

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

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Addressing New Variants: A Federal Perspective on the COVID-19 Response

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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 600 million doses of vaccine and 3.9 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 the Pfizer, Moderna, and Johnson & Johnson vaccines and boosters. While the data suggests that primary doses of vaccine confer reduced levels of protection against Omicron, we know that boosters strengthen protection significantly. 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 6.7 million doses delivered for this population. Significant work with the 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.

In addition to vaccines HCORE continues to purchase and distribute to states and jurisdictions a wide variety of treatments including monoclonal antibodies and oral antivirals. In total, we have bought nearly 30 million treatment courses for patients with COVID-19.

Some of these therapies may be less effective against Omicron, however. The new variant is predicted to have markedly reduced susceptibility to two of the monoclonal antibody treatments we have purchased (Lilly's bamlanivimab/etesevimab and Regeneron's REGEN-COV). However, two of the monoclonal antibody treatments we have procured are expected to retain activity against Omicron—GSK's Sotrovimab and AstraZeneca's EVUSHELD. We are increasing our supply of the GSK monoclonal to 1 million courses over the next few months and are on track to have more than 250,000 courses available in January. AstraZeneca's monoclonal is a pre-exposure therapy which is targeted for immunocompromised individuals at high risk. We will have more than half a million courses on hand in January.

In addition to these monoclonal antibody treatments, the newly authorized oral antiviral pills developed by Merck and Pfizer are expected to retain activity against Omicron and HCore is distributing doses to all states and jurisdictions. More than 360,000 courses were delivered to dispensing sites in December—with a total of about 3 million courses of the Merck antiviral and more than 265,000 of the Pfizer antiviral on the way in January. The Administration recently announced plans to double the Pfizer antiviral order from 10 million to 20 million treatment courses.

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 78 medical countermeasure projects to aid the COVID-19 response to date. All of these contract awards are listed on [medicalcountermeasures.gov](https://www.medicalcountermeasures.gov) in detail and include 16 therapeutics, 55 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 3.3 million doses of monoclonal antibodies, and shipped more than 182 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, many of the available monoclonal antibodies are administered by infusion which must be done in clinical settings. BARDA's collaboration with industry on developing oral antivirals offer an important alternative to monoclonal antibodies. As a result, there are now two antivirals available under EUA for the prehospital treatment of patients at high risk for progression to severe COVID-19.

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 point of care and home use tests and for two molecular and five

antigen point of care only tests. In addition, 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 last spring. 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 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.

I highlighted in my testimony in July that ASPR continues to work 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 December 29, 2021, the SNS has utilized approximately \$12 billion from COVID-19 supplemental appropriations provided by Congress to have in its inventory approximately: 747 million N95 respirators (59 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 billion gloves (240 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels). SNS has also made investments to ensure there is capacity to make these critical supplies.

In addition, to better identify and understand baseline issues during the COVID-19 response and improve future response operations, we supported three meetings with Tribal representatives to determine if changes or updates are needed regarding how federally recognized Tribal governments request SNS support. These listening sessions were in collaboration with the Indian Health Service (IHS), the Centers for Disease Control and Prevention (CDC)/Division of State and Local Readiness, and the HHS/Office of Intergovernmental and External Affairs (IEA). The SNS team continues to engage other key state and local leaders and organizations as it seeks input on how to improve access to the stockpile.

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.

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.

As you are likely aware, several groups outside of ASPR are reviewing the SNS as well as other federal stockpiles. Specifically, the HHS Inspector General (IG) is completing a three-year SNS review. The IG began the review when the SNS transitioned from CDC to ASPR in 2018 but shifted the review slightly in 2020 with the onset of the COVID-19 pandemic to review holdings, requirements, and available resources to meet needs.

In addition, the National Academies (NAS) has reviewed at our request the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), the interagency group of experts that advise, among other things, what should go into the SNS. The full report is available via the NAS website: <https://www.nap.edu/read/26373/chapter/1>. We are reviewing the findings in the National Academies report to determine how to strengthen both the PHEMCE and the SNS. Restoring and rebuilding the SNS is one of my priorities and I look forward to reviewing both of these reports and incorporating their findings or recommendations into the strategic work we are undertaking to rebuild and restore the stockpile and realign it with the PHEMCE. I would be happy to discuss both of these reports with this Committee once both are released and made public. As chair of the PHEMCE, I plan to incorporate lessons learned from the COVID-19 response into future PHEMCE planning. I'm pleased to report that we will relaunch the PHEMCE next month.

Healthcare System Preparedness

Next, I want to share more about ASPR's work to prepare our healthcare system to surge to meet the demands of those being treated for COVID-19, without compromising day-to-day healthcare needs.

Through ASPR's Hospital Preparedness Program (HPP), ASPR has invested \$350 million from supplemental appropriations in the National Special Pathogen System (NSPS). These investments span the 62 HPP funding recipients, their associated 55 Special Pathogen Treatment Center sub-recipients, 10 Regional Ebola and Special Pathogen Treatment Centers (RESPTC) recipients, the National Ebola Training and Education Center (NETEC) (a consortium of three academic medical centers), and 53 hospital associations, while leveraging and amplifying technical guidance from the CDC. These components work together to provide a coordinated, national approach to preparing healthcare systems to surge for public health and medical emergencies.

We also continue to support our Regional Disaster Health Response System (RDHRS) demonstration sites. The goal of the RDHRS is to link together existing health systems to address health care preparedness challenges, establish best practices, expand access to specialty clinical care, and increase medical surge capacity at the regional level. As I mentioned in my November 2021 statement, a fourth RDHRS demonstration site was established at Emory University. With this award, we now have demonstration sites based at Massachusetts General Hospital, Nebraska Medical Center, and Denver Health and Hospital Authority. The ultimate goal of this system is to support a more coordinated, comprehensive, and capable health care disaster response system able to respond to health security threats.

As part of our COVID-19 pandemic response, the National Special Pathogen System coordinated national expertise, regional capabilities, and state and local healthcare capacities across the public and private sectors to support an effective pandemic response. Looking ahead, I look forward to examining ways to strengthen investments like these in preparedness to ensure the healthcare system is ready to surge for future public health and medical incidents.

Further, if a public health or healthcare system becomes overwhelmed with patients, States can request National Disaster Medical System (NDMS) personnel to provide additional support. Since July 2021, forty National Disaster Medical System teams – nearly 880 team members – were deployed to support sites in nineteen separate states and the Commonwealth of the Northern Mariana Islands (CNMI). There is currently an NDMS team in New York and Missouri. For these deployments, NDMS personnel support a range of functions including hospital augmentation and decompression, setting up medical overflow centers for patients, and mortuary support. As we learn more about Omicron, and if additional needs are identified, we will continue to make resources available to states and communities to respond.

Of note, this critical system requires a renewal of its direct hiring authority, which was set to expire on September 30, but was extended as part of the continuing resolution. 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.

Testing

In addition to the Industrial Base Expansion efforts I mentioned previously, ASPR continues to support COVID-19 testing for the Nation. The HHS Testing and Diagnostics Working Group (TDWG) mission was established early in the pandemic to increase testing capacity through interagency coordination and partnerships with industry and state, tribal, local, and territorial public health agencies. TDWG was created as part of the Federal response to COVID-19 in March 2020, residing with Operation Warp Speed temporarily, and then established under the Office of the Assistant Secretary of Health (OASH) leadership and was located in the Joint Coordination Cell (JCC) run by the U.S. Coast Guard. In March 2021, when the JCC was officially stood down, TDWG's administrative and contracting support were moved to ASPR.

While there is more work to do to increase the supply of rapid tests, we have significantly increased our country's testing capacity over the past several months. In fall 2021, ASPR invested \$3 billion to accelerate the production of rapid tests and expand capacity. As a result, we have quadrupled the number of rapid at home-tests available since we made those investments in September. To further increase testing supply, ASPR, is leading the Administration's procurement of 500 million Over-the-Counter (OTC) tests, an investment of over \$3 billion, with plans for initial tests to be available this month. ASPR has also shipped over 40 million rapid antigen tests and 2.3 million point-of-care PCR tests to our most vulnerable populations, including nursing homes, federally qualified health centers, and long-term care facilities since May 2021. 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.