

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Strategic Preparedness and Response

Testimony before the
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Chairs McMorris Rodgers, Griffith, and Guthrie, Ranking Members Pallone, Castor, and Eshoo, and distinguished members of the Committee, it is an honor to appear before you today to discuss the work of the Administration for Strategic Preparedness and Response (ASPR) in supporting the ongoing COVID-19 response, the lessons we have learned, and how we will apply those moving forward.

ASPR plays a unique role in the nation's public health ecosystem. Our mission is to help the country prepare for, respond to, and recover from public health emergencies and disasters whether man-made or naturally occurring. Our mission manifests itself in several ways but most often it is in the development, procurement, stockpiling, and distribution of the needed tools to respond to any given threat. We have done this most recently in the ongoing COVID-19 response; the mpox response; the Ebola Sudan response in Uganda; and the response to the surge in respiratory illnesses across the country this winter. In each of these we have applied lessons learned and innovations developed along the way.

COVID-19 Response

As we enter the fourth year of the COVID-19 response, ASPR continues to play a lead role, in partnership with CDC, in the development, procurement and distribution of vaccines, therapeutics, and tests. While the initial Operation Warp Speed partnership with the Department of Defense (DOD) ended in December 2021, much of this work continues within ASPR. The Biomedical Advanced Research and Development Authority (BARDA) supports the advanced research and development of vaccines, therapeutics, and diagnostic candidates and the HHS Coordination Operations Response Element (HCORE) manages the ongoing procurement and distribution of the vaccines and therapeutics.

In partnership with CDC, ASPR has helped develop and deliver over 953 million doses of vaccine and 21.6 million treatment courses to date to protect the American people from COVID-19. BARDA alone has awarded contracts for the development of 81 medical countermeasure projects to support the COVID-19 response. These contract awards are listed on [medicalcountermeasures.gov](https://www.medicalcountermeasures.gov) in detail and include 18 therapeutics, 59 diagnostics, and seven vaccine candidates. Meanwhile, HCORE has supported, in partnership with CDC, the distribution of vaccines to 106,000 locations and therapeutics to over 64,000 locations nationwide.

ASPR continues to support access to COVID-19 tests. ASPR has invested over \$8 billion in domestic test manufacturers to accelerate production of rapid tests and expand manufacturing capacity. In January 2022, President Biden announced a plan to make one billion free at-home tests available to the American people and mail them directly to their homes via [COVIDTests.gov](https://www.COVIDTests.gov). Since this effort began in January 2022, ASPR, in partnership with the U.S. Postal Service, has delivered more than 720 million at-home tests, including the Ellume test to support low-vision and blind citizens, to homes across the country.

As the acute phase of the COVID-19 response effort winds down, the Department of Health and Human Services (HHS) is working with commercial partners to transition the development and

distribution of vaccines and therapeutics to the private sector. Timelines regarding commercialization are different for each product and depend on several factors including the products' regulatory status and the manufacturers' ability to manufacture enough product for nationwide distribution. As we work through these and other issues our aim is to provide a smooth transition for each product as it enters the commercial market. One monoclonal antibody therapy produced by Eli Lilly made available under Emergency Use Authorization authorities transitioned from USG-directed distribution to traditional commercial distribution channels in August 2022.

Over the course of the COVID-19 response, the Strategic National Stockpile (SNS) has worked to backstop the medical supply needs of states, Tribal nations, territories and large metropolitan areas 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, ventilators, Federal Medical Stations, and pharmaceuticals.

In the summer and fall of 2021 the United States saw a surge of COVID-19 cases and hospitalizations related to the Delta variant. Using medical materiel procured during an earlier stage of the pandemic, SNS responded to this uptick in cases by rapidly deploying ventilators and High Flow Nasal Cannulas (HFNC) to 18 states. Additionally, starting in January 2022, SNS began deploying National Institute for Occupational Safety & Health (NIOSH)-certified N95 respirators to the American public. These respirators were available for pick-up at retail pharmacies and community health centers nationwide. In total more than 282 million N95 respirators were distributed through this program.

As of January 19, 2023, the SNS has utilized approximately \$11.5 billion from COVID-19 supplemental appropriations provided by Congress to restock its inventory. It currently has: 531 million N95 respirators (42 times pre-pandemic levels); 207 million surgical and procedure face masks (6.7 times pre-pandemic levels); 12.2 million face shields (2 times pre-pandemic levels); 47.4 million gowns and coveralls (10 times pre-pandemic levels); 4.8 billion gloves (285 times pre-pandemic levels); and 158,000 ventilators (10 times pre-pandemic levels).

While replenishing the SNS is essential, it is also critical to address the root cause of the strain in supply chains witnessed throughout the pandemic. 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 public health and medical supply chains.

Throughout the COVID-19 response, ASPR has leveraged the authorities delegated to the Secretary under the Defense Production Act (DPA) 70 times, including by granting 54 priority ratings for United States Government (USG) contracts for health resources, 10 priority ratings for USG contracts for industrial expansion, six 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.

ASPR is also equipping the domestic public health industrial base to secure and develop its manufacturing capacity, retool and expand industry machinery, scale production facilities, train a skilled workforce, and ultimately infuse the supply chain and marketplace with products the United States needs to contain future pandemic waves. ASPR is doing this through targeted investments in domestic manufacturing of such critical supplies as gloves, gowns, and N95 masks.

As ASPR has executed its COVID-19 response priorities, we have learned critical lessons and innovations that we are now applying to all response-related activities.

Mpox and Other Responses

In addition to the COVID-19 response, ASPR supported several other public health responses during 2022. These included both the domestic mpox response and the Ebola Sudan virus outbreak in Uganda, as well as the winter surge of respiratory viral illnesses like RSV and flu – for which ASPR mobilized to ensure sufficient supply of Tamiflu and clinical personnel in local jurisdictions. Our work for all of these efforts benefited from the lessons we learned during COVID-19.

For example, in mpox we adjusted the vaccine and therapeutics ordering and distribution platforms to reflect key learnings from COVID-19. These vaccines and therapeutics, unlike those in the COVID-19 response, are being provided by the SNS—rather than the manufacturers themselves. To increase the efficiency of the SNS’ ordering system we moved from a paper process to a more sophisticated digital process. As we digitized the ordering system, we opted to use a program that allowed states to order both vaccines and therapeutics from the same system rather than using separate, non-interoperable systems as they have had to do in the COVID-19 response. Using this multi-platform ordering system is a step towards modernizing our public health infrastructure for the current response and for future responses.

In the mpox response we have also expanded the number of sites to which the SNS delivers to better serve our healthcare partners. At the start of the outbreak, the SNS was only able to deliver to five sites in each jurisdiction, resulting in the jurisdiction having to forward distribute the products to their hospitals and vaccination clinics. While such a system is more than enough for the high-consequence large-scale chemical, biological, radiological, nuclear, and explosive events that the SNS plans for, there was increased burden on the jurisdictions in this nationwide mpox response. After seeing the advantage of multiple distribution sites in the COVID-19 vaccine and therapeutics effort and hearing jurisdictions’ preference for this direct distribution capability, the SNS contracted with a commercial medical distribution vendor that leveraged its existing distribution capabilities and was able to rapidly reach a diverse set of requestors and recipients to create a distribution network for mpox that was similar to that used in COVID-19. These are just two examples of the lessons we have learned from one response and applied them to another.

Strengthening ASPR for Future Responses

As an organization, ASPR continuously evaluates best practices and calibrates our responses to ensure we are fully meeting our mission and doing so in a way that allows us to move quickly and decisively against a range of complex threats. As we move out of the acute phase of the COVID-19 response, I have begun looking at our response capabilities and evaluating what additional authorities and structure changes we might need to improve our work going forward.

For example, early in the pandemic HHS could not move contracts as quickly and flexibly as it needed to in order to keep up with pace of the pandemic. ASPR entered into a relationship with DOD to take on some of the necessary procurements. Our agreement with DOD to provide these services ends at the end of fiscal year 2023 and we need to be ready to take over that work internally. To match the speed and flexibility of DOD's contracting capabilities for future outbreaks ASPR needs additional acquisitions authorities—such as expanded Other Transaction Authority and streamlined acquisition authorities to enhance the speed of contracting and access innovative products and vendors.

Throughout the response, filling critical workforce gaps across the organization has been a challenge. Similar to our reliance on DOD for contracting support, we relied heavily on FEMA and the Coast Guard to bolster our limited staff. Having additional hiring flexibilities would go a long way towards ensuring that we are able to quickly scale up our responses when necessary. ASPR must have the appropriate authorities to prepare for, respond to, and recover from whatever comes next—no matter what that might be. We look forward to working with Congress to explore options to strengthen our workforce capacity.

These are just some examples of additional authorities ASPR could benefit from in future emergency and disaster responses. I look forward to further collaboration with you and your staff as you consider these and other potential authorities for ASPR in the upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA) this Congress.

As for structure, we will soon implement a reorganization that both fully incorporates our new capabilities and creates additional accountability in existing programs. This will strengthen our ability to prepare for and respond to whatever comes next. The following are key elements of the upcoming reorganization: (1) two new programs that were launched during the COVID-19 response will become stand-alone offices directly reporting to the ASPR: H-CORE and the Office of Industrial Base Management/Supply Chain; (2) one program that has increased significantly in budget and mandate will become its own stand-alone office directly reporting to the ASPR: the Strategic National Stockpile; and (3) to better coordinate and align ASPR's external engagement and policy work across the organization, several components are moving into the Immediate Office of the ASPR. These include Legislative, Communications, External Affairs, Policy, Strategy and Requirements. Each of these changes will improve line-of-sight and accountability as well as strengthen ASPR's ability to meet its mission on behalf of the American people.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the COVID-19 response, lessons learned, and thoughts for the next iteration of PAHPA. I look forward to answering your questions and working with you and your staff as we move forward in the 118th Congress.