

PATTY MURRAY, WASHINGTON, CHAIR

BERNARD SANDERS (I), VERMONT  
ROBERT P. CASEY, JR., PENNSYLVANIA  
TAMMY BALDWIN, WISCONSIN  
CHRISTOPHER S. MURPHY, CONNECTICUT  
TIM Kaine, VIRGINIA  
MARGARET WOOD HASSAN, NEW HAMPSHIRE  
TINA SMITH, MINNESOTA  
JACKY ROSEN, NEVADA  
BEN RAY LUJÁN, NEW MEXICO  
JOHN HICKENLOOPER, COLORADO

RICHARD BURR, NORTH CAROLINA  
RAND PAUL, KENTUCKY  
SUSAN M. COLLINS, MAINE  
BILL CASSIDY, LOUISIANA  
LISA MURKOWSKI, ALASKA  
MIKE BRAUN, INDIANA  
ROGER MARSHALL, KANSAS  
TIM SCOTT, SOUTH CAROLINA  
MITT ROMNEY, UTAH  
TOMMY TUBERVILLE, ALABAMA  
JERRY MORAN, KANSAS

## United States Senate

COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

EVAN T. SCHATZ, STAFF DIRECTOR  
DAVID P. CLEARY, REPUBLICAN STAFF DIRECTOR

<http://help.senate.gov>

July 13, 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,

I write to you regarding the United States' failure to rapidly respond to the ongoing monkeypox outbreak. The United States is once again significantly behind the curve, failing to learn from the devastating effects of COVID-19, and other recent infectious disease threats, like Ebola and Zika. Despite the once in a century pandemic caused by a novel coronavirus, the US response to an existing threat is falling short, failing to develop and issue a research plan to understand the threat and its characteristics, failing to rapidly engage the private sector to develop tests for the virus, and failing to make vaccines quickly available and help states effectively use them. The administration has the tools and authorities necessary to combat these threats. Your failures to act are a threat to public health, and especially for gay and bisexual men who are at highest risk. The government failed this population at the beginning of the HIV/AIDS epidemic, we should not fail them again. You and your subordinates must change course and take proactive, decisive action to detect and respond to monkeypox cases in the United States, and you must do it now.

### **Failure #1: The lack of a clear, concise, and efficient research plan to understand the threat facing Americans.**

Understanding the threat we face is key to combatting it appropriately. For example, in recent years, previously studied viruses have been found to have characteristics that contradict our existing knowledge base. The Ebola virus was first identified in 1976 and sporadically reemerged in rural areas over the next 40 years, before spreading to urban areas in 2014, causing a multi-country epidemic in West Africa.<sup>1</sup> As a result, we now know that the Ebola virus can, in some cases, remain dormant in the human body for long periods of time, which can result in

---

<sup>1</sup><https://www.cdc.gov/vhf/ebola/history/summaries.html#:~:text=Since%20its%20discovery%20in%201976,a%20global%20epidemic%20within%20months.>

survivors unknowingly spreading the infection, including through sexual transmission.<sup>2</sup> Further, some individuals who recover from Ebola virus disease can experience long-term, adverse health effects.<sup>3</sup>

Now, we are faced with monkeypox, which is causing large-scale outbreaks in non-endemic countries. While there have been more frequent and larger outbreaks over the past few years, these new cases are presenting differently from the traditional presentation of monkeypox in endemic countries, and the virus has more mutations than would be expected.<sup>4,5</sup> Yet, the federal government has not articulated a comprehensive and clear research plan to better understand these differences and verify our previous assumptions about the virus. Federal public health officials also did not effectively communicate these differences in clinical presentation to health care providers early in the response, which likely delayed or even missed the identification of cases.<sup>6</sup>

**Failure #2: Despite investing \$100 billion in testing capacity for COVID-19, the testing response is slow, inaccurate, and testing uptake is still low.**

The administration's slow approach to testing actions in the early days of this monkeypox response have been reactive rather than proactive, repeating the same mistakes the Centers for Disease Control and Prevention (CDC) has made during the COVID-19 pandemic. Similar to the early stages of the COVID-19 response, the CDC has primarily utilized state and local public health laboratories to perform tests, and the process of getting approval to test a suspected case has required health care professionals to consult with public health officials, delaying diagnosis, contact tracing, and treatment.<sup>7</sup> In another failure, the administration did not announce their engagement with commercial laboratories, which have the expertise and capacity to scale up testing, until June 22.<sup>8</sup> Yet, under this partnership, commercial laboratories are expected to utilize the CDC-developed orthopoxvirus test, rather than their own tests that are specific to monkeypox.

As of June 25<sup>th</sup>, the positivity rate for monkeypox testing was reportedly around 30 percent, and it is likely that a significant number of cases are going undetected and risk further transmission of the virus.<sup>9</sup> Although health officials have worked with commercial laboratories to scale up testing and enable doctors to directly order tests beginning in July, these announcements came more than a month after the first case was detected in the United States and almost two months

---

<sup>2</sup> <https://www.science.org/content/article/new-ebola-outbreak-likely-sparked-person-infected-5-years-ago>

<sup>3</sup> <https://www.cdc.gov/vhf/ebola/treatment/survivors.html>

<sup>4</sup> <https://www.cidrap.umn.edu/news-perspective/2022/07/study-monkeypox-outbreak-shows-differing-symptoms>

<sup>5</sup> <https://www.statnews.com/2022/06/02/mutations-in-monkeypox-virus-explainer/>

<sup>6</sup> <https://www.washingtonpost.com/health/2022/06/23/monkeypox-response-biden-administration/>

<sup>7</sup> <https://www.npr.org/sections/health-shots/2022/06/25/1107416457/monkeypox-outbreak-in-us>

<sup>8</sup> <https://www.hhs.gov/about/news/2022/06/22/hhs-expanding-monkeypox-testing-capacity-five-commercial-laboratory-companies.html>

<sup>9</sup> <https://www.npr.org/sections/health-shots/2022/06/25/1107416457/monkeypox-outbreak-in-us>

after early cases began to be detected in Europe.<sup>10,11,12</sup> The signs were there. HHS should have acted on the lessons we learned from the COVID-19 pandemic particularly that an effective response requires swift engagement of the private sector and an immediate increase to testing.

**Failure #3: The absence of a vaccination plan and strategy, even though a vaccine already exists to fight this threat.**

Beyond failures in testing, the administration's strategy to utilize vaccines and treatments that are effective against monkeypox has also been appalling. We have vaccines and treatments that we can use during this response. These tools are available in large part due to the resources the United States has provided for smallpox preparedness through Project BioShield. The availability of these products is a true success story of biodefense. But securing a stockpile of vaccines is only effective if we are able to get shots in arms.

Given the lack of increased testing in the United States, vaccines and treatments should be made widely available to try to protect individuals at increased risk for the virus. Yet, the administration waited until June 28<sup>th</sup> to announce an "enhanced" strategy to offer vaccines to at-risk individuals, in addition to known contacts.<sup>13</sup> This strategy was announced only after some local jurisdictions had already begun using vaccine doses in this manner, which suggests that the announcement was neither strategic nor the result of proactive planning but, rather, an after-the-fact reaction to decisions made by local leaders who were quick to respond.

This pattern of reactive policymaking is disturbing. Planning for national-level medical countermeasure needs has been articulated by Congress as a core responsibility of the Department of Health and Human Services (HHS).<sup>14</sup> Given the importance of these issues, please respond to each of the following questions no later than July 21, 2022:

1. What is the Department's detailed strategy for addressing monkeypox? Please provide a copy of the strategy.
2. During the Ebola and COVID-19 responses, HHS and the White House repeatedly failed to lead the federal response through their existing offices and coordination mechanisms. We have seen this pattern of lack of leadership repeated, yet again, with monkeypox. In recognition of these failures, the bipartisan PREVENT Pandemics Act would establish an entirely new office, known as the Office of Pandemic Preparedness and Response Policy, within the White House. This office would fill gaps in our current framework by serving

---

<sup>10</sup> <https://www.fiercebiotech.com/medtech/labcorp-launches-monkeypox-pcr-tests-through-cdc-initiative>

<sup>11</sup> <https://www.reuters.com/world/us/massachusetts-identifies-first-2022-us-case-monkeypox-infection-2022-05-18/>

<sup>12</sup> <https://www.ecdc.europa.eu/en/monkeypox-multi-country-outbreak/situation-update-eueea-western-balkans-turkey>

<sup>13</sup> <https://www.hhs.gov/about/news/2022/06/28/hhs-announces-enhanced-strategy-vaccinate-protect-at-risk-individuals-from-current-monkeypox-outbreak.html>

<sup>14</sup> See sections 319F-2, 2811, and 2811-1 of the Public Health Service Act.

as the principal advisor to the president on these issues, providing strategic direction to federal departments to meet preparedness and response objectives, and ensuring that the federal government has the right expertise and capabilities in place to achieve these goals. This mission requires day-to-day focus and cannot be fulfilled by the National Security Council or any other entity that already has broad-sweeping responsibilities.

- 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?
3. Have you developed and implemented a research plan to address knowledge gaps and verify previous scientific findings about monkeypox and the epidemiology of the virus?
- a. If yes, please provide a copy of the research plan.
  - b. If no, please explain why there is no research plan or strategy in development. Please also describe what research is being supported by the Department related to monkeypox.
4. The test being used by most laboratories to identify monkeypox was developed to screen for smallpox. The test does not specifically detect monkeypox itself. While officials have exercised enforcement discretion to allow providers to treat individuals who test positive on the test as a confirmed monkeypox case, this inherently relies upon a presumption that other orthopoxviruses are not circulating.
- a. Which other viruses could produce a positive result on this test?
  - b. How prevalent are these other viruses, in either humans or animals, within the United States and globally?
  - c. If someone became infected with vaccinia after having contact with the lesions of an individual who received ACAM2000, could that individual test positive for a non-smallpox orthopoxvirus on this test?
  - d. If yes to the previous question, what steps are you taking to communicate with health care providers and laboratory personnel about that possibility and conduct confirmatory testing to determine whether presumed positive individuals who had contact with recipients of ACAM2000 are infected with monkeypox or vaccinia?

- e. What steps are you taking to support commercial and academic laboratories in developing monkeypox-specific tests?
  - f. How are you helping interested entities access monkeypox samples and positive controls to support the development of additional tests? Please describe in detail how entities can access these samples.
  - g. The bipartisan PREVENT Pandemics Act included a provision requiring HHS to develop and make publicly available its policies for facilitating access to samples to support responses to emerging infectious diseases, like monkeypox. Does HHS currently have this type of publicly available policy? If yes, where can interested individuals find it, and, if not, why not?
5. Are you supporting development of a rapid diagnostic test for clinicians?
  6. What is the United States' current testing capacity for monkeypox, including both public health and other laboratories?
  7. How much of this testing capacity is being used per week, and what is the current positivity rate?
  8. Are there any differences between states in either weekly testing capacity or positivity rate?
  9. To date, how many vaccine doses and treatment courses of have been made available to states by the Strategic National Stockpile (SNS), distributed, and administered? Please provide a breakdown for each specific product.
  10. What is the current formula for allocating both vaccine doses and treatment courses to jurisdictions?
  11. How frequently are vaccines and treatments being allocated and delivered to jurisdictions?
  12. What steps have you taken to provide forecasts of this information to jurisdictions so they can incorporate it into their plans for dispensing and administration?
  13. While Jynneos is licensed by the Food and Drug Administration for the prevention of monkeypox, other vaccines and treatments are not. Do jurisdictions or health care providers need to go through any additional steps in order to use these products off-label for monkeypox? If yes, what are they, and are you aware of any challenges associated with these steps?

14. Do health care providers, including laboratories, currently have the ability to bill insurance for costs associated with providing monkeypox tests, treatments, and vaccines? If no, what specific barriers prevent them from doing so?
15. How are you incorporating smallpox stockpiling goals and scenario-based requirements into your strategy for procuring and distributing countermeasures as part of the monkeypox response?
16. What is your projected shortfall of SNS inventory of smallpox countermeasures based on its stockpiling goal, and what is your strategy and timeframe for replenishing deployed inventory?
17. What actions has FDA taken to expedite the availability of monkeypox vaccines for Americans?
18. Media reports indicate that FDA was in contact with Bavarian Nordic in early May about the new fill-finish facility, and began conducting an inspection of the new facility in early July. When did FDA begin its inspection of the facility? Why did it take FDA two months to initiate an inspection of the new facility?
19. Was the facility the subject of previous inspections conducted by other regulatory authorities, such as the European Medicines Agency? If so, did FDA rely on the results of such inspections to facilitate availability of doses produced in the facility in the period before FDA could conduct an inspection, particularly given the growing public health threat posed by the current outbreak? If not, why not?
20. Did FDA conduct, or consider conducting, a remote evaluation of the facility in advance or in lieu of an in-person inspection to more quickly inspect the facility? If FDA did not conduct a remote evaluation, why not?

Thank you for your attention to these matters. I look forward to your prompt reply.

Respectfully,



Richard Burr

cc: Dr. Ashish Jha, White House COVID-19 Response Coordinator