

TESTIMONY

OF

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CHIEF SCIENTIFIC OFFICER
COVID-19 RESPONSE**

BEFORE THE

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

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

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Introduction

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

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

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

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

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

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

One of the first tasks that we undertook, when Pfizer and Moderna supplied the only

two authorized vaccines, was to make 300 million doses of each available by July 31st of this year. Working with each company, we were then able to get them to agree to deliver 200 million doses each by the end of May.

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

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

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

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

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

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

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

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

next iteration of these vaccines. We will remain vigilant and pursue options to protect Americans if the need arises.

The third issue I want to address today is our planning around the questions of if and when Americans who have been vaccinated might need a booster dose. In collaboration with my colleagues testifying today, we are studying the durability of the existing vaccines to continue to mount an effective immunological response.

Preliminary data show that neutralizing antibodies persist for some time after the second dose of an mRNA vaccine with a relatively slow decline over time. As with other vaccines, such as the influenza vaccines, a subsequent dose may be important to provide continued protection against the wild-type strain but also may be critical to maintain protection against variants. The good news is that there are many potential options that we can consider for potential booster doses. We are evaluating and expanding studies to determine which options would be effective to achieve ongoing protection. As you can imagine there are numerous potential combinations of vaccine doses that might help protect Americans in the future. Therefore, we are also planning now to make sure we have sufficient vaccine available to support this potential need.

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