U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Hearing Titled
Hybrid Hearing with Secretary of Health and Human Services Alex M. Azar II

Witness appearing before the
House Select Subcommittee on the Coronavirus Crisis

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October 2, 2020

It is an honor to submit written testimony for the House Select Subcommittee on the Coronavirus Crisis. I wish to express my gratitude, on behalf of the Department of Health and Human Services (HHS) and the Trump Administration, for the support that Congress has provided for our response throughout the COVID-19 crisis. The funding, flexibilities, and innovative programs Congress has passed into law have saved American lives and helped slow the spread of the virus.

Together, we have made tremendous progress against this unprecedented crisis. As of late September, the number of new cases was down approximately two-thirds from its peak earlier this summer. The number of hospitalizations and deaths from the virus continue to decline. Thanks to efforts by American scientists and healthcare providers, America's fatality rate from confirmed cases of COVID-19 has dropped significantly over time and is substantially lower than many of our peer nations in Europe.

These results are possible because of the all-of-America approach led by President Trump's administration and Congressional support. I will mention three particular areas where the administration has constructed a successful response strategy from the ground up: testing, personal protective equipment, and Operation Warp Speed's efforts on vaccines and therapeutics.

As soon as the United States learned of the virus—and received the information necessary from China to begin diagnostic work—our public health agencies began in earnest to prepare capabilities to diagnose the virus. On January 22, we stood up an interagency diagnostics working group with partners across HHS and the Department of Defense. On February 4, when there were just 11 cases in the United States, the Food and Drug Administration (FDA) issued an Emergency Use Authorization for the diagnostic test developed by the Centers for Disease Control and Prevention (CDC), which was soon available for order and shipped to public health labs in the United States and around the globe. When a performance issue with one reagent in the CDC test was identified, it was rectified promptly.

But, we quickly learned, our public health testing infrastructure was not designed to handle such a serious, nationwide threat. That is why, back in January, FDA began working with private-sector test developers, sharing templates for emergency use authorizations. On January 21, the first day that a U.S. case was confirmed (from travel), the Biomedical Advanced Research and Development Agency (BARDA) began development activities with diagnostics developers. On February 29, FDA allowed private labs to begin patient testing, with notification to the agency.

Around this time, we now know from retrospective work by the CDC, there was still only limited community spread in the United States—slowed, in significant part, by the decisive actions President Trump had taken to restrict travel from China. The Administration's unprecedented action to allow private labs to begin testing was a bold step toward building what has now become the world's largest and most successful testing system.

As of September 23, more than 104 million tests have been performed with, just a 4.3 percent positivity rate nationwide. 96 percent of commercial test results are being completed in less than 3 days, excluding the millions of point-of-care tests performed that deliver results in less than an hour.

FDA has now authorized more than 200 different diagnostics for the virus, and more convenient, faster options enter the market, with HHS's assistance and support, all the time. We supported the creation of more than 1,000 community-based testing sites, the majority in vulnerable communities. Rapid point-of-care tests have now been supplied by HHS to all eligible nursing homes in America, as well as to tribal healthcare facilities and to historically Black colleges and universities.

Similar to our testing efforts, work to ensure our country had sufficient medical supplies began as soon as the virus was identified as a serious public health threat to the United States. In late January, HHS convened a Disaster Leadership Group to align government-wide partners regarding the outbreak situation, communications strategies, and the potential medical countermeasure pipeline, including reviewing and making use of the 2017 pandemic influenza plan. In the final week of January, conversations began with U.S. manufacturers of N95 respirators, enabling production on U.S. soil to rise from about 250 million a year in January to about 640 million a year in March.

Throughout the crisis, HHS has worked with the Federal Emergency Management Agency on an unprecedented effort to coordinate America's complex private supply chains, directing and shipping tens of thousands of tons of supplies where they were needed most. Today, many hospitals are now building 60 to 90 days of supplies.

Building on these lessons, President Trump has already launched a next-generation Strategic National Stockpile, which enables us to use existing private-sector supply chains by having total visibility into where resources are going and need to go. We are also refilling the stockpile itself: We are on track to have 90 days of supplies on hand this fall. Since the start of the pandemic, we now have six the amount of N95s on hand than pre-pandemic levels, at more than 85 million, and are on track to have over ten times as many by the end of this fall. These efforts involve major support for manufacturing of medical products here at home, including through vendor-managed inventory at the stockpile.

Third, our success through Operation Warp Speed also had its roots in early work by American scientists and public health experts, under the leadership of President Trump. On January 10, the same night the viral sequence was shared by researchers in China, scientists at the National Institutes of Health (NIH) and their collaborators at Moderna began work on a vaccine. That vaccine entered human trials on March 16 in record time. On February 3, we began repurposing and obligating flexible funds to go to private partners to support vaccine and therapeutic development. The next day, we made our first therapeutic funding announcement, a partnership

with Regeneron to develop therapeutics from monoclonal antibodies, which are now in Phase 3 trials—an unprecedented time frame for an antiviral therapeutic.

On February 25, NIH began enrolling patients in a clinical trial for the promising antiviral remdesivir, which reported positive results at the end of April. In short order, the Trump Administration secured a donation of approximately 150,000 treatment courses of the drug from the maker, Gilead, which was distributed in May and June to the hardest hit areas of the country, and then secured more than 90 percent of Gilead's production through September. At this point, some states and hospitals have reported a surplus of the drug.

Working with our partners across the administration, we built on these early efforts to create Operation Warp Speed, which has provided unprecedented support to simultaneously begin all of the work, from development to manufacturing, that is necessary to deliver these potentially lifesaving products to the American people.

Today, we have four candidate vaccines in U.S. Phase 3 clinical trials. Pending FDA approval or authorization, we anticipate to have manufactured enough vaccine by the end of 2020 to vaccinate certain priority populations and enough to vaccinate all Americans by March to April 2021. Meanwhile, trials for other promising therapeutics continue, with the FDA having reviewed more than 310 clinical trials for treatments.

Science and evidence—including the FDA's gold standard and the expertise of its career scientists—will continue to guide Operation Warp Speed's work as we progress toward a lifesaving vaccine that will help us end this crisis.

These are extraordinary results—made possible by the men and women of HHS, by the support we have received from Congress, and by the bravery and sacrifices of the American people.

We grieve for every American we have lost to this unprecedented virus, and our deepest sympathies are with their loved ones and their communities. Our united efforts will continue to save lives and, in time, bring this pandemic to an end and leave us a stronger nation, readier to protect ourselves from such threats in the future.