

**AN UPDATE FROM FEDERAL OFFICIALS  
ON EFFORTS TO COMBAT COVID-19**

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

FIRST SESSION

ON

EXAMINING AN UPDATE FROM FEDERAL OFFICIALS ON EFFORTS TO  
COMBAT COVID-19

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MAY 11, 2021  
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## AN UPDATE FROM FEDERAL OFFICIALS ON EFFORTS TO COMBAT COVID-19

Tuesday, May 11, 2021

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

The Committee met, pursuant to notice, at 10:04 a.m., in room 106, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Casey, Baldwin, Murphy, Kaine, Hassan, Smith, Rosen, Hickenlooper, Burr, Paul, Collins, Cassidy, Murkowski, Braun, Marshall, 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 hearing the latest update from Federal officials about our efforts to fight the COVID-19 pandemic. Ranking Member Burr and I will each have an opening statement, and then I will introduce our witnesses, Doctors Walensky, Fauci, Marks, and Kessler.

I am glad to have you all back before our Committee today, and I know we will continue to hear from you as we work to end this pandemic.

After the witnesses give their testimony today, each senator will have 5 minutes for a round of questions.

Before we begin, I want to again walk through the COVID-19 safety protocols that are in place today. We will follow the advice of the Attending Physician and Sergeant at Arms in conducting this hearing. We are again grateful to all of our Clerks and everyone who has worked so hard to get this set up and help everyone stay safe and healthy.

Committee Members are seated at least 6 feet apart, and some Senators are participating by videoconference. And while we are unable to have this hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at [help.senate.gov](https://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.

While we are not yet through this pandemic, it is clear we are making significant progress. We administered well over 200 million COVID-19 vaccines in President Biden's first 100 days. Over half the adult population has gotten at least one dose; one-third of the

Country is fully vaccinated. Schools, businesses, and communities are working to safely reopen. And, the Food and Drug Administration has now authorized vaccines for adolescents. So, we have come a long way in the last few months.

But, even as we are encouraged by the progress so far, we are all keenly aware more work lies ahead. This pandemic has touched every community in our Country and every corner of the world. To truly end it, vaccines have to be just as widespread.

While some progress is being made, for example in my home State of Washington, they have released a dashboard with vaccination data, the latest numbers from which show Washington State has vaccinated over five million people, and we are vaccinating around 50,000 more a day. The data also shows vaccinations are lagging in some areas, especially for Black, Latino, Tribal, and rural communities, and not just in my state, but across the Country.

In some states, we are still lacking key data on demographic characteristics, including race and ethnicity. We have to address systemic inequities and tear down barriers that are making it harder for some people to get vaccines. Everyone must have the opportunity to get vaccinated regardless of race, zip code, disability, primary language, or internet access.

We are also seeing vaccination rates slow. It is a reminder that making sure people can get vaccines is just half the battle. We need to make sure they do get them. To make that happen, we need to make sure people are getting reliable information about vaccines and hearing from voices they trust about why getting vaccinated is so important, not just to protect themselves, but to protect those around them and stop this disease from spreading or mutating into new deadly strains.

I am glad the Biden administration is continuing to release funds from the American Rescue Plan to help address some of these challenges, including last week when they announced almost a billion dollars to strengthen our response in rural communities, and one-quarter of a billion dollars to develop and support a community-based workforce to help underserved groups get information about vaccines, schedule appointments, arrange transportation, and more.

As we work to get our Nation vaccinated, we have to also acknowledge this is a global fight and do our part to lead on the world stage. The deadly outbreak in India is a heartbreaking reminder of what can happen when this virus spreads unchecked, when it mutates into more contagious, more deadly strains, and when it overwhelms healthcare systems. It is a reminder this pandemic will not fully be over for our Country until it is over for the world, which is why I am glad the Biden administration is sending medical support to India, sharing some of our excess doses globally, and even considering other steps to remove barriers to vaccines for countries that need them, including a targeted waiver of COVID-19 patent protections.

These moves will not just save lives in India. They will ultimately save lives in Washington State, North Carolina, and across the Country. Because people get that when there is a fire down the street, it is in their best interest to put it out before it gets to their

family's home, not to mention that helping your neighbor is always the right thing to do.

I am also hearing from lots of people in my home state who really feel we cannot simply end this crisis and never look back. We have to learn from it. We have to be better prepared for the next public health emergency so that we are never again in a situation like this, which is why Ranking Member Burr and I plan to develop bipartisan legislation to address and build on lessons learned from the COVID-19 response; ensure robust public health and medical capacity to provide services to those most at risk; improve and supply the supply chain for critical medical supplies; tackle the health disparities that afflict so many of our communities; and strengthen the Nation's public health infrastructure and medical preparedness and response programs at every level.

I look forward to having more hearings specific to that work soon and hearing what our witnesses today have to say on that subject, as well.

As Federal officials on the front lines of this pandemic, you all have an important perspective into the progress we are making today, as well as the lessons we must learn for tomorrow.

Now, 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. I am glad we are holding another hearing to update us on the status of COVID-19 response. And, to our witnesses, thank you for the work you have done. More importantly, welcome back to the Committee.

It has been almost 18 months since the initial reports of severe pneumonia in Wuhan, China surfaced. Since that time, we have tragically seen over a half million deaths in this Country from COVID-19. Government-backed shutdowns have jeopardized the livelihood of millions of Americans, and we have spent more taxpayer money than I could have ever imagined in response to this virus and the devastating effect it has had on our economy.

But, now, more than ever, there is reason for hope. We are seeing the promise of vaccines and treatments in real time. A month ago, the case count in the United States was over 70,000 new cases per day. Today, we are down to roughly 40,000 and headed south. The CDC is projecting continued declines in death and hospitalization rates.

Because of Operation Warp Speed, Dr. Marks, Dr. Fauci, Dr. Hahn, and the FDA, we have fully vaccinated 115 million Americans, which is roughly 44 percent of adults, and delivered almost 330 million doses to states. Operation Warp Speed and BARDA spent more than \$18 billion to make vaccines available to Americans, manufacturing vaccines at risk, and the American people are benefiting from that today. Manufacturers were able to produce vaccines, enough vaccines, that the United States is now able to help provide vaccines to countries in need, like India.

Because of the collaborative efforts over the last year, we are ready to turn the corner. The partnerships developing in manufacturing the COVID-19 vaccines have been one of the biggest scientific success stories in generations. Industry answered the call at

the start of the pandemic and partnered in an unprecedented way to bring us these life-saving products.

Intellectual property is part of the reason we have these life-saving products today. If these protections are not in place for innovators of life-saving medicines, we will not have them for the next pandemic. It is that simple.

We held a hearing on the threat of China taking intellectual property from U.S. research, and now the Biden administration has agreed just to hand it over. There is a way to support the manufacturing of vaccines globally and help countries in need without acting in bad faith against innovators who stepped up when the world needed them the most.

It is the partnerships we are already seeing today that are saving lives, not silly ideas about socializing means of production. The action from the Biden administration to support waiving intellectual property rights will undermine the innovation we are relying on to bring this pandemic to an end and will leave us with a less-prepared future.

I am encouraged that some of our European allies cautioned against this reckless action, and I hope the adults in the Biden administration will realize that what sounds good in a grad school ivory tower thesis paper does not make sense in the real world. You four are the adults in the room. I urge you to think about the real consequences if we just give away this science and this technology.

The next part of our job is going to be the difficult part. I have been looking to Israel to help predict the challenges that we may be in store for in the U.S. since they are ahead of us on vaccination rates today. Israel was able to vaccinate 40 percent of the adult population by the end of February. Their data shows that uptake stalled once they vaccinated about 60 percent of the adult population. While there are differences between our countries, we have to use the information we have to best predict our road ahead.

Every adult has the opportunity to be vaccinated, and supply is starting to exceed demand. In other words, we have more shots than we have arms to put it in. We need to address vaccine hesitancy, and it needs to be done now.

I know this is the case in my state with recent reports from Wilmington, North Carolina that local officials are changing their approach as vaccine demands slow. We must paint a picture for the American people showing the benefits of both a vaccination and a reopening of our Country. This is a simple message for those in leadership positions.

I got the vaccine. My wife got the vaccine. My sons got the vaccine. Their wives got the vaccine. I have encouraged all of my staff to take it as soon as it is available to them. And, I have gone through the last 24 hours with a real fear that I had a one-and-a-half year old grandson who might have had COVID. Fortunately, it all came back negative and he will hopefully leave the hospital sometime today.

But, I would guess that everyone in this room is vaccinated, which means if we follow the CDC guidelines, we can dispense with masks and social distancing. Tomorrow, I hope that we are going



to have a vaccine that is approved for kids over 12, and ones younger hopefully in the not-too-distant future.

We must reassure Americans that COVID vaccines are safe. Vaccines save lives. I might have been naive when we started this, believing that staying out of the hospital and not dying might have been motivation enough to get people vaccinated. It clearly was not. And that is why we must reassure Americans that if you get a COVID vaccine, our lives can and will return to normal. But, we cannot assure, without painting that picture for them, what that looks like. Today's response is preparing us for tomorrow's threat.

As Senator Murray said, we have launched a joint effort to strengthen our public health preparedness programs for the next threat, which we will inevitably face. That threat could be emerging today, or it could be a new virus, another curveball from Mother Nature, or the result of deliberate, manmade attacks on our Country.

Our framework has always been flexible and it needs to stay that way. There will always be lessons that we learn from each response, and our threat landscape is constantly evolving. Our experience with this pandemic has made that even more clear.

Senator Murray and I look forward to working with each of you and the Members of the Committee on this project to take stock of lessons learned and to actually put them into action.

To our witnesses today, thank you for all you have done up to this point of the response, but know that the most challenging days may be the next several weeks and months ahead as we attempt to get to a vaccination level that changes the glidepath to one that is permanently in the decline.

With that, I thank the Chair.

The CHAIR. Thank you, Senator Burr, and I look forward to working with you on that, and I wish your grandson well.

Senator BURR. Thank you.

The CHAIR. I will now introduce today's witnesses.

Dr. Rochelle Walensky is the Director of the Centers for Disease Control and Prevention and the Administrator of the Agency for Toxic Substances and Disease Registry.

Dr. Walensky, welcome back. Thank you for joining us today.

Next, I would like to introduce Dr. Anthony Fauci, who is the Director of the National Institute of Allergy and Infectious Diseases and the Chief Medical Advisor on President Biden's COVID-19 Response Team.

Dr. Fauci, good to have you back before the Committee, as well. Thank you for joining us.

Dr. Peter Marks is the Director of the Center for Biologics Evaluation and Research for the Food and Drug Administration.

Dr. Marks, we are glad to have you here again, as well. Thank you.

Finally, I would like to introduce Dr. David Kessler. Dr. Kessler is the Chief Science Officer of the Biden administration's COVID-19 Response Team.

Dr. Kessler, glad to have you with us, as well.

With that, we will begin our witness testimony. Dr. Walensky, we will begin with you for your opening statement.

**STATEMENT OF ROCHELLE WALENSKY, M.D., MPH, DIRECTOR,  
UNITED STATES CENTERS FOR DISEASE CONTROL AND PRE-  
VENTION, ATLANTA, GA**

Dr. WALENSKY. Thank you, Chair Murray, Ranking Member Burr, and Members of the Committee for the invitation to speak with you today.

I last testified before this Committee less than 2 months ago. Since that time, the dedicated professionals at CDC have been working diligently to provide additional resources to states, localities, territories, and tribes thanks to support from Congress. We are updating our guidance based on the latest scientific evidence, and we are working with our partners around the Country and around the globe to reduce the burden of COVID-19.

I am pleased to report that since January, we have seen a consistent downward trend with daily averages of new infections dropping 76 percent, hospitalizations down 71 percent, and reported deaths decreasing by 75 percent.

This progress is also reflected in our data on the county-level risk. Just a few months ago, 85 percent of all counties in the U.S. were experiencing high COVID-19 transmission rates and increased community risk. This morning, that is down to 33 percent of counties.

These trends give me hope. And, still, I continue to emphasize that we must remain diligent and committed to our surveillance and prevention efforts because the emergence of variants could set us back.

With your help, CDC is using the \$1.7 billion Congress provided to expand nationwide genomic sequencing efforts. Since January, we have dramatically increased sequence output from 3,000 samples per week to approximately 35,000 samples per week.

We are also keeping our commitment to prioritize health equity. Since March, we have announced a number of investments that center in health equity. These include \$2.25 billion to address COVID-19-related health disparities and advance health equity among high-risk and underserved populations; \$3 billion to strengthen vaccine confidence, with a focus on increasing uptake and equity in administration, particularly in communities hardest hit by the pandemic; \$332 million in community health workers to support COVID-19 prevention and control; and \$250 million to develop targeted strategies for vaccine education and outreach for uptake in specific communities.

In addition, CDC continues to update our guidance as we learn more. This includes a recent update outlining levels of risk of activities for fully vaccinated and unvaccinated people. We will continue to update this guidance to be clear that vaccines are a means of returning to activities we stopped as a result of the pandemic.

I am so proud to report the administration of more than 261 million vaccine doses, including more than 133 million since I last testified before you in March. Over 84 percent of Americans age 65 and older, and over 58 percent of all adult Americans have now received at least one vaccine dose.

With these cases trending down in the United States and more people getting vaccinated, we are cautiously optimistic. However, globally, the pandemic is more severe than ever. India's surge of

cases is tragic and a reminder that the virus can rapidly outstrip our efforts to contain it if we are not careful. We will not end this pandemic without working hand in hand with countries around the globe to fight COVID-19.

I want to take a moment to acknowledge that while we have made great progress over the last few months, more than 579,000 people in the United States have died from COVID-19 during this pandemic. And just since I saw you in March, over 39,000 of our loved ones have died from COVID-19 in the United States. Every death is a stark reminder of why we must remain vigilant and focused to end this pandemic as quickly as possible.

I want to close with a promise and an appeal to the American people. My promise is that CDC will continue to follow the science as our guide. And, my appeal is to implore everyone to get a COVID-19 vaccine as soon as possible as the fastest way to end this pandemic.

But, even with this powerful tool, while we continue to have community transmission, we must also maintain public health measures we know will prevent the spread of this virus—masks, hygiene, hand hygiene, and physical distancing.

Finally, as we get through this pandemic, we must work together over the months and years ahead to build on the investments, partnerships, and innovations that we have created during this crisis. This includes achieving sustainable investments in public health infrastructure to be better prepared for whatever comes next. It is one way we can turn tragedy into lasting progress and improved health for all.

Thank you again for the opportunity and invitation to testify today, and I look forward to answering your questions.

[The prepared statement of Dr. Walensky follows:]

#### PREPARED STATEMENT OF ROCHELLE WALENSKY

Chairman Murray, Ranking Member Burr, and distinguished Members of the Committee. It is an honor to appear before you again today to discuss the Centers for Disease Control and Prevention's (CDC) ongoing response to the COVID-19 pandemic. 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 health, safety, and security. CDC is proud of its key role in preparedness and response to public health concerns here in the United States and abroad. 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 over 4 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**

While COVID-19 cases have recently decreased, COVID-19 transmission remains widespread across the Nation. We are hopeful. We have made significant progress

in getting shots in arms. But, given that many people around the country are not yet fully vaccinated and given the threat of variants, we must remain cautious.

It goes without saying, we have been tested over the past nearly year and a half. It has been an extraordinarily difficult time for the United States. And I want to take a moment to recognize the more than 570,000 Americans—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. We also acknowledge the millions of others who have suffered with this disease and recognize there are so many who will require long-term care and support.

As hard as this has been, we can still persevere. If we can just stay the course a little longer by strengthening and maintaining evidence-based prevention 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 has expanded sequence surveillance across the United States 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 locations across the United States 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 250 COVID-19 studies have been published in the *Morbidity and Mortality Weekly Report* (MMWR) on topics ranging from health disparities exacerbated during the pandemic, to prevention strategies, to emergence of new variants. CDC has also produced more than 6,000 documents to provide information and guidance for government agencies, businesses, and the public. CDC is actively studying the epidemiology of post-COVID conditions (often referred to as long COVID), including the prevalence, duration, and severity of symptoms following acute SARS-CoV-2 infection, as well as risk factors for developing post-COVID conditions. This work will help to establish a more complete understanding of the natural history of SARS-CoV-2 infection and post-COVID conditions, which can inform healthcare strategies, clinical decision-making, and the public health response to this virus that will be required over the long term. A recent MMWR article found that among 3,000 adults with COVID-19 who didn't require a hospital stay, two out of three returned for at least one outpatient visit within one to 6 months after COVID-19 diagnosis; many with recurring symptoms potentially related to COVID-19.

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. There is also 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 prevention 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. This group is also engaging with international partners to improve global surveillance of variants and identify synergies in our collective assessment of the impact of variants globally.

We are monitoring dozens of variants and conducting ongoing and comprehensive risk assessments through the SARS-CoV-2 Interagency Group and in consultation with our international colleagues. Of the emerging variants, five have captured our attention and have the highest risk to public health: B.1.1.7, B.1.351, B.1.427, B.1.429, 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. Data from CDC national surveillance project that B.1.1.7 viruses represented 72 percent of the viruses circulating for the two-week period ending April 24. The B.1.1.7 variant is the predominant strain of SARS-CoV-2 in the country now and has likely continued 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. Data from CDC national surveillance project that B.1.351 viruses represented approximately 0.6 percent of the circulating viruses, and the P.1 variant represented approximately 5.6 percent for the two-week period ending April 24. The proportion of cases attributed to the B.1.427 and B.1.429 variants, which were first identified in California, have decreased in recent weeks. According to data for the two-week period ending April 24, the combined prevalence of B.1.427 and B.1.429 is 2.6 percent.

Available data suggest that antibodies elicited by vaccination with the currently authorized vaccines are able to neutralize the B.1.1.7 variant but have reduced neutralization against the B.1.351 and P.1 variants. Based on preliminary data from a Johnson & Johnson vaccine clinical trial in South Africa where the prevalence of the B.1.351 variant was estimated to be 95 percent, the vaccine efficacy was 64 percent and had 81.7 percent efficacy in preventing severe disease, and promising efficacy data have been released from the Pfizer clinical trial in South Africa. Studies are currently underway to understand the impact on the real-world effectiveness of current vaccines against the B.1.351 variant and other variants of concern. Efforts are ongoing to better understand the impact of the variants on medical countermeasures.

Since January, CDC has dramatically built up our domestic genomic surveillance platforms to monitor circulating variants, increasing the Nation's sequencing output 75-fold, with over 36,000 specimens now sequenced weekly. With support from the funding the Administration announced in February as well as the resources provided by the American Rescue Plan Act, we're contracting with several large commercial diagnostic laboratories to get viral sequence data from around the country. These laboratories are providing data on over 22,000 virus samples per week. 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 approximately 7,000 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 7,000 viruses per week. These efforts are coordinated through CDC's SPHERES collaboration, which is a national genomics consortium to coordinate large-scale SARS-CoV-2 sequencing across the country. In all, the United States is sequencing about 10 percent of the roughly 350,000 weekly cases. These partnerships with commercial labs, state and local health departments, and academic and research institutions will continue to grow. We are on our way to sequencing an even higher percentage of cases, a tremendous accomplishment. CDC is working with state and local public health de-

partments to use these sequencing data as part of their COVID-19 response strategy. CDC has also made significant strides to make our genomic surveillance data more accessible to the public through an interactive dashboard on our COVID Data Tracker website. This site is updated regularly with the prevalence of SARS-CoV-2 variants at the national, regional, and state levels.

Each new variant can present different challenges. But each can be stopped by the same methods: rigorous and increased compliance with public health prevention 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. CDC's Chief Health Equity Officer has been leading implementation of our Health Equity Strategy to accelerate progress in reducing COVID-19 disparities. The strategy outlines an approach to expand evidence-based approaches to reduce disparities in COVID-19 hospitalizations and deaths; increasing testing, contact tracing, isolation options, and healthcare access in populations at increased risk for COVID-19; prioritizing equity in distribution and administration of COVID-19 vaccines; reducing stigma and bias; and expanding a diverse workforce, equipped to address the needs of a diverse population. We are engaging with community-based organizations and diverse leaders to conduct outreach that is culturally and linguistically responsive to the needs of 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 they serve. They have also helped us craft and convey tailored prevention messages about COVID-19 to these important populations across the country. 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.

We know we need the best possible data to more clearly understand these 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 almost 40 percent of the COVID-19 cases reported to CDC. Progress has been slow because there are many data requisition forms and data interfaces in the data exchange pathway that must be updated. Moreover, public health data systems are not set up in a way that captures the underlying drivers for which race and ethnicity are markers. Those drivers include social determinants of health such as occupation, housing, education, access to healthcare and other factors that are the underlying causes for the disparities we see by race and ethnicity. There are multiple barriers to collecting some of these data elements, including at the state and individual level—including reticence to report income or other socio-economic factors.

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 antiquated public health data systems by providing resources to CDC for the data modernization initiative, the first comprehensive strategy to modernize public health data, technology, and workforce capabilities—together and at once. CDC is collaborating with our partners in the field to improve data collection and sharing.

In the last few months, data continue to document ongoing health disparities. In February, CDC's National Center for Health Statistics (NCHS) released data that highlighted disparities in life expectancy between 2019 and 2020, demonstrating the impact of COVID-19 on Black and Hispanic/Latino communities. Additional CDC data<sup>1</sup> released in February noted that racial and ethnic minority groups have experienced disparities in mental health and substance use disorder related to access to care, psychosocial stress, and social determinants of health, exacerbated by the pandemic. Hispanic/Latino adults reported a higher prevalence of psychosocial stress related to not having enough food or stable housing than did adults in other racial and ethnic groups. And more recently, in April, we published a report<sup>2</sup> that found racial and ethnic disparities in hospitalization rates during the early months of the pandemic, with rates being highest for Hispanic or Latino patients, although these disparities generally declined later in 2020 as the proportion of cases in White patients increased.

While it is important to document these disparities, we do not need further documentation to take action, and we are making strides toward change using the data we have. These data compel us to do what we do best at CDC—to turn our research and science into policy and action to improve the health of all. CDC, in collaboration with other components of HHS, has made historic investments in the last month to address COVID-19 health disparities and promote health equity.

In March, CDC announced plans to invest \$2.25 billion over 2 years to address COVID-19 related health disparities and advance health equity among populations that are at high-risk and underserved, including racial and ethnic minority groups and people living in rural areas. This funding represents CDC's largest investment to date to support communities affected by COVID-19-related health disparities. CDC's new *National Initiative to Address COVID-19 Health Disparities Among Populations at High-Risk and Underserved Communities, Including Racial and Ethnic Minority Populations and Rural Communities*, will offer grants to public health departments to improve testing and contact tracing capabilities; develop innovative mitigation and prevention resources and services; improve data collection and reporting; build, leverage, and expand infrastructure support; and mobilize partners and collaborators to advance health equity and address social determinants of health as they relate to COVID-19.

CDC is also investing \$300 million over 3 years in jurisdictions for community health worker services to support COVID-19 prevention and control, and an additional \$32 million for training, technical assistance, and evaluation related to this effort. This funding will be used to address disparities in access to COVID-19 related services, such as testing, contact tracing, and vaccinations, and it will help address factors that increase risk of severe COVID-19 illness. This effort will benefit populations with increased prevalence of COVID-19 and disproportionately impacted by long-standing health disparities.

Through this funding CDC is committed to addressing these gaps, not only for the COVID-19 response, but across public health. And as we do this work, we will simultaneously take action on what we know—that these disparities exist, and they are unacceptable; addressing them is critical in ensuring success against COVID-19 and future pandemics.

### Vaccines

Vaccination is a critical tool in bringing this unprecedented pandemic to an end. In the year since SARS-CoV-2 infections were first identified, the FDA has issued Emergency Use Authorizations for 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 and appreciate how vaccine efficacy helps prevent serious illness, hospitalization, and death from COVID-19. As of April 19, every person aged 16 and over in every state and territory is now eligible to get vaccinated, and 90 percent of Americans now have a vaccine site within 5 miles of their home. The country has exceeded President Biden's goal of administering 200 million shots in the first 100 days of his Administration.

A CDC study reviewing data from the first 3 months of vaccinations among health care personnel, first responders, and other frontline and essential workers found that both Moderna and Pfizer vaccines were 90 percent effective in preventing COVID-19 infection, two or more weeks after full vaccination. In addition, another

<sup>1</sup> [https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a3.htm?s\\_cid=mm7005a3-w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a3.htm?s_cid=mm7005a3-w).

<sup>2</sup> [https://www.cdc.gov/mmwr/volumes/70/wr/mm7015e2.htm?s\\_cid=mm7015e2-w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7015e2.htm?s_cid=mm7015e2-w).

recent CDC study<sup>3</sup> found these two vaccines were 94 percent effective against hospitalization among fully vaccinated adults aged 65 years and older. These findings demonstrate the high, real-world effectiveness of these vaccines.

COVID-19 vaccine safety is a top priority for the Federal Government, and we take all reports of health problems following COVID-19 vaccination seriously. On April 23, following a thorough safety review, including two emergency meetings of the CDC's Advisory Committee on Immunization Practices, the FDA and CDC determined that the previously recommended pause regarding the use of the Janssen (Johnson & Johnson) COVID-19 Vaccine in the United States should be lifted and use of the vaccine should resume. The pause had been recommended after 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 (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. The identification of this rare complication is an important validation of the sensitivity of vaccine safety monitoring systems to be able to pick up even very small numbers of vaccine safety concerns.

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 May 6, about 325 million doses have been delivered, and more than 251 million doses of COVID-19 vaccine have been administered. Over 70 percent of all Americans age 65 years and older were fully vaccinated by this date, and about 57 percent of adult Americans had received at least one vaccine. This is a whole-of-society effort, and it is inspiring to see people across government, business, and communities coming together to complete this important life-saving task.

I would like to touch on four core areas that drive CDC's vaccine work: safety, confidence, access, and equity. As shown during the recent Janssen (Johnson & Johnson) vaccine pause, our commitment to safety remains paramount to our work. 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.

Further supporting efforts to prioritize equity in our vaccine strategy, CDC announced an investment of \$3.15 billion to support local efforts to increase vaccine access, uptake, and equity. In early April, these funds were awarded directly to states, territories, and some large cities, enabling them to support local health departments and community-based organizations in launching programs and initiatives intended to increase vaccine access, acceptance, and uptake. The funding will focus on reaching communities hit hardest by the pandemic, including those with a high social vulnerability index, minority communities, and rural areas.

In order to enhance vaccine uptake among underserved communities of color and to build trust and confidence in the authorized COVID-19 vaccines, CDC has developed a comprehensive program of approximately 20 national organizations that support hundreds of local and community-based organizations to improve both COVID-19 and influenza vaccination coverage among racial and ethnic groups who have historically had, and continue to experience, health disparities.

Improving access to underserved communities and populations who have historically experienced greater barriers to healthcare access is another critical component to prioritizing equity in vaccine distribution. Improving access also requires a multi-pronged approach. To that end, CDC is working closely with the Federal Emergency

<sup>3</sup> [https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s\\_cid=mm7018e1-w](https://www.cdc.gov/mmwr/volumes/70/wr/mm7018e1.htm?s_cid=mm7018e1-w).



Management Agency (FEMA) and the Health Resources and Services Administration (HRSA) on two critically important programs with the goal of bringing vaccines to communities and improving access for populations disproportionately impacted by COVID-19. CDC partners with FEMA on the implementation of their Community Vaccination Centers. CDC also partners with HRSA to support COVID-19 vaccinations in select HRSA-funded health centers.

The Federal Retail Pharmacy Program is integral to the work CDC is doing to maximize access to COVID-19 vaccines in all communities, including communities of color and other underserved populations, such as rural communities. CDC is partnering with 21 national pharmacy organizations and independent pharmacy networks that represent over 40,000 locations nationwide—including 45 percent in highest-need neighborhoods—to ensure that the public has access to COVID-19 vaccines in a familiar setting. Almost 90 percent of Americans live within five miles of a retail pharmacy. The retail pharmacy program was also instrumental in attaining the goal of prioritizing Pre-K through 12th grade educators, school staff, and childcare workers for COVID-19 vaccination in the month of March. As a result of this effort, our estimates show that approximately 80 percent of these essential frontline workers across the United States received at least one shot in March and more than 2 million teachers, school staff, and childcare workers were vaccinated through the Federal Retail Pharmacy Program in March. More than 52 million doses of vaccine in total have been administered through this program.

Last month, CDC also announced a new partnership with certain clinics to provide COVID-19 vaccinations to people receiving dialysis, as well as health care personnel working in these clinics. Dialysis patients are disproportionately affected by COVID-19 and are at high risk for severe illness and death from COVID-19. It is estimated that 34 percent of people receiving dialysis are Black and 19 percent are Hispanic; and that 22 percent of staff in dialysis clinics are Black. People on dialysis who get COVID-19 have a 50 percent hospitalization rate and a 20 to 30 percent mortality rate. This effort is another important step in making sure that vaccines reach the most medically vulnerable communities and that prioritizing equity in vaccination continues to anchor our efforts to end the COVID-19 pandemic.

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. CDC recently released updated guidelines for fully vaccinated people, providing guiding principles on how to assess their own risk for COVID-19 and determine what prevention measures, including masks, should be used. 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: Trans-*

*mission of SARS-CoV-2 in K-12 Schools*,<sup>4</sup> which informed CDC's *Operational Strategy for K-12 Schools through Phased Prevention*.<sup>5</sup> 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 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. In March, CDC updated its school guidance reflecting the latest evidence to recommend that, with universal masking, students should maintain a distance of at least three feet in classroom settings. However, middle school students and high school students should be at least six feet apart in communities where transmission is high, if cohorting (or podding) is not possible. 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 guidance, as well as tools and best practices about how to apply this 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. 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 (including 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.

In April, CDC provided \$10 billion to states and jurisdictions to support COVID-19 screening testing for K-12 teachers, staff, and students to assist schools in reopening safely for in-person instruction. In addition to ensuring diagnostic testing of symptomatic and exposed individuals, serial screening testing will help schools identify infected individuals without symptoms who may be contagious so that prompt action can be taken to prevent further transmission. With this funding, states can support the critical testing and testing supports schools need to implement screening testing programs. Recognizing that establishing a testing program is new for many schools, CDC and state and local health departments will support technical assistance to assist states and schools in standing up and implementing these programs. A recent article in CDC's MMWR found participation in a free, in-school COVID-19 testing program within Utah elementary schools was higher among students belonging to a racial or ethnic minority group and among students living in areas with higher rates of COVID-19. In-school testing could help reach underserved populations and reduce the spread of COVID-19 across the community.

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

As I've said before, 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

<sup>4</sup> <https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/transmission-k-12-schools.html>.

<sup>5</sup> <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/operation-strategy.html>.

responses to each of these threats, none resulted in the sustained improvements 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, including 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 COVID-19 cases remain widespread, there are reasons to be hopeful. 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.

Ending this pandemic requires more equitable access to affordable and timely testing, treatment, and vaccination. Looking forward, we will continue to take a health equity approach, not only in future emergency responses, but in everything we do at CDC. And even when this crisis is over, we will still need a strong public health system. The COVID-19 pandemic has illuminated long-standing inequalities in health among racial and ethnic minority groups; demonstrated the need for resilient, fast, and accurate data systems; and showed the essential role a robust, skilled, and diverse public health workforce plays in protecting Americans.

The next few weeks and 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 cannot strengthen the public health infrastructure our Nation needs to combat public health emergencies—like pandemics and other infectious disease threats—overnight or in the middle of an emergency crisis. We must work together over the months and years ahead to reinforce the foundations, partnerships, modernizations, and innovations that we have initiated during this pandemic—ensuring robust public health systems continue to be grounded in science. It is one way we can turn tragedy into lasting progress and improved health outcomes for all. Thank you again for the invitation to testify today and I look forward to answering your questions.

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The CHAIR. Thank you.  
Dr. Fauci.

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

Dr. FAUCI. Madam Chair, Ranking Member Burr, Members of the Committee, thank you for giving me the opportunity to discuss with you this morning the role of the National Institute of Allergy and Infectious Diseases and the NIH and research addressing the COVID-19 pandemic.

As I had mentioned to this Committee during the last hearing that we attended, we have a strategic plan that has four major

components—fundamental knowledge of the virus, diagnostics, therapeutics, and the development of safe and effective vaccines. For the purpose of today’s discussion, I will focus on the issue of vaccines.

We often get asked how it could be possible that the virus was discovered in January 2020 and we had doses of vaccine going into the arms of individuals, a vaccine that was highly efficacious and safe, 11 months later in December 2020. Well, the story behind that has been the decades of investment in basic and clinical, biomedical research that has led to our ability to accomplish this extraordinary feat.

Just some examples. The basic preclinical and clinical research in developing vaccine platform technology, particularly the highly successful mRNA platform.

In addition, scientists at the Vaccine Research Center at NIAID, as well as grantees and contracts—contractors throughout the Country developed the optimal immunogen, which is the confirmationally correct spike protein, which is used by virtually all the vaccines that are being tested right now.

Finally, the utilization of a clinical trial network that we had set up decades ago for influenza and for HIV.

When one thinks of efficacy, it really is what are the results of a clinical trial. Often, when you get into the real world, the effectiveness of vaccines falls short of the original efficacy. That is not at all the case with the vaccines for COVID–19 because the real-world effectiveness is even more impressive than the results of the clinical trial.

One example, the University of Texas looked at 23,000 of their employees and found that the incidence of infection was 0.05 percent, markedly lower than unvaccinated individuals.

The CDC has multiple MMWRs reporting on various aspects of the real-world effectiveness. Importantly, a recent paper in *The Lancet* reported on the experience in Israel, which, as Senator Burr had mentioned, has done an extraordinary job of getting their citizens vaccinated. And, what we have seen is a remarkable diminution in the number of infections that reached a critical turning point when they reached a certain percentage of the individuals who were vaccinated.

It was not only limited to Israel. Another recent paper in the country of Qatar showed a similar type of result in which, not only was the mRNA vaccine highly effective in over 300,000 individuals tested in preventing the original wild-type virus, but it also had a very interesting capability of protecting against mild to moderate disease of a problematic variant from South Africa, the 351, and protected virtually 100 percent from severe disease, including hospitalization and death.

When the President makes the goal of 70 percent of adults receiving at least one vaccine by the 4th of July, we believe that is an attainable goal. The reason we feel it is important is that I believe that we are about at that critical turning point when we get a certain percentage—we do not know exactly what it is, but clearly the majority of individuals in the Country vaccinated, we will see a sharp turning point and a marked diminution in cases.

As I said the last time I testified before you, we are in a race between the vaccine and the virus, if left to its own devices will continue to surge. Based on experience thus far in this Country and globally, I feel confident that if we continue to vaccinate people at the rate that we are doing, that we will very soon have a situation where we will have so few infections in this Country, we will begin to return to normality that all of us desire so much.

Thank you very much.

[The prepared statement of Dr. Fauci follows:]

PREPARED STATEMENT OF ANTHONY FAUCI

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

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

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

These successes have helped slow the progression of the pandemic in the United States. Currently, we are vaccinating approximately 2.5 million people per day, and we must continue to vaccinate as many people as we can as quickly as possible. FDA-authorized COVID-19 vaccines are safe and highly effective. The high levels of vaccine efficacy observed in the carefully controlled conditions of a clinical trial setting have been subsequently confirmed by their effectiveness in studies of vaccines administered to broad segments of the public. Vaccination and adherence to public health measures are the fundamental tools that will help us head off another COVID-19 surge.

While we are cautiously optimistic about the future, we know that many challenges remain. One of the most concerning developments of the ongoing pandemic is the spread of genetic variants of SARS-CoV-2, some of which appear to be more transmissible than the original virus, more virulent, and/or 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 Authorizations (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 continuing to work directly with these communities, as well as 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 the COVID-19 pandemic. NIAID also

recognizes that while many individuals with SARS-CoV-2 infection fully recover after a relatively short time period, some individuals suffer longer-term effects after the initial phase of illness and after the virus is cleared 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 broad 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 research investments by NIAID in the years prior to the emergence of SARS-CoV-2 enabled the unprecedented pace of COVID-19 vaccine candidate development. Two activities predate successful COVID-19 vaccines: the development of versatile vaccine platforms and the adaptation of structural biology tools to design agents (immunogens) that powerfully stimulate the immune system. Long before the pandemic, NIAID VRC scientists and their collaborators made the critical scientific discovery of how to stabilize in a highly immunogenic form viral proteins that are important for infection, including the spike protein of the Middle East respiratory syndrome coronavirus (MERS-CoV), using a double mutation known as S2P. This key finding 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 in January 2020, VRC researchers rapidly generated a stabilized SARS-CoV-2 spike protein for use in COVID-19 vaccine development. This crucial breakthrough in structure-based vaccine design for coronaviruses has led to the development of safe and effective COVID-19 vaccine candidates across a range of vaccine platforms.

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

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

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

#### ***mRNA-1273 (Moderna)***

As part of a longstanding collaboration, the NIAID VRC worked with the biotechnology company Moderna to develop a vaccine candidate designated mRNA-

1273, which uses a messenger RNA (mRNA) vaccine platform to express the stabilized SARS-CoV-2 spike protein. Early clinical trials demonstrated that mRNA-1273 was generally well tolerated and induced robust immune responses in healthy adults. NIAID and BARDA then began working with Moderna on a Phase 3 clinical trial through the CoVPN that showed that mRNA-1273 was 94.1 percent efficacious in preventing symptomatic COVID-19. On December 18, 2020, after a thorough review of comprehensive data on mRNA-1273, the FDA issued an EUA for the mRNA-1273 vaccine for prevention of COVID-19 in individuals 18 years of age and older. In subsequent observational studies under “real-world” conditions in broader segments of the population, mRNA-based vaccines continue to display a high level of effectiveness. In an article published in *Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention (CDC) researchers and their collaborators showed that among health care personnel, first responders, and other essential workers, the mRNA-1273 and the Pfizer-BioNTech mRNA vaccine were 90 percent effective against SARS-CoV-2 infections 14 or more days after receiving a second dose. In another *MMWR* article, these vaccines reduced the risk of COVID-19 hospitalization by 94 percent among people 65 years of age and older. Recently, NIAID scientists and their collaborators demonstrated that anti-SARS-CoV-2 antibodies persist for at least 6 months after the second dose of mRNA-1273.

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

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

#### ***Other COVID-19 Vaccine Candidates***

NIAID, through the CoVPN, is supporting Phase 3 clinical trials of COVID-19 vaccine candidates from AstraZeneca (AZD1222) and Novavax (NVX-CoV2373). AstraZeneca’s AZD1222 COVID-19 vaccine candidate uses a chimpanzee adenovirus-vectored vaccine approach developed by researchers at the University of Oxford in collaboration with scientists at NIAID’s Rocky Mountain Laboratories. On March 25, 2021, AstraZeneca announced an updated interim analysis of AZD1222 reporting that the vaccine candidate was 76 percent effective at preventing symptomatic COVID-19, including 85 percent effective in participants aged 65 years and over. Importantly, the efficacy of AZD1222 against severe COVID-19 disease was reported to be 100 percent.

#### ***Clinical Trials of COVID-19 Vaccine Candidates in Special Populations***

To effectively end the COVID-19 pandemic, it will be important to vaccinate as many people as possible, including those in special populations, such as pregnant and lactating women, children, and people with immune deficiencies. Tens of thousands of pregnant and lactating women already have received the COVID-19 vaccines under FDA EUAs, and available data indicate that these vaccines are safe and effective in these populations. In addition, protective antibodies against SARS-CoV-2 have been detected in babies born to pregnant women who received mRNA COVID-19 vaccines. NIAID-supported investigators plan to continue to monitor the safety and further study the immune responses to these vaccine candidates in preg-

nant and lactating women. Efforts to evaluate COVID-19 vaccines in pediatric populations are ongoing. On March 16, 2021, Moderna, in collaboration with NIAID and BARDA, announced the launch of KidCOVE, a Phase 2/3 study to evaluate the safety and efficacy of mRNA-1273 in children ages 6 months to less than 12 years. This study is in addition to Moderna's ongoing TeenCOVE study of mRNA-1273 in adolescents between the ages of 12 and 17. Other vaccine developers also have begun, or are planning to begin, trials to test their vaccine candidates in children, adolescents, and other special populations. On April 23, 2021, NIAID launched an observational study at the NIH Clinical Center assessing how people with immune system deficiencies or dysregulations respond to COVID-19 vaccination. NIAID investigators also will gather information about COVID-19 illness in these individuals. This study will inform decision-making about COVID-19 vaccination in people with immune deficiencies and dysregulation conditions.

#### ***Monoclonal Antibodies to Prevent COVID-19***

NIAID scientists, collaborating with Regeneron Pharmaceuticals and Eli Lilly and Company, also initiated two Phase 3 clinical trials to evaluate whether their investigational monoclonal antibodies, REGEN-COV and bamlanivimab alone and in combination with etesevimab 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. These studies have completed enrollment and further analysis of the data from the trials is ongoing. Due to the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab—when administered alone—the FDA revoked the EUA for bamlanivimab alone for the treatment of mild-to-moderate COVID-19 on April 16, 2021. In light of these concerns of variant resistance, the use of bamlanivimab alone is no longer being pursued for the prevention of COVID-19. The FDA now includes information on the susceptibility of SARS-CoV-2 variants in its fact sheets for health care providers for each of the monoclonal antibody therapies currently available through an EUA (REGEN-COV and bamlanivimab in combination with etesevimab). In separate studies, NIAID-supported scientists and collaborators are evaluating the potential impact of emerging SARS-CoV-2 variants on the efficacy of monoclonal antibodies.

#### ***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 hospitalized COVID-19 patients with remdesivir plus interferon beta-1a, which is used to treat individuals with multiple sclerosis. ACTT-4, a study assessing baricitinib plus remdesivir versus the glucocorticoid dexamethasone plus remdesivir in adults hospitalized with COVID-19, has closed to enrollment because the study met pre-defined futility criteria.

NIAID, in collaboration with other NIH Institutes, also launched two clinical trials as part of the ACTIV partnership, which utilizes master protocols allowing the addition of other investigational therapeutics as the trials continue. The two studies, ACTIV-2 and ACTIV-3, initially evaluated the use of the monoclonal antibody bamlanivimab to treat COVID-19 in outpatient and inpatient settings, respectively. ACTIV-2, which is focused on outpatients, has since been expanded to evaluate a combination monoclonal antibody therapy, BRII-196 and BRII-198, as well as four investigational therapeutics: SAB-185, a fully human polyclonal antibody produced in cattle; SNG001, an inhalable beta interferon; AZD7442, an investigational long-acting antibody combination; and camostat mesilate, an orally administered drug that may block SARS-CoV-2 from entering cells. ACTIV-3 currently is evaluating the AZD7442 monoclonal antibody combination in hospitalized patients. On April 22, 2021, NIAID and NHLBI launched the ACTIV-3 Critical Care study to test



Zyesami and remdesivir (alone and in combination), for their safety and efficacy in hospitalized COVID-19 patients who are experiencing acute respiratory distress syndrome, a life-threatening condition. Zyesami is a synthetic version of vasoactive intestinal peptide, which is made naturally in the human body and appears to have lung-protective antiviral and anti-inflammatory effects.

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

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

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

### ***Responding to Emerging Variants of SARS-CoV-2***

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

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

CoV-2 variants by targeting several viral antigens, all of which are highly conserved among viral strains.

NIAID also plans to test new vaccine formulations that may protect against certain variants that show early indications of reduced sensitivity to existing countermeasures. On March 31, 2021, NIAID launched a Phase 1 clinical trial of an investigational Moderna vaccine based on its FDA-authorized COVID-19 vaccine, designed specifically to target the B.1.351 SARS-CoV-2 variant first detected in South Africa. NIAID and Moderna are evaluating this vaccine candidate as a precautionary measure as we gain more data to confirm that current vaccines provide an adequate degree of protection against currently circulating SARS-CoV-2 variants.

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

#### ***Understanding the Immunology and Pathogenesis of COVID-19***

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

NIAID, along with FDA, is supporting a National Cancer Institute (NCI) effort to determine the sensitivity and specificity of certain SARS-CoV-2 serological tests, which can detect antibodies indicative of a prior exposure to SARS-CoV-2. NCI and NIAID also are working to establish a collaborative network to increase national capacity for high-quality serological testing with rapid return-of-results to subjects. These efforts include the use of serological testing to support clinical trials of convalescent serum and the establishment of registries for seroprotection studies. 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 experience continued symptoms or other sequelae as they transition from the acute to post-acute phases of the disease, and we continue to learn more about the duration and manifestations of COVID-19 as we hear from these patients. In December 2020, NIAID hosted a Workshop on Post-Acute Sequelae of COVID-19 with clinicians, immunologists, virologists, and members of the patient community to present existing data, identify key knowledge gaps, and explore different perspectives on this heterogeneous condition. A report from this workshop highlighting the key scientific questions and knowledge gaps regarding PASC was recently published in the *Annals of Internal Medicine*. NIH has announced 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 more than 1,200 hospitalized COVID-19 patients of diverse race and ethnicity at approximately 20 hospitals nationwide. The cohort will be followed during hospitalization and up to 1 year after discharge to assess their functional and immunologic recovery.

#### ***Conclusion***

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

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The CHAIR. Thank you.  
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, thank you for the opportunity to testify before you again to describe FDA's continued COVID-19 response efforts, and particularly our efforts on vaccines.

First, yesterday evening, the FDA announced the expansion of the emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine to include adolescents down to age 12 years. We know that this is a big step for our Country as vaccinating a younger

population can bring us closer to a sense of normalcy and to ending this pandemic.

To look at the safety of the vaccine, the FDA evaluated a clinical trial of more than 2,000 adolescents age 12 through 15. Half of the participants received the Pfizer-BioNTech vaccine, and half received a saline placebo. The side effects experienced by those age 12 through 15 were similar to those experienced by individuals age 16 and older.

To look at effectiveness, the FDA evaluated data about how participants' immune systems responded to the vaccine, comparing 190 individuals, age 12 through 15, to 170, age 16 through 25.

The FDA also evaluated data on cases of COVID-19 among adolescents age 12 through 15, 7 days after the second dose of vaccine was given. And no cases of COVID-19 occurred among 1,005 adolescents who received the vaccine, compared to 16 cases in 978 placebo recipients, thus indicating the vaccine was completely effective in preventing COVID-19 in the trial that was symptomatic.

Parents and guardians can rest assured that the Agency undertook a rigorous and thorough review of all available scientific data, as we have with all of our COVID-19 vaccine authorizations, and the CDC's Advisory Committee on Immunization Practices will next review the data tomorrow.

Also, as we announced yesterday, we intend to convene a virtual meeting of the Vaccines and Related Biological Advisory Committee on June 10, 2021, during which we will provide a status update on our approach to emergency use authorization in individuals age 12 through 17 years of age. And, we will also discuss the data needed to support an emergency use authorization and a biologics license application in children less than age 12.

Second, as COVID-19 vaccination expands into adolescents, we continue to work diligently with CDC and other partners on safety surveillance of the authorized vaccines. We are grateful to Congress for the American Rescue Plan funds, which are supporting expanded vaccine safety surveillance, among other critical priorities. We have seen that our safety surveillance systems are doing what they are supposed to do in detecting important adverse events.

Recently, our surveillance systems detected a safety signal for rare blood clots and low blood platelets, known as thrombosis thrombocytopenia syndrome, with the Janssen or Johnson & Johnson COVID-19 vaccine. Following a brief pause taken to evaluate the situation and educate providers, based on the rare but increased risk of this adverse event, mainly in women age 18 through 50 years of age, FDA modified the fact sheet for healthcare providers to include a warning pertaining to the risk of thrombosis with thrombocytopenia, and the fact sheets for recipients and caregivers was also updated.

We will continue to diligently monitor the safety of all of these vaccines.

Third, the CDC and FDA are working closely together to track the emergence and the spread of COVID-19 variants. Currently available evidence suggests that the three available FDA-authorized vaccines adequately address COVID-19 variants circulating in the United States. However, we are working with manufacturers

and government partners to plan the composition of the vaccine so that we can administer booster vaccinations if necessary of an appropriate composition.

Fourth, the FDA recently completed an inspection of Emergent BioSolutions, the proposed manufacturing facility for the Janssen COVID-19 vaccine. At the close of the inspection of Emergent BioSolutions, FDA investigators cited several observations concerning whether the facility's practices met our regulatory requirements and standards. We are now working with Emergent BioSolutions to address the conditions identified. It has been made public that no product has been released from this facility for use in the United States, and we will not agree to the release of any product from this facility until we are truly confident that it meets our expectations for quality.

Additionally, moving forward, the Agency is refining how to optimally evaluate the manufacturing quality during this and any future public health emergency. We are committed to maintaining the trust of the public in the vaccines and hope that every eligible individual will consider getting vaccinated to help end this pandemic.

Thank you.

[The prepared statement of Dr. Marks follows:]

PREPARED STATEMENT OF PETER MARKS

### **Introduction**

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 coronavirus disease 2019 (COVID-19) response efforts. All of our efforts are in close coordination and collaboration with our partners, both within the Department of Health and Human Services (HHS) and across the Federal Government, to help ensure the development, authorization, licensure, and availability of critical, safe, and effective medical products to address the COVID-19 public health emergency.

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 issued 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 the data support the safety and effectiveness of a vaccine and is on track for regulatory approval. These vaccines were developed without cutting corners or sacrificing our standards. Intensive interactions between FDA and manufacturers minimized the time between different studies in the clinical development process; allowed seamless movement throughout the different phases of clinical trials; and simultaneously proceeded with manufacturing scale-up before it was clear whether the safety and effectiveness data for a vaccine would support emergency use authorization.

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 effectiveness in large, well-designed phase 3

trials and that meet rigorous standards for safety and effectiveness to support emergency use authorization. Vaccines are helping us in the fight against this pandemic, which has claimed almost 600,000 lives here in the United States alone. All the COVID-19 vaccines that FDA has authorized for emergency use have far surpassed being at least 50 percent more effective than placebo in preventing COVID-19, which was recommended in our June 2020 guidance document, *Development and Licensure of Vaccines to Prevent COVID-19*.<sup>1</sup> A vaccine with at least 50 percent efficacy would have a significant impact on disease, both at the individual and societal level.

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

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

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

Finally, manufacturers whose COVID-19 vaccines have been authorized for emergency use are expected to continue their clinical trials in order to obtain additional safety and effectiveness information and pursue licensure (approval) 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 developing these vaccines 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, including vaccines, from early product development to when a product application is submitted to FDA for our evaluation of safety and effectiveness to support authorization or approval.

Following approval of a BLA or issuance of an EUA request, the Agency uses real-world data to monitor the safety and effectiveness 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 through the Vaccine Adverse Event Reporting System (or VAERS). The Agency also performs active post-market surveillance of safety and effectiveness of vaccines through various data bases, including an FDA partnership with the Center for Medicare & Medicaid Services (CMS) to use Medicare data and use of the FDA's of BEST (Biologics Evaluation and Safety) 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.

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

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

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 scientific and regulatory advice, 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*.<sup>3</sup>

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 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 previous 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 permit 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 may be 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 follow-up 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).

FDA, CDC, Centers for Medicare & Medicaid Services (CMS), Veteran's Health Administration and Department of Defense are conducting post-authorization safety and effectiveness monitoring in their surveillance systems including VAERS, CMS Medicare data, FDA BEST, the CDC Vaccine Safety Datalink and others.

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

### **Pfizer COVID-19 Vaccine**

As Pfizer announced, FDA received the company's request to amend its emergency use authorization (EUA) to expand the authorized age range for its COVID-19 vac-

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

cine to include individuals 12 through 15 years of age. Currently, the vaccine is authorized for emergency use to prevent COVID-19 in individuals ages 16 and older. While the Agency cannot predict how long its evaluation of the data and information will take, we will review the request as expeditiously as possible using a thorough and science-based approach. Based on an initial evaluation of the information submitted, at this time the Agency does not plan to hold a meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) pertaining to this request to amend the EUA for the Pfizer-BioNTech COVID-19 Vaccine. The original EUA request was discussed at a VRBPAC meeting in December 2020. The VRBPAC voted in favor of the determination that based on the totality of scientific evidence available, the benefits of the Pfizer-BioNTech COVID-19 Vaccine outweigh its risks for use in individuals 16 years of age and older. After considering all the evidence, including the VRBPAC's advice, FDA issued an EUA for the Pfizer vaccine. As with all FDA-authorized COVID-19 vaccines, we are committed to transparency with this EUA review process.

#### **Moderna COVID-19 Vaccine**

On April 1, 2021, FDA announced two revisions regarding the number of doses per vial available for the Moderna COVID-19 Vaccine. The first revision clarifies the number of doses per vial for the vials that are available, in that the maximum number of extractable doses is 11, with a range of 10-11 doses. The second revision authorizes the availability of an additional multi-dose vial in which each vial contains a maximum of 15 doses, with a range of 13-15 doses that can potentially be extracted. The type of syringes and needles used to extract each dose affect the number of doses that can be extracted from the vials.

Both of these revisions positively impact the supply of Moderna COVID-19 Vaccine, which will help provide more vaccine doses to communities and permit more people to be vaccinated. Ultimately, more vaccinations administered in a timely manner in the United States and around the world should help bring an end to the pandemic more rapidly.

Depending on the type of syringes and needles used to extract each dose, there may not be sufficient volume to extract more than 10 doses from the vial containing a maximum of 11 doses or more than 13 doses from the vial containing a maximum of 15 doses.

To support these changes to the EUA, FDA evaluated data showing the number of doses that could be extracted from the vials and on the fill volumes for both vials that were submitted by ModernaTX, Inc. The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Prescribing Information<sup>4</sup> have been revised to reflect the new information and are intended to help frontline workers administering COVID-19 vaccines understand the number of doses that can potentially be extracted per vial.

#### **Janssen (Johnson & Johnson) COVID-19 Vaccine**

As part of our regulatory processes for reviewing all manufacturing facilities, FDA recently completed an inspection of Emergent BioSolutions, a proposed manufacturing facility for the Janssen COVID-19 Vaccine. As Johnson & Johnson announced last month, FDA has not authorized this facility to manufacture or distribute any of the Janssen COVID-19 Vaccine or components and, to date, no COVID-19 vaccine manufactured at this plant has been distributed for use in the U.S.

FDA's inspections are thorough, and these assessments review the quality of manufacturing procedures, including records, staff training, facility operations, drug production and testing, and the systems in place to ensure product quality. At the close of the inspection of Emergent BioSolutions, FDA investigators cited a number of observations concerning whether the facility's practices met our regulatory requirements and standards. These observations are outlined in an inspection closeout report, also known as an "FDA Form 483."<sup>5</sup>

Typically, firms respond to the observations cited on an FDA Form 483, and the Agency then works with a company to help identify a path forward to remedy the issues.

Indeed, it is often in the public's best interest that FDA work with firms to quickly resolve inspectional observations to ensure that the public has access to medical

<sup>4</sup> <https://www.fda.gov/media/144637/download>.

<sup>5</sup> <https://www.fda.gov/media/147762/download>.



products that meet the Agency's high standards for quality, safety, and effectiveness.

In the case of Emergent BioSolutions, we are working with the company to address the conditions identified. At the Agency's request, Emergent BioSolutions has agreed to pause new production while it works with FDA to resolve potential quality issues. For the vaccines already manufactured, the products will undergo additional testing and will be thoroughly evaluated to ensure their quality before any potential distribution. We will not allow the release of any product until we are confident that it meets our expectations for quality.

We have notified various health authorities regarding the findings we observed at the Emergent facility and are providing additional information as requested. FDA will continue to work closely with its international partners, as it has throughout the pandemic. Additionally, moving forward, the Agency is considering how best to further evaluate manufacturing quality during this and any future public health emergency.

These manufacturing actions are unrelated to an ongoing evaluation by FDA and CDC of clinical reports of blood clots along with low levels of platelets that have occurred in some people after receiving the Janssen COVID-19 Vaccine, described further below.

We are committed to ensuring that the COVID-19 vaccines given to the people of this Nation have met the Agency's high standards for quality, safety, and effectiveness. We know that every time a person, including members of our own families, receives a COVID-19 vaccine, they are putting their trust in us. We are committed to maintaining that trust.

#### **COVID-19 Vaccine Safety Surveillance**

On April 13, 2021, FDA and CDC issued a joint statement, announcing that, out of more than 6.8 million doses administered as of that date, six reports of a rare and severe type of blood clot combined with low blood platelet levels occurring in people after receiving the Janssen COVID-19 Vaccine had been reported to VAERS. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this circumstance, administration of heparin may be dangerous, and alternative treatments need to be given.

Out of an abundance of caution, FDA and CDC recommended a pause in the use of the Janssen COVID-19 Vaccine while we investigated reports of these serious adverse events. This was important, in part, to help ensure that health care providers were made aware of the potential occurrence of these adverse events and could plan for proper recognition and clinical management due to the unique treatment required for thrombosis with thrombocytopenia syndrome.

FDA and CDC have reviewed all of the available data, and CDC's Advisory Committee on Immunization Practices (ACIP) held emergency meetings to discuss the data on April 14 and April 23, 2021. Those data, plus the deliberations and recommendations of the ACIP, informed our assessment that the known and potential benefits of Janssen COVID-19 Vaccine outweigh its known and potential risks in individuals 18 years of age and older. We concluded that, at this time, the available data suggest that the chance of this serious adverse event occurring is very low. Thus, on April 23, 2021, FDA and CDC determined that the recommended pause regarding the use of the Janssen COVID-19 Vaccine in the U.S. should be lifted and use of the vaccine should resume. However, investigation into the level of potential excess risk due to COVID-19 vaccination is ongoing.

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) has been updated to include a Warning pertaining to the risk of thrombosis with thrombocytopenia.<sup>6</sup> The Fact Sheet for Recipients and Caregivers has also been updated to include information about these serious adverse events.

FDA and CDC will continue to closely monitor the safety of these vaccines. We will continue to closely monitor the safety of the Janssen COVID-19 Vaccine.

<sup>6</sup> <https://www.fda.gov/media/146304/download>.

The pause in the use of this vaccine was an example of our extensive safety monitoring system working as it is designed to work—identifying even this small number of cases.

As of May 4, 2021, a total of 23 cases of thrombosis with thrombocytopenia following post-authorization use of Janssen COVID-19 Vaccine were confirmed, involving cerebral venous sinuses and other sites in the body. These cases have been associated with three deaths. FDA anticipates these numbers will change over time as additional cases are reported and investigated.

FDA continues to inform the public of these cases and has noted that a causal relationship with Janssen COVID-19 Vaccine is plausible for thrombosis with thrombocytopenia syndrome. 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. The outreach also provided information so that they could properly clinically 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). Specific risk factors for thrombosis with thrombocytopenia after vaccination continue to be investigated.

As noted earlier, CBER is monitoring the safety of *all* authorized COVID-19 vaccines through both passive and active safety surveillance systems. CBER is doing so in collaboration with CDC, 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 COVID-19 vaccine manufacturers for authorized vaccines. A coordinated and overlapping approach using state-of-the-art technologies has been implemented.

### 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.

Having three vaccines authorized to date that meet FDA’s expectations for safety and effectiveness only 1 year after the declaration of the COVID-19 pandemic is a tremendous achievement and a testament to the dedication of developers and FDA’s career scientists and physicians, many of whom have been working tirelessly to conduct comprehensive and rigorous evaluations of the data submitted for vaccines to prevent COVID-19. We are highly engaged in ensuring that all COVID-19 vaccines meet the high quality that Americans expect and deserve and are also actively engaged in ensuring the safety of these vaccines following deployment. The Agency is very proud of these efforts, and we hope that the vaccines will help bring this pandemic to an end.

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The CHAIR. Thank you.  
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, thank you for the invitation to provide an update on our COVID-19 response.

Allow me to succinctly set out what we are focused on today. First, we have delivered to date 330 million doses of vaccine in the United States and have administered over 260 million of them. The most important thing we all need to do is to get a vaccine to everyone who wants to be vaccinated in the United States.

The current vaccine supply exceeds demand. Nothing is more important than achieving the President’s goal of having 70 percent of

adults with at least one shot before—by July 4. The long-term fate of many of our communities depends on getting people vaccinated.

There are many reasons why many people have not yet been vaccinated. We need to recognize at the core for many is simply a fear of the unknown. All the data support the basic proposition that these vaccines are safe and effective. Getting vaccinated will prevent hospitalization and death.

Second, the FDA took a significant step yesterday in the fight against COVID-19 by expanding the Pfizer EUA to adolescents ages 12 to 15. Pending the recommendation of the ACIP tomorrow, we plan to offer the Pfizer vaccine to all young people ages 12 to 15.

Right now, the Pfizer vaccine is available at many local pharmacies and larger health clinics. We are working to make smaller trays available so that the Pfizer vaccine can be administered by more pediatricians, family doctors, and rural healthcare providers.

By late fall, we expect to have data on the safety and effectiveness of vaccines for children under 12.

Third, we are planning—and I underscore the word planning—to have booster doses available if necessary for the American people. Increased age, the natural waning of antibodies over time, and new variants all increase the probability that booster doses may be needed.

Fourth, it is absolutely essential that we begin sharing doses made in the United States with the rest of the world. Supplying other nations with vaccines is not just the right thing to do for life-saving, humanitarian purposes; it is also in the best interest of the United States to mitigate the risk of viral evolution.

Fifth, we need to hasten our search for an antiviral. I am concerned that even after we finish vaccinating most of the people who want to be vaccinated by this summer, there will still be a significant number of cases and an unacceptable number of deaths. People who are immunosuppressed, who do not mount an immune response for a number of reasons, or choose not to be vaccinated will continue to be vulnerable, and we need options for them. The antibody treatments are one approach, but a simple oral antiviral can add to our armamentarium to bring this epidemic under control.

Last, we need to build a program for vaccine preparedness for future pandemics. This will need to be done in partnership with the private sector and build on all the lessons we have learned to date.

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 KESSLER

### **Introduction**

Chair Murray, Ranking Member Burr, and 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. Thank you 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 that have met our standards for safety and effectiveness and are authorized for the prevention of COVID-19. 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. I am pleased to report that more than 83 percent of people over the age of 65 have received at least one dose and over 70 percent of them are fully vaccinated. As of April 19, 2021, every person aged 16 and over in every state and territory is now eligible to get vaccinated. The country has exceeded President Biden's goal of administering 200 million shots in the first 100 days of his Administration.

We are carefully monitoring the supply chain, raw materials and our manufacturing capacity for vaccines. I am pleased to report that our supply remains strong as we work toward achieving President Biden's goal of having 70 percent of adult Americans with at least one shot and 160 million Americans fully vaccinated by July 4.

We have provided Federal support and Federal personnel for over 1,800 community vaccination centers and mobile sites across the country. 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. Today 90 percent of all Americans have a vaccination site within 5 miles of where they live. 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 just 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.

I want to stress how important it is that our fellow citizens get vaccinated and that we help ease the minds of those who are considering getting vaccinated. We need to confront the reality of vaccine hesitancy. I have focused my career on studying drug safety. We can help people overcome their concerns about vaccines by being transparent with them about the safety of these products. When it comes to the mRNA vaccines, real world data show that they are more than 90 percent effective in preventing infection two or more weeks after the second dose, and that these vaccines have to date an excellent safety profile.

I also want to emphasize that we are committed to helping other countries fight COVID-19, most recently India. We delivered 20,000 treatment courses of the antiviral drug remdesivir to India to help treat hospitalized patients. We have redirected the United States' own order of AstraZeneca vaccine manufacturing supplies to India. This will allow India to make over 20 million doses of COVID-19 vaccine. We are also delivering critical supplies to help provide oxygen to patients and additional personal protective equipment for healthcare workers. Supplying other nations with vaccines and personal protective equipment (PPE) is not just the right thing to do for life-saving humanitarian purposes, it is also in the best interests of the United States to mitigate the risk of viral evolution. The best way to stop new variants from emerging is to prevent outbreaks that allow mutations to occur.

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

First, we are developing plans to provide booster doses to Americans, if determined to be necessary later this year. We know that neutralizing antibodies persist for some time after the second dose of an mRNA vaccine, with a relatively slow decline over time. We are supporting research to determine who would benefit from booster doses and when these should be administered. We expect to have more information this summer about the potential benefits that a booster dose could provide, as well as the process and timing for regulatory review of these vaccines. We are also supporting research to evaluate the use of different combinations of booster doses, so that a person's booster dose might be from a different manufacturer than that person's initial vaccine regimen. As part of our plans, we will carefully evaluate whether we might need doses that are modified to address variants. As these efforts progress, we will work with manufacturers to make those doses available, as needed, to continue to protect Americans from COVID-19.

Second, if the Food and Drug Administration (FDA) authorizes vaccines for adolescents between the ages of 12 and 15, we will make sure those adolescents have access. After a careful review of the data by FDA and the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP), we plan to have about 20,000 pharmacy sites across the country ready to vaccinate adolescents. We will also work to get vaccines into the offices of pediatricians and family physicians so that parents and their children can talk to their doctor about vaccines and have an option of receiving their dose from a trusted provider.

Finally, I want to talk about our work on therapeutics. Taking a whole of government approach, we have worked to accelerate the clinical development and manufacturing scale-up of therapeutic candidates most likely to have a broad public health impact to complement the vaccine effort, with successful therapies at sufficient quantities. There are two monoclonal antibody (mAb) treatments with emergency Use authorization (EUAs) currently available, Regeneron's cocktail (casirivimab and imdevimab) and Eli Lilly's combination treatment (bamlanivimab + etesevimab). We have procured almost 3 million monoclonal antibody doses that are being provided to the US healthcare system at no cost, with approximately 980,000 total doses shipped to 5956 (suggest—almost 6000) provider sites. As of April, mAbs were being administered to approximately 1 out of 5 eligible high-risk patients. We continue to support efforts to increase awareness of treatments and expand infusionsites and services to help ensure fair and equitable administration of mAbs.

Our efforts are also focused on the research and development of antiviral drugs, particularly small molecule oral antivirals to treat individuals who are not vaccinated or who might become infected after vaccination. These drugs could also help patients in the event of rapidly emerging variant strains. Monoclonal antibodies and other drugs in development target those at high risk of severe disease, but a safe and effective oral drug that demonstrates an endpoint of symptom resolution would be an important treatment option for Americans. We are committed to supporting research and development of antivirals for COVID-19.

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.

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The CHAIR. Thank you to all of our witnesses for being here today and your testimony.

We will now begin a round of 5-minute questions of our witnesses, and I ask our colleagues to keep track of your clock and stay within those 5 minutes. We do have votes starting at 11:30 today.

Dr. Fauci, I am going to start with you. The surge of COVID-19 that is devastating India is a painful reminder, really, that we cannot end the pandemic here until we end it everywhere. And I am glad the Biden administration is leading that global fight by re-joining the World Health Organization and funding global vaccine efforts and committing to donate 60 million AstraZeneca vaccines to other countries by July 4th. India's outbreak really underscores the need for a robust public health infrastructure in the U.S. to respond appropriately to this pandemic and future outbreaks, as well.

I wanted to ask you today, Dr. Fauci, what can we learn from India's outbreak that we should apply to our response here in the U.S.?

Dr. FAUCI. Well, I think one of the important things is do not ever underestimate the situation. You know, the reason that India is in such dire straits now is that they had an original surge and made the incorrect assumption that they were finished with it. And what happened, they opened up prematurely and wind up having a surge right now that we are all very well aware of is extremely devastating. That is the first thing.

The second thing is preparedness with regard to public health preparedness, which we, as a lesson learned for future pandemics, have to realize that we need to continue to buildup our local public health infrastructure. Which, over the last decades, we have let actually, in many respects, go into disarray, likely because of our successes in controlling so many diseases.

The other lesson that is learned, Madam Chair, is that this is a global pandemic that requires a global response. And, we need to pay attention to the responsibility that we have, not only for our own Country, but to join with other countries to make sure that we have the access to interventions, particularly vaccines, throughout the world because if it continues to have dynamics of virus anywhere in the world, we have a threat here in the United States, particularly with variants. And, there is one variant in India that is also a new variant, number 617B617.

Those are just a few of the lessons that I believe we can take from what is going on in India. Thank you.

The CHAIR. Thank you.

Dr. Marks, I am really encouraged by how the FDA has worked both quickly and carefully to get multiple COVID vaccines authorized. But, having said that, I am very concerned about the reports involving Emergent BioSolutions. You mentioned it in your remarks. It is a contractor that received \$628 million to manufacture COVID vaccines, and I wanted to ask you to explain FDA's recent findings. Because after receiving reports of cross-contamination with another vaccine, FDA inspected the Emergent facility, as you said, and asked the contractor to pause manufacturing, and the cross-contaminated vaccine was not distributed for any use.

But, Dr. Marks, what steps is FDA taking to make sure the quality, safety, and effectiveness of all COVID-19 vaccines?

Dr. MARKS. Chair Murray, thank you for that question. So, we are currently, for the Emergent facility, we are actively working with all of the parties involved to ensure that the facility's deficiencies are all remediated so that before they actually are able to release vaccine, it meets all of our quality standards that Americans deserve from vaccines.

Also, as we move on to other facilities that may be producing vaccines, we will take the approach of using all of our inspectional tools to ensure that the quality of those is the highest nature. And, as with all of our biologics license applications, we, for the—generally, will be performing onsite inspections of those facilities to ensure the quality of those products.

The CHAIR. Thank you. And I am really deeply concerned about what happened, and my expectation is in the future, nothing like that happens again.

Dr. Walensky, in my last minute here, let me just ask you. The CDC says that while fewer children have been sick with COVID-19 compared to adults, children can be infected, get sick, and spread the virus. With the authorization of Pfizer yesterday for children 12 to 15, what would you say to parents who are considering getting their kids vaccinated now?

Dr. WALENSKY. I would encourage all parents to get their children vaccinated. I know many parents are enthusiastic and have been texting me, cannot wait to get their children vaccinated. I recognize that there—some parents want to sort of see how it goes first. But, I am encouraging all parents to get their children vaccinated. Some parents will not want to be first.

But, I am also encouraging children to ask for the vaccine. I have a 16-year old myself, and I can tell you he wanted to get the vac-

cine. He wants his life back. These kids want to go back to school. They want to go back to the things they love.

The CHAIR. Thank you.

Senator Burr.

Senator BARR. Thank you, Chair.

Dr. Kessler, we have shipped 2.7 million doses of AstraZeneca, I think, to Mexico. That is the only country we have shipped to. We have additional doses of AstraZeneca in inventory in this Country. We talked about July 4th exporting more. Why have we not taken the AstraZeneca, which is not approved for vaccination in the United States, why have we not mobilized that to other countries of the world today?

Dr. KESSLER. Senator, it is a very important question. We have shipped a total of four million doses to date, including to Mexico, and I believe 1.5 to Canada. We are ready to ship up to 60 million doses of AstraZeneca. But, as the Chair pointed out, and as my colleague, Dr. Marks, responded, there are issues with Emergent that are under review by the Food and Drug Administration. If and when those issues are resolved and we can say that these are quality doses, we will do just as you say.

Senator BARR. Correct me if I am wrong. I did not think the Emergent Baltimore facility had anything to do with AstraZeneca production. Am I wrong, Dr. Marks?

Dr. MARKS. Senator Burr, no. The AstraZeneca vaccine was being produced in that facility, and the FDA feels it is imperative that before vaccine can be shipped to any other partner, it has to meet the quality standards that it would meet for any American, as well.

Senator BARR. How long do you anticipate that testing the AstraZeneca vaccine that is currently manufactured would take to verify?

Dr. MARKS. We are working on that as quickly as we can. We understand the imperative here. There is a working group across our Office of Regulatory Affairs and our center and others at FDA that are working together to try to clear that—those doses as quickly as we can. I cannot give you an exact time, but we understand the imperative to be able to have them available so that Dr. Kessler can arrange for them to be shipped to those in need.

Senator BARR. Okay. Dr. Kessler, one of the reasons we are as successful today is that partnerships have been leveraging vaccinations around the world, and over 275 partnerships have been created to scale up vaccine production and manufacturing.

I guess I am asking you this. If we waive intellectual property in the United States, do we not stand the risk of affecting innovation in the future when, if we did it to scale up manufacturing capacity, the private sector has done that through partnerships already and that is the reason that we have been so successful? Should we not let the private sector continue to do something that—I think Dr. Fauci and I have said in the past, we never anticipated this. This is novel that they would have the relationship to do it. Why mess with a good thing?

Dr. KESSLER. I applaud the actions of the pharmaceutical industry. Senator, this is a once-in-a-century pandemic. I think we all recognize that extraordinary circumstances call for extraordinary measures. We know—and I agree with you, Senator—that a waiver

alone will not result in the scale and speed we need to make enough vaccines to end the pandemic. That is why we will continue to ramp up our efforts working with the private sector and all possible partners to expand vaccine manufacturing and distribution around that, around the world. I mean, our job is to do, as you say, to increase that supply. That is what we are focused on. We want to make vaccines available to the world.

Senator BURR. David, here is the reality. When Pfizer went to open up its Kansas plant to produce vaccine, it took them, I believe, 7 months to retool and to get everything done. This belief that you can export intellectual property and you are going to have a standup around the world instantaneously of vaccine production is a joke. Dr. Marks has already expressed concern over the backlogs for inspections and how long would it take for us to inspect foreign sites, if in fact there was a vaccine pool that found its way in and out of the United States.

Let me just get this before my time runs out. Can anybody give me the number? There has been 33 million Americans infected with COVID that have actually tested positive. How many of that 33 million have then been vaccinated? Does anybody know what that number is?

[Brief silence.]

Senator BURR. Here is why I make the point, and here is why I think it is relevant. If we are looking at a certain number that we do not know exactly what it is, Dr. Fauci, that we want to get to, and we have vaccinated 115 million, it is important for us to know, of the counted vaccine number, how many of those already had protection because they were COVID-positive.

If we are trying to reach a number—when the President says 70 percent vaccination, if we get to 65 vaccinated and 5 percent got COVID and they had protection, is that not like being at 70?

I think one of the problems that—the goal post continues to be too far. And we now have the harder part of how do we take the 40 percent that are not real comfortable with getting vaccinated and at least have a shot at vaccinating 50 percent of that 40 percent. And, it may be that our number is higher today on the protected. I know it is. I do not think 33 million have all been vaccinated that were positive, but I think it is absolutely crucial that we figure out what that number is. I am not sure whose responsibility it is that we figure out what that number is and put that into our formula of how many Americans have protections.

I thank the chair.

The CHAIR. Thank you, Senator Burr.

Senator Casey.

Senator CASEY. Chair Murray, thank you very much. And I want to thank our guests, Dr. Fauci, Dr. Kessler, Dr. Marks, and Dr. Walensky. I think I will have at least one question for Dr. Walensky and one for Dr. Marks.

I am going to start with you, Dr. Walensky. I want to thank you for your leadership and the leadership of the CDC and your efforts to ensure that children and adolescents are up to date on vaccinations, particularly as students return to in-person learning.

You and others have noted, there are over 11 million doses through the Vaccines for Children Program that have been missed.



These missed doses could seriously and negatively impact efforts to protect children, their families, and communities from vaccine-preventable diseases and conditions. Of course, we are talking here about diseases other than COVID-19.

At the same time, with 12 to 15 year olds now able to get vaccinated against COVID-19, there is an even greater need to ensure parents are aware of all the vaccines, all the vaccines that children should receive in order to remain healthy. The Rescue Plan contains funding to build vaccine confidence, and specifically includes provisions to ensure funding is allocated toward increasing vaccination rates throughout the U.S.

Here is the question, Doctor. In addition to the public awareness efforts that you and CDC have already undertaken, will the CDC be releasing the funding to both states and communities to ensure that children and adolescents are caught up on both routine and recommended vaccinations, particularly as children return to in-person learning?

Dr. WALENSKY. Thank you, Senator, for that. You raise an issue that is near and dear to my heart and I am very worried about. More than 20 percent of our measles vaccines were not used this year. We have the same issue with meningococcal vaccines, and especially among our adolescents.

Unfortunately, we actually do not have data on whether we can co-administer the COVID-19 vaccine and other routine immunizations and whether we get the same protection from the COVID-19 vaccines and the routine administration of other immunizations. That is one issue that the experts at ACIP are going to address tomorrow as to whether that can safely be done and that we could potentially get adequate protection.

You are right. We need to, as we are putting forward these efforts in vaccine confidence for the COVID-19 vaccine, we need to take this outreach and make sure that we are breaching these communities and not only conveying the importance of getting the COVID-19 vaccine, but, if we are not able to co-administer them, to make sure we get back to these children and be able to administer the routine vaccines that they have lost before the school year.

Senator CASEY. In terms of the funding, though, that will be released? Do you have any sense of the timing of that?

Dr. WALENSKY. I do not, but we can get back to you.

Senator CASEY. Okay. Thank you.

Dr. Marks, I wanted to start with you regarding Pfizer. We have heard a lot this year about emergency use authorization, and we know that Pfizer has recently filed their application for full licensure of their COVID-19 vaccine. I think we get a lot of questions at home on a range of these issues, and, in particular, what does it mean? What does it mean? What does full licensure mean? One of the concerns that we have heard a lot about as the vaccines are provided, this emergency use authorization, but what is the next step for a vaccine? Can you explain what it means to get full licensure? That is question No. 1.

Second, what additional information would a company need to submit beyond what was required just for so-called EUA?

Dr. MARKS. Senator, thanks very much for that question. The full licensure is something that a manufacturer submits with a full data package, which I will go into in a moment.

But, I just want to go back to pick up on something that Dr. Fauci said. These COVID-19 vaccines, they were expedited not by cutting corners, but by going through a development plan in which kind of empty space, space that would have been normally just not stuff happening, was taken away. So, manufacturing was done while the clinical trials were done.

The large clinical trial programs were of the size of normally licensed vaccines in the United States. The one place where we are a little bit short was the duration of safety follow-up. But, we are very confident from the amount of safety follow-up, at least a meeting of 2 months safety follow-up on this safety data set for the emergency use authorization, that the large majority of adverse events became apparent. So, we are very confident in recommending these vaccines for everyone—our families, all Americans.

The difference that will happen with the biologics license application is that the manufacturers will be able to submit additional safety data, perhaps 6 months of safety data rather than just the median 2 months safety data. And, additionally, there are some technical things that will be there that many people may not care a lot about, but we do. That is, manufacturing conformance lots, the formal facilities inspections will occur, and additional ancillary studies will be put in that package.

I think the main message to the American public is that for all intents and purposes, the vaccine that is being used is very close to what we would normally have in a biologics license application. There are some little things around the margins that will go into the biologics license application when we have a formal approval.

Senator CASEY. Thank you.

Thank you, Chair Murray.

The CHAIR. Senator Paul.

Senator PAUL. Dr. Fauci, we do not know whether the pandemic started in a lab in Wuhan or evolved naturally, but we should want to know. Three million people have died from this pandemic, and that should cause us to explore all possibilities.

Instead, government authorities, self-interested in continuing gain-of-function research, say there is nothing to see here. Gain-of-function research, as is juicing up naturally occurring animal viruses to infect humans.

To arrive at the truth, the U.S. Government should admit that the Wuhan Virology Institute was experimenting to enhance the coronavirus' ability to infect humans. Juicing up super viruses is not new. Scientists in the U.S. have long known how to mutate animal viruses to infect humans.

For years, Dr. Ralph Baric, a virologist in the U.S., has been collaborating with Dr. Shi Zhengli of the Wuhan Virology Institute, sharing his discoveries about how to create super viruses. This gain-of-function research has been funded by the NIH. The collaboration between the U.S. and the Wuhan Virology Institute continues. Doctor Baric and Shi worked together to insert bat virus spike protein into the backbone of the deadly SARS virus and then used this manmade super virus to infect human airway cells.

Think about that for a moment. The SARS virus had a 15 percent mortality. We are fighting a pandemic that has about a 1 percent mortality. Can you imagine if a SARS virus that has been juiced up and had viral proteins added to it, to the spike protein, if that were released accidentally?

Dr. Fauci, do you still support funding of the—NIH funding of the lab in Wuhan?

Dr. FAUCI. Senator Paul, with all due respect, you are entirely and completely incorrect that the NIH has not ever and does not now fund gain-of-function research in the Wuhan Institute of Virology.

Senator PAUL. Do they fund Dr. Baric?

Dr. FAUCI. We do not fund gain—

Senator PAUL. Do you fund Dr. Baric's gain-of-function research?

Dr. FAUCI. Dr. Baric is not doing gain-of-function research. And, if it is, it is according to the guidelines, and it is being conducted in North Carolina, not—

Senator PAUL. You do not think—

Dr. FAUCI [continuing]. In China.

Senator PAUL [continuing]. Inserting a bad virus spike protein that he got from the Wuhan Institute into the SARS virus is gain-of-function?

Dr. FAUCI. That is not—

Senator PAUL. You would be in the minority because at least 200 scientists have signed a statement from the Cambridge Working Group—

Dr. FAUCI. Yes.

Senator PAUL [continuing]. Saying that it is gain-of-function.

Dr. FAUCI. Well, it is not. And, if you look at the grant and you look at the progress reports, it is not gain-of-function, despite the fact that people Tweet that and—

Senator PAUL. Do you still—

Dr. FAUCI [continuing]. Write about it.

Senator PAUL [continuing]. Support sending money to the Wuhan Virology Institute?

Dr. FAUCI. We do not send money now to the Wuhan—

Senator PAUL. Do you support—

Dr. FAUCI [continuing]. Virology Institute.

Senator PAUL [continuing]. Sending money? We did, under your tutelage. We were sending it through EcoHealth. It was a sub-agency and a sub-grant. Do you support that the money from NIH that was going to the Wuhan Institute?

Dr. FAUCI. Let me explain to you why that was done. The SARS-CoV-1 originated in bats in China. It would have been irresponsible of us if we did not investigate the bat viruses and the serology to see who might have been—

Senator PAUL. Or perhaps it—

Dr. FAUCI [continuing]. Infected in China.

Senator PAUL [continuing]. Would be irresponsible to send it to the Chinese government that we may not be able to trust with this knowledge and with these incredibly dangerous viruses.

Government scientists, like yourself, who favor gain-of-function research—

Dr. FAUCI. I do not favor—

Senator PAUL [continuing]. Maintain——

Dr. FAUCI [continuing]. Gain-of-function research in China.

Senator PAUL [continuing]. That the disease arose naturally.

Dr. FAUCI. You are saying things that are not correct.

Senator PAUL. Government defenders of gain-of-function, such as yourself, say that COVID-19 mutations were random and not designed by man. But, interestingly, the technique that Dr. Baric developed forces mutations by serial passage through cell culture that the mutations appear to be natural. In fact, Dr. Baric named the technique the no-see-um technique because the mutations appear naturally.

Nicholas Baker of the New York Magazine said nobody would know if the virus had been fabricated in a laboratory or grown in nature. Government authorities in the U.S., including yourself, unequivocally deny that COVID-19 could have escaped a lab. But, even Dr. Shi in Wuhan was not so sure.

According to Nicholas Baker, Dr. Shi wondered, could this new virus have come from her own laboratory? She checked her records frantically and found no matches.

That really took a load off my mind, she said. I had not slept for days.

The director of the gain-of-function research in Wuhan could not sleep because she was terrified that it might be in her lab.

Dr. Baric, an advocate of gain-of-function research, admits the main problem that the Institute of Virology has is the outbreak occurred in close proximity. What are the odds, Baric responded.

Could you rule out a laboratory escape? The answer in this case is probably not.

Will you, in front of this group, categorically say that the COVID-19 could not have occurred through serial passage in a laboratory?

Dr. FAUCI. I do not have any accounting of what the Chinese may have done, and I am fully in favor of any further investigation of what went on in China.

However, I will repeat again, the NIH and NIAID categorically has not funded gain-of-function research to be conducted in the Wuhan Institute of Virology.

Senator PAUL. You do support it in the U.S. We have 11 labs doing it, and you have allowed it here. We have a committee to do it, but the committee is granted every exemption. You are fooling with Mother Nature here. You are allowing super viruses to be created with a 15 percent mortality. It is very dangerous and it was a huge mistake to share this with China, and it is a huge mistake to allow this to continue in the United States. And, we should be very careful to investigate where this virus came from.

Dr. FAUCI. I fully agree that you should investigate where the virus came from. But, again, we have not funded gain-of-function research on this virus in the Wuhan Institute of Virology. No matter——

Senator PAUL. You are parsing words.

Dr. FAUCI [continuing]. How many times you say it, it did not happen.

Senator PAUL. There was research done with Dr. Shi and Dr. Baric. They have collaborated on gain-of-function research where

they enhanced the SARS virus to infect human airway cells, and they did it by merging a new spike protein on it. That is gain-of-function. That was joint research between the Wuhan Institute and Dr. Baric. You cannot deny it.

The CHAIR. Senator Paul, your time is expired.

Dr. Fauci, I will let you respond to that. We need to move on.

Dr. FAUCI. Excuse me?

The CHAIR. I will allow you to respond to that, and then we will move on.

Dr. FAUCI. Yes. I mean, I just wanted to say, we—I do not know how many times I can say it, Madam Chair. We did not fund gain-of-function research to be conducted in the Wuhan Institute of Virology.

The CHAIR. Thank you.

Senator Smith.

Senator SMITH. Thank you, Chair Murray. And thank you so much to our panelists for being here today.

I want to just, following up on that exchange, just ask Dr. Fauci a question.

Dr. Fauci, what is the impact of conspiracy theories pedaled by Senator Rand Paul and others on Americans' willingness to take this vaccine? A vaccine that, by all accounts, is remarkable for its safety and efficacy.

Dr. FAUCI. Well, conspiracy theories certainly are not helpful in what we are trying to do. I guess I can say that with some degree of confidence.

Senator SMITH. Well, I would agree. And I think, in this moment we are at a critical moment for our response to this pandemic. And, in only 14 months since we—this pandemic started, we are here today to acknowledge that we have 261 million doses of vaccine in people's arms. We have over 58 percent of Americans with at least one dose. I mean, this is an incredible and—an incredible accomplishment.

We also know that we have more work to do, and it seems to me that we ought to be focused on that work. We have to make sure that our comprehensive strategy that you have been working on, Dr. Fauci, for a long time, and I am so grateful for the support that you are getting from the Biden-Harris administration. A comprehensive strategy that is around vaccinations, around surveillance testing, around treatment, social distancing and masks, and also centering our work around health equity. I mean, this is what we need to be really focused on, seems to me.

I would like to ask Dr. Walensky a question about how we go about this question on this issue of getting people—getting vaccines into people's arms now.

Vaccines—an acceptance of vaccines seem to be really a spectrum, from people that are gung-ho and ready to go to people who have a serious resistance to taking vaccines. And, we are seeing some learning, it seems to me, about what works.

I have a great example of that in Duluth, Minnesota where public health nurses set up a pop-up vaccine clinic at the Duluth Transportation Center. And, Minnesotans, who were taking their bus home or going to pick up their children at childcare can go to that vaccine pop-up clinic, fill out their paperwork, and get their

shot, all in one dose. So, it is breaking down some of the logistical challenges that a lot of Americans and Minnesotans still have, and they are finding just great success.

There was a story on Minnesota Public Radio just in the last couple of days about a woman named Karen Moore, who was waiting to get a vaccine and hoping that she would be able to get it at a convenient location, and was able to do it all in one spot. And that made all the difference in the world to her in terms of overcoming her so-called vaccine hesitancy, which was not hesitancy. It was just the logistics challenges.

Dr. Walensky, can you tell us a little bit about what the CDC is doing, working with states and localities, to deploy methods like we are seeing in Duluth, Minnesota to help people get easy access to vaccines?

Dr. WALENSKY. Thank you so much, Senator. We have spent \$3 billion getting money to states and localities to advance these efforts in trying to get vaccines into people and to enrich vaccine confidence.

I would invite all of you to take out your cell phones and to text GETVAX, 438829. You put in your zip code. You get a list of all the places where vaccines are available to you. You can do that by an 800 number, or you can go to *vaccines.gov* and type your zip code and find out which vaccines are available nearby to you.

We are trying to make it—we are working to make it easy. We do have to do some of the pivoting, as you discussed, and ensure that—

Places now have pop-up sites. They have mobile vaccination units; that we are reaching out to rural communities; that we are putting vaccines in federally qualified healthcare centers; that we have a We Can Do This campaign now, a campaign with 5,000 community core members from everyone from NASCAR and NFL to Infectious Disease Society of America, to faith-based organizations, sending our messages, being the trusted messengers. And we are starting to see the effects of this work.

Just this morning, CDC released new racial and equity data on how we are doing in reaching racial and ethnic minorities with vaccines. The bar graph now shows not just our overall progress, but what we have done in the last 2 weeks. And, in the last 2 weeks, we have been really successful in reaching racial and ethnic minorities in ways we had not up until this time.

We have to do more. We recognize we have to do more. We have vaccine confidence consults that you can—locals and states can call the CDC and say, we are having a hard time reaching people in this community, what are the things that we can do.

This is just a brief list of the many, many activities that we are engaged with every single day to get vaccines into people for—and to recognize that all hesitancy is not the same flavor. Some people, it is convenience. Some people want to understand the science more. Some people just need the time off.

Senator SMITH. Thank you so much.

Thank you, Madam Chair. I want to just say I appreciate the work of the CDC and others to support the innovative and strategic efforts of states like mine to overcome some of those barriers. Thank you.

Dr. WALENSKY. Thank you so much, Senator.

The CHAIR. Senator Collins.

Senator COLLINS. Thank you.

Dr. Walensky, I used to have the utmost respect for the guidance from the CDC. I always considered the CDC to be the gold standard. I do not anymore, and I want to give you three examples where I think the conflicting, confusing guidance from your agency has undermined public confidence and contradicts the scientific guidance of many experts.

The first has to do with school openings, an issue that we have talked about before. The New York Post reported that a powerful teachers' union, the AFT, successfully secured changes, verbatim, in draft guidance on school reopenings. This came about because of an outside group that did a FOIA request that revealed extensive interactions between the AFT and the CDC.

This has been described by Dr. Monica Gandhi, a professor who has written extensively about the coronavirus, as very, very troubling. She is referring to the emails back and forth between the CDC and the AFT. And, she says, this is not how science-based guidance should work or be put together.

My second example is from a New York Times story that appeared today. It talks about CDC guidelines on mask wearing, and it—where the CDC announced that less than 10 percent of COVID-19 transmission was occurring outdoors. The article points out that this is, quote, almost certainly misleading, and goes on to say, there is not a single documented COVID infection anywhere in the world from casual outdoor interactions, such as walking paths, someone on a street, or eating at a nearby table.

The third example has to do with new guidance the CDC has issued for summer camps, and here are the reactions of two experts. One, a pediatric immunologist at Columbia referred to the recommendations as, quote, senseless. The editor-in-chief of the Journal of the American Medical Association Pediatrics called the guidance, quote, unfairly draconian.

Here we have unnecessary barriers to reopening schools, exaggerating the risks of outdoor transmission, and unworkable restrictions on summer camps. Why does this matter? It matters because it undermines public confidence in your recommendations, in the recommendations that do make sense, in the recommendations that Americans should be following.

I would like you to respond to why the CDC is not following the standard procedures, why it is having offline, secret negotiations with one stakeholder that was revealed only through reporting in a FOIA request, why it is exaggerating outdoor transmission. We know that masks make a big difference indoors. They do not outdoors.

Dr. WALENSKY. Thank you for that question. Maybe if I could take each of your examples one by one.

First, the school guidance. As a matter of practice, the CDC engages with stakeholders, with consumers who take our guidance, who use our guidance, before it is finalized so we can understand whether it addresses their needs. For our school guidance, we did that with 50 different stakeholders. Over 50, actually. I personally engaged with both parents and teachers and many different stake-

holders to address what could be done to improve the draft guidance we had.

One of those stakeholders recognized that in our guidance we had addressed what you do if you have immunocompromised children at risk of severe disease, but we had neglected in our draft to address what happens if you have immunocompromised teachers—teachers who are getting chemotherapy, who have immunocompromising diseases.

The request was that we add some language for what happens if you have immunocompromised teachers and how they should behave in school. That is what we did. We used CDC-based science to make that addition, but the request was to address what happens if you have immunocompromised teachers. And that was an oversight in our initial draft, and we included a science-based response—or science-based language in our guidance.

With regard to the New York Times piece this morning, there is a meta-analysis from Journal of Infectious Diseases that was published in November, I believe, where the topline result of all studies that were included in the systematic review said less than 10 percent of cases were transmitted outdoors. It is that meta-analysis that combined science from all sorts of—all different science from many different places. I think over 19 studies were included. The topline result was less than 10 percent, published in the Journal of Infectious Diseases, one of our top infectious disease journals. That is where that came from. It was a published study that synthesized studies from many places.

With regard to camp, I have a 16-year old. Every day—every year, he comes home from camp and he writes the number of days until he returns to camp the next year. This year, it got to zero and I told him he was not going. I want our kids back in camp. We now have 38,000 new infections on average per day. Last May 11, it was 24,000, and we sent a lot of kids home and camps were closed. The camp guidance is intended to get our kids to camp and allow them to stay there.

Thank you.

Senator COLLINS. Madam Chair, I would just ask unanimous consent that the full New York Times story, dated today, be placed in the record because it answers—I realize I am out of time. It answers Dr. Walensky's response.

The CHAIR. So ordered.

[The information referred to can be found on page 70]

The CHAIR. Senator Kaine.

Senator KAINE. Thank you, Madam Chair, and thank you to the witnesses for your important testimony.

Some of you have been before this Committee so often. I can remember the first time you were before us on January 24, 2020. And so much has happened since then and there is so much to talk about, but my colleagues have done a good job already in addressing many of my interests.

At the last hearing that we had together, which I believe was in March, Dr. Fauci, I talked to you a little bit about long COVID. When the day comes where the President declares that the national emergency is over, there is still going to be at least two chal-



lenges: Long COVID, and then the mental health challenges that have resulted from a year of such loss.

I want to ask Dr. Fauci and Dr. Walensky to dig into a little bit how you are using the funds that have been provided to deal with the long COVID issue for folks who are suffering symptoms after they have recovered from COVID.

Dr. FAUCI. Thank you very much for that question, Senator. This is really an important problem. The NIH has been given \$1.15 billion to study this, and we are doing this in collaboration with CDC and other organizations.

Long COVID is a real issue. Anywhere from 10 to, in one study, as high as 30 percent of individuals who recover from the acute manifestations of COVID-19, who have virologically no virus in them at all and they should be on the road to an uneventful recovery. But, unfortunately, what we have been able to find out now—and we are going to be putting together a number of cohort studies to determine the extent, the duration, any possible underlying pathogenesis, and any intervention.

But, the symptoms are somewhat common. There is a commonality among them. It is extreme, sometimes debilitating fatigue; muscle aches; temperature dysregulation, you feel hot or cold; dysautonomia, which is related to that; unexplained rapid heartbeat, or tachycardia; neurological symptoms and what people refer to as brain fog, or the inability to focus or concentrate over an extended period of time.

These are real symptoms, and they can last for a long time. We have people that we have followed now up to 9 months or longer where this occurs. It is a very important problem. We take it very seriously.

We have a task force at the NIH. Multiple NIH institutes—not only my own—Heart, Lung, and Blood, Neurology, and Mental Health, all of which are going to be looking at this over the next year or so because it is something that we really do feel we need to find out what is the underlying cause and what we can do about it.

Senator KAINE. Thank you for that, Dr. Fauci. That is going to provide a lot of comfort to people who are grappling with these symptoms.

Dr. Walensky, I want to shift to the second concern that I have. Again, we are not at a point yet where the emergency is over. And, yet, even when we are at that point, the mental health impact of this very, very challenging time on the American public and people all around the world is very significant.

I have worked closely with colleagues, including Senator Cassidy, really to pinpoint mental health impact on frontline healthcare workers, whose experience of dealing with death and illness at such a massive scale, having to manage end-of-life conversations with people who would normally be having those conversations with their own family members. This is a real significant concern.

My colleagues supported inclusion of provisions of the Dr. Lorna Breen Act in the recent work that we have done, and I understand that CDC and NIOSH are starting to focus on a public information campaign to frontline healthcare providers to reduce stigma to seeking mental health assistance should they need it.

Could you talk a little bit about those efforts, and more broadly, the question of keeping our healers healthy?

Dr. WALENSKY. Thank you very much for that question, Senator, and for the resources. I think it would be hard to overestimate the trauma that our healthcare providers, our frontline workers, have seen over this last year. Having been there before I was here, I can tell you, pulling up to driveways in your hospital that have morgues in the parking lot is really a striking thing to find.

I am grateful for the resources. We are collaborating—NIOSH is collaborating with our Injury Prevention Center within the CDC to create mechanisms and support tools to do outreach for our healthcare workers.

I would also mention that we saw mental health challenges ahead of COVID-19, so these are not just mental health challenges because of COVID-19. Even among our youth, between 2009 and 2019, before COVID ever started, we saw 40 percent increase in mental health challenges. So, we need this not just for our healthcare workers, but through—for the society at large.

Senator KAINE. Thank you very much.

Thanks, Chair Murray.

The CHAIR. Thank you.

Senator Cassidy.

Senator CASSIDY. Doctors, thank you all for being here. I approach you now kind of as a physician who has done research in vaccines as much as a—more so than I am approaching you as a Senator.

I was struck—and, by the way, I am incredibly frustrated, and the American people are frustrated because they hear you are following science, but then they just have a sense that the lag time between the implementation of that and recommendations is far too long. It is not just the American people. I will put it this way. Not just the people in my state.

Here is a Stat Article, CDC's Slow Cautious Messaging Seems Out of Step with the Moment.

Want to Go Back to the Office? Don't Wait on the CDC. That is from the Wall Street Journal.

The Liberals Who Can't Quit Lockdown from The Atlantic.

First, I was struck when Senator Burr suggested that previous immunization actually confers immunity. Do any of you agree with that? Dr. Fauci?

Dr. FAUCI. Does previous immunization confer—

Senator CASSIDY. Does previous infection confer immunity?

Dr. FAUCI. It does. We do not know what the durability of it is, but—

Senator CASSIDY. Okay.

Dr. FAUCI [continuing]. It certainly does confer immunity.

Senator CASSIDY. Now, so, but we still recommend that they be vaccinated?

Dr. FAUCI. Yes, we do.

Senator CASSIDY. That seems out of step.

Dr. FAUCI. No, actually—actually, Senator, a study has shown very clearly that if you vaccinate someone who has previously gotten infected and recovered, the level of neutralizing antibodies and T cells are extraordinarily high not only against the wild type—

Senator CASSIDY. Let me——

Dr. FAUCI [continuing]. Virus, but also against——

Senator CASSIDY. Let me interrupt.

Dr. FAUCI [continuing]. The variants.

Senator CASSIDY. I am aware of that research. I pulled some of the research that refers to that.

Dr. FAUCI. Right.

Senator CASSIDY. My concern is that would happen if you had another infection. All the immunization does is mimic a pre-existing infection. That is very well established with other viruses. No one has not established it for this virus. And, indeed, some of this research shows that within 4 days, which is the window period, if you will, for an infection to become an illness, those antibodies rise quite precipitously.

But, we still recommend that they get two doses, even though the same literature shows that there is an increase in side effects when someone gets a second dose and they have been previous immunized. So—now, not life threatening, but, nonetheless, an increase in side effects. But, nowhere do I see a recommendation that, well, do not get the second dose because the literature shows that after one dose, you have topped out your immunologic response and you are at an increased risk with the second dose.

Would anybody like to speak to that?

Dr. MARKS. There are studies ongoing to look at the first versus second dose. I agree with you, it is a very reasonable proposition for study. But, the purpose of immunizing somebody who has been infected previously is to develop higher antibody titers. Those high antibody titers are what is so critical in preventing a——

Senator CASSIDY. If I may, again, the studies of other viruses show—hopefully we have research showing here, but it appears to that a second—that a re-immunization merely mimics what would happen if somebody were exposed to the virus. All it does is kind of mimic that which would occur.

Dr. MARKS. Senator, this is a different virus. Each virus——

Senator CASSIDY. It is a different virus.

Dr. MARKS [continuing]. Has its unique——

Senator CASSIDY. Dr. Marks, is there research going to explore that which I am referring to? Because the research so far shows that within 4 days, you get a significant increase in antibody titer.

Dr. MARKS. There is research that has been done to show that after the vaccination, the nature of the immune response gives a sufficiently high titer antibodies that the post——

Senator CASSIDY. That is with every virus.

Dr. MARKS [continuing]. Vaccination immune response——

Senator CASSIDY. That is with every virus. That is not unique to this.

Dr. MARKS. It is likely superior to natural infection in this case in preventing against some of these variants, and I think that is what Dr. Fauci was getting to.

Senator CASSIDY. I also point out that the vaccines themselves, and presumably the previous infection, is also effective against the variants.

By the way, can people go back to work if they have been vaccinated and not wear a mask, assuming they are not immunocompromised?

Dr. WALENSKY. We have about a third of people in this Country who are vaccinated. We have about a third of counties in this Country that still have over 100 cases per 100,000. We are working to review our guidance and to update our guidance. We have put out three different guidances.

Senator CASSIDY. I am sorry. Let me just ask again. If I am vaccinated and I have antibody and I am exposed to somebody else, what is my risk of coming down with symptomatic infection?

Dr. WALENSKY. Five percent.

Senator CASSIDY. Five percent if I am—no, that is overall. Not if I have been vaccinated and if I have antibody. That is if I am vaccinated overall, correct. If I have antibody—

Dr. WALENSKY. We do not have—I do not think we have data on what you are looking at. We did not check antibodies on everybody who was vaccinated.

Senator CASSIDY. But, we could.

Dr. WALENSKY. We absolutely could, but—

Senator CASSIDY. Absolutely could.

Dr. WALENSKY [continuing]. To date, we only have information about—

Senator CASSIDY. We do know that if we are in a—if we know that critical mass or if we know that herd immunity is somewhere north of 60 or 70 percent, if we go into a workplace where, within that workplace, there is 100 percent immunization, such as here, we have achieved herd immunity. Yes, there is somebody in here that may not be responding to the vaccine, but because everybody else has, they are protected. That is nowhere reflected. And right now, we have Federal agencies, which we have had employees not working for a year, because the union says that they have to have special workplace precautions for them to return to work. There is consequence to this kind of delay, as the Stat article shows, of the kind of updating of these recommendations.

The American people are incredibly frustrated. And, as Senator Collins said, they are beginning to disregard what you say that is true because what you—so much of what you say is patently not true. I have to wear a mask when I am outside and the wind is blowing at 20 miles an hour. That has been changed, but it was only changed recently. They seek not to believe those things which are true. You have got to realize. You have got to be more real time.

Let me finish with this. I think—I do not know if it was the Stat article or the New York Times that pointed on the HIV epidemic. The recommendations were much more kind of calibrated to real life. Listen, we know people are going to do this. If you are going to do it, please accept this recommendation.

This is a blanket. Walk outside and wear a mask. You are vaccinated and everybody else in the room is vaccinated, but you are wearing a mask.

The American people have just lost patience with us, with you guys. I just ask you just kind of be aware of their frustration and get a little real time into updating these things.

I am sorry to be so frustrated. I respect you all and thank you for your service. I yield back.

The CHAIR. Senator Baldwin.

Senator BALDWIN. Thank you, Madam Chair.

Dr. Walensky, as I led the effort to ensure that the American Rescue Plan included funding for CDC's work to address variants of the coronavirus, specifically through genomic sequencing. I am really encouraged to hear from your testimony that we are now sequencing 10 percent of our Nation's weekly cases, and this is up from about—well, less than half of 1 percent in February when I introduced my Tracking COVID-19 Variants Act.

A couple questions about what we are finding. Last month, the White House announced that it would provide initial funding to jurisdictions so that health departments could conduct, expand, and improve activities to sequence genomes and identify mutations of the coronavirus. I would like to have you describe how health departments are making use of this funding and how this investment will improve our response to future public health threats. But, also, any new variants that we should know about that—particularly anything troubling from the perspective of eluding the therapeutics and vaccinations that we have produced?

Dr. WALENSKY. Thank you so much, Senator. I am—we are so grateful for those resources and our ability to scale up. As you note, we are now sequencing about 35,000 virus samples per week. That is a broad collaboration with commercial labs, with public health labs, with academic partners, and then with public health labs sending samples to CDC so we can address them more completely.

In terms of moving forward, I am looking forward to bolstering the infrastructure to be able to do these sequences at the local level; to producing the infrastructure within CDC to be able to follow these in a pandemic-related way, not just for this pandemic, but for future public health threats; and then, further, to expand our ability and our workforce in genomic sequencing and analytics and bioinformatics to be able to not just address COVID-19, but these are longstanding things that we are going to need to address antimicrobial resistance and other infectious threats.

Thank you.

Senator BALDWIN. Thank you. Last week, the Administration announced support for the waiver of intellectual property protections on COVID-19 vaccines to help end the pandemic. I believe that this news is the beginning of our work to restore America's public health leadership on the world stage. But, there is more to be done when it comes to addressing COVID-19 worldwide.

Dr. Fauci, can you explain how increases in new cases of COVID-19 worldwide threaten the progress that we have made here in the United States? And how can we avoid repeating history when it comes to combatting infectious diseases worldwide?

Dr. FAUCI. Thank you for that question, Senator. Yes, indeed, as we have said so often, and it is true, that a global pandemic requires a global response. And, even if we successfully vaccinate our population and get the level of infection down to a very low level, as long as there is a dynamic of infection spread throughout the world, any place in the world, there always is the danger that variants will be generated and ultimately will come to the United

States because of the travel that we know makes no place in the world separate completely from any other place in the world.

That is something that we really need to pay attention to, and it is for that reason that I keep saying, and many of my colleagues keep saying, we really do have a responsibility to the United States first. We do, for sure.

But, we also need to take part in an effort, whatever effort, and it is going to be multifaceted effort, to make sure that the rest of the world contains the outbreak. And that could be from some of the things we are doing right now with India by giving them immediate help with oxygen and drugs and PPEs, but also to provide for the availability of doses of vaccine that we can make available to them. Not alone, not just the United States, but the rest of the developed world.

Senator BALDWIN. Thank you. One quick last question to Dr. Kessler. In its first few months, the Biden administration has surpassed every goal and expectation it has set in terms of getting shots in arms. Because of this effort, we are moving into the next phase of our vaccination effort in which the focus is less on mass vaccination sites and more about meeting folks where they are to get shots to hesitant and hard-to-reach individuals.

As these vaccines come with certain logistical challenges and limitations, including cold storage and use-by requirements, as well as specific numbers of doses in each vial.

As we shift to a more individualized effort, how will the Administration work to ensure that we are using our existing vaccine supplies effectively and maximizing the potential—and minimizing the potential for wasted doses?

Dr. KESSLER. Senator, a very, very important question. Because, as everyone on this Committee has recognized and has been part of this heroic effort, initially certain decisions were made on how to maximize the number of doses produced.

The decision—in order to get the hundreds of millions of doses that we have already administered, we have had to make certain tradeoffs, and that is why you see the packaging the way it is, which is in a considerable number of doses, and we have to reduce that packaging.

But, every day, Senator, I am in awe of the contributions that many of our local community health professionals, community leaders, ordinary citizens are taking to be able to bridge the barriers that people are having.

I would like to get this eventually down into very small individual doses, but that is going to take time. And right now, we are going to do everything possible to speed that up.

The CHAIR. Thank you.

Senator Murkowski.

Senator MURKOWSKI. Thank you, Madam Chair. Thank you all for being here.

A lot of frustration this morning, and I think, as Senator Cassidy mentioned, it kind of reflects the frustration that Americans have with where we are. We are all tired with COVID. We are done with COVID. But, as many have said, COVID is not yet done with us. But, how we are able to make sense of the guidance that comes out of CDC is critically important.

Alaska was very early on in making sure that the vaccine was available to all very quickly, and, as a consequence, we are pretty proud of the fact that our numbers of vaccination were strong and we were No. 1 in the Country. But, when you start out first, you also then are the forerunner in demonstrating what it means to really see this vaccine hesitancy, and we are seeing that play out in different ways and different shapes.

I appreciated your comments, Dr. Walensky, to Senator Smith about the ways that we can address the concerns that have been raised, whether it is where can I get the vaccine, is it safe, who do I look to for guidance.

The State of Alaska did a survey that was released on Thursday that indicated that people are not looking to you all for guidance. They are not looking to our chief medical officer in the State of Alaska. They are looking to see what their friends and their neighbors do. They do not care what their Senator or the folks from CDC do. So, we have a lot more work to be doing with regards to that.

I want to speak to my particular frustrations, which you have had the benefit of multiple conversations with me, and that is how we can get our tourist sector back to work for even a small sliver of the season.

One point three million tourists come to the State of Alaska on a cruise ship. There were 48 tourists that came to Alaska on a cruise ship last year. And, right now, it does not look much better.

We have been working back and forth with CDC, trying to deal with these—this conditional sail order. After many months of requests, we finally get to a place where we think we have some guidance out there. I just, at 11:30, got new information that the CDC's last tranch of guidance still requires additional guidance to be published. And, I say, yes, it is minor, but the fact of the matter is it is still yet one more gate that has to be gone through. Our reality is if you cannot get ships turned north now, there is no season, whether it is for 1 week or 1 month.

I guess, Dr. Walensky, I am going to ask you one more time, can you give Alaskans any guidance at all with regards to the ability to finally get this guidance fully resolved? You have cruise lines that are saying, we are going to require everybody be vaccinated. All of our crews will be 100 percent vaccinated. We will require that those who want to sail on our ships this summer be vaccinated. Those in the communities who are welcoming them are also equally committed to the vaccine.

Should I just tell folks back home do not even bother ramping up your seasonal operations because it is just not coming, we cannot get that guidance from the CDC?

Dr. WALENSKY. First of all, Senator, let me congratulate you and Alaskans for getting vaccines into arms because you have been a role model in being able to do that.

With regard to sail, I was here in March. We were waiting on 2A guidance. That 2A guidance of working with ports has since come. We have been now engaging, as I noted we do with schools, with our consumers, with our key stakeholders. We have had twice-weekly calls now with the cruise ship industry to understand what—how they are interpreting their guidance and what they

need in order to be able to get boats back in the water. That is our goal for this season. Mid-summer was our goal.

2A has been released. 2B has been released. Our guidance on how we get conditional—how we get trial voyages into the water, as well as Step 3 released, how you get conditional sail certificates. All three of those have been released.

They have—we have been in this dialog with the industry so that we can understand what are the challenges in the current guidance that are hard to be met. And, we are actually having these conversations and then going back and addressing those challenges. We had a dear colleague's letter that went out after 2A, and we have others that are in the works.

We are working with those in the industry to do our best to get ships back in the water this season, and we have actually agreed to a 5-day turnaround when those proposals come to us.

Senator MURKOWSKI. Well, it was news to me to, again, just see that there is yet another thing that has come up just this morning, so I would ask you to take a look at that.

My time is expired here, but I must raise this fishing mask mandate. If you think about those mandates that really do not make sense, the fact that the Coast Guard is requiring, because they—it is Federal law out there that persons traveling on a conveyance or at a transportation hub wear a mask for the duration of their travel.

I have fishermen, commercial fishermen, that are out there in the water. I have crabbers and salmon fishermen and cod fishermen that are trying to deal with a mask because they are concerned about failure to comply. This is more of a safety hazard than anything else. You are out on a boat. The winds are howling. Your mask is soggy wet.

Tell me, tell me, how anybody thinks that this is a sane and a sound policy to do. So, I—we have a situation right now where the fishermen are more concerned about the liability in failing to have the mask on rather than prudent marine safety protocols. This is absolutely, absolutely a crazy policy.

I just do not understand. I do not understand how we put our Coast Guard men and women in a situation where they know that safety is at issue, a broader safety issue, than the fear of transmission when you are outdoors, in the elements, and you are now being required to wear a mask. So, I would hope that the CDC would reconsider this quickly, quickly, quickly.

Dr. WALENSKY. We are in the process of finalizing industry-specific guidance for exactly this reason. Thank you.

Senator MURKOWSKI. Thank you.

Thank you, Madam Chair.

The CHAIR. Thank you. We will turn to Senators Murphy, Marshall, and Hassan. A vote has been called. I am going to go over to the floor and vote. Senator Burr will preside, and I will be back as quickly as possible. We will go to Senator Murphy.

Senator MURPHY. Thank you, Chair Murray. Thank you all for the fantastic work you do to protect the Country.

Just a quick word on this frustration you are hearing regarding guidance from the CDC. I mean, listen, our witnesses today could sit here and claim that we have definitive information on risks or



means of transmission or asymptomatic transmission, but they would not be telling the truth. We suffered through 4 years with a president who literally made things up about this virus; who simplified the story over and over and over again because he thought simplifying things and being definitive would make him look good, including giving free medical advice to Americans on what therapies they should take; making claims that the virus would disappear after a matter of weeks.

That was not good for the Country. It did not help us fight this disease. We still have a lot to learn. And, so, I frankly appreciate the fact that we have leaders today who recognize that we still have gaps in information, who occasionally may err on the side of caution in order to save lives. And I share the frustration, but the frustration is rooted in the fact that we are still less than a year and a half into a virus that we are still beginning to understand.

To that end, Dr. Walensky, on this question of outdoor transmission. So, Senator Collins was asking you about a paper you put out suggesting that it could be 10 percent of cases. There are other folks that say it could be 1 percent of cases. There are some epidemiologists who say that it could be .1 percent of cases. That is a really important difference, and I assume the difference between 5 percent and .1 percent would likely educate decisions you would make about what recommendations you make to summer camps.

How do we, on this question, close the gap in information that we have? Given that there are so many competing analyses out there of outdoor transmission, what do we do to try to make sure, especially heading into this summer, that we have the best information possible? How do we solve this problem?

Dr. WALENSKY. Thank you, Senator, for that question. I think it is important for—to realize that we, at CDC, are responsible for putting out guidance for individuals, as well as for populations, for public health. We are responsible for putting out guidance for counties that have less than five cases per 100,000 and for counties that have greater than 100 cases per 100,000, as well as for counties that have less than 10 percent of people vaccinated and counties that have more than 50 percent of people vaccinated. Our guidance has to be science-based for all of these situations.

In our last iteration of what vaccinated people can do, safely do, we did update our guidance not only for not wearing masks outdoors, but also for not wearing masks outdoors in certain settings for people who are unvaccinated. In those situations, we also said if people are gathered with other unvaccinated people dining with their masks off and close by, there may be a risk to that if they are dining close by.

Certainly, this meta-analysis that was put forward that demonstrated the top line result of less than 10 percent transmission occurring outdoors was helpful scientific evidence, and we are following the science as it continues to emerge.

I think it is also really important to recognize that now, with vaccination of 12 to 15 year olds, our summer camp guidance is probably going to have to change in those settings, and we plan to do so.

Senator MURPHY. Great.

Dr. Kessler, question for you on booster shots. You have got—you included in your testimony an expectation that we may be in the business of purchasing and distributing booster shots, maybe as soon as later this year.

I asked a question at the last hearing about the transparency of contracts with the companies that are supplying vaccines. I still think that we could do better in terms of letting the American public know and policymakers know about the financial terms of these contracts.

But, what do we expect when it comes to contracting for booster shots? Are we going to go back to the same companies that provided the vaccine, or are we going to open that tender up to a broader set of companies? How do we expect the process of procuring booster shots to work, and how do we make sure that it adequately protects taxpayer dollars?

Dr. KESSLER. Senator, thanks for the question. Very important. We are in that process now. In order to plan, because that is really what we are doing, if we want a vaccine, let's say both the duration of immunity increasing age so there is less antibodies, and the variants, we have to take all of those things into consideration. And if we want vaccine end of the year, we have to do that now, and we are, in fact, in those negotiations.

The best science to date—I mean, the data we have, and I do not want to get too technical, but the question is are we dealing with homologous boosts or heterologous boosts. Basically, are you going to boost with the same vaccine or are you going to—can you switch that out and do mix and match? And that requires data. We are collecting that data, and it is going to be the data that drives what we boost with.

But, for planning purposes, I think the simplest and safest assumption—and I underline the word assumption—is that it may be for, at least the short term, the homologous boost with the same type of vaccine makes the most scientific sense. But, I need a couple of more months in order to give you definitive answer, but I have to plan now.

Specifically to answer your question, we are dealing with the same companies because we want to continue with the safety and efficacy that we have seen in those vaccines. Down the road, that may change as we get other, for example, protein-based vaccines available, Senator.

Senator MURPHY. I was just going to say this. I hope that this Committee is actively involved with the Administration on the construction of those contracts, to make sure that we are adequately protecting our taxpayers' investment.

Thank you, Mr. Chairman.

Senator BURR. [Presiding] Senator Braun.

Senator BRAUN. Thank you, Senator Burr.

Dr. Walensky, I think from the get-go, there has been an uncertainty of when we arrive at the moment when many of us feel that this is truly in the rearview mirror. And, from the early conversations I have had being on this Committee, it has always been interesting to understand, I think, if and when that comes with clarity, that is the only way I think we get true comfort back into the Country.

Senator Murphy, others, have mentioned how things have changed, goal posts have moved. I think that is inherently confusing to people, especially ones that might have other reasons for not getting vaccinated, and I think that is so important that we get there, everyone vaccinated.

My question is, I think, on the education side of it, more emphasis and resources need to be put into rural America, I think along with the logistics, that have seen some effort made there to improve it. I think it is inherently more difficult to get vaccines in the arms when it is spread out in areas like that.

I would like you to zero in on it was 3 feet, or 6 feet and then 3 feet, indoors and outdoors. So many things have evolved. And I think with something as uncertain as this, it is natural to have that dynamic.

Where in time, and does natural infection go along with vaccination to have some weight in that point in time where cases really start to fall off the chart?

Dr. WALENSKY. Thank you so much for that—those questions, Senator. Maybe I will start briefly with the rural and say in our efforts over this last several weeks, resources have gone broadly to rural communities. We are now funding federally qualified healthcare centers, getting vaccines into areas in those centers. Over five million vaccine doses have been given through federally—FQHCs. So, we know we need to do that outreach, and that is part of this next chapter.

In terms of the 6 versus 3 feet, I think from the school guidance—I know from the school guidance, the first iteration that was put out in February, the biggest challenge to getting children back to school was the 6 foot guidance. What happened soon thereafter is science emerged. And because 6 feet proved to be such a challenge, within a month, we had three studies that demonstrated that 3 feet and 6 feet were equivalent for younger children. And, so, it was based on the science. I would really like to say that we are in a static situation here and that the science is not changing, but we are changing our guidance with—as the science evolves and as the science emerges, and we have to remain humble to that science.

With regard to your question regarding natural immunity, we have several challenges there. The CDC on its website has a map of presumed seroprevalence by state as to how much—how many people out there have antibodies. And, of course, we do not know all of the infection that has happened, right, because much of this infection has been asymptomatic.

As Dr. Fauci has said, that prior infection likely confers some immunity. It might confer full immunity for some period of time.

But, I will say that we are still learning and being humble here. This past week, our genomic surveillance data demonstrated that 72 percent of our sequences are now the B117 variant. What do we know about how long prior infection will last with regard to new infection and a B117 variant if you are not vaccinated? We do not have all of those data yet. We are doing studies. We are evaluating it. But, I do think that we should continue to encourage vaccination of people who have had disease before.

Senator BRAUN. Thank you.

Dr. Fauci, the J&J vaccine, which I think for many people was a preference in terms of just being one shot and had a high efficacy rate to boot. Do you think it was a mistake in that we pulled it when statistically the rate of an incident was so, so low—lower than I think on many other drugs out there that seemingly have much higher side effect consequences? Was that a setback that put us in a place that has really hurt us, or have we recovered from it?

Dr. FAUCI. I do not believe it was a setback, Senator, and I think if it was, we certainly have recovered from it because we now know. When you ask people, there is a lot of people who really want to get a one-dose vaccine, who are waiting for the availability of this.

What I do think it did that you do not fully appreciate is that it really underscored how seriously we take safety. Because to call a pause on an adverse event that, as you mentioned correctly is really quite rare, because at the time, there were six cases in about seven million people, which is less than one per million, which is really a very, very low amount.

The FDA and the CDC looked at the data. They wanted to find out if there were any more. They wanted to alert the physicians who might be out there seeing patients about what is the proper way to treat them, because there is one general way to treat that people might use that would actually be contraindicated, namely with heparin.

In the long run and the big picture, when all is said and done, I do not believe it was a setback. I think it really underscored how seriously we all take safety.

Dr. BRAUN. How many vaccinations do we need to get fully in the arms to be at what the theoretical herd immunity would be and cases crash? Anybody?

Dr. FAUCI. Yes. I think that is going to be a difficult number to give because herd immunity as a concept means you get enough people vaccinated, enough people infected, so that you have a core of protected people that is a blanket of protection over even the vulnerables who cannot. The threshold of herd immunity is a number we do not know yet for this particular virus. We know it for measles, but we do not know yet what that is. We can—

Senator BRAUN. I think that—

Dr. FAUCI [continuing]. Guess it is somewhere between—

Senator BRAUN. That uncertainty is probably the thing that is going to be the hardest thing to grapple with to get this fully in the rearview mirror. So, thank you.

Senator BURR. Thank you, Senator Braun.

Senator HASSAN.

Senator HASSAN. Well, thank you, Ranking Member Burr, and I thank the Chair for holding this hearing. And, really, thank you to all of our witnesses today for not only being here, but for your service.

Before I get to a question, Dr. Walensky, I just want to second what Senator Murkowski said about getting the guidance to the fishing industry out as quickly as you can. I just met with my fishermen at the Yankee Fishermen's Co-op in New Hampshire this week, and we have boats of fishermen who are fully vaccinated who

see the Coast Guard coming, telling them they have to keep their masks on. Not only is a wet mask dangerous out on the open water, but because of the noise, both the wind and the equipment, these guys are used to relying on kind of sign language on the boat. And with the mask on, they really cannot, and it is a real safety issue. So, I hope you will take this under advisement and get the guidance out as quickly as you can.

Dr. Fauci, I wanted to follow-up a little bit. We have been talking about the very good news of the Pfizer authorization for 12 through 15 year olds, and it looks like they may be seeking at least emergency authorization for 2 to 11 year olds in September. And that is really welcome news, but many families are still looking for guidance about how to protect children under the age of 12 from the virus until a vaccine is authorized for them, especially as public health restrictions are being lifted around the Country. And I am hearing some from parents that the schools are mostly reopened, or hybrid reopened, but they are kind of nervous about sending their children to school.

What advice do you have for families about what steps they can take to protect their children from the virus while we await FDA authorization for use of the vaccine for kids?

Dr. FAUCI. My recommendation, Senator, would be really to follow the CDC guidelines. I mean, what both—when the children are in the home with vaccinated individuals, the guidelines are clear what needs to be done. When they are outside, many things you can do without a mask outside. But, if you are not vaccinated and you are interacting with people outside of the home from different locations, you want to be careful and have the children have masks.

I think a good following of the CDC guidelines, which, as Dr. Walensky says, continue to evolve in real time as they get more data. The guidelines get updated and upgraded. So, that would be my recommendation.

One other thing that I think is important is that there is a lot of work that we are doing now in clinical trials to get vaccinations for children younger than 12. So, a bunch of companies, several of them, are doing what is called age de-escalation studies where we are looking at children from 12 to 9, 9 to 6, 6 to 2, and then 6 months to 2 years. We think by the time we get to the end of this year that we will have enough information to vaccinate children of any age.

Senator HASSAN. Well, that would be very welcomed news to a lot of parents.

Dr. FAUCI. Right.

Senator HASSAN. Thank you.

Dr. Kessler, I want to follow-up on a line of questioning that Senator Murphy was following. We have heard encouraging news, certainly, that the protections from the COVID-19 vaccines remain strong for at least 6 months and likely longer, but, also, that Americans will need booster shots, as you all—may need booster shots, as you all just discussed. It is going to be really critical that these vaccines remain accessible and that their price reflects the large investments that American taxpayers made in the research and development of the technology.

What steps should Congress take to ensure that COVID-19 vaccines, including booster shots if needed, remain available to Americans even after the end of the public health emergency? And how can we ensure that pharmaceutical companies price these vaccines in a way that account for taxpayer investment?

Dr. KESSLER. Senator, a key question. Let me assure you that because of what this Committee has done and your colleagues on Appropriations, we do have the funds to purchase the next round, again, if, if they are necessary. So, we will be able to purchase the next round and to assure that if there are boosters, they are free, just as the last round. I think you raise a very good question.

Beyond that, beyond 2022, I mean, I look to your guidance and your colleagues on at what point do you transition back to a commercial market. But, I think for this coming round, we are going to proceed as we have proceeded, and you have made those funds available.

Senator HASSAN. Well, I look forward to continuing the discussion. I see that I am almost out of time here, but I did want to just ask Dr. Walensky quickly. Can you speak to the importance of continued access to COVID-19 testing even as we work to distribute the vaccine and people are getting—we are building up our community and herd immunity?

Dr. WALENSKY. Yes. Thank you very much for that question. First of all, we recognize that right now we have done an extraordinary job in getting vaccine to one-third of Americans, and yet two-thirds of Americans do not yet have vaccine. And, in fact, our young children will not have access to vaccine for the rest of this year. We have put out \$10 billion toward states to be able to do testing programs within schools. Some higher ed have been able to successfully engage in this past semester through testing programs on their college campuses. We are going to need to continue testing through our long-term care facilities, as well as our correctional facilities, our dense industries. And, so, yes, I think there has to be a huge corner of what we are doing that is related to testing.

Also, surveillance water testing, sewage testing, to look for outbreaks. So, we are doing a lot in the testing area. We are really grateful for the resources to be able to do so.

Once we have vaccine in the majority of people, we are still going to have disease out there and we are going to need to rapidly be able to detect it. Thank you.

Senator HASSAN. Thank you very much.

Thank you, Madam Chair.

The CHAIR. [Presiding] Senator Marshall.

Senator MARSHALL. Thank you, Madam Chair.

Dr. Fauci, do you think it is possible that COVID-19 arose from a lab accident at a lab in Wuhan, and should it be fully investigated?

Dr. FAUCI. That possibility certainly exists, and I am totally in favor of a full investigation of whether that could have happened.

Senator MARSHALL. Great. Is it possible COVID-19 is not naturally occurring?

Dr. FAUCI. Again, that is a possibility. I do not know if we are ever going to be able to prove that. But, you always need to open up and leave all possibilities, which is the reason why I and so

many of my colleagues are very much in favor of what the WHO said, that they want to go back again and take another look in there and see what was going on in that lab.

Senator MARSHALL. Will you commit to get this Committee all the records, anything to do with any type of viral experiments, say from 2013 to the present so we can review those?

Dr. FAUCI. Certainly. I would comply with any request of the Committee.

Senator MARSHALL. Do you and others at NIH have a conflict of interest when determining if the labs and lab work you help fund should be investigated and how it is investigated?

Dr. FAUCI. No. I do not think it is a conflict of interest. We are very open and wanting to make sure that everything that has any question is looked into, at all. I have no problem with that.

Senator MARSHALL. Okay. In 2013, President Obama placed a moratorium on viral gain-of-function studies with some loopholes, which you were able to use at certain times. I know we disagree—I do not know if we disagree. We can discuss what is viral gain-of-function and what is not. But, in 2017, you had a long process, and I assume it was you that decided to lift this moratorium, and during this review—my question is this.

During the review, did you consider the risk of dual applications by military, terrorists, or other foreign actors?

Dr. FAUCI. I am not sure what you mean by that, Senator. Did I consider applications from dual actors?

Senator MARSHALL. Yes. I will say it again. Did you consider the risk of dual application, that there might be other folks that would use some of the—

Dr. FAUCI. Sure.

Senator MARSHALL [continuing]. Function of discoveries, that they might be used by a military—

Dr. FAUCI. Sure.

Senator MARSHALL [continuing]. Terrorist, or other foreign actors?

Dr. FAUCI. Well, in any research that we do, we publish the research. It is available for anyone to use it in any manner in which they can. That is the modus operandi of the NIH. We fund research. The research is—

Senator MARSHALL. Is there not a—

Dr. FAUCI [continuing]. Made public.

Senator MARSHALL. Is there a national security consideration, though, in that type of decision with—thinking the viral gain-of-function could be more powerful than the nuclear weapons to—

Dr. FAUCI. No, but—

Senator MARSHALL [continuing]. Share that information with a government—

Dr. FAUCI. Right.

Senator MARSHALL [continuing]. Foreign actor may be considered—been like trying to do the Manhattan Project in nuclear energy, nuclear weapons, doing it with, say, Hitler or the Soviet Union?

Dr. FAUCI. I am not sure what you are getting at, Senator, but we do not fund research. We have committees that look at that to

make sure that research that is of any potential danger is not funded. So, I am not exactly sure what your point is.

Senator MARSHALL. My point is, is there national security implications with something as theoretically lethal as viral gain-of-function?

Dr. FAUCI. Sure, there is. That is why we have committees. We have a P3CO committee, which is the Potential Pathogen—Pandemic Pathogen Care and Observation—and Oversight, excuse me. And that is a committee separate from the NIH that looks at these types of grants to see if they need to be funded. So, there is a considerable amount of oversight to make sure grants that are doing research that would obviously be of danger is not performed.

Senator MARSHALL. When you make a decision to stop the moratorium on gain-of-function, was—were there national security advisors in the room? Was there State Department? Was there Defense Department? Who were those people that might have been part of that decision?

Dr. FAUCI. First of all, I did not make the decision to stop, to pause the gain-of-function. If one looks at what actually happened, we put a pause on, and I was the one that was very much in favor of that pause. In 2013—

Senator MARSHALL. You are talking the 2013 pause?

Dr. FAUCI. In 2014—

Senator MARSHALL. Okay.

Dr. FAUCI [continuing]. To 2017, the pause was lifted because we established a committee that looked at what we called P3CO.

Senator MARSHALL. I am familiar with it.

Dr. FAUCI. Right. Exactly. And when that committee then was able to make decisions about granting, apart from the NIH so that we would not have any decision and it would be a decision—

Senator MARSHALL. I have one last question I wanted to sneak in. I still do not know that you answered was there national security people in the room when you—when that process—someone made the decision. I think you led that decision, but we will come back to that.

Here is my last question. If COVID-19 is indeed a product of lab manipulation, can you sit here and unequivocally say the viral studies that NIH funded—helped fund, could not be indirectly or directly related to this final COVID-19 virus?

Dr. FAUCI. Yes. Looking at the experiments that were done that we funded, there would not be that possibility.

Senator MARSHALL. Unequivocally?

Dr. FAUCI. Well they are talking about a hybrid virus of a mouse virus that was adapted to a mouse that anyone that knows anything about virology would realize that is not something that would infect a human, much less be pathogenic and transmissible.

Senator MARSHALL. But we helped make the mouse that had the HLA receptor that this COVID-19 was specific for, and you were—NIH was involved in the development of—

Dr. FAUCI. Yes.

Senator MARSHALL [continuing]. Humanized mouse?

Dr. FAUCI. Yes, but as I mentioned in response to Senator Paul, the NIH and NIAID did not fund gain-of-function research to be conducted at the Wuhan Institute of Virology.



Senator MARSHALL. But that is not my question. You know, the question is, could some of the—some of the funding you did—you can call it gain-of-function or not, developing the HLA receptor with the mouse. I am not sure if you are going to call that gain-of-function or not. Probably not.

But, could some of the funding indirectly ended up to the contribution of this—of COVID-19?

Dr. FAUCI. I am not sure exactly where that question is going. You could do research on something as benign as looking at something that has nothing to do with it and it could indirectly, someday, somehow, be involved. So, if you want to trap me into saying yes or no, I am not going to play that game.

Senator MARSHALL. But we need to look at that very deeply and consider exactly—that is why you committed earlier to make sharing all the viral—

Dr. FAUCI. I would be happy to share any information you would like with the Committee.

Senator MARSHALL. Thank you so much. I yield back.

The CHAIR. Thank you.

Senator Rosen.

[Brief silence.]

The CHAIR. Senator Rosen, I believe you are on mute.

[Brief silence.]

The CHAIR. We are going to hold 1 second for Senator Rosen's mute function to work.

[Brief silence.]

The CHAIR. I believe they are trying to undo Senator Rosen's mute function from the studio.

Senator Rosen, if you can just be patient with us for a minute while we get that fixed.

I am going to go ahead and ask a question, and if—Senator Rosen, if you can just hold for just a minute.

I wanted to ask Dr. Walensky. There are variant strains of COVID-19 that threaten to disrupt progress made toward ending the pandemic, and the CDC reports that the B117 variant is now the predominant strain in the United States. We need to know which variants are out there and how they are spreading and why they—and who they are spreading to, which is why we approved \$1.75 billion in the American Rescue Plan to help CDC shore up its genomic sequencing and surveillance activities.

Do you have enough data? Do you have the right data and the right data systems to be able to track these variants as they spread?

Dr. WALENSKY. Thank you, Senator. We are—we have scaled up our sequencing dramatically, as I have noted, and every 2 weeks or so, we get an update on data and we look at the—where these sequences are. Just yesterday, I believe, we had the most recent update that demonstrated 72 percent of our cases are now B117. Six percent are now P1. And, we are grateful for the resources to be able to do so.

Generally, our ballpark was to have 10 percent of viral sequences able—10 percent of all circulating virus to be able to be sequenced. And, so, with cases coming down and our sequencing rising up, we have been able to reach about that 10 percent mark right now.

That has required a lot of collaboration across government, across commercial labs, and whatnot.

The function is a—and the impact of these, whether they are variants of concern, variants under investigation, how we understand these, is related to an interagency collaboration with BARDA, NIH, and CDC in terms of seeing how transmissible they are, as well as how well they function against monoclonal antibodies and our vaccines.

The CHAIR. Thank you for that.

Senator Rosen, do we have you back?

Senator ROSEN. I think we are back. Can you hear me now?

The CHAIR. Yes, we do.

Senator ROSEN. Oh, very good. Sometimes that Zoom happens. There you go.

Well, thank you, Chair Murray. I appreciate your patience. I appreciate you calling this hearing. It is extremely important. And, so, for you, for all the scientists, the medical personnel, the front-line workers, I am so grateful for what everyone has been doing to be sure that we can keep the American people, really, people around the world, safe, healthy, and informed.

Dr. Fauci, when we last spoke in March, you shared that NIH had just launched a billion-dollar initiative to study the long-term effects of COVID-19 and identify potential prevention and treatment measures for the long-haulers. Because COVID-19, of course, is a novel virus, there are so many gaps in our research and unknowns for the people who have been affected and are still suffering. And that is why I introduced bipartisan legislation that will ensure that NIH will continue to be able to work with the CDC on comprehensive and longitudinal studies of a diverse group of COVID-19 patients. I know some of the research has already been done. It is going to go forward.

You shared earlier some updates on long COVID. Could you speak to the research gaps that remain for learning more about the long-term effects, such as lung capacity, heart function, some of the things that people really seem to be struggling with once they have recovered from their initial symptoms?

Dr. FAUCI. Well, thank you very much for that question. Yes, we have initiated a series of studies, first of all, building up cohorts so that we can get enough individuals in the cohort to be able to do the kinds of studies that you are going to do.

As I mentioned in response to a prior question, it is a multi-institute endeavor involving multiple NIH institutes with differences—different interests in different organ systems, just as you said. The National Institute of Heart, Lung, and Blood is one that is looking at some of the issues that you raised in your question, the National Institute of Neurological Diseases and Stroke, the National Institute of Mental Health, and my institute, the National Institute of Allergy and Infectious Diseases.

We have also just now started the request for applications to be able to gather the cohorts and do those types of studies. So, there is a considerable amount of interest in this and a major commitment on the part of the NIH to study this thoroughly to fill in some of the gaps that still remain as to what the pathogenesis of this

particular syndrome is because it is a real syndrome that is very troubling to a large number of patients.

Senator ROSEN. Thank you. I would like to move to the other part of this equation, which is the therapeutic research and development. Because even though people are getting vaccinated, of course, there are still people getting sick and there are people, like we said, still suffering chronic pain, chronic illness, as a result of COVID-19. And, so, we have to be sure that we have those tools to continue to treat any cases that come forward.

Could you give us any updates about what therapeutics might be in the pipeline? And do you think is there a potential for any of these treatments to help some of the long haulers? You know, maybe it can treat acute and chronic illness as a result of this function of COVID?

Dr. FAUCI. Senator, it is an excellent question but it is almost impossible to talk about treatment when you do not know what the underlying pathogenesis is. So, that is the reason why the studies are starting off by gathering the cohorts and trying to find out if there is a mechanism for some of the symptomatology—the profound fatigue, the muscle aches, the temperature dysregulation, the sleep disorder, the brain fog, as they call it.

We do not know exactly what the mechanism of this symptomatology is and, for that reason, it becomes very difficult to do anything other than symptomatic treatment for these individuals. That is why it is so important to do the studies that we are planning to do, so that hopefully when we understand the mechanisms, we will be able to have some therapeutic intervention.

Senator ROSEN. Well, thank you. I appreciate that because it is really going to be important moving forward. It is going to be important to our healthcare workers, to our surging of hospital capacities, and actually globally around the world.

I just thank you for that. I look forward to reconnecting with you as we begin to see more results of this really important longitudinal research and the progress that it is making.

Thank you, Madam Chair. I yield back.

Dr. FAUCI. Thank you.

The CHAIR. Thank you very much.

I wanted to ask, the pandemic's deadly impact on communities of color shows we have a long way to go to address systemic racism and health inequities in this Country. Black and Latino people are receiving vaccinations at disproportionately low rates, and some of the systems that are designed to make vaccinations easier, like online registration for appointments, have actually made it harder for some, like our native Hawaiian and Pacific Islander elders. Additionally, AAPI communities have experienced higher rates of discrimination and violence, as we know, since the start of this pandemic.

Dr. Kessler, I wanted to ask you, how is the Federal Government working to decrease COVID-19-related health inequities?

Dr. KESSLER. Senator, thank you for the question. Enormously important. There is some at least initial good news. You know, we have seen that deaths are down dramatically since January, and we all know that they are down 80 percent among seniors. But, they also include—that drop includes a drop among Hispanics of 80

percent, and among African Americans of about 70 percent. And, in the past 2 weeks, 55 percent of the people vaccinated were White, but 45 percent were non-White. That compares to the general population that is about 60 percent White and 40 percent non-White.

We have much more to do, especially in the area of confidence. We do see that people's confidence in the vaccine is increasing. Black Americans' confidence increased by 24 points since January, and Latino Americans' confidence increased by 22 points since January.

But, outreach access is absolutely critical. These vaccines are free. Every adult in America is eligible in about 80,000 locations. But, we have a lot more work to do, and we are keeping equity at the center of the response, and we will not leave anyone behind.

The CHAIR. Okay. Thank you so much for that effort, and I appreciate it.

Senator Burr, do you have any closing questions or comments?

Senator BURR. Madam Chair, thank you. Yes, I do. I have a little bit of cleanup if I can.

What I have been able to piece together since we started—and this is to you Dr. Marks and maybe Dr. Kessler. BARDA signed a contract for \$1.2 billion for 300 million doses of AstraZeneca vaccine. That is currently authorized in 70 countries around the world; its manufacturing capacity in 15 countries and 25 sites. In addition to the Baltimore Emergent facility, two sites in the U.S. manufacturing, in Ohio and New Mexico, of AstraZeneca vaccine.

Here is my question. Of the stock that we currently have on hand, which I estimate to be about 60 million doses, is all of that being held because it came from Emergent? Or, in that 60 million inventory that we have today, is some of that either foreign manufactured and/or Ohio or New Mexico and would not have to be held up because of the current inspection concerns at Baltimore?

Dr. KESSLER. Senator, I have been talking to AstraZeneca, even last night. I have been talking to them regularly over the last several weeks. I—to answer your question very specifically, the 60 million that you reference, all of that drug substance was made at Emergent.

There is another facility at Catalent that manufactures drug substance, but we are not—we have not contracted and we are not involved, and that is for global.

There are two other facilities, one in West Chester that you referenced, that is for drug product.

But, everything that we have involvement in is that 60 that has been produced for that first initial hundred, and they stopped at 60 when—because of the problems at Emergent were—are all being reviewed by our colleagues at FDA because of issues at Emergent.

Senator BURR. Follow-up question. Of the over two million doses that went to Mexico, a million and a half doses that went to Canada, have there been any indications from those vaccines if they have—one, I assume they have been used. Is there any reason to believe that they are reporting any adverse effects?

Dr. MARKS. Senator Burr, no, and in—and those came from a time when that facility was not being used for more than one vaccine, to produce more than one vaccine, sir.

Senator BURR. The fact that they produce not only AZ, but J&J, now makes them susceptible?

Dr. MARKS. It is a matter of public record that the problem that occurred at the facility involved a contamination event between two vaccines.

Senator BURR. Okay.

Dr. MARKS. That was the issue that we are dealing with. But, I just should add that you have our commitment that we are going to work as quickly as we possibly can to get both clearance of the doses that are currently being held—because we do not have clearance of the safety of those doses yet—and also to get that plant back up and running in a manner that is fully consistent with what Americans expect from their pharmaceutical products.

Senator BURR. Okay. This question, I am going to go to Dr. Fauci, Dr. Marks, and Dr. Walensky.

What percentage of the employees in your institute, your center, or your agency, of your employees, has been vaccinated?

Dr. FAUCI. I am not 100 percent sure, Senator, but I think it is probably a little bit more than half. Probably around 60 percent.

Senator BURR. Dr. Marks.

Dr. MARKS. I cannot tell you the exact number, but it—it is probably in the same range. Some people vaccinated at our facility and others outside of the facility.

Senator BURR. Dr. Walensky.

Dr. WALENSKY. We are encouraging our employees to get vaccinated. We have been doing town halls and education seminars. We have—our staff have the option to report their vaccination status. But, as you understand, the Federal Government is not requiring it, so we do not know.

Senator BURR. Okay. And, listen, you are the face of why people should get vaccinated, and no one—and promoting and confidently giving numbers, percentages, I think is really, really important as we go into this last part.

Now, if you tell me that there is some statute that says you cannot require somebody to tell you, imagine being the parent of a school age kid who for generations has been required to have their kids vaccinated before they could start school. And, the fact that, even within our health organizations, we cannot require that of people, we are going to have tough decisions to make.

Employers are going to make those decisions. There have been decisions already made by colleges around the Country that said if you are on faculty or you are a student, you are not coming next year if you are not vaccinated. Now, they have the ability to do that.

These are tough questions with even tougher answers. But, if we are going to get that last mile coverage, we are going to have to start portraying that we are willing to do to ourselves what we are asking the American people to do.

Dr. Walensky, I think it is safe to say that the 21st Century is something that the CDC has not totally entered, but I am confident that you are going to take them there, and especially as it relates to science and technology.

My question is simple. Do you believe the CDC director should meet with private industry and innovators who have new technologies that can help modernize the CDC?

Dr. WALENSKY. Thank you. I think I have an extraordinary opportunity as being the director of the CDC during this period of time. I think that much of what we are going to need to do in public health is going to take collaboration with academia, with government, with private sector, with non-profits. And I am looking forward to engaging in those in a transparent, open way so that we can have that dialog and create those collaborations.

Senator BURR. Let me go back and ask you one more time. Do you believe that the CDC director should meet with private industry and innovators that have new technologies?

Dr. WALENSKY. I believe that we should—I should be encouraging all of those collaborations, and I am relying on my senior leadership team, my subject matter experts, to engage in many of those conversations.

Senator BURR. But not you?

Dr. WALENSKY. If it is a subject matter where I am an expert, I would be happy to, absolutely.

Senator BURR. I think in a question to your staff, they suggested that you could not, but I will revisit that through my staff to yours.

I have to say that I am little bit confused on the issue of CDC guidance after hearing my colleagues, Senator Collins and Senator Cassidy, about exactly who is involved in content and language. So, I sent to CDC an oversight letter, and I got your response to it on 22 April, and I will just highlight a few things.

CDC uses its emergency response clearance protocol to clear items during emergency responses. This emergency response clearance is applicable to all CDC-authored, CDC-branded information products with content related to an active or ongoing response, such as COVID-19 response.

The clearance process consists of a series of formal reviews, approvals, by relevant CDC subject matter experts, SMEs, and Agency clearance officials. This typically consists of content, development, and review by CDC's relevant COVID-19 Response Task Force or SMEs, followed by additional review coordinated by CDC's Joint Information Center.

At no point, given the opportunity, did the letter mention anything about people outside of government. It could be parents. It could be the National Education Association. It basically said this all happens within government.

Now, that is not what I heard my colleagues say as it related to the guidance on schools, that there was input provided by outside entities. And, as a matter of fact, I went ahead and pulled all the email chains that I think was accessed by the media outlets that made them write this story.

I will just say that it is a little bit alarming because it is all done on a timeline, and it suggests that AFT leadership—not sure what the issue was they raised, but they certainly changed the language of the guidance because there is actually email that thanked them for the language that they provided.

When you look at the timeline between that and White House announcement, one would have a hard time believing that every-

thing went through a clearance process that was described in the oversight response letter to me. So, I would ask you clear it up for me, if you would.

Dr. WALENSKY. Thank you. Thank you for that question. So, as I mentioned to Senator Collins, prior to our putting our guidance through a formal clearance process, we do an enormous amount of stakeholder engagement to ensure that the guidance can actually address the questions asked. In fact, I can tell you, on the other side, when I was a healthcare provider at Massachusetts General Hospital, I would frequently call my colleagues at the CDC and say, we need guidance on X, it needs to address X, Y, and Z.

In the stakeholder engagement for the schools, we did outreach with over 50 organizations. We spoke to teachers. We spoke to parents. We spoke to superintendents. We spoke to many different stakeholders to understand what it is that they needed from our guidance.

As I mentioned previously, in doing so, we recognized, in meeting with the teachers, that we had actually failed to comment on what happened if teachers were immunosuppressed, if teachers were undergoing chemotherapy, if they had a family member with a transplant at home, how we were going to engage and provide guidance to those. It was the CDC scientists that provided the guidance, that provided the science around what we should do. It was the request from teachers to say, you did not address this issue, and we had not.

Senator BURR. The first contact by AFT with your staff was on February 1st, Monday, February 1st. And your staff person—we were able to review a copy of the draft guidance or—excuse me.

Troutner with the AFT. We were able to review draft guidance documents over the weekend. We are able to provide some initial feedback to several staff this morning about possible ways to strengthen the document.

That is on February 1st in the morning. On February 2nd, your staff emailed to you that they had followed-up with suggested language on accommodations per exchange.

On February 3rd at a White House press conference, you say schools can open, reopen without teachers being vaccinated.

Would one reading this be concerned with this timeline and what the oversight letter told me was the protocol that you went through to have guidance signed off on?

Dr. WALENSKY. In the February 3rd press—first of all, in the February 3rd press conference, that was before our guidance was released. That was speaking to science and studies that demonstrated that schools had effectively reopened without teachers being vaccinated and keeping students and children safe. February 3rd pre-dated our guidance release, which I believe was February 12th, although I would have to confirm.

You may recall at the time that in the media I took quite a hit for commenting on that from teachers themselves. They were not happy with me at the time.

Senator BURR. With the success of AFT, the NEA engages you, and you actually committed to do an NEA town hall meeting. Is that right?

Dr. WALENSKY. We were engaging at the time with over 50 organizations—teachers, superintendents, parents alike—at the time when our school guidance came out as a matter of practice and in an unbiased fashion.

Senator BURR. Well, Madam Chair, I am going to ask that the letter and the emails be included as part of the record.

The CHAIR. Without objection.

[The information referred to follows:]

Senator BURR. I want to make this observation, that I hope you can understand why Members express frustrations on guidance, that there is a chain of information that suggests people had a preferred access to not only advice, but actual language that went into the guidance.

I know what your answer to my last question is going to be because I have stated it in one of the emails.

Should CDC guidance suggest that all states should require teachers to be vaccinated?

Dr. WALENSKY. I would encourage all teachers to be vaccinated. We spent the month of March providing vaccines through our Federal pharmacy programs and we got over 80 percent of our teachers and educators vaccinated as a—through that process. So, I am certainly encouraging that all teachers be vaccinated.

I think that the guidance with regard to mandatory vaccination in schools is going to have to be done at the local level.

Senator BURR. Would you provide guidance that suggested to schools that they vaccinate teachers?

Dr. WALENSKY. We have been encouraging vaccination of teachers—

Senator BURR. All teachers.

Dr. WALENSKY. We have been encouraging vaccination of all teachers, of all educators, of all parents, of all students.

Senator BURR. Is that in guidance?

Dr. WALENSKY. I would have to confirm because I do not know whether our most recent updated guidance for schools actually had widespread availability of vaccine.

Senator BURR. Okay. The Chair has been awfully kind to me, and I am not trying to pick.

As I said when I started, the next several months are going to be extremely tough at getting people vaccinated. I do not want any of us to lose focus on what the mission is out there. I know for all of you, I am stating the obvious, that we have to stay focused on vaccines.

But, the confidence the American people have in you is a lot of what is going to make us successful. As Dr. Fauci and I have talked many times about, thank God we had in place an architecture that we perfected over the last 20 years that allowed things to happen organically, like EUAs and this type of thing.

It was not because we experienced anything. We went through little red flags, H1N1, SARS, Ebola, where we looked at it and said, boy, if this had been the big one, what would we have changed, and collectively, we went through and changed them. We were much better prepared a year ago architecturally, and 80 percent of what we did was following the statute that is out there and the authorities that were given to many of your institutes or agencies. Or, in



Dr. Marks' case, to the FDA. And, I have to tell you that I believe what the FDA has accomplished, I never dreamed they could do.

My goal now is to make sure we do not roll back. Because as we move into technology platforms, that is not something that is easy to go back and do clinical trials on again if you are just looking for a new indication. But, I have to tell you that I believe that schools going back in person in the fall is absolutely crucial to getting a majority of the parents who have yet to be vaccinated, vaccinated. And knowing that at least by the end of this month, if we are not already there, every adult that wants to be vaccinated can be vaccinated.

It is time for us to start setting the stage and paint the picture for what the fall looks like; that people can go on vacation this year and they can eat in a restaurant, in the Outer Banks of North Carolina, preferably; that they can plan their summer vacation; hopefully, in a few more weeks or days, maybe they can go to camp; that in the fall, we expect every school to be in person, short of some drastic change in the infection glidepath; and next Thanksgiving, you ought to plan to have Thanksgiving with your family and extended family; and Christmas, you ought to be able to enjoy.

If we paint that type of picture, I believe, David, we are going to get people vaccinated. But, if we continue to fail at the trust that they have in us making the calls that are appropriate at the time, feeling like they are influenced in any way, feeling like we are not out there where we need to be interpreting the science, we are going to fail, and we are going to fail for the American people. But, more importantly, we are going to fail for the world because the world right now is relying on us getting to that number and us providing the technology and the manufacturing capacity for them to be vaccinated. So, we have a big step ahead of us.

I am delighted that all four of you are here today. I thank you for the work that you have done up to this point and, more importantly, for the work you are going to do in the future.

I thank the Chair.

The CHAIR. Thank you. That will end our hearing today.

I want to thank all of our colleagues who are here. I especially want to thank all of our witnesses today. Thank you all, Doctors Walensky, Fauci, Marks, and Kessler, for joining us to update on this fight against this pandemic, and to tell you thank you to all of those who work for you and have been diligent and trying to make tough decisions in a difficult time to help protect all Americans. So, thank you very much to you and to all the people that work with you.

For any Senators who wish to ask additional questions, questions for the record will be due in 10 business days, on Tuesday, May 25th, at 5 p.m. The hearing record will remain open until then for Members who wish to submit additional remarks and materials for the record.

The Committee will next meet tomorrow, Wednesday, May 12th, to mark up the nominations of Jocelyn Samuels to be a member of the Equal Employment Opportunity Commission, Jennifer Abruzzo to serve as General Counsel of the National Labor Relations Board, and Seema Nanda to serve as Solicitor for the Department of Labor.

With that, the Committee stands adjourned.

## ADDITIONAL MATERIALS

### A Misleading C.D.C. Number

By David Leonhardt

*The New York Times*

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When the Centers for Disease Control and Prevention released new guidelines last month for mask wearing, it announced that “less than 10 percent” of Covid-19 transmission was occurring outdoors. Media organizations repeated the statistic, and it quickly became a standard description of the frequency of outdoor transmission.

But the number is almost certainly misleading.

It appears to be based partly on a misclassification of some Covid transmission that actually took place in enclosed spaces (as I explain below). An even bigger issue is the extreme caution of C.D.C. officials, who picked a benchmark—10 percent—so high that nobody could reasonably dispute it.

That benchmark “seems to be a huge exaggeration,” as Dr. Muge Cevik, a virologist at the University of St. Andrews, said. In truth, the share of transmission that has occurred outdoors seems to be below 1 percent and may be below 0.1 percent, multiple epidemiologists told me. The rare outdoor transmission that has happened almost all seems to have involved crowded places or close conversation.

Saying that less than 10 percent of Covid transmission occurs outdoors is akin to saying that sharks attack fewer than 20,000 swimmers a year. (The actual worldwide number is around 150.) It’s both true and deceiving.

This isn’t just a gotcha math issue. It is an example of how the C.D.C. is struggling to communicate effectively, and leaving many people confused about what’s truly risky. C.D.C. officials have placed such a high priority on caution that many Americans are bewildered by the agency’s long list of recommendations. Zeynep Tufekci of the University of North Carolina, writing in *The Atlantic*, called those recommendations “simultaneously too timid and too complicated.”

They continue to treat outdoor transmission as a major risk. The C.D.C. says that unvaccinated people should wear masks in most outdoor settings and vaccinated people should wear them at “large public venues”; summer camps should require children to wear masks virtually “at all times.”

These recommendations would be more grounded in science if anywhere close to 10 percent of Covid transmission were occurring outdoors. But it is not. There is not a single documented Covid infection anywhere in the world from casual outdoor interactions, such as walking past someone on a street or eating at a nearby table.

Today’s newsletter will be a bit longer than usual, so I can explain how the C.D.C. ended up promoting a misleading number.

### The Singapore Mystery

If you read the academic research that the C.D.C. has cited in defense of the 10 percent benchmark, you will notice something strange. A very large share of supposed cases of outdoor transmission have occurred in a single setting: construction sites in Singapore.

In one study, 95 of 10,926 worldwide instances of transmission are classified as outdoors; *all* 95 are from Singapore construction sites. In another study, four of 103 instances are classified as outdoors; again, all four are from Singapore construction sites.

This obviously doesn’t make much sense. It instead appears to be a misunderstanding that resembles the childhood game of telephone, in which a message gets garbled as it passes from one person to the next.

The Singapore data originally comes from a government data base there. That data base does not categorize the construction site cases as outdoor transmission, Yap Wei Qiang, a spokesman for the Ministry of Health, told my colleague Shashank Bengali. “We didn’t classify it according to outdoors or indoors,” Yap said. “It could have been workplace transmission where it happens outdoors at the site, or it could also have happened indoors within the construction site.”

As Shashank did further reporting, he discovered reasons to think that many of the infections may have occurred indoors. At some of the individual construction sites where Covid spread—like a complex for the financial firm UBS and a sky-

scrapper project called Project Glory—the concrete shells for the buildings were largely completed before the pandemic began. (This video of Project Glory was shot more than 4 months before Singapore’s first reported Covid case.)

Because Singapore is hot year-round, the workers would have sought out the shade of enclosed spaces to hold meetings and eat lunch together, Alex Au of Transient Workers Count Too, an advocacy group, told Shashank. Electricians and plumbers would have worked in particularly close contact.

### **Are schools outdoors?**

How, then, did the Singapore cases get classified as they did?

When academic researchers began collecting Covid data from around the world, many chose to define outdoors spaces very broadly. They deemed almost any setting that was a mix of outdoors and indoors to be outdoors.

“We had to settle on one classification for building sites,” Quentin Leclerc, a French researcher and co-author of one of the papers analyzing Singapore, told me, “and ultimately decided on a conservative outdoor definition.” Another paper, published in the *Journal of Infection and Public Health*, counted only two settings as indoors: “mass accommodation and residential facilities.” It defined all of these settings as outdoors: “workplace, health care, education, social events, travel, catering, leisure and shopping.”

I understand why the researchers preferred a broad definition. They wanted to avoid missing instances of outdoor transmission and mistakenly suggesting that the outdoors was safer than it really was. But the approach had a big downside. It meant that the researchers counted many instances of indoors transmission as outdoors.

Yet even with this approach, they found a minuscule share of total transmission to have occurred outdoors. In the paper with 95 supposedly outdoor cases from Singapore, those cases nonetheless made up less than 1 percent of the total. A study from Ireland, which seems to have been more precise about the definition of outdoors, put the share of such transmission at 0.1 percent. A study of 7,324 cases from China found a single instance of outdoor transmission, involving a conversation between two people.

“I’m sure it’s possible for transmission to occur outdoors in the right circumstances,” Dr. Aaron Richterman of the University of Pennsylvania told me, “but if we had to put a number on it, I would say much less than 1 percent.”

### **Britain’s Scientific Approach**

I asked the C.D.C. how it could justify the 10 percent benchmark, and an official there sent this statement:

There are limited data on outdoor transmission. The data we do have supports the hypothesis that the risk of outdoor transmission is low. 10 percent is a conservative estimate from a recent systematic review of peer-reviewed papers. CDC cannot provide the specific risk level for every activity in every community and errs on the side of protection when it comes to recommending steps to protect health. It is important for people and communities to consider their own situations and risks and to take appropriate steps to protect their health.

Erring on the side of protection—by exaggerating the risks of outdoor transmission—may seem to have few downsides. But it has contributed to widespread public confusion about what really matters. Some Americans are ignoring the C.D.C.’s elaborate guidelines and ditching their masks, even indoors, while others continue to harass people who walk around outdoors without a mask.

All the while, the scientific evidence points to a conclusion that is much simpler than the C.D.C.’s message: Masks make a huge difference indoors and rarely matter outdoors.

The health authorities in Britain, notably, seem to have figured this out. They have been more aggressive about restricting indoor behavior, locking down many businesses again late last year and requiring masks indoors even as most of the country is vaccinated. Outdoors, however, masks remain rare.

It certainly doesn’t seem to be causing problems. Since January, daily Covid deaths in Britain have declined more than 99 percent.

[Whereupon, the hearing was adjourned at 12:42 p.m.]

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