

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051
MINORITY (202) 225-5074
<https://oversight.house.gov>

August 10, 2022

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

Dear Secretary Becerra:

I write to commend the Department of Health and Human Services (HHS) for recent steps it has taken to address the monkeypox outbreak in the United States and to urge the Department to build on this progress to ensure that every patient who needs treatment for monkeypox can safely and easily access it.

TPOXX (tecovirimat) is an antiviral medication that can be used to treat patients with monkeypox, a viral infection that can lead to severe symptoms, including painful skin lesions, fever, and respiratory complications.¹ In the United States, monkeypox patients and health care providers can only access TPOXX by requesting it through the federal government's expanded access investigational new drug (EA-IND) protocols—an emergency use pathway requiring the submission of a formal written request to the Food and Drug Administration (FDA).²

In other countries experiencing monkeypox outbreaks, TPOXX has been authorized or approved to treat patients infected with the virus. The European Medicines Agency authorized TPOXX across the European Union to treat monkeypox this past January, and the United Kingdom approved TPOXX for the treatment of monkeypox in July.³ European regulatory

¹ SIGA Technologies, Inc., *TPOXX (Tecovirimat) Fact Sheet* (online at www.siga.com/wp-content/themes/sigahba/TPOXX-Fact-Sheet.pdf) (accessed Aug. 10, 2022); Centers for Disease Control and Prevention, *Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol During 2022 U.S. Monkeypox Cases* (Aug. 3, 2022) (online at www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html).

² Centers for Disease Control and Prevention, *Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox* (July 22, 2022) (online at www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html); Food and Drug Administration, *Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers, Guidance for Industry* (online at www.fda.gov/media/85675/download) (accessed Aug. 10, 2022).

³ European Medicines Agency, *Tecovirimat Siga* (online at www.ema.europa.eu/en/medicines/human/EPAR/tecovirimat-siga#authorisation-details-section) (accessed Aug. 10, 2022); SIGA Technologies, Inc., *Press Release: SIGA Technologies Receives Approval from the European Medicines Agency for Tecovirimat* (Jan. 10, 2022) (online at <https://investor.siga.com/news-releases/news-release->

agencies have authorized or approved TPOXX for the treatment of monkeypox because the drug has been shown to reduce the severity and duration of monkeypox infection in animal subjects, and in light of the exceptional circumstances facing monkeypox patients.

Across the United States, nearly 10,000 monkeypox cases have been reported—including nearly 3,000 cases reported in just the past week.⁴ The Administration has taken crucial steps to promote access to monkeypox treatment—including streamlining EA-IND protocols and declaring a public health emergency to empower a more robust response to the outbreak—but health care providers and monkeypox patients continue to face difficulties prescribing and obtaining TPOXX.

Reports from health care providers make clear that even after the Centers for Disease Control and Prevention and FDA streamlined EA-IND requirements to prescribe TPOXX last month, the process has remained a barrier to ensuring that monkeypox patients can access treatment. To prescribe TPOXX, physicians must sign up to become investigators in a clinical trial—a step that requires providers to submit their resumes and informed consent forms from all monkeypox patients to whom they intend to prescribe the drug. Completing all of the required paperwork for each patient is so burdensome that some providers have reportedly declined to prescribe TPOXX to patients.⁵

Providers who have overcome these administrative hurdles and prescribed TPOXX to monkeypox patients have reported that the drug has been highly effective in treating the condition, with lesions in several instances reportedly disappearing within days of initiating treatment.⁶ As a result, many physicians have called on the federal government to make the medication more available, including at local pharmacies.⁷ The Medical Society of the State of

details/siga-technologies-receives-approval-european-medicines-agency); SIGA Technologies, Inc., *Press Release: SIGA Technologies Receives Approval from UK for Tecovirimat* (July 8, 2022) (online at <https://investor.siga.com/news-releases/news-release-details/siga-technologies-receives-approval-uk-tecovirimat>).

⁴ Centers for Disease Control and Prevention, *2022 U.S. Map and Case Count* (online at www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html) (accessed Aug. 10, 2022); Centers for Disease Control and Prevention, *U.S. Monkeypox Case Trends Reported to CDC* (online at www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html) (accessed Aug. 10, 2022).

⁵ *There's Just One Drug to Treat Monkeypox. Good Luck Getting It*, New York Times (Aug. 6, 2022) (online at www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.html); *Alternate Monkeypox Treatment Caught in Regulatory Delays*, Axios (Aug. 4, 2022) (online at www.axios.com/2022/08/04/alternate-monkeypox-treatment-caught-in-regulatory-delays).

⁶ *There's Just One Drug to Treat Monkeypox. Good Luck Getting It*, New York Times (Aug. 6, 2022) (online at www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.html); *NY Doctors, Legislators Call on Biden to Make Monkeypox Drug TPOXX Easier to Access*, Gothamist (Aug. 3, 2022) (online at <https://gothamist.com/news/ny-doctors-legislators-call-on-biden-to-make-monkeypox-drug-tpoxx-easier-to-access>).

⁷ *There's Just One Drug to Treat Monkeypox. Good Luck Getting It*, New York Times (Aug. 6, 2022) (online at www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.html); Medical Society of the State of New York, *Press Release: MSSNY Urges Biden Administration to Declare a Public Health Emergency* (Aug. 1, 2022) (online at www.mssnynews.org/special-announcements/press-releases/mssny-urges-biden-administration-to-declare-a-public-health-emergency/); *NY Doctors, Legislators Call on Biden to Make Monkeypox Drug TPOXX Easier to Access*, Gothamist (Aug. 3, 2022) (online at <https://gothamist.com/news/ny-doctors-legislators-call-on-biden-to-make-monkeypox-drug-tpoxx-easier-to-access>).

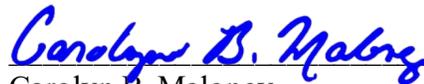
New York has advocated for FDA to evaluate TPOXX for emergency use authorization, with President Dr. Parag Mehta emphasizing that TPOXX “shows great promise in the treatment of monkeypox infection,” but the current EA-IND protocols “have limited the ability to treat patients with this medication.”⁸

The Department should build on its progress responding to the monkeypox outbreak by further streamlining EA-IND requirements so that patients and providers can obtain TPOXX with greater ease. As Secretary, you can also issue a determination under Section 564 of the Federal Food, Drug, and Cosmetic Act to memorialize that the circumstances of the outbreak in the United States justify future emergency use authorizations for monkeypox treatments.⁹

As the Department continues its efforts to contain the spread of the monkeypox virus, it must ensure that no patient with a monkeypox infection is barred from safe and effective treatment. I urge the Department to take all steps necessary to ensure that patients and providers can easily access monkeypox treatment—including any steps required to evaluate a potential emergency use authorization for TPOXX to treat monkeypox.

Thank you for your immediate attention to this matter.

Sincerely,



Carolyn B. Maloney
Chairwoman

cc: The Honorable James Comer, Ranking Member

⁸ Medical Society of the State of New York, *Press Release: MSSNY Urges Biden Administration to Declare a Public Health Emergency* (Aug. 1, 2022) (online at www.mssnyenews.org/special-announcements/press-releases/mssny-urges-biden-administration-to-declare-a-public-health-emergency/); *NY Doctors, Legislators Call on Biden to Make Monkeypox Drug TPOXX Easier to Access*, Gothamist (Aug. 3, 2022) (online at <https://gothamist.com/news/ny-doctors-legislators-call-on-biden-to-make-monkeypox-drug-tpoxx-easier-to-access>).

⁹ Food and Drug Administration, *Emergency Use Authorization* (Aug. 9, 2022) (online at www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization).