THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

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Senate Committee on Health, Education, Labor, and Pensions

Hearing Titled:
Stopping the Spread of Monkeypox: Examining the Federal 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 the efforts within the U.S. Department of Health and Human Services (HHS) Administration for Strategic Preparedness and Response (ASPR) to support the ongoing response to the monkeypox outbreak. I am grateful for this opportunity to address this Committee and appreciate your continued support for the ongoing response efforts.

ASPR's core mission is to ensure that we are prepared and able to respond to public health and medical emergencies. In ASPR's 16-year history, ASPR has invested in a range of efforts to prepare for threats identified by the Department of Homeland Security (DHS). One of the key identified threats – by DHS, ASPR, and Congress – is smallpox. ASPR and other federal partners have invested in preparing for the threat of smallpox for over a decade. We have a number of countermeasures within the Strategic National Stockpile (SNS) to aid in a response, should this country experience any sort of smallpox attack. Certain medical countermeasures we procured and stockpiled for smallpox also protect against and treat the symptoms of monkeypox. We are grateful to be in a position where our existing smallpox medical countermeasure portfolio can be leveraged against monkeypox. In doing so we must not lose sight of the need to maintain a strong smallpox preparedness posture and replace those countermeasures intended for smallpox that we have distributed in response to the current monkeypox outbreak.

Since becoming the ASPR in the summer of 2021, one of my priorities has been to ensure that programs within the organization are appropriately resourced. The SNS has played a large role in the current response. One of the biggest challenges ASPR faces is fully funding the SNS. Despite growing responsibilities, the SNS has had a relatively flat budget for a number of years. The Administration requested $975 million in the FY 2023 President's Budget to ensure SNS could better carry out its mission. As this committee knows well, ASPR's authorizing structure is such that the Biomedical Advanced Research and Development Authority (BARDA) advances the development of medical countermeasures, the Public Health and Emergency Medical Countermeasures Enterprise—or PHEMCE—makes a recommendation regarding their usefulness in our stockpile, and then then SNS is supposed to be able to purchase the products PHEMCE determines to be needed within available resources.

While BARDA has been successful in supporting the advanced development of a number of medical countermeasures to aid our preparedness and response portfolio, the SNS's flat budget has made it challenging to fully meet PHEMCE-identified goals for these countermeasures. We are fortunate to have products in the SNS to combat the ongoing monkeypox outbreak, but there will be lasting impacts on overall preparedness against other threats, such as smallpox, because of the realignment of medical countermeasures for this outbreak.

The Administration's continuing resolution proposal requests $3.9 billion for HHS to aid in the continued monkeypox response and ensure stockpile preparedness is restored. I look forward to continuing to brief Congress on preparedness levels and the impact that the current response is having on our overall future preparedness efforts.

For the current response to the monkeypox outbreak, ASPR is partnering with many sister agencies within HHS and across the federal government, industry representatives, as well as state, tribal, and other jurisdictional health leaders to accelerate progress on vaccines and

treatments – and strengthen our response. I will now highlight ASPR's efforts to support development, procurement, and distribution of vaccines and therapeutics and how we are disseminating information relevant to these efforts.

National Vaccine Strategy

Since the first reported case of monkeypox in the United States on May 18, 2022, ASPR has worked tirelessly to accelerate the acquisition and delivery of vaccines and therapeutics to jurisdictions.

This important work first started with an examination of our holdings within the SNS. As reported publicly, the SNS contains both ACAM2000 – our first line of defense to vaccinate Americans in the event of accidental or intentional release of smallpox – and JYNNEOS, for which we keep a small stockpile to routinely vaccinate laboratory workers at risk of exposure to smallpox and other orthopoxviruses such as monkeypox. In addition to the 2,400 doses the SNS kept on-hand for rapid deployment, ASPR kept an additional 1.4 million vials of JYNNEOS in -50 degree storage at Bavarian Nordic (BN) to be available if needed for response to a larger outbreak. Those doses are now being deployed for use in the current outbreak. ASPR also had an additional 16.5 million vial equivalents in bulk drug substance to be lyophilized (or "freeze dried") in the coming years for easier storage and longer shelf-life. 5.5 million vial equivalents of that bulk drug substance are being filled and finished now and in the coming months to respond to the current outbreak.

ACAM2000, which is not approved or authorized by the U.S. Food and Drug Administration (FDA) for emergency use to prevent monkeypox disease, contains live, replicating virus and may not be advisable for those who are immune compromised. Given the potential of monkeypox cases in persons who may also have HIV or other immune compromising conditions, ASPR worked with other HHS agencies and offices to determine the JYNNEOS vaccine was our best line of defense against this monkeypox outbreak.

On Wednesday, May 18, the first case was identified in the United States. By Friday, May 20, there were two known cases of monkeypox in the United States, and CDC recommended those known to be exposed to the virus get vaccinated. On Sunday, May 22, the SNS deployed the first vials of JYNNEOS vaccines to Massachusetts to be used as post-exposure prophylaxis for those first exposures.

At this time, while there were still only two known cases of monkeypox in the US, ASPR requested 36,000 JYNNEOS vaccine vials be shipped to the SNS from our U.S. government-owned reserve stored by BN in Denmark. When there were only 13 known cases, ASPR ordered an additional 36,000 vials from its reserve. And when there were only 35 known cases, ASPR ordered an additional 300,000 vials from its reserve. All of this was done to stay ahead of the virus. Though case counts were very low in the United States, we were watching the quick spread of cases in Europe, which was about 2-3 weeks ahead of us, and moved out quickly anticipating similar rapid transmission in the weeks to come.

Ultimately, of the additional 5.5 million vials we have ordered filled and finished, we anticipate that deliveries will begin arriving at the SNS in the next few weeks and will continue through early 2023. To support this effort, 3 million vials will be manufactured at BN's line in Denmark and 2.5 million will be manufactured here in the United States at Grand River Aseptic Manufacturing (GRAM) in Grand Rapids, Michigan. The GRAM facility is the first fill and finish line for the JYNNEOS vaccine in the U.S. and not only supports our current response to monkeypox but enhances preparedness for smallpox as well. Within ASPR, we helped spur this agreement and the technology transfer that was necessary for this production at GRAM and have invested $11 million in securing supplies and staff to ensure the line is up and running as quickly as possible. The transfer is on track to start manufacturing later this year. I was pleased to visit GRAM on August 29, where I met with the CEO and leadership team, and observed the hard work being done to bring the line up as quickly as possible.

ASPR has made over 1.1 million vials of JYNNEOS available to states and jurisdictions for use against the current outbreak – the largest JYNNEOS monkeypox vaccine program in the world. Moving fast and distributing the product ensures equity and access for those who require the product. To support the allocation and distribution of vaccine, in late June 2022, HHS announced an enhanced National Vaccine Strategy (Strategy) to mitigate the spread of monkeypox. This Strategy outlines efforts to ensure that those at higher risk of monkeypox disease receive vaccine, vaccines are prioritized for areas with the highest numbers of cases, and that guidance is provided to state, territorial, tribal, and local health officials to aide their planning and response efforts. Using this strategy we have made vaccine available in phases throughout the summer. Phase 4 of the Strategy that focuses on distribution and allocation efforts is well underway. Currently, allocation amounts are based on a combination of case counts and population (population is based on the estimated size of the underlying population in the jurisdiction that might benefit from expanded vaccination at this point in the outbreak). Jurisdictions are eligible to draw down doses against their allocations once they have attested to adequate utilization of their currently allocated vials. Requiring jurisdictions to inform HHS of their administration data plays an important role in informing the response and ensuring monkeypox doses make it into the arms of those most at risk, rather than sitting on shelves. Once jurisdictions receive vaccine, they are responsible for distributing vaccine within the jurisdiction and setting their eligibility criteria for vaccination. Jurisdictions may choose to expand eligibility in the future depending on the state of the outbreak and the available supply of the JYNNEOS vaccine as it continues to increase.

Currently, doses are held in a small stockpile within the SNS and, as such, distribution of the product has been managed by the SNS. The SNS' traditional distribution framework is based on getting material into jurisdictions quickly to respond to high-consequence events such as hurricanes and other large-scale disasters. Having access to five distribution points in any given jurisdiction has been satisfactory under these traditional circumstances to move the necessary medical units and countermeasures into place. As the SNS is now being asked to distribute vaccines nationwide from its stockpile, something it has not traditionally done, it is in the process of making arrangements with a large distributor to increase distribution to more sites. This is not a static response effort. At each point that I receive feedback from jurisdictions on ways to make the response easier for them to manage, I have worked with the programs here to

adjust and incorporate the feedback just as we are doing now with SNS distribution efforts. You have my commitment that I will continue to do that throughout this and future responses.

We are also providing a portion of vaccine for distribution through existing federal channels (the Departments of Veterans Affairs and State, and agencies within HHS including the Health Resources and Services Administration, the Indian Health Service, and the National Institutes of Health). ASPR is working closely with HRSA to ensure they are able to vaccinate individuals via their Ryan White networks; IHS is able to vaccinate tribal members, often in rural and remote areas of the country; VA is able to vaccinate our nation's veterans; NIH is receiving doses to conduct research; and DoS is able to ensure at-risk personnel serving overseas are protected.

Treatment to Combat Symptoms of Monkeypox

Tecovirimat (TPOXX), a therapeutic drug licensed for smallpox treatment, was developed with BARDA support and can be used to treat individuals with monkeypox with an appropriate regulatory mechanism. CDC currently holds, through FDA's Expanded Access program, an Expanded Access Investigational New Drug (IND) protocol that allows its use for monkeypox.

Prior to the start of the outbreak, the SNS held more than 1.7 million courses of TPOXX, or tecovirimat, in its immediate holdings. In addition to deploying bottles directly to those who qualify under CDC's IND protocol, on August 18, ASPR made available 50,000 patient courses of TPOXX for pre-positioning throughout the country. Jurisdictions have been allocated courses of TPOXX using a formula based 75% on the number of cases in their jurisdiction and 25% on the number of individuals who are at the highest risk of contracting the virus, including individuals who are living with HIV or who could benefit from HIV pre-exposure prophylaxis. This allocation is in addition to the over 20,000 courses ASPR deployed to jurisdictions from the SNS prior to August 18.

Engaging Those at Highest Risk for Severe Disease

HHS has launched two pilot programs to provide additional vaccine allocations to state and local health departments. The first provides doses to jurisdictions that are hosting large events that attract gay, bisexual, and other men who have sex with men in the coming weeks and months and the second provides doses to smaller more targeted outreach efforts. The larger pilot program is setting aside 10,000 vials of vaccine from the SNS that jurisdictions can request to order on top of their existing vaccine allocations and supply. The number of additional doses made available to a jurisdiction will be based on the size and nature of the event, and the ability to reach attendees at highest risk for monkeypox. The smaller pilot program is setting aside 10,000 vials of vaccine from the SNS that jurisdictions can also request on top of their existing vaccine. Working with CDC, ASPR is pleased to provide these additional doses for targeted equity interventions.

Conclusion

Thank you again for inviting me to testify before you on efforts within ASPR to support the ongoing monkeypox response. I look forward to answering your questions and working with my team at ASPR and our colleagues across HHS to mitigate the impact of this virus.