfaction.

Senator COLLINS. But they can't do their work if they are not present.

Dr. CALIFF. Well, if it is a job that they will do their work best. If they are present, they will be—they are required to be there.

Senator COLLINS. Well, I would really appreciate getting the data on that.

Dr. CALIFF. I look forward to bringing the data to you. I think it is going to be interesting. I will just say I was at Google before this. As opposed to Elon Musk, I think Google is doing pretty well with their hybrid program.

Senator COLLINS. Let me switch to another issue. I am very alarmed by the response that I heard to Senator Sanders' question, where he said you should be able to just dial 1–800 to get a prescription.

The Administration has pushed very hard on the Test and Treat program so that you test positive, you get paxlovid right off. And here is why I am concerned. The first is that paxlovid interacts in a negative way with a lot of commonly taken medications, including blood thinners, for example.

Second, just on Tuesday, Pfizer announced it was halting enrollment in a trial for paxlovid in standard risk patients, both vac-

cinated and unvaccinated, after its study revealed that the treatment was not effective in reducing symptoms in that group.

What we heard today and what the Administration seems to be pushing is this notion that paxlovid is going to be the answer if you have a positive COVID test. Do you really calling 1–800 is a good way to handle the prescription of a drug that has been found to not be effective for standard risk patients and has interactions with a lot of medications?

Dr. CALIFF. Thank you for asking that question. The place I agree with Senator Sanders is that we have a vastly inequitable distribution of lifesaving vaccines and antivirals. Now, particularly, I know you are from a predominantly rural state. Particularly rural people are suffering because they have lower vaccination rates and less access.

I don't agree that an individual just calling a 1–800 number with no clinician involved is a good idea. First of all, because the drug is not indicated except in people who are at higher risk. It is not that it is totally ineffective in lower risk. If you look at those data, I love to go over those with you later, but it is not worth the prescription. In that case, the benefits are minimal.

I think there does need to be an intermediary, either a pharmacist or a physician, who can look at the risks and the drug interactions and make a good judgment. But the concept is right that having to find a physician, get an appointment, can take over 5 days for many Americans. We have to have a system that deals with that issue.

Senator COLLINS. Dr. Walensky, David Leonhart recently wrote in The New York Times that while masks can work, the evidence suggests that broad mask mandates have not much to reduce COVID caseloads over the past 2 years. And in fact, he says that daily average cases per capita during last winter's surge were practically the same in counties and states that had mask mandates and those that did not.

We have seen that Hong Kong, despite almost universal mask wearing, recently endured one of the world's worst COVID outbreaks. There are proven ways to lower hospitalizations and deaths.

We know that vaccinations, therapeutics, but mask mandates have contributed to a breakdown of trust in public health officials given the scant evidence that they actually lower caseloads. What specific data has the CDC examined that demonstrate that broad based mask mandates lead to lowered caseloads, because I can't find any.

Dr. WALENSKY. Thank you, Senator Collins. I actually believe that that is a piece that has undergone substantial criticism for moving forward.

But I will say that there are numerous studies that have demonstrated—and we have to look at this over time, because there are secular trends as to when these mask mandates have occurred, there are population and aggregate anonymized data that have demonstrated decreased rates of disease when mask mandates have been put in place earlier in the pandemic.

We have to control for all of the things as to what has been open, what interventions have been available. But there have been other studies for certain to refute those data. Thank you.

The CHAIR. Senator Smith.

Senator SMITH. Thank you very much, Chair Murray, and thanks to all of our panelists for being here today. I am going to focus my questions on—questions of data and data sharing and how that risks—how that reflects our ability to respond to the pandemic. But I just want to, before I do that, I want to reinforce the comments that Chair Murray made at the beginning of this hearing, that we are making progress on the pandemic, and we are in a much better position than we have been.

But it is essential that we have got sustained resources so that we are ready as we look to whatever comes next with this pandemic. I just want to associate myself with Chair Murray in urging my colleagues to support the funding that we need so that our COVID response can continue.

I appreciate very much my colleagues, Senator Cassidy and Senator Collins and their work on accountability, but I just want to ask you all a simple yes or no question. Has the work of your agency been hampered in any way by people not being in the office? Could you just say just yes or no?

Dr. WALENSKY. No.

Dr. CALIFF. No.

Ms. O'CONNELL. No.

Senator SMITH. Dr. Fauci.

Dr. FAUCI. No.

Senator SMITH. Okay. Thank you very much. Dr. Walensky, I want to bring up something that you and I have talked about. This has to do with the resolving the issues around sharing public health data with tribes. So this is a challenge that I think we both are aware of and have been talking about.

For folks who aren't paying close attention to this, tribal epidemiology centers were created by Congress as an essential public health authority in Indian Country, and since the beginning of the pandemic, they faced real challenges accessing public health data through the CDC. I have introduced a bill to resolve this issue. I am grateful for the work of my colleagues as well on this, especially Senator Luj̀an.

Dr. Walensky, as you know, the GAO has issued a report outlining recommendations to resolve the issues. I would just appreciate knowing—and I know you appreciate the challenges of this.

Can you commit to working with us to make sure that those GAO recommendations for the CDC, the report back on that is August 31st, 2022, could you please commit us to following through on those recommendations?

Dr. WALENSKY. Thank you, Senator Smith. I have appreciated the conversations I have had with you as well. We are working with our tribal epidemiology consortium and meeting with—Center Consortium, a meeting with them later this month, as well as

through the summer meeting with the tribes, specifically about how best to work for data sharing.

We are aware of the GAO report and that we have two specific items to address, and we are on a track to provide timely response to those. But I do want to just comment that this is not just a data issue with tribes, but a larger data issue at hand. The CDC does not have the authority to request, receive, share data in a way that gives us a comprehensive overview, not only through CDC and a national forecast, but to tribes, to localities, from one county to another.

We do not have the authority to do so. We have gotten some of that through the public health emergency, through the CARES Act, where we were able to receive lab data through CMS authorities, where we have been able to receive hospital data. But it has been really challenging during this pandemic that we still have holes in the data that we are able to receive.

Now as we look to monkeypox and the outbreaks of monkeypox, we are again revisiting the challenges that are—that we are not able to see all of the data that would be necessary to receive and to share so that we can have a coherent response. Thank you.

Senator SMITH. Well, Dr. Walensky, you have anticipated my next question. I appreciate that. I want to get to that in a minute. Just to close out on the tribal data sharing, I would just ask that we stay in close touch on this as we approach January 20—excuse me, August 31st, so that we can resolve this, and those tribal epidemiology centers can have access to the data that they are legally required to have.

Looking more broadly, I am aware that the CDC does have challenges with data, and I just want to try to help to tease this out a little bit in the few seconds that I have left. For example, does the CDC have the authority to require hospitals to report their COVID data? And if they do, is that authority permanent or is it temporary?

Dr. WALENSKY. It is temporary through the public health emergency, and it is not CDC's. It is through CMS.

Senator SMITH. Have hospitals been reporting the data that—I mean, do we have all the data that we need at this moment?

Dr. WALENSKY. We do not. We receive the data that CMS has the authority to request, but we don't receive all the data that we would like to receive.

Senator SMITH. I want to just acknowledge that Senator Kaine has a bill which I co-sponsor, the Improving Data in Public Health, which would make the crucial improvements that I have come to understand we really need to make to strengthen data sharing between public health authorities and the CDC and the Federal Government more broadly.

Let's make sure that this data sharing isn't temporary but that it is permanent so that we can continue to be responsive at the Federal level and have the data so that we all can make good decisions about how best to respond to the public health challenges that we will continue to have.

Dr. WALENSKY. We are very grateful for your support and Senator Kaine on that bill. Thank you very much.

Senator SMITH. I look forward to working with my colleagues and with Senator Kaine on that as well. Thank you very much.

The CHAIR. Senator Braun.

Senator BRAUN. Thank you, Madam Chair. Dr. Walensky, it was about a month ago in an Appropriations hearing I asked Dr. Fauci about lockdowns, and it was based upon the Johns Hopkins study that said that tactic basically was neutral on mortality.

I don't think it got into maybe what mortality might have been caused due to the fact that we were locked down in other areas. But would you agree with Dr. Fauci on that, that we probably won't ever need to use lockdowns again on COVID as we currently know it?

Dr. WALENSKY. I certainly hope not, Senator Braun. I know that that Hopkins study had some flaws and that there have been other studies that have refuted that. We would be happy to get you more details on that. But certainly we are doing everything in our power to prevent that from happening. But COVID has sent us numerous curveballs, so I will never say never.

Senator BRAUN. I might also add that in everything I observed and keeping in touch with the business community who took it pretty seriously, they did not think that transmission was occurring at work. It was mostly elsewhere. And that locking those businesses down, of course, I think we are dealing with those consequences currently.

Another question, when it comes to vaccine mandates, Supreme Court finally weighed in and said that did not make sense when we were going to try to force businesses down to 100 employees to either have their employees get a vaccine or lose their job. That seemed like the ultimate heavy hand of Government.

Would you ever recommend doing that again? Because the Administration seemed to err on the side of vaccine mandates and lockdowns, which I talked about earlier.

Dr. WALENSKY. Mandates are generally, vaccine mandates are generally a local decision. And what I will say is, we at CDC are for promoting more people to get vaccinated because those who are vaccinated and boosted have decreased risk of severe disease and death. Generally, we would support getting more people vaccinated.

Senator BRAUN. Well, I would like to cite the fact that the Administration has forced it through all Federal employees, and I believe that initiation of what would have been the biggest mandate for getting vaccinated came from the Biden administration, so through an Executive Order. I agree with you that local prerogative should come into play. But this was not that. Do you care to comment further on that?

Dr. WALENSKY. CDC stand is that the more people who are vaccinated and boosted, the decreased risk of severe outcomes and death.

Senator BRAUN. So, we have now gone a couple of years. We have learned a lot. I think the data has shown that this has ravaged, in a disproportionate way, in the elderly with co-morbidities.

I would like your kind of assessment, going forward, with the general dynamics of what we know about COVID, does it make sense that we protect better where the data has shown that we have had the most issues with? And also parallel this to the flu. I know it is more transmissible.

But the flu generally has a broader fatality rate. In here, as Senator Paul talked about it a little earlier, we know that it has really hit one category very hard. And do you think we are protecting them well enough, and you think it makes sense to take the broad approaches for so much of the country that was either asymptomatic or had mild symptoms?

Dr. WALENSKY. I think we need to do both. Certainly, our elder community has been among those that have been the highest risk, highest risk of severe disease and death. But I will also say that COVID is one of the top leading killers of children right now. Deaths among children during the COVID pandemic have been higher than we generally see—from COVID have been higher than we have seen for flu.

I actually think we need to protect young children as well as protect everyone with the vaccine and especially protect elders. I will say that we have recently endorsed and recommended boosters for all those over the age of 50, a second booster for all those over the age of 50, and we will have forthcoming data later this week that will demonstrate, compared to a third booster, that those over the age of 50 who have gotten a fourth have a seven fold decreased risk of death.

We are actually doing both of those simultaneously, and that is what I think we need to be doing.

Senator BRAUN. Thank you. And then finally for Dr. Fauci, of course, we read this week after 675 years, we finally found the origins of the Black Plague. Care to give us an update on where we are at on tracking down the origins of COVID–19?

Dr. FAUCI. Thank you for that question, Senator. There have been a number of papers that have come out from highly qualified virologists and viral file geneticists that indicate that this is very, very likely a jumping species from an animal host, perhaps through an intermediate host into a human species, which then spread throughout the human population, certainly, and almost certainly originating in China, in Wuhan.

We still open up and keep always an open mind as to whether or not this had to do with a virus that was isolated out in the environment and that came into a lab and then had what most people refer to as a lab leak.

I believe that is less likely that that is the case. But I also believe we need to keep an open mind and have all possibilities be investigated. But the evidence from the virology community point strongly toward a natural occurrence.

Senator BRAUN. Very quickly, do you think the Chinese will cooperate with you to try to get to the thorough bottom of it?

Dr. FAUCI. Senator, I certainly hope so, because we are not going to get an answer that is a definitive answer—I mean, even if they do cooperate, we may not do that. But certainly, for example, if we

want to continue surveillance among bat populations and other wild animals that might serve as an intermediary host, as well as understanding what was going on in some of the laboratories, I believe it is essential to have cooperation and collaboration with the Chinese.

The CHAIR. Thank you.

Senator BRAUN. Thank you.

The CHAIR. Senator Hickenlooper.

Senator HICKENLOOPER. Thank you, Madam Chair. I want to just first thank all of you again. You have been here repeatedly. I often wonder watching these, the back and forth in these hearings, what message it sends to young people deciding whether they want to get into public service.

It doesn't always look pleasant, but I appreciate your maintenance of good spirits as you go through obviously difficult, but I think important discussions. Dr. Califf, I am going to start—I am going to try and look a little more forward just because I am worried about the future equally as much as trying to review the mistakes we made in the past.

You know, the unprecedented COVID–19 clinical trial landscape has allowed for timely availability of vaccines and therapies that have been essential to fighting this pandemic. In this increasingly global world, we can, and I think really have to work closely with our allied partners to advance scientific and research efforts.

My question to you is, should we be thinking about multi regional clinical trials as a way to expand volume and scope of clinical trial data? And if so, how do we get there? And that is, I know we have talked about it before, but I just keep coming back to this as well.

Dr. CALIFF. Well, thanks for giving me a chance to talk about my favorite thing. That is what I have done for a living my entire career is multi-regional clinical trials in cardiovascular disease, and that is what we need to do.

We are all very focused on diversity in clinical trials within the United States, but we are only 4 percent of the world's population. So if we really believe that we need to be doing trials that are relevant to the populations all over the world. I will point out, again, as Dr. Walensky pointed out, we have a fragmented system in the U.S. So, yes, we depend on Israel for data.

The fourth dose decision by the FDA was made based on Israeli data. For, in many cases we depend on the UK for a clinical trial results that are critical to us. With all the technology and prowess we have in this country, we have got to do better, and it is going to be a focus.

The CDC needs to have the authority to get the data it needs so that we can be as good as the Israelis in producing just in time data that is needed.

Senator HICKENLOOPER. Yes. When I was a kid, Marshall McLuhan wrote a book and one of the key elements was information is power. I think that is more true today than ever. Dr. Fauci, many of us here, I have been beating the drum loudly on pandemic preparedness and pandemic prevention. I think it is imperative

that we make investments today that will help us better understand and prepare for viruses tomorrow.

You know this has been—we have watched some of the discussion on this already. The President has put out a pandemic preparedness plan and submitted a mandatory 5 year funding request to Congress to truly stay ahead of the curve.

What progress do you think we have lost due to the inability of Congress to significantly invest in the pandemic preparedness and pandemic prevention?

Dr. FAUCI. Yes. Well, thank you for that question, Senator. Pandemic preparedness involves multiple buckets. Basic clinical and translational science to develop the products such as the vaccines and the antivirals that have helped us so dramatically during the current outbreak, as well as a number of public health issues involving, for example, the CDC, the FDA, BARDA, ASPR, and others.

When you look at what has not been available from the standpoint of resources, we have a pandemic preparedness plan that is based on what we call the prototype pathogen approach, which was to look at various families of viruses particularly, and to develop commonalities among them, so that we will be able, in the next challenged with an emerging microbe, mostly likely a virus, that we will have enough back lot experience that will be able to do it in the timeframe that we did with coronavirus, which, as you know, was 65 days from the recognition of the virus to a phase one trial.

Senator HICKENLOOPER. Right, so, let me interrupt you just because I am going to run out of time here. The real question, though, is how much do we lose by delaying the appropriate investments to complete that preparedness work?

Dr. FAUCI. Yes. You lose a significant amount. I mean, every time you pull back on resources, the pace and the cadence of the work slows down. Sometimes you can't even start a new project. But the projects that are ongoing, if you don't get the resources to fully implement them, you will delay the development of interventions.

Senator HICKENLOOPER. Or have to take money from one other pool that gets sidelined, and you interrupt something else. Right. I follow that. Okay. I am out of time. I yield back to the Chair. But I again want to thank each of you for your public service. I realize science is not perfect, it is not binary, and you have difficult, complicated jobs. I am grateful.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. Thank you, Madam Chair. Just yesterday we learned that in the month of May, our Border Patrol encountered an unprecedented 239,000 migrants at the Southern border, the highest monthly total in DHS history. And now, thanks to our inhumane open border policies, every state is now a border state.

In my home State of Kansas, a person dies most every day from fentanyl poisoning. Nationwide, over 200 people are dying daily from fentanyl. The number is on the rise, and this is now an epi-

demic. Just last week in Kansas City, authorities seized 15,000 counterfeit pills laced with fentanyl.

Chair Murray, in your State of Washington, five people are dying per day from drug overdose. Ranking Member Burr in your state, nine North Carolinians are dying every day from drug overdose. I don't have to remind people on this Committee or panel that fentanyl precursors are made in China.

Then the Chinese work with the cartels to process that into a lethal fentanyl, often lacing other opioids, marijuana, meth, Adderall, xanax, among others. And all across the Nation, a counterfeit oxycodone pills like the ones behind me are now actually laced with fentanyl.

Unfortunately, just one pill can kill. And in the case of one young student in Shawnee, Kansas, it only took half of a fake Percocet pill to take his life. Dr. Walensky, my colleague, Senator Hagerty from the great State of Tennessee, has introduced a bill that would expand Title 42 expedited removal authority to combat the drug overdose epidemic resulting from drug smuggling across our Southern border.

Dr. Walensky, I would like to ask you, yes or no, would you commit to expanding the Title 42 authority to turn back migrants to combat this prolific drug smuggling across the U.S.-Mexico border in an effort to stop the flow and the epidemic of fentanyl that is killing Americans every day?

Dr. WALENSKY. Thank you, Senator. I would like to just back up and say that CDC is a public health agency, not an immigration agency. And the question of Title 42 is a public health policy. The question of Title 42 that was posed to me is, is there a public health emergency that should bar people from coming into the United States?

We now have, as of April 1st, when I commented on this, we now have the tools, the tests, the vaccines, and the therapeutics that are available. Our hospitals are not full. Everyone and most people in this room are not wearing a mask. There is no longer a public health emergency——

Senator MARSHALL. So, Dr. Walensky, I appreciate that. But I hope you realize that fentanyl poisoning is killing more individuals ages 18 to 45 than COVID–19. So for the same reasons that you instituted Title 42 for COVID, why wouldn't you consider instituting it for fentanyl poisoning, as well as would you commit yes or no to tracking this similarly to the way you did for COVID?

Dr. WALENSKY. To the larger immigration question, I turn things back to you and Congress to address the larger immigration question. As a public health emergency for COVID, which is what Title 42 was put up to do, there was no longer need——

Senator MARSHALL. Do you deny that there an epidemic of fentanyl poisoning across this country?

Dr. WALENSKY. I do not.

Senator MARSHALL. Thank you. Secretary O'Connell, I have a question I am going to submit for the record for the sake of time. It has to do with, we are going to be giving some 300 million more doses of Moderna, more for Pfizer.

From by understanding of the marketplace, there is still a substantial supply chain challenges for our medical products. And to Ranking Member Burr's point, I hope that the Administration can give us a plan to provide the ancillary medical products to support the vaccine Administration, and we would appreciate some type of a plan in writing. Thank you. My last question for Dr. Fauci.

Dr. Fauci, the NIH is still funding research in China, at least some $8 million since 2020. In the intelligence community's 2022 annual threat assessment, the Chinese Communist Party is presented as one of the top threats to the United States, along with Russia, Iran, Syria, and North Korea.

To my knowledge, only China is receiving U.S. research dollars. The CCP controls their scientists and controls the release of research results they work on. However, NIH grants policies requires a grantees to maintain supporting research records, which they cannot do when those records are under control of the Chinese Communist Party. When were you as Director of NIAID stop funding research in China?

Dr. FAUCI. Now, thank you for that question, Senator Marshall. We have at the NIH and in other agencies in the Federal Government, have very productive, peer reviewed, highly regarded research projects with our Chinese colleagues that have led to some major advances in biomedical research.

I don't think I would be able to tell you that we are going to stop funding Chinese. We obviously need to be careful and make sure that when we do fund them, we have the proper peer review, and we go through all the established guidelines.

I might point out that grants that go to foreign countries, including China, have State Department clearance. So any time that we do fund anything in China or any other country, it has to go through a clearance with the State Department.

Senator MARSHALL. But you would not deny that the research done through EcoHealth, that the records, the studies from there, that we still do not have access to them. Is that correct?

Dr. FAUCI. We have—no, Senator Marshall, we have access to an extraordinary amount of information that has gone there. There is a question that people raise with things going on there that we didn't have access to.

But if you look at the grant, the $120,000 to $130,000 a year grant that was given from EcoHealth as a sub award in China to ask a very relevant, high priority question. We have received from them published literature with data that shows that they have done what they were given the grant for.

Now, obviously, none of us know everything that is going on in China. But if the question at hand is that we have a small grant, peer reviewed, high priority grant that was given from Eco to China in a sub award, we have a lot of good information that is in the public——

Senator MARSHALL. Do you have all the information that you think that we should—?

The CHAIR. Senator Marshall, at this point, I am going to move on. We have a number Senators. We have three votes that have

been called. I am going to move on to the next person. I am going to turn this the Chair over to Senator Hickenlooper while I go vote. This next Senator, I will call on as I do that, is Senator Baldwin. Senator Hickenlooper, thank you for coming up to Chair.

Senator BALDWIN. Thank you, Madam Chair. I have been encouraged by the work of this Committee and those of you on the panel who have helped make more COVID–19 treatments available. Unfortunately, local health Departments in Wisconsin have experienced some obstacles when it comes to getting paxlovid to those in need.

Dane County public health officials recently contacted my office to raise their concerns about the lack of a clear policy guidance and reimbursement for this critical treatment. So, Ms. O'Connell, how is ASPR working with states to ensure that local public health Departments have the information that they need to make paxlovid available through the Administration's Test and Treat initiative?

How can folks who are uninsured receive treatment, and what additional resources might the Administration need to make treatment available to everyone who needs it?

Ms. O'CONNELL. Thank you so much, Senator Baldwin. I will take that in two parts. First of all, as far as communicating with state public health Departments to make sure they know that this treatment is available and how to access it, we do weekly stakeholder calls and regular engagements with state health officials. We also know it is on us to be—we need to take responsibility for communicating very clearly the importance of this therapy and its availability.

We have taken that on in numerous ways with various outreach efforts. But, and we continue to work with states to make sure that they are positioning these therapies in places where folks are the most high risk. So that continues to be an ongoing pursuit of ours, and we will continue to work at it. Thank you for the feedback on Wisconsin.

We will reach out and make sure that we have closed that loop and that they have the information they need. And then part two of your question is about access for the uninsured. So, one of the impacts of not getting additional supplemental funding is we have had to shut down the uninsured fund.

The uninsured fund was one of the easiest ways for those without insurance to get coverage during the COVID response, to be able in this once in a lifetime pandemic get the care that they need. We continue to make paxlovid even without the uninsured fund. The paxlovid is available for free.

Pharmacies are not allowed to charge a dispensing fee, so those that are uninsured should be able to access it. We understand an important component of receiving paxlovid is also having a health care assessment, and we know that that comes with a fee.

We encourage those that are uninsured to go to the federally qualified health centers, which provide these services on a sliding scale and acknowledge whether you are uninsured or not, or to seek care at their public health Departments or now these new federally run test or treat sites.

But this is a challenge, and it is one that we are continuing to overcome in light of the shutdown of the uninsured fund.

Senator BALDWIN. Thank you. I have heard also from state health officials about declines in vaccination coverage for routine immunization, such as the measles, mumps, and rubella, that vaccine.

Dr. Walensky, how is the CDC working to ensure that any forthcoming recommendation on the COVID–19 vaccine for kids gives parents the information that they need to feel confident about getting not just this vaccine, but as well as all other routine immunizations? And is there an opportunity to up the rate of vaccination for these other conditions at the same time as you are vaccinating kids?

Dr. WALENSKY. Yes. Thank you so much, Senator Baldwin. So we recently reported data that demonstrated a decrease of about 1 percent of all incoming kindergartners are completely vaccinated for all of the recommended vaccines.

That is 35,000 children across this country who are no longer up to date on all of their other vaccines, even before COVID. We have a lot of make-up work to do there in addition to what we need to do with COVID. As we roll out our pediatric vaccines for children between the ages of 6 months to 5 years, and in fact, as we continue to enforce the importance of vaccination for our 5 to 18 year olds, we are seeing differences in vaccine confidence and differences in rates and vaccination.

We are doing a lot of work in terms of vaccine confidence, putting these vaccines in pediatricians' offices and federally qualified health care centers, in pharmacies, places where parents trust, where they normally get this information. We are also canvasing and understanding the vaccine confidence around these areas so that we can focus our attention in areas where confidence might be lacking.

We also, importantly, are starting to see really critical data that show that much of this confidence is lacking in areas—in rural areas. That we have about two times the vaccination rate in urban areas compared to rural areas of our children. So areas that we really need to focus, and we are aware of that and are doing those activities as well.

Senator BALDWIN. Thank you. I yield back, Mr. Chair.

Senator HICKENLOOPER. Thank you.

Senator Casey.

Senator CASEY. Mr. Chairman, thank you very much. I want to thank members of the panel for their public service and for being here today. I just have, in the interest of time, I think everybody—I just have got one question for Dr. Fauci. Doctor, I want to wish you a speedy recovery, as well as congratulate you on the naming of the science complex at Holy Cross College in your honor.

I wanted to ask you a question, though, about our parents. So many parents across the country right now are unsure about whether to get their kids vaccinated. Uptake of the vaccine has been relatively low for kids who are already eligible. I am told that

under something, like under 30 percent of children ages 5 to 11 are fully vaccinated.

When the vaccine becomes available for children under five, we will need to meet parents where they are and with the information that they need to make informed decisions about that vaccination.

Dr. Fauci, can you expand upon how the Administration is working with trusted messengers in our society, whether they are physicians or community leaders or others, to get accurate information about the vaccinations to parents?

Dr. FAUCI. Yes. Thank you for that very important question, Senator Casey. Certainly, now that we have the data, which looks very favorable, we really want to get these children vaccinated because we know vaccinations prevent infection, but to a greater extent prevent severe disease.

As you have heard from a number of us, including and particularly Dr. Walensky, that there are more deaths and serious consequences of COVID among children than there are in influenza.

The Department, HHS, has a very comprehensive rollout plan, which they have been literally preparing now for several weeks, 2 months in anticipation of if we do, and we did, get favorable results on the clinical trials from Moderna and from Pfizer, that we would be able to get children and get parents to understand where these vaccines are available in pediatrician offices and pharmacies and clinics.

This is something that the Department has taken very seriously and hopefully we will do a very high uptake of vaccines, because many parents, as we all know, have been waiting some time now to get their children vaccinated. And hopefully the program that HHS is rolling out will facilitate that. Thank you.

Senator CASEY. Doctor, thanks very much. Thank you, Mr. Chairman.

Senator HICKENLOOPER. Great.

Senator Kaine.

Senator KAINE. Thank you, Senator Hickenlooper. And thanks to our witnesses, I want to echo comments that I know Chair Murray made earlier about the importance of more law—more COVID funding in a variety of ways. We are—thankfully, we are seeing hospitalizations come down dramatically in Virginia. It was about 4,000 a day in January, about 500 a day now. That is very, very positive.

I am looking at hospitalization and death data a lot more intensely than the case data, because I think cases continue to be high. But the—because transmissibility is high, but the severity is dropping, which is what we would want. But I do think we still need more funding to deal with COVID issues, especially for low income people.

I would also say that U.S. vaccine diplomacy around the world has been a real positive investment that has both helped our own public health, helped the health of others around the world, but built up goodwill. I am strongly for it. I do want to just quibble with one thing.

Senator Smith asked you all the questions about whether you are equally as effective, if you are working virtually or in the office. And you said, yes, as effective. I am going to be honest. There is one area, and it is in the FDA space, Dr. Califf, where it is not as effective, and that is inspections.

The AP had a story that was out earlier this week that said during the period largely from March 2020 till June 2021, you were not at the FDA then, but during that period the FDA missed 15,000 inspections that would normally have done.

The FDA is racing to catch up, has cleared a backlog of about 5,000 of those. But there is no substitute for an inspection. There is just no substitute for it. And what troubled me about that is, the folks working at plants that need inspection like an infant formula plant, they are essentially essential workers.

We can't stop producing formula, so they have to be there. If they have to be there to do something that the public needs, then the inspectors should be there, too. I recognize that poses health challenges. But, and again, you were not at the FDA during this period when the inspections were stopped.

But I frankly worry a little bit about, are there other surprises around the corner for us in these spaces where we weren't doing inspections? I am not even going to ask you about it because I know you take it seriously and you are trying to catch up on the backlog and——

Dr. CALIFF. Can I just comment that I agree? I was asked about the office. So if you asked about—definitely, we had inspections that were put on hold and there has been a price to pay for that.

Senator KAINE. Yes. I would say an inspector is every bit as essential a worker as the worker that we require to go to the plant to produce medicine, to produce infant formula, etcetera. I want to ask a question that I always ask of Dr. Fauci. Dr. Fauci, I hope you are feeling well, and I am glad you are able to join us virtually.

I started to share my own experiences with long COVID nerve tingling symptoms about a year ago because, hey, I was having them, and they are exactly the same as they were when I got COVID in March 2020. But b, I was running into a lot of people who were experiencing more serious symptoms and weren't being believed. I felt like sharing from this podium that, yes, no, I believe you because I am dealing with nerve tingling that I would never felt in 62 years, might open up a discussion and make people feel like they were being heard.

As I expected when I started to talk about this, my office has become a real nerve center for people who want to share their experiences with long COVID and ask for help. So what I want to ask you to know, given that we have put in some significant funding for long COVID research, what is the current status of the NIH Recover Project?

Dr. FAUCI. Yes. Thank you for that very important question, Senator Kaine. Let me assure you that from the patients that we have seen and the input we have seen from so many people, this is a real syndrome. It is a real problem, and it is something we really

need to get to the bottom of. There are two tracks that are going on.

One is a broad cohort track, which many people referred to as the recovery program, where launch cohorts of individuals are now being followed in long range to determine the incidence, the prevalence, and hopefully learn about the pathogenesis of this real syndrome. They are now accumulating very large numbers of individuals.

One of the problems, Senator, is that there is no yet identifiable pathogenic process. So people ask, why aren't you treating it, what are you doing for it, is very, very difficult to do that because this is a heterogeneous syndrome, as you probably know from the people that now are essentially addressing your own office because of your own personal involvement.

But there are other things that are going on simultaneously. For example, there's a pediatric research immune network called PRISM, which is looking at this in children, particularly children that might have the multisystem inflammatory syndrome of children. There is the, what we call immuno phenotyping to determine is there anything that relates to a hyperactivity or an aberrant triggering of immune response that is triggering some of the things that you might be feeling, including the tingling in your nerves.

There is the broader cohort project and a number of individual projects. I do hope, and I say that sincerely, because there are so many people now, when you talk about the tens and tens of millions of people who have COVID in this country, that even a small percentage, and I am not so sure it is that small, who wind up with varying degrees of long-covid—we have to address this problem, find out the underlying mechanism, and do something about it. Thank you.

Senator KAINE. Dr. Fauci, thank you so much. I yield back, Senator Hickenlooper.

Senator HICKENLOOPER. Thank you.

Senator Rosen.

Senator ROSEN. Well, thank you, Chair Hickenlooper. Dr. Fauci, I know we all hope you are feeling all right. Thank you for being here. And thank you to all of you for your continued presence, your work, and your commitment to doing that good work going forward. I want to talk about the vaccines and booster shots just a little bit, because we know the COVID virus, the COVID–19 virus, is going to continue to mutate.

It is critical that we use our best defense, we all know this, it is vaccines, to keep our most vulnerable populations safe. We are going to protect lives and livelihoods. I just want to focus for 1 second on one of our highly vulnerable populations, our seniors. Many of them may have unique challenges because of their mobility or a variety of other issues. So, Dr. Walensky, we know more than 90 percent of seniors are fully vaccinated.

Nearly 70 percent have received their first booster dose. But only a little over 30 percent of our seniors have received their recommended second booster. So what are you doing to I would say, just not just improve outreach, but what about those access bar-

riers that may—we may have with seniors in assisted living, or nursing homes, memory care, and the like?

Dr. WALENSKY. Yes. Thank you, Senator Rosen. So several weeks ago, we increased our recommendation—strengthen our recommendation for a second booster shot. And that is in the context of this increased number of infections for our elderly. What I will tell you is we have data forthcoming later this week that will demonstrate that that fourth dose compared to the third dose has decreased the risk of death by seven fold.

We now have actually data from the United States that has demonstrated the value of this booster dose, especially among the elderly and the most frail. We are—we now have vaccine in tens of thousands of sites. We have vaccines in pharmacies. We have vaccines in providers, physicians' offices. We have vaccine throughout the country and in our long term care facilities.

We are continually looking at vaccine confidence and canvasing our states to understand where we have challenges in vaccine confidence. One of the areas, as I indicated earlier for pediatrics. But also true for adults, is in our rural, urban divide that we actually have challenges in reaching our rural communities, both for vaccine confidence, but actually to get folks boosted—for their first shot as well as their second.

We are continuing outreach there through media, through social media. I have done media with our collaborations through the U.S. DEA and through Rural Public Health Association. So we are continuing that outreach. Once we can understand where the data are and where the challenges are, we focus on those areas so that we can do more in those areas.

Senator ROSEN. Well, maybe that is where our mobile health, rural mobile health clinics can make a difference. But would you follow-up on that really for our general population. You said the updated guidance is going to come out in a few weeks for access to the second booster dose for general population, because we know it keeps people out of the hospital and from suffering more severe disease.

Dr. WALENSKY. Yes. So we continue at CDC to follow the data with regard to how our vaccines are performing. And so far, the data on decreases of severe disease, hospitalizations, and death have been limited—and the waning has been limited to the elderly population. But we are continuing to follow the data for the younger population to see if and when there is waning in that population as well, and if and when we should bring another booster dose to that population as well.

Senator ROSEN. Thank you. I want to keep a little bit on seniors, because we know that the pandemic has had real mental health challenges for, of course, our children—for all of us but I am going to focus on seniors today because ARP, as really noted, that is critical to find a balance between patient health and caregiving.

How the absence of caregivers or if the caregivers themselves are vaccinated. It really makes a difference. I just would like to know what lessons the CDC has learned from the pandemic about caring

for seniors and addressing the social isolation that we felt prior to the vaccine. What can we do there, do you think?

Dr. WALENSKY. We have learned really—hard learned lessons, I would say, through the last two and a half years with regard to mental health, not just in our seniors, but across the aged demographic, in our in our students and in our seniors and across the age demographic.

We at CDC are doing a lot of work across the country with the VA, with NGO's, with community based organizations, within our tribes to strengthen mental health resources, to decrease suicide, to allow children to get back to school, to allow parents and caregivers get the mental health resources that they need so that they can combat the challenges of mental health right now.

Senator ROSEN. Thank you. I know my time is up. I appreciate that going forward. For the K-through–12 population, Senator Murkowski and I introduced bipartisan legislation to bring mental health down. That was funding for health grants that normally go to universities and colleges, but to bring it down K through 12, because we have seen increased suicide, increased mental health challenges.

Nevada, at one point, our Clark County School District was the highest of youth suicide, I believe in the year 2020, a list no one wants to top. I look forward to working with all of you and trying to do what we can to promote good mental health services and suicide prevention. Thank you.

Senator HICKENLOOPER. Thank you, Senator Rosen. I am going to take just a moment of privilege. I want to ask one last question to Dr. Walensky, just because I don't think the people of America really understand how interconnected we are. I want to just take a moment to—I mean, we have seen from the current COVID pandemic that viral pathogens don't pay any attention to national borders.

The reality is, I think it creates real danger for the probability that new COVID variants or other pathogens like monkeypox can emerge and spread quickly undetected in our interconnected world. The number I have is 62 percent of the global population is fully vaccinated against COVID, and clearly there are significant disparities between countries.

Many countries just do not have the resources to get to a significant part of their population. The more vaccines and therapeutics we can distribute around the world, the less chance we give variants to spread. I think that is the—we don't really have a number on that yet in terms of what is the—how are we increasing the probability of some new variant? How serious is this danger by us allowing these large populations in isolation to almost incubate new pathogens or more importantly, new variants?

Dr. Walensky, how has the CDC tracking of viral threats globally changed with the launch of the Center for Forecasting and Outbreak Analytics? And what more do we need to do now to address this global reality that we face in terms of public health threats? And again, how do we—I will take responsibility for how we spread

that information to the public, but it is something most people are not aware of.

Dr. WALENSKY. Thank you. Senator Hickenlooper. So we launched the Center for Forecasting in Outbreak Analytics. This is a Center that will be able, is currently able to scale up and look at forecasting to inform local jurisdictions as well as global jurisdictions to understand where the pathogens are in their risk of coming to us, as well as to innovate and to think about new ways that we might be able to forecast and understand pathogens headed on our direction.

That Center has been really helpful in understanding the importance of new variants, the Omicron variant. They have stood up and in forecasting and understanding where we need to put our resources at the local level. I do want to take one moment to say, I think you are exactly right. We know through this pandemic that no one is safe until everyone is safe. The disparities that we have in vaccination coverage around this world are likely to potentially lead to new variants.

If we don't control these new variants, they will likely reach our shores again. I am concerned that with the lack of supplemental funding that we at CDC will not be able to continue our global vaccine efforts that we have in terms of our technical assistance on the ground, our surveillance, our genomic sequencing, and our ability to do vaccine surveillance and vaccine safety surveillance within countries that we support. So thank you very much for noting that.

Senator HICKENLOOPER. Thank you.

Senator Burr.

Senator BURR. Thanks, Senator Hickenlooper. I am going to wrap up. I guess the Chair is not coming back. Couple of quick questions. Dr. Walensky, public health emergency. It expires July 15th. Do you intend to extend that?

Dr. WALENSKY. I am not the one who would extend it, actually. Thank you, Senator Burr. That is for the Secretary.

Senator BURR. But you will make the recommendation, won't you?

Dr. WALENSKY. I think it will be an all of HHS recommendation.

Senator BURR. Okay, well, let me just say, we have removed the mask requirement. We have eliminated the testing requirements to reenter the country. Title 42 is a CDC decision, and you said in your response to a letter to me that you were lifting it because—and I will refer to how you, I think, address Senator Marshall. You said, we have—you said we have the tools, test and vaccinations, therefore, there is no longer a public health emergency.

Dr. WALENSKY. Yes. I misspoke. We have the tools, tests, and vaccinations, therefore, there is no longer a public health reason to bar people from entering this country. Thank you. I appreciate the opportunity to correct that.

Senator BURR. But there is a public health emergency still?

Dr. WALENSKY. I think the question of a public health emergency is a different question for then, is there a public health reason to

bar people from entering into the country. I would like to make that distinction.

Senator BURR. Well, it is already in the record, I think what you wrote to me, which I think basically said we don't have a public health concern. Let me ask you, what are you looking forward to end the public health emergency?

Dr. WALENSKY. Maybe if I could defer that question to the ASPR, that might—I think as part of HHS, that would be helpful. Thank you.

Ms. O'CONNELL. Sure. Thank you, Dr. Walensky. And thank you, Senator Burr. So the Secretary does have this authority, and he did, the Secretary declared it in January 2020, previous Secretary, and it has been extended multiple times.

One of the commitments we have made in this Administration is that we are going to give states and local Governments 60 days' notice before we take it down in deciding whether to take it down, we are in daily communication with our clinicians, our scientists, the folks on the ground.

With the public health emergency unlocks, is health care system flexibilities, that is something that CMS relies on significantly. It extends Medicaid coverage for folks during times of an emergency. It extends to health coverage to those on Medicare. And it allows hospitals and nursing homes and other health care facilities some flexibilities in responding to the situation at hand.

We continue to be in touch to understand whether these are still necessary. And as Dr. Walensky said, the Department will come together and make that decision or recommendation to the Secretary for him to decide. But we will give 60 days' notice before it comes down.

Senator BURR. You have answered the question that I asked, which was will it be extended? Yes, it will be extended because 60 days from now is past July 15th, right? So no notification has been made to the state, so it will be extended past there. I will write the Secretary and ask him what the criteria is to end the state of emergency—the public health emergency, excuse me.

I would only point out that the guidance that we currently have going out does not suggest that there is a public health emergency. We are beginning to dismantle everything. I am not sure it is for any reason other than the fact that everybody around the world is doing it, because we are 60 or 90 or 120 days behind them.

Now, all of you just told Senator Smith that remote work hasn't hampered your agency's response efforts. Okay. FDA failed to identify a crisis with baby formula. CDC, I think, failed to lead as it relates to monkeypox. Secretary Becerra, when I wrote him and asked him about HHS staffing and were they actually at work when—were they actually working when not at the office, wouldn't provide me anything.

Now, none of you seem to know how many people in your complex—and Tony, I will leave NIH out of this because of the unique nature of the work there. How many of you can tell me how many people aren't at work? Pilot programs. Executive declarations. That

makes me wonder how you measure whether people are actually working when at home. And then I come to today.

I always like to bring things back to the present because I have a tremendous amount of respect for all four of you. Some I have dealt with longer than others. I supported where there was public acknowledgment of it. Everybody—Tony outdates me. He was here before I got here 28 years ago. Because I believed you had the capacity, the intelligence, the education, and the independence to serve in the role you are in. And for two of you, I asked when you were confirmed.

Would you provide me with all the questions I ask as the Minority Ranking Member? The answer was yes. Now we come to today. This has been the most well-orchestrated event that I have seen in the 28 years that I have been here. And for most of you, you have been willing participants in it. This was designed to pressure Republicans to open a checkbook, sign the check, and let the Administration fill in the balance. With no detail on how, when, for what that was being asked for.

I have never in 28 years seen an attempt to get an outcome without answering questions. I leave today extremely disappointed that maybe my judgment's been flawed. But I will say this to each and every one of you. Nobody has worked harder on this issue, I think, on the Hill than I have. Nobody has gone to bat for emergency money with no strings attached than I have.

But there is a point in time where my patience runs out, where the requirement I have for my constituents in North Carolina, my colleagues in the minority, which are 50, exactly which are in the majority, requires a degree of detail. That you and this Administration are not willing to share.

I personally believe that if the Federal Government doesn't lead by forcing employees back to work—and Rob, Google is a hell of a lot different than the FDA. Google can pull it off. But the Federal Government has to set the example for the rest of the country that it is time to leave your house.

I hate to see what the healthcare cost is going to be to our Country for mental health now on the adult side. Husbands and wives aren't used to spending all day together. Just like kids need the interaction of school. Folks let's get back to running your agencies. Let's bring the employees back into the office.

Let's answer the questions that every Member of Congress has for you and not just the ones the Administration wants to do. You serve in a uniquely special capacity. And when you address public health, it is not for some, it is for all. I hope you will look at this dais in these Members and realize there is no difference between one that sits on this side or that side.

They are on this Committee because they are passionate about the issues that we take up. I thank the Chair for his indulgence. I thank the witnesses for their expertise and their willingness to be here today. I yield back.

Senator HICKENLOOPER. Thank you, Senator Burr. I echo his appreciation for all of your hard work. I realize that science and espe-

cially medical sciences, is some of the most daunting—present some of the most daunting challenges that we face.

I remember when I was a small business, the times that caused me greatest anxiety and serious mental health challenges was when I didn't have enough information to make important decisions that were going to affect the lives of my employees or sometimes even my customers.

That that challenge of having to deal with the facts we have and not the facts that we would like, having to make decisions that affect people's, well, their lives, is some of the hardest decisions you can make when you don't have all—one size doesn't give you all the answers or enough information to know that you have got the answer. And yet you have all stood up and continued your work and dealt with this evolving situation.

I am very grateful. I would like to thank all my colleagues on the Senate side of this, but also all of our witnesses, Dr. Walensky, Dr. Fauci, Dr. Califf, Assistant Secretary O'Connell. This is an important conversation. I hope after this discussion it is clear, how critical it is that we pass emergency funding and make sure that we can protect our communities from what this pandemic throws next, which, again, we can't be certain of.

For any Senators who wish to ask additional questions, questions for the record will be due in ten business days, July 1st at 5.00 p.m.

This Committee stands adjourned.

ADDITIONAL MATERIAL

FACT SHEET: Consequences of Lack of Funding for Efforts to Combat COVID–19 if Congress Does Not Act

The U.S. has made tremendous progress in our fight against COVID–19. Over the past 14 months, the Biden Administration has made vital investments—using resources Congress provided on a bipartisan basis—to make sure the American people have free and widely available access to lifesaving tools: vaccines, booster shots, treatments, tests, and high-quality masks. As we enter a new moment in the pandemic, Congress has not provided us with the f4nding we need to continue the COVID–19 response and minimize the pandemic's impact to tie Nation and our economy. With cases rising abroad, scientific and medical experts have been dear that in the next couple of months there could be increasing cases of COVID–19 here in the U.S. as well. As the Administration has warned, failure to fund these efforts now will have severe consequences as we will not be equipped to deal with a future surge. Waiting to provide finding once we're in a surge will be too late.

Without funding, the United States will not have enough additional boosters or variant specific vaccines, if needed, for all Americans. The Federal Government is unable to purchase additional life-saving monoclonal antibody treatments and will run out of supply to send to states as soon as late May. The Federal Government cannot purchase sufficient quantities of treatments for immunocompromised individuals. And, the Federal Government will be unable to sustain the testing capacity we built over the last 14 months, as we head into the second half of the year.

Earlier this month, President Biden laid out a comprehensive plan to ensure that the country can continue to move forward safely and remain prepared to fight new variants and future surges of the virus. And the Administration has been clear that we need Congress to provide additional resources, including $22.5 billion in immediate emergency funding. Inaction will set us back in this fight, leave us less prepared, and cost us more lives.

Consequences of lack of critical funding include:

- **Inability to Secure Sufficient Booster Doses and Variant Specific Vaccines, If Needed:**

The Federal Government does not have adequate resources to purchase enough booster vaccine doses for all Americans, if additional doses are needed. The shortages will be even more acute if we need a variant-specific booster vaccine, since we will not have any existing supply.

- **Providers No Longer Able to Submit Claims for Testing, Treating, and Vaccinating the Uninsured:**

The fund that reimburses doctors and other medical providers for caring for uninsured individuals will start to be scaled back this month and end completely in early April. Specifically, 1 week from today—March 22—the Uninsured Program will stop accepting new claims for testing and treatment due to lack of sufficient funds. Providers will no longer be able to submit claims for providing these services to uninsured individuals, forcing providers to either absorb the cost or turn away people who are uninsured, increasing the disparity in access to critically needed health care and putting additional burdens on safety net providers. Three weeks from today-April 5-the Uninsured Program will also stop accepting vaccination claims due to a lack of sufficient funds.

- **Ending the Purchase of Monoclonal Antibody Treatments, Scaling Back State/Territory Allocations:**

The Federal Government has no more funding for additional monoclonals, including a planned order for March 25. To date, the Federal Government has been able to provide these life-saving treatments free of charge to Americans and work with states to make sure they get to as many people as possible who need them. In order to keep these treatments free and available to the American people for as long as possible, the Administration will now have to stretch our current supply and, starting next week, will be forced to cut state allocations of our limited existing supply of life-saving monoclonal antibody treatments by more than 30 percent.

- **Halting Critical Testing, Vaccine, Treatment Efforts:**

The President's National Preparedness Plan was clear that the Federal Government must invest in next-generation vaccines and treatments and maintain our testing capacity in order to fight COVID–19 in the future. Now, without additional funding, we do not have the ability to:

  - Purchase additional oral antiviral pills beyond the 20 million already secured.
  - Pre-purchase promising new antivirals. The reason why the Administration has been able to secure more oral antiviral pills than any other country is because we committed to purchasing them early, even prior to an Emergency Use Authorization (EUA). As even more effective pills potentially become available, the Federal Government is no longer able to make advance purchase commitments to ensure America is one of the first countries in line.
  - Accelerate the creation of a next-generation, pan-COVID vaccine that would provide broad protection against a range of variants. Vaccines are the most effective tool to prevent COVID–19, and the Administration does not have the funding for necessary investments in research and to support the development of promising new vaccine candidates. Such next-generation vaccines hold potential to broaden protection against known and future variants, reduce dosing through single-dose primary regimens with extended duration of protection (i.e., longer interval between boosters or possible elimination of boosters altogether), and reduce costs by increasing manufacturing yields and extending shelf life.
  - Maintain our domestic testing capacity beyond June. After spending the last year building up our testing capacity, that progress will be squandered, the Administration will be unable to help keep domestic manufacturers online starting in June. That means, heading into the second half of the year, there will be significantly diminished domestic testing capacity and we may be unprepared for surges.

- **Scaling Back Planned Purchases of Preventive Treatments for Immunocompromised:**

The Federal Government has been planning to move forward with a purchase of preventative treatments for the immunocompromised as soon as

March 31 that would begin delivery in September, once the treatments are manufactured. However, absent additional funding the Federal Government will now be forced to scale back that purchase of treatments for our most vulnerable. Because these treatments take more than 6 months to manufacture, the United States will likely not have enough of these treatments by the end of the year. And being unable to make additional purchase commitments now likely means that fewer treatments will be available next year as well.

- **Reducing Ability to Rapidly Identify and Assess Emerging Variants.**

Robust surveillance and research are critical to identify, understand and monitor emerging variants. With reduced capability to perform adequate surveillance, the country will be prone to being "blindsided" by future variants. In the absence of funding to immediately assess lab-based efficacy and real-world effectiveness of existing vaccines and treatments as new variants emerge, health care professionals will be forced to make insufficiently informed treatment decisions. The Administration will need to wind down some COVID surveillance investments, leaving us less able to detect the next variant.

- **Damage to Global Vaccination and COVID–19 Treatment Efforts:**

Without additional funding to support getting shots into arms, USAID and interagency partners will have to cut short efforts to turn vaccines into vaccinations across the globe. Leaving large unvaccinated populations worldwide will increase the risk of new deadly variants emerging that could evade our current vaccines and treatments. Without additional funds, the Administration would be unable to extend Global VAX surge support to 20 plus additional under-vaccinated countries that will need intensive support this year to get shots in arms. This will devastate our ability to ensure those countries can effectively deploy safe and effective vaccines. USAID will also be unable to provide life-saving supplies, tests, therapeutics, oxygen, and humanitarian aid to countries still struggling to manage a continuing COVID disease burden.

In addition to the immediate need for funding, in order to facilitate a smooth transition to insurance coverage of life-savings COVID treatments the Administration is requesting that Congress provides authority to ensure seamless access to Medicare and insurance coverage for treatments under an Emergency Use Authorization (EUA).

HON. PATTY MURRAY, CHAIR,
HON. RICHARD BURR, RANKING MEMBER
U.S. Senate Committee on Health,
Education, Labor, and Pensions,
Washington, DC 20510.

DEAR CHAIR MURRAY AND RANKING MEMBER BURR:

Thank you for the opportunity to provide this feedback on the discussion draft of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act and in particular, Subtitle C of Title VIII which includes the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2022. The undersigned organizations represent a diverse and broad community of healthcare professionals, patient advocates, industry organizations, medical institutions, and pathology departments who practice laboratory medicine, provide clinical testing services, and deliver high quality care to patients throughout the U.S..

We write to you today to express our significant concerns with the VALID Act of 2022 and request that you provide additional and sufficient time to resolve these concerns prior to advancing this legislation. We recognize that the user fee reauthorization offers a fast moving legislative vehicle; however, since this proposal dramatically modifies the current regulatory framework for an entire category of medical services, it's critical that this is done right to protect patient access to innovative diagnostics. **As such, we respectfully request that you allow time for further refinement of the VALID Act and do not rush this very flawed, problematic legislation through the user fee reauthorization legislative process.**

In 2019, bipartisan, bicameral sponsors of the VALID Act in concert with staff from your Committee and the Energy and Commerce Committee held a series of 2 hour roundtable discussions with stakeholders and officials from the Food and Drug

Administration (FDA) on draft legislative language that was ultimately introduced as the VALID Act of 2020. Since then, stakeholders, including many on this letter, have provided extensive written comments on each iteration of the legislation, met with your offices and the bill's sponsors numerous times, participated in staff briefings, and most recently, responded to dozens of written questions from your staff circulated to stakeholders this past winter. Given this immense and active engagement over the past 4 years, we were very dismayed to see that the VALID Act of 2022 failed to incorporate most of our recommendations, even the most significant.

To illustrate our concerns, the current discussion draft failed to resolve these key areas:

1. Stifling Innovation and Constricting Patient Access to Care.

While each of our organizations hold specific positions, we are unified in our view that the VALID Act of 2022 creates an onerous and complex system that would radically alter the way that laboratory testing is regulated to the detriment of patient care. The VALID framework would be costly as laboratories would be subject to user fees and need to finance the internal FDA compliance activities that would be required. This would force many laboratories, especially community laboratories, to consolidate their testing menu which would disrupt localized patient care and minimize the innovative efforts at our most prestigious institutions. While we appreciate that the laboratory developed testing services offered today would be grandfathered, the utility of these tests would diminish over time as the VALID Act puts overly restrictive constraints on how they can be modified. Further, testing consolidation away from academic and other laboratories would result in a reduction in training opportunities for an already strained laboratory workforce. Unfortunately, the laboratory workforce shortages were a significant barrier for this country's ability to respond to the COVID–19 pandemic and we are greatly concerned about the potential impact the VALID Act would have on patient care in the decades to come.

2. Duplication With and Lack of Modernization of the Clinical Laboratory Improvement Amendments (CLIA).

The VALID Act's provisions on quality systems, adverse event reporting, and laboratory inspections duplicate requirements that laboratories already comply with under the federally administered CLIA program. The bill also references terms and aspects of the current medical device regulations that are not translatable to laboratory developed testing services. Simply directing the Secretary to avoid duplication as is written in the VALID Act of 2022 is insufficient, especially when other aspects of the legislation call for requirements and activities that lead to duplicative and unnecessary regulatory burden. Further, many stakeholders acknowledged the need to modernize the CLIA program implemented more than thirty years ago. Any update to the oversight of laboratory testing is incomplete and potentially duplicative without considering updates to CLIA.

3. Preemption of State Requirements.

Many stakeholders actively participate in validity and quality review programs such as those administered by the New York State Department of Health (NYSDOH). The NYSDOH program in particular has successfully incorporated the concept of reviewing certain testing services into their assessment of the quality of a laboratory's operations and its personnel which has resulted in a harmonious and effective approach to regulating laboratory practice. As such, stakeholders have encouraged the Committee to recognize the value of such programs, prevent duplication with state efforts, and apply lessons learned. The VALID Act of 2022 fails to incorporate any of these recommendations and instead allows states with programs in place prior to 2022 to continue their programs only if their requirements match those of the FDA. Further, as developers will still need to comply with both the FDA requirements and those state requirements, this will create unavoidable duplication as drafted.

4. Lack of Clarity in the Risk Categorizations, Definitions, Eligibility Criteria for Technical Certification, and Other Key Aspects of the Legislation.

Lack of clarity in key aspects of the VALID Act of 2022 including the definitions of high, moderate, and low risk, create ambiguities that make it impossible to understand the implications of various provisions on laboratory medicine and patient care. For instance, the newly created definition of moderate risk appears to overlap with the definition of high risk. Further, the criteria for the technical certification

program are unclear as to the types of tests eligible for authorization under such an order. Even more concerning, terms previously defined in an earlier version of the VALID Act such as "well characterized" and "adverse event" have been removed from this version yet are still referenced in the legislation.

5. Unpredictable Regulatory Process Due to Significant Discretion Given to the Secretary.

Throughout the legislation, the text grants discretion to the Secretary creating an unpredictable regulatory process and ambiguities in the significance of the policy. This is especially problematic as stakeholders try to understand the implications for their laboratories and practices. For example, in the section on an abbreviated premarket review, the legislation says that developers will not need to provide raw data as part of their submission unless requested by the FDA. The requirement of providing raw data is a meaningful distinction between full premarket review and abbreviated premarket review, and yet the Secretary has the discretion in any instance to require that data. Additionally, in the grandfathering provision, the Secretary has the discretion to direct any grandfathered test for premarket review. This further creates confusion as laboratories determine which of their tests will be subject to review. There are dozens of instances in the legislation similar to these examples. We strongly urge the Committee to narrow the discretion so that stakeholders may better evaluate and understand the implications of this legislation.

6. Subject Matter Experts, i.e. Test Developers, are Unable to Actively Participate in the Accreditation Process.

The VALID Act of 2022 prohibits test developers from becoming accredited third-party reviewers unless FDA waives this requirement, which is in sharp contrast to how the medical and scientific community usually act. These professionals are the subject matter experts most qualified to assess the validity of a diagnostic test and as such, their participation in these processes should not be left to the discretion of the Secretary or agency. This country has a long history of understanding the merits of and thus supporting scientific peer review and without such a system, FDA will greatly lack access expertise needed to regulate the tens of thousands laboratory developed testing services that are used in clinical care.

7. FDA Lacks Adequate Resources to Meet These Obligations.

During the COVID–19 pandemic, the FDA was quickly overwhelmed by the volume of applications submitted for the emergency use authorization, so much so that they had to pause review of all other non-EUA applications. This meant delays to the review and subsequent access to potentially lifesaving tests such as for oncology indications. Even with the funding infusion from user fees, based on the experience during the pandemic, we are very much concerned that FDA will be unable to handle implementing and administering the VALID Act. In 2021, there were more than 160,000 individual genetic tests on the market and FDA could not handle the influx of 2133 emergency use authorization requests for COVID–19 from March 2020—April 2021.

8. The Emergency Use Authorization (EUA) Provision Will Create a Similar Crisis Experienced in Winter and Spring 2020.

At the onset of the pandemic, a contaminant in the only EUA-authorized test kit plus restrictions on clinical laboratories that prevented them from offering laboratory developed testing services without FDA review, led to a crisis in the United States in which we had no testing for COVID–19 for over 1 month. Guidance published on February 29, 2020 allowing the use of tests while laboratories awaited an EUA decision was critical for the country's response. Recognizing the importance of this guidance, the VALID Act of 2020 and the VALID Act of 2021 included EUA language that allowed a similar approach. It's unclear why this was removed in the VALID Act of 2022, and we encourage the Committee to allow for similar approach in which laboratories can quickly mobilize during a public health emergency.

These are just eight examples of instances in the VALID Act that need major overhaul to address the concerns stakeholders have shared countless times in writing and in meetings with the bill's sponsors and with Committee staff. Before advancing this legislation, we implore you to modify the legislation to reflect stakeholders' input and to do so in a timeframe that ensures that policy fosters patient safety and innovation instead of creating barriers and delays to access novel diagnostics.

For these reasons, the undersigned organizations request that you do not advance the VALID Act as part of the Food and Drug Administration Safety and Landmark Advancements Act and instead work with stakeholders to refine this legislation.

Sincerely,

20/20 GeneSystems, Inc.
Academy of Clinical Laboratory Physicians and Scientists
AdventHealth
Akron Children's Hospital
Alphadera Labs
American Association for Clinical Chemistry
American College of Medical Genetics and Genomics
American Society for Clinical Pathology
American Society for Histocompatibility and Immunogenetics (ASHI)
American Society of Hematology
American Society of Transplantation
Amerimmune
ARUP Laboratories
Association for Molecular Pathology
Association for Pathology Informatics
Association of American Medical Colleges
Association of Organ Procurement Organizations
Association of Pathology Chairs
Atrium Health
Baylor Scott & White Health
Cancer Genomics Consortium (CGC)
Cedars-Sinai
Children's Hospital Los Angeles
Clinical Immunology Society (CIS)
Coalition for Innovative Laboratory Testing
Columbia University Irving Medical Center
Dartmouth Health
Department of Pathology & Laboratory Medicine, University of California, Irvine
Department of Pathology & Laboratory Medicine, University of Miami School of Medicine
Department of Pathology and Laboratory Medicine, Hartford Hospital
Department of Pathology and Laboratory Medicine, Northwell Health
Department of Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania
Department of Pathology and Laboratory Medicine, University of Florida—Jacksonville
Department of Pathology and Laboratory Medicine, University of Louisville
Department of Pathology and Laboratory Medicine, University of North Carolina School of Medicine
Department of Pathology, Duke University
Department of Pathology, East Carolina University Brody School of Medicine
Department of Pathology, Texas Tech University Health Sciences Center, El Paso, Texas
Department of Pathology, University of Arizona College of Medicine Phoenix
Department of Pathology, University of Illinois at Chicago
Department of Pathology, University of Pittsburgh Medical Center
Department of Pathology. University of Alabama at Birmingham
Diaceutics, Inc.
Diamond Medical Laboratories
Emory Healthcare
Entvantage Diagnostics, Inc.
Everly Health
Gene By Gene
GeneMatters
Genome Medical, Inc.
Genomind
GenXys Health Care Systems Inc.

GoDx, Inc.
Gravity Diagnostics
Harbor–UCLA Medical Center
Helix Op Co, LLC
Invitae Corporation
IVD Logix, LLC
Johns Hopkins Health System
Kaiser Permanente
KRAS Kickers
Laboratory Access and Benefits Coalition
Lighthouse Lab Services
Mass Spectrometry & Advances in the Clinical Lab (MSACL)
Medical Group Management Association
My Gene Counsel
Nationwide Children's Hospital
Nebraska Medicine
NorthShore University HealthSystem
Northwest Pathology, P.S.
NYU Langone Health
Olive View-UCLA Medical Center
Oregon Health & Science University
Pan-American Society for Clinical Virology (PASCV)
PathGroup
Premier, Inc.
Progentec Diagnostics, Inc.
Pulmonary Pathology Society
Sapere Bio
Sema4 and GeneDx
TriCore Reference Laboratories
UC Davis Health
UC San Diego Health
UCI Health
UCLA Health
University of California Health
University of California San Francisco
University of Chicago Medical Center
University of Cincinnati Health
University of Nebraska Medical Center (UNMC)
University of New Mexico
University of Rochester
University of Vermont Health Network
UVA Health
UW Health
UW Medicine
Vanderbilt University Medical Center
Virginia Commonwealth University
Weill Cornell Medicine
West Virginia University Health System

QUESTIONS FOR THE RECORD

Response by Rochelle Walensky to Questions of Senator Burr, Senator Murkowski, and Senator Scott

senator burr

Question 1. I want to talk about CDC's COVID–19 community levels metrics. For those who are not familiar, CDC uses green, yellow, and red to represent the impact of COVID–19 in each county, which you have said is based on the health system's capacity to deal with the virus. The color is determined by looking at the number of new cases in the county, COVID hospital admissions, and the percent of inpatient beds occupied by COVID patients.

I have heard that states are not using this tool at all, because it does not accurately reflect the level of severe disease and ability to surge. You can have one county in the green with COVID hospital admissions well above another county that is in the yellow.

In North Carolina, for example, CDC identifies Rockingham County as a green county, meaning low impact of COVID–19, Wake County as yellow, and Durham County as red. Despite the color ratings, the number of COVID hospital admissions is actually higher in Rockingham—a green county—than it is in Wake—a yellow county—and the percent of inpatient beds occupied by COVID patients in each of these three counties hovers around 5 percent.

What outreach have you conducted to states and local public health authorities to see if this tool is accurate and even helpful at all?

Answer 1. CDC Response: The Centers for Disease Control and Prevention (CDC) has held calls with jurisdictions about the COVID–19 Community Levels (CCLs) and used the feedback shared as we continue to evaluate and assess ways to improve the tool. Jurisdictions have indicated they find the CCLs a useful informational tool. CDC has also held over 20 meetings with public health partners regarding CCLs. Topics included community levels data and technical assistance, CCL report feedback and updates, and CCL Report Mockup/Pre-decisional discussions. Attendees were jurisdictional and tribal partners including State, Territorial, and Local Health Officials; state epidemiologists; senior leadership from the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the Association of Public Health Laboratories (APHL), the Big Cities Health Coalition (BCHC), and the Council of State and Territorial Epidemiologists (CSTE); and the CDC Foundation.

Question 2. CDC is encouraging doctors to test for monkeypox. However, the only way to currently test for monkeypox in the United States is through public health laboratories. Has CDC started working with commercial and other private sector labs to develop tests for monkeypox? If so, what is the timeline for their availability? If not, why not? Why haven't you learned the lessons of CDC's failure at the beginning of the COVID pandemic?

Answer 2. At this time, available testing capacity through public health capacity is far greater than demand. 69 U.S. public health laboratories are able to test for orthopoxvirus, producing a throughput capacity between 6,000–8,000 specimen weekly. Orthopoxvirus testing is utilizing approximately 2 percent of Laboratory Response Network capacity as of June 16, 2022.

CDC is working with the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), and other Federal partners to explore options for expanding testing convenience and options into the commercial space. CDC is working with commercial, hospital, and academic laboratories to be prepared to expand testing capacity. In particular, CDC began engaging with key commercial laboratory partners about expanding orthopoxvirus testing capacity on May 23, less than a week after the first detected U.S. case of monkeypox was confirmed.

Unlike the currently circulating monkeypox virus, COVID–19 is a novel pathogen that required development of an entirely new diagnostic test. The United States is better positioned to respond to the monkeypox outbreak, having a historic scientific basis of information on the nature and effective medical counter measures for orthopox viruses. Investments made in the Smallpox Research Agenda have contributed to the availability of an FDA-cleared non-variola orthopoxvirus test, therapeutic measures including the anti-viral tecovirimat, and a deployable vaccine, JYNNEOS. Investments in the Laboratory Response Network have helped build testing capacity, which at this point have provided capacity far greater than current testing demand.

SENATOR MURKOWSKI

Question 1. Dr. Walensky, as you are aware by now the Alaskan tourism economy took the largest hit from the COVID–19 pandemic in the country, with a 33 percent loss in revenue to the state. We are hearing that cruises this year are operating at around 70 percent capacity on average. This past December, as we were looking ahead to the upcoming cruise season in Alaska and safely rebuilding our economy, the Centers for Disease Control elevated their Travel Risk Advisory for cruise ships to a Level 3 Risk Advisory, which at the time was the same risk as traveling to Ukraine.

The cruise industry was the only industry targeted by the travel advisory during the COVID Pandemic, as all other risk advisories were for geographic regions. At the time of this announcement, the U.S. was seeing a surge in positive cases due to the Omicron variant; however, vaccination rates onboard a cruise ship were typically upwards of 95 percent—significantly higher than the overall U.S. population which was at about 60 percent.

Question 1(a). Why did CDC issue the Travel Advisory on cruise ships when they had the highest level of safety precautions in place?

Answer 1. CDC has historically used Travel Health Notices (THNs) to alert travelers and other audiences about current health issues that impact travelers' health, like disease outbreaks, special events or gatherings, and natural disasters, in destinations around the world. These range from a watch level 1 to a warning level 3.

CDC issued a separate COVID–19 THN for cruise ships because the risk of COVID–19 transmission on cruise ships is different from that of shoreside travel and entertainment settings (such as U.S. resorts, restaurants, bars, and theme parks). Specifically, cruise ships are congregate residential settings with high risk of COVID–19 transmission among travelers (passengers and crew). They have thousands of travelers living for multiple days (or months for crew) on the same ship—eating, sleeping, and participating in activities together in one location. Data from the pandemic suggest COVID–19 spreads quickly in group settings, including on cruise ships.

During the first 2 years of the pandemic, large outbreaks were identified on many cruise ships during periods that coincided with major pandemic waves. These outbreaks posed a health risk to travelers on board by exposing them to the virus. In addition, on many affected ships, COVID–19 cases overwhelmed onboard medical facilities, which led to reduced access to healthcare services for travelers on board who needed to seek medical care for COVID–19 or other health conditions. Hence, CDC developed COVID–19 THN levels and criteria specific to cruise ships to inform the public regarding COVID–19 conditions on board. CDC used COVID–19 data reported by cruise ships and relevant public health authorities to make determinations about the cruise ship THN level. Additional information such as new variants of concern, vaccination rates, severity of disease (such as hospitalizations, medical evacuations, and deaths for crew or passengers) were considered when determining the cruise ship THN level. Furthermore, CDC worked with the cruise industry and public health authorities to gather additional data as appropriate.

CDC removed the COVID–19 Cruise Ship Travel Health Notice on March 30, 2022. While cruising continues to pose some risk of COVID–19 transmission, travelers can make their own risk assessment when choosing to cruise, much like they do in other travel settings, based on factors such as their health and vaccination status, and personal risk tolerance.

Question 1(b). Will CDC commit to ending COVID related travel advisories that single out U.S. destinations?

Answer 1(b). CDC remains committed to leading with science and protecting the American public during this pandemic. CDC issued a THN for cruise ships to notify travelers and other audiences about a major health issue that impacted cruise ship travelers (passengers and crew) at the time. The cruise ship THN was not designed to single out any U.S. or international destinations.

Question 1(c). When will CDC cease ending COVID related travel advisories for the cruise industry?

Answer 1(c). CDC removed the COVID–19 Cruise Ship THN on March 30, 2022. While cruising continues to pose some risk of COVID–19 transmission, travelers can make their own risk assessment when choosing to cruise, much like they do in other travel settings, based on factors such as their health and vaccination status, and personal risk tolerance.

Question 2. Dr. Walensky, I continue to be concerned about the impacts of COVID–19 on the well-being of children and youth in Alaska. We know that there have been devastating affects to our children and youth's mental health, as we have seen a wave of emotional health needs. Alaska continues to have the second highest rates of suicide in the Nation, and suicide is the second leading cause of death for individuals ages 25–44. And we have seen an alarming increase in mental and behavioral health issues and suicide attempts by children.

Additionally, I am concerned about the well-being of our children and youth due to the disrupted school years. There has been documented learning loss due to the shift to virtual learning, and this is not accounting for the social-emotional impacts. An analysis by McKinsey suggests that students were (on average) 5 months behind mathematics and 4 months behind in reading by the end of the 2021 school year.

In Alaska, I have heard from programs caring for young children, that there have been significant increases in developmental delays amongst babies' speech and language development—possibly attributed to mask wearing.

Question 2(a). Has the CDC evaluated the negative impacts of the COVID–19 pandemic, not just the mental health of children and youth, but the effects on developmental delays and learning loss?

Answer 2(a). CDC remains committed to working with our state and local partners to improve access to mental health resources as we continue to address the long-term impacts of the pandemic. CDC is analyzing data to understand the trends associated with students' mental health during COVID. Data were collected as part of the Monitoring School COVID–19 Mitigation Strategies Project, a project funded by the CDC Foundation to inform CDC's Operational Strategy for K–12 Schools through Phased Prevention COVID–19 recommendations. Data were also collected as part of the Adolescent Behaviors and Experiences Survey (ABES), a project funded through the CARES Act to assess the impact of COVID–19 on behaviors and experiences of U.S. high school students. ABES provides a nationally representative sample of high school students experiences during the COVID–19 pandemic. According to the new data, in 2021, more than a third (37 percent) of high school students reported they experienced poor mental health during the COVID–19 pandemic, and 44 percent reported they persistently felt sad or hopeless during the past year.

CDC's Study to Explore Early Development (SEED) conducted a COVID–19 Impact Assessment (January through June 2021) with over 1,000 parents of children 5–9 years of age who were already enrolled in SEED. Study findings showed disruptions to regular health services were common across all study groups (58 percent–65 percent) and disruption to specialty services were more common for children with autism spectrum disorder (76 percent) versus children with other developmental disabilities (58 percent) and the general population (23 percent). Between 70 percent–81 percent of children who received developmental services through telehealth had a worse response compared to in person visits. Ongoing analyses will address changes in daily living skills and behavior problems, factors associated with childhood resiliency, response to mitigation strategies and infection, and impact of pandemic on parental mental health.

With COVID funding, CDC expanded its Act Early Ambassador program to further support families with young children in high need communities across the country by bolstering collaboration among early childhood programs to identify and support children with developmental delays and disabilities, and to promote resiliency skills among families during the pandemic. Forty-three state and territorial "COVID–19 Act Early Response Teams," including a team in Alaska, completed a national needs assessment that described the impact of COVID–19 on early identification of developmental disabilities across early childhood system.

Question 3. I have had several conversations with Alaskan public health officials, on lessons learned from the Federal response to the COVID–19 pandemic. I am disappointed that CMS and IHS are not testifying today, as we know they were pivotal in the response to COVID–19. This pandemic was not only a public health crisis, but a crisis affecting our health systems and the delivery of healthcare. I believe that we must apply lessons learnt, to address new public health epidemics, such as the drug overdose crisis that many of our communities are experiencing. The Federal Government has to improve transparency and integrate Federal services, to allow states to respond to future public health crisis that arise. An example of this is the drug overdose epidemic that many of our states are now experiencing. The Federal Government has a responsibility to promote data-sharing throughout all health systems. For example, we did not see a significant improvement in the surveillance of COVID–19 until CMS required hospitals to share data on bed capacity with ASPR. Sharing data between hospital systems and state lines, is essential in addressing future public health issues and most notably, the drug overdose epidemic.

Question 3(a). How can HHS continue to work internally and with other Federal agencies, such as the VA and DOD to integrate Federal services and promote data-sharing throughout healthcare systems?

Answer 3(a). CDC participated in the VA/DOD hosted COVID–19 Data Collaboratory during the week of May 16, 2022. The focus of the Collaboratory was to discuss efforts at developing further coordination across a host of areas, including common ways to collect, analyze, and share data findings to track the burden of disease and the effectiveness of prevention and treatment efforts. Engagement is ongoing with the VA/DOD with a follow-up large group meeting schedule in Fall 2022. Additionally, CDC is working with HHS leadership, such as the Office of the National Coordinator for Health IT (ONC), as well as other HHS OpDivs such as CMS, to better understand and coordinate the way data is collected, shared, and analyzed. These efforts also support ongoing work to update the HHS data strategy and en-

sure that data is available, accessible, timely, equitable, meaningfully usable, protected—and being actively used by HHS, our partners, and the public to realize HHS' mission.

CDC currently lacks the authority to coordinate and require the reporting of public health data from state and local health departments and healthcare facilities. The result is a fragmented approach to public health reporting that is hindered by a patchwork of policies which vary from jurisdiction to jurisdiction and prohibits CDC from developing the clear national picture of disease burden across the country. The lack of a consistent, comprehensive reporting framework is burdensome on healthcare providers, who must attempt to meet many and varied requirements, and leaves large gaps in the Federal Government's ability to prepare for and respond to disease outbreaks. This discordance also reduces the quality of data that can be shared back with jurisdictions and with interagency partners, such as the VA and DOD.

Providing CDC with a modernized public health authority could improve CDC's ability to share high quality data with our interagency partners, like the VA and DOD, on a wide array of public health issues, including the overdose epidemic. For example, the ability to require emergency department data would help CDC and states to more rapidly detect unusual spikes in visits related to overdoses, facilitating a more rapid response.

Question 3(b). What can the CDC and ASPR do to continue to streamline healthcare workforce efficiency and improve data modernization?

Answer 3(b). The National Healthcare Safety Network (NHSN) is the most comprehensive USG data collection and quality improvement system for healthcare and is currently in use in more than 38,000 healthcare facilities in the U.S., with more than 136,000 individual users tracking and identifying emerging and enduring threats across healthcare. At the outset of the COVID–19 pandemic, CDC rapidly leveraged the reach that NHSN has into thousands of healthcare facilities to collect urgently needed COVID–19 data from hospitals, nursing homes, dialysis clinics, and other facilities. With support from COVID supplemental funding, CDC now collects and analyzes COVID–19 data from every nursing home in the country (?15,400), including vaccination coverage of their 1.2 million residents and 1.8 million staff, as well as hospital staff COVID–19 vaccination from more than 7.6 million healthcare personnel.

CMS also relies on NHSN for regulatory functions, public reporting, and incentive payment programs, including mandatory COVID–19 reporting from all U.S. nursing homes and mandatory COVID–19 staff vaccination reporting from all U.S. hospitals. CDC has consistently worked with CMS to provide data from healthcare settings that is reported in NHSN and other systems, including CMS public reporting of facility level COVID data from NHSN. CDC has coordinated with VA and IHS to improve reporting of COVID and other healthcare data by relevant facilities and share data as appropriate to assist these agencies with their prevention efforts. CDC has also worked with health departments throughout the pandemic to provide access to NHSN reports and data to inform their efforts.

CDC is working with other agencies, public health partners, and industry to increase the automation of data reporting to NHSN and modernize user interface and support. The goal is to accelerate the integration of electronic healthcare records and other emerging data standards to NHSN and provide a modern, flexible platform that can serve as the hub of USG healthcare data for CDC, CMS, ASPR, and HHS to identify and to respond to emerging and enduring health threats in healthcare facilities. CDC is also exploring additional capabilities to address future health emergencies as described in CMS's recently proposed rule requiring ongoing reporting of COVID–19 data from hospitals; reporting of pathogens of pandemic or epidemic potential during future public health emergencies; as well as CMS' recently finalized rule which extends nursing home COVID–19 reporting for several years beyond the end of the current Public Health Emergency. CDC will also work with health departments and other public health partners to continue to expand and improve provision of analytic reports and electronic data provided from NHSN to state and local health departments, other Federal Government agencies—such as CMS and ASPR—and public health partners to support infection control and prevention activities and improve patient safety.

CDC, the Association of Public Health Laboratories (APHL), and the Council of State and Territorial Epidemiologists (CSTE) are working with healthcare organizations and their EHR vendors to automate the reporting of conditions of significance to public health agencies that is required of healthcare providers. Electronic case reporting (eCR) modernizes the reporting by using data entered in electronic health

records as part of care delivery by healthcare providers. The automation of this reporting reduces the burden on the providers to submit reports in a manual process, typically by filling out a paper form and faxing it to public health.

Question 4. We talk a lot about the importance of health equity, and focusing on populations that have documented inequities. I have been a vocal advocate for addressing health equity issues, particularly the issues affecting Alaska Native and American Indian populations to die at higher rates than other Americans in many categories, including chronic liver disease and cirrhosis, diabetes mellitus, unintentional injuries, assault/homicide, intentional self-harm/suicide, and chronic lower respiratory diseases.

However, I want to discuss a different type of equity today, which is an important part of the health equity discussion. When we are evaluating our Federal response to COVID–19, we fail to discuss state equity. States with larger populations, tend to have more purchasing power for therapeutics, testing, and other medical supplies, leaving many rural states (the majority Western states) behind. We saw this during the COVID–19 pandemic, when Alaska was unable to compete with New York City, California, or private investors in purchasing PPE, therapeutics, and testing supplies.

Question 4(a). As we move to toward a new phase of COVID–19, how are we going to ensure there is state equity when accessing these supplies on the private market?

Answer 4(a). CDC defers to ASPR.

Question 4(b). What is HHS going to do to address these issue of unequal purchasing power to ensure equal access?

Answer (b). Please see the answer from ASPR.

Question 4(c). What is HHS doing to continue to conduct surveillance of COVID–19, to ensure states can plan appropriately for different waves to come?

Answer 4(c). CDC has been sharing with Americans and the rest of the world what we've learned about COVID–19. COVID Data Tracker contains a wealth of numbers and tools to analyze COVID–19 cases, deaths, and trends at the local, state, and national levels. Data Tracker tool contains total cases; average number of daily cases during the previous 7 days; total number of deaths; and total number of vaccinations. The information, which is updated daily, is both big-picture (with national data) and granular (down to the county level).

CDC is also working to detect and characterize new variants of the virus that causes COVID–19. As CDC has learned new information about the variants, the agency has been providing updates to the public and our partners around the world. CDC's COVID-NET program collects data on laboratory-confirmed, COVID–19-associated hospitalizations among children and adults through a network of over 250 acute-care hospitals in 14 states.

Question 5. The impacts of COVID–19 have exacerbated mental health issues across the country and within the military. We've seen this first hand in Alaska where 17 soldiers died in 2021 by suicide. Service members and their families face difficult and unique circumstances living in an austere and remote location, and COVID protocols increased their isolation without providing enough access to resources such as mental health providers. Just last week, Senator Sullivan and I introduced the Don Young Arctic Warrior Act, which focuses increasing the help and assistance they need and deserve.

Question 5(a). Is HHS working on any long-term solutions to address the rise in military suicides, as exacerbated by the isolation brought on by COVID?

Answer 5(a). CDC uses data to understand the contributors to suicide, including its scope and magnitude, who is most impacted, and to track trends over time to inform prevention and response efforts. For almost 20 years, CDC has collected data on suicide deaths through the National Violent Death Reporting System (NVDRS). CDC has ongoing collaborations with the Departments of Defense (DoD) and the Department of Veterans Affairs (VA) to strengthen suicide-related data to better tailor prevention efforts for veterans and active-military. CDC and the Department of Defense link and analyze data from the DoD's Suicide Event Report (DoDSER) and NVDRS. DoD collects information on active-duty service members while NVDRS collects data on people who have ever served in the military, and civilian populations. Combining NVDRS and DoDSER provides the opportunity to examine and better understand suicides among, civilians, veterans, and active-duty military to inform upstream prevention, tailor effective strategies, and identify hotspots and gaps to target efforts. For example, this project creates detailed mapping of suicide burden by county, as well as a thorough description of the characteristics of veteran and active-duty suicides in areas with the highest incidence. These maps are overlaid

with military installations, mental health clinics, and suicide prevention programs to see which hotspots may lack infrastructure to address suicide burden and to highlight areas in need of suicide prevention resources, including upstream prevention. Additionally, CDC works with the VA to link mortality data from CDC's National Death Index to VA data to improve understanding of veteran suicide.

In addition, CDC is funding approaches to primary prevention of suicide. CDC's Comprehensive Suicide Prevention (CSP) program funds states and communities to implement multiple strategies and approaches with attention to populations disproportionately affected by suicide, including military and rural populations. These strategies are discussed in further detail in the response below.

Question 5(b). Are there any lessons the military could learn from the CDC or NIH on what strategies work in reducing suicides in highly isolated populations?

Answer 5(b). While anyone can experience suicide risks, certain groups have substantially higher rates of suicide than the general U.S. population, and CDC recognizes that active-military and veterans bear a disproportionate burden. Suicide is preventable, and the same scalable prevention and protective strategies CDC has demonstrated effective for individuals, families, and communities work for veterans and active military too. CDC's Preventing Suicide: A Technical Package of Policies, Programs, and Practices (*https://www.cdc.gov/suicide/pdf/suicideTechnicalPackage.pdf*) highlights strategies based on the best available evidence to prevent suicide including strategies that address isolation such as. promoting connectedness, teaching coping and problem-solving skills, and identifying and supporting people at risk.

A comprehensive approach to suicide prevention that includes multiple strategies tailored to population needs (including military and rural populations) can help reduce suicide and suicide risk. CDC's Comprehensive Suicide Prevention (CSP) program funds states and communities to implement multiple strategies and approaches from the technical package with attention to populations disproportionately affected by suicide, including military and rural populations. The program seeks to reduce suicide and suicide attempts by 10 percent over the course of the 5-year program. CDC also funds the Veteran Suicide Prevention Evaluation Demonstration Project (VSPE) to improve the evaluation capacity of veteran serving organizations (VSOs) to measure the impact of their upstream suicide prevention programs (e.g. those focused on improving connectedness). This project just completed its fourth year. We know firsthand from working with VSOs participating in this project that social connectedness is crucial in supporting veterans in their communities and in reducing suicide risk.

To address isolation and reduce access barriers, some of our funded partners are exploring the use of technology to reach and connect veterans. For example, CDC funded Objective Zero Foundation (a VSO) to develop a mobile app that helps veterans and community members 1) independently access wellness tools, trainings, and resources; 2) seek support through a crisis hotline or Ambassador; and 3) provide support and resources to Ambassadors. The program is currently evaluating outcomes, including social connectedness, awareness, and user intent to access mental health and other resources and skills to help others. Other CDC funded projects, such as Zero Suicide, are exploring telehealth to reach at-risk populations to implement evidence-based practices that engage and retain individuals at increased risk for suicide in care services. Telehealth is a strategy that has been found to be effective in reaching veterans and rural populations at risk of suicide. Relaxed state laws allowing use of telehealth services enacted during the COVID–19 pandemic helped reduce transportation barriers and increase access through use of Medicaid funds to reimburse providers for telehealth visits.

FROM SENATOR SCOTT

Question 1. Dr. Walensky—South Carolina had the 5th highest prevalence of diabetes among adults in the U.S. in 2017 and it is the 7th leading cause of death in my state. I have a bill with Senator Warner, the PREVENT DIABETES Act (S. 2173), which would align Medicare coverage for diabetes prevention programs with the existing and highly successful CDC recognition of these programs to simplify compliance and expand patient access by allowing virtual suppliers of these services. I was pleased to see that the National Clinical Care Commission, a panel of national diabetes care experts recently made a similar recommendation to HHS—recommending that the Medicare program better align its coverage of these services with the CDC's national program by allowing virtual access to diabetes prevention programs.

Can you discuss the public health and wellness opportunity that would be created by expanding access to diabetes prevention programs for seniors? Specifically, can you discuss the opportunity virtual Diabetes Prevention Programs create to effectively help address the increased rates of pre-diabetes—particularly rural areas without in-person providers—as a result of the pandemic?

Answer 1. Approximately 26 million American adults 65 years and older have prediabetes. Expanding Medicare beneficiaries' access to the Medicare Diabetes Prevention Program (MDPP) can be critically important to the health and well-being of this population. CMS offered greater flexibility to provide virtual delivery of MDPP services during the COVID–19 public health emergency (PHE) to ensure continuity of services when in-person classes are not safe or feasible.

The MDPP expanded model was originally intended to provide primarily in-person MDPP services and does not include a "virtual only" option. CMS has not permitted virtual-only suppliers to furnish MDPP services while the Public Health Emergency Policy is in effect. This is because MDPP suppliers must remain prepared to resume delivery of MDPP services in-person to start new cohorts and to serve beneficiaries who wish to return to in-person services when the PHE has concluded. At this time, CMS does not have a path for continuing virtual delivery of MDPP post PHE except for the limited virtual options that existed prior to the PHE.

A 2017 study in rural communities found that for the National Diabetes Prevention Program (National DPP) lifestyle change program, which the MDPP is modeled after, participants who participated through telehealth videoconferencing had similar participation rates and achieved similar weight loss outcomes as participants who attended in person.1 More than 300,000 (. 60 percent) enrollees in the National DPP lifestyle change program have participated in a virtual program, making it the most popular delivery method. It seems virtual participation could improve access while improving health care outcomes. The National DPP lifestyle change program is cost effective and can contribute to cost savings.

RESPONSE BY ANTHONY FAUCI TO QUESTIONS OF SENATOR BURR AND SENATOR MURKOWSKI

SENATOR BURR

Question 1. Dr. Fauci, we have seen evidence that BA.4 and BA.5 are more transmissible than other Omicron subvariants and are likely to evade immunity from vaccines. A recent study from Israel indicates that individuals who were vaccinated and recovered from Omicron may have some more protection. What do we know about BA.4 and BA.5 so far and what questions are we still asking-or what should we be asking?

Answer 1. Initial data indicate that the BA.4 and BA.5 variants of SARS-CoV–2 are more transmissible than previous variants and may partially evade the immune response from previous infection and/or vaccination. The continued emergence of SARS-CoV–2 variants with such attributes is a cause for concern. The National Institute of Allergy and Infectious Diseases (NIAID) has launched collaborative research to help answer key scientific questions related to BA.4, BA.5, and other SARS-CoV–2 variants, namely the effectiveness of vaccines, monoclonal antibodies, and antiviral drugs.

The National Institutes of Health (NIH), including NIAID, participates in the Department of Health and Human Services-established SARS-CoV–2 Interagency Group (SIG) along with the Centers for Disease Control and Prevention (CDC), U.S. Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority (BARDA), Department of Defense (DOD), and U.S. Department of Agriculture. The SIG tracks variants in real time to address the potential impact of emerging variants on critical SARS-CoV–2 countermeasures. As part of SIG, NIAID leads the SARS-CoV–2 Assessment of Viral Evolution (SAVE) program to rapidly prioritize variants for studies to characterize their properties, including whether immunity is maintained against these variants. Through the SAVE program, NIAID-supported scientists have generated in vitro neutralization data with post-vaccination sera that show a reduction in neutralization titers for BA.5 compared to earlier Omicron subvariants (BA.1). Studies are ongoing to assess how sera from people who experienced a breakthrough BA.1 or BA.2 infection are able to neutralize BA.4 or BA.5. NIH continues to assess this phenomenon as other emerging variants may be able to further escape immunity.

With both the Delta and Omicron variants, protection against mild and moderate disease begins to decrease over time following the primary vaccine series. As SARS-

CoV–2 variants have emerged, NIAID moved rapidly to investigate the potential of targeted boosters to enhance immune responses to emerging variants. NIAID now will examine whether people who received boosters—either mRNA–1273 or variant-specific COVID–19 boosters—generate antibodies that can bind to and neutralize the Omicron variant and its sublineages, including BA.4 and BA.5. NIAID also 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. NIAID recently launched the Phase 2 COVID–19 Variant Immunologic Landscape (COVAIL) trial to learn whether different vaccine booster regimens can broaden and increase the durability of immune responses in adults who already have received a primary vaccination series and a first booster shot.

NIAID also conducts and supports research to determine the impact of SARS-CoV–2 variants on the effectiveness of monoclonal antibodies and other therapeutics. For example, research suggests that although the activity of certain monoclonal antibodies against Omicron is markedly diminished, the monoclonal antibody bebtelovimab, discovered by the NIAID VRC in collaboration with AbCellera, is active in vitro against all circulating Omicron subvariants, including BA.4 and BA.5. In addition, NIAID is working to develop new drugs, including therapeutics that inhibit essential processes in the virus replication cycle or that address the host response to COVID–19, with an eye toward agents that maintain their effectiveness against emerging variants.

Additional SARS-CoV–2 variants can be expected to arise and NIAID is supporting the development of next-generation COVID–19 vaccines that could provide additional protection against disease caused by emerging SARS-CoV–2 variants. Strategies for next-generation COVID–19 vaccines include targeting viral antigens that are highly conserved among SARS-CoV–2 strains, testing innovative antigen presentations, and utilizing alternative routes of inoculation, such as intranasal vaccine approaches to generate better mucosal immunity to potentially limit infection and transmission. NIAID also is conducting research on pan-coronavirus vaccines designed to provide broad protective immunity against emerging SARS-CoV–2 variants, such as BA.4 and BA.5, and other coronaviruses with pandemic potential.

SENATOR MURKOWSKI

Question 1. I have had several conversations with Alaskan public health officials, on lessons learnt from the Federal response to the COVID–19 pandemic. I am disappointed that CMS and IHS are not testifying today, as we know they were pivotal in the response to COVID–19. This pandemic was not only a public health crisis, but a crisis affecting our health systems and the delivery of healthcare. I believe that we must apply lessons learnt, to address new public health epidemics, such as the drug overdose crisis that many of our communities are experiencing. The Federal Government has to improve transparency and integrate Federal services, to allow states to respond to future public health crisis that arise. An example of this is the drug overdose epidemic that many of our states are now experiencing. The Federal Government has a responsibility to promote data-sharing throughout all health systems. For example, we did not see a significant improvement in the surveillance of COVID–19 until CMS required hospitals to share data on bed capacity with ASPR. Sharing data between hospital systems and state lines, is essential in addressing future public health issues and most notably, the drug overdose epidemic. How can HHS continue to work internally and with other Federal agencies, such as the VA and DOD to integrate Federal services and promote data-sharing throughout healthcare systems?

Question 1(a). What can the CDC and ASPR do to continue to streamline healthcare workforce efficiency and improve data modernization?

Answer 1(a). NIAID defers to CDC and ASPR on the above questions.

Question 2. We talk a lot about the importance of health equity, and focusing on populations that have documented inequities. I have been a vocal advocate for addressing health equity issues, particularly the issues affecting Alaska Native and American Indian populations to die at higher rates than other Americans in many categories, including chronic liver disease and cirrhosis, diabetes mellitus, unintentional injuries, assault/homicide, intentional self-harm/suicide, and chronic lower respiratory diseases.

However, I want to discuss a different type of equity today, which is an important part of the health equity discussion. When we are evaluating our Federal response to COVID–19, we fail to discuss state equity. States with larger populations, tend to have more purchasing power for therapeutics, testing, and other medical supplies, leaving many rural states (the majority Western states) behind. We saw this during

the COVID–19 pandemic, when Alaska was unable to compete with New York City, California, or private investors in purchasing PPE, therapeutics, and testing supplies.

Question 2(a). As we move to toward a new phase of COVID–19, how are we going to ensure there is state equity when accessing these supplies on the private market?

Question 2(b). What is HHS going to do to address these issue of unequal purchasing power to ensure equal access?

Question 2(c).What is HHS doing to continue to conduct surveillance of COVID–19, to ensure states can plan appropriately for different waves to come?

Answer 2. NIAID defers to CDC and ASPR on the above questions.

Question 3. The impacts of COVID–19 have exacerbated mental health issues across the country and within the military. We've seen this first hand in Alaska where 17 soldiers died in 2021 by suicide. Service members and their families face difficult and unique circumstances living in an austere and remote location, and COVID protocols increased their isolation without providing enough access to resources such as mental health providers. Just last week, Senator Sullivan and I introduced the Don Young Arctic Warrior Act, which focuses increasing the help and assistance they need and deserve.

Question 3(a). Is HHS working on any long-term solutions to address the rise in military suicides, as exacerbated by the isolation brought on by COVID?

Question 3(b). Are there any lessons the military could learn from the CDC or NIH on what strategies work in reducing suicides in highly isolated populations?

Answer 3. NIAID defers to CDC on the first question above.

The National Institute of Mental Health (NIMH) works with the Department of Veterans Affairs (VA), the Department of Defense (DoD), and clinicians and researchers to address the mental health needs of active duty, National Guard, and Reserve service personnel, as well as veterans and their families. NIMH-supported suicide prevention research focuses on understanding risk factors, identifying effective prediction and screening approaches, and developing effective, evidence-based interventions. Additionally, the NIMH Office of Rural Mental Health helps to ensure that such efforts positively impact highly isolated populations, by supporting research to improve the delivery of services for residents of rural areas.

NIMH funds research on coordinated services for individuals at elevated risk of suicide across the health care system. This approach is often referred to as the Zero Suicide framework, which emphasizes the role of leadership, training, and continuous quality improvement to optimize delivery of evidence-based strategies to identify, engage, treat, and assist with transitions of care across clinical settings.[1] NIMH-funded research has shown that implementation of Zero Suicide preventive practices is effective at decreasing suicide risk. 1A[2] In line with this approach, NIMH staff and grantees have published a clinical pathway for suicide risk identification in adult primary care settings, which emphasizes the importance of pairing screening with evidence-based assessment and intervention strategies associated with suicide risk reduction. 1A[3] Provider training in suicide prevention is important for ensuring that evidence-based clinical care is delivered with high quality, and that care is appropriately tailored to the level of risk. For example, for lower risk individuals, early detection and intervention, with a focus on recovery and stress management, can help reduce concerns about negative impact on employment.

Other strategies that complement the Zero Suicide approach can also help to create safer, healthier environments. For example, NIMH-supported research has demonstrated that safe storage of lethal means is an effective strategy for reducing suicide deaths. 1A[4] Interventions to build cohesion, shared purpose, and the capacity to manage career and personal stressors have also proven effective at improving healthy behaviors and reducing psychiatric symptoms, including suicide ideation. 1A[5] Creating multi-level strategies for suicide prevention is consistent with previous efforts by the military that were associated with reduced suicide rates. 1A[6]

Understanding risk associated with specific deployment contexts is also important. As one example of ongoing research in this area, NIMH-supported researchers

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[1] *https://www.sprc.org/zero-suicide*
[2] Layman et al. (2021), *https://doi.org/10.1176/appi.ps.202000525*
[3] *https://www.nimh.nih.gov/news/research-highlights/2022/a—clinical-pathway-for-suicide-risk-screening-in-adult-primary-care*
[4] Shenassa et al. (2004), *https://doi.org/10.1136/jech.2003.017343*
[5] Wyman et al. (2022), *https://doi.org/10.1016/j.socscimed.2022.114737*
[6] Knox et al. (2010), *https://doi.org/10.2105/ajph.2009.159871*

aim to identify risk factors for suicide by analyzing data from the Substance Use and Psychological Injury Combat Study (SUPIC), a longitudinal data base of over 865,000 Army Active Duty and National Guard/Reserve Soldiers returning from Operation Enduring Freedom/Operation Iraqi Freedom/Operation New Dawn deployments, along with clinical and administrative data from the Veterans Health Administration. 1A[7] Findings from this study could substantially improve suicide risk assessment and intervention strategies.

Beyond the military context, implementation of evidence-based approaches in isolated settings requires additional considerations. Prior to the COVID–19 pandemic, telehealth had already been found to be as effective as in-person treatments for mental illnesses, including PTSD. 1A[8] Expansion of telehealth services during the COVID–19 pandemic has provided further evidence that mental health care can successfully be delivered to individuals in remote areas. The National Action Alliance for Suicide Prevention issued guidance on screening for suicide risk during telehealth visits. 1A[9] Ensuring that individuals maintain continuous access to their healthcare providers, regardless of where they are physically located, remains a challenge for the mental health field, with several notable efforts to solve this problem underway. 1A[10], 1A[11] Finally, efforts to embed mental healthcare in the primary care setting, known as behavioral health integration, can help address shortages in the behavioral health workforce in rural communities. One such approach, the Collaborative Care model, has been shown to reduce the severity of suicidal ideation in a recent meta-analysis. 1A[12]

The NIMH Suicide Prevention website contains additional examples of effective suicide prevention strategies, as well as resources for people in suicidal crisis or emotional distress. [13]

RESPONSE BY ROBERT CALIFF TO QUESTIONS OF SENATOR BURR, SENATOR CASSIDY, AND SENATOR MURKOWSKI

SENATOR BURR

Question 1. We have heard concerns from some parents about the delay between Moderna's EUA submission and the advisory committee meeting. I've seen reporting that one of the reasons for the delay was so that parents would not confuse the two different vaccines as each has different doses and timelines. It's this kind of continued nanny state approach that raises questions about what exactly FDA is doing, as it seems FDA is evaluating other factors in addition to its role of reviewing safety and efficacy.

Question 1(a). Can you provide any clarity regarding the reason for the delay of authorizing one vaccine for children under 5?

Question 1(b). Did FDA consider waiting until the other vaccine was submitted to make its decision about the first? If so, why?

Answer 1. On May 23, FDA revised the dates of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meetings due to new data from sponsors and expected submissions of emergency use authorization (EUA) amendment requests. June 15 was the new meeting date for the Moderna EUA amendment request for 6 months through 5 years of age and Pfizer-BioNTech EUA amendment request for 6 months through 4 years of age, based on expected completion of an EUA submission to FDA. FDA noted its plans to hold the VRBPAC meetings in anticipation of complete submissions of EUA requests that had been publicly announced by COVID–19 vaccine manufacturers. FDA also noted that the dates were tentative as none of the submissions were complete.

FDA recognized that many parents and caregivers of children under the age of 5 were eager to get their children vaccinated. The agency proceeded with holding a 2-day VRBPAC meeting to present the safety and effectiveness data for both vaccines to our committee of outside experts. We believed that this was the best approach to solicit the most informed advice from the VRBPAC because the committee had the comprehensive analyses for both vaccines in the youngest pediatric popu-

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[7] *reporter.nih.gov/project-details/10437762*
[8] Marchand et al. (2011), *https://doi.org/10.1080—percent2F10926771.2011.562479*
[9] *https://theactionalliance.org/resource/covid-guidance-screening-suicide-risk-during-telehealth-visits*
[10] *https://psypact.site-ym.com/*
[11] *https://www.imlcc.org/*
[12] Grigoroglou et al. (2021), *https://doi.org/10.1016/j.genhosppsych.2021.04.004*
[13] *www.nimh.nih.gov/health/topics/suicide-prevention*

lations before them and did not have to wonder about results that were mentioned only in a press release. Our top priority was ensuring that the relevant data pertaining to the safety and effectiveness of both vaccines were available for public consideration before we decided whether to authorize these COVID–19 vaccines for pediatric populations.

SENATOR CASSIDY

Question 1. When do you expect your respective workforces to return to pre pandemic levels of in-office or field work on a full-time basis?

Answer 1. Throughout COVID–19, FDA staff have never stopped working and continue to work extremely hard to successfully fulfill our public health mission—regardless of whether work is performed from a FDA office, or from an alternative work location. FDA initiated a Workplace Flexibilities Pilot in April 2022 and will evaluate the best approach for FDA's work environment moving forward, informed by how we can best accomplish our mission and attract and retain highly qualified talent, supported by our personnel policies.

FDA's reentry process is completely consistent with Government-wide guidance. It is important to note that FDA must recruit highly skilled and talented staff, often with specialized technical expertise, to keep up with the innovative industries we regulate. To meet our mission, the Agency must compete with industry for the most qualified staff and that will require us to continue to leverage workplace flexibilities as appropriate.

Question 2. What percent of your respective workforces, including headquarters, agency, regional office, and field office employees are currently working full or part time remotely?

Answer 2. As of June 2022, approximately 5,000 employees regularly come into facilities or to work sites to perform non-portable work. Other FDA employees are participating in the Workplace Flexibilities Pilot, which provides remote-and telework-eligible options for employees who receive supervisory approval for a period of 6 months.

Question 3. What agency-wide data have you collected regarding remote work productivity levels that will help advise any agency plans for increased telework in the future?

Answer 3. FDA initiated a Workplace Flexibilities Pilot in April 2022 for a limited time, after which time we will evaluate the best approach for FDA's work environment moving forward, informed by how we can best accomplish our mission and attract and retain highly qualified talent, supported by our personnel policies.

Question 4. I hear that there are some companies that are trying to bring new competitors on to the market relevant for COVID response but are having difficulty getting samples of the products from the original manufacturers, and thus don't have the supplies necessary to carry out appropriate trials. They haven't been able to get good answers from the Administration about what to do. I'm told that when a product is under an EUA, the FDA cannot compel the that company to share samples. Dr. Califf, is this something you've heard about and is this something that the FDA could address through regulatory action?

Answer 4. As a general matter, if companies are blocking access to product samples needed by competing product developers, there are multiple pathways for addressing this. The law widely known as the CREATES Act creates a pathway for eligible developers of generic, 505(b)(2) and biosimilar products to obtain needed samples of drug products approved under sections 505(c) or (j) of the FD&C Act or biological products licensed under sections 351(a) or (k) of the Public Health Service Act. The CREATES Act establishes a private right of action that allows eligible product developers to sue companies that refuse to sell them samples of these products needed to support their applications. If the product developer prevails, the court will order the sale of samples, award attorneys' fees and litigation costs to the product developer and may impose a monetary penalty on the company withholding samples.

We note that, as a general matter, we also understand that the Federal Trade Commission (FTC) takes enforcement action to address the anticompetitive blocking of access to samples and other materials needed for drug product development. While outside of FDA's purview, it is our understanding that this action may result in, among other things, issuance of an order requiring a company to make samples of their product available to competing developers. While the CREATES pathway is limited to obtaining samples of approved drug or biological products, to the extent companies are engaging in the blocking of access to other products or materials

needed for product development, we recommend that the matter be raised with the FTC so that they can consider appropriate enforcement action.

In terms of issues that may be occurring in the COVID–19 vaccine space, FDA intends to work with the Biomedical Advanced Research Development Authority (BARDA) on making U.S. Government owned supply available to developers.

Question 5. Dr. Califf, a Politico article published on May 19th described the chaos and disarray of the foods program at FDA, which was driven by lack of clear leadership over the program between CFSAN Director Susan Mayne and Deputy Commissioner Yiannes. How do you think that this lack of clear leadership contributed to the infant formula crisis? May 19 article: *https://www.politico.com/news/2022/05/19/infant-formula-fallout-fda-woodcock—00033699*

Answer 5. Deputy Commissioner Yiannas and Dr. Mayne are leaders with tremendous experience in their respective fields. FDA's response to the infant formula crisis required their vast array of skills. I am committed to taking a close look at the foods program to determine what investments, changes, and authorities may be needed to better position the program for the future. I have asked Dr. Steve Solomon, Director of the Center for Veterinary Medicine, to conduct a top-down review of the events and activities that led up to the current situation involving infant formula. Dr. Solomon has been with FDA for more than 30 years, runs one of FDA's most efficient centers, and has familiarity with Foods and Field-based issues, having previously worked in our Office of Regulatory Affairs. I am confident that that review will provide even more detail that will support our ability to implement the processes and changes needed to prevent this situation from happening in the future.

SENATOR MURKOWSKI

Question 1. I have had several conversations with Alaskan public health officials, on lessons learnt from the Federal response to the COVID–19 pandemic. I am disappointed that CMS and IHS are not testifying today, as we know they were pivotal in the response to COVID–19. This pandemic was not only a public health crisis, but a crisis affecting our health systems and the delivery of healthcare. I believe that we must apply lessons learnt, to address new public health epidemics, such as the drug overdose crisis that many of our communities are experiencing. The Federal Government has to improve transparency and integrate Federal services, to allow states to respond to future public health crisis that arise. An example of this is the drug overdose epidemic that many of our states are now experiencing. The Federal Government has a responsibility to promote data-sharing throughout all health systems. For example, we did not see a significant improvement in the surveillance of COVID–19 until CMS required hospitals to share data on bed capacity with ASPR. Sharing data between hospital systems and state lines, is essential in addressing future public health issues and most notably, the drug overdose epidemic.

Question 1(a). How can HHS continue to work internally and with other Federal agencies, such as the VA and DOD to integrate Federal services and promote data-sharing throughout healthcare systems?

Question 1(b). What can the CDC and ASPR do to continue to streamline healthcare workforce efficiency and improve data modernization?

Answer 1. FDA defers to CDC and ASPR for a response to these questions.

Question 2. We talk a lot about the importance of health equity, and focusing on populations that have documented inequities. I have been a vocal advocate for addressing health equity issues, particularly the issues affecting Alaska Native and American Indian populations to die at higher rates than other Americans in many categories, including chronic liver disease and cirrhosis, diabetes mellitus, unintentional injuries, assault/homicide, intentional self-harm/suicide, and chronic lower respiratory diseases.

However, I want to discuss a different type of equity today, which is an important part of the health equity discussion. When we are evaluating our Federal response to COVID–19, we fail to discuss state equity. States with larger populations, tend to have more purchasing power for therapeutics, testing, and other medical supplies, leaving many rural states (the majority Western states) behind. We saw this during the COVID–19 pandemic, when Alaska was unable to compete with New York City, California, or private investors in purchasing PPE, therapeutics, and testing supplies.

Question 2(a). As we move to toward a new phase of COVID–19, how are we going to ensure there is state equity when accessing these supplies on the private market?

Question 2(b)1. What is HHS going to do to address these issue of unequal purchasing power to ensure equal access?

Question 2(c)1. What is HHS doing to continue to conduct surveillance of COVID–19, to ensure states can plan appropriately for different waves to come?

FDA defers to CDC and ASPR for a response to these questions.

Question 3. The impacts of COVID–19 have exacerbated mental health issues across the country and within the military. We've seen this first hand in Alaska where 17 soldiers died in 2021 by suicide. Service members and their families face difficult and unique circumstances living in an austere and remote location, and COVID protocols increased their isolation without providing enough access to resources such as mental health providers. Just last week, Senator Sullivan and I introduced the Don Young Arctic Warrior Act, which focuses increasing the help and assistance they need and deserve.

Question 3(a)1. Is HHS working on any long-term solutions to address the rise in military suicides, as exacerbated by the isolation brought on by COVID?

Question 3(b)1. Are there any lessons the military could learn from the CDC or NIH on what strategies work in reducing suicides in highly isolated populations?

FDA defers to CDC and NIH for a response to these questions.

RESPONSE BY DAWN O'CONNELL TO QUESTIONS OF SENATOR KAINE, SENATOR BURR, SENATOR MURKOWSKI, AND SENATOR TUBERVILLE

SENATOR KAINE

Assistant Secretary O'Connell, at a recent HELP hearing on the ongoing Federal response to COVID–19, we discussed the importance of next generation vaccines. I first want to acknowledge the success of the important government and private sector partnerships that have taken place over the last 2 years. BARDA, in coordination with other government agencies, has led the way in working with researchers and other entities on the development of several effective vaccines against COVID–19. Yet COVID–19 has shown us that it can change. As new variants emerge, we need vaccines that offer universal coverage against emerging variants.

Question 1. Assistant Secretary O'Connell, what is the current state of research on next generation vaccines and how has delayed COVID–19 funding impacted BARDA's timeline?

Answer 1. Response: At this time, any investment in next generation COVID–19 vaccines by the Biomedical Advanced Research and Development Authority (BARDA) has been put on hold given the lack of supplemental funding for such efforts. However, BARDA, in collaboration with partners at the National Institutes of Health (NIH) as well as other interagency partners, continues to assess the pipeline of vaccine candidates and has put out Requests for Information to make sure that the Federal Government is poised to act quickly, should funding be made available. Since additional funding has not been provided, BARDA does not have the resources to invest in next-generation vaccine candidates that may offer key improvements in technical performance. Every day that additional COVID–19 funding is delayed is a day lost in terms of applying invaluable government resources, both financial and technical, to such programs. With any current remaining funds, BARDA is exploring whether it can—in partnership with NIH—establish a scientific framework for consideration of next generation vaccines (assays, etc.) so should next generation funding come available both teams can move out quickly.

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.

SENATOR BURR

Question 1. The recently released ASPR strategic plan is silent on status or plan for National Disaster Medical System (NDMS). Can you please provide your priorities, plans and intentions for NDMS?

Answer 1. ASPR has not released a new strategic plan. Rest assured, ASPR continues to view the National Disaster Medical System (NDMS) as a critical tool to aid and support response to public health emergencies with communities are overwhelmed by disaster. As included in the fiscal year 2023 President's Budget request, an additional $50 million was requested for NDMS to support the recruitment, hir-

ing, and training of NDMS intermittent staff. If appropriated, funding would ensure that NDMS is best positioned and resourced to aid communities in need. The fiscal year 2023 request also includes an additional $13 million to maintain NDMS caches and equipment that support the deployment of personnel during response operations. It is critical that additional funding be provided to support continued operation of NDMS. The system remains a priority for me as the ASPR and is recognized as a national tool that has been successful in bridging the gap when communities are overwhelmed during a public health emergency or disaster.

Question 2. ASPR has created new models to predict potential scenarios for the trajectory of COVID in our Country over the next few months. While these models have been around for a few weeks and supposedly have some important predictions for the next few months, the American people have yet to get a read-out.

Question 2(a). What are these models predicting for the next 30, 60, and 90 days?

Answer 2. Response: ASPR's models support internal, operational planning and are not intended or appropriate for public release. ASPR defers to CDC's Center for Forecasting and Outbreak Analytics (CFA) on the release of available public models.

Question 2(b). Should I expect to see different numbers and predictions out of CDC's new forecasting center?

Answer 2(b). The CDC and ASPR models have different purposes. The CDC forecasting ensemble CFA is focused on short-term projections over the next 4 weeks. This is built on a 'wisdom of the crowds' approach that incorporates multiple academic and external models and are validated during seasonal influenza before the pandemic.

ASPR Modeling is focused on actionable decision and planning support that require longer-term timelines, providing scenarios that capture key uncertainties and show how those might play out over the next few months. The purpose of ASPR modeling is for planning of ASPR-specific operational activities like procurement of Therapeutics, PPE, tests etc. and is not targeted for general consumption or forecasting.

Despite these intentionally different purposes, the CDC forecasting has projections for hospitalization and deaths 4 weeks out and the ASPR models include scenarios consistent with these estimates.

Question 3. As new COVID variants emerge, they have learned to evade some of our available treatments. We need to stay ahead of the curve by maintaining a strong pipeline of new antivirals and treatments. What is ASPR's plan to invest in the next generation of COVID countermeasures for the long term, and your plan to balance this important work with the other very real threats on your radar?

Answer 3. BARDA continues to closely monitor for the emergence of new COVID–19 variants, evaluate potential impacts to the portfolio of available products to determine which of the currently available treatments would be most effective. The COVID–19 therapeutics team continues to monitor the development of novel medical countermeasures (MCMs) and next generation therapeutics for the treatment of COVID–19. BARDA's TechWatch program affords companies an opportunity to present their capabilities to BARDA and other interagency partners. Industry partners are encouraged to request a TechWatch meeting to discuss their products and explore the potential for future partnering opportunities.

There are no existing funds at this time to support the research and advanced development of any new antivirals or treatments for COVID–19. This spring, the Administration requested $22.5 billion to support immediate needs to avoid disruption of ongoing response to COVID–19. Funding would support additional investments in developing, procuring, deploying and administering vaccines and therapeutics, including oral antivirals, to aid this response and expand the COVID–19 therapeutics portfolio and ensure we have effective MCMs available for use in the future.

Question 4. Our current availability of vaccines and antivirals that work against monkeypox is due to the successes of Project BioShield and the efforts of the U.S. Government to prepare for smallpox, but that means we have less smallpox vaccine to deploy from the stockpile should we need it for its intended purpose—smallpox. I hope that we will never have to use it for this purpose, but it is still a threat, and on the material threat list. What modeling has ASPR conducted on the depletion of our smallpox vaccine supply as a result of the monkeypox outbreak? How quickly can we backfill our doses?

Answer 4. To ensure we are prepared for a potential smallpox incident, the SNS currently holds a significant number of doses of ACAM2000 and a much smaller stockpile of JYNNEOS vaccine. In the event of a smallpox incident, JYNNEOS

would be made available to special populations who should not take ACAM2000 (immunocompromised, pregnant, heart condition, etc.). Ultimately, all JYNNEOS and ACAM2000 that will be deployed from the stockpile as part of the monkeypox response will need to be replenished to ensure there is some product available in the SNS to protect against a potential subsequent public health emergency caused by smallpox or monkeypox. The cost to replace those doses is more than replacing costs to fill/finish for the monkeypox outbreak—it is replacing the previously purchased bulk vaccine that is being utilized. As of the date of this hearing, ASPR estimated the cost to replace vaccine used for the monkeypox outbreak will be $382M.

SENATOR MURKOWSKI

Question 1. I have had several conversations with Alaskan public health officials, on lessons learnt from the Federal response to the COVID–19 pandemic. I am disappointed that CMS and IHS are not testifying today, as we know they were pivotal in the response to COVID–19. This pandemic was not only a public health crisis, but a crisis affecting our health systems and the delivery of healthcare. I believe that we must apply lessons learnt, to address new public health epidemics, such as the drug overdose crisis that many of our communities are experiencing. The Federal Government has to improve transparency and integrate Federal services, to allow states to respond to future public health crisis that arise. An example of this is the drug overdose epidemic that many of our states are now experiencing. The Federal Government has a responsibility to promote data-sharing throughout all health systems. For example, we did not see a significant improvement in the surveillance of COVID–19 until CMS required hospitals to share data on bed capacity with ASPR. Sharing data between hospital systems and state lines, is essential in addressing future public health issues and most notably, the drug overdose epidemic.

Question 1(a). How can HHS continue to work internally and with other Federal agencies, such as the VA and DOD to integrate Federal services and promote data-sharing throughout healthcare systems?

Answer 1. 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). ASPR, CDC, CMS, and ONC are also closely coordinating on all hazards healthcare information sharing together with government and healthcare partners.

Question 1(b). What can the CDC and ASPR do to continue to streamline healthcare workforce efficiency and improve data modernization?

Answer 1(b). ASPR, CDC, CMS, and ONC are working together on all hazards healthcare situational awareness, leveraging ongoing initiatives and work to improve pathways for data collection. Access to private sector data, capabilities, guidance and participation are critical to successful government engagement on supply chain challenges, to include deployment of stockpiled resources, strategic investment in production capacity, or coordinated allocation of scarce resources during shortages or supply chain disruptions.

Question 2. We talk a lot about the importance of health equity and focusing on populations that have documented inequities. I have been a vocal advocate for addressing health equity issues, particularly the issues affecting Alaska Native and American Indian populations to die at higher rates than other Americans in many categories, including chronic liver disease and cirrhosis, diabetes mellitus, unintentional injuries, assault/homicide, intentional self-harm/suicide, and chronic lower respiratory diseases.

However, I want to discuss a different type of equity today, which is an important part of the health equity discussion. When we are evaluating our Federal response to COVID–19, we fail to discuss state equity. States with larger populations, tend to have more purchasing power for therapeutics, testing, and other medical supplies, leaving many rural states (the majority Western states) behind. We saw this during the COVID–19 pandemic, when Alaska was unable to compete with New York City, California, or private investors in purchasing PPE, therapeutics, and testing supplies.

Question 2(a). As we move to toward a new phase of COVID–19, how are we going to ensure there is state equity when accessing these supplies on the private market?

Answer 2(a). Equitable access to life-saving products is one of the most challenging and critical aspects we are working through as we transition COVID–19 vaccines and therapeutics to the commercial market. We must ensure that vaccines and therapeutics continue to be available to anyone who needs them. I commit to

keeping you updated as we finalize plans for commercialization. We also continue to invest in industrial base expansion efforts to bolster domestic manufacturing of PPE and tests. Increased domestic manufacturing will increase the supplies in the commercial market and support states' access to these needed tools.

Question 2(b). What is HHS going to do to address these issues of unequal purchasing power to ensure equal access?

Answer 2(b) HHS would be happy to provide your staff a briefing to discuss the ongoing efforts for COVID–19 product commercialization. In short, we hope that a transition to a commercial market will rely less on state purchases and more on the existing health care infrastructure. However, we recognize that this presents challenges, especially for the un-and-under insured. As noted in the prior response, we are also supporting efforts to invest in industrial base expansion to ensure needed products are available commercially, as and when needed.

Question 2(c). What is HHS doing to continue to conduct surveillance of COVID–19, to ensure states can plan appropriately for different waves to come?

Answer 2(c). I defer to my CDC colleagues who are responsible for this function.

Question 3. The impacts of COVID–19 have exacerbated mental health issues across the country and within the military. We've seen this first hand in Alaska where 17 soldiers died in 2021 by suicide. Service members and their families face difficult and unique circumstances living in an austere and remote location, and COVID protocols increased their isolation without providing enough access to resources such as mental health providers. Just last week, Senator Sullivan and I introduced the *Don Young Arctic Warrior Act,* which focuses increasing the help and assistance they need and deserve.

Question 3(a). Is HHS working on any long-term solutions to address the rise in military suicides, as exacerbated by the isolation brought on by COVID?

Answer 3. This is a critical issue and is best addressed by colleagues at the Departments of Defense and Veterans Affairs.

Question 3(b). Are there any lessons the military could learn from the CDC or NIH on what strategies work in reducing suicides in highly isolated populations?

Answer 3(b). I defer to my CDC colleagues on such strategies and whether they are applicable.

SENATOR TUBERVILLE

Monoclonal Antibody Treatments

Question 1. Much has been made lately about the administration's desire for more money to combat the ongoing pandemic. I have been a big supporter of common sense pandemic response efforts since the outset. However, every time I have asked HHS questions about its COVID spending decisions, I have been met with silence. For example, Ms. O'Connell, at a hearing on November 4 of last year, I asked you why HHS wasted $142million on a contract with accounting firm KPMG to promote a monoclonal that HHS had stopped buying months before. You responded that you were, "expecting a memo any day with the team's recommendations" on whether the program should be kept going.

Two weeks later and you had not shared that decision with me. As a result, I and six of my colleagues on this Committee sent Secretary Becerra a letter asking about the purpose of the KPMG contract and who conjured it up. No explanations were provided. Weeks of failed efforts to receive any information from your staff led us to write another letter on March 8. To date, more than 3 months later, your office has provided no information. I am asking you to explain $142 million spent at an accounting firm to administer medicine to sick Americans but you can't justify your decisions. And now, you want more money.

Question 1(a). If you can't answer questions about past money spent, how do you expect our support to provide you with more?

Question 1(b). Will you commit right now that you will personally work with your staff to respond to our multiple letters about the KPMG contract so this Committee can implement guardrails on additional funding so it isn't similarly wasted on sham contracts?

Question 1(c). As part of that commitment, will you—at a minimum—provide the Committee with a copy of the decision memo you alluded to in your November 4 testimony, where you stated you were the decisionmaker for funding this program?

Answer 1. HHS is committed to ensuring fair and equitable distribution of COVID–19 therapeutics across the country. We partnered with KPMG earlier this year to help improve use and increase access of monoclonal antibody therapeutics

in vulnerable communities. As part of its agreement with DoD, KPMG facilitated onsite support in communities across the country to help expand and/or establish capacity to administer monoclonal antibody treatments.

The current COVID–19 therapeutics landscape is different with different requirements than at the start of the pandemic. As such, the specific support KPMG provided is no longer required. Overall use of these therapies has improved across the country, and treatment and provider options have expanded.

This contract has been terminated.

I commit to working with you and your staff to address and respond to any pending correspondence.

Question 2. I understand that roughly 20–30 percent of high risk COVID–19 patients cannot take oral antiviral treatments due to drug-to-drug interactions and the 40 percent shorter treatment window.

Question 2(a). If this is the case, why is ASPR buying 10 million more doses of the oral antivirals and only a small quantity of the treatment monoclonal antibodies?

Answer 2. One of the benefits of the oral antivirals Paxlovid and Legevrio is that they have not been impacted by SARS-CoV–2 variants. In fact, both Paxlovid and Legevrio have retained activity against all circulating SARS-CoV–2 variants to date. The mechanism of action of the monoclonal antibodies, which depends on binding to the virus, is a distinct disadvantage as new viral variants arise. Looking to the future , 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.

Question 2(b). Without additional COVID–19 appropriations, shouldn't ASPR increase the purchase of treatment mAbs and decrease the purchase of the orals, so that hundreds of thousands of high-risk patients who cannot take the orals are not left without a treatment option in the fall?

Answer 2(b). COVID–19 therapeutics can be used to prevent or treat eligible non-hospitalized patients who have tested positive for COVID–19 and have mild to moderate symptoms and are at high risk for disease progression. Prevention and early treatment for eligible patients can help improve patient outcomes, reduce stress on healthcare facilities, and even save lives. When it comes to COVID–19 therapeutics, we have approached it like filling a medicine cabinet—we are not relying on one type, or one brand, or one treatment. We ensured that we would invest in and buy a broad variety of monoclonal antibody and oral antiviral treatments. To date, over the course of the COVID–19 response, the U.S. Government (USG) has purchased the following therapeutic products: Bebtelovimab, Evusheld, Lagevrio (molnupiravir), Paxlovid, sotrovimab, REGEN-COV, bamlanivimab/etesevimab; and bamlanivimab. Due to the high frequency of the Omicron variant, REGEN-COV (casirivimab and imdevimab), bamlanivimab and etesevimab, and sotrovimab are not currently authorized for use in any U.S. region. In addition, the U.S. Food and Drug Administration revoked the emergency use authorization (EUA) that allowed for the investigational monoclonal antibody therapy bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate COVID–19.

Currently the USG allocates Bebtelovimab, Lagevrio, Paxlovid, and renal-Paxlovid on a weekly basis to states, territories, Federal entities, and pharmacy partners. Evusheld is allocated monthly. Current estimates (based on case counts and utilization rates) estimate that the federally purchased supply of Bebtelovimab will be exhausted later this summer; that the federally purchased supply of Evusheld will be exhausted by the end of the year or in the first quarter of 2023; that the federally purchased supply of Paxlovid will be exhausted in the first or second quarter of 2023; and that the federally purchased supply of Lagevrio will be exhausted in calendar year 2023. Our focus remains working with state and territorial health departments as well as national healthcare and medical organizations and associations to get COVID–19 therapeutic products into the hands of healthcare providers quickly, with a focus on areas of the country hardest hit by the pandemic. However, unless Congress provides additional appropriations, we will not have funding to purchase additional COVID–19 therapeutics.

[Whereupon, at 12:14 p.m., the hearing was adjourned.]

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