

**EXAMINING OUR COVID-19 RESPONSE:
AN UPDATE FROM FEDERAL OFFICIALS**

HEARING
OF THE
**COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS**
UNITED STATES SENATE
ONE HUNDRED SEVENTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING THE COVID-19 RESPONSE, FOCUSING ON AN UPDATE FROM
FEDERAL OFFICIALS

—————
MARCH 18, 2021
—————

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



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

—————
U.S. GOVERNMENT PUBLISHING OFFICE

46-755 PDF

WASHINGTON : 2022

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

PATTY MURRAY, Washington, *Chair*

BERNIE SANDERS (I), Vermont	RICHARD BURR, North Carolina, <i>Ranking Member</i>
ROBERT P. CASEY, JR., Pennsylvania	
TAMMY BALDWIN, Wisconsin	RAND PAUL, M.D., Kentucky
CHRISTOPHER S. MURPHY, Connecticut	SUSAN M. COLLINS, Maine
TIM KAINE, Virginia	BILL CASSIDY, M.D., Louisiana
MAGGIE HASSAN, New Hampshire	LISA MURKOWSKI, Alaska
TINA SMITH, Minnesota	MIKE BRAUN, Indiana
JACKY ROSEN, Nevada	ROGER MARSHALL, M.D., Kansas
BEN RAY LUJAN, New Mexico	TIM SCOTT, South Carolina
JOHN HICKENLOOPER, Colorado	MITT ROMNEY, Utah
	TOMMY TUBERVILLE, Alabama
	JERRY MORAN, Kansas

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

C O N T E N T S

STATEMENTS

THURSDAY, MARCH 18, 2021

Page

COMMITTEE MEMBERS

Murray, Hon. Patty, Chair, Committee on Health, Education, Labor, and Pensions, Opening statement	1
Burr, Hon. Richard, Ranking Member, a U.S. Senator from the State of North Carolina, Opening statement	3

WITNESSES

Fauci, Anthony, M.D., Director, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD	7
Prepared statement	9
Kessler, David, M.D., Chief Science Officer, COVID Response, United States Department of Health and Human Services, Washington, DC	14
Prepared statement	15
Marks, Peter, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, United States Food and Drug Administration, Silver Spring, MD	16
Prepared statement	18
Walensky, Rochelle, M.D., MPH, Director, United States Centers for Disease Control and Prevention, Atlanta, GA	24
Prepared statement	25

QUESTIONS AND ANSWERS

Response by Anthony Fauci, M.D., to questions of:	
Senator Hickenlooper	67
Senator Burr	69
Senator Murkowski	70
Response by David Kessler, M.D., to questions of:	
Senator Murray	72
Senator Hickenlooper	73
Senator Lujan	73
Senator Burr	74
Senator Murkowski	75
Senator Braun	76
Senator Marshall	76
Senator Tuberville	77
Response by Peter Marks, M.D., Ph.D., to questions of:	
Senator Hickenlooper	78
Senator Burr	79
Senator Paul	81
Senator Murkowski	82
Response by Rochelle Walensky, M.D., MPH, to questions of:	
Senator Smith	84
Senator Burr	84
Senator Murkowski	85
Senator Braun	86
Senator Tuberville	87

EXAMINING OUR COVID-19 RESPONSE: AN UPDATE FROM FEDERAL OFFICIALS

Thursday, March 18, 2021

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

The Committee met, pursuant to notice, at 10:08 a.m., in Room 216, Hart Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

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

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. Good morning. The Senate Health, Education, Labor, and Pensions Committee will please come to order. Today we are holding a hearing on the Federal response to the COVID-19 pandemic with Administration officials at the forefront of these efforts. Ranking Member and I will each have an opening statement and then I will introduce our witnesses, Doctors Fauci, Walensky, Kessler, and Marks. I appreciate each one of you being here today, and I expect to be hearing from you often as we continue to work to end this pandemic. After the witnesses give their testimony, Senators will each have five minutes for a round of questions.

Before we begin, I again want to work through the COVID-19 safety protocols that are in place. We will follow the advice of the Attending Physician and the Sergeant-at-Arms in conducting this hearing. Committee Members are seated at least six feet apart. Some Senators are participating by video conference. And while we are unable to have the hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at help.senate.gov. And if you are in need of accommodations, including closed captioning, you can reach out to the Committee or the Office of Congressional Accessibility Services. We are all very grateful to everyone, including our Clerks, who have worked very hard to get this set up and help everyone stay safe and healthy.

Thank you to all of them. We have seen a lot of change, and recently change for the better, since this Committee had its first COVID-19 hearing with Federal officials over a year ago. The difference between how President Biden has been handling the crisis and how former President Trump refused to is staggering when it comes to public health guidance. Former President Trump spread

misinformation about masks, refused to wear them, but one of President Biden's first acts as President was to call on all Americans to wear masks and keep each other safe. When it comes to listening to the experts, former President Trump consistently interfered with their work.

President Biden has empowered them to lead a science based response to this pandemic. When it comes to testing, former President Trump was concerned that testing too many people would make him look bad, while President Biden is concerned that not testing enough will leave people at risk and let new variants of this virus spread undetected. When it comes to getting vaccines into arms, Trump administration's approach on distribution was essentially giving vaccines to states, call it mission accomplished. The Biden administration is directing vaccines to pharmacies through a partnership reaching over 40,000 locations, to community health centers through a program they have expanded to 950 total locations, and to patients by standing up to Federal vaccine—standing up Federal vaccination sites, which it announced last week it will double.

The result, recently, my home State of Washington administered its 2 millionth vaccine. Our Country administered its 100 millionth vaccine. We saw the first day without a thousand COVID-19 deaths in our Country since November. And President Biden announced he will direct all states, tribes, and territories to make all people 18 and over eligible to be vaccinated no later than May 1st. Well, we aren't through this pandemic yet, we are finally on the right track and we can see the light at the end of the tunnel, but we are going to have to keep pushing to make sure we get there.

That is why the American rescue plan makes investments in testing, contact tracing, and sequencing so we can identify new variants of it and slow the spread, investments in vaccines so we can distribute and administer them quickly, widely and equitably, fight misinformation, promote vaccine confidence, and engage trusted partners in communities, investments to recruit and train 100,000 new public health workers for those efforts, and investments to address inequities that have made this pandemic more deadly for communities of color, to address mental health, behavioral health, and substance abuse challenges that this pandemic has worsened, to support home and community based services that help people with disabilities and older Americans, and to support community health centers which continue to be a lifeline to so many hard hit and hard to reach communities.

Now we must work to make sure these investments have the impact we need them to in order to bring an end to this pandemic. And for this to happen, we need to fight vaccine hesitancy. While over half of people now say they will get vaccinated compared to around a third at the end of December, that is still far too low. And as we promote vaccines, we also have to ensure equity and get vaccines and information to communities of color, rural communities, people with disabilities, people who don't speak English, and people who do not have access to the Internet. The Biden administration's plan to develop a federally run website showing vaccine locations and a 1-800 number to help those without Internet are a promising start, as are efforts being spearheaded by community groups

like the Pacific Islander Community Association in Washington State, which I talked about in our last hearing.

But we have to keep our focus on this because this pandemic will not truly be over for anyone until we can vaccinate everyone that we can. And even when we are all safe from COVID-19, our work to recover will not be over. We have to rebuild our Country stronger and fairer. And that work needs to start with building a stronger and fairer public health infrastructure, which is why I introduced the Public Health Infrastructure Saves Lives Act last week. But it can't end there. And that is why Ranking Member Burr and I, along with the Members of this Committee, are focused around the need to learn the lessons of this pandemic and take action so nothing like this ever happens again. Together, I hope to work with Ranking Member Burr and Members of this Committee to hold a set of hearings, talk with experts, and stakeholders, and work across the aisle with our colleagues over the next few months to consider the many lessons of this pandemic and draft bipartisan legislation to act on those lessons.

I know we will have different views on this Committee about what that means, but I also know we share a common goal, to keep our families and communities safe from future pandemics and public health threats. And I am hopeful that we will find common ground when it comes to what we can do to address the need for a strong public health system, the painful health inequities that hurt communities of color, the way this pandemic was exacerbated by a lack of paid leave for every worker and affordable child care for working families, the importance of protecting schools and workers and more.

We all want to make sure we learn from this moment in our history because we owe it to every American who has suffered or who is grieving after this year to make sure we never find ourselves here again. With that in mind, I would like to thank all of our witnesses today for joining us. I look forward to hearing from each of you about the issues we face as we work to end this pandemic. And with that, I will turn it over to Ranking Member Senator Burr for his opening remarks.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Madam Chair, and welcome to Dr. Kessler, Dr. Marks, and Dr. Walensky. It is great to see all of you. Continuity will be critical as we work through the lessons learned from the COVID-19 pandemic and move into the next phase of our response and hopefully our recovery. This hearing is meant to take stock of our Federal COVID-19 response. But I think it is now time to talk about where we are going in the next 30, 60, and 90 days and beyond. America needs to reopen our schools. We need to reopen our businesses.

We need to open up to global commerce, a much more challenging thing. The actions taken by each of your officers affect these goals. Some of you are new to the response and some of you have been in the fight for the last year alongside Members of this Committee. My request of each of you, however, is the same. This pandemic has shown us very clearly how we can better prepare for the next threat, and that it is being a better partner to the private

sector is one of the things at the top of the list. Dr. Walensky, I am going to start with you because you have the hardest job, I think, ahead of you. The bottom line is there is a clear and compelling need for significant reform at the CDC. Your agency is responsible for communicating to the American people, based on facts, how to return to some form of normalcy.

But the guidance documents coming out of CDC have been two steps behind the data. All I am asking is for CDC communications to be fast and transparent. Tell the American people what we know, when we know it, and when we don't, so that they can make the best decisions for themselves and their families. As I mentioned, your best tool to keep pace with science is the private sector. Last week during the Committee's COVID hearing, I said that CDC can no longer be in charge of all testing in early days of novel threats. Let me be blunt, CDC's go alone mentality of the past on testing was arrogant and it was wrong. Let me propose a solution based upon the success that Dr. Hahn at the FDA led last year. Lean on your private sector partners, commercial labs, academic centers, large scale test makers like Beedi and Roche to rapidly develop diagnostics that serve as one great asset during an outbreak of an emerging infectious disease.

The same is true of the surveillance system. Last week, Dr. Jha from Brown University's Public Health School said, we need, "a new approach" to our surveillance. We discussed leveraging data sets like weather patterns and mobility information alongside traditional dedensified testing and patient data from health care providers. We need a layered surveillance system in partnership with the private sector, states, and local public health experts to get a true picture of the threats on the ground. The COVID relief packages have given CDC billions of dollars to modernize these systems. CDC must not hoard that money for yourselves. Instead use these funds to identify technologies that better equip us. I implore you to not build internal systems that only become obsolete before they even get up and running. Dr. Fauci, welcome back. You are everywhere these days. You and I have worked on these issues together for two decades. A lot of what we built together worked.

The NIH recognized the importance of technology, leveraging existing clinical trials and research networks, extending partnerships with the private sector through the NIH foundation and other avenues, establishing programs like RADx in partnership with BARDA to cast the widest net possible for novel technologies and testing. Now, the challenge will be for your center, along with the other institutes and centers at NIH, to maintain this pace and to apply to the next challenge or set of health care challenges in the future.

I am reminded this morning, as I read yesterday's article on Ebola breakout, that it seems that the strain of Ebola in this breakout might have been dormant for five years. That, yes, this is about what we know, but this is about what we don't know as well. Voices at the NIH will be important to determine how we can expand, solidify, and maintain this public, private approach to the biggest health care issues facing our Country. Dr. Marks, this is where you and your efforts at CBER come in. I can't think of another medical products center at FDA that will see more of the technologies that will benefit America's patients in the next decade.

The COVID vaccine comes through CBER for review, but so do cell and gene therapies. Many of them relying on new platforms that can be used for multiple devastating diseases and diagnosis. The pandemic, I believe, has altered the model at FDA and the agency should not go back to its historical approach. Dr. Hahn used his emergency authorities exactly as we envisioned the FDA using them.

In my mind, he, you and the dedicated professionals at the FDA are the unsung heroes of the Federal response. The EUA standard calls for the benefit to outweigh the risk, and we can adjust these authorizations as we learn during a response. This is how the statute is designed to work. Now, as the makers of these products, vaccines, tests, the treatments apply for full approval, the agency should take this opportunity to use real world information to inform their review. And I hope that you take advantage of the unique opportunity you have had. Each medical product center at FDA can apply their practices during the pandemic to the applications that come across their reviewers' desk. We can accelerate development to the benefit of patients here in the United States and more importantly around the world for more than just COVID, but for cancer, diabetes, and more. Stacking clinical trials, receiving rolling sets of data, coordinating with our global colleagues have been available tools at the agency for a long time. I urge you to continue to use these as you have over the past 12 months.

Dr. Kessler, David, it has been a long time. Much of what we have implemented, we didn't even talk about when you were FDA Commissioner. I don't think it was a lack of vision. I think it was yet developed future technologies. You were serving as FDA Commissioner when our first conversation about pandemic preparedness began though. Now, you are in a position to help use those authorities to their fullest extent. Operation Warp Speed or the new name, the Operation—did I get that right? Has used NIH expertise in early research, BARDA's contracting, advanced development and manufacturing capabilities, and the DOD's logistic muscle to achieve scientific breakthroughs that can rescue the world from this virus.

The Operation Speed was a huge success, and I am glad that you are planning on building on that success going forward. In the next few months, this project will have made available vaccines for all eligible Americans in record time without cutting any safety or efficacy corners at the FDA. The operation showed us where our gaps in countermeasure development exist. We need ways to rapidly identify candidates for tests, treatments, antivirals, and vaccines. This is an area primed for partnership with academia and especially the private sector. We also learned that our manufacturing capabilities came up short. But we saw a remarkable thing when private sector drug makers partnered with their competitors to make vaccines.

It is my hope that you are willing to work with my office to address the gaps that we found during the establishment of the operation and to uphold many pieces that worked for the future. Now, one year into the pandemic, even as the vaccine offers hope that a return to normal will continue and speed up, the offices and responsibilities that each of you hold, I believe, will become more

challenging. Not only will you be required to maintain the pace and urgency of our current response, but to begin to change the architecture of our public health agencies.

The novel coronavirus has irreversibly altered our ability as the Federal Government to interact with innovators that bring real solutions to the greatest health care challenges in generations. Do not take this moment for granted. Strengthen the relationships and partnerships that have been established during this response. Take stock of the needs that still exist and how partnerships like these can help us all to address them.

My staff and I are in the midst of a review with the same goal and my office is available to each of you at any time for us to work together on these efforts. I thank you for your willingness to serve at such a difficult time for our Country. I look forward to working with each of you to reopen our Country and memorialize what we have learned along the way. Thank you, Madam Chair.

The CHAIR. Thank you, Ranking Member Burr. I will now introduce today's witnesses. I am pleased to start by welcoming back Dr. Anthony Fauci, who has been a trusted voice and a guiding hand throughout the COVID-19 pandemic, and who now serves as Chief Medical Adviser on President Biden's COVID-19 response team.

Dr. Fauci, thank you for the work that you have done and continue to do to help us all get through this pandemic. Dr. Fauci was appointed Director of the National Institute of Allergy and Infectious Diseases in 1984 and has led that institute ever since. Over the years, he has advised six Presidents through deadly global health crises like HIV and AIDS, Zika, Ebola, and now COVID. Dr. Fauci received his M.D. from Cornell University and completed his residency at the New York Cornell Hospital Medical Center, now called the Weill Cornell Medical Center. He has been recognized with the National Medal of Science and the Presidential Medal of Freedom, among many others. Dr. Fauci, welcome and thank you for joining us again today.

Dr. Rochelle Walensky is the Director of the Centers for Disease Control and Prevention and Administrator of the Agency for Toxic Substances and Disease Registry. Prior to her appointment in January, Dr. Walensky was the Chief of the Division of Infectious Diseases at Massachusetts General Hospital and a Professor of Medicine at Harvard Medical School. Dr. Walensky has worked throughout her career to help advance the national and global response to HIV and AIDS and is also an expert on the testing and treatment of deadly viruses. During the COVID-19 pandemic, she has conducted crucial research on vaccine delivery and helped develop strategies to support underserved communities. Dr. Walensky received her M.D. from Johns Hopkins School of Medicine, trained in internal medicine at Johns Hopkins Hospital, became a fellow in the Massachusetts General Hospital and Brigham and Women's Hospital Infectious Diseases Fellowship program, and earned an MPH in Clinical Effectiveness from the Harvard School of Public Health. Dr. Walensky, congratulations on your appointment as Director. We are glad to have you here for what I am sure will be the first of many productive conversations with the Committee in your new role. Thank you.

Next, I want to introduce Dr. David Kessler. He is the Chief Science Officer of the Biden administration's COVID-19 response. In this role, Dr. Kessler is focused on crucial issues such as vaccine review and approval and the logistics of manufacturing millions more doses of vaccine. He has been instrumental in helping reach President Biden's goal of 100 million vaccinations in 100 days. Congratulations on that, doctor. He brings to his role a wealth of experience from his time serving as Commissioner of Food and Drugs under Presidents George H.W. Bush and President Bill Clinton, and from his work on a range of public health issues like HIV, AIDS, tobacco regulation, and helping Americans improve their nutritional habits. Dr. Kessler completed his J.D. at University of Chicago Law School, received his M.D. from Harvard Medical School, and completed his residency in Pediatrics at Johns Hopkins Hospital. Dr. Kessler, I am glad to have you with us today.

Dr. Peter Marks is the Director of the Center for Biologics Evaluation and Research for the Food and Drug Administration. It is a position he assumed in 2016, after serving as Deputy Director of the Center for several years. He has helped lead the center through the approval of several groundbreaking treatments, including the first CAR T-cell therapy for advanced cancer, the first gene therapies, and the first Ebola vaccine. Dr. Marks has played a critical role in the development of guidance for vaccine manufacturers and the authorization of COVID-19 vaccines. Dr. Marks received his M.D. and his Ph.D. in cell and molecular biology at New York University, and completed an internal medicine residency in hematology and oncology college fellowship at the Brigham and Women's Hospital.

After completing his training, Dr. Marks worked as a Clinician Scientist and later as Clinical Director of Hematology for Brigham and Women's Hospital, and later managed the adult leukemia service at Yale University and served as the Chief Clinical Officer of the Yale New Haven Hospital Cancer Center. Dr. Marks, we are very glad to have you with us today.

With that, we will begin our testimony. Dr. Fauci, I will start with you.

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, 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 and research addressing COVID-19. I think we have some slides, so if we could show them. If not, I will go without them. Next slide. The NIAID's strategic plan has four major components to it, improving fundamental knowledge of the virus, developing diagnostics and assays, characterizing and testing therapeutics, and finally developing safe and effective vaccines.

If I could have the next slide. The first that we will discuss—no back one, back one sorry. The first I will discuss is the characterization and testing of therapeutics. Next slide. When one thinks about therapeutics—next slide. When one thinks about thera-

peutics for COVID-19, one thinks of first, early to moderate disease and next moderate to advanced disease. In the first category, there are a number of interventions that have been approved either by the FDA, such as remdesivir, or have received emergency use authorization from the FDA, including monoclonal antibodies from Lilly and Regeneron.

In addition, convalescent plasma has received an EUA. If you move on to moderate or advanced disease, the standard of care now is dexamethasone, which in a randomized placebo controlled trial, has clearly shown a diminution in the overall mortality, over 28 days, in patients with advanced disease, including those requiring the mechanical ventilation as well as high flow oxygen. Next slide. However, the future of therapeutics we feel strongly lies in the identification of vulnerable targets in the SARS-COVID-2 replication cycle, and to design drugs to specifically inhibit those vulnerable targets. This has been a strategy that has been successful to a great degree with HIV drugs as well as the curative drugs for hepatitis C.

Next slide, the development of safe and effective vaccines—next. Although we have done very, very quickly with regard to the development of a vaccine, the work on a vaccine started literally decades before the January recognition that we were dealing with a new virus. And I refer specifically to the role of NIH, particularly the Vaccine Research Center, and our large number of grantees and contractors who for decades were doing basic preclinical and clinical research to develop new vaccine platforms, including the messenger-RNA, which has been so successful. In addition, at the Vaccine Research Center, the groundbreaking work of the stabilization of the pre-fusion spiked protein, which has served as the immunogen for five out of the six vaccines that are currently being tested under the auspices of the United States. And finally, we pivoted our extensive NIAID domestic and international clinical trials networks that have previously been established for HIV and influenza and have used them in the extensive clinical trials for COVID-19.

This slide shows the three platforms and six companies that have now been used successfully to develop the three vaccines that currently have an EUA with a very high degree of efficacy and a good safety profile, as well as two others that are on the way. Next slide. This slide is a prototype of what has happened with multiple vaccine candidates. It is an extraordinary reflection of scientific advances. On January 10th, the sequence of the virus was known. 65 days later, a Phase 1 trial was started. On July 27th, two of the vaccines went into Phase 3 trial, and in an extraordinary feat, 11 months later, less than 1 year, there was vaccines that had shown to be highly efficacious with a good safety profile. This is something that is unprecedented in the history of vaccinology and really is a reflection of not only the fundamental basic science advances, but extraordinary partnerships between the Government and the private sector.

On this final slide, although this is all good news, there still are challenges ahead, particularly with regard to the variants that have now become very familiar to us. They are mutational changes in the virus strains that challenge us both from the standpoint of spreading more rapidly, having a greater degree of pathogenesis,

and even evading some of our monoclonal antibodies. But we can counter that in two ways. One, by vaccination, maintaining the immune response against wild type, either by continuing to get a good quarter of vaccinations or boosting potentially in the future.

Also, and finally, as always, to continue to implement the public health measures in the forms of masks, distance, avoiding congregate settings, and washing hands. I will stop there and be happy to answer questions later, Madam Chair. Thank you.

[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's research addressing this pandemic.

COVID-19 is a once-in-a-lifetime global infectious disease pandemic requiring an unprecedented public-private research effort. NIAID plays a central and important role in the public health response to COVID-19. NIAID has capitalized on decades of investment in fundamental basic research, including groundbreaking structure-based vaccine design at the NIAID's Vaccine Research Center (VRC); engaged domestic and international research infrastructure; and leveraged highly productive partnerships with industry and longstanding relationships with community partners. NIAID utilized its existing domestic and international clinical trials infrastructure, originally established to conduct research on HIV and influenza, and worked with partners in the public and private sectors to establish the COVID-19 Prevention Network (CoVPN). CoVPN has supported multiple COVID-19 vaccine candidates to progress in record time from concept to authorization for emergency use by the U.S. Food and Drug Administration (FDA). NIAID initiated clinical trials with creative and adaptive designs, allowing the evaluation of multiple new and existing therapeutics for use against COVID-19. Several of these trials demonstrated safety and efficacy of COVID-19 therapeutics and helped support authorization by the FDA. These successes have helped slow the progression of the pandemic. Cases are decreasing, and the administration of FDA-authorized vaccines is increasing rapidly.

While we are cautiously optimistic about the future, we know that many challenges remain; we must continue to employ the proven public health measures that have brought us to where we are today. One of the most concerning developments of the ongoing pandemic is the detection of genetic variants of SARS-CoV-2, some of which appear to be more transmissible than the original virus and less responsive to certain therapeutic agents and vaccine formulations. So far, scientific evidence suggests that the COVID-19 vaccines distributed in the United States under FDA Emergency Use Authorization (EUA) continue to be effective against these variants, but we must remain vigilant. NIAID is rapidly conducting research to better understand these emerging variants of SARS-CoV-2, how they interact with the immune system, and their implications for COVID-19 therapeutic and vaccine formulations.

We also know that our fellow Americans in underserved and minority communities have been disproportionately affected by this pandemic. NIAID is committed to working directly with these communities and partnering with other agencies in the Federal Government, and with industry, and academia, to ensure that individuals in underserved and vulnerable communities are not left behind as we move forward toward defeating COVID-19. NIAID also recognizes that while many infections with SARS-CoV-2 resolve after a relatively short time, some individuals continue to suffer longer-term effects even after the virus has been eliminated from the body. NIAID is supporting collaborative efforts to study outcomes in patients across all ages, genders, and co-morbid conditions, who have experienced a wide range of severity of original disease, to identify and characterize these post-acute sequelae of SARS-CoV-2 infection (PASC) and develop effective strategies to address them.

Developing Vaccines and Therapies to Prevent COVID-19

Sustained investments by NIAID in structure-based vaccine design and coronavirus research over the years prior to the emergence of SARS-CoV-2 have enabled the unprecedented pace of COVID-19 vaccine development. Long before the pandemic, NIAID VRC scientists and their collaborators made the critical scientific discovery of how to stabilize in a highly immunogenic form viral proteins that are important for infection, including the spike protein of the Middle East respiratory syndrome coronavirus (MERS-CoV), using a mutation known as S2P. This key finding has facilitated the design of vaccine candidates that generate robust immune responses against coronaviruses and other viruses of public health importance such as respiratory syncytial virus. As soon as the sequence of SARS-CoV-2 was made available, VRC researchers were able to rapidly generate a stabilized SARS-CoV-2 spike protein for use in COVID-19 vaccine development. This crucial breakthrough in structure-based vaccine design for coronaviruses has led to the development of safe and effective COVID-19 vaccines across a range of vaccine platforms.

Five candidate COVID-19 vaccines have entered Phase 3 clinical trials in the United States thus far, and three subsequently have received an EUA from the FDA. Clinical trials to test COVID-19 vaccine candidates in pediatric populations are ongoing. On December 11, 2020, based on data from a Pfizer-supported Phase 3 clinical trial, an investigational vaccine developed by Pfizer and BioNTech became the first to receive an EUA from the FDA for the prevention of COVID-19 in individuals 16 years of age and older. NIAID has helped to advance four additional COVID-19 vaccine candidates through support for research on the foundational biology underlying the vaccine concepts as well as for clinical testing through the CoVPN. Two of these vaccine candidates have received EUAs.

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

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

mRNA-1273 (Moderna)

As part of a longstanding collaboration, the NIAID VRC worked with the biotechnology company Moderna, Inc., to develop a vaccine candidate designated as mRNA-1273, which uses a messenger RNA (mRNA) vaccine platform to express the stabilized SARS-CoV-2 spike protein.

Early clinical trials demonstrated that mRNA-1273 was generally well tolerated and induced robust neutralizing antibody responses in healthy adults. NIAID and BARDA then began working with Moderna on a Phase 3 clinical trial utilizing the CoVPN that showed that mRNA-1273 was 94.1 percent efficacious in preventing symptomatic COVID-19. On December 18, 2020, after a thorough review of comprehensive data on mRNA-1273, the FDA issued an EUA of the mRNA-1273 vaccine for prevention of COVID-19 in individuals 18 years of age and older.

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

Decades of NIAID support for basic, pre-clinical, and clinical research on adenovirus (Ad)-based HIV vaccines underpin the development by Janssen/Johnson & Johnson of a coronavirus vaccine based on the Ad26-vector, known as Ad26.COV2.S or JNJ-78436735. NIAID is supporting a Phase 3 clinical trial of Ad26.COV2.S through the CoVPN and has provided immunological testing of the

candidate using NIAID-funded core laboratory infrastructure. In late January 2021, Janssen/Johnson & Johnson released an interim analysis of the Phase 3 clinical trial indicating that the one-dose vaccine candidate was 66 percent effective overall at preventing moderate to severe/critical COVID-19 occurring at least 28 days after vaccination and 85 percent effective overall in preventing severe/critical COVID-19 across several geographical regions, including areas where emerging viral variants predominate. In the United States, the efficacy against moderate to severe/critical disease 28 days after vaccination was 72 percent. On February 27, 2021, the FDA issued an EUA for Ad26.COV2.S for prevention of COVID-19 in individuals 18 years of age and older.

Other COVID-19 Vaccine Candidates

NIAID, through the CoVPN, is supporting Phase 3 clinical trials of COVID-19 vaccine candidates from AstraZeneca (AZD1222) and Novavax (NVX-CoV2373). AstraZeneca's AZD1222 COVID-19 vaccine candidate uses a chimpanzee adenovirus-vectored vaccine approach developed by researchers at the University of Oxford in collaboration with scientists at NIAID's Rocky Mountain Laboratories. AstraZeneca has reported promising results from their international Phase 3 clinical trial of AZD1222; data from the U.S. trial of AZD1222 are pending.

Monoclonal Antibodies to Prevent COVID-19

NIAID scientists, collaborating with Regeneron Pharmaceuticals and Eli Lilly and Company, also initiated two Phase 3 clinical trials to evaluate whether their investigational monoclonal antibodies, known as REGEN-COV and bamlanivimab respectively, can prevent infection or symptomatic disease in people at high risk of exposure due to their living or working conditions. Each company recently reported promising initial results, and further analysis of the data from the trials is ongoing.

Identifying Therapeutics to Treat COVID-19

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

NIAID, in collaboration with other NIH Institutes, also launched two clinical trials as part of the ACTIV partnership, which utilizes master protocols allowing the addition of other investigational therapeutics as the trials continue. The two studies, ACTIV-2 and ACTIV-3, initially evaluated the use of the monoclonal antibody bamlanivimab to treat COVID-19 in outpatient and inpatient settings, respectively. Bamlanivimab was discovered by the company AbCellera in collaboration with the NIAID VRC and developed by Eli Lilly. Bamlanivimab received an FDA EUA in November 2020 for treatment of mild-to-moderate COVID-19 in patients with high risk for COVID-19 disease progression, based on data from a Lilly sponsored Phase 2 clinical trial. ACTIV-2, which is focused on outpatients, has since been expanded to evaluate a combination monoclonal antibody therapy, BRII-196 and BRII-198, as well as three investigational therapeutics: SNG001, an inhalable beta interferon; AZD7442, an investigational long-acting antibody combination; and camostat mesilate, an orally administered molecule that may block SARS-CoV-2 from entering cells. ACTIV-3 currently is evaluating the AZD7442 monoclonal antibody combination in hospitalized patients. In addition, NIAID launched a Phase 3 trial called, "Inpatient Treatment with Anti-Coronavirus Immunoglobulin," or ITAC, to evaluate hyperimmune intravenous immunoglobulin for treatment of COVID-19 in hospitalized adults. NIAID also began a Phase 3 CoVPN trial of an Eli Lilly combination therapy, bamlanivimab and etesevimab, for treatment of mild to moderate COVID-19.

NIAID also announced the ACTIV-5/Big Effect Trial (BET), which is designed to streamline the identification of experimental COVID-19 therapeutics that dem-

onstrate the most promise. BET, an adaptive Phase 2 clinical trial, compares different investigational therapies to a common control arm to identify treatments with relatively large effects as promising candidates for further study in large-scale trials. BET initially is evaluating two therapeutics: risankizumab, an immunomodulatory monoclonal antibody developed by Boehringer Ingelheim and AbbVie, which is FDA-approved for the treatment of severe plaque psoriasis; and lenzilumab, an investigational immunomodulatory monoclonal antibody developed by Humanigen.

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

Responding to Emerging Variants of SARS-CoV-2

NIAID is fully engaged in efforts to mitigate the potential impact of emerging variants of SARS-CoV-2. NIH, including NIAID, participates in the SARS-CoV-2 Interagency Group (SIG), which works to detect and characterize these new variants and to develop and adapt countermeasures to address them. The SIG was established by HHS to facilitate coordination among NIH, the Centers for Disease Control and Prevention (CDC), FDA, BARDA, the Department of Defense (DOD), and the U.S. Department of Agriculture (USDA) to detect and address SARS-CoV-2 variants as they emerge. NIH, CDC, and DOD are assessing whether vaccine-induced immunity, or natural immunity from prior infection, can be effective in combating the variants. NIH, BARDA, and DOD also are determining the efficacy of certain authorized therapeutics against emerging variants in cells and in animal models. In addition, NIAID is collaborating with vaccine manufacturers on key areas of research to investigate whether vaccines designed for the original strain of SARS-CoV-2 could maintain efficacy against emerging variants. NIAID also plans to test new vaccine formulations designed specifically to protect against certain variants that show early indications of reduced sensitivity to existing countermeasures.

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

Understanding the Immunology and Pathogenesis of COVID-19

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

NIAID, along with FDA, is supporting a National Cancer Institute (NCI) effort to determine the sensitivity and specificity of certain SARS-CoV-2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV-2. NCI and NIAID also are working to establish a collaborative network to increase national capacity for high-quality serological testing with rapid return-of-results to subjects.

These efforts include the use of serological testing to support clinical trials of convalescent serum and the establishment of registries for seroprotection studies. NIAID, NCI, the National Center for Advancing Translational Sciences, and the National Institute of Biomedical Imaging and Bioengineering are partnering on a study, called the Serological Sciences Network or SeroNet, to investigate whether adults in the United States without a confirmed history of SARS-CoV-2 infection have antibodies to the virus, thus indicating prior infection. The study is evaluating the durability of the immune response and aspects of the immune response that contribute to protection against COVID-19.

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

Monitoring the Long-term Effects of COVID-19

Many people who have had COVID-19 report continued symptoms as they transition from the acute to post-acute phases of the disease, and we continue to learn more about the duration and manifestations of COVID-19 as we hear from these patients. In December 2020, NIAID hosted a Workshop on Post-Acute Sequelae of COVID-19 with clinicians, immunologists, virologists, and members of the patient community to present existing data, identify key knowledge gaps, and explore different perspectives on this heterogeneous condition. Subsequently, NIH announced a trans-NIH effort to address PASC, including targeted funding for research in this critical area. The NIH PASC Initiative will complement ongoing NIAID studies to better understand the various post-acute manifestations of COVID-19 in various populations.

NIAID intramural scientists initiated the Longitudinal Study of COVID-19 Sequelae and Immunity to better understand PASC and determine whether people who have recovered from acute SARS-CoV-2 infection develop an immune response to SARS-CoV-2 that provides protection against reinfection. NIAID-supported investigators also have established the Immunophenotyping Assessment in a COVID-19 Cohort (IMPACC) to determine how immunological markers correspond to, or may even predict, the clinical severity of COVID-19. Since May 1, 2020, IMPACC researchers have collected detailed clinical data along with blood and respiratory samples from 1,800 hospitalized COVID-19 patients of diverse race and ethnicity at approximately 20 hospitals nationwide. The cohort will be followed during hospitalization and up to one year after discharge to assess their functional and immunologic recovery.

Conclusion

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

The CHAIR. Thank you, Dr. Fauci. We will turn to Dr. Kessler.

STATEMENT OF DAVID KESSLER, M.D., CHIEF SCIENCE OFFICER, COVID RESPONSE, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC

Dr. KESSLER. Chair Murray, Ranking Member Burr, distinguished Members of the Committee, I am Dr. David Kessler, and I am honored to be serving as the Chief Scientific Officer of the COVID-19 response. 40 years ago, I had the privilege of sitting in those seats behind you as the most junior member of the staff of this Committee led by Senator Hatch and Senator Kennedy. Thank you for having me back and for the opportunity to testify before you today.

Senator BURR. David, would you make sure that microphone is on or could you pull it just a little bit closer? There you go.

Dr. KESSLER. Today, the United States is in a very special position with three authorized vaccines for the prevention of COVID-19. I want to acknowledge the significant work of those who came before, who worked tirelessly to make this happen. If I can have the first slide, please. As you can see from that slide, when we get it up, we now have enough vaccine available for all American adults by May 31st.

When we first arrived at the President's direction, the operation, building on the work of our predecessors at BARDA, DOD, NIAID, FDA, CDC, HHS and the private sector, we made additional purchases of the Pfizer and Moderna vaccines, making 300 million doses of each available by July 31st. Working with Pfizer and Moderna, we were able to get each company to agree to deliver 200 million doses each. That is 200 million regimens each by the end of May. Then we also worked with Johnson and Johnson to help accelerate their delivery of 100 million doses by the end of May. To provide additional vaccine availability, we worked to forge an historic manufacturing collaboration between Johnson and Johnson and Merck. I want to update you, if I may, on three critical initiatives. First, as a pediatrician, we need to carefully evaluate data on the safety and effectiveness of the vaccines in adolescents and children.

We are currently supporting multiple clinical trials to help us understand vaccine safety and immunogenicity in pediatric populations, which is a high priority for us. Second, we are also working to address questions about variance. While the current vaccines have proven highly effective, we are also supporting studies on variants and efforts to reduce the next iteration of these vaccines. We will remain vigilant and pursue options to protect Americans if the need arises.

Finally, we are planning for a potential boost dose of vaccines if they are needed. We are studying the durability of existing vaccines and their ability to maintain an immunological response. As with other vaccines, a subsequent dose may be needed. There are many options that we can consider for booster doses. We are studying potential booster doses and planning now to have sufficient vaccine available, if necessary. I look forward to working with Members of this Committee as we address the issues that I have high-

lighted. Thank you for the opportunity to testify today and I look forward to your questions.

[The prepared statement of Dr. Kessler follows:]

PREPARED STATEMENT OF DAVID A. KESSLER

Chair Murray, Ranking Member Burr, distinguished Members of the Committee, I am Dr. David Kessler, and I am honored to be serving as the Chief Scientific Officer for the COVID-19 Response. I had the privilege of sitting in those seats behind you forty years ago, as a junior member of the Committee Staff when this Committee was led by Senator Hatch and Senator Kennedy. Thank you for having me back and for the opportunity to testify before you today, provide this update, and discuss our planned actions and priorities going forward.

Today, the United States is in a special position, with three vaccines authorized for the prevention of COVID-19. I am pleased to report that we are sending out more than 20 million doses each week, which has resulted in more than 27 percent of adults having their first dose, and more than 15 percent of all adults being fully vaccinated.

I want to acknowledge up front the important work that was done to bring a vaccine to the American people in record time. We are grateful for these efforts, including the contributions of Moncef Slaoui. As we advance new plans to deliver vaccines and therapeutics, I have the great privilege of working closely with General Gustave Perna and his team from the Department of Defense (DoD), as well as my colleagues from the Department of Health and Human Services (HHS) who are also appearing before you today.

It is important for Members of this Committee to know that today, there is one COVID-19 Response team that is coordinated throughout all levels of government. We are all part of that team. I have served in government before and I can tell you that this is an extraordinary level of coordination, focus, and commitment across government.

I pledge to work with all Members of this Committee and Congress as we advance our COVID-19 Response efforts to bring COVID-19 under control.

Today, I am here to share with you the latest information on vaccine supply and production and to discuss some of the challenges we need to address.

One of the first tasks that we undertook, when Pfizer and Moderna supplied the only two authorized vaccines, was to make 300 million doses of each available by July 31st of this year. Working with each company, we were then able to get them to agree to deliver 200 million doses each by the end of May.

Johnson & Johnson received an Emergency Use Authorization (EUA) for its COVID-19 vaccine from the U.S. Food and Drug Administration (FDA) on February 27, 2021. Soon after, we worked with Johnson & Johnson to accelerate their delivery of 100 million doses also by the end of May. Based on these commitments, President Biden announced that we would have enough vaccine available for all adults in the United States by May 31, 2021.

In addition, we helped forge a historic manufacturing collaboration between Johnson & Johnson and Merck to expand production of the Johnson & Johnson COVID-19 vaccine. The collaboration will increase manufacture of vaccine substance, as well as fill-finish capacity. President Biden recently announced that the United States plans to purchase another 100 million doses of the Johnson & Johnson vaccine.

While Moderna, Pfizer, and Johnson & Johnson have made combined commitments to provide enough vaccine for all American adults, these doses are not yet in hand and still need to be produced. I have worked throughout my career on drug regulation and I know that quality in the manufacturing of these vaccines is essential. There is a very strong government team supporting the efforts to produce these vaccines, working with the manufacturers to provide operational and logistical assistance to help them achieve these goals.

As President Biden has stated, there is a difference between simply having a vaccine supply and getting shots in arms. I am privileged to work with colleagues on the COVID-19 Response who coordinate efforts with state and local partners to deliver and administer those doses. We have provided Federal support for over 600 community vaccination centers, with Federal personnel on the ground at more than 200 community vaccination centers and mobile sites. We have also launched a program to directly send doses to 21 pharmacy companies, now including over 14,000 stores, and over 25 percent of doses were administered in high-risk communities. In addition, we have launched a program to directly send vaccine to community

health centers, with the initial phase to reach 250 centers, and the second phase to reach up to 700 additional centers. We stood up 19 high-volume, federally run sites that combined have a capacity to administer nearly 70,000 shots per day and which have already administered over one million shots in some of America's most disadvantaged neighborhoods. Sixty percent of doses administered at these federally run sites have gone to minorities. Underlying all of these efforts is an unwavering commitment to vaccine equity. We are committed to providing all Americans with equal access to these important vaccines.

Today, I want to provide specific updates on three topics that we know are vitally important to the overall effort to bring COVID-19 under control in America.

First, as a pediatrician, I know it is essential that we carefully evaluate data on the safety and effectiveness of the vaccines in adolescents and children. We are currently supporting multiple clinical trials in adolescents and children, including clinical trials with messenger RNA (mRNA), adenovirus, and recombinant protein vaccine platforms. Those studies will help us understand vaccine safety and immunogenicity in pediatric populations, which is a high priority for us. We expect to have that data in the coming months and they will be carefully reviewed by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), which, as it normally does, will rely on the recommendations of its Advisory Committee on Immunization Practices (ACIP).

In addition, we are confronting new and emerging variants. Over the last several months, we have witnessed an increasing prevalence in viral variants that have raised questions about how effective current vaccines will be in the future. Through our own funding of additional studies and close collaboration with developers that have funded independent trials, we have been able to get, and to continue to obtain, critical insight into this situation. While the current vaccines have proven highly effective, we continue to plan for the future. To that end, and as my colleagues will describe further, we have begun partnering with product developers to support efforts to produce the next iteration of these vaccines. We will remain vigilant and pursue options to protect Americans if the need arises.

The third issue I want to address today is our planning around the questions of if and when Americans who have been vaccinated might need a booster dose. In collaboration with my colleagues testifying today, we are studying the durability of the existing vaccines to continue to mount an effective immunological response. Preliminary data show that neutralizing antibodies persist for some time after the second dose of an mRNA vaccine with a relatively slow decline over time. As with other vaccines, such as the influenza vaccines, a subsequent dose may be important to provide continued protection against the wild-type strain but also may be critical to maintain protection against variants. The good news is that there are many potential options that we can consider for potential booster doses. We are evaluating and expanding studies to determine which options would be effective to achieve ongoing protection. As you can imagine there are numerous potential combinations of vaccine doses that might help protect Americans in the future. Therefore, we are also planning now to make sure we have sufficient vaccine available to support this potential need.

I look forward to working with Members of this Committee as we address the issues I have highlighted. Thank you for the opportunity to testify today on our recent COVID-19 Response actions.

The CHAIR. Thank you, Dr. Kessler. We will turn to Dr. Marks.

STATEMENT OF PETER MARKS, M.D., PH.D., DIRECTOR, CENTER FOR BIOLOGICS EVALUATION AND RESEARCH, UNITED STATES FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. MARKS. Chair Murray, Ranking Member Burr, distinguished Members of the Committee, I am Peter Marks, Director of the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration. Thank you for the opportunity to testify before you today to describe the agency's COVID-19 response efforts. All of our efforts are in close coordination and collaboration with our partners across the Federal Government to help ensure the de-

velopment, authorization, or licensure and availability of safe and effective medical products to address the COVID-19 public health emergency.

While my testimony will focus on FDA's work regarding COVID-19 vaccines, I want to note at the outset that this is in the context of the breadth of work that we are doing across the agency to address the pandemic, including our work on therapeutics and diagnostics. With the urgency called for during this pandemic, FDA, through our transparent scientific review process, has provided Emergency Use Authorization, or EUA for short, for three COVID-19 vaccines.

In doing so, we have relied upon the agency's rigorous standards for safety, effectiveness, and manufacturing quality. Though there may be some differences in the results obtained using these three COVID-19 vaccines, it should be noted that they were not compared in a head to head clinical trial. All three were found by FDA and its external advisory committee to exceed the standards for an EUA that we articulated in guidance, and importantly, all did an excellent job in preventing hospitalization and death from COVID-19. Following vaccine authorization or approval, FDA works with manufacturers to help ensure continued supply and availability of these critical medical products. The agency does this by promptly reviewing proposed technical or manufacturing changes and monitoring the continued quality of these products.

For example, FDA recently reviewed the data submitted by Pfizer to allow undiluted frozen vials of the Pfizer-BioNTech vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers for up to two weeks. This will help ease the burden of procuring ultra-cold storage equipment for vaccination sites and should help to get vaccines to more places. FDA also plays an integral role in the monitoring of the safety of authorized COVID-19 vaccines. FDA is doing so in collaboration with the Centers for Disease Control and Prevention, the Center for Medicare and Medicaid Services, Department of Veterans Affairs, and other academic and large non-Governmental health care data systems.

In addition, FDA actively participates in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities and the World Health Organization. These efforts are in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers of the authorized vaccines. Given the importance of passive and active safety monitoring, a coordinated and overlapping approach using state of the art technology has been implemented. These systems can also potentially be leveraged to assess safety in specific populations and assess vaccine effectiveness including against emerging variants. The emergence of such virus variants raises new concerns about the performance of the authorized COVID-19 vaccines, as well as therapeutics and diagnostics. Just last month, FDA issued three new guidances and an update to our vaccine EUA guidance to address the emergence of SARS-COVID-2 variants.

By issuing these, we want the American public to know that we are using every tool at our disposal to fight this pandemic, includ-

ing pivoting as the virus adapts. These guidances will help manufacturers develop medical products to provide healthcare providers with the best available diagnostics, therapeutics, and vaccines to fight this virus even as variants emerge. We remain committed to getting these lifesaving products to the front lines. In closing, I would like to stress that having three vaccines authorized by FDA only one year after the declaration of the pandemic is a tremendous achievement and a testament to the dedication of a multitude of partners. And these include FDA's career scientists and physicians who have been working tirelessly to conduct comprehensive and rigorous evaluation of the data submitted for vaccines to prevent COVID-19.

All of those working at the agency are also grateful to be able to contribute immeasurably toward bringing this pandemic to an end. Thank you and I look forward to responding to your questions.

[The prepared statement of Dr. Marks follows:]

PREPARED STATEMENT OF PETER MARKS

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

While my testimony will focus on FDA's work regarding COVID-19 vaccines, I want to note at the outset that this is in the context of the breadth of work FDA is doing across the Agency to address this pandemic, including our efforts on diagnostics and therapeutics.

With the urgency called for during this pandemic, FDA, through our transparent scientific review process, has provided Emergency Use Authorization (EUA) for three COVID-19 vaccines. In doing so, we have relied upon the Agency's rigorous standards for safety, effectiveness, and manufacturing quality. Vaccine development is a highly de-risked process that generally proceeds sequentially through the various stages of clinical development, and manufacturing scale-up only takes place when it is very clear that the vaccine is safe and effective and is on track for regulatory approval. These vaccines were developed without cutting corners or sacrificing our standards. Intensive interactions between FDA and manufacturers eliminated the time between different studies in the clinical development process; allowed seamless movement between the different phases of clinical trials; and simultaneously proceeded with manufacturing scale-up before it was clear whether the vaccine would be shown to be safe and effective. For the three vaccines authorized to date, our EUA process not only included a thorough evaluation of the data by the Agency's career staff, but also included input from independent scientific and public health experts through our public advisory committee process. Throughout this process, FDA took additional steps to facilitate transparency, such as posting sponsor and FDA briefing documents and key decisional memoranda.

The three authorizations make available COVID-19 vaccines in the United States that have shown clear and compelling efficacy in large, well-designed phase 3 trials and that meet rigorous standards for safety and effectiveness. Vaccines will help us in the fight against this pandemic, which has claimed over half a million lives here in the United States alone. All the COVID-19 vaccines that FDA has authorized for emergency use have surpassed the standard of being at least 50 percent more effective than placebo in preventing COVID-19, which was the standard recommended in our June 2020 guidance document, *Development and Licensure of Vaccines to Prevent COVID-19*.¹ A vaccine with at least 50 percent efficacy would have a significant impact on disease, both at the individual and societal level.

¹ <https://www.fda.gov/media/139638/download>.

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.² The information includes fact sheets with important information such as dosing instructions; information about the benefits and risks of each vaccine; and topical Questions and Answers developed by FDA for each vaccine.

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

At this time, data are not available to make a determination about how long the vaccines will provide protection, nor are we certain that the vaccines prevent transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) from person to person.

Finally, manufacturers whose COVID-19 vaccines have been authorized for emergency use are expected to continue their clinical trials in order to obtain additional safety and effectiveness information and pursue licensure (approval) through the submission of a Biologics License Application (BLA).

FDA's Role Working With COVID-19 Vaccine Manufacturers

FDA plays a critical role in the development and authorization or licensure of vaccines, spanning the entire product lifecycle. The Agency provides scientific and regulatory advice to industry, researchers, and other stakeholders across the vaccine development spectrum. Interactions with product developers begin long before any formal regulatory submission is made and continue throughout development under FDA's investigational new drug application process. FDA is committed to working with all manufacturers developing products to prevent or treat COVID-19 and has had numerous interactions with COVID-19 vaccine manufacturers studying these products and seeking emergency use authorization.

FDA makes use of all available regulatory tools and expedited programs, as appropriate, to help advance products critical for public health, from product development to when a product application is submitted to FDA for our evaluation of safety and effectiveness to support approval.

Following approval of a BLA or authorization of an EUA request, the Agency uses real-world data to monitor the safety of vaccines through both passive and active post-market surveillance. Passive surveillance involves the submission of adverse event reports by patients, providers, and manufacturers to FDA. The Agency also performs active post-market surveillance of vaccines through various data bases, including FDA's Sentinel system.

FDA works with manufacturers of approved or authorized products to help ensure continued supply and availability of critical medical products. The Agency does this by promptly reviewing proposed technical or manufacturing changes and monitoring the continued quality of these products. For example, CBER recently reviewed data submitted by Pfizer to FDA to allow undiluted frozen vials of the Pfizer-BioNTech COVID-19 vaccine to be transported and stored at conventional temperatures commonly found in pharmaceutical freezers for up to two weeks. This will help ease the burden of procuring ultra-low cold storage equipment for vaccination sites and should help get vaccine to more sites.

FDA is committed to providing timely scientific and regulatory advice to support rapid COVID-19 response efforts. To assist manufacturers with the development of COVID-19 vaccines, provide recommendations, and outline FDA's expectations, the Agency issued specific COVID-19 vaccine guidances. In June 2020, FDA issued guidance titled *Development and Licensure of Vaccines to Prevent COVID-19*. In October 2020, FDA issued guidance titled *Emergency Use Authorization for Vaccines to Prevent COVID-19* and updated it in February 2021.³

During the COVID-19 public health emergency, FDA is utilizing all available tools and sources of information to support regulatory decisions on applications or EUA requests that include manufacturing sites where FDA's ability to inspect facilities is impacted due to COVID-19. During this interim period, we are using additional tools, where available, to determine the need for an onsite inspection and to

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

³ <https://www.fda.gov/media/142749/download>.

support the application assessment, such as reviewing a firm’s previous compliance history, and requesting records in advance of or in lieu of onsite inspections or voluntarily from facilities and sites. Following notice by a sponsor of intent to submit an EUA request, FDA will continue to work with the sponsor regarding resolution of any necessary manufacturing site issues resulting from a site visit or other information submitted. FDA will assess current good manufacturing practices (CGMP) or CGMP compliance for each manufacturing site using all available tools and information.

The EUA Process for COVID-19 Vaccines

A determination by the HHS Secretary issued on February 4, 2020, declared that there is a public health emergency that has significant potential to affect national security or the health and security of U.S. citizens living abroad. Declarations were issued stating that circumstances exist justifying the authorization of emergency use of unapproved products. These declarations permitted FDA to issue EUAs to allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent COVID-19 when there are no adequate, approved, and available alternatives.

The issuance of an EUA is different than an FDA approval (licensure) of a vaccine, in that a vaccine available under an EUA is not approved. In determining whether to issue an EUA for a vaccine, FDA evaluates the available evidence to determine whether the product may be effective, and assesses any known or potential risks and any known or potential benefits. If there is evidence that convinces us that the vaccine may be effective and the benefit-risk assessment is favorable, it is made available during the public health emergency. Once a manufacturer submits an EUA request for a COVID-19 vaccine to FDA, the Agency evaluates the request and determines whether the relevant statutory criteria are met, taking into account the totality of the scientific evidence about the vaccine that is available to FDA.

The EUA requires fact sheets that provide important information, including dosing instructions and information about the benefits and risks of the COVID-19 vaccines, be made available to vaccination providers and vaccine recipients.

Each of the manufacturers of FDA-authorized COVID-19 vaccines submitted a pharmacovigilance plan to FDA describing their commitment to monitor the safety of their vaccines. The pharmacovigilance plans include plans to complete longer-term safety followup for participants enrolled in ongoing clinical trials. The pharmacovigilance plans also include other activities aimed at monitoring the safety profile of the COVID-19 vaccines and ensuring that any safety concerns are identified and evaluated in a timely manner. FDA also expects manufacturers whose COVID-19 vaccines are authorized under an EUA to continue their clinical trials to obtain additional safety and effectiveness information and pursue approval (licensure).

Specific details about each of the authorized vaccines are provided below.

PFIZER COVID-19 VACCINE

On December 11, 2020, FDA issued the first EUA for a vaccine for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The EUA allows the Pfizer-BioNTech COVID-19 Vaccine to be distributed in the United States.

The Pfizer-BioNTech COVID-19 Vaccine contains messenger RNA (mRNA), which is genetic material. The vaccine contains a small piece of the SARS-CoV-2 virus’ mRNA that instructs cells in the body to make the virus’ distinctive “spike” protein. When a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to produce an immune response against SARS-CoV-2.

FDA Evaluation of Available Safety Data

The Pfizer BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart. The available safety data to support the EUA include 37,586 participants enrolled in an ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants. These participants, 18,801 of whom received the vaccine and 18,785 of whom received saline placebo, were followed for a median of two months after receiving the second dose. The most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, and fever. Of note, more people experienced these side effects after the second dose than after the first dose, so it

is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but more after the second dose.

FDA Evaluation of Available Effectiveness Data

The effectiveness data to support the Pfizer BioNTech EUA include an analysis of 36,523 participants in the ongoing randomized, placebo-controlled international study, the majority of whom are U.S. participants, who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Among these participants, 18,198 received the vaccine and 18,325 received placebo. The vaccine was 95 percent effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. Of these 170 COVID-19 cases, one in the vaccine group and three in the placebo group were classified as severe.

MODERNA COVID-19 VACCINE

On December 18, 2020, FDA issued an EUA for the second vaccine for the prevention of COVID-19 caused by SARS-CoV-2. The EUA allows the Moderna COVID-19 Vaccine to be distributed in the U.S for use in individuals 18 years of age and older.

Like the Pfizer-BioNTech COVID-19 Vaccine, the Moderna COVID-19 Vaccine contains a small piece of the SARS-CoV-2 virus' mRNA that instructs cells in the body to make the virus' distinctive "spike" protein. After a person receives this vaccine, their body produces copies of the spike protein, which does not cause disease, but triggers the immune system to produce an immune response against SARS-CoV-2.

FDA Evaluation of Available Safety Data

The Moderna COVID-19 Vaccine is administered as a series of two doses, one month apart. The available safety data to support the EUA include an analysis of 30,351 participants enrolled in an ongoing randomized, placebo-controlled study conducted in the U.S. These participants, 15,185 of whom received the vaccine and 15,166 of whom received saline placebo, were followed for a median of more than two months after receiving the second dose. The most commonly reported side effects, which typically lasted several days, were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, swollen lymph nodes in the same arm as the injection, nausea and vomiting, and fever. Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but more after the second dose.

FDA Evaluation of Available Effectiveness Data

The effectiveness data to support the Moderna COVID-19 EUA include an analysis of 28,207 participants in the ongoing randomized, placebo-controlled U.S. study who did not have evidence of SARS-CoV-2 infection prior to the first dose of vaccine. Among these participants, 14,134 received the vaccine and 14,073 received placebo. The vaccine was 94.1 percent effective in preventing COVID-19 disease among these clinical trial participants with 11 cases of COVID-19 in the vaccine group and 185 in the placebo group. At the time of the analysis of these 196 COVID-19 cases, none in the vaccine group and 30 in the placebo group were classified as severe. After the analysis of these 196 cases was completed, one severe case in the vaccine group was identified and was awaiting confirmation at the time the EUA was issued.

JANSSEN (JOHNSON & JOHNSON) COVID-19 VACCINE

On February 27, 2021, FDA issued an EUA for the third vaccine for the prevention of COVID-19 caused by SARS-CoV-2. The EUA allows the Janssen COVID-19 Vaccine to be distributed in the United States for use in individuals 18 years of age and older.

The Janssen COVID-19 Vaccine is manufactured using a specific type of virus called adenovirus type 26 (Ad26). The vaccine uses Ad26 to deliver a piece of the DNA, or genetic material, that is used to make the distinctive "spike" protein of the SARS-CoV-2 virus. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body or cause illness. After a

person receives this vaccine, the body can temporarily make the spike protein, which does not cause disease, but triggers the immune system to produce an immune response against SARS-CoV-2.

FDA Evaluation of Available Safety Data

The Janssen COVID-19 Vaccine is administered as a single dose. The available safety data to support the EUA include an analysis of 43,783 participants enrolled in an ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the United States. The participants, 21,895 of whom received the vaccine and 21,888 of whom received saline placebo, were followed for a median of eight weeks after vaccination. The most commonly reported side effects were pain at the injection site, headache, fatigue, muscle aches, and nausea. Most of these side effects were mild to moderate in severity and lasted one to two days.

FDA Evaluation of Available Effectiveness Data

The effectiveness data to support the Janssen EUA include an analysis of 39,321 participants in the ongoing randomized, placebo-controlled study being conducted in South Africa, certain countries in South America, Mexico, and the United States who did not have evidence of SARS-CoV-2 infection prior to receiving the vaccine. Among these participants, 19,630 received the vaccine and 19,691 received saline placebo. Overall, the vaccine was approximately 67 percent effective in preventing moderate to severe/critical COVID-19 occurring at least 14 days after vaccination and 66 percent effective in preventing moderate to severe/critical COVID-19 occurring at least 28 days after vaccination.

Additionally, the vaccine was approximately 77 percent effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85 percent effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination.

There were 116 cases of COVID-19 in the vaccine group that occurred at least 14 days after vaccination, and 348 cases of COVID-19 in the placebo group during this time period. There were 66 cases of COVID-19 in the vaccine group that occurred at least 28 days after vaccination and 193 cases of COVID-19 in the placebo group during this time period. Starting 14 days after vaccination, there were 14 severe/critical cases in the vaccinated group versus 60 in the placebo group, and starting 28 days after vaccination, there were five severe/critical in the vaccine group versus 34 cases in the placebo group. In this trial, no individuals receiving the vaccine required hospitalization or died starting 28 days after the vaccine compared to 16 individuals receiving placebo.

COVID-19 VACCINE SAFETY SURVEILLANCE

CBER is monitoring the safety of authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with CDC, the Center for Medicare & Medicaid Services (CMS), the Department of Veterans Affairs, and other academic and large non-government healthcare data systems. In addition, CBER participates actively in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities and the World Health Organization. These efforts are in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers for authorized vaccines. A coordinated and overlapping approach using state-of-the-art technologies has been implemented.

Passive Surveillance

Passive surveillance is defined as unsolicited reports of adverse events that are sent to a central data base or health authority. In the United States, these are received and entered into the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety monitoring system co-managed by FDA and CDC. In the current pandemic, these reports are being used in conjunction with other vaccine safety systems to monitor the occurrence of certain adverse events including serious adverse events, as providers of COVID-19 vaccines are required to report these to VAERS. FDA efforts complement those of the v-safe text-based monitoring system for adverse events that CDC has implemented. An example of the work done with passive safety surveillance during the current pandemic has been the evaluation of severe allergic reactions following vaccination with the authorized mRNA-based COVID-19 vaccines. Through this work, we have come to understand that these re-

actions are quite rare, happening in fewer than five in one million vaccine doses administered.

Active Surveillance

Active surveillance involves proactively obtaining and rapidly analyzing information occurring in millions of individuals recorded in large healthcare data systems to verify safety signals identified through passive surveillance or to detect additional safety signals that may not have been reported as adverse events to passive surveillance systems. FDA is conducting active surveillance using the Sentinel BEST (Biologics Effectiveness and Safety) System and the CMS system, and is also collaborating with other Federal and non-Federal partners.

BEST

To elaborate further, the BEST system, which is part of the Sentinel initiative, comprises large-scale claims data, electronic health records (EHR), and linked claims-EHR data bases with a data lag of approximately three months. The system makes use of multiple data sources and enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines. The linked claims-EHR data base makes it possible to study the safety of vaccines in sub-populations with pre-existing conditions or in pregnant women. The major partners for BEST currently are Acumen, IBM Federal HealthCare, IQVIA, and Columbia University and many affiliated partners such as MedStar Health, BlueCross BlueShield of America, the Observational Health Data Sciences and Informatics, OneFlorida, University of California, and several others.

Using BEST, CBER plans to monitor about 15 adverse events that have been identified with the deployment of previous vaccines but have yet to be associated with a safety concern for an authorized COVID-19 vaccine at this time. CBER further plans to use the BEST system to conduct more in-depth analyses should a safety concern be identified from sources such as VAERS.

Collaboration with CMS

CBER has worked over the past several years with CMS to develop capabilities for routine and time-sensitive assessments of the safety of vaccines for people 65 years of age and older using the Medicare Claims data base. Because it was already in place, having demonstrated its use for the evaluation of influenza vaccine safety and efficacy, this system was immediately put into use for COVID-19 vaccine surveillance to monitor for adverse events.

During the current pandemic, FDA, CMS, and CDC have already used the Medicare data to publish a study showing that frailty, comorbidities, and race/ethnicity were strong risk factors of COVID-19 hospitalization and death among the U.S. elderly.

In summary, in collaboration and coordination with several different partners, CBER has assembled passive and active surveillance systems that can detect and refine safety findings with the recently authorized COVID-19 vaccines in a relatively rapid manner. These systems can also potentially be leveraged to assess safety in specific subpopulations and to assess vaccine effectiveness, including against emerging variants.

NEXT STEPS

The emergence of the virus variants raises new concerns about the performance of these authorized vaccines, as well as therapeutics and diagnostics that FDA has authorized for COVID-19. In February 2021, FDA issued two new guidances and an update to its vaccine EUA guidance to address the emergence of SARS-CoV-2 variants of concern.⁴ By issuing these guidances, we want the American public to know that we are using every tool in our medical toolbox to fight this pandemic, including pivoting as the virus adapts. These guidances will help manufacturers to develop medical products to provide health care providers with the best available diagnostics, therapeutics, and vaccines to fight this virus—even as variants emerge. We remain committed to getting these life-saving products to the frontlines.

⁴ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

CONCLUSION

The process FDA uses to evaluate the safety and effectiveness of medical products is respected worldwide and commonly referred to as the “gold standard.” Because of a well-established history, the Agency’s review processes are globally recognized as the most rigorous and accurate.

Having three vaccines authorized that meet the FDA’s expectations for safety and effectiveness only one year after the declaration of the pandemic is a tremendous achievement and a testament to the dedication of developers and FDA’s career scientists and physicians, many of whom have been working tirelessly to conduct comprehensive and rigorous evaluations of the data submitted for vaccines to prevent COVID–19. The Agency is very proud of these efforts, and we hope that the vaccines will help bring this pandemic to an end.

The CHAIR. Thank you, Dr. Marks. We will turn to Dr. Walensky.

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

Dr. WALENSKY. Thank you, Chair Murray and Ranking Member Burr, for your invitation to talk with you today and for your leadership during the U.S. response to COVID–19. I have had the honor of being the Director of the Centers for Disease Control and Prevention for two months. Taking on this role in the middle of a pandemic has presented no shortage of challenges. And I am so grateful for the guidance of the dedicated staff at CDC and the deep expertise they bring.

CDC staff continue to work tirelessly to respond to the COVID–19 pandemic, and I am committed to supporting their efforts to ensure that science and evidence drive our path forward. Last week we crossed the one-year mark since WHO declared COVID–19 a global pandemic. I want to take a moment to recognize the more than 500,000 American lives lost during the past year. That is half a million mothers, fathers, sisters, brothers, grandparents, and children who have died because of this virus. Every loss is felt by grieving families, by friends unable to say goodbye, and by communities that have been devastated by this pandemic. While we have recently seen reductions in cases and deaths, we must remain cautious.

The average daily death rate is still tragically still more than twice the rate seen last September. We are in a race to stop transmission, and the emergence of variants that spread more easily has made us even more challenging. I am committed to closely monitoring the proliferation of these variants in this Country and around the world. We are doing that by rapidly scaling up genomic sequencing and we are well on our way to 25,000 samples per week. As we monitor disease transmission and variants, we are getting vaccines into arms quickly, safely, and as equitably as possible. Having three vaccines that you just heard about that are highly effective at preventing serious illness, hospitalization, and death will help us end this pandemic. As of March 17th, more than 113 million doses of COVID–19 vaccine have been administered, over 73 million people have received at least one dose, including 40 million who are fully vaccinated. This is a remarkable accomplishment, and yet we have so much more to do.

CDC is working in coordination with national, state, tribal, local, Governmental, and non-Governmental partners to build trust in the vaccines, the vaccinator, and the vaccination system. Instrumental to this work is addressing barriers to vaccinations in communities of color and disproportionately affected groups. COVID-19 has highlighted long standing systemic health disparities and health equity must be a cornerstone of our public health work. CDC is committed to expanding evidence based approaches to reduce disparities and COVID-19 cases, hospitalizations and deaths, prioritizing equity in vaccine distribution and expanding a diverse workforce. This is not our first emergency. Since 2009, the U.S. has faced four significant emerging infectious disease threats, the H1N1 influenza pandemic, Ebola, Zika, and now COVID-19.

While urgency demanded rapid and unique approaches in response to each of these threats, none resulted in the necessary sustained investments for public health infrastructure. This lack of preparation continues to present significant challenges in our ongoing fight on COVID-19. If we don't act with permanent fixes, these challenges will continue to exist when the next public health threat emerges. I would like to leave you with four points today. First, CDC is leading with science and will continue to be the public health resource, scientific resource for the American public and for our international partners.

Second, we are expanding the reach of lifesaving vaccines and improving vaccine confidence. To end this pandemic, we must also maintain proven effective prevention measures, masks, and hygiene, and physical distance. Third, health equity must be at the intersection of everything we do in public health, and I am committed to doing that as CDC Director. And we must work toward sustainable investments in public health infrastructure to be better prepared for whatever comes next. I look forward to working together to address both the immediate challenges ahead and the deficiencies in our public health infrastructure that left our Country vulnerable to this pandemic.

We will get through this pandemic and I look forward to working with you to support CDC and address our public health challenges at home and abroad. Thank you again for the invitation to testify today and I look forward to answering your questions.

[The prepared statement of Dr. Walensky follows:]

PREPARED STATEMENT OF ROCHELLE P. WALENSKY

Madam 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. I am grateful for this opportunity to address this Committee as well as for your partnership and leadership in responding to COVID-19.

It is my privilege to represent CDC. CDC is America's health protection agency. We work 24/7 to prevent illness, save lives, and protect America from threats to our health, safety, and security. CDC is proud of its key role in preparedness and response to public health concerns here in the U.S. and abroad. Addressing infectious diseases and pandemics, like COVID-19, is central to our mission. CDC's expertise lies in our ability to study emerging pathogens like SARS-CoV-2, to understand how they are transmitted, and to translate that knowledge into timely public health action. By deploying experts on the ground to support our state, Tribal, local, and territorial partners, we translate science into guidance that protects individuals, communities, and populations. In our work with other Federal agencies we ensure the

safe and appropriate use of medical countermeasures, including vaccines, and collaborate with the academic sector to further our understanding of new diseases.

I've had the honor of being the Director of this agency for just under two months, and it is clear to me that all of this work is done by expert staff with great dedication to, and pride in, their work. They work tirelessly to respond to the COVID-19 pandemic, and I am committed to making sure that their efforts to conduct and analyze the data allow science to drive our path forward.

CDC Efforts to Date

As you are aware, COVID-19 cases have decreased from their highest points in December and early January. As of March 12th, the weekly average number of cases has decreased by 11 percent over the previous week's average. The number of deaths has also fallen, with an 19 percent change over the same period.

We are hopeful. And, still, we must remain cautious. The average daily case rate is still more than twice the rate seen last September before cases started rising through the fall.

It goes without saying, we have been tested over the past year. It has been an extraordinarily difficult time for the United States. And I want to take a moment to recognize the more than 500,000 Americans, half a million mothers, fathers, sisters, brothers, wives, husbands, grandparents, and children, who have died because of the pandemic. Every loss is felt. By grieving families, by friends who are unable to say goodbye because of hospital mitigation strategies, by communities devastated by the disparate impact of this virus.

As hard as this has been, we can still persevere. If we can just stay the course a little longer and maintain evidence-based mitigation measures, while vaccinations continue to ramp up, we can prevent a lot of disease and save a lot of lives.

Right now, we are in a race to stop transmission. Variants of this virus that have slight genetic differences from the initial strain have emerged and available data suggest some are more transmissible. CDC is taking steps to expand sequence surveillance across the U.S. to improve our understanding about the impact of these variants on vaccine effectiveness, severity of disease, transmission, and mortality.

We must continue to use every tool we have to fight this virus: wearing masks, social distancing, handwashing, and administering vaccines.

The scale of this unprecedented public health emergency requires unprecedented action—at CDC, more than 8,500 CDC personnel have been part of our COVID-19 response, both at CDC headquarters and in the field. More than 1,500 staff have taken part in over 3,000 deployments to nearly 300 cities across the U.S. and around the world.

CDC is working to ensure that public health decisions are based on the highest-quality scientific information.

Since the start of the pandemic, over 200 COVID-19 studies have been published in the Morbidity and Mortality Weekly Report (MMWR) on topics ranging from health disparities exacerbated during the pandemic, to mitigation strategies to prevent spread, to emergence of new variants, and CDC has produced more than 5,000 documents to provide information and guidance for government agencies, businesses, and the public.

The new resources provided by **President Biden's American Rescue Plan** will further **scale up the public health efforts needed to contain the virus**, through six critical priorities:

- a strengthened national vaccination program,
- increased testing to protect at-risk populations,
- expansion of the public health workforce,
- protection for vulnerable populations,
- a commitment to U.S. leadership in the global response, and
- enhanced surveillance to identify emerging strains.

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

Variants

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

In the fall of 2020, several SARS-CoV-2 variants emerged, some of which appear to spread more easily than others. An increase in viral transmission could reverse the progress we've made and the downward trend in COVID-19 cases that we have seen since early January. We are at risk, once again, of overtaxing an overwhelmed health system. Furthermore, there is concern with how well the variants are neutralized by antibodies elicited through prior infection or vaccination. The emergence of variants is, of course, concerning, and it underscores the critical need for genomic surveillance and increased vigilance in the implementation of public health mitigation measures.

In anticipation of these ongoing threats, the Department of Health and Human Services (HHS) established the SARS-CoV-2 Interagency Group to improve coordination across the CDC, National Institutes of Health, Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority, United States Department of Agriculture, and Department of Defense. This interagency group is focused on the rapid characterization of the emerging variants of concern and is actively monitoring the potential impact on critical SARS-CoV-2 countermeasures including vaccines, therapeutics, and diagnostics.

Of the emerging variants, three have captured our attention and have the highest risk to the public health: B.1.1.7, B.1.351, and P.1.

The B.1.1.7 variant, originally identified in the United Kingdom, was first identified in the United States on December 29, 2020. As of March 15, 2021, CDC is reporting 4,500 cases in 50 jurisdictions that are attributed to the B.1.1.7 variant. As of March 10, data from CDC national surveillance showed that B.1.1.7 viruses represented 7 percent of the viruses circulating for the week ending February 27th, but the current trajectory suggests that the B.1.1.7 variant may now account for as much as 25–30 percent of US viruses. The prevalence of B.1.1.7 is expected to continue to increase as a proportion of all cases. Importantly, variant proportions are dynamic and are not the same in all parts of the country.

The B.1.351 variant, first identified in South Africa, and the P.1 variant, first identified in Brazil, have also been identified in the United States. CDC is reporting 81 B.1.351 cases in 20 jurisdictions and 15 P.1. cases in nine jurisdictions.

New data from a collaboration between CDC and Emory University suggest that antibodies generated against previous infection or vaccination with the Moderna vaccine are able to neutralize the B.1.1.7 variant but have reduced neutralization against the B.1.351 variant. It is unclear what impact this will have on the real-world effectiveness of current vaccines against the B.1.351 variant, and efforts are ongoing to better understand the impact of the variants on medical countermeasures. CDC has been acting on multiple fronts to increase surveillance in the United States to detect variants of SARS-CoV-2.

At CDC, we're contracting with several large commercial diagnostic laboratories to get viral sequence data from around the country. These laboratories are currently providing data on about 6,000 virus samples per week and will expand to capture 25,000 samples per week, with support from the funding the Administration announced last month and resources provided by the American Rescue Plan Act. In addition, public health laboratories around the country are sending CDC samples from 750 cases each week. These samples will allow us to both get the viral sequences and isolate the viruses so that we can do additional laboratory testing to better understand virulence, transmissibility and the potential impacts on diagnostic tests, therapeutics, and vaccines. Moreover, U.S. state and local public health laboratories are also sequencing 4,000 specimens per week and using the data to better understand the local epidemiology and to control outbreaks. In addition, U.S. academic institutions and industry are also sequencing another 4,000 viruses per week. These efforts are coordinated through CDC's SPHERES collaboration, which is a new national genomics consortium to coordinate large-scale SARS-CoV-2 sequencing across the country. In all, the U.S. is currently sequencing about 4 percent of the roughly 400,000 weekly cases. These partnerships with commercial labs, state and local health departments, and academic and research institutions will continue to grow and the amount of sequencing will increase in coming weeks especially with the investment in sequencing included in the American Rescue Plan.

Each new variant can present different challenges. But each can be stopped by the same methods: rigorous and increased compliance with public health mitigation strategies such as vaccination, physical distancing, use of masks, hand hygiene, and isolation and quarantine.

Health Equity

COVID-19 has highlighted long-standing systemic health and social inequities. Data repeatedly show the disproportionate impact of COVID-19 on racial and ethnic minority populations, as well as other population groups such as people living in rural or frontier areas, people experiencing homelessness, essential and frontline workers, people with disabilities, people with substance use disorders, people who are incarcerated, and non-U.S.-born persons. Inequities in social determinants of health, such as poverty, housing, and healthcare access, have influenced a wide range of health and quality-of-life outcomes for these groups experiencing disproportionate impacts.

These factors and others are associated with more COVID-19 cases, hospitalizations, and deaths. Not surprisingly, they intersect with higher rates of some medical conditions in these same populations that increase one's risk of severe illness from COVID-19.

Health equity must be a cornerstone of our public health work. We need the best possible data to identify the challenges and measure our progress as we implement solutions. While we have seen big improvements over the last year, we know that there are still critical gaps in these data. For example, race and ethnicity data continue to be missing from approximately half of the laboratory tests reported to CDC. Progress has been slow because there are many data requisition forms and data interfaces in the data exchange pathway that have to be updated. This pandemic response has illustrated the long-standing need for improvements in the public health data network. Congress has been supportive of CDC and has responded to our partners' concerns about our antiquated data systems by providing resources to CDC for the data modernization initiative, the first comprehensive strategy to modernize data, technology, and workforce capabilities—together and at once. CDC is collaborating with our partners in the field to improve data collection and sharing.

CDC is committed to addressing these gaps, not only for the COVID-19 response, but for all public health data. And as we do this work, we will simultaneously take action on what we know—that these disparities exist and that they are unacceptable.

CDC's Chief Health Equity Officer has been leading our Health Equity Strategy to accelerate progress in reducing COVID-19 disparities. The strategy commits to expanding evidence-based approaches to reduce disparities in COVID-19 hospitalizations and deaths; increase testing, contact tracing, isolation options, and healthcare in populations at increased risk for COVID-19; prioritize equity in distribution and administration of COVID-19 vaccines; reduce stigma and bias; and expand a diverse workforce. We are engaging with community-based organizations and diverse leaders to conduct outreach that is culturally and linguistically responsive and make strides for populations at increased risk of getting sick and dying from COVID-19.

To operationalize the Health Equity Strategy, CDC is supporting activities and interventions with organizations across multiple sectors, including community- and faith-based organizations that have been able to provide more insight about the challenges and needs of the populations of focus. They have also helped us to reach these populations with tailored prevention messages about COVID-19. With their guidance, CDC has developed toolkits and other resources to address the unique needs of, and to help, communities that have been disproportionately impacted by COVID-19.

For example, CDC is providing funding for the Southern Alliance to address COVID-19 among non-Hispanic Blacks and/or African Americans living in the southeast region of the United States. The goal of this project is to enlist established and trusted community members to encourage the adoption of COVID-19 preventive and community mitigation strategies. These include improving chronic disease management, COVID-19 testing, facilitating contact tracing, promoting face covering and social distancing, and identifying mental health issues associated with COVID-19.

CDC is also funding the National Center for Farmworker Health to enhance coordination among a national network of agricultural worker-serving organizations and to strengthen their outreach capacity to address the ongoing COVID-19 threat to agricultural communities. With a focus on addressing COVID-19 educational needs among farmworkers, using materials in their native language, the National Center for Farmworker Health is encouraging vaccination, collaborating with other state and local organizations to facilitate farmworkers' access to the vaccines and other prevention resources, and finding and sharing replicable promising practices

that support agricultural workers and employers during the pandemic and that may prevent COVID-19 outbreaks in rural communities.

CDC has also led and supported initiatives to reduce the spread of COVID-19 in Tribal communities. We know that clean water is essential to meeting basic health needs—and in the context of the pandemic, necessary to ensure handwashing and hygiene. CDC led a survey of all 110 Navajo Chapters to identify those with the lowest level of water access and the highest COVID-19 infection rates. CDC and the Indian Health Service partnered with the Navajo Tribal Utility Authority and the Navajo Engineering and Construction Authority to install new water access points for 59 Navajo Chapters with the greatest needs.

Another example of CDC efforts to support critical and underserved populations is CDC's funding of the University of Minnesota's National Resource Center for Refugees, Immigrants, and Migrants (NRC-RIM), which provides assistance and resources to state and local health departments working with refugee, immigrant, and migrant communities that have been disproportionately affected by COVID-19. Their work provides health departments with toolkits to improve communication, community engagement, case investigation, contact tracing, and testing in these populations. The resource center also provides a centralized location for resources related to COVID-19 vaccines, which are accessible in multiple languages and tailored to refugee, immigrant, and migrant communities.

CDC has directed its COVID-19 funding toward activities and programs that will help lay the foundation for long-term improvements in health equity. As we expand our testing and mitigation efforts through the American Rescue Plan, we also will be focused on prioritizing increased access to testing in the communities hardest hit by the pandemic and expanding screening testing in at-risk populations. CDC remains focused on this goal and dedicated to working as a partner with others.

Vaccines

Vaccination is a critical tool in bringing this unprecedented pandemic to an end. In the year since COVID-19 infections were first identified, the FDA has issued Emergency Use Authorizations (EUA) for three vaccines that meet the expectations for safety and effectiveness for emergency use that are being distributed and administered as we speak. We should all take a moment and acknowledge that this is a remarkable accomplishment. When someone asks me which of these vaccines is the best vaccine to take, my answer is simple: take whichever vaccine you are offered. Each vaccine—Johnson & Johnson/Janssen, Moderna, and Pfizer—is very effective at preventing serious illness, hospitalization, and death from COVID-19.

Building on long-standing relationships with state and local partners, CDC has worked tirelessly to ensure that we are getting vaccines into arms as quickly, safely, and equitably as possible. As of March 15, over 135 million doses have been delivered, and more than 109 million doses of COVID-19 vaccine have been administered in just 13 weeks. This is a whole-of-society effort, and it is inspiring to see people across government, business, and communities coming together to complete this important lifesaving task.

I would like to touch on four core areas that drive CDC's vaccine work: safety, confidence, access, and equity. Vaccines are rigorously studied during clinical trials and there is a vast network of safety systems that monitor vaccines once they are in use and safety protocols to monitor people when they receive the vaccine. It is important that we continually deliver the message that these vaccines are safe.

Strong confidence in vaccines within communities leads to more people getting vaccinated, and to fewer COVID-19 illnesses, hospitalizations, and deaths. CDC is working in coordination with national, state, tribal, and local governmental and non-governmental partners to build trust in the vaccine, the vaccinator, and the vaccination system. We will continue to work with these critical partners to address barriers to vaccinations, including in communities of color and disproportionately affected groups.

In January 2021, CDC awarded \$3 billion from the 2021 Coronavirus Response and Relief Supplemental Appropriations Act to state, local, and territorial health departments to ensure broad-based distribution, access, and vaccine coverage nationwide. CDC requires that at least 10 percent of these funds be directed to vaccinating high-risk and underserved populations.

In order to enhance vaccine uptake among underserved communities of color and to build trust and confidence in the vaccine itself, CDC has developed a comprehensive program of approximately 20 national organizations that support hundreds of local and community-based organizations to improve both COVID-19 and influenza

vaccination coverage among racial and ethnic groups who have historically had, and continue to experience, health disparities.

Also critical to prioritizing equity in vaccine distribution is improving access to underserved communities and disproportionately affected populations who have historically had less access to healthcare. To that end, CDC is working closely with the Federal Emergency Management Agency (FEMA) and other Federal partners to get vaccines to communities that may have limited healthcare access. This includes coordination with FEMA around their Community Vaccination Centers and partnering with the Health Resources and Services Administration (HRSA) to launch a program to directly allocate COVID-19 vaccines in select HRSA-funded health centers. Both approaches will help ensure that our Nation's underserved communities and disproportionately affected populations are equitably vaccinated.

The Federal Retail Pharmacy Program (RPP) is another important component in the work CDC is doing to provide greater access to COVID-19 vaccines to communities of color and other underserved populations. CDC is partnering with 21 national pharmacy organizations and independent pharmacy networks that represent over 40,000 locations nationwide to ensure that the public has access to COVID-19 vaccines in a familiar setting. Almost 90 percent of Americans live within 5 miles of a retail pharmacy. Earlier this month, the RPP began to prioritize vaccinating teachers, school staff and childcare workers. Pharmacies have also been critical to vaccinating residents and staff in long-term care settings. Currently, there are over 14,000 pharmacy locations participating in the program nationwide—an increase of over 10,000 since the program began, including 4,000 new locations in just the past week—that have received nearly 14 million doses of vaccine, increasing access to COVID-19 vaccination across the country while decreasing the burden on state, local, and territorial health departments.

Health equity remains a cornerstone of CDC's vaccination efforts, and we need the best possible data to both identify the challenges and measure our progress as we implement solutions. At the end of February, CDC hosted a virtual National Forum on COVID-19 Vaccine. The Forum focused on vaccine confidence, data to drive vaccine implementation, and equity in vaccine distribution. We gathered over 13,000 people from 6,700 organizations, from every state, Washington DC, nearly all territories and 197 Tribes or tribal organizations—excited to learn, teach, and bring back to their communities a renewed enthusiasm for the massive task ahead and the urgent need to administer COVID-19 vaccines as efficiently and equitably as we can. They each provided critical feedback, which we are actively incorporating into our plans.

Looking to the future, we are optimistic that, in collaboration with our state, Tribal, local, and territorial partners, we have built a vaccine implementation infrastructure that will expand vaccination coverage to allow our communities to resume some aspects of a normal life. Active investigations will continue to determine how much vaccines reduce asymptomatic infection and transmission, how long vaccine protection lasts, and to what extent vaccines protect against emerging SARS-CoV-2 variants. Last week, CDC released new guidelines for fully vaccinated people, and we look forward to revising this guidance as the science develops and as more of the population is protected through vaccination.

Schools

Since becoming the director of the CDC, I have stressed the importance of getting children back to school for in-person learning. The safest way to open schools is to ensure that there is as little disease as possible in the community. The lower the amount of disease in the community, the less likely it is that cases will be introduced into the school environment. This means that all community members, students, families, teachers, and school staff should take actions to protect themselves and the community where they live, work, learn, play and worship.

CDC recommends that, among community institutions, schools should be the first to open and the last to close. Because of the benefits of in-person learning and the key support services schools offer, it is critical for K-12 schools to open, and stay open, as safely and as soon as possible. This is especially true in low-resourced communities, which may include large representations of racial and ethnic minority groups and students with disabilities. CDC began working on guidance, resources, and tools for safe school reopening in March 2020 when the first schools closed. As CDC learned more about COVID-19, we continually updated our guidance, resources, and tools for schools, parents, teachers, and other staff.

In February of this year, CDC released new science-based resources and tools to help schools safely reopen and stay open for in-person learning. Specifically, CDC

conducted an in-depth review of the science and released the *Science Brief: Transmission of SARS-CoV-2 in K-12 Schools*,¹ which informed CDC's *Operational Strategy for K-12 Schools through Phased Mitigation*.² In developing the K-12 Operational Strategy, CDC gathered input from school superintendents, school officers and nurses, national associations with a focus on education, organizations that represent elected officials, and others. These new resources complement CDC's existing guidance and tools for K-12 schools, including a toolkit to assess risks and implement prevention strategies to reduce the spread of SARS-CoV-2 in schools, a quick guide to assist teachers in modifying the layout of their classroom in a way that reduces the risk of virus spread, and updated materials about ventilation strategies in school and child-care settings. CDC will continue to collaborate closely with our colleagues at the U.S. Department of Education to make sure that all schools have access to the latest understanding and guidance.

Evidence indicates that many K-12 schools that have implemented prevention strategies to reduce the spread of SARS-CoV-2 consistently and correctly have been able to safely open for in-person instruction and remain open. The K-12 Operational Strategy outlines options for all schools—at any level of community transmission—to provide either full or hybrid in-person instruction through strict adherence to prevention strategies. Regardless of the level of SARS-CoV-2 spread in the community, CDC recommends using a combination of five key strategies to reduce the spread of SARS-CoV-2 in schools and help protect teachers, students, and staff. These strategies are universal and include the correct use of masks, physical distancing, handwashing and respiratory etiquette, cleaning and maintaining healthy facilities, proper ventilation, and contact tracing, in combination with isolation and quarantine, in collaboration with the health department. We also point to the added layers of prevention to be gained from regular testing and vaccination.

Universal and correct use of masks and physical distancing are two prevention strategies that are most essential to reducing SARS-CoV-2 transmission, but a layered approach that uses all five of these strategies will provide the greatest level of protection.

Teachers and school staff hold jobs critical to the continued functioning of our communities and our society, and are at potential occupational risk of exposure to SARS-CoV-2. We must treat in-person learning like the essential service that it is and get teachers, childcare workers, and other school staff vaccinated as soon as possible. Vaccination for teachers, staff, and among surrounding communities is one of the several layers of prevention strategies to reduce SARS-CoV-2 transmission in schools outlined in our K-12 Operational Strategy. CDC is committed to working with our Federal, state, and local partners to achieve President Biden's goal, in accordance with the *HHS Secretarial directive* related to making educators eligible along with other priority groups, to provide a first dose of the vaccine to every educator, school staff member, and childcare worker by the end of March.

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

Looking to the Future

I want to highlight that I'm cognizant that over the last 12 years, the United States has faced four significant emerging infectious disease threats—the H1N1 influenza pandemic, Ebola, Zika, and COVID-19. While urgency demanded rapid and unique responses to each of these threats, none resulted in the sustained improvements and investments needed in our Nation's public health infrastructure.

This lack of preparation continues to present significant challenges in our ongoing fight to tackle COVID-19. These experiences have proven that public health emergencies and, specifically, infectious disease threats are here to stay.

Looking to the future, I want to work within the Administration and with you to address long-standing vulnerabilities in our core public health infrastructure, in-

¹ <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/transmission-k-12-schools.html>.

² <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html>.

cluding data, workforce, laboratory, domestic preparedness, and global health security.

To avoid the substantial economic costs associated with both large-scale emergencies and chronic public health concerns, we must be willing to make investments in our public health system. We also must offer up our technical expertise to support efforts to advance global health security.

Conclusion

In closing, I want to emphasize that, while we must remain vigilant and continue to use every tool we have to fight this virus, there are reasons to be hopeful. I am optimistic that we are moving in the right direction. I am looking forward to seeing more kids in school, more families able to connect with one another safely, and our Nation beginning to move forward and heal. We are committed to continuing to advance the science around COVID-19; moving more vaccines into more communities—especially those communities most at-risk for COVID-19 infection—and working to improve health equity.

The next few months will be critical, and we need everyone to continue to wear masks properly, practice social distancing and handwashing, and get vaccinated. I recognize that everyone is fatigued after a very long year. It is as critical as ever to continue these lifesaving efforts.

I look forward to working together to address both the immediate challenges ahead in our fight against COVID-19, along with the weaknesses in our public health infrastructure that left our country vulnerable to this pandemic. CDC is grateful for your support.

We will continue to work tirelessly to ensure the health of this Nation and the world. Together, we will get through this pandemic and work to continue building a sustainable and resilient public health system that can respond effectively to emerging threats and to the ongoing public health needs of every American. Thank you again for the invitation to testify today and I look forward to answering your questions.

The CHAIR. Thank you, Dr. Walensky. We will now begin a round of five minute questions of our witnesses. I want to thank you all again for being here today. I ask my colleagues to keep track of your clocks, stay within those five minutes. Dr. Fauci, we have spent over a year responding to the biggest public health crisis in a century. Since you last testified before this Committee, lifesaving therapeutics and vaccines have reached patients with increasing speed and saved lives.

However, we must do—all do more to end this pandemic and build back stronger and fairer. The majority of the people in this Country are not yet vaccinated, and the variants are continuing to threaten our progress. As the nature of this pandemic and the virus itself changes, our response has to change too. What is the biggest challenge ahead in our response to this pandemic?

Dr. FAUCI. Right now, the biggest challenge—excuse me, right now, the biggest challenge, I think, is multifaceted. One is the staying ahead of this virus itself. We are doing a good job now, up to 2 to 3 million vaccinations per day. The more we get vaccinated, literally every day that goes by and more and more people get vaccinated, we can stay ahead of what I would consider a race between our ability to vaccinate people and the emergence of variants. We have variants that are well-established, like the 117.

Luckily, as Dr. Kessler has mentioned, the vaccine does very well against it. But there are other variants that, in fact, when you look at the antibodies induced by the vaccine and the capability of essentially fighting against these variants, they are diminished by anywhere from two to five or six fold. Fortunately for us, the re-

sponse to the vaccine has been so robust that there still has been enough cushion that you likely would maybe not necessarily prevent infection, but certainly prevent severe disease resulting in hospitalizations and deaths.

The challenge is to stay ahead of the variance. The other is to make sure, and it looks like we are doing a good job and it is getting better and better every day, of getting accessibility and implementation of getting the vaccine into people's arms, particularly making sure that we do it not only quantitatively, but with equity. Equity with regard to underserved populations. And there is a lot of activity right now that is focusing on making that happen. Thank you.

The CHAIR. Thank you. I have been really encouraged to hear good news about ramping up vaccine supply in the coming weeks. But I want to ask about what the Administration is doing to make sure people trust the safety of COVID-19 vaccines. We have to overcome skepticism about the science as well as active disinformation campaigns and false rumors. So I want to ask Dr. Walensky and Dr. Kessler, how are you working to debunk misinformation about vaccine safety and encourage people to get vaccinated? Dr. Walensky, I will start with you.

Dr. WALENSKY. Thank you for that. I think we need to understand exactly the reasons for vaccine—for lack of vaccine confidence, and we need to address them at the local level. We are working very closely with our state, local health departments. Resources from the American Rescue Plan will help in that regard toward education. We need to address vaccine hesitancy with regard to its roots. Is it because it is not convenient? Is it because people are not deeming it safe? Is it because they felt that it could happen too fast, or they are worried about side effects?

They need to hear this information from trusted messengers. We have been working last week or two weeks ago, we had a vaccine forum. Over 13,000 people sharing ideas of how they are addressing at the local community. And we are continuing in those efforts. We have vaccine confidence consults where we have people who are able to call in and get advice, receive toolkits as to how they can promote vaccine confidence. Thank you.

The CHAIR. Thank you. Dr. Kessler.

Dr. KESSLER. Madam Chair, we will have as a Country, through the hard work of this Committee and everyone who has come before, we will have within 90 days, in essence, quadruple our vaccine supply. I believe that we are going to be shifting from a supply issue to a demand issue pretty soon. Just as a pediatrician, I have dealt with the issue of vaccine hesitancy in children. And I think it is very important that we understand that the American people look to their health professionals for guidance.

We are approaching 100 million shots in arms. That is a remarkable number. And I think that one of the most important things that we can all do is to when we look at those 100 million shots in arms, look at the remarkable, knock wood, safety profile. Things can happen. We are ever vigilant. That is the job of my former agency and Dr. Marks. But I think that to date, we can sit here in front of the American public and say these are very safe vaccines.

The CHAIR. Thank you very much. I will turn it over to Senator Burr for his questions.

Senator BURR. Thank you, Madam Chair. Tony, I will start with you and I will just work my way down. You and other experts have suggested that we need to get 60 percent to 70 percent of the population vaccinated to achieve herd immunity. If the numbers are higher now, can we reach the number without vaccination of children under 18, which is roughly 140 million Americans?

Dr. FAUCI. Senator Burr, I would like to maybe backtrack a bit and say I think we should be careful about wedding ourselves to this concept of herd immunity because we really do not know precisely, for this particular virus, what that is. I have been saying lately calculation, and it is purely an estimate, of 70 to 85 percent of the population. If it is that, we would probably have to get more children.

I believe as we get high school students vaccinated in the fall, we will be able to reach that. But let me just emphasize that comment. As was said in my response to Chair Murray, that every day we get 2 to 3 more million and we get closer and closer to where we want to be, we don't really know what that magical point of herd immunity is, but we do know that if we get the overwhelming population vaccinated, we are going to be in good shape. And you are right in your question, we ultimately would like to get and have to get children into that mix.

Senator BURR. David, we can both agree that Operation Warp Speed is a success story of American innovation and ingenuity. What do you see as the biggest challenge that we face over the next 30, 60, 90 and beyond?

Dr. KESSLER. The next 30 days, 60 days?

Senator BURR. 30, 60, and 90 and beyond.

Dr. KESSLER. But let's take the first 30, 60. I think it is what the Chair raised, vaccine hesitancy. I think we are going to have to make sure that people understand how important being vaccinated is and what the safety profile is. I wasn't convinced when I started, but I am convinced now that, as Dr. Fauci said, we are in a race against these variants.

The most important thing we can do currently as citizens is to step up, not for us, but for our families and for our fellow citizens to become vaccinated. I think, Senator, I mean, in your opening comments, I think you hit the nail on the head. I think there are many things we can do to learn the lessons over the last year. I think it is a phenomenal story, but I think there are lessons to learn, and I look very much forward to working with you and your staff to doing that.

Senator BURR. Thank you for that. Peter, FDA now has experience evaluating the messenger or any platform, and a baseline understanding of the technology. What steps will FDA take to make sure that the technology does not have to go through approval again, but new indications would? If you look at our annual flu process, we use the same technology, but with a different formulation on an annual basis and that is sort of an expedited process. Can we expect to see over time a similar type of approach to messenger-RNA platform and the clinical requirements only for the new indications?

Dr. MARKS. Thank you for that question, Senator Burr. So I think we can say that is the case over the course of time. For the first couple of changes that might be made for variants, we probably will have to go through having some clinical studies, but they won't be clinical outcome studies. They will be ones where we look at the immune response. It is possible that once we understand how these perform, that we won't actually even need studies and people will be able to do like what we do for influenza. Ultimately, the place we would like to get to is, really understanding which pathogens go with which platforms, because it turns out that the mRNA platform seems to be very good for certain pathogens, but it may not be good for others.

Just as the vesicular stomatitis virus platform that was used for the Ebola vaccine seems to be very good for certain pathogens, but not for others. So we need to be able to do the science to understand that matching, and that in the future will hopefully expedite this even further to rely on these platforms that we understand.

Senator BURR. Madam Chair, quick question for CDC, if I could have the indulgence of the Chair. Rochelle, can you understand why the American people were somewhat baffled when it took three months for CDC to issue guidance on what vaccinated Americans should do, precautions they should take, things that they could forget they had been told? You said we are leaning on the science and the science certainly suggested something. Is that the norm in the future that it is going to be delayed like that or do you see that being expedited in the future?

Dr. WALENSKY. Thank you for that question. We are working and looking at the science as it emerges and evaluating the science in real time. Our CDC guidance on what to do when you are vaccinated came when less than 10 percent of the American public was vaccinated. During a time of emerging variants and emerging science around those variants, and during a time when we were looking to see whether vaccinated people could actually transmit disease. So we needed to see what that science was before we were able to provide those—before we were able to provide that guidance.

We are working in real time as additional science emerges to update that guidance as, in fact, more people get vaccinated. May I just return to the question of herd immunity? And I just want to make sure folks understand the concept of herd immunity is an epidemiologic term that is one over one minus R_0 . R_0 is the transmissibility of the virus and that actually turns out to be a moving target as we have different variants. So as we think even conceptually about herd immunity, I think we need to understand that as we have more transmissible variants, our target for herd immunity may change. As well when we look at children, if they actually are not as transmissible to the young children, that in fact we may not have to vaccinate at the same level young children. I believe that children should be vaccinated, but I just want to make sure we understand the target.

Senator BURR. Thank you, Chair.

The CHAIR. Thank you very much.

Senator Baldwin.

Senator BALDWIN. Thank you, Chair Murray. It seems to me, and certainly I have heard testimony from our witnesses today, that one of the most significant threats to the progress we are making in this pandemic is the emergence of variants and mutations that could possibly elude the treatments that have been developed and the vaccines that are being deployed. Fortunately, the American Rescue Plan contains—provides \$1.75 billion for CDC to ramp and scale up efforts on genomic sequencing and surveillance. I was a proud champion of this provision because I think it is so important that we know what possible threats to our progress exist. Dr. Walensky, can you describe how the CDC will use this \$1.75 billion to combat emerging mutations and variants of the coronavirus? And also give us a sense of how many of the positive test samples ought to be sequenced in order to really have a firm grasp on the emergence of variants?

Dr. WALENSKY. Thank you so much, Senator, and thank you for all of your support in getting us resources to be able to do so. The initial \$200 million that was given to the CDC to scale up to sequencing, we are now doing somewhere between 10,000 and 14,000 sequences a week and that is in collaboration with commercial labs, that is in collaboration with public health labs, with academia. The additional \$1.75 billion is in fact essential to help fund jurisdictions for next genome sequencing capacity. Not all jurisdictions have this capacity and we really do need to be able to scale this up across the Country.

We actually need to be able to scale up our own surge capacity within the CDC for sequencing infrastructure, for clear, competent labs, for having scientific computing and IT in CDC so that we can use that infrastructure for when the next surge arises. We need to develop a workforce so that people understand how to do genomic epidemiology. That is not standard education. That is not what people standardly know. And so we need to develop that workforce, and then we need to bolster exactly what is being done already because we are only at 14,000 right now.

We really would like to be up at the 25,000 range. Of course, the number of sequences you do very much depends on the number of virus—the amount of cases that we have circulating. And so we would like to be up to around 25,000, somewhere in the 5 to 10 percent of the amount of cases that we have. Thank you.

Senator BALDWIN. Thank you. As Government looks to invest in supply chain resiliency using funds provided by Congress for COVID response and pandemic preparedness, we know one thing to be true, that we can no longer afford to have an inadequate domestic vaccine supply chain. While the delivery method will always be vaccine dependent, there are certain supplies that it seems to me would make sense to have advanced purchase of and sufficient stockpiles of, things like vials, stopper syringes, needle caps.

Manufacturers must be able to rapidly surge production for a future pandemic without doing long term damage to their broad customer base. So, Dr. Marks, can you describe some of the early obstacles that FDA faced as a result of our overreliance on foreign manufacturers of critical medical supplies? And what role do you think our national stockpile system could play in helping to main-

tain search capacity for American made critical medical supplies, including those needed for vaccinations?

Dr. MARKS. I may defer some of the stockpile question to Dr. Kessler, but I will say that there clearly was a critical shortage of vials and other manufacturing equipment to be able to move ahead and rapidly produce vaccines. I think that was part of what was overcome by a cooperative effort between industry and Government partners early on in this pandemic to try to pick up the pace on that. But I think a key piece of learning for the future is that we have to start to rely on more advanced manufacturing technologies, things that allow us to scale up production not just for drugs and biologics, but also for devices so that we can move more quickly.

Dr. KESSLER. Senator, if I could—

Senator BALDWIN. Please, go ahead.

Dr. KESSLER. Senator, if I could just add there is a team, a very dedicated team at DOD, BARDA, HHS, who spend their days and have been doing this for months, sourcing the globe for supplies. In the Rescue Plan, there is a specific provision that will enhance our ability to make sure going forward things like lipids that are key ingredients, that we will have adequate supplies prior to the time we need them.

Senator BALDWIN. Chair Murray, with your indulgence, I would just like to formally request that our Committee receive a briefing on the state of the strategic national stockpiles and that the Administration provide Members with detailed breakdowns of supply chains associated with the current approved vaccine candidates, including manufacturing locations. And that would be classified if necessary. I know some of the information regarding the national stockpiles is sensitive.

The CHAIR. Thank you. We will do that. Thank you very much.

Senator BALDWIN. Thank you.

The CHAIR. Senator Paul.

Senator PAUL. Dr. Fauci, in a recent British study, David Wiley and others found that no symptomatic infections from COVID-19 after following 2,800 patients for several months. In fact, there have been no reports of significant numbers of infections after acquiring COVID-19 naturally. Shane Crotty, a virologist at La Jolla Institute for Immunology concludes from his experiments that the amount of immune memory gained from natural infection would likely prevent the vast majority of people from getting hospitalized disease, severe disease for many years. In this study, which was published in Science, Dr. Crotty showed that antibody levels stayed relatively constant with only modest declines over six to eight months.

Dr. Crotty reported that notably memory B-cells specific for the spiked protein, or RBD, were detected in almost all COVID-19 cases with no apparent half-life at five to eight months after infection. In other words, Dr. Crotty found significant evidence of long term immunity after COVID infection. Furthermore, Dr. Crotty noted, B-cell memory to some other infections has been observed for as long as 60 plus years after smallpox vaccination or even 90 years after a natural infection with influenza. There was a woman who got the Spanish flu who still showed immunity 90 years later. So rather than being pessimistic toward people gaining immunity

after they have had COVID or had a vaccine, studies argue for significant optimism.

In fact, there have been no scientific studies arguing or proving that infection with COVID does not create immunity. There have been no studies showing significant numbers of infections. Of the 30 million Americans who have had COVID, only a handful of infections have been discovered. In fact, The New York Times reported last fall more than 38 million people at the time worldwide had been infected with the coronavirus. And as of that date, fewer than five of these cases had been confirmed by scientists to be reinfections.

Scientists interviewed for the article concluded, in most cases, a second bout with the virus produced milder symptoms or none at all. Given that no scientific studies have shown significant numbers of infections of patients previously infected or previously vaccinated, what specific studies do you cite to argue that the public should be wearing masks well into 2022?

Dr. FAUCI. I am not sure I understand the connection of what you are saying about masks and reinfection. We are talking about people who have never been infected before—

Senator PAUL. You are telling everybody to wear a mask, whether they have had an infection or a vaccine. What I am saying is they have immunity, and everybody agrees they have immunity. What studies do you have that people that have had the vaccine or have had the infection are spreading the infection? If we are not spreading the infection, isn't it just theater?

Dr. FAUCI. No, it is not—

Senator PAUL. If you have had a vaccine and you are wearing two masks, isn't that theater?

Dr. FAUCI. No, it is not. Here we go again with the theater. Let's get down to the facts, Okay? The studies that you quote from Crotty and Setit look at in-vitro examination of memory immunity, which in their paper, they specifically say this does not necessarily pertain to the actual protection. It is in-vitro.

Senator PAUL. What can you point to that shows reinfection? There are no studies that show—

Dr. FAUCI. Let me finish the response to your question, if you please. The other thing is that when you talk about the infection and you don't keep in the concept of variance, that is an entirely different ballgame. That is a good reason for a mask. In the South African study conducted by Jay and Jay, they found that people who were infected with wild type and were exposed to the variant in South Africa, the 351, it was as if they had never been infected before. They had no protection. So when you talk about reinfection, you have got to make sure you are talking about wild type. I agree with you that you very likely would have protection from wild type for at least 6 months if you are infected. But we in our Country now have variants that are circulating—

Senator PAUL. What study shows significant reinfection, hospitalization, and death after either a natural infection or the vaccine? It doesn't exist. There is no evidence that there are significant infections after vaccine. In fact, I don't think we have a hospitalization in the United States after the two-week period after the second vaccination. We don't have a death in the United States.

Dr. FAUCI. You are not hearing what I am saying about variants. We are talking about wild type versus variants. Now we—

Senator PAUL. What proof is there that there are significant infections with hospitalizations and deaths from the variants? None in our Country, zero.

Dr. FAUCI. Well, because we don't have a prevalence of a variant yet. We are having one—can I finish? We are having 117 that is becoming more dominant.

Senator PAUL. But you are talking about conjecture. You are making policy based on conjecture. You have the conjecture that we are going to get variants—

Dr. FAUCI. No, it isn't based on conjecture.

Senator PAUL. You want people to wear masks for another couple of years. You have been vaccinated and you parade around in two masks for show.

Dr. FAUCI. No.

Senator PAUL. You can't get it again. There is almost—there is virtually 0 percent chance you are going to get it. And yet you are telling people that have had the vaccine, who have immunity—you are defying everything we know about immunity by telling people to wear masks who have been vaccinated. Instead, you should be saying there is no science to say we are going to have a problem from the large number of people to vaccinate. You want to get rid of vaccine hesitancy, telling people to wear their mask after they get the vaccine—you want people to get the vaccine, give them a reward instead of telling them the nanny state is going to be there for three more years and you got to wear a mask forever. People don't want to hear it. There is no science behind it.

Dr. FAUCI. Well, let me just state for the record that masks are not theater. Masks are protective. And we—

Senator PAUL. As immunity, they are theater. If you already have immunity, you are wearing a mask to give comfort to others. You are not wearing a mask because of any science.

Dr. FAUCI. I totally disagree with you.

The CHAIR. Dr. Fauci, if you could respond so that we could understand the difference between the virus itself and the variance and the reason for a mask.

Dr. FAUCI. I am sorry, ma'am, I can't—

The CHAIR. If you could respond to the question so that we could all understand the difference between the vaccine in controlling the wild type versus the variants that are out there and the reason for wearing a mask. I would appreciate it.

Dr. FAUCI. Yes, I mean, yes. First of all, when you have a variant, you have an immunity that you get with convalescent sera and the same sort of thing. If I vaccinate you or me against a wild type, you get a certain level of antibody that specific for a particular viral strain. If there is a circulating variant, you don't necessarily have it. You have some spillover immunity, to be sure, but you diminish by anywhere from two to eight fold the protection.

The point I am saying is that there are variants now circulating. The point that Senator Paul was making was that if you look at wild type only, there is some clear-cut credence to what he is saying. But we are living right now in a situation where we are having a dominance of 117, which was the original UK. We have a very

troublesome variant in New York City, a 526. We have got two variants in California, a 42749. And we have a number of others. So we are not dealing with a static situation of the same virus. That was the only point I am making.

The CHAIR. Thank you very much. Thank you.

Senator Murphy.

Senator MURPHY. Thank you very much, Madam Chair. Dr. Fauci, thank you for setting an example over the course of the last year for Americans. You have made it clear that masks saved lives. And the example that you have set that has not been followed by other leaders in this Country has made a difference, has kept tens, if not hundreds of thousands of Americans from contracting this disease. Thank you.

I wanted to turn to the question of the massive contracts that we have signed with vaccine makers and to talk a little bit about the path forward. Pfizer reported about \$9.6 billion in profit last year. Moderna, a very small company before entering the vaccine market, their Chief Executive owns shares that are probably now worth about \$5 billion. Thank goodness for these companies. They have done remarkable work in a short period of time. They have saved lives. At the same time, we want to make sure that we are making wise use of taxpayer dollars. And so I am going to direct this question to Dr. Kessler and others can weigh in.

Dr. Kessler, do you sort of understand what the difference is between AstraZeneca and Johnson & Johnson, who have said that they are pursuing a nonprofit model in developing the vaccine versus Pfizer and Moderna, who I assume because they have not made the same statement, are pursuing a for profit model. Help me understand what the difference is between those two.

Dr. KESSLER. Senator, all those are good questions, and you have every right to be confused because it is very confusing. I lived very much in the 1990's. We worked on HIV when I was at FDA and chaired the Elizabeth Glaser Pediatric AIDS Foundation. So we cared a lot about getting drugs in that instance to the world. And that led to something called tiered pricing. And you will see that there are multiple numbers. I mean, there is this number that is cost and there is cost plus, there is a not for profit cost, and all those have very honestly different definitions.

I think the most important thing to stress right now, and I have been no defender of the pharmaceutical industry and certainly not on pricing, I mean, over my career, but I think the fact is that this Committee, the Congress, you allowed the Administration to go at risk, right? And we bought different vaccines, the Administration bought different vaccines, regardless of even whether they worked and, at the best price. And the reality is, thank God for that, because we are in a very fortunate position today. I am sure with hindsight, there are a lot of legitimate questions and we have to do better at understanding these prices. And I pledge to you, we will do that. It is not an easy answer.

Senator MURPHY. Let me just because I have got a minute left, let me just ask two quick follow-up questions. On an earnings call last month when asked about profit margins for the vaccine, the Chief Financial Officer at Pfizer suggested that the company is going to, "get more on price" after what he called the pandemic

pricing environment. One analyst projected that the company could make vaccine prices three to four times higher than they are today. Do you believe that we have the ability to keep vaccine prices at a point that is favorable for the American taxpayers? And then what do you think about making these contracts disclosable so that—it is sort of hard for the American public or, outside groups to do oversight when they can't see the contracts.

Dr. KESSLER. I can tell you, Senator, the President believes very firmly, in making sure that there are affordable medicines and vaccines, and we will work very hard. It is my understanding that the contracts are publicly available, albeit with redactions. I am happy to work with you to even improve on that.

Senator MURPHY. Great. I appreciate it. I know this Administration has a commitment to getting the best value. Obviously, the priority is getting shots in people's arms. And so let's not let the perfect be the enemy of the good. At the same time, hearing that we might be looking at three to four times the amount of price as we move into booster shots or childhood immunizations, certainly should be something we should all pay attention to. Appreciate it. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Collins.

Senator COLLINS. Dr. Walensky, the CDC school reopening guidance has been at odds with what many public health experts are recommending. When we discussed this issue recently, I really detected a lack of a sense of urgency on your part to reopen schools. Let me just share a little bit with everyone here what the public health experts are saying. In USA Today, four prominent experts said the recent school reopening guidance released by CDC is an example of fears influencing and resulting in misinterpretation of science and harmful policy. The American Academy of Pediatrics cautioned against strict adherence to six feet of distancing, if that forces students to enter remote learning. And Dr. Jha who testified before it just last week said in an interview that the guidance, "didn't feel to most of us in the public health world as particularly well grounded in evidence and science." Maine's own CDC Director made the point to me that children are less likely to contract COVID in schools than they are in other settings.

Dr. Jha also said that we were focusing on the wrong things. We should be focusing on mask wearing, ventilation. And he said, it did not mention three feet versus six feet. It did not mention deep cleaning of surfaces. There is a lot that is going on that has gotten us distracted. We can keep teachers safe. We can keep kids safe. We can open schools and we have the ability to do that now. In the meantime, the negative effects on our children continue to grow. And I am not just talking about the lost learning. I am talking about social development. I am talking about behavioral problems, stress on the children, on their parents.

A hospital administrator told me just yesterday that they are having children dropped off at the emergency room with behavioral problems and the grandparents or the parent who brought them just driving away, just leaving them there. We have got to get the schools reopened. And you have presented no timeline at all for doing that. And the CDC recommendations, particularly on phys-

ical distancing of at least six feet, are just not in sync with what most public health experts are recommending. So I would like to know what you are going to do, and when, to get our schools reopened.

Dr. WALENSKY. Thank you for that question. Thank you for the conversation we had. And I am very sorry you—it appeared like it wasn't urgent to me. I am the mother of three, one of whom has been home for this entire year. This is an urgent issue. I understand the mental health challenges. I understand the educational challenge. There is food insecurity. This is urgent. Please don't get me wrong. This is urgent.

There was a study out of Wisconsin that demonstrated in schools that in a time of high disease prevalence, that if there was 92 percent mask wearing and dedensification of classrooms, somewhere between 11 and 20 students, we could get students back to school safely. There is also a similar study from Georgia that showed without masking and without the proper mitigation strategies, there were outbreaks in nine elementary schools. So our guidance was intended to lean in. We specifically articulated as it was released that schools that were doing well, and were open, we wanted to keep open.

As we released this guidance several weeks ago, it was intended for schools to lean in—for schools that were clamped shut to use this guidance to decide what mitigation strategies they needed to do, recognizing that the MNWR that we reported several weeks ago, 60 percent of students were wearing masks in classrooms. We needed to get those numbers up if this was going to be done safely, and this was the roadmap to do so. On the question of three feet and six feet, we looked for science to determine what was the proper distance on the question of three feet and six feet.

At the time, you may recall, there were about 250,000 cases per day and much of our communities were in a very high rates of community spread. We agree on the science that the spread was happening less so in the schools than in the community. But if mask wearing was not happening, we were seeing breakouts and we had science for that. Just last Thursday, I believe, there was a study out of SID from Massachusetts in a place where there was about 100 percent mask wearing that three feet and six feet yielded the same amount of infections.

That was the first study we had seen that looked at three feet versus six feet. Indeed, because six feet has been such a challenge, science has leaned in, and there are now emerging studies on the question between three feet and six feet. I am aware of several that will be released in the next several days, and we are actively looking at our guidance to update it to address that science. Thank you.

Senator COLLINS. You need to do it now. And I agree with you on mask wearing, but I really wish that you would look at this testimony and what these public health experts are saying. Thank you.

The CHAIR. Thank you, Senator Collins.

Senator KAINE.

Senator KAINE. Thank you, Madam Chair and Ranking Member, and thanks to the witnesses. I generally don't like to respond to a colleague after the colleague has left the room because it doesn't

seem kosher. But the public is watching this hearing. And I want to just get into this mask issue just briefly. I have had COVID, and I have been vaccinated and I wear a mask. I wore a mask to make other people feel safer, even if there weren't variants. I went to my grocery store during senior hour when there aren't a lot of people there and my grocery clerk who cannot telecommute is petrified about getting COVID. So she is petrified about getting COVID and she stands eight hours a day, a few feet away from people down the line, and she is petrified. She doesn't want to take COVID home to her child in the small apartment where they live. She doesn't want to take COVID home to her mother, who also lives in that small apartment with her. And many, 30 million Americans have had COVID. That is the reported cases, so say it is double. I would say it is 60 million.

Hundreds of millions of Americans have not had COVID and they are afraid of getting it because they have seen 500,000 people die and they have seen a whole lot of people suffer and they have seen people lose their jobs and lose their income and lose their business. There are people in this room who haven't had COVID. It makes people around you feel a little bit safer, it makes my grocery store clerk feel a little bit safer if people she is standing a few feet from every day are wearing a masks. And if that is so hard to understand, is it so hard for us to do? We don't care about these workers? I mean, if she saw me come through with no mask, she would be afraid.

I could say, well, look, I have been vaccinated and I have had COVID. Well, maybe she isn't reading the science about what that means. It is just such a minor thing to do, to try to protect the hundreds of millions of Americans who are deathly afraid of getting COVID. That is a reasonable fear, and this is a reasonable step that we can take to try to bring down the fear level that people legitimately have. So I have two issues that I just want to put on the table, and I would love any of you to address them in there kind of long term issues. There will be a day when a President will say the public health emergency is over. There will continue to be a very long tail of consequences on people's mental health, seeing death, seeing illness, losing their jobs, losing income, isolation, that will be a long consequence.

Many Members of the Committee have worked together on this already, but we think we have more to do. Second, many Americans who have had COVID will have continuing symptoms. I have these weird neurological symptoms a year later. They are not debilitating. They are not painful, but they are weird, and they are 24/7. Many people have symptoms that are more serious heart impairment, respiratory impairment, impairment of mental functioning, fatigue challenges.

How should we as a community, how should we as a Nation, how should the institutions you work for be thinking, planning, investing in these two long term sets of consequences, mental health and the physical needs of the COVID long symptoms?

Dr. FAUCI. Let me address the one that you mentioned about the persistence of post COVID sequelae, which is a really serious and real issue. It is not imaginary. It varies from person to person. The NIH, with the generosity of the Congress, has invested \$1.15 bil-

lion in collaboration with the CDC and other agencies. And looking at the scope of this real phenomenon, the sequelae, what the ultimate pathogenesis is—because we don't know what the mechanisms are. You mentioned a weird neurological symptom. We are not really quite sure what that is. And we are putting together a large cohort studies to be able to find out what the incidence of it is, what the variability, what the range of organ system dysfunctions are, and what the underlying pathogenic mechanisms.

It is really very puzzling, Senator, because it is different than if someone is in ICU and has long damage and you have a pulmonary function abnormality, so you have a cardiomyopathy and you have a stroke volume that is down. It is different than that. It is people who recover, have the virus no longer there, and have a persistent of things like chronic fatigue, muscle aches, temperature dysregulation, funny kind of neurological issues that they can't explain. That is what we are really focusing on in cohorts of tens of thousands of people. So we are looking at that seriously.

Dr. WALENSKY. Maybe I will just chime in on the mental health side and say that we are working—first of all, we need to collect the data. We need to understand in real time what the impacts of this are. We need to work with our state and local health departments to ensure that the resources that they have can be disseminated to their local jurisdictions. That we have toolkits on culturally sensitive prevention strategies for prevention of depression, toolkits for mental health resources to provide.

We need to get those disseminated into the local jurisdictions. And then we are working to do the science to, and cohort studies, exactly, as Dr. Fauci noted, on both the mental health issues as well as on the long haul issues.

The CHAIR. Thank you very much.

Senator Cassidy.

Senator CASSIDY. Thank you all. Doctors Kessler and Fauci, all generous in your comments of the previous administration's effort without specifically saying them, so thank you for that. I have to admit, the Chairwoman's opening comments would have imagined that Operation Warp Speed was a Biden administration initiative. Obviously, it was not. But all due credit to the current administration. They are making great strides. I appreciate that. And Dr. Walensky, I just also want to point out as we speak of equity, the Kaiser Family Foundation, the COVID-19 vaccine tracker, shows that the greatest hesitancy for vaccination right now is among those in the rural areas and Republicans. For some reason, when people speak about equity and the need for special outreach, those folks never come up.

I know that you are aware of that, but I just want to say that for the record. Frank Luntz just recently did a survey group and found that if you present them with facts over and over again, they will be persuaded, but they need to be spoken to by trusted folks. Somebody mentioned that earlier. Just to say that. And I am not scolding, I am just pointing that out because that is the need. Dr. Fauci, always enjoy your comments.

Dr. Kessler, we have spoken before. It is kind of a mixed message here, that we know that we need to test in children, but we also know that the incidence among children is going to be so low

that it could be difficult to have an outcomes based result. Again if the incidence in the community is so low, nobody is getting infected anyway, how do you compare a vaccine versus a placebo group? Second, and that begs the question, we do need that kind of surrogate marker, those T-cells and those B-cell markers that would correlate with immunity.

I am struck that there is a letter to the New England Journal of Medicine in which it says that antibody response and seropositive persons after a single dose of the mRNA vaccine and showing that antibody titers after a single dose than those previously infected shoots up much more than those who have never been who are naive, so to speak, never before been infected. A second dose does not improve that. It just stays flat. Where are we in establishing a surrogate marker that could be used to see if children are immunized related to that?

Where are we in establishing that if you have been previously infected, granted variants or a wild card, but if we have a shortage of vaccine worldwide, it would be very important in Asia and Africa, Mexico, to know that if someone was previously infected at the most, they would need one more dose of vaccine. It seems like we are being fairly conservative about this. When will we have some answers? And I am not scolding, I am just asking. Dr. Fauci?

Dr. FAUCI. Thank you for that question, Senator Cassidy. You make a very good point. And we will get what you are referring to is a correlate of immunity, the surrogate marker. And right now we are collecting data from the trials that we did in adults in which we clearly showed a high degree of efficacy that is associated with a very high degree of neutralizing antibodies, measuring also T-cell responses, but mostly neutralizing antibodies. When we get a firm correlate of immunity, I think we are going to be able to answer the question you say about what sort of surrogate marker that we could tell that someone is actually protected. And I think in the next couple of months, at the latest, we are going to get that data.

Senator CASSIDY. Let me ask because you said correlate. Already, you correlate as an association the increase in antibody titer and some sort of proliferation of the T-cells. Presumably these are neutralizing antibodies similar to those used in the monoclonal antibodies. So what additional information do we need? Because obviously, the sooner we know this, the better.

We are probably—I have been infected, I have been vaccinated. I really don't think I needed the vaccine, but my wife told me not to come home unless I took it. So I guess the question is, but we could have given that vaccine to somebody else. So when do we think we will have it and what is going to be in addition to that which we already know?

Dr. FAUCI. Again, another very good question, Senator Cassidy. In the long run, the real proof of the pudding is when the level of antibody goes down below a certain level. If you still have protection, that means that isn't a direct correlation with the height of the antibody level. We know now—

Senator CASSIDY. That is not necessarily true though. If I may in all due respect, what you really want to know is if there is amnestic memory, as if you are reexposed to the vaccine, and within that window period, your vaccine rises back to a protective level.

It seems like that would be fairly easily done with the folks who are infected now and maybe their antibody titer has fallen off.

Dr. FAUCI. No, you are quite correct. And in fact, the example that you gave is a really excellent example of people who have been infected, and even if you look at them and they don't have necessarily a very high level of antibodies, multiple months later, when you vaccinate them, their level goes up 100 fold as opposed to 10 fold. It is just extraordinary, which means they have many more competent memory B-cells than they do have a level of circulating antibody.

Senator CASSIDY. But that is what always happens. I guess I am asking, since we know that is the case and you already see evidence of it, it does seem like there is a great hesitancy to admit, if you will, that this could be protective when we know the same thing is true of other viruses. That your antibody titer falling to zero does not mean that you are not protected. Your memory B-cells will quickly proliferate. And again, this has such implications for how we use our vaccine now. If you could answer this, and then I will yield back because I am over time.

Dr. FAUCI. No, yet again you are making good points, Senator Cassidy, but since this is a virus for which we don't have previous experience, it is a bit risky to make a direct extrapolation, for example, to influenza or others. It is certainly conceivable that it will match what we have seen with other viruses, but we don't know that as a definite scientific fact yet.

Senator CASSIDY. Okay, I yield back. Thank you.

The CHAIR. Thank you, Senator Cassidy.

Senator HASSAN.

Senator HASSAN. Well, thank you, Madam Chair and Ranking Member Burr, for having this hearing. Thank you to all of our witnesses for your extraordinary hard work and for your commitment to helping us get through this pandemic and beyond. I also want to just take a minute to thank Senator Kaine for the remarks he just made about the importance of mask wearing at this moment in time as we continue to combat the pandemic. As somebody with a highly vulnerable family member who is cared for by a woman who is 80 years old, I have been holding my breath throughout this and the fear is real.

I am very grateful to you, Senator, for your comments. Dr. Kessler, earlier this month, I led a group of my colleagues in writing a letter to the Departments of Health and Human Services and Justice to urge them to address serious barriers for individuals with disabilities in the COVID-19 vaccine distribution process. This letter followed reports from constituents in my home State of New Hampshire that they could not access the vaccine registration website using a screen reader, which is a crucial tool for people with vision loss.

Ensuring that individuals with disabilities and other vulnerable communities can easily register for appointments and access vaccination sites is essential for an equitable distribution of the vaccine. So, Dr. Kessler, how will the Federal Government partner with states to improve access to the COVID-19 vaccine for individuals with disabilities and older adults?

Dr. KESSLER. Senator, absolutely key points. And no doubt we can do better on that. I think we have all been frustrated getting appointments, people staying up throughout the night, refreshing their computers, trying to get appointments. What we have been trying to do is to increase the number of access points, increase the number of vaccinators. As you have heard, we are going to increase not only the number—we are increasing the number of appointments, the vaccinators, the number of sites, but also working on the information systems. This was a mad dash at getting this out. And what you see is just very real, but there is a real commitment at the state level, at the Federal level to improving those information systems and the ease of use, right. And we have to do better.

Senator HASSAN. Yes, I appreciate that. I just also want to point out that it is a civil rights issue. The Americans with Disabilities Act does apply here. And it is really critically important that whether it is a telephone system that somebody who has a hearing impairment can use, or a screen that somebody with a visual impairment can use, or a vaccination site where somebody who might have difficulty being exposed to bright lights or a lot of noise for long periods of time has space to be. These are all requirements under the law for access.

It is—another time we will have another discussion about how far the health care system has to go in this kind of accessibility generally. But for vaccinations right now, it is an issue we are hearing about a lot from constituents. So I just wanted to bring that to everybody's attention. Let me move on to another question for Dr. Kessler and Dr. Fauci.

As vaccinations continue to ramp up across the Country, you have both mentioned the possibility that we will need to develop booster shots to ensure long term protection from COVID-19 and respond to existing and future variants of the virus. Are there additional steps we should be taking now in order to ensure that Americans will have timely access to any necessary COVID-19 boosters and make sure that they will understand the importance of taking them, including when the current public health emergency declaration ends? Maybe Dr. Kessler and then Dr. Fauci.

Dr. KESSLER. First, we are looking at the data. We know, at least for some of the vaccines, that there appears to be durability at the six-month point. The reason I use the six-month point is because that is how long the first people have been immunized. So we are continuing to monitor that. And I think what we see, I mean the good news is that durability seems to exist. There is a slow decline and there is some variability between individuals. So we can sit here today and tell you when, and definitely there will be boosts.

But I think we have to plan for it. And I think at some point, like my colleagues, I think it is—it may be more likely than not that at some point we will need to boost with the durability. But it depends on a number of questions. So we need to make sure that we have enough vaccines in the cupboard, right, that are ready to go when we need to do that. And we are doing that planning, Senator.

Senator HASSAN. Dr. Fauci, do you want to—I know I am a little over time, but if you could briefly comment.

Dr. FAUCI. Yes. I agree completely with Dr. Kessler. But let me just add one thing that adds into the mix of variability, is that there is a considerable degree of variability across the population in the responsiveness to the original vaccine. Remember, we have a lot of people in this Country who have underlying conditions. Many people are on drugs for autoimmune diseases, cancers and things. They get vaccinated. Their level of antibody may not be as high or even multifold lower than an otherwise normal, healthy young person. That person would likely need to be boosted well before the others.

As Dr. Kessler said, there is a considerable amount of variability. What we need to find out is what is the minimum cutoff? Where is the point where absolutely you have got to start giving boosters? And I think we don't know that yet. We just have to follow people long enough to know when the level of antibody goes way down, because if a healthy person may hang up there for months and months and months, somebody who is on chemotherapy for cancer or glucocorticoids for an autoimmune disease may come way down. That is the point.

Senator HASSAN. Thank you. Thank you, Madam—

Dr. WALENSKY. If I may, Senator, may I just chime in and let you know that CDC does have active, on your prior question, active toolkits and playbooks for folks with disabilities. We are working with our local partners and jurisdictions to make sure that these vaccine sites have equitable access, there is access to another round. So I just want to let you know those resources are available.

The CHAIR. Thank you very much.

Senator Murkowski.

Senator MURKOWSKI. Madam Chairman, thank you. To our witnesses, thank you so very much. It is not very often that Alaska makes the news in the good news category when it comes to health and our statistics, but we are No. 1. We have moved out early in terms of the vaccination of Alaskans. Right now, it is 18.9 percent that are fully vaccinated, 28 percent have received their first vaccine. We have some communities that are approaching 90 percent vaccination. So we are pretty, pretty proud of that.

The rest of the Country is looking at the model as to how we were able to do it, open it up to everybody over 16. So I think you are looking at that. You don't perhaps need to follow the model of us delivering the vaccine to the clinics by way of snow machine with a sled in back. But the model is good, and it is one that has demonstrated how quickly we can move out. The vaccine guidance and the vaccines shots in arms has given us a kind of ray of hope here. Spring is coming, vaccines are getting in arms, and people are feeling better.

But the economy is still struggling. And the guidance that seems to be coming is not perhaps consistent with what we are seeing on the ground and this is what Alaskans are sharing with me. We have a significant tourist industry. We welcome people to come up. We want them to be safe. We are going to encourage all of the continuing protocols. But we have been struggling in trying to get the economy back on track. When 60 percent of your tourists that come to the State of Alaska come by cruise ship, we have got a conditional no sale order or conditional sale order in place. It is effec-

tively a no sale order. Dr. Walensky, we have had an opportunity to speak with folks on your team. Alaskans aren't pushing to say don't send people our way if it is not safe, don't use this if it is not safe.

But what they are asking for is some kind of guidance in terms of timeline. It is the timeline so that you can know to plan. Do we go ahead and the hundreds of small businesses that are reliant on these tourists coming up, do they open up or do they acknowledge that this is going to be the second season in a year where they will have nothing and effectively no weather to shutter their operations now.

When we are talking about health impacts, we all want to make sure that we are following the guidance and the science and all that comes with that. But there is also this recognition of the economic impact. Certainty is helpful. We haven't had much certainty with this virus, and it has been challenging.

Can you give me any kind of guidance to give Alaskans in terms of what we might be able to expect with where this guidance is in the process? When you say later, does that mean at the end of 2021? Does it mean in three months? Does it mean in one month? What kind of guidance can you provide when it comes to the CDC's order as it relates to the conditional sale order?

Dr. WALENSKY. Thank you for that question. Yes. So first of all, I understand the economic impact of the no sale, or the no sale, the conditional sale and the travel. And so we don't take that lightly. We have provided technical assistance on the conditional sale where we have provided a four phase strategy for how we could get sale open. We are in phase one of that, moving toward phase two. This is an interagency decision. It is not a decision solely up to the CDC. So this it would be—I would be remiss if I was able to do that by myself, because the decision is not solely up to us.

Senator MURKOWSKI. Second phase, going to that second phase. Can you give me some indicator in terms of a timeline there?

Dr. WALENSKY. I can't simply because I don't believe it is solely in our jurisdiction to address. It is not necessarily CDC.

Senator MURKOWSKI. Who else is part of the decisionmaking process then beyond CDC?

Dr. WALENSKY. I believe Department of Transportation, OMB, there are numerous others that are making these decisions.

Senator MURKOWSKI. I want to follow-up with you, and I know we have an opportunity for that later and I will look forward to that. But again, you need to—CDC's role is to work through the health safety. We understand and we respect that, but just trying to gain some sense as to timing. Quick question for you with regards to vaccine hesitancy. We have got Alaskans vaccinated, they are ready to go.

Understand that, Okay, we got to keep masks on. We have to continue social distancing. There is still the issue of whether or not the guidance for the schools is going to allow kids to get back in. One of the things that I am hearing from folks is why am I even going to bother getting the vaccine if after I am fully vaccinated everything is still the same?

I am told that it is not safe to be on an airplane or on a cruise ship. If I am exposed to someone who has the virus, I still have

to quarantine, maybe not for as long a period. How much of the guidance that we have in place, and to Senator Burr's point about how long it takes to get that clear guidance. To Senator Collins' point about the school guidance and the reopening, is that contributing to the hesitancy that we are seeing?

Dr. WALENSKY. Thank you for that question. I think there are a lot of reasons for vaccine confidence. We articulated some of those earlier, convenience, speed at which this happened, and personal, concerns about side effects and whatnot. I do think as more people are vaccinated, we are working—I know we are working to move forward on that guidance. The initial guidance was put forward with just 9 percent of the population vaccinated. That allowed actually for a small gatherings in people's homes, for grandparents to hug their grandchildren even if they were unvaccinated.

There has been since nursing home guidance so that we can visit our loved ones in long term care facilities. One of the things that has been challenging with travel is that, as I think as people are aware, last Friday was the busiest travel day of the season—since COVID-19 was declared a pandemic in March 2020, 1.3 million people traveling through our airports. This just at a time when we have 50—still 50,000 cases a day and we know our variants have traveled through these airports.

We know that travel is a time when people, not necessarily in flight itself, but travel is a time when people bring these variants home, bring these variants to other places. So we are balancing the fact that vaccinated people will likely travel with unvaccinated people. There is travel happening. We had surges after July 4th. We had surges after Labor Day. We had certain surges after the Christmas holiday. And we want to just make sure we are doing it safely. We are actively reviewing it right now.

Senator MURKOWSKI. I am well over my time, Madam Chair. Thank you.

The CHAIR. Thank you.

Senator CASEY.

Senator CASEY. Chair Murray, thank you very much. I want to thank the witnesses not only for appearing, but especially for your service to the Country. I will start—I just, I think I have two questions. I will start the first one with Dr. Kessler and Dr. Walensky. And this comes right from home. Local communities are asking, and frankly asking me and I am sure others, to ask this question. And here is the predicate for it, as vaccine production increases dramatically in the coming months, and that is good news, and the venues in which people are vaccinated increase, it is critical that every stakeholder in the distribution and administration process have access to the information, the data that they need.

At the state and local level, that includes getting data from the Federal Government, not just about the vaccines allocated to that jurisdiction directly, but information about vaccines that will be flowing to that jurisdiction through some of the direct Federal partnerships like the Program for federally Qualified Health Centers and the Retail Pharmacy Partnership. So here is a question for Dr. Kessler and Dr. Walensky, will you commit to ensuring transparency of this information to assist state and local leaders in making decisions about the vaccine campaigns within their jurisdiction?

Dr. WALENSKY. I am happy to start with that. Thank you, Senator. The operation is responsible for how vaccines are allocated. Those vaccines are allocated directly to the states. I have been on weekly Governors calls where we have provided the Governors a three-week timeline for how many vaccines they can expect this week and two weeks after this week. That is the first thing that has happened during this Administration so that we have been able to give Governors a line of sight so that they can plan three weeks ahead of time. There is also allocation to Federal agencies, Department of Defense, the VA, Bureau of Prisons, and FEMA. And then there is allocations that go directly to federally qualified health centers and the Federal Reserve Retail Pharmacy Program. Those decisions are made after extensive deliberation and discussion. They are made by the operation, but those discussions happen at all levels of HHS. Thank you.

Senator CASEY. Dr. Kessler, anything you wanted to add on this?

Dr. KESSLER. Senator, the answer is yes, we commit to that transparency. As Dr. Walensky said, the Administration is giving three weeks, looking ahead three weeks. The reason why it is only three weeks is the realization that vaccine is being made real time. It is coming off the line and they are projections. We have every confidence that we will have enough vaccines. But it is a very human, when you are dealing with a very human process, biologics have to be made very carefully. So we are making projections three weeks ahead of time, but we want to be fully transparent on what we see coming and we are trying to do that.

Senator CASEY. Thank you, doctor. I guess my last question. I will try to, in the remaining time, ask this question of Dr. Fauci, if others wanted to chime in, we have time. But this is really just projecting the biggest challenge you think we face, the most urgent, the most difficult. I realize they can be multiple and at the same time.

But Dr. Fauci, when you look forward just down the road a few months in terms of just the public health challenge we have, how would you rank or itemize the challenges that we face? Are you more concerned about the impact of variants or the struggle to get people vaccinated or is it both? Or do you have some other worries that I haven't articulated? I know others may have spoken of this earlier, but I would like to get your view.

Dr. FAUCI. Thank you for the for the question. There are a couple of things that concern me. Probably the one that is the most prominent is my concern that we will declare victory prematurely. If you look at the dynamics of the outbreak, it is a very, very high peak that we had following the holiday season that was expected to have a peak, but not that high. It really went up to 300,000 to 400,000 new cases a day at one point. It is coming down sharply now, but we seem to be plateauing at a level that is unacceptably high, around 50,000 or so cases a day.

This is what has happened in previous surges where you come to a plateau at a high level and then you start to surge. Europe is generally about three to four weeks ahead of us in the dynamics of their outbreak and what they saw a little while ago was a plateauing of their decrement. They were coming down nicely and then they plateaued. And just as you might have predicted, then

one started to go up. In a couple of weeks ago, they had a 9 percent increase.

Now they have about a 5 percent increase. I am concerned that if we pull back in our enthusiasm for the fact that vaccines are rolling out and things look good, if we pull back prematurely, we may trigger another surge and that would really set us back in all the things that we are trying to do.

The CHAIR. Thank you, Senator Casey.

Senator CASEY. Thank you.

The CHAIR. Senator Braun.

Senator BRAUN. Thank you, Madam Chair. My questions are going to be for Dr. Fauci and Dr. Marks. It is going to be two questions. One, you can sense the frustration from Senator Paul, Cassidy, Murkowski, many of us, because we know we don't have complete data. We know we have got to stay disciplined before we get this thing under control. But in kind of a top level way that I am looking at it, we have got to get the herd immunity through natural infection or vaccination.

I want to make sure that you can take that and vaccinations and come up with herd immunity. If the conferred immunity is going to be about as good with a vaccination versus getting the infection, I am taking 30 million as the number of cases tested. I would like your opinion on how many completed vaccinations there have been and then the big variable, how many untested cases to get to that 250 million. And would like your opinion on those numbers, because when you can give us a little bit of certainty or idea on that, it gives us hope, like Senator Paul said, to maybe stay tough and get through it.

Second question would be, if vaccinations aren't as effective as we want them to be due to a cascade of variance, then do we need to turn our attention to therapeutics if this is going to be something we battle with over the long haul?

Dr. FAUCI. Thank you for that question. I want to just hearken back to what I had said some time ago to Senator Burr and some of the comments that Dr. Walensky had made about this magical terminology of herd immunity. We could get to where you and Senator Murkowski and others want to get without necessarily reaching this arbitrary percentage, because as Dr. Walensky said, it is going to really depend on a number of things because it depends on what the R_0 of the virus is.

If you have variants that come in, they will modify it. There are a lot of things that modify it. I like to look at it in a different way. I would like to look at it in that every day we get 2 to 3 million more people vaccinated. We also still get people infected.

If you look at the number of people that are protected, we don't necessarily have to reach 85 percent of the population to get to the things that you were asking for about your businesses in Alaska and about schools being open the way Senator Collins had said. We can approach that in a real, meaningful way before we get to this magical number.

Senator BRAUN. How many cases do you think there are untested out there? Because to me, that is a big plug in variable. I am reading four to five—is it four to five or is it closer to two or three? And if we have no idea, that is the biggest variable, when you get to

that point, where you get to what you are talking about. What do you do in your modeling? How many untested cases do you plug into the model you are using?

Dr. FAUCI. No, see there really is no model right now for herd immunity. It is purely an estimate. The only—take measles for a second. We absolutely know what the level of herd immunity is for measles, because we have had multiple instances where when you went below a certain level of protection in the community, you had outbreaks. It is a highly transmissible virus. The vaccine is excellent, 98 percent effective. When you get down below 90 percent of the population being immune, when you get into the 80's, you get the kind of outbreaks that we saw in the New York City metropolitan area. We don't know that yet for coronavirus. We just don't know what it is yet.

Senator BRAUN. I understand that. And what about if it seems to be an elusive thing to get through vaccinations and natural infection, where do we start putting more emphasis on therapeutics?

Dr. MARKS. Maybe I will chime in. There is a fundamental difference between measles and COVID-19. Measles is a virus that does not vary with time the way that COVID-19 is varying. And the reason for having this issue of needing to have the best immunity you can and potentially vaccinating people who have already had COVID-19 is to get to high enough antibody levels to make sure that as these new variants come along, we are not basically decimated by yet another version of COVID-19 coming across the population. So it is essentially doing it right the first time to prevent another set of closures.

Senator BRAUN. Which has a lot of kind of uncertainty, timeline, indefinite. And I think that is a tough thing I think you guys have to contend with. Let's get to the question of then therapeutics versus vaccines, because isn't that the way we finally hammered AIDS was with the therapy, because a vaccine was never—

Dr. MARKS. For a global pandemic like we have here, I think we really have to probably—I am going to defer to Dr. Walensky, who is more expert than I am. But I think vaccination is probably, and don't get me wrong, we need better therapeutics, you are absolutely right.

Senator BRAUN. Or natural infection, right?

Dr. MARKS. I think we would like to avoid natural infections because I think as was already mentioned at this hearing, we have this COVID long haul syndrome. So I probably prefer not to have those people have those long term effects. So we would like to prevent natural infection by providing immunity through vaccination.

Senator BRAUN. You want to add anything?

Dr. FAUCI. I agree completely that the idea of treatment as prevention as we have with HIV doesn't work because you are dealing with an acute syndrome that lasts just literally for a few weeks. Virological, you may have persistence of symptoms. Treatment is important because you don't want people to get ill. And we have had 530,000 plus deaths. You can avoid that with good treatment. But the dynamics of an outbreak absolutely is going to depend upon the vaccine.

The CHAIR. Thank you. Thank you very much. And I would just like to note that Dr. Fauci does need to leave at 12:15 p.m. so we are going to try and get through as many as we can.

Dr.—Senator Smith.

Senator SMITH. Thank you very much, Madam Chair. I think you almost promoted me to doctor, but sure.

[Laughter.]

Senator SMITH. I want to thank our panelists for being with us today. And as I have been listening to the testimony and also the questions that are being asked, I am thinking about a conversation I had yesterday with the folks at Hennepin Health Care, which is a safety net health system in Minnesota, level one trauma center in Minneapolis. And one of the things that one of the caregivers said really has stuck with me. He said, we are just so worried here as we continue to grapple with the impacts of COVID in this community that the world is going to move on.

As Dr. Fauci and others have said, we are still seeing somewhere in the neighborhood of about 50,000 cases or more of COVID a day and 1,200 daily deaths. So I think it is important that we stay vigilant and keep our focus. And, of course, also look to where the good news is. And I think we can do both of those things. Dr. Walensky, I want to ask you about something around vaccine distribution. This is a bright spot. So tribal nations in Minnesota have done an exceptional job in distributing the COVID-19 vaccine.

Here is just one example. The White Earth Nation in Northwestern Minnesota partnered with Bannermen County to distribute the vaccine and has now, this county, one of the highest vaccination rates in the whole state. And what they did is they had—they established a joint task force with the county, help to streamline vaccine distribution, and manage the supply in order to get the vaccine out. And today, White Earth Reservation, where, of course, there is a mix of native and non-native people living and is a sovereign nation, so they set their own guidelines about who can be vaccinated, today because of this close collaboration and the partnership that they have, they have been able to—anyone who is over 18, who lives on White Earth reservation, has been able to be vaccinated.

Another example is the Boise for Mobile Vaccination Clinic, which is they have brought this as—another Northern Minnesota Ojibway tribe, they have brought their mobile vaccination unit to tribal members in Duluth and Minneapolis, those who don't live on tribal lands. So, Dr. Walensky, could you just comment on why you think this is working and what this can teach us about addressing the challenges that we see around the Country in getting equitable distribution of vaccines?

Dr. WALENSKY. Thank you so much for that question, Senator. I think, as I mentioned, several weeks ago we had a vaccine forum where we brought people together to talk about their best practices, lessons learned, how they have been able to distribute. We had over 100 tribal participants and I don't know if those were specific examples that were given, but those are among the examples where we can say this is trusted partners, this is community engagement, this is people getting the message from people they know, places that they trust. This is part of why we want to engage

at not necessarily only the state level, or we need to get that down to the local level.

People don't necessarily want to hear from me that they should be getting their vaccine. They want to hear it from their local pharmacist. They want to hear it from their tribe members to say, we have all been doing this together. They may actually need to have it not just be convenient, but be able to revisit it and say, well, maybe I am not ready today. But it turns out tomorrow I have noticed that five of my friends, five of my community members have gotten it and then they are willing to engage.

I think these are important lessons that we need to be—that we are learning, and that we need to replicate those lessons and not just the tribes, but in other areas around the Country as well as rural areas around the Country.

Senator SMITH. Thank you. I really, I couldn't agree more with that. I think one of the things that is important about this is that we sometimes think that what we are experiencing is vaccine hesitancy, when actually what we are experiencing is a lack of access and especially a lack of access from trusted providers. So I think it is important. Dr. Fauci, I want to try to get this question into you quickly.

The Minneapolis Star Tribune recently reported that Minnesotans are using websites or vaccine shopping, so they are trying to figure out what is the best brand and then shopping around for that and trying to figure out the benefits of one vaccine versus another. Dr. Fauci, what would be your message to people who are trying to compare the efficacy of these different vaccines as they are making decisions about how to move forward? What would you tell them?

Dr. FAUCI. Yes, thank you for bringing that up, because that really is an important issue. We have three highly efficacious vaccines with a good safety profile. I think it is not appropriate, understandable, but not really appropriate to be shopping around to see which one you could get because you are making a guess of which one is better. The only way you know, if one is better than the other is to do a head to head comparison in a clinical trial.

My advice when people ask me is that what is the most important thing is to get vaccinated as quickly as possible when your turn comes up to get a vaccine. Which particular candidate you get is really not nearly as relevant as getting it as soon as you can. So if you go into a clinic and they have any of the one of the three available, I would just take it rather than waiting maybe a few weeks to a month for something that you think might be better. All three or highly efficacious.

Senator SMITH. Thank you so much. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Marshall.

Senator MARSHALL. Thank you, Madam Chair. Leadership is what America is now looking for. They are looking for a strong, consistent, honest voice from the NIH, from the CDC, the FDA and from the White House. And frankly, Dr. Fauci, a Nation is turning its lonely eyes to you for leadership. Let's talk about schools for a second. I think you all know and agree with me, our schools, our youth are in a mental health crisis. Our youth are suffering from

increased instances of suicide, substance abuse, overdoses, depression, a true epidemic.

This was very predictable for all of us from the health care field that when we closed down schools without the social interaction, we would see increased mental health crisis. Totally predictable. Let's talk about the science of viruses for just a second. As a private practice OBGYN for 25 years, I would tell you that viruses are predictably unpredictable. That how they impact a nonpregnant versus a pregnant woman certainly is different. And what I feel like when I try to listen very hard to you all is that this little science we do have is being presented as dogma, as gospel.

We know it is not. It is anecdotal at best. All I have heard so far today is basically anecdotal experiences. When it comes to schools, we need to hear a stronger voice from you all, from leadership. We need to hear a stronger voice, not a wishy washy voice. And Dr. Fauci, I would ask you, do you agree with me that the benefits outweigh the risk of getting children back in school? Will you tell America we need to get our kids back to school?

Dr. FAUCI. Yes. I have said that repetitively, as you know. You have obviously been following what I have been saying. I have been saying the most important thing we need to do is to try as best as possible to get our children back to school safely. And that is exactly what I have been saying over and over again right in this room in previous hearings. I think the Chair has heard me say that—

Senator MARSHALL. Based on everything we know about the virus, the epidemic we have now, do you feel the benefits outweigh the risk of getting children into schools across America?

Dr. FAUCI. Well, if you listen to the CDC's recommendations, that is exactly what they are saying. They are talking about the benefits versus the risk. And as you know, their guidelines, they are trying to get people to follow guidelines that will get the children back to school with the minimum risk.

Senator MARSHALL. I was hoping a yes or no answer, but I will move on to mask one masks. One mask, two masks, oh me, oh my. President Biden recently said that we should all wear masks until everyone is vaccinated. That is probably the worst thing that could have been said for compliance. So many people have said, why would I go get a vaccine when the President says we have to keep wearing masks until everyone is vaccinated? We Americans feel like the goal line keeps moving, and I understand your fear of different variants and all those different things going on here, but where is the science that clearly shows wearing mask is helpful after you have had the vaccines? And for the sake of time, I need to move on.

But I have heard the question asked already and I have heard anecdotal evidence. But I would love to have you all send me the studies that show that it is absolutely beneficial to wear a mask after you have been vaccinated or if you have had the virus. And we all want to know, where is the goal line? When can we stop moving masks? I want to talk about the border, though. That is what I am really concerned about.

I just visited the border, my third trip. There is certainly a humanitarian crisis, and I am sure anyone that has been down there

would agree with me. That is a national security crisis, but I want to talk about the health care crisis going on there. When I went down with a group of physicians three years ago or so, I was concerned about just the doctors, the nurses being overwhelmed. I was concerned about tuberculosis, hepatitis, scabies, sexually transmitted diseases and other communicable diseases. But now, based upon what we know, the incidence of COVID is 5 to 25 percent of the people coming across the border. And then what I see is they take a group of folks, 50 to 60 people, they put them on one bus, then they do a couple of exams and they all put them in some type of a dorm setting.

If they all didn't have the virus, they soon will. And then we let them go out into the public. That just seems hypocritical. The application that you are talking about for when we can let ships come to Alaska, and the concern about variance from South Africa, that just seems hypocritical to me. While I respect completely where you are coming from, it seems like it is a double standard. Dr. Fauci, are you comfortable with what we are doing on the border from an ID standpoint?

Dr. FAUCI. The reason I would have to hedge on that, because I am not really very deeply familiar with the details of what is going on at the border, and that is perfectly honest with you, Dr. Marshall. I really am not familiar enough with the situation at the border to be able to make a comment. If I was, I would.

Senator MARSHALL. Whose job is it to know that?

Dr. WALENSKY. I can chime in and say that I am aware that at CBP sites there is overcrowding and that we need to, from an infectious disease standpoint, from a COVID standpoint, we need to dedensify what is happening at CBP. We have been working closely with ORR as children leave CBP and move to the ORR sites to work toward getting them screened and tested, which is why they have, what percent positivity they have there. Those ORR sites are much improved compared to the CBP sites with regard to how those children are cared for, who is caring for them, and we are providing technical guidance on those ORR sites to work to make sure that they are as safe as possible using mitigation strategies—

Senator MARSHALL. But do you see the hypocrisy in what we are doing to America? We are saying that I can't have a barbecue with my entire family on the July 4th. I can't have Easter service worship together. But we are going to let people come across the border in mass numbers and just release them into—does that not seem hypocritical?

Dr. WALENSKY. I think there are two different situations, and we have to handle in two different ways. And we have guidance and strategies for how we are providing technical guidance for the challenges that are occurring in the density at the border. And then we are trying to keep the public safe using the evidence based strategies there. Thank you.

Senator MARSHALL. Thank you. I yield back.

The CHAIR. Thank you very much.

Senator Rosen.

Senator ROSEN. Thank you, Chair Murray and Ranking Member Burr. I really would like to thank all of the doctors for being here,

for their tireless service to our Nation, for their information, for their hard work and studying. And I would like to just make this other comment that most of us here do understand that data takes time, good data takes time. Coronavirus is a new virus. It hasn't been around that long. We haven't collected all the data to show us what the trends or variants may be. It is, of course, evolving. And that good data that will help us do the predictions that epidemiologists and doctors like yourselves helped to do will be there, it is just a matter of time.

I appreciate how quickly you are working on that. But we also have to keep focused, I believe, on treatment options as we have more variants. And of course, people will continue to contract the disease. And we want to—we know vaccinations need to go up, but we want to reduce the deaths if you do contract the disease. 5,100 Nevadans have already, over 5,100 have already died from COVID. I don't want to see that going up. And so I have introduced bipartisan legislation to hopefully track a diverse set of COVID patients, long term, longitudinal study and report those findings on a regular basis.

Dr. Fauci, I really appreciated so much the conversations we have had in the past. Talk about monoclonal antibodies, other antivirals. We know both have helped. Like I said, people are still dying. So is it an issue of patients not having access to some of these? And what can you maybe tell us about what is in the pipeline for therapeutics for those who unfortunately will, may still contract the disease?

Dr. FAUCI. I had outlined, and I will briefly repeat it, in my opening statement that we have therapeutics for people with early disease, the difficulty logistically is that getting people early enough to make it work. Monoclonal antibodies clearly work in the setting of getting people before they enter the hospital and before they develop advanced symptoms. Every study that has looked at monoclonal antibodies after a person has advanced disease in the hospital has shown no benefit.

We do have good drugs for advanced disease, particularly the state of the art of using dexamethasone with advanced individuals. We have a number of others under emergency use authorization. But getting to the point that I think you are suggesting, Senator, is that the real endgame for this is to develop targeted antiviral drugs, very similar to what we did so successfully with antiretrovirals for HIV and for curative therapies for hepatitis C.

We are now beginning to be investing a considerable amount of resources in doing that. We have a couple of candidates now that look good that actually had been developed previously that we are putting into Phase 1, 2, and 2a and 2b trials. So you are absolutely correct. We need to do better on therapy, and the strategy for the future is to direct antiviral therapies that are similar to what we did with HIV. Thanks.

Senator ROSEN. I would like to build on that then, because we hear about the long haulers or the long term effects of COVID-19. We see people really suffering from this. We know about 30 percent of all COVID patients really continue to suffer from some form of ill-defined symptoms, prolonged fatigue, brain fog, as some people are calling that. It may render folks unable to go to work. It puts

them at risk for continued social isolation and other kinds of issues that may certainly decrease their immune system. And so, we have to be sure that we don't deny benefits to these folks who have the long haul symptoms, but what can you tell me about Dr. Fauci, about NIH, how you are evaluating these troubling long term health consequences? And are there treatments available? What is in the pipeline there for those that are continuing to suffer? Some people's sense of smell. I have heard rancid smell. Now they get their smell back, but everything smells sour or rotten. What are you doing?

Dr. FAUCI. We have initiated a major program to the tune of \$1.15 billion that we are doing at the NIH, also in collaboration with the CDC, and following cohorts of individuals to determine the incidence, the prevalence, how long these symptoms last. We have some studies say they go out up to eight months or longer.

You asked a very relevant question. What about treatment of them? It is very difficult to devise a therapeutic regimen when you don't know what the underlying pathogenic mechanism of the disease is. And that is the real stumbling block here and why we are intensively studying these individuals, because although it is an absolutely real phenomenon, we don't have any pathogenic mechanisms right now that we are certain of that has a commonality among all of them. We will find that out. And when we do, then we will be able to devise hopefully appropriate and effective therapies.

Senator ROSEN. Thank you. Again, appreciate everything you are doing. Madam Chair, I yield back.

Senator BURR. Thank you, Senator Rosen.

Coach Tuberville.

Senator TUBERVILLE. Thank you, Senator Burr. Thank you very much. Thank you all for your service. Kind of reminds me of my old job, 40 years coach in college football, sitting there listening to armchair quarterbacks. Everybody has got the right idea of how to run your job. Thank you for what you are doing, because this Country and I guess 340 million people are counting on you all and several billion that are not in this Country. So it is very important and, it just brings to the fact where we are in this Country.

On the campaign trail for the last two years, I keep telling people, this is really the last year that, everybody thinks they are going to come up with a vaccine. Americans are going to come up with this vaccine because that is what we do. But we need leadership. Dr. Fauci, you are the Tom Brady of the COVID team. You have had good days and you had bad days, and we thank you for what you have done. We just need leadership from you and consistency. Everybody that I talk to, they understand where you are coming from but sometimes we change in midstream. Coaches can't do that. You got to say what you believe in.

We just ask you to, just be firm with us, tell us. You had people in here today, Senator Rand, talking about the mask. Tell us what you believe because we know very little about it. The American people don't know anything about it. Dr. Walensky, you got a tough job in front of you. And thank you for taking it on, really. Again, this is not a Republican or Democrat disease. This is a worldwide disease. And our kids are hurting, I will say that. Our kids are

hurting. I have had friends that have died. I have had people go out of business.

We got to get this Country back open as soon as we can. I mean, we can't drag their feet much longer, but we can't put people in harm's way either. We really can't. So thank you for what you are doing. I will reiterate what Mr. Marshall said, Senator Marshall said about people in Alabama can't understand why we are letting people in when we know some of them have the coronavirus. We are in a loving Country. We like everybody. My God, we put our lives on the line, our Country on the line, our businesses and everything else on the line for the last year. And for some reason, the White House continues to let people in with this virus.

It is just mind boggling to us that pay taxes, everybody that pays taxes, that—we will help them. This isn't the time. This is not the time to do it. And I think it is your, you guys' job is to go up there and say, listen, what are we doing? We can't do this anymore. We have got to get the people back to work and kids back in school and go back to church and get back to normal life. And we just got a double standard here right now that—it just amazes me. But again, I don't have any questions. Thank you for what you are doing.

We are looking up to you all and tell us what to do. Please tell us what to do and how to get through this, because we have a lot of people in trouble, mentally in trouble, not just physically but mentally. Thank you very much. Thank you, Chair.

Dr. FAUCI. Senator, can I make a comment just in response to something that you said it is really very important. When you have a static situation that doesn't change, when you do change your mind, then you are flip flopping. But would you have an evolving situation when the scientific evidence and data roll out and you learn more things in March that you didn't know in February, that you didn't know in January, that is the reason why you may hear us saying things that seem to be different from one month to another, because you make a decision, you make a policy, you make a recommendation based on what is going on and the data at the time. So I just wanted to say that because you make a very good point. when you were talking about consistency. We try to be consistent, but we have to be consistent with the data as it exists.

Senator TUBERVILLE. The game plan changes then?

Dr. FAUCI. You bet. If you are playing against the zone or you are playing against a man to man, it is different.

Senator TUBERVILLE. You are exactly right. You are exactly right. But when you do change it, sell it and stick with it. I mean, that is what we are all counting on.

Dr. FAUCI. Thank you.

Senator TUBERVILLE. We are counting on you all. Thank you.

Dr. FAUCI. Appreciate it, sir.

Senator BURR. Senator Moran.

Senator MORAN. Gentlemen, ma'am, thank you for being here. Thank you for your service to our Nation. Dr. Marks, it is nice to see you all. See you and the FDA in the appropriations process. And Dr. Kessler, thank you for your help in regard to helping us with the care for veterans. And we have—we are working to pass legislation passed the Senate last night with a conversation we had

in our hearing about spouses and caregivers for veterans. So that issue that I raised with you is progressing. And Dr. Fauci, I didn't have enough of you in the appropriations process, so I joined the HELP Committee.

Dr. FAUCI. Great to see you.

Senator MORAN. Thank you very much. Let me just ask you a question and then I think I will visit with Dr. Walensky. It is going to be a bit outside of COVID-19, all that is related. So you better than anyone know the resources that NIH has devoted to combating COVID-19, the research and the response. I would like to be reassured that despite that important work, that the other things that are important to America that are led by NIH research are not suffering. So how would you—how do you see the overall picture at NIH during this time of COVID-19?

Dr. FAUCI. I think I would not be totally frank with you if I told you that things are just exactly the way they were prior to COVID, Senator. There has been a diminution of activity in some areas for the simple reason that a lot of the clinical center, for example, is not going at full capacity for reasons that relate to the outbreak itself. As far as our grantees on the outside, we are continuing the same sort of support for all the other diseases that I know you are interested in cancer, heart disease, diabetes, Alzheimer's, Parkinson's, all of those are going well.

But I think across the Country, the same way that other areas of our society have been dampened down a bit by this outbreak, I think some of the research endeavor, by the very nature of when you shut down, you shut down a lot of things, including accessibility, for example, of certain types of approach. But I want to give you my absolute promise, and I am sure that Dr. Collins, where he here would tell you the same thing, we give you our absolute commitment that we will do everything we can to make sure that nothing important slips in the other areas of research.

Senator MORAN. It is a matter of saving lives with COVID and outside. There are other afflictions and diseases that Americans are afflicted with. Let me turn to the CDC, Dr. Walensky, it seems important to me, I mean, I have heard the—well I have three hearings going on this morning at the same time. I have heard most of the testimony and responses to questions. And I certainly am a promoter and proponent of people being vaccinated.

I think that the CDC could be helpful if there are guidelines for instructions and suggestions for those who have been vaccinated were current and consistent and timely. So what is it that CDC would tell someone today that their behavior or conduct can change or what their behavior or conduct should be following vaccination?

Dr. WALENSKY. Thank you for that question, Senator. About a week ago, we released our first guidance on the first step on what you can do if vaccinated, and that included things like small visits in your home, visits with other vaccinated people unmasked and undistanced, so that you could dine with other vaccinated people in your home. You can also visit with unvaccinated people as long as people in their home don't have risk, high risk of severe disease. So that is we are still looking at data regarding whether people who are vaccinated can be asymptotically infected and potentially transmit to other people. In that case, we wouldn't want you

to be living with somebody who was immunocompromised, on chemotherapy and whatnot, because we would worry about severe disease in that household.

We have also released guidance on the fact that you don't have to quarantine if you have been exposed and you are vaccinated. So the quarantine has gone away with regard to people who are being vaccinated. We are revisiting what we should do regarding travel for those who are vaccinated, and that should be coming forward soon. That is going to likely be the next step in this regard. I want to remind people that we have now 12 percent of the population fully vaccinated, 39.9 million people. The initial guidance was released when we had 9 percent of people vaccinated.

As more and more people are getting vaccinated, as we are getting more and more data about the implications of vaccination with regard to asymptomatic infection and potential transmission, those guidelines will continue to emerge as you are requesting.

Senator MORAN. Let me suggest in the two-seconds that I have left, that I had left five seconds ago, that I would ask you to be concerned, this is true for every agency here as it is represented here, a rumor in today's social media world, a rumor about a problem with a vaccine, a consequence which could be false, but it is easy for fear to spread among Americans, you need to be prepared with the science and medicine to respond quickly to put down a rumor. And I hope that is the case in all of your circumstances.

Senator BURR. Thank you, Senator Moran.

Senator Luján.

Senator LUJAN. Thank you so very much, Chair. I really appreciate that. Dr. Fauci, before I get to my questions, just wanted to ask you, does wearing masks stop the spread of COVID? Or help prevent the spread of COVID?

Dr. FAUCI. I am sorry, sir, I didn't hear your question.

Senator LUJAN. Dr. Fauci, does wearing masks help stop the spread of COVID?

Dr. FAUCI. Absolutely.

Senator LUJAN. Should people keep wearing masks?

Dr. FAUCI. Absolutely.

Senator LUJAN. I think there is a reason, Dr. Fauci, that even physicians, when they are in surgery and practicing, that they wear face coverings because it stops the spread of infection. And I think it is important. I just wanted to make sure that we gave you time to clarify that after some of the previous questions that have been asked today. Dr. Fauci, first to each and every one of our panelists including yourself, thank you for what you have been doing to save people's lives and to defeat COVID-19. There are a couple areas where I do have some concerns, and it is based on some of the data.

According to the CDC, Native American and Latino populations living in the United States are more than twice as likely to die of COVID-19 and more than three times as likely to be hospitalized as their white counterparts. Despite this data showing us that communities of color in the United States have been hit the hardest by this pandemic, Latino and Black people are receiving a smaller share of vaccines compared to the larger population.

On February 19, Dr. Fauci, you said that that racial disparity was very disturbing. And I appreciate that. Given the recent polling that there is little difference between racial groups in terms of how much they want a vaccine, how can the Federal Government and will the Federal Government increase access to vaccine in Latino, Native American and Black communities?

Dr. FAUCI. This is a major initiative, Senator, that the Administration, the President himself is very serious about, and it has to do with any of a number of things that are being put in place to allow equity and easy accessibility.

For example, community vaccine centers in areas that are demographically represented by minority communities, community health centers, the same thing, having pharmacies that are stocked with vaccines in areas where there are representation of minorities to a high degree, to have mobile units to go out into the community, particularly in those areas that are underserved, and to increase the number of vaccinators, people who can put vaccine into people's arms, be they military, be they retired physicians, nurses, and healthcare providers.

This is a high, high priority for the Administration to include equity into a vaccine program.

Senator LUJAN. Appreciate that response. And while I do have some concerns and questions surrounding the decisions that were made by HRSA with the initial 250 sites that were identified, including the first 25, I appreciate the expansion of those sites to 750, which has expanded more sites in New Mexico, including in rural communities. With that being said, Dr. Fauci, I believe that the CDC social vulnerability index, a measure that takes into account racial and socioeconomic factors and also rural communities, would be a useful index to allocate a certain percentage of vaccine doses to address these disparities.

The State of New Mexico has designated 25 percent of vaccine doses based on SVI. And I know it was announced last month that FEMA has partnered with CDC to launch vaccination sites based on their SVI. Yes or no, do you agree that using SVI as a measure in allocating vaccine doses could potentially help address vaccine disparities?

Dr. FAUCI. I think it would, Senator. I would probably ask Dr. Walensky since it is a CDC issue, if you have any comments on that.

Dr. WALENSKY. Yes, we are using that. We are using SVI as a mechanism by which to include FEMA sites. We actually look, in collaboration with FEMA, look at both census data to make sure we are getting large populations as well as SVI. We have a benchmark SVI. We are also looking at the SVI data for distribution. We know we have work to do in this area. And while we are looking at the data, we also know we don't need the data in order to improve because we know we have improvements to make.

Senator LUJAN. I raise my concerns about HRSA's initial decision with the first 250 sites that were announced, the rollout of the first 25, and the first 250 in New Mexico, which is a large geographical state that has many challenges, was only identified with one center. Dr. Kessler and Dr. Walensky, can I get your commitment today that future programs focusing on vaccine equity will serve

not only underserved communities in urban centers, but also those in rural regions as well?

Dr. WALENSKY. Maybe I will just chime in here and say that I was really pleased yesterday when CDC announced \$2.25 billion in funding to go toward testing in areas that needed more with regard to health equity. This was the first time that we have been able to directly give 19 percent of that funding specifically to rural jurisdictions. And so that effort is intended to reduce disparities, increase testing, increase mitigation strategies and education, and actually leave a workforce capacity in those areas.

Senator LUJAN. Can I get your commitment that future programs will make that commitment to rural regions as well?

Dr. KESSLER. Senator, the answer is yes, absolutely.

Senator LUJAN. Thank you. I appreciate that. That is what I was looking for. I very much appreciate the explanation there. Thank you very much, Chair, and I yield back my time.

The CHAIR. Thank you, Senator Luján.

Senator Burr, do you have any additional questions?

Senator BURR. Thank you, Senator Murray. Guys, we are at the end. I do want to make some comments to sort of tie together much of what we have heard today. Senator Kaine said about a reference to a woman, maybe she didn't read the science. Well, I have got to tell you something, you already know most Americans don't read the science. And if they do, they are like me. They don't understand the data.

I think there is a lesson to that, and that is that when we put out guidance, when we make suggestions, you can reference to the science, but you have to say it in a way that the American people understand it. So it is not just the guidance that we need, it is an explanation in a common sense way as to why that is the guidance today so that they can apply that to their own lives.

Two, Senator Murray said something really important, that we need to do everything we can to raise the confidence of the American people to take the vaccine. To you, Dr. Walensky, guidance contributes to that. To Dr. Fauci, where he here, a simple pitch of if you take the vaccine, the data shows us you won't die and you won't go to the hospital. That is the most compelling argument to make to the American people today that I can think of. But we don't use plain words like that. We come up with something that is a way to expand it, that references something versus something that the American people will understand.

Now, these are my comments. I hope the vaccine policy will change in the not too distant future with the appropriate focus on geographical underserved needed areas. Where the policy is, we are going to stick the next person in line. Now that we have addressed long term care facility, congregate care, the most at risk, I fear, David, that in the not too distant future, we are going to be sitting there with vaccines and no arms to stick based upon the inability of the American people to sort through this or the frustration of staying up all night to try to get your reservation at CVS, and you finally say, I am just going to wait until it opens wide open.

I may be wrong, but what if I am right. And I just implore all of you to begin to think through, at what point do we pivot where we say to the American people, if you are over 17, then the vaccine

is available to you, you are going to—might have to go stand in line. You might have to get a reservation. But I remember the day I walked into a hospital that their specialty was bypass surgery. And when they explained to me that the first two surgeries in the morning actually spent the night in the hospital the night before, I was bewildered at this and I said, why?

They said, because if we if they don't show up on time for their preop, then we miss two surgery windows, and those surgery windows are our profit. We break even that day if we miss those two. Well, if we miss that next person in line, if we have to wait five minutes to stick that person, we haven't maximized the limitations that we have of people, professionals that can load that syringe and stick it in the arm. And I think that is going to become more and more a concern.

Lastly—well, this first. With what we know today, our goal of everybody who would like a vaccine by the end of May, I think it is fairly easy to say to the American people, next fall, schools should open, and they should all be in person. I think it is fairly easy to say by the time we get to summer, Americans should fly, and they should feel comfortable on an airplane. I think we should be able to tell people to plan their summer vacations. I think we should say next Thanksgiving and Christmas plan to spend it with your families, both immediate and extended. We have to accept the fact that our goal right now is to be fully vaccinated then.

Dr. Walensky, I am not saying travel to Germany or travel wherever, because we are at the mercy of their vaccination schedule as to when we open it up, but let me just say to you, providing some certainty for next Thanksgiving, next Christmas, next school year, even if the CDC policy or the Administration policy is not that we are going to open all schools today, we can sort of lean out over our skis and say, but if everything goes like we have got it designed, we can open in the fall, we can open in person, and there are a lot of parents out there that will be relieved and teachers are on notice and students are on notice. Last thing, I recognize the fact that a year ago when the pandemic hit, businesses altered what they did and how they did it.

Schools altered what they did and how they did it. Government altered what they did and how they did it. Congress altered what we did and how we did it. The one thing that did not change at your agencies was the responsibility for everybody to show up to do their job. For a year, we have been relying on the health care professionals that work for you, with you, and beside you to do their job. If not, we would not be here a year later with three vaccines. We would not be here with an ample supply of syringes and all the accompanying devices and PPE that is needed to carry out the most massive vaccination program that the world has ever seen. We wouldn't be in a position where we could be talking about, let's look around the corner and see how we prepare and what we learn from this.

I ask you all to go back to the people that work with you and for you and thank them on behalf of this Committee and this Congress, because without them, we would not have the ability to have hope that this could soon be over, and we wouldn't have a commitment that we could explore how to make sure this doesn't happen

again. So I thank each of you for your testimony. And I thank you for your indulgence, Madam Chair.

The CHAIR. Thank you, Senator Burr. And what Senator Burr just said, I think, is probably the most important thing we have said to all of you in this Committee hearing. Thank you to all of your staff, to everyone who has been working really hard on this, and I appreciate all that they are doing. So thank you for bringing that up. I just have two additional questions and we will close the hearing.

First of all, Dr. Marks, I wanted to ask you, for a year now, your team has been working around the clock and making sure vaccines and therapeutics are being developed and are safe and effective, and we are all grateful for that, but an important phase of this work is making sure that vaccines are safe for our children. And I know vaccine manufacturers have now begun work on clinical trials in pediatric populations. Can you update us quickly on what FDA is doing to authorize or approve vaccines and therapeutics for children?

Dr. MARKS. Thanks very much for that question. So all of the manufacturers of the three currently authorized vaccines have plans. Either they have clinical trials ongoing or about to start trials in children. There are already trials very advanced in the adolescent age group that is 12 and over. And so there is hope, I think, as Dr. Fauci said, that we will be able to get that population vaccinated for the fall for junior high and high school students. And for the younger children, we do this step program of the trials.

We will look at the older young children and then move down. And that is to make sure that we don't injure any children as we are looking at the vaccines. We have to make sure that every step is safe, and we don't skip any steps because obviously the safety of our children is paramount. So I think we have a good program in place. We are working with the operation to make sure that program really will move through. And the hope would be that by, toward the end of this year, we will have data in the younger children.

The CHAIR. Okay, very good. Thank you very much. And Dr. Walensky, this pandemic, as has been especially deadly for communities of color and has exasperated longstanding health inequities. Recent CDC data shows that Black and Latino people are more likely to die from COVID-19 compared to white people. In order to address these disparities effectively, we need to collect complete, reliable data that fully reveals the scope of the problem.

Unfortunately, we are still dealing with incomplete race and ethnicity data when it comes to COVID-19, especially in regard to vaccinations. And even when we do collect data, it often doesn't break out in important groups like Native Hawaiian or Pacific Islanders. I wanted to ask you, what is the CDC doing to streamline data reporting and make sure it includes information on race and ethnicity from the states and other entities?

Dr. WALENSKY. Thank you for that question. I think there are numerous components there. First of all, I think we need to realize that we know we have a problem before we collect the data. So we are actually actively working toward resolution of some of these issues even without seeing the data. We know that access to vac-

cines is more among the white community than in the communities that have been hit hardest hit. So we need to act before we even see the data. But we need data as well. We are a data driven organization and we need to see where the data are.

When I came in, there were at least seven or eight states, I believe, that actually their data use agreements didn't allow them to report data to us, that was in racial and ethnic divide. So we have been working closely with those states to make sure that we can resolve those data use agreement so that we can actually get those data. Once we get them, though, that is not actually the only challenge, because, in fact, patients don't want to report. And so we have, a, we have providers who don't ask the question. Many of these states data forms say unknown. And so we get, the race and ethnicity data, it is checked off, but it says unknown, and that is not particularly helpful. So we are working with a lot of states to ensure that we can maybe get rid of that slot so that people have to report it.

We are working to try and encourage people to report their race and ethnicity data. One way that we have been able to do this is through the electronic case reporting forms. So those reporting forms and we have been scaling this up over the last several months actually can link the test positivity with their medical record in Cerner or Epic, which actually report the race and ethnicity data. So we are working hard, and I think this is going to be a key component of data monitorization.

The CHAIR. Okay, thank you very much for that explanation. That ends our hearing today. And I really want to thank all of our colleagues and our witnesses, Doctors Fauci, Walensky, Kessler, and Marks for a really thoughtful discussion.

I think everybody wants you to say it is going to be over tomorrow and nobody can predict that. And I know you are all working really hard to make sure we have the best scientific, informative information that we can to make good decisions about ourselves and our entire Nation. For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, on Thursday, April 1st, at 5 p.m.

The hearing record will also remain open until then for Members who wish to submit additional materials for the record. And this Committee will next meet on Wednesday, March 24th in Dirksen 430 at 10 a.m. for a hearing on the nomination of Cynthia Marten to serve as Deputy Secretary of Education. Thank you again to our witnesses. The Committee stands adjourned.

QUESTIONS AND ANSWERS

RESPONSES BY DR. ANTHONY FAUCI TO QUESTIONS OF SENATOR HICKENLOOPER,
SENATOR BURR, AND SENATOR MURKOWSKI

SENATOR HICKENLOOPER

Question 1. In the year-end omnibus package \$40 million was appropriated through the National Institute of Allergy and Infectious Diseases (NIAID) for Regional Biocontainment Laboratories (RBLs). Colorado State University is the location of one of twelve labs nationwide and is located furthest west geographically in the country. Unfortunately, the funding included last year is the first Federal funds that these labs have received since 2010. These important labs conduct research on dangerous pathogens and develop new vaccines and treatments for emerging infectious diseases. Given the enormous challenge we face as we recover from COVID

and prevent against further pandemics, consistent support for these labs is urgently needed.

Would you commit to working with me and the Committee to ensure that these twelve facilities receive regular Federal support?

Answer. The National Institute of Allergy and Infectious Diseases (NIAID) is committed to conducting and supporting research on emerging and re-emerging infectious diseases. The twelve U.S. Regional Biocontainment Laboratories (RBLs) were constructed with NIAID support to enhance the research infrastructure required to safely and securely conduct research on biodefense and emerging and re-emerging infectious disease pathogens. Since their construction, the RBLs have received support from Federal grants and contracts awarded on a competitive basis to fund investigators conducting research within the facilities as well as fees charged to outside entities, which may themselves be recipients of funding from the National Institutes of Health (NIH). NIAID will continue to support highly meritorious biomedical research in biocontainment laboratories, including the RBLs, which are essential for the development of novel diagnostics, therapeutics, and vaccines for emerging and re-emerging infectious diseases.

Question 2. BioMARC is a non-profit infectious disease research and development facility that is part of Colorado State University and was established with funding from NIH. The facility is currently working on a COVID-19 vaccine candidate using a platform manufacturing technology developed at CSU. They received funding from the NIH to work on the development of the manufacturing method and testing of the vaccine candidate. They were recently told by the National Institutes for Allergy and Infectious Diseases (NIAID) that there may not be funding for future testing of this vaccine.

Given that COVID continues to mutate, stopping funding for the development of additional vaccine candidates seems short sighted.

Would you commit to work with me and our Committee to ensure that vaccine candidates like BioMARC's continue to get the proper funding needed to advance them and keep our communities protected?

Answer. NIAID conducts and supports basic and applied research to better understand, diagnose, treat, and ultimately prevent infectious diseases such as COVID-19. NIAID remains committed to supporting a wide range of highly meritorious extramural research through the standard, competitive NIH peer review process. This includes research related to vaccine development for SARS-CoV-2, the virus that causes COVID-19. In addition, NIAID provides a broad range of preclinical services to the research community to fill gaps in the vaccine development pipeline and facilitate the development of vaccine candidates.

Colorado State University was awarded a contract through NIAID's Omnibus Broad Agency Announcement solicitation in 2020 to develop a SARS-CoV-2 vaccine using novel viral inactivation technology. In addition, the Biomedical Advanced Research and Development Authority (BARDA) made an award to Colorado State University for the same technology, and the agencies collectively determined complementary funding. BioMARC's vaccine candidate is in preclinical development and may provide a vaccine platform for use in future infectious disease outbreaks.

NIAID plays a central and important role in the public health response to COVID-19 and is supporting the development and evaluation of several vaccine candidates. Five candidate COVID-19 vaccines have entered Phase 3 clinical trials in the United States thus far, and three subsequently received Emergency Use Authorizations (EUAs) from the U.S. Food and Drug Administration (FDA). NIAID has helped to advance four of these COVID-19 vaccine candidates through support for research on the foundational biology underlying the vaccine concepts, as well as for clinical testing through the COVID-19 Prevention Network (CoVPN). Two of these vaccine candidates from Moderna, Inc., and Johnson & Johnson/Janssen have received EUAs. In addition, NIAID is conducting a Phase 1 clinical trial of an investigational vaccine, developed by Moderna based on its authorized COVID-19 vaccine, designed specifically to target the B.1.351 SARS-CoV-2 variant first detected in South Africa. NIAID also is supporting research to develop a SARS-CoV-2 vaccine that is broadly protective against emerging SARS-CoV-2 variants and is testing strategies to achieve the ultimate goal of developing a universal coronavirus vaccine.

The Administration and NIAID are committed to working with the Committee and others in Congress to support the development and clinical evaluation of investigational COVID-19 vaccines, including vaccine candidates designed to target SARS-CoV-2 variants should they be needed, and ultimately a universal coronavirus vaccine. NIAID will continue to provide funding and resources to the research community to advance the development of COVID-19 candidate vaccines.

SENATOR BURR

Question 1. I have long advocated for improved coordination within our medical countermeasures enterprise and mechanisms that enable us to rapidly develop countermeasures by screening drugs, biologics, and platform technologies to determine potential utility against novel threats. Efforts like the Rapid Acceleration of Diagnostics (RADx) Initiative and the work of the Biomedical Advanced Research and Development Authority and other partners during the COVID-19 response have demonstrated that this type of rapid, coordinated screening and development work is possible.

Question 1(a). How should we institutionalize these mechanisms and related lessons learned from the COVID-19 response so we do not have to start from scratch the next time a novel threat emerges?

Answer. Throughout the COVID-19 pandemic, the NIAID has leveraged highly productive partnerships with industry, academia, and the public-sector; and made use of longstanding relationships with community partners to facilitate the biomedical research response by engaging existing domestic and international research infrastructure. NIAID also is an integral partner in the whole-of-government approach that began under Operation Warp Speed and has continued under the current Department of Health and Human Services (HHS) and Department of Defense (DOD) Countermeasure Acceleration Group (CAG) partnership to promote the development of safe and effective COVID-19 medical countermeasures. This effort led to the identification of safe and effective therapeutics for the treatment of COVID-19, as well as multiple COVID-19 vaccine candidates progressing in record time from concept to EUA from the FDA.

Early in the COVID-19 pandemic, the NIH initiated the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to advance a coordinated research strategy for prioritizing and speeding development of the most promising treatment and vaccine candidates. Coordinated by the Foundation for the NIH, ACTIV brought together NIH and other HHS organizations, including the BARDA, Centers for Disease Control and Prevention (CDC), and FDA; other government agencies including the DOD and Department of Veterans Affairs; the European Medicines Agency; and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.

In addition, NIAID established the CoVPN by leveraging four existing NIAID-funded clinical trials networks in cooperation with the DOD. The CoVPN enrolled thousands of volunteers in large-scale clinical trials to test a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19. The CoVPN also participated in harmonized protocols developed in collaboration with the ACTIV public-private partnership, vaccine manufacturers, and BARDA.

NIH also is partnering with BARDA, CDC, FDA, and the Defense Advanced Research Projects Agency (DARPA) on the Rapid Acceleration of Diagnostics (RADx S*ERR17*M)*ERR17* initiative to speed innovation in the development, commercialization, authorization, and implementation of technologies to test for SARS-CoV-2, the virus that causes COVID-19 disease. On March 31, 2021, CDC, in collaboration with NIH, launched an initiative in Pitt County, North Carolina, and Chattanooga/Hamilton County, Tennessee, to provide residents with access to free, rapid antigen tests supplied by the RADx initiative that can be administered at home three times a week for one month.

NIH and CDC plan to expand the at-home testing initiative to other communities as well. NIH and CDC will be evaluating whether frequent self-administered SARS-CoV-2 testing helps residents reduce community transmission of SARS-CoV-2. The development of innovative, at-home SARS-CoV-2 diagnostics also may inform the development of rapid diagnostic tests for other emerging and re-emerging infectious disease threats.

Efforts to develop COVID-19 medical countermeasures also capitalized on decades of NIAID investment in basic research and pandemic preparedness efforts, which focused on pathogen-specific work, platform-based technologies, and prototype-pathogen efforts. NIAID-supported research has advanced the development of “plug and play” platform technologies, such as the messenger RNA (mRNA) platform that enabled COVID-19 vaccine candidate development to occur at an unprecedented pace. In addition, NIAID prototype pathogen efforts—in which scientists study and develop vaccine candidates for representatives from a family of pathogens with pandemic potential—also can shorten the time needed to create investigational vaccines using platform-based methods. In the course of research on the Middle East respiratory syndrome coronavirus (MERS-CoV) and other coronaviruses, NIAID Vac-

cine Research Center researchers and their collaborators discovered a technique to modify and stabilize a key coronavirus protein—known as the spike protein—for use in vaccine development. When the novel SARS-CoV-2 virus emerged, scientists were able to adapt these modifications and stabilize the spike protein of SARS-CoV-2, a close relative of MERS-CoV. Ultimately, this technology was used in all three of the COVID-19 vaccines currently authorized under an EUA from the FDA. These investments in basic research will enable NIAID to prepare for the next inevitable infectious disease outbreak.

HHS, DOD, and other Federal partners continue to collaborate to support the research response to COVID-19. Lessons learned from the COVID-19 pandemic will inform our efforts to prepare for—and respond to—subsequent infectious disease threats.

Question 1(b). What steps are you and others involved in the medical countermeasures enterprise taking to bolster the enterprise, including tests, therapeutics, and vaccines so that the Federal Government continues to effectively coordinate after this pandemic ends?

Answer. As discussed in response to question 1.a., the Federal response to the COVID-19 pandemic has strengthened existing partnerships and coordination mechanisms, as well as established new partnerships that will inform the response to future infectious disease pandemics. The coordinated efforts through the RADx initiative, ACTIV, and the CoVPN allowed us to leverage the intrinsic strengths from public and private sector partners to achieve an unprecedented level of scientific achievement in the midst of perhaps the most challenging public health crisis of our lifetime. It should be noted that these efforts would not have been possible without the longstanding Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) structure. The existing relationships developed through the PHEMCE and the understanding of the capabilities, portfolios, and expertise of the constituent partners facilitated by previous work under PHEMCE allowed for Operation Warp Speed to be quickly established, staffed, and implemented and for the continued work under the current CAG partnership.

When the COVID-19 pandemic ends, lessons learned from our experiences with RADx, ACTIV, and the CoVPN will continue to help inform efforts to address other emerging and re-emerging infectious diseases. NIH and NIAID will continue to work with HHS Operating Divisions and other Federal agencies to research and develop safe and effective diagnostic tests, therapeutics, and vaccines for COVID-19. NIH and NIAID will participate in collaborative efforts to identify the actions that were most effective in responding to the COVID-19 pandemic, which may result in new initiatives, strategic plans, and/or formal assessments of pandemic preparedness. NIAID is committed to ensuring that the biomedical research enterprise is poised to respond rapidly to the next, inevitable infectious disease threat.

SENATOR MURKOWSKI

Question 1. Dr. Fauci, I understand that the Pfizer and Moderna vaccines are about 95 percent effective in preventing “symptomatic COVID-19” and that Moderna’s vaccine is 66 to 85 percent effective in preventing “moderate to severe/critical COVID-19 infections”. Can you explain the distinction between these two values? I understand that your advice has been to get whichever vaccine we’re offered, but for Americans that would like an apples to apples comparison between the vaccines, is that information available?

Answer. Efforts by Federal agencies, as well as partners in academia and industry, to develop COVID-19 vaccines that meet rigorous standards for safety and effectiveness have been remarkably successful. The three COVID-19 vaccines currently available under FDA EUAs were shown to provide a high level of protection against severe disease, hospitalization, and death in large-scale Phase 3 clinical trials. NIAID supported the trials for two vaccine candidates, developed by Moderna, Inc., and Johnson & Johnson/Janssen, through the CoVPN. These vaccine candidates were evaluated for safety and efficacy in separate clinical trials, and the results from these trials should not be directly compared because the trials were conducted in different geographic regions where different variants were known to be circulating and at different points in time with varying incidence of COVID-19. As noted in the question, the trials also compared different endpoints that were defined by the trial sponsors. These endpoints provided valuable information on the safety and efficacy of the candidate vaccines which ultimately informed FDA’s assessment of the data and their decision to issue EUAs.

The FDA has stated that a COVID-19 vaccine with at least 50 percent efficacy against symptomatic SARS-CoV-2 infection would have a substantial impact on

COVID-19 disease, both at the individual and societal level. All three of the COVID-19 vaccines available under an EUA have significantly exceeded FDA's 50 percent threshold.

In order to contain the spread of SARS-CoV-2, it is important that individuals become vaccinated—as soon as they are eligible—with one of the COVID-19 vaccines currently authorized. Each of the available vaccines provides significant protection from severe COVID-19 disease and death. In addition, the clinical trials are ongoing and accruing additional data pertaining to safety and effectiveness, and observational data is emerging that further demonstrates the high level of efficacy of these vaccines in “real-world” conditions. As we accelerate vaccination efforts, we must also continue to follow the public health measures outlined by the CDC to limit the spread of SARS-CoV-2.

Question 2. Dr. Fauci, do scientists have enough data to understand exactly where the COVID-19 variants are and to what degree? If not, what more must the Federal Government, state public health agencies, and health practitioners do to ensure that we can track and protect ourselves from these variants that exist or may exist in the future?

Answer. A concerning development of the ongoing pandemic is the detection of SARS-CoV-2 variants, some of which appear to be more transmissible than the original virus. Additional data is needed to fully understand the location and prevalence of SARS-CoV-2 variants, and extensive efforts to expand and improve our ability to detect where and to what degree these variants are circulating are underway through Federal efforts led by the CDC. The Biden administration recently announced plans to invest \$1.7 billion from the American Rescue Plan to expand CDC-led efforts to help states and other jurisdictions more effectively combat these viral variants. This funding will help to bolster the ongoing Federal Government's efforts to track and protect from SARS-CoV-2 variants described below.

NIAID is participating in the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) initiative. SPHERES is a national genomics consortium led by CDC that includes State Public Health Laboratories, academic institutions, and other partners and helps to coordinate SARS-CoV-2 sequencing across the United States. Information on the proportion of SARS-CoV-2 variants circulating in the United States can be found on the following CDC website: <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>. Further, NIAID has established relationships with international partners through the Centers of Excellence for Influenza Research and Response, Centers for Research in Emerging Infection Diseases, Genomic Centers for Infectious Diseases, and intramural programs that support sequencing and ultimately offer insights into SARS-CoV-2 variants that emerge globally. This ensures that the United States will be well-positioned to assist partnering countries, as well as anticipate variants prior to their detection in the United States.

NIAID also is fully engaged in efforts to mitigate the potential impact of emerging variants of SARS-CoV-2. NIH, including NIAID, participates in the SARS-CoV-2 Interagency Group (SIG), which works to identify and characterize the potential impact of viral variants on medical countermeasures and public health control efforts. The SIG is developing a robust response to provide the evidence needed for rapid decisionmaking in the face of a constantly evolving variant landscape. The SIG was established by HHS to facilitate coordination among NIH, CDC, FDA, BARDA, DOD, and the U.S. Department of Agriculture to detect and address SARS-CoV-2 variants as they emerge. In addition, NIAID is working with partners to identify, monitor, and calculate the frequency of current variations in the SARS-CoV-2 genome to help predict emerging variants.

A critical component to protecting against SARS-CoV-2 variants is understanding how variants might affect interactions between the virus and the immune system and their implications for COVID-19 therapeutics and vaccines. To advance this knowledge, NIAID is rapidly conducting research to better understand the impact of viral variants using cutting-edge modeling, structural biology tools, and *in vitro* and *in vivo* testing. NIAID scientists also are helping to inform our understanding of transmissibility of the variants by studying their stability in the environment and their ability to grow in human lung cells. These efforts add to a growing body of knowledge about SARS-CoV-2 variants and our ability to combat them.

While the emergence of SARS-CoV-2 variants that are more transmissible has made efforts to contain the spread of SARS-CoV-2 more challenging, current scientific evidence suggests that the COVID-19 vaccines available in the United States under EUAs continue to be effective against SARS-CoV-2 variants. Given this, it is important that individuals become vaccinated when they are eligible with one of

the COVID-19 vaccines currently available under EUAs, as well as continue to follow the public health measures outlined by the CDC.

Question 3. Do you anticipate that Americans will need to get vaccinated against COVID every year, as we do against the flu? If so, do you anticipate that such vaccines will be as easy to get as flu vaccines are now, through our workplaces, doctors' offices, and pharmacies? What are the barriers to achieving that?

Answer. All vaccines available in the United States after authorization by FDA meet rigorous standards for safety and effectiveness. The durability of COVID-19 vaccine effectiveness is not yet known, and it is possible that periodic boosting and/or changes in vaccine composition may be necessary. NIAID is conducting and supporting research that will help understand the immune response to vaccines to inform whether boosters are needed, and to develop broadly effective coronavirus vaccines and variant-specific vaccines if needed. NIAID defers to FDA and CDC on questions regarding vaccine approval and access.

NIAID is supporting research to monitor the duration of protection provided by current COVID-19 vaccination regimens. In addition, encouraging data on the durability of immune responses to the mRNA COVID-19 vaccines recently have been released by Moderna and Pfizer/BioNTech. Six months after vaccination, immune responses to the Moderna COVID-19 vaccine remained robust, and the Pfizer/BioNTech vaccine maintained 91.3 percent vaccine efficacy against COVID-19 after 6 months. We likely will have enough data by late Summer or early Fall 2021 to better assess the need for a booster dose of these COVID-19 vaccines.

Out of an abundance of caution, NIAID also is supporting the evaluation of candidate vaccines against SARS-CoV-2 variants. NIAID currently is supporting a Phase 1 clinical trial to test the safety and efficacy of the vaccine candidate mRNA-1273.351, which was developed by Moderna and designed to protect against the B.1.351 SARS-CoV-2 variant. A BARDA-supported Phase 2a trial of mRNA-1273.351 also is underway to evaluate the safety and efficacy of this vaccine candidate as a booster in individuals who already received two Moderna COVID-19 vaccine doses. In addition, investigators at the NIAID Vaccine Research Center are collaborating with Moderna to evaluate mRNA-1273.351 in animal models.

NIAID also is supporting research to develop a SARS-CoV-2 vaccine that is broadly protective against emerging SARS-CoV-2 variants and is testing strategies to achieve the ultimate goal of a universal coronavirus vaccine. On March 25, 2021, NIAID launched a Phase 1 clinical trial in healthy adults to assess the safety and immunogenicity of second-generation COVID-19 vaccine candidates developed by Gritstone Oncology, Inc. Gritstone's COVID-19 vaccine candidates utilize a strategy aimed at inducing both neutralizing antibodies and T cell responses to elicit a broad immune response.

This approach could provide protection against emerging SARS-CoV-2 variants by targeting several viral antigens, all of which are highly conserved among viral strains. NIAID also is conducting early stage research on the development of pan-coronavirus vaccines designed to provide broad protective immunity against multiple coronaviruses, including SARS-CoV-2 and others with pandemic potential.

RESPONSES BY DR. KESSLER TO QUESTIONS OF SENATOR MURRAY, SENATOR HICKENLOOPER, SENATOR LUJÁN, SENATOR BURR, SENATOR MURKOWSKI, SENATOR BRAUN, SENATOR MARSHALL, AND SENATOR TUBERVILLE

SENATOR MURRAY

Question 1. Given the critical role that BARDA plays in the advanced research, development, manufacturing, production and procurement of diagnostics, vaccines, and therapeutics against COVID-19, we are aware that BARDA has failed to invest in the advanced research and development of therapeutics to date. Can you explain why BARDA has not invested in the research and development of therapeutics for COVID-19 especially given the continuing loss of life and the threat of variants? The American Rescue Plan provided \$6.05 billion for research, development, manufacturing, production and purchase of vaccines, therapeutics and ancillary medical products for COVID-19 or any disease with potential for creating a pandemic. How much of this funding that was appropriated to the HHS Secretary will be provided to BARDA for the advanced research and development of therapeutics for COVID-19?

Answer. Therapeutics are an important element of the COVID-19 response. Since February 2020, BARDA has obligated more than \$10 billion for the development and purchase of 14 therapeutics. Investments include: development of Regeneron's

monoclonal antibody therapy; early discovery work for AstraZeneca’s prophylactic monoclonal antibodies; two Phase 3 trials testing anti-IL-6 monoclonal antibodies as a treatment for hospitalized COVID-19 cases; a Phase 2 screening trial for two immune modulators with Genentech; early investments in hyperimmune globulin development with Grifols and Emergent; antiviral screening and therapeutic development efforts with Janssen; and, as of March 18, 2021, 1.7 million courses of an investigational antiviral treatment, molnupiravir (MK-4482) from Merck, if granted emergency use authorization (EUA) or approval from the U.S. Food and Drug Administration (FDA).

Since May 2020, BARDA has been an integral part of the Operation leadership and colleagues at the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) to identify promising candidates that may be close to receiving Emergency Use Authorization (EUA) from the FDA. If new candidates are a strategic fit for the existing portfolio, those products are considered for potential funding through the Operation.

SENATOR HICKENLOOPER

Question 1. We are learning that for COVID-19, many key areas for vaccine and therapeutic development, as well as increasing U.S. manufacturing capabilities for better domestic resilience, have been on hold for many months, including funding for the product development group at BARDA. What is the plan to release the funds that have already been allocated for these purposes?

Answer. BARDA is working closely with other parts of HHS and the Administration to ensure that the Nation has the vaccines and therapeutics needed to provide Americans as much protection from COVID-19 as is feasible. Funds are available for obligation consistent with agreed-upon plans.

SENATOR LUJÁN

Question 1. At the onset of this pandemic, we all quickly realized the vulnerabilities in the existing Strategic National Stockpile (SNS). Since then, the SNS has entered into short-term public-private partnership contracts to leverage the capabilities of the distribution industry to ensure a continuously replenishing inventory system. Contracts such as these strive to ensure that health systems and physicians have access to necessary drugs, medical devices, and protective equipment subject to surge demand due to the COVID-19 pandemic.

As the Administration prioritizes policies to avoid future shortages of critical goods, as evidenced by the recent 100-day supply chain review executive order, how can public-private partnerships with the SNS improve preparedness to address future demand-driven shortages caused by pandemics, national emergencies, and any other unforeseen challenges?

Answer. Public-private partnerships are critical for the success of the Strategic National Stockpile (SNS). The relationships SNS has cultivated with industry partners provides the SNS real-time visibility of market capacity, allowing better decisionmaking in support of preparedness planning and response operations. These partnerships improve the resiliency of the SNS through:

- Improved monitoring of commercial supply chain inventory and performance;
- Improved access to personal protective equipment (PPE);
- Improved public access to MCMs;
- Improved coordination of the timing and quantity of release of SNS assets to best support a response; and,
- Education on challenges associated with over-ordering or hoarding of needed materiel during a public health incident.

During the COVID-19 pandemic, SNS built upon these relationships by partnering with Strategic Marketplace Initiative (SMI). SMI is a group of medical distributors and providers committed to driving meaningful improvements in supply chain agility, efficiency, and resilience.

To improve future response operations, throughout the COVID response, the SNS has captured lessons learned and is now working to incorporate changes and improvements. Going forward, the SNS will continue to coordinate and partner with industry partners. The supply chain is dependent on close coordination and communication between all partners. Early identification of stress points, challenges, limited supply, etc. helps to mitigate the lasting impact.

Question 2. While increasing medical supplies is important, we need to ensure that all Federal acquisition procedures ensure that health care providers receive the quality materials and supplies they need to keep patients and personnel safe. Last year, there were reports that the Indian Health Services purchased \$3 million of potentially substandard respirator masks and then distributed those masks without proper quality screening to Navajo Nation hospitals in New Mexico and Arizona. Why is it important for the Federal Government to regularly review their acquisition contracts and audit their inventory to protect patients and providers?

Answer. Regular reviews of government contracts are important and are performed to ensure government needs are adequately defined, that appropriate contract terms are included, and that contract administration is done properly. In addition, regular inventory audits are important and are done to ensure adequate supplies are on hand and to ensure orders are placed timely for re-supply.

SENATOR BURR

Question 1. President Biden recently announced that 90 percent of the adult U.S. population will be eligible for the COVID-19 vaccine and 90 percent will have a vaccination site within 5 miles of their home by April 19th. The Administration plans to accomplish this goal by doubling the number of COVID-19 vaccine doses available through retail pharmacies, expanding the Federal Retail Pharmacy program, and adding another twelve mass vaccination sites to the federally run mass vaccination site program.¹ Recent news reports indicate, however, that federally run mass vaccination sites have been less efficient in administering COVID-19 vaccine doses than other types of sites, such as retail pharmacies.² While announcing that 90 percent of adults will be eligible for the vaccine in just a few weeks, our ability to keep Americans safe and reopen our economy is contingent on our ability to get shots in arms.

Question 1(a). What criteria were considered when deciding to expand the mass vaccination site program compared to other distribution channels that have been more effective?

Answer. HHS has worked with our government partners in a whole-of-government response to vaccinate all eligible Americans. As of March 2021, we have provided Federal support for 1,800 community vaccination centers and mobile sites across the Country. In addition to mass vaccination sites, we have also launched the Federal Retail Pharmacy Program, a collaboration between Federal Government, states, and territories, and to 21 national pharmacy networks to expand access to vaccines for the American public, with over 40 percent of locations in highest need neighborhoods. We increased the number of pharmacies providing vaccines to nearly 40,000. In addition, we have launched a program to directly send vaccine to community health centers, currently reaching over 750 centers who have ordered nearly 6 million COVID-19 vaccine doses for over 2,000 sites. HHS also launched a Rural Health Clinic program and announced expanded COVID-19 Testing and Mitigation funding for small rural facilities and critical access hospitals—to mitigate the spread of the virus in ways tailored to local rural communities.

Question 1(b). About half of supermarket pharmacies that are participating in the Federal Retail Pharmacy Program have not received COVID-19 vaccines to administer. Will all participating supermarket pharmacies be receiving COVID-19 doses through this expanded initiative announced on March 29, 2021?

Answer. The Federal Retail Pharmacy program supports more than 40,000 pharmacies. The program works to ensure that nearly all enrolled pharmacies receive COVID-19 vaccine doses.

Question 1(c). During the HELP Committee hearing on March 25, one witness discussed a collaboration in North Carolina between Atrium Health, Honeywell, and other partners that resulted in one of the most successful mass vaccination efforts in the Nation to date. This demonstrates that mass vaccination sites can be effectively run without direct Federal support. How is the Administration working with states, local governments, and the private sector to share information about these innovative approaches and encourage more of these types of partnerships?

Answer. States and communities are considering a variety of approaches to increase COVID-19 vaccine uptake that involve innovative partnership across sectors.

¹ <https://www.whitehouse.gov/briefing-room/statements-releases/2021/03/29/fact-sheet-president-biden-announces-90-of-the-adult-u-s-population-will-be-eligible-for-vaccination-and-90-will-have-a-vaccination-site-within-5-miles-of-home-by-april-19/>.

² Erin Banco, "Biden Admin Remakes Vaccination Strategy after Mass Vaccination Sites Fizzle," *Politico Pro*.

CDC shares information, including through toolkits, to support states and communities in putting together events to improve vaccine confidence. Jurisdictions are also leading efforts using local public-private partnerships to conduct outreach and host vaccine clinics.

Question 1(d). How is the Administration working with states and local governments to support their efforts to reach underserved communities, including rural communities, to increase vaccine uptake for the newly eligible over the next few weeks?

Answer. Thanks to the American Rescue Plan, the White House announced HHS will invest nearly \$10 billion to expand access to vaccines and better serve communities of color, rural areas, low-income populations, and other under-resourced communities in the COVID-19 response.

The Health Resources and Services Administration (HRSA) will support Rural Health Clinics (RHCs) to increase the availability of COVID-19 vaccines in rural communities and expand outreach to build vaccine confidence. Working in partnership with the Centers for Disease Control and Prevention (CDC), HRSA is inviting Medicare-certified RHCs to join the new Rural Health Clinic COVID-19 Vaccine Distribution (RHCVD) Program to directly receive Federal allocations of vaccines. HRSA and CDC will continue to enroll interested RHCs to receive COVID-19 vaccines, the allocation for which is separate from jurisdictions' weekly allocations.

In addition, through the Rural Health Clinic Vaccine Confidence (RHCVC) Program, HRSA will make nearly \$100 million available in grants to eligible RHCs nationwide to address health equity gaps by offering support and resources to medically underserved rural communities where COVID-19 vaccine uptake lags in comparison to more populated areas. HRSA will fund all eligible RHCs that apply. The RHCVC Program is the first targeted RHC grant since the passage of the Rural Health Clinic Service Act in 1977. RHCs will be able to use the funds to increase vaccine confidence, improve health care in rural areas, and reinforce key messages about prevention and treatment of COVID-19 and other infectious diseases.

HRSA and CDC launched the Health Center COVID-19 Vaccine Program to ensure our Nation's medically underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated. The program provides a direct supply of COVID-19 vaccines to HRSA Health Center Program-funded health centers and Health Center Program look-alikes in addition to COVID-19 vaccines that health centers might receive through their states. This program started on February 9th with an initial cohort of 25 health centers, and expanded in less than two months to include all HRSA Health Center Program-funded health centers and LALs on April 6, increasing its reach to 1,470 health centers nationwide.

Health Center Program-funded health centers and Health Center Program look-alikes have administered more than 10 million COVID-19 vaccine doses nationwide—with 61 percent provided to racial and ethnic minorities. Community health centers, which largely serve the Nation's underserved and most vulnerable communities, have been central to President Biden's commitment to ensuring equity and access in the COVID-19 response and vaccination program.

On March 15, 2021 CDC announced plans to launch a new grant program starting in June 2021 called *Reducing Racial and Ethnic Disparities in Adult Immunization*. This program of about 20 national organizations supports hundreds of local and community-based organizations to improve both COVID-19 and flu vaccination coverage among racial and ethnic minority groups. In addition to funding support, the new program creates opportunities for partners to collaborate with and learn from one another through a learning community. Additionally, CDC is helping state, territorial, and local health departments, as well as community-based organizations, to deploy COVID-19 relief funding in a community-driven way through guides that support the design and implementation of activities to increase vaccine confidence and access. CDC will also engage organizations in a social media strategy to detect, assess, address, and intervene in vaccine-related misinformation circulating throughout communities.

SENATOR MURKOWSKI

Question 1. Do you anticipate that Americans will need to get vaccinated against COVID every year, as we do against the flu? If so, do you anticipate that such vaccines will be as easy to get as flu vaccines are now, through our workplaces, doctors' offices, and pharmacies? What are the barriers to achieving that?

Answer. Based on *current clinical considerations*, a patient is considered fully vaccinated 2 weeks after a 2-dose mRNA COVID-19 vaccine series or 2 weeks after

a single dose of Johnson & Johnson (J&J) COVID-19 Vaccine. The need for COVID-19 booster doses has not been established yet. No additional doses are recommended at this time.

CDC has launched several vaccine effectiveness studies that will evaluate how well COVID-19 vaccines are working in real-world conditions, and additional studies are underway as vaccines are administered across the United States among different groups. Since vaccination of priority groups with COVID-19 vaccines has only begun in the last 4 months with eligibility expanding to additional people in the last 2 months, data to determine vaccine effectiveness are being collected and published in an ongoing manner. As data on vaccine effectiveness become available, CDC will provide regular updates with that information.

Primary care providers (PCPs) play an influential role in building confidence in and improving access to vaccines; however, currently fewer than 5 percent of all COVID-19 vaccine doses have been administered by PCPs. CDC has developed guidance for expanding vaccine distribution (from existing jurisdiction vaccine allocations) to PCPs and increasing PCP enrollment for COVID-19 vaccine administration. This involves identifying priority PCPs in communities with the highest Social Vulnerability Index (SVI) scores and allocating vaccines to those PCPs and expanding community outreach. States and local health departments will also continue to leverage existing partnerships with pediatricians and primary care providers through established immunization programs to administer COVID-19 vaccines to eligible populations.

SENATOR BRAUN

Concerning Vaccine Distribution

As COVID-19 vaccine distribution has ramped up in the Biden administration, it seems there has not been enough of an effort to leverage major distributors or key regional distributors in the process.

Question 1. What efforts, if any, have been made to leverage other distributors to date?

Question 2. Also, why have other distributors not been leveraged for vaccine distribution, or even distribution planning, to date?

Answer to both questions: COVID-19 vaccine distribution utilized existing infrastructure to ensure that vaccine could be ordered, delivered, and administered to combat the ongoing pandemic in line with the urgency of this effort. As the COVID-19 vaccination effort continues, we will continue to monitor distribution processes.

SENATOR MARSHALL

Question 1. BARDA has played a critical role in the development of vaccines, therapeutics and diagnostics. Focusing on vaccines, BARDA made initial investments in multiple technologies since it was unknown which technology would prove successful. The investments were based on technologies that had clinical data from other diseases showing safety of their technology and also had a robust or licensed manufacturing process that was scalable. BARDA's previous investments have also accelerated COVID-19 vaccine development. BARDA invested in Moderna for their Zika vaccine and these investments provided clinical data and improved the manufacturing process that is currently being used. BARDA invested in Janssen and has had a partnership since 2015 to develop their viral vector technology for Ebola, currently licensed in the EU. The same technology is being used for their COVID vaccine. The early investments made by BARDA provided the foundation for the vaccine portfolio currently supported by BARDA and JPEO. BARDA has supported clinical studies, scale up of manufacturing and validation and large-scale manufacturing of vaccines being distributed.

Question 1(a). Will the Biden administration continue to support ongoing projects and contracts BARDA established last year?

Answer. Yes, the Administration plans to support the investments made previously by BARDA in the fight against COVID-19. The parallel development, manufacturing, and regulatory review processes critical to the successful development of multiple COVID-19 vaccines and therapeutics have seen extraordinary success because of the dedicated scientists and researchers who reviewed both the vaccine and therapeutic candidate portfolios to ensure that Federal investment was leveraged behind the most promising candidates.

Question 1(b). How will BARDA continue to both respond to the current pandemic as well as prepare for future pandemics that could be bacterial in nature, pandemic influenza or other emerging infectious diseases?

Answer. As of March 18, 2021, BARDA has obligated more than \$32 billion to support 7 vaccines, 42 diagnostics (21 with EUA shipping over 120M tests to testing centers), 13 therapeutics, 12 rapidly deployable capabilities, and numerous other supporting programs. BARDA has supplied 945,000 treatment courses of 3 monoclonal antibody products (bamlanivimab monotherapy, bamlanivimab etesevimab and casirivimab imdevimab) that have achieved EUA to treatment sites across the US. BARDA has also provided access to our Clinical Trials Network for support of the ACTIV trials. BARDA has and will continue to limit the impact of supply chain shortages, including ancillary supplies like needles and syringes, as the USG prepares for the fall. The fact that not one, but three vaccines are available in a little over a year from the start of the pandemic is an amazing feat.

Going forward, BARDA will continue to develop its COVID-19 vaccine portfolio. This includes procuring additional doses of vaccine as needed for pediatric populations as well as to address waning immunity and/or strain changes. BARDA will continue to support vaccines that have not yet received EUA based on funding availability and determination of need. Finally, BARDA will continue to support clinical trials in adolescents and pediatrics to further expand the number of individuals that can be vaccinated.

BARDA is always at the forefront of critical efforts during epidemics or pandemics. This was shown in the response to H1N1, Ebola in 2014/2015, Zika, Ebola in 2018-2020 and now COVID. The funds provided to BARDA lead to results. For example, during the Ebola responses, BARDA investments and collaboration with industry, interagency colleagues, and the WHO, BARDA has supported the first licensed Ebola vaccine (ERVEBO), two licensed Ebola therapeutics (Inmazeb, first licensed therapeutic and Ebanga the second licensed therapeutic that transitioned from NIAID), and the first FDA cleared rapid diagnostic (OraQuick). The BARDA model has proven successful. As shown with the COVID-19 response, early investments have the potential to reduce the lead time to develop a medical countermeasure.

SENATOR TUBERVILLE

Vaccine Distribution

Question 1. In Alabama, almost 1,200 providers are enrolled in the Federal program to distribute vaccines. Unfortunately, only around 40 of these providers in the state actually have the freezer capacity to store and distribute Pfizer vaccines.

Question 1(a). What can the Administration do to account for the storage compatibility of different states' distribution capacity, especially when it comes to urban vs. rural states?

Answer. The US Food and Drug Administration (FDA) has amended the Pfizer-BioNTech COVID-19 Emergency Use Authorization (EUA) to include a new Pfizer 450-dose order configuration, and changes in storage temperatures should decrease the need for dry ice and make storage of the Pfizer vaccine more manageable for sites.

Question 2. The Alabama Department of Public Health (ADPH) has also struggled with transparency from the Federal level as they continue to be left in the dark in terms of how many vaccines to expect each week and what the breakdown of each vaccine type will be. Without knowing these factors in advance, it's impossible to appropriately plan and broadcast which categories of individuals will be able to receive the vaccine in the next phase of distribution.

Question 2(a). Now that the J&J vaccine is being distributed along with Moderna and Pfizer candidates, what can the Administration do to increase transparency when it comes to the amount and breakdown of upcoming shipments?

Answer. The Federal Government has made specific amounts of FDA-authorized COVID-19 vaccine doses available to states and jurisdictions on a weekly basis. CDC provides detailed information on their website, available at: <https://www.hhs.gov/coronavirus/covid-19-vaccines/distribution/index.html>.

Question 3. Two of Alabama's 17 federally Qualified Health Centers (FQHCs) have yet to be invited to participate in the Federal vaccine program, though they very much would like to be involved.

Question 3(a). What can be done to include such facilities that have capacity and desire to be included in the Federal program without Federal outreach?

Answer. The *Health Center COVID-19 Vaccine Program* is a collaboration between HRSA and CDC, which provides a direct allocation of COVID-19 vaccines to HRSA Health Center Program-funded health centers in addition to COVID-19 vaccines that health centers might receive through their states. This program started

on February 9 with an initial cohort of 25 health centers, and expanded in less than two months to invite all HRSA Health Center Program-funded health centers and look-alikes on April 6, increasing its reach to 1,470 health centers nationwide.

To participate in the Health Center COVID-19 Vaccine Program and place orders, health centers must have completed their Readiness Assessment and Conditions of Participation Agreement. They also need to have completed additional steps with both CDC and HRSA prior to ordering vaccines through an online portal, the VTrcks Provider Order Portal (VPoP). Additional details regarding these steps are posted on HRSA's website in the Vaccine Program Community landing page.

COVID-19 Treatments

Question 4. A constituent of mine, Dr. Timothy Taylor (MD Chief Medical Officer, MainStreet Family Urgent Care; Birmingham, AL) recently participated in an HHS webinar where he spoke about the positive role of monoclonal antibodies for COVID treatment across his clinics in Alabama including the original pilot site in Pelham. One of the keys to their positive outcomes is the ability to conduct rapid testing which allows medical professionals to present the option of COVID treatments to patients. So far, they had not seen any adverse incidents, and the clinical trial data for these products indicate that they are effective in preventing death and hospitalization. I understand that infusions have been somewhat complicated, but they are being done in Alabama and they prevent death and hospitalization. With many of the treatments and therapeutics, early intervention greatly increases the likelihood of positive outcomes. I hope the Administration understands the urgency for getting patients who test positive for COVID into treatments that will keep them out of the hospital. Investing in infusion centers and temporary sites coupled with expanded access to rapid testing has the potential to reduce hospitalization and death. Congress has provided billions in funds for testing and treatments.

Question 4(a). What is the Administration doing to integrate testing and treatment?

Answer. Rapid testing is critical to mitigating the spread and impact of COVID-19. The Federal Government has made tremendous progress in historic speed to develop and support the manufacturing of monoclonal antibody therapeutics. ASPR conducted external outreach efforts to major laboratories including Quest, LabCorp, PWN, Aegis to connect patient test results with information and resources about monoclonal antibody therapeutics. In all efforts, ASPR ensured that product reached those in the greatest need and in the most equitable way possible. These outreach efforts are reaching up to 14.4 million people per month.

Since May 2020, ASPR has hosted weekly calls for state and territorial health officials as well as national health care and medical organizations and associations to provide current information regarding the allocation, distribution, and drug administration surrounding the COVID-19 monoclonal antibody therapeutics available to help combat the pandemic. ASPR also hosts a weekly virtual office call session which provides an opportunity for individuals to ask questions or raise topics of concerns pursuant to the distribution and/or drug administration of COVID-19 monoclonal antibody therapies. These weekly virtual office call sessions are open to all state, local, tribal and territorial health officials, health care providers and other monoclonal antibody therapeutics administration sites of care. This call also serves as an informal opportunity to share relevant best practices, lessons learned, and discuss challenges or concerns with peers. HHS/ASPR is currently conducting five separate pilot programs to reach underserved populations and establish much needed infusion sites. We are currently assessing means to tie positive test results for those patients who meet eligibility requirements with infusion centers across the Nation.

RESPONSES BY DR. PETER MARKS TO QUESTIONS OF SENATOR HICKENLOOPER,
SENATOR BURR, SENATOR PAUL, AND SENATOR MURKOWSKI

SENATOR HICKENLOOPER

Question 1. As we continue to scale up access to vaccines, we also know that effective treatments play a critical role in reducing hospitalizations, serious disease, and deaths among those who become infected. We have a few such treatments right now, but we will soon have the first oral agents to treat COVID.

How do we expedite access to these new treatments for the American people, and in particular, ensure that vulnerable populations like Medicare Part D beneficiaries have access to new oral therapies that will first be approved under an Emergency Use Authorization (EUA)?

Answer. We defer this question to the Centers for Medicare and Medicaid Services, who did not appear as a witness at the hearing.

SENATOR BURR

Question 1. FDA provided guidance on the type of data needed to establish efficacy against new and emerging COVID-19 variants, which included non-inferiority requirements for supplemental applications for previously authorized COVID-19 vaccines.

Question 1(a). What type of data is FDA requiring to demonstrate immunologic comparability?

Question 1(b). Are there multiple methods to demonstrate immunologic comparability or immunogenicity that could be compared to authorized vaccines? If so, how will you work with manufacturers to ensure appropriate flexibility regarding methods to demonstrate immunogenicity or immunologic comparability?

Answer. FDA has been communicating with vaccine manufacturers to provide information and scientific advice as they evaluate the ability of their vaccines to protect against SARS-CoV-2 variants.

In February 2021, FDA issued an update to its October 2020 vaccine EUA guidance to address the emergence of SARS-CoV-2 variants.¹ The updated guidance outlines FDA's scientific recommendations for data needed to amend emergency use authorizations for COVID-19 vaccines to allow for use of modified vaccines to address SARS-CoV-2 variants. For example, FDA expects that manufacturing information will remain generally the same for an authorized vaccine and a modified vaccine candidate from the same manufacturer. For clinical data, the guidance recommends that a determination of effectiveness be supported by data from clinical immunogenicity studies, which would compare the immune response to the virus variant induced by the modified vaccine to the immune response to the "prototype" virus induced to the authorized vaccine. At this time all the authorized COVID-19 vaccines express the SARS-CoV-2 "spike" or S-protein, and while an immune marker(s) protective of protection has not been established, it is thought that neutralizing antibody to the S-protein is a major component of the vaccine protective response. The guidance explains that the immunogenicity parameter of interest is an assessment of virus neutralizing antibody levels.

Manufacturers are encouraged to study the modified vaccine in both naïve (non-vaccinated) individuals and in individuals previously vaccinated with the authorized vaccine.

Additionally, the guidance outlines FDA's recommendations for assessments of safety to support an EUA for a modified vaccine. Finally, the guidance states that further discussions will be necessary to decide whether in the future, modified COVID-19 vaccines may be authorized without the need for clinical studies.

Question 2. What requirements, if any, are manufacturers of authorized COVID-19 vaccines required to meet in order to receive FDA approval to use additional contract manufacturers to expand manufacturing capacity?

Answer. For all vaccine manufacturers, including contract manufacturers used to expand manufacturing capacity, sufficient data should be submitted to support drug substance (DS) and drug product (DP) manufacturing to ensure the quality and consistency of the vaccine product that is produced. Evidence should be provided that all DS and DP manufacturing sites, including testing sites, are adequately qualified/validated to ensure that the equipment and process meets all predetermined specifications, intended purposes, and that the production process is controlled and operates with quality oversight consistent with current good manufacturing practice (CGMP) requirements. If more than one manufacturing facility is used to produce DS and DP, data should be provided to support the consistency of vaccine quality between manufacturing sites (See FDA guidance, *Emergency Use Authorization for Vaccines to Prevent COVID-19*, for more information).

Facility information should be submitted to demonstrate that the facilities are of suitable size and adequately designed to prevent contamination, cross-contamination, and mix-ups (See FDA guidance, *Emergency Use Authorization for Vaccines to Prevent COVID-19*,² for more information).

¹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

Part of FDA's evaluation of a request for emergency use authorization (EUA) for COVID-19 vaccines and drugs includes evaluation of the chemistry, manufacturing, and controls and facility information. FDA expects manufacturers to submit sufficient data to ensure the quality and consistency of the product. FDA uses all available tools and information, including site visits, and previous compliance history, to assess compliance with CGMP requirements. As part of the authorization, FDA may include several conditions of authorization related to the manufacture of the product. For example, as a condition of authorization for each COVID 19 vaccine, the Letter of Authorization stated "No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency." FDA must concur with the proposed changes.

Question 3. What is the average time it takes for FDA to approve a contract manufacturing facility to manufacture an authorized COVID-19 vaccine? Does FDA have the authority to approve a contract manufacturing facility prior to, or at the same time as, authorizing a vaccine?

Answer. FDA's scientific and regulatory advice to vaccine developers, as well as FDA's evaluation to determine the safety and effectiveness of vaccines, are among the most robust in the world.

FDA approval of a facility, irrespective of whether it is a contract manufacturing facility, and when it is approved, is dependent on the adequacy of the data and information submitted to FDA. The time between the submission to FDA and the authorization allows the FDA to thoroughly evaluate the product and facility data and information submitted in the EUA request and may also include further requests for information. The amount of data submitted to FDA typically includes thousands of pages of data and technical information that are analyzed and evaluated by FDA career staff with specific expertise.

Once a product is authorized, no changes can be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by the Agency. If a contract manufacturing facility has been described as a facility to be utilized for manufacturing of the product under the EUA at the time of the authorization request, it may be possible for the contract manufacturing facility to be authorized as part of the authorization.

Question 4. How many drug or biological product inspections have been delayed due to COVID-19? By what date will FDA have acted on all delayed inspections?

Answer. Throughout the COVID-19 pandemic, FDA has continued to complete foreign and domestic inspections determined to be critical to our public health mission, and also conducted prioritized domestic inspections where and when it was safe to do so.

The prioritized inspections include those associated with product application goal dates (pre-approval, pre-market or pre-license inspections) that FDA determined to be necessary to support an application decision, as well as for-cause compliance follow-up inspections. If these did not meet mission-critical criteria they were still prioritized and were conducted (if domestic) when and where it was safe to travel. Sometimes this resulted in delays relative to goal dates and scheduled follow-up. If the inspection was to be conducted at a foreign facility and did not meet mission-critical criteria, it was not conducted and would be considered to be "delayed."

As of March 2021, a total of 58 drug or biological product application approval decisions have been delayed because FDA could not conduct an inspection. Of these 58 delayed applications, six have been determined to be mission critical. FDA plans to complete inspections in support of these six mission-critical drug and biological product applications by the end of the fiscal year (September 2021).

Regarding delayed compliance follow-up target dates for some for-cause inspections, FDA plans and publicly tracks follow-up to compliance actions related to a prior domestic inspection that was classified as "official action indicated" (OAI). In fiscal year 2020, eight human drug OAI follow-up inspections were delayed due to COVID-19. These eight inspections carried over to the fiscal year 2021 OAI follow-up target.

Most inspections that have been postponed due to the pandemic are routine surveillance inspections that are planned for each fiscal year, based on established drug and biological product inspection risk factors. These inspections do not meet the criteria FDA has employed to identify mission-critical inspections and are not otherwise prioritized. In fiscal year 2020, FDA postponed approximately 650 drug and biological product surveillance inspections, as well as many additional inspections in other regulated commodity programs. As of March 2021, FDA has 1,124 drug and biological product surveillance inspections remaining to be conducted by the end of

the fiscal year (September 2021), including 857 human drug, 157 animal drug, and 110 biological product surveillance inspections.

FDA recognizes that addressing the large number of postponed surveillance inspections will be challenging and given the continued uncertainties and travel restrictions posed by the COVID-19 pandemic it is difficult to determine when this can be accomplished. To confront the inventory of postponed inspections while continuing to conduct mission-critical inspectional work, FDA will use additional prioritization strategies, employ alternative and remote tools, and take an overall flexible and strategic approach to optimize FDA oversight of the products we regulate. FDA has released the “Resiliency Roadmap for FDA Inspectional Oversight”³ that describes the effect of the pandemic on our inspectional activities for each regulated commodity as well as FDA’s detailed plan for resuming a more consistent state of operations employing these strategies, using base, best, and worst-case scenarios.

Question 5. FDA received \$500 million in the American Rescue Plan Act of 2021, Public Law 117-2. How much of this funding will be spent to address the backlog of drug inspections? Please include a timeline for this resource spend.

Answer. The American Rescue Plan Act of 2021 (Public Law 117-2) appropriated FDA \$500 million to respond to emerging variants, ensure that COVID-19 tests, therapeutics, and vaccines continue to be safe and effective, conduct critical inspections, and prepare for the next challenge by accelerating work in areas such as advanced manufacturing and supply chain monitoring. Of the \$500 million appropriated, FDA’s spend plan reflects approximately \$73.5 million to address inspections delayed due to the COVID-19 public health emergency. This total includes \$38.3 million supporting FDA’s Center for Drug Evaluation and Research (CDER) Pandemic Recovery: Medical Product Inspections and \$35.1 million supporting FDA’s Office of Regulatory Affairs (ORA)’s COVID-19 recovery activities, including inspectional modernization, preparing to adjust staffing and bringing on staff to conduct inspections delayed due to COVID-19 public health emergency. Of the amount dedicated for inspectional work, FDA intends to obligate approximately 17 percent in fiscal year 2021, 42 percent in fiscal year 2022, 21 percent in fiscal year 2023, 14 percent in fiscal year 2024, and 6 percent in fiscal year 2025.

SENATOR PAUL

Dr. Marks: FDA should be commended for their pro-active approach to COVID-19 vaccine development. The agency’s focus on flexibility and speed—while maintaining rigorous safety standards—has resulted in three COVID-19 vaccines receiving emergency use authorization in just over a year. We will need to develop next-generation COVID-19 vaccines moving forward, with a focus on single-dose vaccines that do not require cold-chain storage and can be rapidly manufactured. I believe FDA should continue to use a flexible approach to vaccine clinical trials.

Question 1. How will FDA approach clinical trial design for next generation COVID-19 vaccines, given the challenges of enrolling trial participants and testing against vaccines which have already received an EUA?

Answer. A COVID-19 vaccine that has been approved or authorized for emergency use by FDA could serve as the control treatment in a study designed to evaluate efficacy with non-inferiority hypothesis testing, as inclusion of placebo control groups could be considered unethical. Clinical development programs for COVID-19 vaccines might be expedited by adaptive and/or seamless clinical trial designs that allow for selection between vaccine candidates and dosing regimens and for more rapid progression through the usual phases of clinical development. In addition, once additional understanding of SARS-CoV-2 immunology is acquired regarding vaccine immune responses that might be reasonably likely to predict protection against COVID-19, accelerated approval of a COVID-19 vaccine (pursuant to section 506 of the FD&C Act (21 U.S.C. 356) and 21 CFR 601.40) may be considered if an applicant provides sufficient data and information to meet the applicable legal requirements. For a COVID-19 vaccine, it may be possible to approve a product under these provisions based on adequate and well-controlled clinical trials establishing an effect of the product on a surrogate endpoint (e.g., immune response) that is reasonably likely to predict clinical benefit. This would allow the conduct of a trial of much smaller size than one requiring a clinical efficacy endpoint.

Question 2. What steps should FDA take to ensure clinical trials of next generation COVID-19 vaccines can be conducted in the United States? Should manufacturers consider conducting clinical trials in other countries if it is not feasible to enroll them in the United States?

³ <https://www.fda.gov/media/148197/download>.

Answer. For the three currently authorized COVID-19 vaccines, the clinical trials did include U.S. sites. The development of drugs and vaccines has become an increasingly global enterprise. Foreign clinical trials of a vaccine demonstrating safety and efficacy may be acceptable; however, FDA may ask for bridging studies looking at immunogenicity to ensure that the U.S. population has a similar immune response to the population in which the vaccine showed efficacy.

Question 3. As you know, most clinical trial subjects must commit to not taking a different COVID-19 vaccine for up to a year. Do you believe FDA should allow flexibility for trial sponsors to modify this requirement?

Answer. Clinical studies of vaccines are conducted to establish the safety and effectiveness of the vaccine. Enrolled participants are often requested to continue in the clinical study for several months after completion of the vaccination series. During the entire clinical study participants are monitored for safety and occurrence of the disease which the vaccine is designed to prevent. Participants are informed about the study follow-up times and procedures as part of the informed consent process. Participants can withdraw consent at any time. FDA's guidance (Emergency Use Authorization for Vaccines to Prevent COVID-19)⁴ recognized that if a COVID-19 vaccine became available under an EUA that study participants (either placebo recipients in the study that supported the EUA or those in a study of another product) may choose to withdraw and encouraged EUA applicants to consider how to continue follow-up of study participants stating: "An EUA request should include strategies that will be implemented to ensure that ongoing clinical trials of the vaccine are able to assess long-term safety and efficacy (including evaluating for vaccine-associated enhanced respiratory disease as well as decreased effectiveness as immunity wanes over time) in sufficient numbers of subjects to support vaccine licensure. These strategies should address how ongoing trials will handle loss of follow-up information for study participants who choose to withdraw from the study in order to receive the vaccine under an EUA."

Question 4. What other steps will FDA take to ensure rapid development of new vaccines?

Answer. Having three vaccines authorized that meet the FDA's expectations for safety and effectiveness only one year after the declaration of the pandemic is a tremendous achievement and a testament to the dedication of developers and FDA's career scientists and physicians, many of whom have been working tirelessly to conduct comprehensive and rigorous evaluations of the data submitted for vaccines to prevent COVID-19. FDA remains committed to providing timely scientific and regulatory advice to support the development of COVID-19 vaccines that meet FDA's expectations for safety, effectiveness, and quality. The guidance documents that FDA released to assist manufacturers with the development of COVID-19 vaccines remain in effect and are a scientific and regulatory resource for industry, providing recommendations and outline FDA's expectations. Specifically, in June 2020, FDA issued guidance titled *Development and Licensure of Vaccines to Prevent COVID-19*.⁵ In October 2020, FDA issued guidance titled *Emergency Use Authorization for Vaccines to Prevent COVID-19* and updated it in February 2021.⁶

SENATOR MURKOWSKI

Question 1. Dr. Marks, you testified that the FDA is gathering data on serious adverse events from the various vaccines currently in use. You also stated that severe allergic reactions occur "in fewer than five in one million vaccine doses administered". Yet, I am concerned that many Americans may be refusing to get vaccinated because of rumors that people have died after receiving a vaccine, or that after-effects can make people feel seriously ill. What can you tell the American people about these concerns that would help them feel more confident about getting vaccinated? And where can Americans go, such as on FDA's website, to find authoritative data from the various vaccine safety monitoring efforts that are underway?

Answer. FDA has implemented a coordinated and overlapping approach for continuous safety monitoring of 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) Spontaneous reporting (or pas-

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

⁵ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>.

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-vaccines-prevent-covid-19>.

sive surveillance) using the Vaccine Adverse Event Reporting System (VAERS) consisting of safety reports submitted by healthcare providers, 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. Together, these provide a greater margin of safety for COVID-19 vaccines. Information on COVID-19 vaccine reporting systems is available here: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/reporting-systems.html>.

FDA utilizes a variety of methods for evaluating COVID-19 vaccine VAERS reports such as review of individual reports, aggregate analysis of reports, generating a case series when indicated and close collaboration with CDC's Immunization Safety Office (ISO). It may also include a comparison of VAERS reporting rates with background rates of disease or reporting rates of other vaccines. The goal of continuous monitoring is to quickly identify any specific safety concerns that may arise, to carefully evaluate and estimate the magnitude of the safety concern, and if warranted, for FDA to take regulatory action to mitigate the risk.

While many people have no effects from vaccination, information on the safety of COVID-19 vaccines, including commonly reported events such as fatigue, fever, muscle pain, and chills, is available here <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>.

Many of these efforts are in collaboration with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs (VA), and other academic and large non-government healthcare data systems.

CBER also participates actively in ongoing international pharmacovigilance efforts, including those organized by the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO).

This is all in addition to the pharmacovigilance efforts being undertaken by the individual manufacturers for authorized vaccines.

CBER is also monitoring the effectiveness of COVID-19 vaccines on several fronts to determine the duration of protection, effectiveness by each dose, effectiveness if the second dose is delayed, and effectiveness against variants. Please visit the following sites for more information:

- FDA's website: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.
- CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>.

Finally, we do want to acknowledge the pause that was recommended for use of the Janssen COVID-19 Vaccine (sometimes called the Johnson and Johnson COVID-19 vaccine). The pause was recommended on April 13 and lifted on April 23, 2021, after initial reports of six cases of a rare and severe type of blood clot in individuals following administration of the Janssen COVID-19 Vaccine. During the pause, medical and scientific teams at the FDA and CDC examined available data to assess the risk of thrombosis involving the cerebral venous sinuses, or CVST (large blood vessels in the brain), and other sites in the body (including but not limited to the large blood vessels of the abdomen and the veins of the legs) along with thrombocytopenia, or low blood platelet counts. The teams at FDA and CDC also conducted extensive outreach to providers and clinicians to ensure they were made aware of the potential for these adverse events and could properly manage and recognize these events due to the unique treatment required for these blood clots and low platelets, also known as thrombosis-thrombocytopenia syndrome (TTS).

FDA and CDC will continue with these efforts to closely monitor the safety of COVID-19 vaccines and will be sure to inform your office of relevant updates.

Question 2. Do you anticipate that Americans will need to get vaccinated against COVID every year, as we do against the flu? If so, do you anticipate that such vaccines will be as easy to get as flu vaccines are now, through our workplaces, doctors' offices, and pharmacies? What are the barriers to achieving that?

Answer. At this time, it is too early to tell if yearly COVID-19 vaccination will be necessary. The duration of protection with the current vaccines appears to be at least 6 to 9 months and may be a year or more. Vaccine manufacturers and others have expressed intent to evaluate whether COVID-19 vaccines can safely be given

at the same time as the influenza vaccine. If the two vaccines can be administered together, that would simplify things and allow routine vaccination against both viruses to be administered through the same mechanisms now used for influenza.

RESPONSES BY DR. WALENSKY TO QUESTIONS OF SENATOR SMITH, SENATOR BURR,
SENATOR MURKOWSKI, SENATOR BRAUN, AND SENATOR TUBERVILLE

SENATOR SMITH

Question 1. The timing of adolescent and pediatric eligibility for the COVID-19 vaccine could impact routine immunization. Back to school season is a time when children and adolescents ensure their vaccination schedules are up to date for the upcoming school year, but current CDC recommendations indicate that no other vaccine should be administered within 14 days before or after COVID-19 vaccination.

Question 1(a). What steps is the CDC taking to ensure adolescents receive their routine vaccinations ahead of COVID-19 eligibility to prevent further declines in adolescent immunization rates?

Answer. The Centers for Disease Control and Prevention (CDC) announced a *Call to Action* that outlines efforts needed to get children caught up on vaccinations so that they can safely return to in-person learning. COVID-19 has disrupted both in-person learning and routine well-child visits for many children over the last year. While families followed public health warnings about going out, an unfortunate result was many missed routine vaccinations. During the COVID-19 outbreak, CDC and the American Academy of Pediatrics (AAP) *recommend* every child continues to receive routine vaccinations.

As vaccine manufacturers begin to seek Emergency Use Authorization for COVID-19 vaccines in adolescents, the Advisory Committee on Immunization Practices (ACIP) will review considerations for co-administration and potential policy options will be discussed.

A multipronged approach is needed to promote optimal access and uptake of COVID-19 vaccination among adolescents, including through pediatric primary care providers, health departments, pharmacies, and school-based clinics. Pediatric primary care providers are trusted sources of vaccine information and vaccination for families. Thus, it is important to continue to encourage pediatric providers to enroll to become a COVID-19 vaccine provider. CDC will work with immunization award-ees and other partners to provide support and materials for adolescent COVID-19 vaccination.

SENATOR BURR

Question 1. The American Rescue Plan Act provided \$1.75 billion to support genomic sequencing, analytics, and disease surveillance. In addition, the Administration previously announced it would allocate \$200 million to the Centers for Disease Control and Prevention (CDC) to scale up public health surveillance. Along with supporting capacity building and modernization of data systems within public health departments, it is critically important to form partnerships with the private sector and academic institutions so that existing capacities and capabilities can be appropriately leveraged.

Question 1(a). How does CDC plan to spend this nearly \$2 billion in funding for sequencing and surveillance?

Answer. In the American Rescue Plan Act of 2021 (ARPA), Congress provided \$1.75 billion to strengthen and expand the workforce and activities related to genomic sequencing, analytics, and disease surveillance. These funds are being used to increase partnerships with commercial laboratories, state and local health departments, and academic institutions for sequencing. Prior to the congressional appropriations, the Administration allocated CDC with \$192 million allowing CDC to contract with commercial laboratories for sequencing.

Question 1(b). Does CDC plan to leverage the private sector and academic institutions and encourage state and local health departments in this effort? If so, how? If not, why not?

Answer. CDC will engage all three sectors to implement the ARPA component of genomic sequencing. CDC has contracted with nine commercial laboratories, among the largest in the United States, capable of obtaining positive specimens across the Nation for sequencing. These laboratories were chosen due to their large volume of SARS-CoV-2 diagnostic testing, geographic reach, and ability to sequence positive specimens.

For seven years, CDC's Advanced Molecular Detection (AMD) program has worked with state and local health departments to develop their capacity for sequencing and bioinformatics. All state public health laboratories have next-generation sequencing capacity, and several laboratories have CDC-supported regional bioinformaticians that can assist states without that capacity. During the pandemic, CDC awarded Paycheck Protection Program and Health Care Enhancement Act-and other COVID-related funds to support state and local health departments for sequencing of SARS-CoV-2. Going forward, CDC plans to use ARPA funds to facilitate the consolidation of state and local capacities to develop a national, cloud-based bioinformatics infrastructure to accelerate collaboration and response capacity.

The AMD program has supported collaborations between academia and public health since the beginning of the program. In late 2020, the agency awarded seven contracts to academic programs across the US to support genomic surveillance, and the agency will shortly award another ten contracts. After the pandemic, CDC intends to use ARPA funds to expand its network of centers of excellence, which represents CDC's partnerships with academic institutions and public health agencies.

SENATOR MURKOWSKI

Question 1. Dr. Walensky, can you commit to providing clarification to the Coast Guard that this mask order does not apply to fishing vessels, as the regulatory definition of "conveyance" clearly shows?

Answer. The Order issued on January 29, 2021, requires wearing masks that completely cover both the nose and mouth while on any commercial conveyance entering, traveling within, or departing the United States, including commercial maritime vessels. This Order also requires that individuals wear masks while at transportation hubs in the United States such as seaports.

Commercial maritime vessels involve the movement of people from different geographic areas in settings with inevitable close contact. Like other close-contact environments, maritime vessels may facilitate the transmission of respiratory viruses from person to person through exposure to respiratory droplets or contact with contaminated surfaces. CDC posted responses to frequently asked questions for maritime environments on the *Requirement for Face Masks on Public Transportation Conveyances and at Transportation Hubs* webpage.

The Order exempts persons from the requirement to wear a mask for whom wearing a mask would create a risk to workplace health, safety, or job duty as determined by the relevant workplace safety guidelines or Federal regulations. However, as stated in current CDC guidance, the exemption only applies while the person is performing that duty. For more information on best mitigation practices for maritime environments please visit *Interim Guidance for Ships on Managing Suspected or Confirmed Cases of Coronavirus Disease 2019 (COVID-19) Quarantine* CDC.

Certain maritime conveyances are exempted from the Order. These are:

- Private maritime conveyances operated solely for personal, non-commercial use (e.g., personal watercraft),
- When the operator is the sole occupant on board the maritime conveyance,
- Mobile offshore drilling units and platforms, to include floating and fixed Outer Continental Shelf facilities as defined in 33 CFR 140.10, and
- Certain maritime conveyances excluded from the definition of vessels under 42 CFR 70.1:
 - Fishing boats including those used for shell-fishing*;
 - Tugs which operate only locally in specific harbors and adjacent waters**;
 - Barges without means of self-propulsion;
 - Construction-equipment boats and dredges; and
 - Sand and gravel dredging and handling boats.

* Fishing vessels, fish processing vessels, and fish tender vessels as defined under 46 U.S.C § 2101 do not fall under this exemption—including shell-fishing vessels. A "fishing boat" is an auxiliary craft as defined under 46 U.S.C § 4502(k) carried on board a fishing vessel.

** Tugs which operate only locally in specific harbors and adjacent waters means tug vessels operating exclusively within a worksite and that have been issued a worksite exemption by the U.S. Coast Guard.

Question 2. Dr. Walensky, you testified that “Vaccination for teachers, staff, and among surrounding communities is *one of the several layers* of prevention strategies to reduce SARS-CoV-2 transmission in schools.” Others have said that vaccinating teachers is not *required* for safe school re-opening. Can you please provide some guidance to Governors and school leaders about the necessity for teacher vaccinations so that schools may reopen in a way that is safe?

Answer. Vaccines are an important tool to help stop the COVID-19 pandemic. Teachers and school staff hold jobs critical to the continued functioning of society and are at potential occupational risk of exposure to SARS-CoV-2. Vaccinating teachers and staff *provides* one layer of prevention and protection. Strategies that minimize barriers to access vaccination for teachers and other frontline essential workers, such as vaccine clinics at or close to the place of work, are optimal.

On March 2, President Biden directed all states to make teachers, school staff, and childcare workers eligible for vaccination and prioritized vaccinations for them within the Federal Retail Pharmacy Program during the month of March.

CDC published the COVID-19 Vaccine Toolkit for School Settings and Childcare Programs to provide COVID-19 vaccine information to staff in schools and childcare programs. The toolkit includes *customizable content for school leadership and childcare program directors* and a letter that parents can send to community schools or childcare programs to encourage review and use of the toolkit materials.

Implementation of layered prevention strategies will need to continue until we better understand potential transmission among people who received a COVID-19 vaccine and there is more vaccination coverage in the community. In addition, vaccines are not yet authorized for use in children under 16 years old. For these reasons, even after teachers and staff are vaccinated, schools need to continue prevention measures for the foreseeable future, including requiring masks in schools and physical distancing.

Question 3. Do you anticipate that Americans will need to get vaccinated against COVID every year, as we do against the flu? If so, do you anticipate that such vaccines will be as easy to get as flu vaccines are now, through our workplaces, doctors’ offices, and pharmacies? What are the barriers to achieving that?

Answer. Based on *current clinical considerations*, a patient is considered fully vaccinated two weeks after a two-dose mRNA COVID-19 vaccine series or two weeks after a single dose of Johnson & Johnson (J&J) Janssen COVID-19 Vaccine. The need for and timing for COVID-19 booster doses have not been established yet. No additional doses are recommended at this time.

CDC has launched several vaccine effectiveness studies that will evaluate how well COVID-19 vaccines are working in real-world conditions, and additional studies are underway as vaccines are administered across the United States among different groups. Since vaccination of priority groups with COVID-19 vaccines has only begun in the last 4 months with eligibility expanding to additional people in the last 2 months, data to determine vaccine effectiveness are being collected and published in an ongoing manner. As data on vaccine effectiveness become available, CDC will provide regular updates with that information.

Primary care providers (PCPs) play an influential role in building confidence in and improving access to vaccines; however, currently less than 5 percent of all COVID-19 vaccine doses have been administered by PCPs. As vaccine supply increases, CDC is developing guidance for expanding vaccine distribution (from existing jurisdiction vaccine allocations) to PCPs and increasing PCP enrollment for COVID-19 vaccine administration. This involves identifying priority PCPs in communities with the highest Social Vulnerability Index (SVI) scores and allocating vaccines to those PCPs and expanding community outreach. States and local health departments will also continue to leverage existing partnerships with pediatricians and primary care providers through established immunization programs to administer COVID-19 vaccines to eligible populations.

SENATOR BRAUN

Concerning Testing Capacity

As attention has been drawn to vaccine development and now distribution, it’s critically important that we ensure that testing for COVID-19 and variants are adequate, especially in rural areas. Proper testing is critical to the reopening of businesses, schools, and workplaces.

Question 1. What is your assessment of our testing capacity and infrastructure, especially in the context of emerging variants?

Answer. The HHS Testing and Diagnostics Work Group (TDWG) estimates that the United States manufactured approximately 187 million COVID-19 tests (NAAT and antigen diagnostic testing) in March 2021. Current test production exceeds throughput and specimen submissions for testing. At commercial laboratories, we estimate that 73 percent of capacity is currently unused. At public health laboratories, this percentage is currently 61 percent. These laboratories employ mainly Nucleic Acid Amplification Tests (NAAT). To date, there have not been significant signals that either NAAT or antigen test performance is diminished by emerging variants. Therefore, our assessment is that test supply meets demand, and should there be a rapid rise in cases due to emerging variants, available supply is anticipated to be sufficient. We are shifting focus more toward testing capacity and infrastructure, including training a qualified workforce and establishing laboratory networks with a focus on underserved populations.

Question 2. If there are gaps, how are you working to address them?

Answer. HHS Testing and Diagnostics Workgroup does not forecast that there will be substantial gaps in testing supply, assuming that there is no large second wave with or without a variant. Test production is predicted to increase and is expected to reach over 250 million tests produced per month by June 2021. This increase is due in part to a variety in USG investments in the supply chain for testing supply components, kits, and the launch of additional testing programs. For example, several testing programs for school testing and testing among underserved populations and those in congregate settings are currently in planning stages and are scheduled to come online starting in May 2021.

SENATOR TUBERVILLE

School Reopening

Question 1. Late last month, you appeared at a White House COVID-19 update briefing where you urged states not to reopen too soon, suggesting that “now is not the time” to ease up on restrictions. Our public education system has been destroyed and our kids are already #37 in the world in math. We don’t have much time.

Question 1(a). Will you ever advocate or recommend for states to reopen?

Question 1(b). What would have to happen for you to take such a step?

Answer. CDC maintains that schools can safely reopen for in-person instruction, as long as layered *prevention strategies* are in-place. Additionally, CDC recognizes it is critical for schools to open as safely and as quickly as possible, and remain open, to achieve the benefits of in-person learning and to ensure provision of key support services for students, families, and staff. CDC’s guidance for schools, the *Operational Strategy for K-12 Schools through Phased Prevention*, presents a pathway for schools to provide in-person instruction safely and states that K-12 schools should be the last settings to close after all other prevention measures in the community have been employed, and the first to reopen when they can do so safely. Evidence suggests that many K-12 schools that have strictly implemented prevention strategies have been able to do just that, safely open for in-person instruction and remain open.

CDC reviews the evolving evidence on spread of COVID-19 in schools and uses new science to inform our guidance. The preponderance of evidence indicates that there is limited COVID-19 transmission in U.S. schools that require proper mask use along with other prevention strategies. In March 2021, CDC updated its guidelines to reflect this new evidence. This update provides more options for schools to reopen for in-person instruction for more students, provided that correct and consistent mask use and other prevention strategies are in place.

It is important to recognize that different parts of the U.S. are experiencing different levels of COVID-19 spread. CDC is partnering with states and local communities to help with their plans to control the spread of the virus that causes COVID-19, and has released a series of decision support tools to assist in making reopening decisions within schools, workplaces, and other community settings.

Border Crisis

Question 2. According to interviews with senior administration officials, the Federal Government does not have a centralized system for tracking or responding to COVID-19 cases among the surge of migrants crossing our southern border.

Question 2(a). Without having a decent understanding of the number of positive cases crossing into the country, how can the Federal Government prevent potential outbreaks in packed detention facilities?

Answer. CDC developed Interim Considerations for SARS-CoV-2 Testing in Correctional and Detention Facilities (<https://www.cdc.gov/coronavirus/2019-ncov/community/correction-detention/testing.html>) to assist administrators of correctional and detention facilities, law enforcement agencies that have custodial authority over detained populations (i.e., U.S. Immigration and Customs Enforcement [ICE] and U.S. Marshals Service), and their respective jurisdiction health departments, in preparing for potential introduction, prevention, spread, and mitigation of SARS-CoV-2, the virus that causes COVID-19, in their facilities.

Question 2(b). How can the Administration prevent these potential hot spots from spreading into the wider U.S. population?

Answer. To help mitigate the continued risks of introduction, transmission, and spread of COVID-19, including emerging variants, among Customs and Border Protection (CBP) personnel, noncitizens in the ports of entry and Border Patrol stations, and people in surrounding communities, CDC's *Order* suspending the right to introduce noncitizens into the United States from countries where a quarantinable communicable disease exists remains in effect.

To reduce the risk of an outbreak, CDC has provided recommendations directly to HHS Administration for Children and Families' Office of Refugee Resettlement (ORR) and has deployed staff to the Emergency Intake Sites to ensure that public health recommendations for COVID-19 and other communicable diseases are being properly implemented.

Question 3. In January, CDC issued guidance requiring anyone, including U.S. citizens, flying into the U.S. possess a negative COVID test conducted within three days of their departure.

Question 3(a). Can the CDC please explain the discrepancy in guidance between the what is required of travelers entering the U.S. by plane and of those entering the U.S. at the land border?

Answer. CDC's *Order* requiring air passengers to present a negative COVID-19 test result or documentation of recovery from COVID-19 before boarding an international flight to the United States was made to help slow the spread of the virus as vaccinations are rolled out to the American public. While the testing does not eliminate all risk, when combined with a period of staying at home and everyday precautions like wearing masks and social distancing, it can make travel safer, healthier, and more responsible by reducing spread in confined spaces like planes, indoors in airports, and at destinations.

Other border measures like the Department of Homeland Security's (DHS's) *limitation to nonessential travel* on land borders and ferries, and CDC's *Order* that decompresses the number of people housed in congregate border settings, can also reduce the number of people who could expose or be exposed to others on the land borders. CDC continues to recommend precautions like wearing masks and social distancing for these populations. CDC will continue to work with partners and evaluate data related to vaccines, travel, and variants to inform decisions on border health measures.

[Whereupon, at 12:48 p.m., the hearing was adjourned.]