

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

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Next Steps: The Road Ahead for 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 support the ongoing response to COVID-19. I am grateful for this opportunity to address this Committee and appreciate your continued support for the ongoing response efforts.

### **Update on ASPR's COVID-19 Response Effort**

The response to the COVID-19 pandemic has required an unprecedented whole of government approach. Secretary Becerra continues to direct me, in my capacity as the ASPR, to lead the ongoing coordination of the COVID-19 response across HHS. In this role I work closely with my fellow panelists on all facets of the Department's response, but please find here an update on the work for which the ASPR organization is chiefly responsible.

#### ***Countermeasures Acceleration Group***

As you are aware, HHS and the Department of Defense (DoD) forged a partnership formerly called Operation Warp Speed (OWS) that is now known as the Countermeasures Acceleration Group (CAG). This partnership brought together the two Departments to develop, manufacture, and deliver safe and effective vaccines and therapeutics to the American people. ASPR has played and continues to play a significant leadership and coordination role on behalf of HHS in the effort. This endeavor has delivered nearly 500 million vaccine doses, and over a million therapeutic doses to protect the American people from COVID-19.

Over the past few weeks, the CAG has led the rollout and distribution of the Pfizer, Moderna, and Johnson & Johnson booster vaccines. These booster shots are being administered widely around the country, and ample supply is available in the field to meet the needs for both booster and primary series vaccinations. The CAG continues to coordinate vaccine ordering and distribution to over 80,000 sites nationwide.

This week, the CAG is in the process of distributing vaccines for children ages 5 through 11. 15 million doses have been made available for use around the country in anticipation of high demand for this vaccine. Significant work with the states, federal partners, territories, and pharmacy partners continues to ensure that there is ample vaccine available at locations where young children are likely to receive their vaccines.

The CAG continues to support efforts to develop and distribute therapeutics. As the Delta variant created a summer surge of COVID-19 cases across the country, demand for monoclonals increased 20-fold from the beginning of the surge to its peak. As a result, the CAG supported a rapid scale up of monoclonal antibody procurement and distribution to meet that rising demand. This included returning to an allocation system to ensure that all states had access to and could order the monoclonal antibodies they needed to treat COVID-19 patients in their jurisdictions. The CAG has also purchased, and continues to prepare for, the distribution of new oral antivirals should they obtain Emergency Use Authorization from the FDA.

ASPR continues to prepare for the transition of the CAG into ASPR. Teams from HHS and DoD have been meeting for months to identify and assign key functions to be transitioned. A permanent Chief Operating Officer has been identified and is in the process of being brought on board. Individuals for other key positions are being hired. The Deputy Secretary of Defense and the Deputy Secretary of HHS meet each month to assess progress and will make the ultimate determination on when the transition is complete.

### ***Biomedical Advanced Research and Development Authority***

The Biomedical Advanced Research and Development Authority (BARDA), in its work with the CAG, 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 77 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 15 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 4.88 million doses of monoclonal antibodies, and shipped more than 144 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 in the CAG portfolio that have not yet been authorized or approved. This ongoing work on vaccines is critical should a variant emerge that is resistant to the current authorized and approved vaccines or a new vaccine be developed that is easier to store, ship, and administer 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 currently available monoclonal antibodies are administered by infusion which must be done in clinical settings. BARDA's collaboration with NIH on developing oral antivirals—single pills that can be taken with a sip of water—may offer an important alternative to monoclonal antibodies should they be authorized by the FDA.

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 four molecular and two antigen point of care and home use tests and for two molecular and five antigen point of care only tests.

### ***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. As of October 1, 2021, 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 more than 3,000 ventilators to 17 jurisdictions since July to respond to the Delta variant case surge. 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 October 25, 2021, the SNS has utilized approximately \$11.9 billion from COVID-19 supplemental appropriations provided by Congress to have in its inventory approximately: 708 million N95 respirators (56 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); 3.21 billion gloves (190 times pre-pandemic levels); and 167,000 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 recently 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), 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 62 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 US needs to contain further pandemic waves. ASPR continues to invest in critical funding in expanding domestic manufacturing including investments of: \$250M in manufacturing PPE; \$268M in manufacturing

of testing consumables; \$14.8M in vaccine raw material manufacturing; \$160M in fill finish capacity; \$65M in vaccine vial manufacturing; \$168M in manufacturing capacity for at home and point of care tests; and, \$53.8M in testing raw materials, with additional funds going out the door every day. 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.

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.

While we wait for the issuance of the HHS IG Report, the National Academies 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 report is planned for release November 3, 2021. I am currently reviewing a final draft of this report and will consider its findings and recommendations to fully leverage the PHEMCE when considering what should be held in 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 they are released and made public.

### ***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 Centers for Disease Control and Prevention (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. Since I last testified in July, we announced a fourth RDHRS demonstration site 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, 24 NDMS teams – nearly 500 team members -- were deployed to ten states in support of the Delta surge efforts. For the COVID-19 deployments, NDMS personnel supported hospital augmentation including emergency room support; hospital decompression, setting up medical overflow centers for patients and mortuary support, establishing monoclonal antibody therapy sites, ICU augmentation, and operating federal vaccine sites. With the aid of NDMS personnel and resources, communities were able to continue to provide care to those in need of medical assistance and treatment.

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 1000 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. .

Over the last several months ASPR has worked hand-in-glove with the CDC, NIH, FDA, and DoD to make over \$3 billion in investments to bring additional rapid point of care (POC) and Over-the-counter (OTC) COVID-19 tests to market. This investment spurred a significant ramp up in testing production. Since September, we have been on track to nearly quadruple the number of rapid, at home COVID-19 tests available by December to nearly 200M tests per month.

ASPR's TDWG executed two significant testing programs: Increasing Community Access to Testing (ICATT) and Operation Expanded Testing (OpET). ICATT provides no-cost testing to underserved populations and OpET expands testing capacity in Kindergarten through 12<sup>th</sup> grade schools and underserved congregate settings. As a result of these two programs, the ASPR TDWG 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.

### **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.