

WASHINGTON, DC 20510

August 23, 2022

Dawn O'Connell, JD Administrator Administration for Strategic Preparedness and Response U.S. Department of Health and Human Services 200 C Street, NW Washington, DC 20201

## Dear Administrator O'Connell:

The monkeypox outbreak continues to spread at an alarming rate in the United States, particularly among the LGBTQ+ community, with over 15,000 cases already reported in 52 jurisdictions as of August 22, 2022. The JYNNEOS vaccine, diagnostic tests, and therapeutics are all critical tools for preventing infection, curbing transmission, and ultimately getting ahead of this outbreak – but I am concerned about their availability and distribution. The Administration must do more to address existing, unacceptable shortages in vaccine supply, institute comprehensive distribution and communication strategies, and develop long-term procurement plans.

ASPR's procurement efforts have so far resulted in an alarming shortage of the supply of the JYNNEOS vaccine, which risks undermining the ability of the United States to address the monkeypox outbreak. The United States has procured more than one million doses of the JYNNEOS vaccines, and the new dose sparing approach approved by the Food and Drug Administration (FDA) will increase the number of doses further.<sup>2</sup> However, there are still alarming gaps in sustained supply due to slow procurement and limited manufacturing capacity, frustrating state health officials, including in my home state of Washington. Given ongoing supply concerns, the Centers for Disease Control and Prevention (CDC) is recommending jurisdictions largely focus on providing vaccines as post-exposure prophylaxis.<sup>3</sup> And, according to recent reports, the private sector could take months to significantly increase capacity of the JYNNEOS vaccine.<sup>4</sup> While I am glad to see agreements put in place to transfer technology and improve production lines, this will still take months to result in more vaccine doses.<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html

<sup>&</sup>lt;sup>2</sup> https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-authorizes-emergency-use-jynneos-vaccine-increase-vaccine-supply

<sup>&</sup>lt;sup>3</sup> https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html

<sup>&</sup>lt;sup>4</sup> https://www.nytimes.com/2022/08/03/us/politics/monkeypox-vaccine-doses-us.html

<sup>&</sup>lt;sup>5</sup> https://www.hhs.gov/about/news/2022/08/18/hhs-facilitates-agreement-accelerate-delivery-additional-smallpox-monkeypox-vaccines-using-new-us-production-line.html

I have also heard from constituents about ongoing challenges with the vaccine distribution strategy that only delivers vaccines to five sites in larger states. This approach relies on states to maintain the cold chain during intrastate distribution, potentially resulting in delays as vaccines are transported to areas in need. I urge you to explore more flexible distribution options that would allow for more sites to receive doses and for faster distribution across the states to communities in need. Additionally, the Administration needs to improve communication with states about the logistical needs for distribution. ASPR must also effectively communicate with states to ensure they know how many vaccines are available, when they are receiving doses, how to distribute them once they are in the state, how to request more doses, and how to carry out their administration.

To address each of these issues, it is imperative that ASPR outline a clear and comprehensive strategy to ensure a robust supply of JYNNEOS vaccines. The strategy must include specific plans for improving communication with state health departments about ongoing supply and ordering options, updating the current distribution strategy to ensure the broad and equitable access to monkeypox vaccines, and long-term manufacturing and procurement enhancements to ensure the vaccine continues to be available when we need it. In addition to addressing short-term shortages, I urge ASPR to develop and implement long-term strategies for the procurement of vaccines, to ensure that the United States is better prepared for future outbreaks. As a first step in developing such a strategy, I urge you to meet with key immunization and public health stakeholders, LGBTQ+ organizations, and relevant federal agencies, including CDC, to inform the strategy and incorporate feedback from on the ground.

As you take the necessary steps to improve availability of these critical tools, I recognize that additional resources are necessary to ensure an ongoing, robust response. The Senate fiscal year 2023 Labor/HHS/Education Appropriations bill provides \$16 billion in additional funding for the COVID-19 response that includes flexible funding for other infectious disease responses, including monkeypox.

It is critical we act quickly to get on top of this outbreak, utilizing essential tools, including vaccines. I expect this to be of the upmost priority for ASPR, and to see improved vaccine procurement and distribution strategies, and increased communication with state partners and other stakeholders. I ask that you continue to keep my staff briefed on such efforts.

Sincerely,

Senator Patty Murray

Chair, Senate Committee on Health, Education, Labor, and Pensions

<sup>&</sup>lt;sup>6</sup> https://www.nytimes.com/2022/08/15/health/monkeypox-vaccine-distribution.html?partner=slack&smid=sl-share