Congress of the United States

Washington, DC 20515

July 21, 2022

President Joseph R. Biden
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

Dear Mr. President:

We write to urge a robust and coordinated federal vaccine program in response to the monkeypox outbreak. We appreciate your Administration's efforts thus far to expand the availability of the JYNNEOS vaccine, but there is still more work to be done to meet the demand for vaccines across the country.

As cases of monkeypox rise across more states, we ask that the Administration act with urgency to ensure that roughly one million ready-to-administer doses of JYNNEOS vaccine arrive in the United States within the next week; that there is a clear, immediately-implemented plan to fill-and-finish the additional 15.1 million doses of raw vaccine substance so that these are also vaccine ready; and that there is a plan, overseen by a dedicated White House liaison, to coordinate a federal strategy to administer them as quickly as possible. We also encourage the Administration to declare a public health emergency and use those authorities to accelerate the federal response.

Since May, the Centers for Disease Control and Prevention (CDC) has confirmed over 2,000 monkeypox cases in the United States and thousands more worldwide, in over 60 countries where monkeypox is not usually present or had not previously been reported. These cases are occurring mainly, but not exclusively, among men who have sex with men and transgender people. With every day that passes, the risk of wider community transmission and transmission among incarcerated populations increases.

In hotspots around the country, such as New York, there are widespread reports of difficulties accessing vaccine appointments due to high demand and a lack of vaccine supply.[1] We are glad to see the Administration announce that more than 4 million additional vaccine doses will be made available in 2022 and 2023. However, experts have argued that millions more doses beyond what the Administration has already pledged are necessary to sufficiently meet demand, and these doses must be made available on a much faster and more specific timeline.[2]

First, we urge the Administration to swiftly remove the regulatory logjam that has delayed shipping to the U.S. vaccine doses already owned by the United States and ready for distribution.

Currently, of the millions of doses of JYNNEOS vaccine owned by the U.S. and produced by Bavarian Nordic, 1.1 million are ready-to-deliver doses that are sitting in Denmark.[3] These doses have yet to be released for use in the U.S. due to a requirement that the Food and Drug Administration (FDA) must inspect the facility to ensure it meets Current Good Manufacturing Practices (cGMP) certification before the doses can be

[1] "No Appointments Left as NYC Monkeypox Surge Fuels Soaring Vaccine Demand," NBC New York, 25 June 2022, https://www.nbcnewyork.com/news/local/more-nyc-monkeypox-vaccine-appointments-expected-to-open-sunday/3749713.
[2] Apoorva Mandavilli, "Will There Be Enough Monkeypox Vaccine?," *The New York Times*, 1 July 2022, https://www.nytimes.com/2022/07/01/health/monkeypox-vaccine-bavarian-nordic.html.
[3] James D. Walsh, "The Painful Wait," *New York Magazine*, 8 July 2022, https://nymag.com/intelligencer/2022/07/monkeypox-vaccine-delayed-after-fda-waited-to-inspect-plant.html.

distributed. Although this vaccine is part of the U.S. biodefense stockpile for a potential smallpox outbreak, the certification had not been conducted when the monkeypox outbreak began in May—and was not scheduled to occur until Q3 2022. The FDA only recently made arrangements with Bavarian Nordic to expedite the inspection, which reportedly began on July 1st and usually takes several months to complete.[4]

It is unclear why the FDA delayed inspection of a stockpile needed for biodefense, and this omission has cost valuable time in the U.S. response to monkeypox. Bureaucratic delays should not prevent us from getting the vaccine doses we need now. To avoid any further delays in securing these doses, we urge you to use your available executive authority to set a deadline of shipping the vaccines in 48 hours, either via swift conclusion of the ongoing FDA certification or by immediately recognizing the European Medicines Authority's (EMA) cGMP certification of this Bavarian Nordic facility. The FDA and EMA have shared a mutual recognition agreement on inspections since 2017.

Second, we ask the Administration to continue securing increased vaccine supplies and consider the use of public health emergency authorities and consultation with Congress for supplemental appropriations as needed.

The U.S. owns more than 15 million additional doses of raw JYNNEOS vaccine substance that is also in storage at the Bavarian Nordic facility. However, these are not filled-and-finished doses yet. Although the Biomedical Advanced Research and Development Authority (BARDA) within Health and Human Services (HHS) authorized Bavarian Nordic in May to freeze dry this stockpile for long-term storage, we ask that you direct BARDA to reverse this order and instead work with Bavarian Nordic to assess its capacity to fill-and-finish these available doses as soon as possible.[5] If Bavarian Nordic itself does not have adequate capacity to do so, we urge BARDA to assess whether its Fill Finish Manufacturing Network (FFMN) can work with Bavarian Nordic to rapidly prepare these additional doses for use. If neither of these options can be implemented, the FDA and BARDA should quickly identify another global FDA cGMP certified contract development and manufacturing organization (CDMO) that can rapidly fill-and-finish these available doses.

Moving swiftly to get these additional doses out to the public and expanding vaccine production capacity are also critical to ensuring an equitable public health response. We are already seeing how limited vaccine supplies are being distributed in overwhelmingly urban, whiter, and wealthier neighborhoods to the detriment of those who tend to have limited access to health care, especially people of color. Expanding vaccine production capacity can also address issues of vaccine equity globally so that other countries have access as we combat this global outbreak.

As the Administration works to broaden vaccine access, we ask your support for expanded access studies to evaluate the safety and efficacy of open-label monkeypox vaccines for individuals between the ages of 12 and 18. People under the age of 18 are equally susceptible to contracting monkeypox, and it is critical that we act quickly now to ensure the vaccines we have can offer them adequate protection.

We encourage the Administration to declare a public health emergency under section 319 of the Public Health Service Act. Doing so would make available a number of authorities to accelerate the federal response and tap into additional resources to procure vaccines and distribute them swiftly across the country. We also

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[4] Ibid.

[5] "Bavarian Nordic to Manufacture First Freeze-dried Doses of Smallpox Vaccine upon Exercise of Contract Option by the U.S. Government," GlobeNewswire, 18 May 2022, https://www.globenewswire.com/en/news-release/2022/05/18/2445603/0/en/Bavarian-Nordic-to-Manufacture-First-Freeze-dried-Doses-of-Smallpox-Vaccine-upon-Exercise-of-Contract-Option-by-the-U-S-Government.html.

welcome the Administration's close consultation with Congress if supplemental appropriations might be needed.

Third, we urge you to designate or appoint an interagency coordinator to organize and lead the Administration's monkeypox response and strategy. This role should include close consultation and collaboration with state and local governments as they establish their responses to monkeypox outbreaks in their jurisdictions.

Furthermore, an interagency coordinator can ensure consistent messaging in support of public awareness with regards to monkeypox to combat any stigmatization that may be harmful to LGBTQ+ people across the country. The history of the HIV/AIDS epidemic shows just how harmful stigmatization of any disease or groups of people can be to public health outcomes. Likewise, false messages about monkeypox as a "gay disease" will lead to under-testing and missed diagnoses in other populations, including pregnant women and other pregnant people, whom the World Health Organization has identified as being at high risk of severe outcomes from monkeypox. As the Administration works to respond to this monkeypox outbreak, a coordinated campaign in public awareness and messaging to combat any stigmatization and ensure accurate messaging for all populations must be a core part of our efforts. An effective response to swiftly curb this outbreak would demonstrate the Administration's commitment to the health and safety of the LGBTQ+ community.

We appreciate the Administration's efforts thus far in response to monkeypox and look forward to working with you on this issue further. Thank you for your consideration.

Sincerely,

Mondaire Jones
Member of Congress

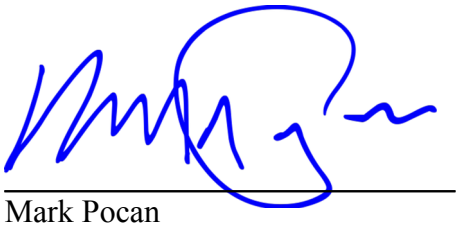
Jerrold Nadler
Member of Congress

Madeleine Dean
Member of Congress

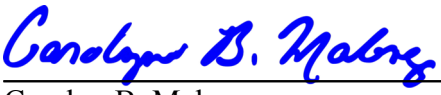
Frederica S. Wilson
Member of Congress

Chris Pappas
Member of Congress

Katie Porter
Member of Congress



Mark Pocan
Member of Congress



Carolyn B. Maloney
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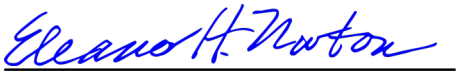
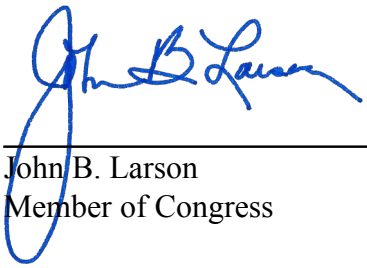


Eleanor Holmes Norton
Member of Congress



John B. Larson
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Bonnie Watson Coleman
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Lisa Blunt Rochester
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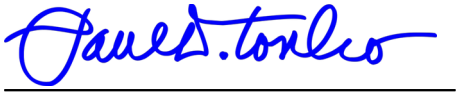

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Darren Soto
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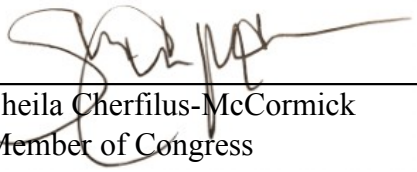
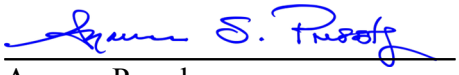


Sheila Cherfilus-McCormick
Member of Congress



Ayanna Pressley
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Rashida Tlaib
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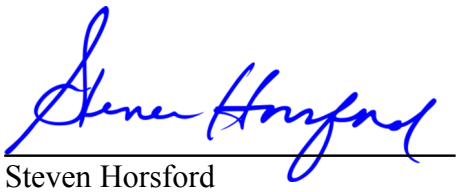

Steven Horsford
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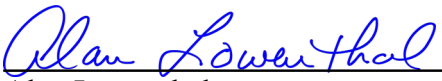
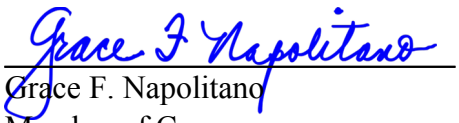


Alan Lowenthal
Member of Congress



Grace F. Napolitano
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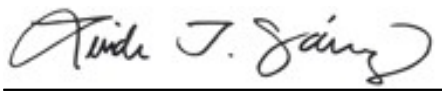

Linda T. Sánchez
Member of Congress

Betty McCollum
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Kathleen M. Rice
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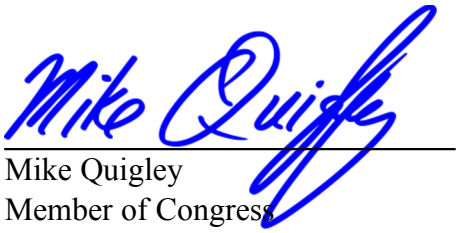
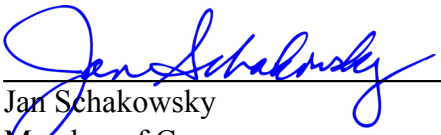
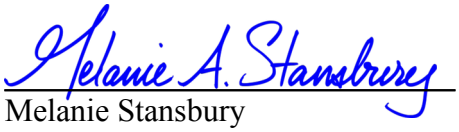


Mike Quigley
Member of Congress



Jan Schakowsky
Member of Congress



Melanie Stansbury
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David N. Cicilline
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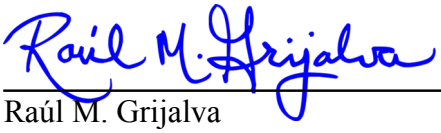
Scott H. Peters
Member of Congress



Raúl M. Grijalva
Member of Congress

CC: The Honorable Xavier Becerra, Secretary of Health and Human Services
Dr. Rochelle P. Walensky, Director, Centers for Disease Control and Prevention
The Honorable Robert Califf, Commissioner, U.S. Food and Drug Administration