

October 21, 2022

Dr. Jeffrey M. Zirger
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H21-8
Atlanta, GA 30329

SUBMITTED VIA *regulations.gov*

RE: Comment on Centralized Institutional Review for the CDC Expanded Access Investigational New Drug (EA-IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections—New—Office of Science (OS), Centers for Disease Control and Prevention (CDC); Docket No. CDC-2022-0099

Dear Dr. Zirger,

Thank you for this opportunity. At the request of the Centers for Disease Control and Prevention, the National LGBTQ Task Force respectfully submits this comment on the Centralized Institutional Review for the CDC Expanded Access Investigational New Drug (EA-IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections; Docket No. CDC-2022-0099.

We appreciate the work that the CDC has done with this program to increase access to treatment for the monkeypox virus (MPXV). We urge the CDC to continue that work by improving accessibility to TPOXX, considering how to best spread information and increase access to care in the communities that are most affected without increasing stigma, and by looking at how to increase access to treatments that will work for people with compromised immune systems (such as those with HIV/AIDS).

The National LGBTQ Task Force advances freedom, justice, and equality for LGBTQ people. We are building a future where everyone can be free to be their entire selves in every aspect of their lives. Today, despite all the progress we have made to end discrimination, millions of LGBTQ people face barriers in every aspect of their lives: in education, housing, employment, healthcare, retirement, and basic human rights. These barriers include the disparate impact that MPXV has on the LGBTQ community. The Task Force recognizes and appreciates the work that the CDC has devoted to reducing the disparate impact that MPXV has on the LGBTQ community by collaborating with the community to improve prevention, treatment, and

diagnosis methods but encourages the CDC to continue to improve accessibility and reduce racial disparities.

The National LGBTQ Task Force's history is deeply rooted in AIDS activism and advocacy. For over 30 years, we fought the stigma associated with HIV/AIDS and other STIs. We continue this advocacy and activism as MPXV disparately affects LGBTQ communities and the risk of stigmatization of our communities increased. We have worked to combat stigma and ensure that LGBTQ voices are heard when it comes to education, prevention, diagnosis, and treatment efforts. Education, medical prevention, and treatment that excludes LGBTQ identities further alienates an already at-risk community. Therefore, we request that the CDC continue to study and improve best practices in reaching affected communities in a culturally sensitive manner, to increase timely treatment access, how to decrease racial disparities, and how to increase access to treatments specifically for people with HIV/AIDS.

1. Our Request: Increase Access in Affected Communities and Reduce Racial Disparities in Access Without Stigmatization

a. Struggles for TPOXX Access

Many people from highly affected communities, including men who have sex with men (MSM), are experiencing difficulties learning about treatment options and how to access them.¹ Unfortunately, this includes both prevention in the form of vaccinations and treatment for current infections, such as TPOXX.² Reports reveal that patients have struggled to get diagnosed with MPXV by providers, or if they are able to get diagnosed, find that their providers lack the expertise to treat them and thus simply send them home.³ Reports also show that people have had to travel to different cities or states in order to access basic treatment.⁴ Even people who are clearly eligible for TPOXX treatment due to the severity of their symptoms, compromised immune systems, and risks of long term effects of the illness (such as blindness) report difficulty receiving approval for TPOXX treatment.⁵ Given the time and difficulty in accessing treatment, some patients with severe MPXV have had to suffer through serious and painful symptoms for so long that the lesions begin to heal on their own before they are able to access TPOXX.⁶ These

¹ Neeraj Patel and Nadia Kounang, *Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say*, CNN, August 2, 2022, <https://www.cnn.com/2022/08/02/health/tpoxx-access-problems/index.html>.

² Id.

³ Id.

⁴ Id.

⁵ Id.

⁶ Apoorva Mandavilli, *There's Just One Drug To Treat Monkeypox. Good Luck Getting It.*, New York Times, August 6, 2022, <https://www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.htm>.

painful symptoms include increasing amounts of lesions on sensitive parts of their bodies that inhibit their ability to use the bathroom, eat, or even see.⁷ While access to treatment has improved as the CDC and FDA have lowered the amount of paperwork required for providers to obtain treatment for their patients, the amount of time and energy that applying for approval for treatment takes remains high.⁸ The process involves providers filling out a 27-page application, signing up to be investigators in a clinical trial, sending in resumes and informed consent forms, and collecting detailed patient information.⁹ This complicated process has caused confusion among providers on how to obtain treatment for their patients or providers having to refer MPXV patients elsewhere or send them home because they don't have time to treat them.¹⁰ Even if providers know how to obtain treatment for their patients, without doses of TPOXX in their offices, it can still take several days before they receive TPOXX from a distribution center.¹¹ Time is of the essence in treating patients' rapidly worsening painful symptoms.¹² Members of the LGBTQ community, particularly MSM who suffered from MPXV, have expressed concerns that the long term difficulties in receiving treatment and vaccinations for MPXV feel dangerously similar to the indifference of the U.S. government and medical community during the early years of the HIV/AIDS crisis.¹³ Many feel that the U.S. government and medical community are not taking queer pain and suffering seriously with the lack of urgency in increasing access to vaccinations and treatment options.¹⁴ Our government must take proactive steps to ensure that continuous information about who is eligible for TPOXX treatment and where TPOXX treatment can be accessed reaches affected communities. We recommend collaborating with community-based organizations to ensure effective distribution of vital information, as well as increased governmental efforts to reach people through providers and directly in any manner possible. We also recommend identifying ways to decrease barriers to receiving timely treatment early in the disease process. The CDC and FDA have full authority to change the laws governing TPOXX access, therefore we urge the CDC to take immediate action to increase access to TPOXX treatment given the highly promising initial treatment results.¹⁵

⁷ Id.

⁸ Neeraj Patel and Nadia Kounang, *Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say*, CNN, August 2, 2022, <https://www.cnn.com/2022/08/02/health/tpoxx-access-problems/index.html>.

⁹ Apoorva Mandavilli, *There's Just One Drug To Treat Monkeypox. Good Luck Getting It.*, New York Times, August 6, 2022, <https://www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.html>.

¹⁰ Neeraj Patel and Nadia Kounang, *Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say*, CNN, August 2, 2022, <https://www.cnn.com/2022/08/02/health/tpoxx-access-problems/index.html>.

¹¹ Id.

¹² Id.

¹³ Fenit Nirappil, *Struggle to Protect Gay, Bisexual Men From Monkeypox Exposes Inequalities*, Washington Post, August 4, 2022, <https://www.washingtonpost.com/health/2022/07/27/monkeypox-gay-men-vaccine-treatment/>.

¹⁴ Id.

¹⁵ Apoorva Mandavilli, *There's Just One Drug To Treat Monkeypox. Good Luck Getting It.*, New York Times, August 6, 2022, <https://www.nytimes.com/2022/08/06/health/monkeypox-treatment-tpoxx.html>.

b. Racial Disparities in TPOXX Access

There have also been clear racial disparities in vaccine and treatment access.¹⁶ Targeted information and increased access could address some of these disparities and improve health outcomes.¹⁷ There have been several reported instances of Latino and Black communities experiencing heavier MPXV spread and additional difficulties in receiving vaccines and TPOXX.¹⁸ Reports reveal that people from Black and Latino communities make up almost half of all MPXV cases, but 80% of the treatments and vaccinations have gone to white communities.¹⁹ Clinicians and public health professionals believe this is due to existing disparities being exacerbated by MPXV.²⁰ Low cost clinics care for a higher amount of patients and receive lower amounts of funding.²¹ As a practical matter, this means that the limited number of providers are presently overwhelmed as it is and their schedules do not allow for the devotion of large amounts of time to apply for TPOXX treatments or track down vaccination doses.²² Therefore, we recommend that the CDC focus efforts on increasing access to TPOXX treatments at low cost clinics and STI clinics. Doing so would, we believe, help reduce racial disparities in both treatment access and healthcare outcomes.

c. Stigmatization Concerns

There is a risk of increasing stigma by using a targeted approach in spreading MPXV treatment information and increasing TPOXX access. We have already seen reports of providers, such as LabCorp and Quest Diagnostics, refusing to draw blood from suspected MPXV patients.²³ This discriminatory treatment exists despite the fact that blood draws remain a normal part of the

¹⁶ Fenit Nirappil, *Struggle to Protect Gay, Bisexual Men From Monkeypox Exposes Inequalities*, Washington Post, August 4, 2022, <https://www.washingtonpost.com/health/2022/07/27/monkeypox-gay-men-vaccine-treatment/>.

¹⁷ Id.

¹⁸ Id.

¹⁹ Priyanka Dayal McCluskey, *In Fight Against Monkeypox, Racial Disparities Emerge*, WBUR, September 23, 2022 <https://www.wbur.org/news/2022/09/23/monkeypox-racial-disparities-vaccines-infections>.

²⁰ Lisa Desjardins and Kaisha Young, *As Monkeypox Cases Rise, So Do Concerns About Disparate Access to Care*, PBS, August 6, 2022, <https://www.pbs.org/newshour/show/as-monkeypox-cases-rise-so-do-concerns-about-disparate-access-to-care>.

²¹ Kristen Jordan Shamus, *Black Michiganders Got 60% of Monkeypox Cases, Only 17% of Vaccines*, Detroit Free Press, September 29, 2022, <https://www.freep.com/story/news/health/2022/09/29/monkeypox-disparities-black-michiganders-vaccines/69524613007/>.

²² Id.

²³ Ayanna Alexander, *AIDS Echoes in Monkeypox Messages Worry LGBTQ Health Advocates*, Bloomberg Law, August 11, 2022, <https://news.bloomberglaw.com/health-law-and-business/aids-echoes-in-monkeypox-messages-worry-lgbtq-health-advocates>.

process of obtaining a MPXV diagnosis and receiving treatment.²⁴ Increased stigma may discourage people from seeking care as well as cause increased prejudice against the LGBTQ and BIPOC communities.²⁵ We encourage the CDC to take all available care to minimize this risk when targeting affected communities with information and increased access. The CDC must continue to communicate across all available channels that while presently our communities are most affected and at highest risk, MPXV may be spread to any person through close skin-to-skin contact. Transmission has nothing to do with race, ethnicity, sexual orientation, gender identity and expression, or any other characteristics.

2. Our Request: Increase Access for Those With HIV/AIDS

The CDC and FDA have currently limited TPOXX treatment to those at risk of developing a severe case of MPXV, which includes those with compromised immune systems and HIV/AIDS.²⁶ Doctors believe that only a fraction of people eligible under this guidance are actually receiving treatment.²⁷ Due to the complicated and time-consuming process of applying for the treatment, many healthcare providers struggle to provide this treatment to their qualified patients.²⁸ This limits access to effective care, even for patients who have increased need such as those with HIV/AIDS.²⁹ In turn, this leads to a higher likelihood of severe illness and undesirable healthcare outcomes such as negative side effects, including blindness, other nerve damage, or even death in immunocompromised populations.³⁰ We urge that their high need for access to treatment be prioritized and for the CDC to create an expedited process for those with an HIV/AIDS diagnosis. This approach is likely to decrease the likelihood of severe disease in this already at-risk population and reduce the number of people likely to suffer from painful prolonged illness, negative side effects, or death.

²⁴ CDC, *Biosafety Laboratory Guidance for Handling and Processing Monkeypox Specimens*, CDC, September 23, 2022 <https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/lab-procedures.html>.

²⁵ Ayanna Alexander, *AIDS Echoes in Monkeypox Messages Worry LGBTQ Health Advocates*, Bloomberg Law, August 11, 2022, <https://news.bloomberglaw.com/health-law-and-business/aids-echoes-in-monkeypox-messages-worry-lgbtq-health-advocates>.

²⁶ Lena H. Sun and Dan Diamond, *New CDC Guidance: Only High-Risk Groups Should Get Monkeypox Antiviral*, The Washington Post, September 15, 2022, <https://www.washingtonpost.com/health/2022/09/15/monkeypox-tpox-antiviral-cdc/>.

²⁷ Neeraj Patel and Nadia Kounang, *Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say*, CNN, August 2, 2022, <https://www.cnn.com/2022/08/02/health/tpox-access-problems/index.html>.

²⁸ Id.

²⁹ Lena H. Sun and Dan Diamond, *New CDC Guidance: Only High-Risk Groups Should Get Monkeypox Antiviral*, The Washington Post, September 15, 2022, <https://www.washingtonpost.com/health/2022/09/15/monkeypox-tpox-antiviral-cdc/>.

³⁰ Neeraj Patel and Nadia Kounang, *Access to Experimental Monkeypox Treatment Remains Uneven, Doctors Say*, CNN, August 2, 2022, <https://www.cnn.com/2022/08/02/health/tpox-access-problems/index.html>.

Summary of Task Force Requests

Thank you for the opportunity to comment and we hope that you will consider our urgent request. The monkeypox virus (MPXV) is having a heavy impact on men who have sex with men (MSM), a disparate impact on Black and Latino communities, and a concerning level of impact on HIV/AIDS patients. MPXV is a painful illness that in severe cases risks blindness, nerve damage, and death and therefore treatment must be accessible on an equitable basis. We would like to reiterate that the Task Force appreciates the work that the CDC to date with this program to increase access to treatment for MPXV. However, to continue to improve access to treatment and in response to reports of difficulties with accessing TPOXX and reports of racial disparities, we urge the CDC to explore how to target the most affected communities with information on how to access treatment and that the CDC explore expanding and simplifying treatment access for those communities. We also request the CDC examine how to increase access to treatments through expedited approval processes for people with compromised immune systems, including people living with HIV/AIDS.

Thank you for your time and attention to our recommendations. For more information, please contact Clermon Acklin, Federal Regulatory Counsel, at ceacklin@thetaskforce.org or 202-604-9830.

Sincerely,



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