THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE of the ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE

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Hearing Titled
The Path Forward: 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 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.

When I first appeared before the committee in early June as the ASPR nominee, I shared my top three priorities for the office, which are reflected in the Fiscal Year 2022 Budget request:

> First, I wanted to ensure that ASPR has the resources and support necessary to continue its critical COVID response work, and help the nation emerge quickly from the current pandemic. This critical work is in addition to our normal preparedness and response efforts for natural disasters, chemical, biological, radiological, and nuclear incidents, and pandemic influenza PI events.
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> Second, I wanted to restore and strengthen capacities that have become strained during the COVID-19 pandemic. Specifically, I wanted to ensure the Strategic National Stockpile (SNS) is appropriately resourced, replenished, and ready to respond to future challenges, and that the medical supply chain is resilient and can support our country's needs.
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> Finally, I wanted the organization to increase readiness for future public health emergencies by working with our colleagues both inside the Department and across the interagency to prepare for whatever manmade or naturally occurring threats may come next.

A month into the job, these remain my top priorities. Every passing day I am awed by the hard work and dedication of the ASPR team. It is clear to me that they are working as hard now to end the pandemic as they did when the outbreak first

began. Today, I am pleased to share with you an update on the tireless work they have been doing to respond to COVID-19.

Update on ASPR's COVID-19 Response Effort

Countermeasures Acceleration Group

The response to the COVID-19 pandemic has required an unprecedented whole of government approach. As you are familiar, 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 a significant leadership and coordination role on behalf of HHS in the effort. This endeavor has delivered nearly 390 million vaccine doses and over a million therapeutic doses to protect the American people from COVID-19.

In addition, the President has committed to sharing 580 million doses of vaccine with the world. This includes half-a-billion Pfizer doses the United States will purchase and donate to 100 countries in need – the largest-ever donation of COVID-19 vaccines by a single country, and a commitment to share 80 million doses of our own surplus U.S. supply. The CAG has delivered nearly 40 million vaccines to 25 countries, with millions more en route.

Now, work is underway to transition DoD's role in the CAG to HHS for long term sustainability and management. Dr. Robert Johnson, the Director of the Influenza and Emerging Infectious Diseases Division of ASPR's Biomedical Advanced Research and Development Authority (BARDA), assumed the responsibilities as the Chief Operating Officer of the CAG earlier this month. Under Dr. Johnson's leadership, ASPR's role in the response is more apparent than ever.

Biomedical Advanced Research and Development Authority

ASPR's BARDA has supported over 65 medical countermeasure projects for the COVID-19 response. All of these contract awards are listed on medicalcountermeasures.gov in detail and include 14 therapeutics, 48 diagnostics, and seven vaccine candidates. Notably, BARDA, as part of the then-Operation Warp Speed, accelerated the availability of three vaccines – Moderna, Pfizer, and

Johnson & Johnson. This was done at historic speed, with the novel virus identified and the first vaccine authorized in under a year.

Looking forward, BARDA will leverage the supplemental appropriations provided by Congress to continue its work as part of the CAG to support the development of additional vaccines and therapeutics to end the COVID-19 pandemic. There are still populations – like children under the age of 12 – that cannot yet receive the vaccine as we complete careful clinical testing. It is critical that the work continue to develop vaccines and to establish successful treatments for those who do become infected. I look forward to working with this Committee on specific plans toward this effort.

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 categories of medical equipment and supplies. Many vital products are primarily made overseas, and practices like "just in time" inventory management resulted in difficulty surging manufacturing when demand surged last spring. This created significant and devastating challenges for States and healthcare systems that needed 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 June 15, 2021, the SNS deployed more than 200 million items to aid the national response including Personal Protective Equipment (PPE), ventilators, Federal Medical Stations, and pharmaceuticals. Now, ASPR is working to replenish the SNS to levels at or above pre-COVID-19 amounts, so it is prepared for any subsequent wave of additional cases.

As of July 9, 2021, the SNS has utilized approximately $10 billion from COVID-19 supplemental appropriations provided by Congress to inventory approximately: 517 million N95 respirators (35 times pre-pandemic levels); 272.5 million surgical and procedure face masks (eight times pre-pandemic levels); 11.9 million face shields (two times pre-pandemic levels); 22 million gowns and coveralls (five times pre-pandemic levels); 524.7 million gloves (17 times pre-pandemic levels); and 167,000 ventilators (10 times pre-pandemic levels).

While replenishing the SNS is essential, it is also critical to address the root-causes 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 supply chain for medical materials, ingredients, and supplies is critical for any national response to public health emergencies.

To start, ASPR is leveraging the authorities delegated to the Secretary under the Defense Production Act (DPA) to ensure that private sector partners making life-saving products are able to acquire raw materials, retool their machinery, scale their production facilities, train their workforces, and ultimately deliver their product. Throughout the COVID-19 response, ASPR has used the DPA authority to issue 46 priority ratings for United States Government (USG) contracts for health resources, eight priority ratings for USG contracts for industrial expansion, 3 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. Going forward, ASPR will continue to build capacity and partnerships with private industry toward the shared goal of ending the COVID-19 pandemic.

In addition, ASPR is working to steward Congress's investment in expanding the domestic industrial base. These industrial base expansion (IBx) efforts seek to reduce supply chain vulnerabilities and generate a domestic "warm-base" for manufacturing that can be leveraged in a crisis. So far, ASPR has supported domestic manufacturing of PPE; active pharmaceutical ingredient manufacturing capacity; and COVID-19 testing, including swabs, tests and kits, and supplies such as reagents and resins. Each of these domestic manufacturing initatives meet current, as well as future COVID-19 needs, and seek to create or sustain high-value domestic jobs.

Healthcare System Preparedness

Finally, 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 health care needs.

Through ASPR's Hospital Preparedness Program (HPP), the only Federal program that supports preparedness efforts within the healthcare system, 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, and helped leverage and amplify technical guidance from the Centers for Disease Control and Prevention (CDC). These components work together to provide a coordinated, national approach to preparing health care systems to surge for public health and medical emergencies.

During the COVID-19 pandemic, the NSPS 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. During the COVID-19 response, NDMS has completed nearly 5,400 mission assignments so far, and counting. For these 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. NDMS will continue to support such requests.

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.