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July 26, 2022

The Honorable Dawn O'Connell  
Assistant Secretary for Preparedness and  
Response  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Rochelle P. Walensky, MD, MPH  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329

The Honorable Robert M. Califf, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Assistant Secretary O'Connell, Director Walensky, and Commissioner Califf:

I write regarding the federal response to the current outbreak of Monkeypox in the United States and the availability of treatments for the disease. To date, the Centers for Disease Control and Prevention (CDC) has confirmed nearly 3,000 cases of Monkeypox in the United States, with cases reported in 44 states.<sup>1</sup> Although Monkeypox is less deadly than other viruses in the orthopoxvirus genus, like smallpox, it still can pose significant risks to infected individuals, including severe illness and death.<sup>2</sup> To ensure the United States is utilizing all available tools to combat Monkeypox and to improve equity in the federal government's response to the virus, I urge the Department of Health and Human Services (HHS) and CDC, in coordination with the Food and Drug Administration (FDA), to reduce barriers to treatments for Monkeypox.

For individuals infected with Monkeypox, symptoms can include fever, aches, sore throat, swollen lymph nodes, and painful lesions on the body. Many patients experience mild symptoms and recover. But even for patients with mild disease, symptoms can persist for weeks and

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<sup>1</sup> 2022 U.S. Map & Case Count, Centers for Disease Control and Prevention (July 25, 2022), <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>.

<sup>2</sup> Monkeypox, National Institute of Allergy and Infectious Disease (June 13, 2022), <https://www.niaid.nih.gov/diseases-conditions/monkeypox>.

sometimes lead to permanent scarring.<sup>3</sup> In addition, as symptoms persist, patients remain at risk of spreading the virus. To help address persistent symptoms, reduce the possibility of severe disease, and limit transmission of the virus, the federal government should take steps to increase access to potentially beneficial treatments.

There are currently no FDA-approved treatments specifically targeting Monkeypox. However, the United States has stockpiles of several therapeutics that may benefit patients with Monkeypox.<sup>4</sup> In particular, the federal government has over 1.7 million courses of tecovirimat, or TPOXX®, an antiviral approved for treatment of smallpox. While indicated for smallpox, tecovirimat has been shown effective in treating disease caused by orthopoxviruses like Monkeypox. Further, clinical trial and early study data shows tecovirimat to be safe and side effects minor.<sup>5</sup> Accordingly, CDC has made tecovirimat available for treatment of Monkeypox, but CDC and FDA require health care providers to follow an extensive expanded access protocol each time the drug is prescribed. This protocol may discourage providers from seeking tecovirimat even in instances when it may benefit Monkeypox patients under their care.<sup>6</sup> To improve access to tecovirimat, CDC and FDA must move quickly to reduce barriers to prescribing tecovirimat and communicate to health care providers the process for obtaining the drug.

I applaud the Biden administration for taking steps to distribute and secure vaccines for Monkeypox. However, supplies of vaccine remain under strain as demand continues to outpace supply in many areas.<sup>7</sup> Given the limited supply of vaccine and growing Monkeypox cases, the United States must use additional tools to respond to the outbreak, including expanding access to tecovirimat, to support patients suffering from this disease.

To help me better understand the federal government's actions related to treatments for Monkeypox, please respond to the following questions in writing by August 8, 2022.

1. CDC and FDA recently announced a streamlined expanded access protocol for obtaining tecovirimat. What steps have your agencies taken to communicate this to providers in areas with Monkeypox outbreaks? Have you solicited feedback from providers about ways the protocol could be further improved?

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<sup>3</sup> Michaelleen Doucleff, *Monkeypox can look different than what doctors thought. Here's what they're learning*, NPR (June 3, 2022), <https://www.npr.org/sections/goatsandsoda/2022/06/03/1102945017/monkeypox-can-look-different-than-what-doctors-thought-heres-what-theyre-learnin>.

<sup>4</sup> *Treatment Information for Healthcare Professionals*, Centers for Disease Control and Prevention (June 22, 2022), <https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html>.

<sup>5</sup> *Prescribing Information, TPOXX®*, Food and Drug Administration (July 2018), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/214518s0001bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214518s0001bl.pdf); Hugh Adler, et. al., *Clinical features and management of human monkeypox: a retrospective observational study in the UK*, *The Lancet* (May 24, 2022), [https://doi.org/10.1016/S1473-3099\(22\)00228-6](https://doi.org/10.1016/S1473-3099(22)00228-6).

<sup>6</sup> Pien Huang, *Monkeypox treatments are difficult to get despite the nation's large stockpile*, NPR (July 18, 2022), <https://www.npr.org/2022/07/18/1112116267/monkeypox-treatments-are-difficult-to-get-despite-the-nations-large-stockpile>.

<sup>7</sup> Emily Anthes, *Demand for Monkeypox Vaccine Exceeds Supply*, C.D.C. Says, N.Y. Times (July 15, 2022), <https://www.nytimes.com/2022/07/15/health/monkeypox-vaccine-supply.html>.

2. Would you consider further changes to the protocol for obtaining tecovirimat, if clinical evidence supports expanded use?
3. Has CDC, FDA, or HHS explored supporting other forms of data collection for use of tecovirimat, including clinical trials, patient registries, or observational studies, that may enhance access to the treatment?
4. In addition to tecovirimat, the Strategic National Stockpile contains other treatments that may benefit patients with Monkeypox. Have you considered taking steps to increase access, in the form of clinical trials or expanded access protocols, for these treatments?
5. Do you need additional support from Congress, such as additional funding or regulatory authority, to support access to treatments for Monkeypox?

Thank you for your attention to this matter.

Sincerely,



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Edward J. Markey  
United States Senator