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Xavier Becerra, Secretary of Health and Human Services
Jonathan Mermin, Director of the National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Kaye Hayes, Assistant Secretary of Infectious Disease at the Office of Infectious Disease and HIV/AIDS Policy
Francisco Ruiz, Director of the White House Office of National AIDS Policy
Paul Friedrichs, Director of the Office of Pandemic Preparedness and Response Policy
Arati Prabhakar, Director of the White House Office of Science and Technology Policy
Nikki Romanik, Special Assistant to the President, Chief of Staff for Office of Pandemic Preparedness and Response Policy

Mpox (formerly monkeypox) is a skin infection caused by the mpox virus, an orthopox virus related to smallpox.¹ Mpox was discovered in humans in 1970² and long caused largely small and zoonotic outbreaks in Central and West Africa.³ In 2022, mpox Clade II spread globally, leading to nearly 100,000 cases and over 100 deaths,⁴ mostly in queer sexual networks.⁵ Since 2022, mpox continues to cause disease globally, although with only sporadic cases reported in most countries.⁶ **Now, an increase in global Clade II infections⁷ alongside a novel outbreak of the more serious Clade I virus in Central Africa⁸ reaffirms the threat of mpox for global health security.**

The similarity between mpox and smallpox, which is named by the Bipartisan Commission on Biodefense as a significant threat,⁹ led to the discovery of molecular mpox tests,¹⁰ administration of a two-dose vaccine, Jynneos, which is highly effective against mpox infection,¹¹ and emergency approval of a drug, TPOXX (tecovirimat), for mpox treatment.¹² However, in spite of decades of research on these interventions in vitro, in animal models, and using immunobridging, essential questions remain about their long term efficacy and implementation, with **multiple recent studies highlighting a rapid reduction in neutralizing antibodies within a year of Jynneos vaccination in those without a prior smallpox vaccination.**^{13,14,15}

While global disparities in access to mpox prevention and treatment are profound and in need of urgent and consistent intervention, we focus here on pressing issues of mpox research and implementation in the United States, many of which have global impact.



Because of the increase in mpox cases in 2024 over 2023,⁷ multiple studies suggesting mpox vaccine efficacy may wane over time,¹³⁻¹⁵ and the outbreak of mpox Clade I in Central Africa,⁶ we urgently request the United States Federal Government immediately invest in the following steps toward mpox prevention and research.

1) Close the Jynneos vaccine access loophole created by its commercialization

Bavarian Nordic, the company that manufactures Jynneos, announced this year it would commercialize the vaccine.¹⁶ Previously, vaccine was only available from the United States Strategic National Stockpile.¹⁷ While commercialization will allow individual clinics and health care providers to order and provide doses, it provides no pathway to access for individuals without health insurance. Mpox vaccination coverage remains low,¹⁸ and the communities that are disproportionately undervaccinated include Black and Latinx Americans,¹⁹ who also have lower levels of health insurance coverage.²⁰ Leveraging existing JYNNEOS supply and expanding outreach with more effective and innovative campaigns to Black and Brown communities, people living with HIV, and people without health insurance should be an immediate and ongoing priority.

We request that the federal government immediately implement a funding structure to provide free access to the Jynneos vaccine for all, regardless of insurance coverage, and to innovate outreach to engage underserved communities.

2) Immediately initiate randomized controlled clinical trials on Jynneos booster doses, in coordination with the FDA for fast-tracked approval if efficacious

The majority of Jynneos doses in the United States were administered in 2022.²¹ While cases did not rise over the summer months in 2023,²² when travel and sexual encounters increase,²³ mpox case data from 2024 indicate an increase in cases.⁷

Studies show that in individuals with no prior smallpox vaccination, Jynneos-induced antibodies wane within 12 months.¹³⁻¹⁵ However, in individuals with previous smallpox vaccination, even decades prior, immunity appears more durable.¹³⁻¹⁵

To our knowledge, no study or trial, even observational, is currently underway to study the immune response to a third dose of Jynneos following the first doses.



We request that the federal government fund and coordinate, via the HPTN, randomized controlled clinical trials on the immunogenicity and efficacy of a booster dose of the Jynneos vaccine.

3) Increase United States surveillance for mpox Clade I introduction, with transparent pathways to community engagement and education, particularly to communities of color and people living with HIV

Mpox Clade I may have a higher severity and a case fatality rate of up to 10%.⁸ The scale of the current and ongoing outbreak in the Democratic Republic of the Congo (DRC) is unknown due to a lack of diagnostic tests,⁸ but the country has recorded more mpox deaths in 2024 than the entire global epidemic in 2022.²⁴ Among the genotypes of mpox Clade I currently in the DRC is one virus with a deletion in the primer site used for the FDA-approved Clade I specific qPCR diagnostic test, meaning the virus would not be detected by this diagnostic.⁸

While public health officials describe a pathway toward Clade I diagnosis upon introduction into the United States via a positive orthopox virus test followed by a negative test in the Clade II specific PCR and a patient travel history,⁸ this may leave significant gaps in disease surveillance. Further, it is unclear how and how quickly public health officials would inform the communities most impacted by mpox in the United States such that individuals could modify their behaviors to avoid infection. Significant gaps in community outreach led to severe disparities in mpox outcomes starting in 2022, particularly in Black communities and people living with HIV. Communication prior to, and after, introduction of mpox Clade I to the United States must actively address these ongoing disparities.

We request an increase in genomic surveillance nationwide to detect any mpox Clade I introductions and a transparent and rapid pathway from disease discovery to community engagement.

4) Combine the US-based STOMP trial of tecovirimat/TPOXX with similar clinic trials in Europe and South America to increase RCT enrollment while maintaining access via compassionate use.

In the US, a randomized controlled clinical trial (RCT), STOMP,²⁵ is underway to robustly test the efficacy of the small molecule inhibitor tecovirimat (or TPOXX) during mpox infection. However, even with the recent uptick in mpox cases, enrollment has not neared the needed number of patients. A separate RCT in Europe and South America, UNITY, is following a



nearly identical protocol. Combining data from the two trials could **lead to an immediate evaluation of TPOXX efficacy** for FDA approval. Further, initial reports indicate that not only mpox lesion clearance but patient pain levels may be associated with TPOXX use.

Additionally, patient access via compassionate use for this FDA approved drug must be maintained. TPOXX is disproportionately prescribed to white patients compared to the burden of cases,²⁶ even under current guidelines, and non-white individuals have lower access to clinical trial participation.²⁷ TPOXX is FDA approved for smallpox treatment via the animal rule,²⁸ and has shown no indications of troubling safety profiles in humans since 2022.²⁹

We therefore request that the federal government immediately signal that a combined analysis of UNITY and STOMP data would be sufficient to support TPOXX for full FDA approval if efficacy is shown and that multiple endpoints, including patient pain, be assessed in terms of TPOXX efficacy. Additionally, we urge the implementation of an equity framework for both STOMP recruitment and ongoing compassionate use.

TPOXX access and clinical trial protocols should be considered and changed prior to an increase in mpox Clade II globally or the introduction of mpox Clade I to the United States.

These four requests offer an opportunity for the federal government to **lead in the ongoing global mpox epidemic.** HHS should be prepared to use a whole of government approach to address ongoing mpox disparities, the potential for increased Clade IIb transmission, and/or the introduction of mpox Clade I to the United States, including by coordinating a letter addressed to existing programs such as SAMHSA, Ryan White, CDC Prevention Grantees, and HOPWA. While these requests represent urgent domestic issues, additional research and implementation efforts are required to address global mpox disparities, especially involving access to mpox vaccination and therapeutics in the DRC. We urge the United States government to take a global leadership role in addressing mpox in addition to meeting the pressing domestic needs we present here.

In 2022, the United States government lagged in implementation of mpox testing, vaccination, and treatment.³⁰ Now, we are failing to act on vaccine implementation after Jynneos commercialization, studying the need for and efficacy of vaccine boosters, disease surveillance that matches the current global threat, and rapid FDA clearance of the mpox drug TPOXX. We must immediately correct course for the ongoing health of our communities and to ensure our nation's biosecurity.



Signed,



Organizational Signatories:

- PrEP4All
- StickItIn LA
- Illinois Public Health Association
- San Francisco AIDS Foundation
- GLIDE
- CAEAR Coalition
- AMAAD Institute (Arming Minorities Against Addiction and Disease)
- Gender Justice LA
- The Fenway Institute, Fenway Health
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- Freedom Oklahoma
- Positively U, Inc
- Prevention Access Campaign
- Foundation for Integrative AIDS Research (FIAR)
- Consortium for the Advancement of Rights for Key Affected Populations (CARKAP)
- H&B MINISTRIES
- Five Horizons Health Services
- African Services Committee
- Sisters of St.Dominic of Blauvelt, New York
- The McGregor Clinic, Inc
- PS Test, Inc
- HIV+Aging Research Project - Palm Springs
- Broadway Cares/Equity Fights AIDS



AIDS Foundation Chicago
Underprivileged Welfare Support Development Association
Being Alive - LA
San Francisco Community Health Center
Neelyx Labs
Let's Kick ASS Palm Springs (AIDS Survivor Syndrome)
The Gubbio Project
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Endnotes:

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