

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE of the ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Testimony before the
House Select Subcommittee on the Coronavirus Crisis

**Moving Beyond the Coronavirus Crisis: The Biden Administration's Progress in
Combating the Pandemic and Plan for the Next Phase**

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Chair Clyburn, Ranking Member Scalise, and distinguished members of the Select Subcommittee, it is an honor to testify before you today on efforts within the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) to respond to the COVID-19 pandemic and prepare for future threats. I am grateful for this opportunity to address this Select Subcommittee and appreciate your continued support.

Update on ASPR's COVID-19 Response Effort

Now in our third year of the pandemic, we continue to apply a whole-of-government approach in responding to the virus, investing in tools and resources to keep Americans safe, and preparing for whatever may come next. At the direction of Secretary Becerra and in my role as ASPR, I am responsible for leading HHS' COVID-19 response coordination. In this role, I work closely with my fellow panelists on all facets of the Department's response; however, for the purposes of this testimony, I will focus my update on the work for which the ASPR organization is chiefly responsible.

Vaccines

The vaccines available to us today are the result of an unprecedented partnership between HHS and the Department of Defense (DoD), through the Countermeasures Acceleration Group (CAG), previously known as Operation Warp Speed. Together, this team along with important contributions from the Biomedical Advanced Research and Development Authority (BARDA), and other HHS components, helped develop and deliver over 700 million free doses of vaccine to protect the American people from COVID-19.

On January 1, 2022, we successfully completed the long-planned transition of this work to the recently established HHS Coordination Operations and Response Element, or HCORE. HCORE institutionalizes the efforts previously led by the CAG within ASPR. It will allow us to build on the progress to date, retain expertise and skills, and continue providing the necessary tools to the American people to respond to the COVID-19 pandemic.

HCORE leads, in partnership with the Centers for Disease Control and Prevention (CDC), the rollout and distribution of the Pfizer, Moderna, and Johnson & Johnson vaccines and boosters. These vaccines are being administered widely, through the CDC COVID-19 vaccination program, at 90,000 locations around the country, and supply is available in the field to meet the needs for both booster and primary series vaccinations. However, should an additional dose or doses of vaccine be recommended, we will need additional funding from Congress. The introduction of vaccines for children ages 5 through 11 has resulted in over 9.8 million children vaccinated in this age group. Significant work with the local, state, federal, territorial, and pharmacy partners continues to ensure that there is ample vaccine available at locations where young children are likely to receive their vaccines. We continue to work with manufacturers and our HHS partners on the development of a vaccine for younger children.

Therapeutics

HCORE has and continues to purchase and distribute to states and jurisdictions a wide variety of treatments including monoclonal antibodies and oral antivirals. We currently allocate monoclonal antibody treatments Sotrovimab, Bebtelovimab, and Evusheld, and oral antiviral

treatments Molnupiravir and Paxlovid to states and territories for free on a weekly basis. We continue to work with state and territorial health department, clinicians, patient advocacy groups, media, and other stakeholders to raise awareness and education around the availability and appropriate use of these lifesaving drugs. Our ability to continue providing therapeutics is contingent upon additional funding from Congress.

As part of President Biden's *National COVID-19 Preparedness Plan* to help America move forward safely, the Administration launched a nationwide Test to Treat Initiative so Americans can rapidly access needed COVID-19 treatments. Through this program, people can visit nearly 2,000 local pharmacy-based clinics, federally qualified community health centers (FQHCs), and other sites to be tested for COVID-19 and those that test positive can be assessed by a qualified health care provider who can prescribe antiviral pills on the spot if they are appropriate. This ensures that if people who are at high risk for developing severe disease test positive and if administration of an antiviral is appropriate, they can get treatment quickly and easily.

Participating Test to Treat locations receive the oral antiviral drugs, including Pfizer's Paxlovid and Merck's Molnupiravir, through a direct federal ordering process. This allocation does not decrease allocations states and jurisdictions are already receiving, which means that individuals can still continue to get a prescription through their regular healthcare provider and pick up the prescription at any location where antivirals are being distributed. This means faster treatment for eligible individuals at highest risk of poor outcomes from COVID-19. Our ability to sustain this program is contingent upon additional funding from Congress.

Testing

Testing continues to be a vital part of disease surveillance, diagnosing illness, connecting patients to treatment, and keeping business and schools open. We've made significant progress in increasing testing supply, availability, and affordability over the past year. We went from zero over-the-counter tests in January 2021, to approximately 300 million tests in December 2021. HHS invested \$3 billion in the fall to accelerate production of rapid tests and expanded capacity. At ASPR, we know partnership with industry is critical to ensuring that success continues, which is why I visited an Abbott BinaxNOW manufacturing facility in Illinois to meet with company leadership, visit with the employees on the production floor, and see the manufacturing process up-close. The advances we have made in testing are reflective of a broader effort within ASPR to bolster our industrial base expansion and supply chain efforts.

In January, President Biden announced a plan to make 1 billion free at-home tests available to the American people and mail them directly to their homes via COVIDTests.gov. In partnership with the U.S. Postal Service, we have delivered hundreds of millions of tests, and recently opened up a second round of ordering.

Since May 2021, ASPR has also shipped over 115 million rapid antigen tests and 5.8 million point-of-care PCR tests to our most vulnerable populations, including nursing homes, federally qualified health centers, and long-term care facilities. In addition to the purchase and distribution of these tests, ASPR continues to work with manufacturers, companies, and laboratories to identify and proactively address any supply issues.

Without additional funding from Congress, the country will be unable to maintain our domestic testing capacity beyond June. And it will take months to rebuild this capacity.

Masks

In January, the Administration announced a plan to make N95 respirators available to Americans for free via ASPR's Strategic National Stockpile (SNS). To date, ASPR's Strategic National Stockpile has shipped approximately 250 million N95 masks to pharmacies and community health centers nationwide. This initiative ensures that any American who wants a mask has access to a free high-quality product.

This effort represents the largest deployment by the Strategic National Stockpile to date and it is also the largest deployment of personal protective equipment in U.S. history. This effort is only possible because of the steps we have taken to restore the SNS over the past year. Since January 2021, we have tripled the number of N95 respirators held in the SNS to more than 539 million. Even after this deployment we will have 350 million surgical, FDA-cleared N95s for use as needed by healthcare workers. That's nearly 20 times as many N95 respirators as there are health care workers in the U.S. We will continue to assess the number of masks needed and replenish the stockpile accordingly – and as we do, we will continue to focus on domestically manufactured masks. It is important to note that this initiative leverages and advances priorities of the Resilient Public Health Supply Chain strategy as well as priorities and requirements included in Congressional legislation aiming to strengthen domestic manufacturing and production of PPE, including the materials and components thereof.

Deploying Medical Response Teams to Communities in Need

Throughout the pandemic, National Disaster Medical System (NDMS) teams have served as a lifeline to hospitals by providing temporary relief to staff, adding bed capacity, decreasing wait times, and improving outcomes for patients. Since the start of the pandemic, NDMS teams – which include doctors, nurses, paramedics, and other medical and support professionals – have provided a range of support including hospital decompression, vaccine and monoclonal antibody administrations, and mortuary support. As we move forward and if any new variants emerge, we will continue to make resources available to states, territories, and communities to respond.

Of note, this critical system, the National Disaster Medical System, requires a renewal of its direct hiring authority, which was set to expire on September 30, 2022 and was extended for another year as part of the FY22 Omnibus Appropriations law (Public Law 117-103). NDMS has utilized this authority to bring on additional personnel – over 1,000 personnel hired to date – and will continue to utilize the expedited authority, if extended by Congress, to continue to enhance the force.

Restoring the Strategic National Stockpile Inventory

The pandemic severely strained our public health and medical supply chains. The medical supply chain ecosystem is complex, with different private sector players and market dynamics across multiple domains of medical equipment and supplies. Many vital products and their raw materials are primarily made overseas, and practices like “just in time” inventory management resulted in difficulty accelerating manufacturing when demand surged last spring. This created

significant and devastating challenges for States, territories, and healthcare systems that required access to these key supplies.

Over the course of the COVID-19 response, the SNS has worked to backstop States' medical supply needs at an accelerated pace. Since the beginning of the pandemic, the SNS has deployed more than 250 million items to aid the national response including Personal Protective Equipment (PPE), ventilators, Federal Medical Stations, and pharmaceuticals. In particular, the SNS deployed almost 3,000 ventilators to 17 jurisdictions between July and October 2021, to respond to the Delta variant case surge. The SNS has deployed more than 300 ventilators and High Flow Nasal Cannula to six jurisdictions since Omicron emerged.

ASPR has worked to replenish SNS inventory to levels at or above pre-COVID-19 amounts to ensure we are prepared for any subsequent wave of additional cases and to do so – to the extent possible – with domestically manufactured supplies and equipment. As of March 21, 2022, the SNS has utilized approximately \$12 billion from COVID-19 supplemental appropriations provided by Congress to have in its inventory approximately: 539 million N95 respirators (42 times pre-pandemic levels); 274 million surgical and procedure face masks (8.5 times pre-pandemic levels); 19.6 million face shields (two times pre-pandemic levels); 59.6 million gowns and coveralls (12.5 times pre-pandemic levels); 4.6 billion gloves (272 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels).

Industrial Base Expansion

While replenishing the SNS is essential, it is also critical to address the root cause of why supply chains were so strained in the first place. ASPR is taking on this work as well since ensuring a safe and consistent public health supply chain for medical materials, ingredients, and supplies is critical for any national response to public health emergencies.

Throughout the COVID-19 response, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) to issue 66 priority ratings for United States Government (USG) contracts for health resources, eight priority ratings for USG contracts for industrial expansion, three priority ratings for non-USG contracts to support the production of resins for both diagnostics and infusion pumps, and the manufacture of closed suction catheters for treatment of patients with COVID-19—all to ensure private sector partners making life-saving products are able to acquire the raw materials, components, and products requisite to deliver for the response.

Also, under the DPA, ASPR is strengthening the industrial base to secure and develop domestic capacity, retool, and expand industry machinery, scale production facilities, train workforces, and ultimately infuse the supply chain and marketplace with products the U.S. needs to contain further pandemic waves. ASPR continues to invest in critical funding in expanding domestic manufacturing including investments in manufacturing PPE, testing consumables, vaccine raw material, vaccine vials, at home and point of care tests, and testing raw materials. Each of these domestic manufacturing initiatives meets current, as well as future COVID-19 needs, and seeks to create or sustain high-value domestic jobs, consistent with the President's strategy to revitalize our manufacturing base, strengthen critical supply chains, and position U.S. workers and

businesses to compete and lead globally in the 21st century. Continuation of these investments is contingent on additional funding.

All of these investments, and the industrial base overall, require dedicated and persistent management and engagement. As such, my intent is to institutionalize this mission in ASPR. I am working to integrate and organize supply chain situational awareness and industrial analysis, domestic industrial base expansion, and supply chain logistics within ASPR. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the COVID-19 response. I look forward to answering your questions and working with my team at ASPR and our colleagues across HHS to end the COVID-19 pandemic.