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ONE HUNDRED SEVENTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE

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August 9, 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 concern and request information regarding the Biden administration's current response to the nationwide monkeypox outbreak. If there is one thing that our nation's leading public health experts should have learned from the last few years fighting the COVID-19 pandemic, it is that we must tackle outbreaks of infectious diseases aggressively and early on before they become unmanageable.

Monkeypox is a virus that causes an infection with symptoms very similar to smallpox, including fever, headache, chills, muscle aches and backache, respiratory symptoms (e.g., sore throat, nasal congestion, and cough), swollen lymph nodes, exhaustion, and most notably a rash that can look like pimples or blisters.¹ The virus can be transmitted from person-to-person through direct contact with the infectious rash, scabs, or body fluids; respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact; or touching items that previously touched infectious rash or body fluids.² Illness typically lasts two to four weeks, and the virus can spread from symptom onset until the rash has fully healed and a fresh layer of skin has formed.³

¹ Centers for Disease Control and Prevention, Monkeypox, Signs and Symptoms, *available at* <https://www.cdc.gov/poxvirus/monkeypox/symptoms.html>.

² Centers for Disease Control and Prevention, Monkeypox, How it Spreads, *available at* <https://www.cdc.gov/poxvirus/monkeypox/transmission.html>.

³ *Id.*

The first reported case of monkeypox in the U.S. was on May 18, 2022. The number of reported cases within the U.S. has increased rapidly, and as of August 8, 2022, more than 8,900 cases have been reported across the U.S.⁴ Globally, there are more than 30,100 cases in 88 countries, and the majority of cases are in countries that have not historically reported monkeypox.⁵ To date, there have been no deaths reported in the U.S., but a handful of fatalities have been reported in areas outside of where monkeypox is endemic, including in Brazil, Spain, and India.⁶ According to the World Health Organization (WHO), about 99 percent of cases in the current outbreak are among men, and at least 95 percent of those patients are men who have sex with men.⁷ As a result of this explosion in reported cases, the WHO declared monkeypox to be a public health emergency of international concern.⁸

The rapid increase in cases is extremely alarming, and it is very frightening to the public to watch these numbers continue to increase in a fashion that is reminiscent of the March 2020 onset of the COVID-19 pandemic. During the COVID-19 pandemic, we saw the extremely negative consequences that lockdowns had on our society, particularly on the economy and our mental health. It is therefore critical that there is a plan in place to get this outbreak under control without resorting to lockdowns or other heavy-handed, ineffective government restrictions or mandates again.

There is no reason for this disease to have spread so rapidly in the U.S. There have been smaller outbreaks of monkeypox in the U.S. in 2003 and 2021, so the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Health and Human Services (HHS) have prior experience responding to this virus. Yet, just weeks into the current outbreak, public health experts are fearful that the window to control the outbreak and eliminate the virus from the U.S. is closing quickly.⁹ You seemed to finally acknowledge that the public health response thus far has not been successful in containing the virus when you declared the ongoing spread of monkeypox in the U.S. a Public Health Emergency (PHE) on August 4, 2022.¹⁰

⁴ Centers for Disease Control and Prevention, Monkeypox, 2022 U.S. Map & Case Count (last updated July 27, 2022), available at <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>.

⁵ Centers for Disease Control and Prevention, Monkeypox, 2022 Monkeypox Outbreak Global Map (last updated July 27, 2022), available at <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>.

⁶ Stephanie Soucheray, *Non-endemic countries record first monkeypox deaths*, CIDRAP News (Aug. 1, 2022), available at <https://www.cidrap.umn.edu/news-perspective/2022/08/non-endemic-countries-record-first-monkeypox-deaths>.

⁷ Spencer Kimball, *WHO recommends gay and bisexual men limit sexual partners to reduce the spread of monkeypox*, CNBC (July 27, 2022), available at <https://www.cnbc.com/2022/07/27/monkeypox-who-recommends-gay-bisexual-men-limit-sexual-partners-to-reduce-spread.html>.

⁸ WHO Director-General's statement at the press conference following IHR Emergency Committee regarding the multi-country outbreak of monkeypox – 23 July 2022, World Health Organization, available at <https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-the-press-conference-following-ihr-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox--23-july-2022>.

⁹ Stephanie Soucheray, *Window to control monkeypox may be closing in US*, Center for Infectious Disease Research and Policy, University of Minnesota (July 18, 2022), available at <https://www.cidrap.umn.edu/news-perspective/2022/07/window-control-monkeypox-may-be-closing-us>.

¹⁰ U.S. Department of Health and Human Services, Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency (Aug. 5, 2022), available at <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.

Currently, there are two FDA-approved vaccines to prevent monkeypox – JYNNEOS and ACAM2000.¹¹ JYNNEOS is administered as two doses 28 days apart and is licensed by the U.S. Food and Drug Administration (FDA) for use in the prevention of smallpox or monkeypox in people ages 18 years and older.¹² Use of the vaccine in younger individuals requires the submission of a single patient Expanded Access Investigational New Drug (IND) application.¹³ ACAM2000 is administered as one dose via a multiple puncture technique and is licensed by the FDA for use against smallpox, with use against monkeypox allowed under an Expanded Access IND.¹⁴

There is currently a limited supply of JYNNEOS in the U.S. In total, HHS has allocated 1.1 million doses to states and jurisdictions in the U.S.¹⁵ To date, more than 602,000 doses of JYNNEOS have been delivered to jurisdictions throughout the U.S., and HHS says that it will make more doses available as jurisdictions use their supply.¹⁶ In addition, the administration has purchased additional doses. However, the delivery and distribution of those doses spans between now and in mid-2023, leaving a shortage of doses in the near-term.¹⁷ HHS has attempted to meet increased demand, announcing on August 4, 2022, that it accelerated the delivery of 150,000 doses that were originally scheduled to arrive in November to instead arrive in September.¹⁸ But that still will not be enough doses to fully cover the at-risk population, let alone the broader population should the outbreak continue to spread.¹⁹

While there is an ample supply of ACAM2000, the vaccine's potentially concerning side effects, the complex way it has to be administered, and limits on who can safely receive the

¹¹ Centers for Disease Control and Prevention, Monkeypox, Considerations for Monkeypox Vaccination, *available at* <https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>.

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ U.S. Department of Health and Human Services, Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency (Aug. 5, 2022), *available at* <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.

¹⁶ U.S. Department of Health and Human Services, HHS Expands Availability of Monkeypox Vaccine to More than 1.1 Million Doses (July 28, 2022), *available at* <https://www.hhs.gov/about/news/2022/07/28/hhs-expands-availability-of-monkeypox-vaccine-to-more-than-1-million-doses.html>; U.S. Department of Health and Human Services, Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency (Aug. 5, 2022), *available at* <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.

¹⁷ Sharon LaFraniere, Noah Weiland and Joseph Goldstein, *U.S. Could Have Had Many More Doses of Monkeypox Vaccine This Year?*, *New York Times* (August 3, 2022), *available at* <https://www.nytimes.com/2022/08/03/us/politics/monkeypox-vaccine-doses-us.html>; Lindsey Dawson, Kellie Moss, et al., *Key Questions About the Current Monkeypox Outbreak*, Kaiser Family Foundation (July 27, 2022), *available at* <https://www.kff.org/other/issue-brief/key-questions-about-the-current-u-s-monkeypox-outbreak/>.

¹⁸ U.S. Department of Health and Human Services, Biden-Harris Administration Bolsters Monkeypox Response; HHS Secretary Becerra Declares Public Health Emergency (Aug. 5, 2022), *available at* <https://www.hhs.gov/about/news/2022/08/04/biden-harris-administration-bolsters-monkeypox-response-hhs-secretary-becerra-declares-public-health-emergency.html>.

¹⁹ Dan Diamond, *'Not enough shots': U.S. faces 'vaccine cliff' on monkeypox*, *THE WASHINGTON POST* (July 30, 2022), *available at* <https://www.washingtonpost.com/health/2022/07/30/monkeypox-jynneos-vaccine-supply-united-states/>.

vaccine complicate the risk-benefit calculation around using it.²⁰ This vaccine should not be given to individuals with health conditions, including cardiac disease; eye disease treated with topical steroids; congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people living with HIV (regardless of immune status); atopic dermatitis/eczema and persons with a history of atopic dermatitis/eczema or other acute or exfoliative skin conditions; infants less than 12 months of age; or pregnancy.²¹

Despite the labeled dosing regimen for the JYNNEOS vaccine, in an attempt to vaccinate as many individuals as possible, some jurisdictions, including the District of Columbia, New York City, and San Francisco have announced that they are prioritizing the first dose of JYNNEOS and will defer second dose appointments until sufficient supply is received.²² While there is some evidence that suggests a single dose of the vaccine may provide sufficient protection against the disease, the FDA has not yet authorized JYNNEOS to be administered as a single dose.²³ In addition, according to recent reports, the administration plans to embrace a dose-sparing approach of vaccination, which would allow health care providers to use an existing one-dose vial of the vaccine to administer a total of up to five separate doses.²⁴ Although FDA claims that the safety and efficacy profile of the vaccine will not be diminished, the data the agency is relying on to justify implementing this approach is from a seven-year old study funded by the National Institutes of Health on smallpox.²⁵ To ensure safe vaccination for all individuals at risk of contracting monkeypox, it is necessary to rapidly make more doses of the JYNNEOS vaccine available in all states for all individuals who want it as soon as possible.

Before monkeypox appeared in the U.S., the U.S. government already owned a stockpile located in a Denmark warehouse of 372,000 doses of the JYNNEOS vaccine for the purpose of preventing a smallpox outbreak.²⁶ When the monkeypox virus was first reported in the U.S., the federal government requested the shipment of only 72,000 of these doses.²⁷ Biomedical Advanced Research and Development Authority (BARDA) officials claim that one reason the U.S. government did not request the entire available supply is because of cold storage and shelf-

²⁰ Keren Landman, *The smallpox vaccine stockpile isn't the monkeypox solution we need — yet*, VOX (July 29, 2022), available at <https://www.vox.com/2022/7/29/23281407/monkeypox-vaccine-acam2000-jynneos-smallpox>.

²¹ Centers for Disease Control and Prevention, *Monkeypox, Considerations for Monkeypox Vaccination*, available at <https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>.

²² Olafimihan Oshin, *DC postpones second monkeypox vaccine citing shortage, increase in cases*, THE HILL (July 25, 2022), available at <https://thehill.com/policy/healthcare/3573994-dc-postpones-second-monkeypox-vaccine-citing-shortage-increase-in-cases/>; Health Department Announces Latest Distribution of Monkeypox Vaccine, NYC Health (July 21, 2022), available at <https://www1.nyc.gov/site/doh/about/press/pr2022/health-department-announces-latest-distribution-of-monkeypox-vaccine.page>; Monkeypox Vaccine, City and County of San Francisco (last updated July 27, 2022), available at <https://sf.gov/information/monkeypox-vaccine>.

²³ Jon Cohen, *There's a shortage of monkeypox vaccine. Could one dose instead of two suffice?*, VOX (July 1, 2022), available at <https://www.science.org/content/article/there-s-shortage-monkeypox-vaccine-could-one-dose-instead-two-suffice>.

²⁴ Erin Banco, *Monkeypox dose sparing? Biden admin looks to NIH-funded study for clues.*, POLITICO (Aug. 8, 2022), available at <https://www.politico.com/news/2022/08/08/monkeypox-dose-sparing-00050375>.

²⁵ *Id.*

²⁶ Joseph Goldstein and Sharon Otterman, *As Monkeypox Spread in New York, 300,000 Vaccine Doses Sat in Denmark*, THE NEW YORK TIMES (July 25, 2022), available at <https://www.nytimes.com/2022/07/25/nyregion/nyc-monkeypox-vaccine-doses-denmark.html>.

²⁷ *Id.*

life reasons.²⁸ In the meantime, the virus continued to spread in states across the nation and the demand for vaccines greatly outpaces the supply.

The CDC's FDA-cleared non-variola orthopoxvirus test can detect monkeypox from a lesion sample.²⁹ Initially the U.S. had the capacity to conduct 6,000 monkeypox tests per week.³⁰ The FDA and CDC started working with commercial laboratories and manufacturers to increase testing capacity, and as of July 28, 2022, testing capacity in the U.S. increased to 80,000 tests per week.³¹ Even though capacity continues to increase, there have been reported challenges and bottlenecks regarding testing for monkeypox. For example, early on in the outbreak, if a health care provider suspected that an individual had monkeypox, the provider first had to consult their state health department, and all specimens were supposed to be sent through the state and territorial public health department, unless authorized to send them to CDC directly.³² Only 74 labs in 46 states had the ability to determine if a sample was positive for an orthopoxvirus—the family of viruses that include monkeypox and smallpox—and if a sample tested positive, the CDC would conduct a confirmatory test.³³ In addition, monkeypox can present similarly and be confused with sexually transmitted infections, and despite CDC's warnings that patients should be carefully evaluated and coinfections are possible, many patients who were at risk for monkeypox were not being tested for it because they were screened and tested for other pathogens.³⁴ Such bottlenecks and limitations to testing have undoubtedly resulted in missed diagnoses and underreporting of monkeypox cases.

There are no treatments specifically targeted for monkeypox. TPOXX is an antiviral approved for smallpox and can be prescribed to reduce the severity of disease. TPOXX, however, is an investigational drug that requires an approval process to be used. CDC has stated that it has taken action to reduce the burden of accessing treatments for monkeypox by decreasing the documentation required to prescribe and allowing providers to prescribe prior to

²⁸ *Id.*

²⁹ U.S. Food & Drug Administration, For Monkeypox Testing, Use Lesion Swab Samples to Avoid False Results: FDA Safety Communication (July 15, 2022), available at <https://www.fda.gov/medical-devices/safety-communications/monkeypox-testing-use-lesion-swab-samples-avoid-false-results-fda-safety-communication#:~:text=Monkeypox%20Test%20Description%20and%20Background,monkeypox%20from%20a%20lesion%20sample>.

³⁰ U.S. Department of Health and Human Services, HHS Expands Availability of Monkeypox Vaccine to More than 1.1 Million Doses (July 28, 2022), available at <https://www.hhs.gov/about/news/2022/07/28/hhs-expands-availability-of-monkeypox-vaccine-to-more-than-1-million-doses.html>.

³¹ *Id.*

³² Centers for Disease Control and Prevention, Emergency Preparedness and Response, Monkeypox Virus Infection in the United States and Other Non-endemic Countries—2022, distributed via the CDC Health Alert Network (May 20, 2022), available at <https://emergency.cdc.gov/han/2022/han00466.asp>; Helen Branswell and Andrew Joseph, 'Testing bottleneck' for monkeypox puts hope of containment at risk, experts warn, STAT (June 7, 2022), available at <https://www.statnews.com/2022/06/07/testing-bottleneck-for-monkeypox-jeopardizes-containment-experts-warn/>.

³³ *Id.*

³⁴ *Id.*; Madison Muller, *Monkeypox Testing Shows the US Learned Little From the Covid-19 Pandemic*, BLOOMBERG (June 16, 2022), available at <https://www.bloomberg.com/news/articles/2022-06-16/monkeypox-cases-could-spread-unseen-in-us-if-testing-bottlenecks-don-t-improve>.

completing the documentation, but reports continue to indicate challenges in accessing the drug.³⁵

We are troubled that CDC and HHS officials underestimated the severity of the threat posed by monkeypox. The administration could have, and should have acted earlier to slow the spread of the virus in the U.S. In the wake of the COVID-19 pandemic, public health officials should have been particularly vigilant and proactively responded to any potential health threat observed throughout the rest of the world. Given that we were better prepared for monkeypox than we were for COVID-19, with an already developed test and medical countermeasures, there is no excuse for the inaction of administration officials whose sole responsibility is to protect the health and wellbeing of our nation. Now, the American public will be forced to endure the spread of yet another viral disease that has the potential to take a serious toll on the already-suffering health, economy, and livelihood of communities across the nation.

We are particularly concerned about recent reports of monkeypox spread among children at daycares and the potential for further outbreaks once schools return in the fall.³⁶ Given the failures of the government, public health officials, and teachers unions during COVID-19 to ensure children were able to continue learning and developing while appropriately managing the risk of COVID-19, it is crucial that this administration does not repeat the same mistakes. We must ensure future outbreaks are mitigated, but monkeypox cannot be used as another excuse for public health officials and teachers unions to shutdown schools and force other extreme and ineffective mitigation measures that harm children's learning and emotional and social development.

The Committee seeks further information regarding the U.S. public health response to the ongoing threat of monkeypox. We therefore request a briefing for Committee Members by August 23, 2022. To assist the Committee's inquiry, we would like the briefing to cover the following questions and topics:

1. A status update on the current number of cases—globally and in the U.S.—and where those cases have been detected, and to the extent known, the age of those cases.
2. How, if at all, the current outbreak is different from previous outbreaks in areas where monkeypox has traditionally been endemic.
3. Any authorities being used, or actions being taken by the administration as a result of declaring monkeypox a PHE.

³⁵ U.S. Department of Health and Human Services, HHS Expands Availability of Monkeypox Vaccine to More Than 1.1 Million Doses (July 28, 2022), *available at* <https://www.hhs.gov/about/news/2022/07/28/hhs-expands-availability-of-monkeypox-vaccine-to-more-than-1-million-doses.html>; Neeraj G. Patel and Nadia Kounang, *Access to experimental monkeypox treatment remains uneven, doctors say*, CNN (Aug. 2, 2022), *available at* <https://www.cnn.com/2022/08/02/health/tpox-access-problems/index.html>.

³⁶ Dan Diamond, Fenit Nirappil, Lena H. Sun, *Children potentially exposed to monkeypox at Illinois day care, officials say*, THE WASHINGTON POST (Aug. 5, 2022), *available at* <https://www.washingtonpost.com/health/2022/08/05/monkeypox-illinois-daycare-center/>.

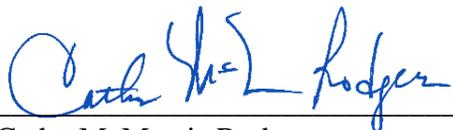
4. The total number of JYNNEOS vaccine doses that the U.S. government previously owned and has purchased since the current outbreak began, including a breakdown of how many doses the U.S. government owned prior to the first case of monkeypox in the U.S. in May, when and how many additional doses have been purchased, and when the newly purchased doses will be available for distribution to jurisdictions in the U.S.
5. Whether and when the U.S. government is planning to purchase additional doses of the JYNNEOS vaccine.
6. How jurisdictions can order their JYNNEOS allocations, and if they are able to order additional doses when their allocated supply is depleted.
7. The benefits and risks of jurisdictions electing to prioritize first doses of JYNNEOS and postpone second doses, including any data on the risks and benefits of administering JYNNEOS as a single dose.
8. Details about any other vaccine administration strategies that are being considered by the administration, including dose sparing, to increase the number of individuals who can be vaccinated with JYNNEOS, including data on the risks and benefits of these strategies.
9. The risks and benefits to the more widespread use of ACAM2000.
10. The total number of ACAM2000 vaccine doses that the U.S. government owns, and how those are being made available to jurisdictions.
 - a. Of those, how many jurisdictions have requested doses of ACAM2000, and how many doses of the ACAM2000 vaccine have been delivered to jurisdictions in the U.S.?
11. What data is CDC currently able to collect on monkeypox? What is the status of Data Use Agreements (DUA) with the states (e.g., what DUAs are already in place, what data is being reported to CDC, what, if any, data have the states been unwilling to share or include in DUAs to share with CDC)?
12. The CDC declared monkeypox a nationally notifiable condition on August 1. However, you stated that the agency cannot force states to provide this information. Under what authority is the CDC able to make monkeypox a notifiable condition?
13. Currently, monkeypox testing can only be conducted through obtaining swabs from open skin lesions. Are there any alternative methods of testing for monkeypox or orthopoxviruses under development? Has the administration considered using existing mechanisms, such as RAD-X, to try to make at-home testing an option?
14. The status of treatments for monkeypox, including when existing treatments are indicated for use and whether federal funding, such as the over \$6.3 billion provided to the

National Institute of Allergy and Infectious Disease for fiscal year 2022, is available to support additional treatments.

15. The indicated use for TPOXX as a therapeutic for monkeypox, the roles of the FDA and CDC with respect to TPOXX, what barriers exist that are preventing TPOXX from being used more widely, and what the administration is doing to reduce such barriers.
16. Current laboratory testing capacity, including whether the laboratories have enough materials needed to run the orthopoxvirus tests (e.g., laboratory staff, assays, positive controls, etc.) to meet the reported capacity of running 80,000 tests per week.
17. How much of the nation's current orthopoxvirus laboratory capacity is being utilized, and how, if at all, utilization has changed since the start of the current outbreak.
18. What CDC is doing to eliminate bottlenecks to ensure testing for monkeypox is decentralized and easily accessible.
19. The amount of funding that the administration has spent to date on the monkeypox response, including a breakdown of how those funds have been used.
20. Plans that have been developed by the administration to contain the current outbreak, including any plans regarding guidance to colleges, day care centers, and schools in the event of a diagnosed case of monkeypox among students, faculty, or staff at those facilities.

Please contact Brittany Havens or Kristen Shatynski of the Minority Committee staff with any questions and to schedule the requested briefing. Thank you for your attention to this request.

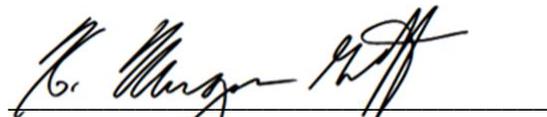
Sincerely,



Cathy McMorris Rodgers
Republican Leader
House Energy and Commerce Committee



Brett Guthrie
Member of Congress



H. Morgan Griffith
Member of Congress