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LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

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<http://help.senate.gov>

August 4, 2022

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

Dear Secretary Becerra,

On July 13th, I wrote to you on the failures of the United States' domestic response to the ongoing monkeypox outbreak. I still have not received a response to my letter which is now two weeks past due. When I sent that letter, the Centers for Disease Control and Prevention (CDC) had reported a total of 1,159 cases in the United States.¹ As of August 3rd, CDC has reported a total of 6,617 cases, a 471 percent increase.² We now lead the world in total cases, higher than early epicenters of the outbreak such as Spain and the United Kingdom.³

In the three weeks since my previous letter, I have been baffled by the degree to which the administration seems to be disconnected from the realities on the ground for health care providers, public health personnel, and, most importantly, patients. Federal officials have downplayed the severe symptoms many patients are experiencing, continuing to refer to monkeypox as a "mild" disease. Federal officials have done an inadequate job explaining to populations highest at risk about tests, treatments, and vaccine availability.

This failure of leadership will only further entrench distrust in government, as hospitalizations and deaths begin to increase, including among individuals with no known comorbidities.⁴ Additionally, the supply of available vaccine doses is still not sufficient to protect those at high risk, leading some states and localities to ration doses without clear evidence regarding effectiveness. Even worse, this rationing is being done without any coherent explanation to patients, increasing distrust, panic, and fear.

The response from this administration is a devastating public health failure. Your department is failing to protect the health of the American people, especially gay and bisexual men and their families.

¹ <https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html>

² <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>

³ <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>

⁴ <https://www.nbcnews.com/news/us-news/two-deaths-reported-spain-thought-first-monkeypox-europe-rcna40803>

Given these growing concerns and the lack of response I received to my previous letter, I request weekly briefings on this issue for my staff. I also request written responses to each of the following questions, and the questions I asked on July 13th, no later than August 11th:

1. During a press briefing on July 28th, you were asked whether it would be possible to contain monkeypox before the disease becomes endemic. Rather than responding to a question that is common at this stage of a response, you reportedly responded to the reporter by asking, “How many vaccines do you think we need at this stage?”⁵ Based on this reported interaction, I am concerned that you are not taking this response seriously or sufficiently informed on the latest strategy, activities, and scientific thinking of public health experts in your department.
 - a. How many times per week are you personally briefed on the monkeypox response? Please provide a list of officials who regularly brief you during these meetings.
 - b. What specific policy decisions have you been involved in related to this response, and how frequently do you communicate with President Biden and the White House to advise the president on these issues?
 - c. What specific steps, including determining the number of vaccines needed, do HHS officials believe are necessary to prevent this disease from becoming endemic?
 - d. How many vaccines are needed to prevent the disease from becoming endemic?
 - e. Do HHS officials believe we are past the point of preventing the disease from becoming endemic?
 - f. How will we know when the disease has become endemic?

2. In the past week, multiple jurisdictions have issued emergency declarations in response to the monkeypox outbreak. While administration officials have indicated that they are contemplating a federal public health emergency declaration, as of today, the HHS Secretary has not issued such a declaration, although news outlets have reported that a decision memo on this subject is under review.⁶
 - a. What criteria is the Department considering when evaluating the need for a public health emergency declaration?

⁵ <https://twitter.com/ArielCohen37/status/1552692095755993089>

⁶ <https://subscriber.politicopro.com/article/2022/08/biden-administration-making-plans-to-use-public-health-emergency-authorities-to-combat-monkeypox-00049831?source=email>

- b. Which specific authorities or flexibilities relevant to this response that would be enabled through a public health emergency declaration would HHS utilize?
 - c. Why have you not already declared a public health emergency?
3. Finally, on August 2nd, the administration announced a career FEMA official as the coordinator of the monkeypox response. Continuous leadership changes, during multiple responses, underscore the need for consistent, steady interagency leadership on preparedness and response. I raised the following questions in my previous letter to you, but given the recent announcement of a monkeypox response coordinator and a lack of response to that letter, I will restate my questions here.
 - a. Do you agree that addressing the ambiguity in federal pandemic preparedness and response leadership will help us better protect the American people?
 - b. Do you agree that it is important to ensure that federal departments have a consistent sense of direction on related goals and objectives so that activities can be appropriately prioritized?
 - c. Do you agree that, in order to accomplish these goals, the federal government needs to have the right expertise and capabilities in place, which requires having appropriate support within the White House?
 - d. Will you recommend to President Biden that he establish a new Office of Pandemic Preparedness and Response Policy, separate from the National Security Council, Office of Science and Technology Policy, or other existing White House office with similar responsibilities?
4. In my last letter, I asked about the reasons for the delay in FDA's inspections. Additional reports have surfaced about the delay in FDA's inspection of the Bavarian Nordic facility awaiting FDA's sign-off on 1.4 million additional, needed monkeypox vaccine. These reports indicate that FDA waited until July to inspect the facility. Why did it take FDA two months to initiate an inspection of the new facility? What bureaucratic sensitivities are more important than protecting the health of millions of Americans?
5. In my previous letter, I also asked whether HHS had developed a research plan to address knowledge gaps and verify previous scientific findings related to monkeypox. On July 21st, the White House Office of Science and Technology Policy (OSTP) published a blog post identifying seven monkeypox research areas, each with high-level priorities. However, the blog post did not provide a detailed plan for addressing each research priority or a description of the specific knowledge gaps or previous scientific findings within each research priority. The priorities highlighted in the blog post seem to reiterate research priorities identified by the U.K. Health Security Agency in its first monkeypox

technical briefing published on June 10, following a two-day World Health Organization meeting on the topic.^{7,8}

- a. Why did it take an additional seven weeks for the administration to publish its monkeypox research priorities?
 - b. What new information or insights are included in the OSTP blog post?
 - c. Please provide an updated timeline for the development of a complete U.S. research plan, including a description of how the administration plans to collaborate with allied governments to address knowledge gaps and validate previous scientific findings.
 - d. Please describe the specific knowledge gaps and/or previous scientific findings associated with each stated research priority.
 - e. The blog post states that \$140 million have been directed to support research priorities identified in the blog post. Please provide the specific accounts from which these funds originated and whether these amounts have been reprogrammed from other activities.
6. Some children and many young adults have been infected so far with monkeypox, which raises concerns about potential transmission as we enter the fall and send students back to college, school, and daycare.
- a. What steps are you taking to communicate with universities, schools, and childcare providers about the possibility of transmission in these settings, and when will guidance be available for each of these settings so they can prepare for the back-to-school season?
 - b. What steps are you taking to coordinate with the U.S. Department of Education on these activities?
 - c. What steps are you taking to make tests, treatments, and vaccines available to children? Have you provided any guidance to states or health care providers in using these products in children, particularly Jynneos, which is only approved for use in adults?
7. In the past month, monkeypox testing capacity has expanded as a result of the efforts of private sector laboratories. During this period, have you seen any changes in demand for monkeypox testing? Please provide weekly testing data since testing in the U.S. began.
8. On July 6, 2022, CDC announced that commercial labs would begin diagnostic testing for monkeypox.⁹ On July 26, 2022, the American Medical Association published a CPT

⁷ <https://www.gov.uk/government/publications/monkeypox-outbreak-technical-briefings>

⁸ <https://www.who.int/news-room/events/detail/2022/06/02/default-calendar/who-monkeypox-research--what-are-the-knowledge-gaps-and-priority-research-questions>

⁹ <https://www.cdc.gov/media/releases/2022/s0706-monkeypox-labcorp.html>

code for tests to diagnose monkeypox.¹⁰ In the month since commercial labs started performing monkeypox testing, please describe each specific step CMS has taken to ensure those Americans in vulnerable communities who are covered by Medicare and Medicaid have access to diagnostic monkeypox testing and are aware of such access?

9. Recently, HHS changed its guidance to allow states to prioritize administering first doses of Jynneos, rather than holding back sufficient inventory to ensure each individual who receives a first dose also gets a second dose in line with the ACIP recommendations.
 - a. What information did HHS use to inform this change to guidance?
 - b. What is currently known about the degree of protection conferred by either receiving only a single dose of Jynneos or waiting more than 28 days between doses, if anything?
 - c. What steps is HHS taking to address knowledge gaps in this area?
 - d. How soon will additional data on this subject be available?

10. FDA Commissioner Robert Califf has suggested that the FDA “is using the full breadth of its authorities to make additional diagnostics and treatments available,” yet the agency has not leveraged the Emergency Use Authorization (EUA) review pathway for vaccines or treatments that could add to the arsenal of countermeasures available to individuals at high risk.¹¹
 - a. Why hasn’t FDA provided the option for sponsors to submit an EUA application and leverage the agency’s expertise to account for the known and potential benefits and the known and potential risks of a vaccine or treatment?
 - b. Given the supply challenges for existing vaccine doses, how is FDA working with developers of additional vaccines or treatments that could help prevent or treat monkeypox?
 - c. What specific clinical trial flexibilities that resulted in faster and more efficient clinical studies during COVID-19 is FDA providing monkeypox vaccine and treatment developers? Please provide specific examples.

11. During the COVID-19 response, CDC established a National Wastewater Surveillance System (NWSS). While some states and private entities have begun expanding their wastewater surveillance efforts to include detection of monkeypox, the CDC program has not yet taken this step.

¹⁰ <https://www.ama-assn.org/press-center/press-releases/ama-announces-cpt-update-monkeypox-testing-and-vaccination>

¹¹ <https://www.fda.gov/news-events/press-announcements/fda-provides-update-agency-response-monkeypox-outbreak>

- a. Why has CDC not yet expanded NWSS to include monkeypox and other diseases that could be detected in wastewater, beyond COVID-19 and waterborne illnesses?
 - b. Is CDC planning to add monkeypox to NWSS?
 - c. What steps have you taken to increase coordination with the private sector to expand capacity beyond current state-based surveillance programs?
12. During the early stages of the monkeypox response, federal officials consistently downplayed the severity of the disease, referring to it as mild and citing the relatively low mortality rate of the West African clade. However, this downplays the severity of symptoms that many patients with supposedly “mild” cases endure, which, in some cases, has led to the use of opioids to manage pain stemming from lesions.
 - a. What steps are you taking to facilitate access to, and uptake of, TPOXX or other products to help manage symptoms?
 - b. How many treatment courses of TPOXX are available, and how are you addressing ongoing challenges related to access?
 - c. How are you ensuring that health care providers understand the full spectrum of potential symptoms, including serious health effects like encephalitis, and can recognize signs of disease progression?
 - d. How are you ensuring that health care providers understand that pregnant women and children are at higher risk for severe disease and how best to treat these populations?
13. What steps are you taking to work collaboratively with states in order to build trust and encourage the voluntary collection and reporting up to CDC of data related to the monkeypox response?
14. What specific actions has HHS taken to ensure that CMS is aware of the most up-to-date guidance on public health actions being taken to slow the spread of monkeypox and is incorporating such guidance into the Medicare and Medicaid programs? What tangible products or policy guidance has been produced from such coordination, if any?
15. CDC confirms that those highest at risk are currently men who have sex with men. Our country cannot tolerate a failed public health response that could lead to stigmatizing or alienating that population. They deserve better than your agency has currently provided.

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- a. What outreach is your agency doing to major advocacy groups that represent and communicate with gay and bisexual men so that there are more avenues through which individuals can receive accurate information about reducing their risk of infection, and accessing tests, treatments, and vaccines?
 - b. Please provide a list of all meetings Department officials have had with major advocacy groups.
 - c. Will you commit to weekly meetings or conference calls with major advocacy groups to keep them up to date on information regarding this outbreak?
 - d. How is the Department communicating with the general public to reduce the stigma of this virus on the gay and bisexual community by emphasizing how the virus is spread and that it's not a sexually transmitted infection?
16. The letter I sent you on July 13th raised critical questions regarding the Department's response to monkeypox. I asked for a response to my questions by July 21st. I still have not received a response. When should I expect to receive a response to my letter?

Thank you for your time and attention to this matter. I look forward to receiving a prompt reply.

Sincerely,



Richard Burr

Cc: Dr. Ashish Jha, White House COVID-19 Response Coordinator
Mr. Robert Fenton, White House Monkeypox Response Coordinator and Regional Administrator, Federal Emergency Management Agency, Region 9
Dr. Demetre Daskalakis, White House Monkeypox Response Deputy Coordinator and Director, Division of HIV Prevention, Centers for Disease Control and Prevention