

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**TESTIMONY**

**OF**

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## **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 infusion sites 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.