THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE of the ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

Testimony before the
Senate Committee on Health, Education, Labor, and Pensions

Hearing Titled
An Update on the Ongoing Federal Response to COVID-19: Current Status and Future Planning

Dawn O'Connell
Assistant Secretary for Preparedness and Response

June 16, 2022

Chair Murray, Ranking Member Burr, and distinguished members of the Committee, 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 current pandemic, restore and strengthen our capabilities, and prepare for future health emergencies. I am grateful for this opportunity to address this Committee and appreciate your continued support.

Update on ASPR's COVID-19 Response Effort

As we enter the third year of the pandemic, we continue to apply a whole of government approach to protect Americans from COVID-19. 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.

HHS Coordination Operations and Response Element (HCORE)

The vaccines and therapeutics available to us today are the result of an unprecedented partnership between HHS and the Department of Defense, through the Countermeasures Acceleration Group (CAG), previously known as Operation Warp Speed. Together this team, has helped develop and deliver over 751.4 million doses of vaccine and 11.3 million treatment courses to protect the American people from COVID-19.

On December 31, 2021, our Memorandum of Understanding with DOD expired and on January 1, 2022, we successfully completed the 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.

Since my last appearance before the committee, HCORE continues to lead, in partnership with CDC, the rollout and distribution of vaccines and boosters. These vaccines are being administered widely at 90,000 locations around the country, and ample supply is available in the field to meet the needs for both booster and primary series vaccinations. Additionally, the introduction of vaccines for children ages 5 through 11 has resulted in over 10.3 million first doses delivered for this population. We are also preparing to support the distribution of vaccine for kids under five, if and when FDA authorizes, and CDC recommends, a vaccine for that population. We have plenty of supply of both Pfizer and Moderna vaccines appropriate for this population, and we are making 10 million doses available to states, pharmacies, community health centers, and federal entities to order initially. Meanwhile, we are also preparing for the potential emergency use authorization of Novavax's protein-based vaccine that, if authorized, would provide those who are allergic to mRNA vaccine or prefer non-mRNA an option to get vaccinated.

In addition to vaccines, HCORE continues to purchase and distribute to states and jurisdictions a variety of treatments including monoclonal antibodies and oral antivirals.

Today we allocate four different products – two oral antivirals, Pfizer's Paxlovid and Merck's Lagevrio; the monoclonal antibody treatment Bebtelovimab from Eli Lilly; and AstraZeneca's Evusheld for pre-exposure prophylaxis for immunocompromised people. We are focused on making sure that providers and patients know these products are available, that they're free and that they are available at approximately 50,000 locations nationwide.

In March, we launched the Test-to-Treat initiative that gives individuals an opportunity to rapidly access free treatments at approximately 2,600 pharmacy-based clinics, federally qualified health centers, and community-based sites. Under this program, people are able to get tested and if they are positive and treatments are recommended for them, receive a prescription from a health care provider (either on-site or via telehealth) and have their prescriptions filled all in one location. In coordination with FEMA, we have also added a federally-supported Test to Treat initiative which allows us to partner with states and territories to support additional Test to Treat sites around the country. We currently have sites in Rhode Island and Minnesota and are evaluating additional proposals from several states.

Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority (BARDA) continues to leverage the supplemental appropriations provided by Congress to support the development of vaccines, therapeutics, and diagnostics to end the COVID-19 pandemic. BARDA has awarded contracts for 81 medical countermeasure projects to aid the COVID-19 response to date. All of these contract awards are listed on medicalcountermeasures.gov in detail and include 18 therapeutics, 56 diagnostics, and seven vaccine candidates. Notably, BARDA has placed 1.5 billion doses of vaccine under contract (including a combination of adult primary, booster, and pediatric doses), distributed over 11.1 million treatment courses of monoclonal antibodies and antivirals, and shipped more than 243 million diagnostic kits.

BARDA also supports research on expanding eligibility for the current authorized and approved vaccines as well as the continued development of vaccine candidates that have not yet been authorized or approved. This ongoing work on vaccines is critical as we begin to look for next generation vaccines that are easier to store, ship, administer and may prove more durable than the current authorized and approved vaccines.

BARDA's work on therapeutics is critical as we seek to balance the ease of administration with the benefits of the treatment. For example, monoclonal antibodies are administered by infusion, which must be done in clinical settings, placing a high burden on patients and healthcare staff. BARDA's collaboration with industry on developing oral antivirals offers an important therapeutic option other than monoclonal antibodies. As a result, there are now two oral antivirals available under EUA for the prehospital treatment of patients at high risk for progression to severe COVID-19. In fact, the administration of oral antivirals has increased six-fold in recent weeks.

BARDA continues to play an important role in the development of diagnostic tests that expand beyond central labs to point of care and at home solutions. This includes contracts for three molecular and two antigen tests for use in both point-of-care and home use settings and for two molecular and five antigen tests for use specifically in point-of-care settings. BARDA has also

expanded its portfolio to include development of respiratory panel tests that, at a minimum, can detect SARS-CoV-2 (the virus that causes COVID-19) plus Influenza, but often can detect for other respiratory viruses. BARDA is funding development of an Omicron-specific molecular test for use in informing monoclonal antibody therapy. Lastly, BARDA has funded six manufacturing capacity expansion efforts to increase domestic testing capacity.

Strategic National Stockpile and Medical Supply Chain

The pandemic has severely strained our public health and medical supply chains. As this Committee is well aware, 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 in the spring of 2021. This created significant and devastating challenges for States 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 610 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.

I highlighted in my testimony in January that ASPR continues to work to replenish SNS inventory to levels at or above pre-COVID-19 amounts to ensure that 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 June 2, 2022, the SNS has utilized approximately $12 billion from COVID-19 supplemental appropriations provided by Congress to have in its inventory approximately: 541 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); 4.8 billion gloves (272 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels). SNS has also made investments to ensure that there is capacity to make these critical supplies.

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.

In response to the COVID-19 pandemic, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) to issue 70 priority ratings. Priority ratings were issued on 54 United States Government (USG) contracts to support the development, production, and/or procurement of critical COVID-19 countermeasures such as vaccines, therapeutics, diagnostics, personal protective equipment, ventilators, and ancillary medical supplies. Additionally, priority ratings were issued on 10 USG contracts to support

manufacturing expansion for vaccines, diagnostics, N95s, and glass vials as well as for vaccine distribution. In six circumstances, the HHS Secretary authorized a private sector partner to apply priority ratings on select purchase orders to ensure continued production of medical devices that were essential in the COVID-19 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.

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 into a new office within ASPR. Bringing these pieces together will strengthen our industry partnerships and support our work to establish and maintain resilient supply chains. I ask for your support as we work to address this effort and would be happy to provide future briefings on this effort as needed.

Testing

In addition to the Industrial Base Expansion efforts I mentioned previously, ASPR continues to support COVID-19 testing for the Nation. 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 available for use in December 2021. HHS has invested billions of dollars in domestic testing manufacturers to accelerate production of rapid tests and expand manufacturing 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 third round of ordering. We are also creating a federal stockpile of COVID-19 tests to rapidly distribute in the event of a surge.

Since May 2021, ASPR has also shipped over 149 million rapid antigen tests and 8.1 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.

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.