Congress of the United States Washington, DC 20515

August 17, 2022

The Honorable Xavier Becerra Secretary U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C., 20201

Dear Secretary Becerra,

We write to express our ongoing concerns regarding limited access to JYNNEOS vaccine doses as the monkeypox virus (MPV) continues to spread throughout our districts in and around Los Angeles County, California. We are encouraged by the Biden administration's recent actions declaring monkeypox a public health emergency and issuing an emergency use authorization (EUA) to help expand JYNNEOS vaccine supply. While these are critical steps in the public health response to MPV, we strongly encourage the Department of Health and Human Services (HHS), in coordination with the White House, to take further steps to procure and distribute additional JYNNEOS vaccine doses to ensure areas that have been hardest hit, including Los Angeles, have adequate vaccine supply.

The Food and Drug Administration (FDA) took a critical step in working to expand vaccine supply by authorizing intradermal administration of the JYNNEOS vaccine for emergency use. This alternative dosing regimen has the potential to increase our nation's JYNNEOS vaccine supply by five-fold. However, it is imperative that the federal government acknowledge the reality that a successful transition to intradermal administration depends heavily on several unknown factors.

First, the efficacy of the JYNNEOS vaccine through intradermal administration for the prevention of MPV is based on a single 2015 study.¹ While the available clinical data is encouraging, it is limited in scope. Further, expanding supply of the JYNNEOS vaccine through intradermal administration relies on the success of rapid, comprehensive provider education and training on how to administer the vaccine through a more specialized method. The federal government will also need access to real-time epidemiological data to properly inform ongoing vaccine allocations among cities and states. These hurdles are in addition to existing barriers that have inhibited vaccine access since the start of the outbreak, including stigmatization and financial burden.

¹ <u>https://www.sciencedirect.com/science/article/pii/S0264410X15008762</u>

The CDC estimates that there are currently 1.6 million to 1.7 million people who are at highest risk for MPV infection.² Under the new alternative dosing regimen, the remaining 400,000 vials of JYNNEOS vaccine that have not yet been distributed could provide, at maximum, approximately 2 million doses. This projection is enough to fully vaccinate only 1 million Americans – but, even then, does not take into consideration logistical hurdles and human error that will ultimately impact vaccine supply. The federal government must also be prepared for the likelihood that MPV will begin spreading at higher rates among communities outside of those already impacted. As the virus begins to circulate in other parts of our communities, the number of people considered high risk will inevitably grow.

As of August 12, 2022, Los Angeles County – the most populous county in the United States with over 10 million residents – has received only 43,290 doses of the JYNNEOS vaccine.³ Supply is not meeting demand, and as the virus continues to spread demand will inevitably increase. While we are encouraged by the potential to expand the number of available doses through implementation of intradermal administration, this approach alone will not suffice. We strongly encourage the Biden administration take additional steps to increase vaccine supply and ensure future vaccine allocations are distributed as soon as possible with an emphasis on hardesthit areas.

Thank you for your attention to this matter. We look forward to working with you on this critical issue.

Sincerely,

Adam B. Schiff Member of Congress

Nanette Diaz Barragán

Nanette Diaz Barragán Member of Congress

² <u>https://www.cnbc.com/2022/08/04/cdc-estimates-1point7-million-gay-and-bisexual-men-face-highest-risk-from-monkeypox-.html</u>

³ <u>http://publichealth.lacounty.gov/media/monkeypox/data/index.htm</u>

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