



# How the federal government can better respond to the monkeypox outbreak

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## EXECUTIVE SUMMARY

Imagine if at the beginning of the HIV or COVID-19 pandemics there was a test available to diagnose individuals, treatment to help them mitigate painful symptoms, and a vaccine to help stop transmission. Imagine how different the history of these diseases and the communities they disproportionately affect would be.

Since its first reported case in the United States in May 2022, monkeypox virus (MPX) has rapidly spread across the country, as well as around the world, disproportionately affecting gay, bisexual, and other men who have sex with men (GBMSM). Our nation's recent experience with disease outbreaks and advanced biomedical resources put it in a position to effectively contain the spread of MPX. Public health authorities could draw from extensive experience managing the COVID-19 and HIV epidemics when designing their national response. American stockpiles of medications that were originally designed to treat smallpox, prophylactic vaccines effective against MPX, and effective tests made the country uniquely prepared to vaccinate those at greatest risk of contracting MPX and diagnose and treat those infected.

Yet despite these material advantages, the United States has failed to contain MPX by failing to mobilize existing public health infrastructure—or create new critical public health supports—to aid communities affected by the virus. Stockpiles of vaccines which can be used to protect against MPX have been rendered inaccessible due to bureaucratic delays coupled with miscalculations of how quickly the virus would spread and how great vaccine demand would be. Testing for MPX was initially hobbled by complex protocols which effectively rationed testing, delayed the identification of cases, and hampered efforts to track the spread of the virus.

Due to poor health communication, many providers and patients are unaware that treatment for MPX is available. However, because existing antiviral treatments for patients with MPX are currently authorized for treating smallpox but not MPX, providers who are aware of this treatment must fill out complex paperwork that can take up to five hours per patient to complete. This has prevented healthcare providers from rendering other services and many patients have been consequently forced to endure the painful lesions caused by the virus with no relief.

Finally, these issues have occurred within the context of racial/ethnic, class, and geographic inequities in health care access which have been exacerbated during the course of the MPX outbreak, as marginalized communities struggle to access vaccines and treatments concentrated in the hands of a few well-resourced institutions, some of which are located in areas that are less accessible to communities of color.

Despite these challenges, there is still time to improve MPX diagnosis and treatment, and share critical health care information with communities most vulnerable to infection. By invoking the Defense Production Act to scale up production of the JYNNEOS vaccine, and by partnering with community-based organizations to educate racially, ethnically, gender and geographically diverse stakeholders about the importance of vaccination, we can protect those at greatest risk of MPX and curb the potential spread of the virus among other vulnerable populations who live in close quarters, such as people who are incarcerated, those in congregate living facilities, and people experiencing homelessness or living in unstable housing situations.

At the same time, we must be diligent in studying the intradermal vaccination strategy authorized by the CDC in August 2022 and monitoring the efficacy of this approach. With this method, the vaccine is administered between layers of skin rather than subcutaneously, or below the skin. Up to five doses of the vaccine can be administered from one vial of the JYNNEOS vaccine. Close monitoring of the intradermal vaccination strategy is especially important for people living with HIV and others who are immunocompromised.

Given the inequitable distribution of vaccines to date, with White gay and bisexual men disproportionately accessing vaccination, it is critical that the federal government work with state and local partners to center racial and ethnic equity in its vaccine dissemination strategy. This should involve working closely with community-based organizations and leaders with long-standing relationships of trust with Black and Hispanic gay and bisexual men and transgender and nonbinary communities.

With regard to testing, we should replicate our successes during the COVID-19 pandemic—making MPX tests free to minimize the impact of financial barriers and emulating the NIH’s RADx (Rapid Acceleration of Diagnostics) initiative to foster innovative development of COVID-19 tests to develop new MPX testing methods and foster equitable access. Provider and patient education is also critically needed to ensure that individuals can access treatment. As noted above, many providers and patients are unaware that antiviral therapeutics are available for painful MPX lesions and those that encroach on sensitive structures, such as the eye. Finally, the FDA should authorize the use of TPOXX for MPX, a move that European public health authorities have already taken, ensuring that the suffering of MPX patients is minimized and facilitating access to an important therapeutic tool.

Finally, we need Congress to step up and appropriate funding for testing, vaccination, treatment, public education and prevention, and research on MPX. Federal agencies have creatively reallocated existing funding, but substantial new funding is needed to pay for all of the care that has been



provided since May 2022 on an emergency basis. Funding is also needed for research to better understand MPX and the biomedical interventions at our disposal to prevent and treat it.

If policy makers and public health officials make concentrated efforts to adopt these strategies and reimagine the nation's approach to MPX testing, treatment, and vaccination, we can make an important course correction and stop repeating the missteps of our responses to the COVID-19 and HIV

epidemics. We have a rare opportunity to stop a major outbreak in its tracks and should take full advantage of the resources and expertise at our disposal.

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## OVERVIEW

Starting with a single diagnosed individual in mid-May 2022 in Massachusetts, as of September 9, 2022, some 21,894 Americans have been diagnosed with MPX, although this figure is almost certainly a significant undercount.<sup>1,2</sup> From late June to late July, according to the Infectious Diseases Society of America, the number of people diagnosed with MPX in the U.S. jumped by over 1,900 percent.<sup>3</sup>

Most U.S. experts believe that there are far more cases than those that have been diagnosed due to limited access to testing and a reluctance by many individuals to seek care because of stigma-related concerns about the disease.<sup>4</sup> These include the presence of unsightly lesions on the face and/or trunk, anal sores, and monkeypox's association with same-sex sexual activity, as well as widely circulated misinformation that treatment is only available for

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<sup>1</sup> WHO Director-General. "Second Meeting of the International Health Regulations (2005) (Ihr) Emergency Committee Regarding the Multi-Country Outbreak of Monkeypox." News release, July 23, 2022, [https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-\(2005\)-\(ihr\)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox](https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox).

<sup>2</sup> "2022 U.S. Map & Case Count." Updated September 9, 2022, <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>.

<sup>3</sup> Congressional briefing: Monkeypox Virus in the U.S.: Perspectives from the Frontlines, July 25, 2022. IDSA, HIVMA, Fenway Health, HRC, NCSD. [https://societycentral.zoom.us/rec/share/h7ZP1Oo\\_BGJe82tTP5uCNAZNfYnsn--kmVLwZu6XnVcfsicAantQZrMWmHkhRyxd.-G7X9IRiGMcL-zF0](https://societycentral.zoom.us/rec/share/h7ZP1Oo_BGJe82tTP5uCNAZNfYnsn--kmVLwZu6XnVcfsicAantQZrMWmHkhRyxd.-G7X9IRiGMcL-zF0)

<sup>4</sup> Treisman, Rachel. "As Monkeypox Spreads, Know the Difference between Warning and Stigmatizing People." NPR, July 26, 2022. <https://www.npr.org/2022/07/26/1113713684/monkeypox-stigma-gay-community>.

severe cases, which causes some providers not to prescribe it when it is indicated.

Nearly all (98%) of the cases detected in the U.S. and other parts of the world where the 2022 MPX outbreak is occurring are among gay, bisexual, and other men who have sex with men (GBMSM).<sup>5</sup> MPX can be transmitted through skin-to-skin contact, prolonged face-to-face contact, and less frequently, contact with bedding and sheets.<sup>6</sup> Intimate contact facilitated through sexual activity appears to be causing much of the current spread. Some MPV lesions have been found in rectal and pharyngeal mucosa, consistent with intimate contact, but sustained skin-to-skin contact has also been associated with transmission.<sup>7</sup> While the strain of MPX spreading throughout the U.S. has a relatively low fatality rate (less than 1% globally, with one death in the U.S. as of this brief's publication), the lesions associated with the infection are extremely painful, with an estimated one in 10 MPX patients in the UK being hospitalized to manage the pain.<sup>8,9</sup>

Due to bureaucratic missteps, monkeypox has quickly spread among gay and bisexual men's networks.

Unlike the COVID-19 and HIV epidemics, we had the tools necessary to diagnose, treat, and vaccinate those at greatest risk from the outset of the current MPX outbreak.<sup>10</sup> However, due to a number of missteps and bureaucratic delays the disease has not been properly contained, resulting in rapid spread among GBMSM networks. MPX testing has involved complicated multi-step regimens and protracted turnaround times. As was the case with SARS-CoV-2, testing

was initially available only through local departments of public health, which severely limited our ability to diagnose individuals and track the virus.<sup>11</sup>

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<sup>5</sup> John P. Thornhill, M.D., Ph.D., Sapha Barkati, M.D., Sharon Walmsley, M.D., Juergen Rockstroh, M.D., Andrea Antinori, M.D., Luke B. Harrison, M.D., Ph.D., Romain Palich, M.D., Ph.D., Achyuta Nori, M.D., Iain Reeves, M.D., Maximilian S. Habibi, M.D., Ph.D., Vanessa Apea, M.D., M.P.H., Christoph Boesecke, M.D., et al., for the SHARE-net Clinical Group. "Monkeypox Virus Infection in Humans across 16 Countries — April–June 2022." *N Engl J Med* 2022; 387:679-691. DOI: 10.1056/NEJMoa2207323. <https://www.nejm.org/doi/full/10.1056/NEJMoa2207323>

<sup>6</sup> Infectious Diseases Society of America. Monkeypox: What to Know. IDSA, June 2022, <https://www.idsociety.org/globalassets/idsa/public-health/monkeypox/idsa-monkeypox-fact-sheet.pdf>.

<sup>7</sup> Ibid.

<sup>8</sup> Gans J. "First death in US of person with monkeypox confirmed in Texas." *The Hill*. August 30, 2022. <https://thehill.com/policy/healthcare/3620986-first-death-in-us-of-person-with-monkeypox-confirmed-in-texas/>

<sup>9</sup> Girometti, Nicolò, Ruth Byrne, Margherita Bracchi, Joseph Heskin, Alan McOwan, Victoria Tittle, Keerti Gedela, et al. "Demographic and Clinical Characteristics of Confirmed Human Monkeypox Virus Cases in Individuals Attending a Sexual Health Centre in London, UK: An Observational Analysis." *The Lancet Infectious Diseases*, August 1, 2022, [https://doi.org/https://doi.org/10.1016/S1473-3099\(22\)00411-X](https://doi.org/https://doi.org/10.1016/S1473-3099(22)00411-X). <https://www.sciencedirect.com/science/article/pii/S147330992200411X>.

<sup>10</sup> Krellenstein, James, Joseph Osmundson, and Keletso Makofane. "To Fight Monkeypox, Remember the Lessons of Covid and H.I.V." *New York Times*, May 29, 2022, <https://www.nytimes.com/2022/05/29/opinion/monkeypox-covid-and-hiv.html>.

<sup>11</sup> Girometti et al., "Demographic and Clinical Characteristics," *The Lancet Infectious Diseases*, August 1, 2022.

Vaccination efforts have been hamstrung by delays in regulatory approval and shipping, and by substantial inequities in vaccine distribution and access.<sup>12</sup> Furthermore, many patients and providers do not even know treatments exist for active MPX infections, and the few who do have faced mountains of complex paperwork to make use of them.<sup>13</sup> As a result, it will be difficult to control this outbreak and eliminate MPX in the U.S. However, there are still critical steps which can be taken to improve access to MPX testing, treatment, and vaccination.<sup>14,15</sup> In addition, there is a need to improve public education about MPX in GBMSM communities and in the broader population, as anyone can get MPX. It is also crucial to improve provider education and government transparency as we make concentrated efforts to track and treat MPX.

## VACCINATIONS

The federal government has mismanaged vaccine supply and distribution, which has enabled the virus to spread among GBMSM in the U.S. and has reinforced racial/ethnic, class, and geographic inequities in health care access. According to *The New York Times*:

The United States once had some 20 million doses [of vaccine to prevent smallpox and monkeypox] in a national stockpile but failed to replenish them as they expired, letting the supply dwindle to almost nothing.<sup>16</sup>

At the start of the current outbreak in the U.S., the U.S. government owned 372,000 doses of finished JYNNEOS vaccine, which can help to protect against monkeypox and smallpox. The U.S. government invested nearly \$2 billion into developing this vaccine.<sup>17</sup>

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<sup>12</sup> Walsh, James D. "The Painful Wait. FDA Officials Took Months to Inspect a Critical Plant in Europe, Leaving Americans without Shots as Monkeypox Spreads." *New York Magazine* (Intelligencer), July 8, 2022. <https://nymag.com/intelligencer/2022/07/monkeypox-vaccine-delayed-after-fda-waited-to-inspect-plant.html>.

<sup>13</sup> Prep4All and Partners in Health. "Prep4all, Partners in Health, and Other Experts' Letter to Biden Officials on Tpoxx." News release, July 15, 2022, <https://www.documentcloud.org/documents/22088010-prep4all-partners-in-health-and-other-experts-letter-to-biden-officials-on-tpoxx>.

<sup>14</sup> Perrone, Matthew. "U.S. Regulators Clear Way for More Monkeypox Vaccine Shipments from Denmark." *PBS News Hour*, July 14, 2022. <https://www.pbs.org/newshour/health/u-s-regulators-clear-way-for-more-monkeypox-vaccine-shipments-from-denmark>.

<sup>15</sup> Letter from PrEP4All, Partners in Health to Raj Panjabi, MD Special Assistant to the President, Senior Director, Global Health Security and Biodefense, National Security Council; Robert Califf, MD, Commissioner US Food and Drug Administration; Dawn O'Connell, Assistant Secretary of Health and Human Services for Preparedness and Response, US Department of Health and Human Services. June 28, 2022. <https://www.prep4all.org/s/P4A-Monkeypox-Vaccine-Letter>

<sup>16</sup> LaFraniere, Sharon, Noah Weiland, and Joseph Goldstein, "Monkeypox shortage was preventable." *New York Times*, August 4, 2022, page A18.

<sup>17</sup> Perrone, "U.S. Regulators Clear Way for More Monkeypox Vaccine Shipments from Denmark" *PBS Newshour*, July 14, 2022.

The doses were held in a Bavarian Nordic facility in Denmark which was awaiting a U.S. Food and Drug Administration (FDA) inspection, although the 372,000 doses of the vaccine had been produced in a separate facility that had already been inspected by the FDA.<sup>18</sup> These 372,000 JYNNEOS doses were in vials and ready to be sent to the U.S. in late May and early June 2022, yet instead of shipping them all in the early days and weeks of the outbreak, the U.S. government only ordered a small amount of the vaccine—36,000 doses on May 20, and 36,000 doses on June 10. Inexplicably, the U.S. government permitted the other 215,000 doses to be delivered to European countries.<sup>19</sup>

In addition to the initial 372,000 JYNNEOS doses which were ordered in June and delivered to the U.S. by July, Bavarian Nordic had some 786,000 additional doses of the vaccine that it could package and ship in June, but the FDA insisted that it had to first inspect and approve this batch of vaccine produced in a different facility.<sup>20,21</sup> The FDA facility inspection was not completed until July 27, which exacerbated the problems created by government's initial meager order and led to a shortage of vaccine supply in the U.S.<sup>22</sup>

Government officials mismanaged the vaccine supply needed to vaccinate large numbers of GBMSM. They also underestimated how much demand there would be for the vaccine within gay and bisexual men's communities. As a result, when local health departments in New York, D.C., and San Francisco announced vaccine availability, appointment slots were taken up within minutes online as demand far outstripped a limited supply.

Government officials mismanaged the vaccine supply and underestimated how much demand there would be.

After months of unnecessary delay, HHS leaders announced on July 28, 2022, that it was shipping the 786,000 additional doses to the U.S. from Bavarian Nordic, and that they would be available for state and local health departments to order in the subsequent days.<sup>23</sup> This represents a total of over

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<sup>18</sup> Letter from PrEP4All, Partners in Health to Raj Panjabi, June 28, 2022.

<sup>19</sup> LaFraniere et al., "Monkeypox shortage was preventable." *New York Times*, August 4, 2022.

<sup>20</sup> Walsh, "The Painful Wait," *New York Magazine* (Intelligencer), July 8, 2022.

<sup>21</sup> Goldstein, Joseph, and Sharon Otterman. "As monkeypox spread in New York, 300,000 vaccine doses sat in Denmark." *New York Times*, July 26, 2022. <https://www.nytimes.com/2022/07/25/nyregion/nyc-monkeypox-vaccine-doses-denmark.html>

<sup>22</sup> LaFraniere et al., "Monkeypox shortage was preventable," *New York Times*, August 4, 2022.

<sup>23</sup> HHS Press Office. "HHS Expands Availability of Monkeypox Vaccine to More Than 1.1 Million Doses." News release, July 28, 2022, <https://www.hhs.gov/about/news/2022/07/28/hhs-expands-availability-of-monkeypox-vaccine-to-more-than-1-million-doses.html>.



1.1 million doses, enough to vaccinate some 579,000 individuals based on the initial protocol of two full doses given four weeks apart. The CDC estimates that 1.5 million Americans, primarily GBMSM and transgender women, are at elevated risk for monkeypox (which could be a significant underestimate), so under the standard two-dose regimen we would need to at least triple this initial allotment as soon as possible.<sup>24,25</sup>

Independent reporting by PBS News Hour and research conducted by PrEP4All—an HIV advocacy coalition of community members, healthcare professionals, lawyers, and academics dedicated to increasing access to medication—has found that the U.S. owns enough vaccine material to produce an additional 15 million doses on top of what had already been distributed or was being shipped in early August 2022.<sup>26,27</sup> But in May 2022, the manufacturer announced plans to freeze-dry these doses.<sup>28</sup> The U.S. government has indicated that it only intends to order an additional five million doses of the JYNNEOS vaccine, stating that these doses will be available by mid-2023.<sup>29</sup> But this allocation may ultimately be insufficient, especially if MPX infections expand to other vulnerable populations and members of the public. Moreover, given the ability of MPX to spread across national boundaries, as evinced by the initial dissemination of the infection traced to parties in the Canary Islands and Antwerp, the lack of leadership by the U.S. in ensuring scaling up for global access is concerning.<sup>30</sup> The U.S. government should work with Bavarian Nordic to stop its plans to freeze dry the vaccine material and find a different manufacturer if needed to put these liquid doses into vials expeditiously. By invoking the Defense Production Act, the U.S. government could mobilize major pharmaceutical companies to scale up MPX vaccine production.<sup>31</sup> This vaccine is urgently needed in the U.S. to vaccinate at-risk communities and achieve herd immunity. Securing millions of

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<sup>24</sup> Dyer M et al. Monkeypox vaccination in adults with HIV. Clinical Guidelines Program. New York State AIDS Institute. July 29, 2022. <https://www.hivguidelines.org/hiv-care/monkeypox/>.

<sup>25</sup> The Associated Press. "Under Fire, U.S. Officials Say Monkeypox Can Still Be Stopped." *NPR*, July 29, 2022. <https://www.npr.org/2022/07/29/1114419900/under-fire-us-officials-say-monkeypox-can-still-be-stopped>.

<sup>26</sup> Perrone, "U.S. Regulators Clear Way for More Monkeypox Vaccine Shipments from Denmark." *PBS Newshour*, July 14, 2022.

<sup>27</sup> Letter from PrEP4All, Partners in Health to Raj Panjabi, June 28, 2022.

<sup>28</sup> Bavarian Nordic, "Bavarian Nordic to Manufacture First Freeze-dried Doses of Smallpox Vaccine upon Exercise of Contract Option by the U.S. Government." News release, May 18, 2022, <https://www.globenewswire.com/en/news-release/2022/05/18/2445603/0/en/Bavarian-Nordic-to-Manufacture-First-Freeze-dried-Doses-of-Smallpox-Vaccine-upon-Exercise-of-Contract-Option-by-the-U-S-Government.html>.

<sup>29</sup> U.S. Department of Health and Human Services. Fact sheet: U.S. Department of Health and Human Services response to the monkeypox outbreak. July 21, 2022. <https://www.hhs.gov/about/news/2022/07/21/fact-sheet-us-department-of-health-and-human-services-response-to-the-monkeypox-outbreak.html>

<sup>30</sup> Cohen, Jon. "Monkeypox Outbreak Questions Intensify as Cases Soar." *Science Insider*, May 20, 2022. <https://www.science.org/content/article/monkeypox-outbreak-questions-intensify-cases-soar>.

<sup>31</sup> Choi, Joseph. "New York Democrats Urge White House to Invoke Defense Production Act for Vaccines to Treat Monkeypox." *The Hill*, August 17, 2022. <https://thehill.com/policy/healthcare/3605270-new-york-democrats-urge-white-house-to-invoke-defense-production-act-for-vaccines-to-treat-monkeypox/>.

additional future doses would prepare our health system to respond to potential new outbreaks among vulnerable populations.

To make the most effective use of a limited vaccine supply, in July 2022 several big city health departments (New York, D.C., and San Francisco), as well as departments within Canada and the U.K., started distributing all doses and not holding second doses aside (JYNNEOS was designed to be a two-dose vaccine).<sup>32,33</sup> In order to be safe, jurisdictions should follow up with individuals four weeks later to ensure they get their second dose (this assumes that they will have second doses to give four weeks later). Some jurisdictions want to adopt a similar strategy but must wait for CDC authorization to do so. CDC guidance, or an Emergency Use Authorization (EUA) for JYNNEOS under Section 564 of the Food, Drug, and Cosmetic Act, would enable more jurisdictions to adopt this strategy.<sup>34</sup>

Although the United States has stockpiled similar vaccines which could have helped to ease shortages of the JYNNEOS vaccine, serious side effects and contraindications have rendered these unusable. Concerns of bioterrorism linked to smallpox led the Clinton Administration to create the Strategic National Stockpile of smallpox vaccines, which could be used to fight MPX prophylactically or following an initial infection.<sup>35,36</sup> Unfortunately, this stockpile (totaling over 100 million doses) is primarily composed of a smallpox vaccine called ACAM2000.<sup>37</sup> This vaccine has seen limited application against monkeypox because a possible side effect of the

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<sup>32</sup> Cohen, Jon. "There's a Shortage of Monkeypox Vaccine. Could One Dose Instead of Two Suffice?" *Science Insider*, July 1, 2022. <https://www.science.org/content/article/there-s-shortage-monkeypox-vaccine-could-one-dose-instead-two-suffice>.

<sup>33</sup> Eisenberg, Amanda, and Shannon Young. "NYC Health Department Switches to Single-Dose Strategy to Fight Monkeypox Outbreak." *Politico*, July 18, 2022. <https://www.politico.com/newsletters/weekly-new-york-health-care/2022/07/18/nyc-health-department-switches-to-single-dose-strategy-to-fight-monkeypox-outbreak-00046250>.

<sup>34</sup> "Emergency Use Authorization." FDA, Updated August 26, 2022, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

<sup>35</sup> Reisinger, Don. "What's in the Strategic National Stockpile, the US Reserve of Life-Saving Materials Stashed in Secret Warehouses That Experts Worry Isn't Big Enough." *Business Insider*, April 14, 2020. <https://www.businessinsider.com/strategic-national-stockpile-location-items-inside-history-size-2020-4>.

<sup>36</sup> Agam K. Rao et al., "Use of JYNNEOS (Smallpox and Monkeypox Vaccine, Live, Nonreplicating) for Preexposure Vaccination of Persons at Risk for Occupational Exposure to Orthopoxviruses: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022," *MMWR. Morbidity and Mortality Weekly Report* 71, no. 22, June 3, 2022, <https://doi.org/10.15585/mmwr.mm7122e1>, [http://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm?s\\_cid=mm7122e1\\_w](http://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm?s_cid=mm7122e1_w).

<sup>37</sup> HHS Press Office, "HHS Orders 2.5 Million More Doses of JYNNEOS Vaccine For Monkeypox Preparedness." News release, July 1, 2022, <https://www.hhs.gov/about/news/2022/07/01/hhs-orders-2-point-5-million-more-doses-jynneos-vaccine-for-monkeypox-preparedness.html>.

ACAM2000 is myopericarditis, a serious but rarely fatal condition.<sup>38,39</sup> In addition, use of the ACAM2000 is explicitly contraindicated for people living with HIV (PLWH), making it unsuitable for many individuals at risk of contracting MPX.<sup>40</sup> These concerns have limited the vaccine's viability for civilian use. Fortunately, the JYNNEOS vaccine developed by Bavarian Nordic does not pose such risks and has thus acted as the primary tool for protecting Americans at risk of MPX.<sup>41,42</sup>

From May through at least mid-August 2022 it was very difficult for GBMSM to access MPX vaccines. Clinics in cities receiving doses of the vaccine were inundated with requests for vaccination slots as soon as availability was announced. With countless individuals eagerly refreshing web pages in a hunt for appointments, the available slots for vaccination were completely booked up within two to 10 minutes of announcing availability.<sup>43</sup> As a result, many individuals at high risk of infection tried repeatedly to get vaccinated without

Many individuals at high risk of infection tried repeatedly to get vaccinated without success, only to later get infected with MPX.

success, only to later get infected with MPX.<sup>44</sup> In addition, the requirement of internet or phone access to schedule a vaccination appointment may have created barriers to accessing vaccination for some low-income individuals. A better approach could involve reaching out to patients with relatively high risk sexual activity (for example, some individuals on PrEP) or those recently diagnosed with sexually transmitted infections.

As public health authorities resolve some of the issues which delayed initial access to such an

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<sup>38</sup> Myopericarditis. *Up to date*.

<https://www.uptodate.com/contents/myopericarditis#:~:text=Myopericarditis%2C%20a%20complication%20of%20acute,and%20treated%20as%20acute%20pericarditis>. Accessed July 29, 2022.

<sup>39</sup> Simon A. Sarkisian et al., "A Case Series of Smallpox Vaccination-Associated Myopericarditis: Effects on Safety and Readiness of the Active Duty Soldier," *Military Medicine* 184, no. 1-2, June 27, 2018, <https://doi.org/10.1093/milmed/usy159>.

<sup>40</sup> Centers for Disease Control and Prevention (CDC). "Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines During the 2022 U.S. Monkeypox Outbreak." Updated August 15, 2022, <https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html>.

<sup>41</sup> HHS Press Office, "HHS Orders 2.5 Million More Doses of JYNNEOS Vaccine," News release. July 1, 2022. <https://www.hhs.gov/about/news/2022/07/01/hhs-orders-2-point-5-million-more-doses-jynneos-vaccine-for-monkeypox-preparedness.html>

<sup>42</sup> HHS Press Office. "Biden-Harris Administration Announces Additional Deliveries of Vaccine as Part of Nationwide Vaccine Strategy for Preventing Monkeypox." News release. July 1, 2022, <https://www.hhs.gov/about/news/2022/07/01/biden-harris-administration-announces-additional-deliveries-vaccine-as-part-of-nationwide-vaccine-strategy-for-preventing-monkeypox.html>.

<sup>43</sup> Ducharme, Jamie. "Why It's So Hard to Get a Monkeypox Vaccine Right Now." *Time*, July 18, 2022. <https://time.com/6198298/monkeypox-vaccine-shortage/>.

<sup>44</sup> Infectious Diseases Society of America, "HHS Monkeypox Letter." July 22, 2022. <https://www.idsociety.org/globalassets/google-ad/hhs-monkeypox-letter-july-2022-final.pdf>.

important tool, there are serious concerns surrounding the equitable distribution of the vaccine and the limitations of the Biden administration's rather conservative stockpile of around 7 million doses (including those completed and ordered for future manufacture).<sup>45</sup> Advocates have highlighted the inequity inherent to the current vaccine rollout, with digital scheduling systems and limited numbers of well-supplied clinics disadvantaging marginalized communities.<sup>46,47</sup>

## ***Racial and ethnic equity concerns***

As of August 2022, nearly 28 percent of MPX cases nationally were among Black people, who comprise just 13.6 percent of the U.S. population; 33 percent of cases were among Hispanic people, who comprise just 18.9 percent of the population.<sup>48</sup> Disparities based on race and ethnicity were even more pronounced in some localities. For example, approximately 82 percent of MPX patients in Georgia are Black, even though Black people comprise just one-third of the state's population. In North Carolina, Black patients make up about 70 percent of MPX cases, though Black people comprise approximately one-fifth of the state's population.<sup>49</sup> In New York City, approximately two-thirds of those infected with MPX are Black or Latino, though Black and Latino people make up a little more than half of the city's population.<sup>50</sup>

By August 2022 nearly 28% of monkeypox cases were among Black people, even though they make up just 13.6% of the U.S. population; 33% of cases were among Hispanic people, who comprise just 18.9% of the population.

Until late July, Maryland residents could only get the MPX vaccine in Montgomery County, a relatively wealthy DC suburb which is almost 60 percent White, while Baltimore (a city with one of Maryland's highest poverty rates where over 60 percent of residents identify as Black) had no access

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<sup>45</sup> HHS. Fact sheet: U.S. Department of Health and Human Services response to the monkeypox outbreak. July 18, 2022.

<sup>46</sup> Ducharme, Jamie. "Why It's So Hard to Get a Monkeypox Vaccine Right Now." *Time*, July 18, 2022.

<sup>47</sup> Infectious Diseases Society of America, "HHS Monkeypox Letter." July 22, 2022.

<sup>48</sup> Messerly, Megan and Krista Mahr. LGBTQ advocates say the government is missing communities of color in its monkeypox response. *Politico*. August 18, 2022. <https://www.politico.com/news/2022/08/18/lgbtq-monkeypox-people-of-color-disparities-00052705>

<sup>49</sup> North Carolina Department of Health & Human Services. Monkeypox Response Update: Equity Data Report on Cases, Vaccines and Testing. August 10, 2022. <https://www.ncdhhs.gov/media/17508/open>.

<sup>50</sup> New York City Department of Public Health. Monkeypox: Data. September 6, 2022. <https://www1.nyc.gov/site/doh/data/health-tools/monkeypox.page#surveillance>

whatsoever.<sup>51,52,53</sup> As of late July, only 200 doses of MPX vaccine had been administered in Baltimore.<sup>54</sup>

It is essential that the CDC and local and state health departments work closely with community-based organizations with long-standing relationships of trust with Black and Hispanic gay and bisexual men and transgender and nonbinary people to ensure equitable, proportional uptake of the MPX vaccine. We welcome the White House's announcement August 30, 2022, that it would "surge vaccine availability and other prevention resources to communities of color" and mobilize large numbers of vaccine doses to Atlanta Black Pride, Oakland Pride, and Southern Decadence in New Orleans to address racial and ethnic equity concerns in the MPX outbreak.<sup>55</sup>

In addition to this focus on increasing equitable vaccine access, we must acknowledge the impact of racism on the health and healthcare experiences of people of color. Black and Hispanic patients are less likely to be insured, less likely to seek and receive preventative medical care, and experience worse health outcomes than their White non-Hispanic counterparts due to racism.<sup>56</sup> It is critical that public health authorities including the CDC, state, and local health departments address and dismantle racist institutions and practices which damage the health of people of color throughout the United States.

### ***The FDA's Emergency Use Authorization allowing the intradermal administration of 1/5 of a dose of JYNNEOS vaccine***

On August 9, 2022, following growing criticism from members of Congress and state and local officials over the mishandling of the JYNNEOS vaccine supply and the manufactured shortage which facilitated the spread of MPX among GBMSM communities, the FDA issued an Emergency Use Authorization allowing each dose of vaccine to be split into 5 doses and administered intradermally instead of subcutaneously. The EAU read:

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<sup>51</sup> Roth, Grant, Monkeypox Vaccination Access Project, updated July 30, 2022,

[https://docs.google.com/document/d/1QO55TTeO6ZKrC0yw\\_LvIrKU56wb1r7rX9kAW\\_WsLLtQ/edit](https://docs.google.com/document/d/1QO55TTeO6ZKrC0yw_LvIrKU56wb1r7rX9kAW_WsLLtQ/edit).

<sup>52</sup> United States Census Bureau. "Quickfacts Montgomery County, Maryland." U.S. Department of Commerce, 2021. <https://www.census.gov/quickfacts/montgomerycountymaryland>.

<sup>53</sup> United States Census Bureau. "Quickfacts Baltimore City, Maryland." U.S. Department of Commerce, 2021. <https://www.census.gov/quickfacts/fact/table/baltimorecitymaryland/PST045221>.

<sup>54</sup> Nirappil, Fenit. "Struggle to protect gay, bisexual men from monkeypox exposes inequities," *Washington Post*, July 27, 2022. <https://www.washingtonpost.com/health/2022/07/27/monkeypox-gay-men-vaccine-treatment/>

<sup>55</sup> White House. Fact sheet: White House Monkeypox Response Team announces new plans to support large LGBTQI+ events and equity interventions to reach communities at highest risk of contracting the virus. August 30, 2022. <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/30/fact-sheet-white-house-monkeypox-response-team-announces-new-plans-to-support-large-lgbtqi-events-and-equity-interventions-to-reach-communities-at-highest-risk-of-contracting-the-virus/>

<sup>56</sup> Williams, D. R., J. A. Lawrence, and B. A. Davis. "Racism and Health: Evidence and Needed Research." [In eng]. *Annu Rev Public Health* 40 (Apr 1, 2019): 105-25. <https://doi.org/10.1146/annurev-publhealth-040218-043750>.



JYNNEOS, the Modified Vaccinia Ankara (MVA) vaccine, was approved in 2019 for prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.... Data from a 2015 clinical study of the MVA vaccine evaluated a two-dose series given intradermally compared to subcutaneously. Individuals who received the vaccine intradermally received a lower volume (one fifth) than individuals who received the vaccine subcutaneously. The results of this study demonstrated that intradermal administration produced a similar immune response to subcutaneous administration, meaning individuals in both groups responded to vaccination in a similar way. Administration by the intradermal route resulted in more redness, firmness, itchiness and swelling at the injection site, but less pain, and these side effects were manageable. The FDA has determined that the known and potential benefits of JYNNEOS outweigh the known and potential risks for the authorized uses.<sup>57</sup>

The European analogue to the FDA, the European Medicines Agency, reviewed this 2015 study and noted that “People receiving the vaccine intradermally received one fifth (0.1 ml) of the subcutaneous dose (0.5 ml) but produced similar levels of antibodies to those who received the higher subcutaneous dose.”<sup>58</sup>

In a letter sent to the FDA just after the August 9 announcement, Bavarian Nordic leaders expressed concern about the approach:

[W]e do have some reservations on the ID [intradermal] approach, due to the very limited safety data available (<200 people), the higher reactogenicity compared to the JYNNEOS standard dose and route (subcutaneous [SC]), and the fact that there was a relatively high percentage of subjects (20%) that failed to receive the second vaccination during a controlled clinical study.<sup>59</sup>

Because the method of injection and the needles used are different from the traditional subcutaneous injection used to date, health care providers and advocates raised concerns about the need for training and funding to ensure proper implementation of the new strategy. Many also raised concerns that the change in strategy is based on one small study, and questioned whether the intradermal approach will provide sufficient protection for people with

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<sup>57</sup> U.S. Food & Drug Administration. "Monkeypox Update: FDA Authorizes Emergency Use of JYNNEOS Vaccine to Increase Vaccine Supply." News release, August 9, 2022, <https://www.fda.gov/news-events/press-announcements/monkeypox-update-fda-authorizes-emergency-use-jynneos-vaccine-increase-vaccine-supply>.

<sup>58</sup> European Medicines Agency. “EMA’s Emergency Task Force advises on intradermal use of Imvanex/Jynneos against monkeypox.” August 19, 2022. <https://www.ema.europa.eu/en/news/emas-emergency-task-force-advises-intradermal-use-imvanex-jynneos-against-monkeypox>

<sup>59</sup> Soucheray, Stephanie. "Fractional Monkeypox Vaccine Dosing Comes under Scrutiny." *CIDRP News*, August 11, 2022, <https://www.cidrap.umn.edu/news-perspective/2022/08/fractional-monkeypox-vaccine-dosing-comes-under-scrutiny>.

compromised immune systems, such as PLWH. Others highlighted the increased risk of keloid formation in Black patients, which could be perceived as disfiguring, and could potentiate community mistrust.<sup>60</sup>

David Harvey, executive director of the National Coalition of STD Directors, said sexual health clinics are severely underfunded and not well-positioned to administer more doses under the new plan. He also questioned whether the new approach would work.

"We have grave concerns about the limited amount of research that has been done on this dose and administration method, and we fear it will give people a false sense of confidence that they are protected," Harvey said in a written statement. "This approach raises red flag after red flag, and appears to be rushed ahead without data on efficacy, safety, or alternative dosing strategies."

Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota, said he had concerns about the immune protection provided by the strategy, particularly for people with health conditions like HIV. "We don't yet have the data to know how effectively an intradermal-administered vaccination will protect immunocompromised persons," he said.<sup>61</sup>

The FDA's shift to promoting intradermal vaccination is based on one 2015 study with 524 participants. This study included a relatively small number of people of color and excluded people living with HIV (PLWH).<sup>62</sup>

Ten days after the FDA's announcement, the European Medicines Agency issued a statement stating that it had reviewed the data from the 2015 study and found that:

"National authorities may decide as a temporary measure to use Imvanex [the European brand name for Jynneos] as an intradermal injection at a lower dose to protect at-risk individuals during the current monkeypox outbreak while supply of the vaccine remains limited."<sup>63</sup>

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<sup>60</sup> Messerly, Megan, and Krista Mahr. "White House strategy for monkeypox vaccines causing 'chaos out in the field'." *Politico*, August 24, 2022. <https://www.politico.com/news/2022/08/24/monkeypox-vaccine-lgbtq-00053410>.

<sup>61</sup> Diamond, Dan, and Fenit Nirappil. "Limited Monkeypox Vaccine Supply Would Be Stretched under FDA Plan." *The Washington Post*, August 9, 2022. <https://www.washingtonpost.com/health/2022/08/08/monkeypox-vaccine-doses/>.

<sup>62</sup> "Most subjects were non-Hispanic (93.3%) and white (82.0%)." PLWH were excluded from the study. Frey SE, Wald A, Edupuganti S, Jackson LA, Stapleton JT, El Sahly H, El-Kamary SS, Edwards K, Keyserling H, Winokur P, Keitel W, Hill H, Goll JB, Anderson EL, Graham IL, Johnston C, Mulligan M, Rouphael N, Atmar R, Patel S, Chen W, Kotloff K, Creech CB, Chaplin P, Belshe RB. Comparison of lyophilized versus liquid modified vaccinia Ankara (MVA) formulations and subcutaneous versus intradermal routes of administration in healthy vaccinia-naïve subjects. *Vaccine*. 2015 Sep 22;33(39):5225-34. doi: 10.1016/j.vaccine.2015.06.075. Epub 2015 Jul 2. PMID: 26143613.

<sup>63</sup> European Medicines Agency. "Intradermal Use of Imvanex / Jynneos against Monkeypox." August 19, 2022. <https://www.ema.europa.eu/en/news/emas-emergency-task-force-advises-intradermal-use-imvanex-jynneos-against-monkeypox>

Individuals receiving an intradermal vaccination should develop a “bleb” soon after the injection—a raised bubble of liquid under the skin that eventually subsides. Some individuals are reporting that they are not developing a bleb, raising concerns that the intradermal vaccination was not administered properly, and raising questions as to whether the vaccination will provide protective benefit equal to the subcutaneous vaccination.

CDC guidance recommends the following course of action should an attempted intradermal injection fail to produce a “bleb” in a patient, which the CDC refers to as a “wheal”:

#### Administration error/deviation

Incorrect route resulting in lower-than-authorized dose administered (e.g., inadvertent subcutaneous administration of 0.1 mL when intradermal route was intended, i.e., no visible “wheal” was formed).

#### Interim Recommendation

Repeat dose immediately via intended route (no minimum interval). Repeated dose should be placed at least 2 inches away from the inadvertent site placement.<sup>64</sup>

Rollout has been rocky, with some local and state health departments and community health centers saying they are having trouble getting five doses from each vial.<sup>65</sup> Some sites across the country are reporting that they are only able to get three or four doses out of a vial.<sup>66</sup> Despite this, the U.S. Department of Health and Human Services has cut back its shipments to state and local health departments by 80%, assuming that all sites will be able to consistently get five doses out of every vial.<sup>67</sup>

“The federal government has patted themselves on the back for how they’re accelerating the delivery of vaccines,” Patrick Ashley, senior deputy director at Washington, D.C.’s Department of Health, told *Politico* in late August. “What they did is they moved numbers around.”<sup>68</sup>

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<sup>64</sup> Centers for Disease Control and Prevention. Vaccine Administration Errors and Deviations. Table 7. Interim recommendations for JYNNEOS vaccine administration errors and deviations. Updated August 15, 2022.

<https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/errors-deviations.html#Table7>

<sup>65</sup> Messerly, Megan, and Krista Mahr. “White House strategy for monkeypox vaccines causing ‘chaos out in the field’.” *Politico*, August 24, 2022.

<sup>66</sup> Conversation with community health center representatives on RESPND-MI LGBTQ+ Community Forum call, August 29, 2022.

<sup>67</sup> Messerly, Megan, and Krista Mahr. “White House strategy for monkeypox vaccines causing ‘chaos out in the field’.” *Politico*, August 24, 2022.

<sup>68</sup> Ibid.

Johns Hopkins University epidemiologist Caitlin Rivers wrote in a Substack post in late August 2022: “I have now heard multiple reports from my state and local colleagues that it is very difficult to extract five doses from a single vaccine vial...Taken together, state and local health authorities now have up to one-third *fewer* doses for use in their communities than they were before the move to intradermal administration.”<sup>69</sup>

It is essential that federal and state health agencies monitor the intradermal approach very closely, especially for PLWH. Health centers and agencies administering the vaccine need to develop systems to track patients and ensure that they come back for a second dose four weeks later. Congress must provide significant additional funding to support this work.

## SOLUTIONS

To address the shortcomings described above, HHS and the White House should adopt the following policy solutions:

**Work to produce 15 million more doses of the JYNNEOS vaccine in the next few weeks to address spread to other at-risk populations:**

The U.S. government has promised that by mid-2023, 5 million more doses will be available, on top of the 1.15 million that have been administered or were en route to the U.S. in late July.<sup>70</sup> The FDA and HHS must learn from their initial underestimation of the demand for JYNNEOS vaccine in June 2022, and the unnecessary vaccine shortages that this caused. The U.S. should work with Bavarian Nordic to stop its plans to freeze dry the 15 million doses of this vaccine and find a different manufacturer if needed to put these doses into vials expeditiously.<sup>71</sup> If Bavarian Nordic cannot produce millions of doses quickly, the FDA should find a different manufacturer that can do this with the vaccine material. On August 18, 2022, Bavarian Nordic announced that it would work with a Michigan manufacturer, Grand River Aseptic, and conduct a technology

The federal government must employ every resource available, including invocation of the Defense Production Act, to produce 15 million additional doses of the JYNNEOS vaccine.

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<sup>69</sup> Diamond D. “Officials ‘cautiously optimistic’ about falling monkeypox cases.” *Washington Post*. August 26, 2022. <https://www.washingtonpost.com/health/2022/08/26/monkeypox-cases-falling/>

<sup>70</sup> U.S. Department of Health and Human Services. Fact sheet: U.S. Department of Health and Human Services response to the monkeypox outbreak. July 21, 2022. <https://www.hhs.gov/about/news/2022/07/21/fact-sheet-us-department-of-health-and-human-services-response-to-the-monkeypox-outbreak.html>

<sup>71</sup> Bavarian Nordic, “Bavarian Nordic to Manufacture First Freeze-dried Doses of Smallpox Vaccine upon Exercise of Contract Option by the U.S. Government,” news release, May 18, 2022, <https://www.globenewswire.com/en/news-release/2022/05/18/2445603/0/en/Bavarian-Nordic-to-Manufacture-First-Freeze-dried-Doses-of-Smallpox-Vaccine-upon-Exercise-of-Contract-Option-by-the-U-S-Government.html>.

transfer within three months to allow the company to package the JYNNEOS vaccine in the U.S.<sup>72</sup>

Expanding the scope of its initial JYNNEOS orders and creating alternative packaging approaches will allow the U.S. government to have millions of doses on hand in case monkeypox starts to spread in prisons and jails, in congregate living facilities such as nursing homes, assisted living facilities, group homes, and homeless shelters,<sup>73</sup> or among populations such as sex workers, migrants, or throughout the general population.

The CDC estimates that 1.5 million Americans, primarily GBMSM, should be prioritized for the monkeypox vaccine.<sup>74</sup> We would need 3 million doses to vaccinate this population. As of early August 2022, the U.S. government had delivered a total of 1.15 million doses under the two-dose regimen. But we need about 3 times this amount of vaccine as soon as possible in order to vaccinate the number of GBMSM and trans women that the CDC says should be vaccinated.

**Invoke the Defense Production Act to accelerate vaccine production:** The Defense Production Act represents a valuable legislative tool for facilitating the rapid manufacture and allocation of critical national supplies and could address the current shortage of JYNNEOS vaccines. This act gives the president the power to expand the production of materials important for national defense, giving them the authority to order businesses to accept production contracts and to utilize financial incentives to convince industries to expand their production capacity.<sup>75</sup>

The current administration has already made judicious use of this legislation to scale up vaccine production and protect vulnerable communities. President Biden invoked the act in March 2021 to supply Merck production facilities with the materials necessary to manufacture the Janssen COVID-19 vaccine.<sup>76</sup> More recently, HHS Secretary Xavier Becerra invoked the Defense Production Act in

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<sup>72</sup> Reuters. "Bavarian Nordic Signs up U.S. Firm for Packaging Monkeypox Vaccine." *Reuters*, August 18, 2022, <https://www.reuters.com/business/healthcare-pharmaceuticals/bavarian-nordic-signs-up-us-firm-packaging-monkeypox-vaccine-2022-08-18/>.

<sup>73</sup> Rodriguez A. "People experiencing homelessness are catching monkeypox. Why experts are worried and what cities are doing." *USA Today*. August 31, 2022. <https://www.usatoday.com/story/news/health/2022/08/31/monkeypox-cases-homeless-cities-take-different-approach-problem/10326741002/?gnt-cfr=1>

<sup>74</sup> The Associated Press. "Under Fire, U.S. Officials Say Monkeypox Can Still Be Stopped." *NPR*, July 29, 2022. <https://www.npr.org/2022/07/29/1114419900/under-fire-us-officials-say-monkeypox-can-still-be-stopped>.

<sup>75</sup> Federal Emergency Management Agency. "Defense Production Act." Updated November 19, 2021. <https://www.fema.gov/disaster/defense-production-act>.

<sup>76</sup> HHS Press Office. "Biden Administration Announces Historic Manufacturing Collaboration between Merck and Johnson & Johnson to Expand Production of Covid-19 Vaccines." News release, March 2, 2021, <https://www.hhs.gov/about/news/2021/03/02/biden-administration-announces-historic-manufacturing-collaboration-between-merck-johnson-johnson-expand-production-covid-19-vaccines.html>.



May 2022 to facilitate the production of infant formula in the midst of a national shortage.<sup>77</sup>

**Push for vaccine equity:** To avoid pitfalls encountered during the COVID vaccine rollout, the CDC should support initiatives to educate the public about MPX vaccinations in multiple languages and partner with community health centers and safety net health systems to expand the rollout outside of areas which are already well-resourced. The CDC and HHS must also address the racial/ethnic, geographic, and class equity concerns highlighted in a *Washington Post* article July 28, 2022.<sup>78</sup> Given the disproportionate burden of MPX on Black and Hispanic/Latino GBMSM, the CDC and state and local health departments should work with community-based organizations and take innovative steps to ensure vaccine uptake in communities of color proportional to the disproportionate impact of MPX in those communities. The administration's late August 2022 prioritization of delivering vaccine to LGBTQIA+ pride events attracting many Black LGBTQIA+ people is a welcome development.<sup>79</sup>

**Authorize state and local health departments to administer all their doses of the vaccine without having to hold onto the second doses:** Should HHS return to the subcutaneous vaccination approach, the CDC should advise state health departments that they can administer all of their JYNNEOS vaccine doses without setting the second doses aside.<sup>80</sup> New York City, DC and San Francisco have already adopted this policy—administering all doses without setting the second doses aside—without authorization.<sup>81</sup> Canada and the UK are also taking this approach. Other state and local health departments in the U.S. wish to replicate this, but are waiting for permission from the CDC.

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<sup>77</sup> HHS Press Office. "HHS Secretary Becerra Invokes Defense Production Act to Accelerate Delivery of Raw Materials and More Needed to Manufacture Infant Formula." News release, May 22, 2022, <https://www.hhs.gov/about/news/2022/05/22/hhs-secretary-becerra-invokes-defense-production-act-accelerate-delivery-of-raw-materials-more-needed-manufacture-infant-formula.html#:~:text=On%20May%2018%2C%20President%20Biden,shortage%20in%20the%20United%20States.>

<sup>78</sup> Nirappil, Fenit. "Struggle to protect gay, bisexual men from monkeypox exposes inequities," *Washington Post*, July 27, 2022. <https://www.washingtonpost.com/health/2022/07/27/monkeypox-gay-men-vaccine-treatment/>

<sup>79</sup> White House. Fact sheet: White House Monkeypox Response Team announces new plans to support large LGBTQI+ events and equity interventions to reach communities at highest risk of contracting the virus. August 30, 2022. <https://www.whitehouse.gov/briefing-room/statements-releases/2022/08/30/fact-sheet-white-house-monkeypox-response-team-announces-new-plans-to-support-large-lgbtqi-events-and-equity-interventions-to-reach-communities-at-highest-risk-of-contracting-the-virus/>

<sup>80</sup> Cohen, Jon. "There's a Shortage of Monkeypox Vaccine. Could One Dose Instead of Two Suffice?" *Science Insider*, July 1, 2022. <https://www.science.org/content/article/there-s-shortage-monkeypox-vaccine-could-one-dose-instead-two-suffice>.

<sup>81</sup> Eisenberg, Amanda, and Shannon Young. "NYC Health Department Switches to Single-Dose Strategy to Fight Monkeypox Outbreak." *Politico*, July 18, 2022. <https://www.politico.com/newsletters/weekly-new-york-health-care/2022/07/18/nyc-health-department-switches-to-single-dose-strategy-to-fight-monkeypox-outbreak-00046250>.

A single-dose protocol could be enacted through an Emergency Use Authorization for the JYNNEOS vaccine under Section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act).<sup>82</sup> The EUA issued August 9 has steered some local and state health departments toward intradermal injections. New York City was still using the subcutaneous approach as of August 22, 2022.<sup>83</sup>

In order to be safe, public health agencies and clinics administering the vaccines should follow up with individuals four weeks later to ensure they get their second dose.

**Closely monitor the one-fifth of a dose, intradermal vaccination approach:**

David Harvey, executive director of the National Coalition of STD Directors, has expressed “grave concerns about the limited amount of research” on the intradermal vaccination approach, while other scientists have questioned whether it will provide enough immune protection to people living with HIV. *The Washington Post* characterized the FDA’s shift to intradermal

Federal and state agencies should use clinical trials to monitor the intradermal vaccine approach.

vaccinations as “a large-scale, real-time experiment.”<sup>84</sup> Federal and state health agencies should monitor the intradermal approach very closely through carefully executed clinical trials, especially for PLWH. Health centers and agencies administering the vaccine need to develop systems to track patients and ensure that they come back for a second dose four weeks later. Congress must provide additional emergency funding to support this work.

## TESTING

Initial testing guidelines for MPX were remarkably cumbersome and may have hampered efforts to stem the initial outbreak.<sup>85</sup> Until early July, physicians had

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<sup>82</sup> Food and Drug Administration. “Emergency Use Authorization.” Updated August 26, 2022, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

<sup>83</sup> Freyer FJ, “Monkeypox vaccine providers start new method of injection,” *Boston Globe*, August 21, 2022. <https://www.bostonglobe.com/2022/08/21/metro/monkeypox-vaccine-providers-start-new-method-injection/>

<sup>84</sup> Diamond, Dan, and Fenit Nirappil. “Limited Monkeypox Vaccine Supply Would Be Stretched under FDA Plan.” *The Washington Post*, August 9, 2022. <https://www.washingtonpost.com/health/2022/08/08/monkeypox-vaccine-doses/>.

<sup>85</sup> Branswell, Helen, and Andrew Joseph, “‘Testing bottleneck’ for monkeypox puts hope of containment at risk, experts warn,” *Stat News*. June 7, 2022. <https://www.statnews.com/2022/06/07/testing-bottleneck-for-monkeypox-jeopardizes-containment-experts-warn/>

to contact a local health department to get a generic orthopoxvirus test and only then (if positive) would the CDC test for MPX.<sup>86,87,88</sup>

A description of the process by the *Washington Post* illustrates the ways in which the public health response to MPX was unnecessarily slowed:

Early on, every monkeypox test required physicians to first get permission from a city or state epidemiologist, often an hours-long process that required multiple phone calls or emails — before the sample was sent to a public health laboratory, which could take days to release results. Following CDC guidance, local officials also imposed strict requirements that tests could be administered only to patients with visible lesions — the telltale sign of monkeypox — or patients with rashes who had been potentially exposed. The CDC's thinking was that testing the most at-risk people, followed by contact tracing, would give the United States the best shot at controlling the outbreak.

The restrictions created a chokehold: Only about a dozen tests per day were being performed nationwide in early June, at a time when officials believed hundreds or thousands of daily tests were needed to detect infection clusters and head off an outbreak.<sup>89</sup>

While some of these issues have been remedied through expanded testing and collaboration with five large commercial labs, there is still a need to build additional testing infrastructure and increase accessibility.<sup>90</sup>

The price of testing represents an important barrier to identifying cases and treating MPX successfully. Some research suggests that sexual minority adults are more likely to be uninsured and to delay accessing healthcare due to the

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<sup>86</sup> Ibid.

<sup>87</sup> Krellenstein, James, Joseph Osmundson, and Keletso Makofane. "To Fight Monkeypox, Remember the Lessons of Covid and H.I.V." *New York Times*, May 29, 2022, <https://www.nytimes.com/2022/05/29/opinion/monkeypox-covid-and-hiv.html>.

<sup>88</sup> Diamond D, Nirappil F, Sun LH. "Inside America's monkeypox crisis—and the mistakes that made it worse." *Washington Post*. August 17, 2022. <https://www.washingtonpost.com/health/2022/08/17/monkeypox-biden-vaccine-testing-mistakes/>

<sup>89</sup> Ibid.

<sup>90</sup> Centers for Disease Control and Prevention (CDC). "LabCorp to Begin Monkeypox Testing Today, Doubling Nationwide Testing Capacity." News release, July 6, 2022, <https://www.cdc.gov/media/releases/2022/s0706-monkeypox-labcorp.html>.

costs of treatment.<sup>91,92,93</sup> Although the expansion of testing to large commercial laboratories may increase our capacity to track infections, burdensome costs may disincentivize individuals from getting tested in the first place, especially seniors, people with disabilities, low-income people, the uninsured and underinsured, and those on public insurance.

The CDC must streamline the authorization process for developing new MPX tests.

Furthermore, advocates have pointed out flaws in the limited collection of demographic information included in CDC testing protocols.<sup>94</sup> The CDC should require state health departments to collect and report deidentified sexual orientation and gender identity data, as well as race and ethnicity, sex, and other demographics. We can't address disparities in disease prevalence, uptake of preventive vaccines, and treatment access without solid data documenting such disparities.

## SOLUTIONS

**Provide free MPX testing nationwide regardless of insurance status:** The White House has previous experience designing programs to minimize financial barriers to testing, as it piloted a program to distribute free/reimbursed COVID tests nationwide earlier this year.<sup>95</sup> Similar frameworks can be utilized to ensure that all Americans are eligible for free MPX testing, including those who are un- or underinsured as well as Medicaid and Medicare beneficiaries.

**Mobilize academia and commercial industries for development of new tests:** The swift development of new forms of COVID-19 testing, such as rapid tests, has proved pivotal throughout the course of the coronavirus pandemic. To build on this success and experience, the CDC should streamline authorizations for developing new MPX tests and contract with companies

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<sup>91</sup> Jackson, Chandra L., Madina Agénor, Dayna A. Johnson, S. Bryn Austin, and Ichiro Kawachi. "Sexual Orientation Identity Disparities in Health Behaviors, Outcomes, and Services Use among Men and Women in the United States: A Cross-Sectional Study." *BMC Public Health* 16, no. 1 (August 17, 2016): 807. <https://doi.org/10.1186/s12889-016-3467-1>.

<sup>92</sup> Tabaac, A. R., A. L. Solazzo, A. R. Gordon, S. B. Austin, C. Guss, and B. M. Charlton. "Sexual Orientation-Related Disparities in Healthcare Access in Three Cohorts of U.S. Adults." *Prev Med* 132 (Mar 2020): 105999. <https://doi.org/10.1016/j.ypmed.2020.105999>.

<sup>93</sup> Charlton, B. M., A. R. Gordon, S. L. Reisner, V. Sarda, M. Samnaliev, and S. B. Austin. "Sexual Orientation-Related Disparities in Employment, Health Insurance, Healthcare Access and Health-Related Quality of Life: A Cohort Study of Us Male and Female Adolescents and Young Adults." *BMJ Open* 8, no. 6 (July 28, 2018): e020418. <https://doi.org/10.1136/bmjopen-2017-020418>.

<sup>94</sup> Infectious Diseases Society of America, "HHS Monkeypox Letter," July 22, 2022.

<sup>95</sup> White House. "Fact Sheet: The Biden Administration to Begin Distributing at-Home, Rapid Covid-19 Tests to Americans for Free." News release., January 14, 2022, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/01/14/fact-sheet-the-biden-administration-to-begin-distributing-at-home-rapid-covid-19-tests-to-americans-for-free/>.

that successfully designed COVID-19 rapid tests to help the US healthcare system quickly expand its testing infrastructure.<sup>96</sup>

The development of new COVID-19 diagnostics was heavily supported by the NIH's RADx initiative, which provided funding for new technology and projects focused on increasing COVID-19 testing access and equity.<sup>97</sup> Creating an analogous MPX RADx program could facilitate similar diagnostic innovations.

## TREATMENT

The JYNNEOS vaccine can be used to potentially prevent the onset of an MPX infection following a confirmed exposure, although the presently limited supply of vaccines means this is often not possible.<sup>98</sup> The other medicine at our disposal is tecovirimat or TPOXX, an antiviral which is currently authorized to treat smallpox, but not monkeypox in the U.S. While TPOXX can shorten the course of the disease and help reduce painful lesions within a few days, many patients and providers are unfortunately not aware that this treatment is available.

*The Washington Post* recently summarized the experiences of three gay men in Baltimore in late June and early July:

In Baltimore on June 25, Brian Thomas spotted what looked like two ingrown hairs on his butt. Two days later in New York, Gerald Febles found what looked like a mosquito bite on his hand. In the same neighborhood, Joshua Wright noticed a scabbed-over lesion in his groin.

But as they sought help, those men and others were often misdiagnosed — or were bounced between health providers.

Seeking a test June 30, Wright called the local health department, who said he would need a physician referral. He went to an urgent care clinic where he recalls the doctor suspecting monkeypox but said the clinic was testing only patients with two or more lesions. The doctor swabbed his lesion anyway and said she would follow up, but Wright did not hear back and called the health department again, which suggested going to an emergency room. He did, and recalled ER staff telling him they believed the lesion was an ingrown hair and to return if symptoms

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<sup>96</sup> Infectious Diseases Society of America, "HHS Monkeypox Letter," July 22, 2022.

<sup>97</sup> NIH Office of the Director. "NIH Mobilizes National Innovation Initiative for Covid-19 Diagnostics." April 29, 2020. <https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>.

<sup>98</sup> Centers for Disease Control and Prevention, "Monkeypox and Smallpox Vaccine Guidance," updated June 2, 2022, <https://www.cdc.gov/poxvirus/monkeypox/clinicians/smallpox-vaccine.html>.



worsened because they could authorize only 20 tests a day — which Wright did a few days later, after more lesions appeared.

The 31-year-old would soon develop a sore in his urethra that caused him to scream in pain when he urinated. He had begged the ER for treatment, but no one informed him that TPOXX, an antiviral in ample supply in the national stockpile, was an option.<sup>99</sup>

We have heard similar stories like this from individuals across the country, even in relatively well-resourced cities like New York.

Because TPOXX comes from a national stockpile and is authorized to treat smallpox but not monkeypox, providers must enroll patients in a clinical trial under Expanded Use of an Investigational New Drug protocols (EA-IND).<sup>100,101</sup> This complex paperwork can take 4 to 5 hours per patient for providers to complete.<sup>102</sup> Patients must also fill out a myriad of forms which are only available in English. In addition, the sex options on EA-IND paperwork are only male and female, which is not affirming for gender diverse individuals and fail to meet best practice standards for collecting data on gender.<sup>103</sup> These forms should be changed and translated into Spanish and other languages to ensure that access to these treatments is not impeded by language barriers.

Recent changes in the EA-IND protocol for TPOXX have brought modest relief by allowing the drug to be administered before receiving bureaucratic authorization, but this fails to ease the logistical burdens associated with TPOXX or improve awareness of the drug's benefits among patients and

Federal officials must lift the administrative requirements for prescribing TPOXX, which is only approved for treatment of smallpox, even though it is also effective in treating monkeypox.

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<sup>99</sup> Diamond D, Nirappil F, Sun LH. "Inside America's monkeypox crisis—and the mistakes that made it worse." *Washington Post*. August 17, 2022.

<sup>100</sup> Prep4All, and Partners in Health. "Prep4all, Partners in Health, and Other Experts' Letter to Biden Officials on Tpoxx." July 15, 2022, <https://www.documentcloud.org/documents/22088010-prep4all-partners-in-health-and-other-experts-letter-to-biden-officials-on-tpoxx>.

<sup>101</sup> Centers for Disease Control and Prevention (CDC), "Guidance for Tecovirimat Use under Expanded Access Investigational New Drug Protocol During 2022 U.S. Monkeypox Cases." Updated August 3, 2022, <https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html>.

<sup>102</sup> Diamond, Dan. "Doctors Treating Monkeypox Complain of 'Daunting' Paperwork, Obstacles." *The Washington Post*, July 15, 2022. <https://www.washingtonpost.com/health/2022/07/15/monkeypox-response-vaccine-treatment-obstacles-adams/>.

<sup>103</sup> Reisner, S. L., K. Biello, J. G. Rosenberger, S. B. Austin, S. Haneuse, A. Perez-Brumer, D. S. Novak, and M. J. Mimiaga. "Using a Two-Step Method to Measure Transgender Identity in Latin America/the Caribbean, Portugal, and Spain." *Arch Sex Behav* 43, no. 8 (Nov 2014): 1503-14. <https://doi.org/10.1007/s10508-014-0314-2>

providers.<sup>104</sup> As a result of these burdensome administrative requirements, it is not easy for patients to access TPOXX. Only highly resourced health care organizations, such as academic teaching hospitals, may have the knowledge and resources needed to manage enrolling patients in a TPOXX clinical trial. In contrast to the U.S., our European peers have not suffered from this regulatory hesitancy, as the European Medicines Agency approved the drug for use in MPX cases in January 2022, while British authorities greenlit the drug in July 2022.<sup>105,106</sup>

Removing unnecessary bureaucratic red tape could help on multiple fronts—alleviating symptoms for those infected, allowing medical professionals to treat MPX cases faster (thus reducing spread), and ensuring that low-resource medical centers that would otherwise struggle to clear the EA-IND logistical hurdles can deploy the medicine. In addition, the NIH should consider setting up projects to study the use of vaccines as post-exposure therapies when JYNNEOS shipments begin to accelerate.

While TPOXX represents the best-validated antiviral treatment for MPX, other drugs are waiting in the wings, including Brincidofovir (another smallpox antiviral approved by the FDA in 2021) and Cidofovir (designed for treating cytomegalovirus in patients with AIDS).<sup>107</sup> These medications are yet to receive EA-IND authorizations and thus cannot be utilized in clinical settings, but show promise as candidates for second and third-line therapies for treating MPX.<sup>108</sup>

## SOLUTIONS

**Lower regulatory barriers to ensure access to critical MPX treatments:** The CDC should rescind the EA-IND Requirements which currently apply to TPOXX's use in MPX cases, which will effectively mobilize an enormous stockpile of the only current treatment for MPX.<sup>109</sup>

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<sup>104</sup> Centers for Disease Control and Prevention (CDC), "Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases" Updated August 3, 2022. <https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html#:~:text=IV%20tecovirimat%20should%20be%20used,given%20immature%20renal%20tubular%20function.>

<sup>105</sup> SIGA. "SIGA Technologies Receives Approval from the European Medicines Agency for Tecovirimat." News release, January 10, 2022, <https://investor.siga.com/news-releases/news-release-details/siga-technologies-receives-approval-european-medicines-agency>.

<sup>106</sup> SIGA. "SIGA Technologies Receives Approval from UK for Tecovirimat." News release, July 8, 2022, <https://investor.siga.com/news-releases/news-release-details/siga-technologies-receives-approval-uk-tecovirimat>.

<sup>107</sup> Centers for Disease Control and Prevention (CDC). "Treatment Information for Healthcare Professionals." Updated July 28, 2022, [https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor\\_1655488353796](https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor_1655488353796).

<sup>108</sup> Ibid.

<sup>109</sup> Prep4All, and Partners in Health. "Prep4all, Partners in Health, and Other Experts' Letter to Biden Officials on Tpoxx." July 15, 2022, <https://www.documentcloud.org/documents/22088010-prep4all-partners-in-health-and-other-experts-letter-to-biden-officials-on-tpoxx>.

If the intent is to collect expanded safety data, protocols, such as the pending clinical trial being launched by the AIDS Clinical Trials Group should be the basis for these assessments, but frontline community providers and patients should have access to TPOXX via compassionate usage protocols.

**Expedite research on TPOXX + Post-Exposure Vaccination:** Domestic research surrounding the use of TPOXX is currently limited to studies piloted by the U.S. Army Medical Research and Development Command.<sup>110</sup> Supplementing these studies with additional research in civilian populations will be crucial for developing the evidence base for TPOXX treatment of MPX.

**Create protocols for additional therapeutics:** The CDC must urgently establish EA-IND guidelines for Brincidofovir and Cidofovir to ensure that all potential therapeutic options are available for use.<sup>111</sup>

## EQUITY

### *Race and ethnicity data*

We are just beginning to get data on race, ethnicity, sex, gender identity, age, and other factors among those accessing testing, vaccination, and treatment. A snapshot of data on MPX released by the CDC in late July indicated that 41% of individuals infected with MPX also had HIV. A majority of those diagnosed with MPX were Black or Hispanic.<sup>112</sup>

More comprehensive data was published by the CDC on August 12, 2022, in *Morbidity and Mortality Weekly Report (MMWR)*. Analyzing cases reported from May 17, 2022, to July 22, 2022, the CDC reported that:

Of 1,054 individuals diagnosed in the first two months of the outbreak for whom there was racial and ethnic data:

- 40.6% were White, non-Hispanic
- 28.1% were Hispanic
- 26.2% were Black, non-Hispanic
- 4.6% were Asian, non-Hispanic
- 0.6% were Multiple races, non-Hispanic, and

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<sup>110</sup> U.S. Army Medical Research and Development Command, "Tecovirimat Intravenous Treatment for Orthopox Virus Exposure (Tpoxx Iv)." Updated May 19, 2022, <https://www.clinicaltrials.gov/ct2/show/NCT05380752>.

<sup>111</sup> Prep4All, and Partners in Health. "Experts' Letter to Biden Officials on Tpoxx," July 15, 2022.

<sup>112</sup> Myers, Landon, Jeffery S Crowley, and Greg Millet. *Quick Take: Tackling MPX in Black and Latino Communities*. Georgetown University Law School O'Neill Institute for National and Global Health Law, August 12, 2022, <https://oneill.law.georgetown.edu/wp-content/uploads/2022/08/QY-MPX-Black-and-Latino-Communities.pdf>.

- 13.4% were missing data on race and ethnicity. (The terminology described here for race and ethnicity is the CDC's.)<sup>113</sup>

The median age at diagnoses in the CDC national data was 35.

New York City's health department, NYC Health, published demographic data on 2,810 individuals diagnosed with MPX there through August 26, 2022:

- 32.0% were Hispanic
- 26.1% were Black
- 24.6% were White
- 3.5% were Asian Pacific Islander
- 1.46% were Other
- 12.3% were missing data. (The race and ethnicity language is NYC Health's).<sup>114</sup>

Most of the NYC cases were diagnosed among 25-44 year-olds.

In terms of vaccine uptake in New York City, of the 69,216 people vaccinated through August 26, 2022:

- 45.6% were White
- 23.3% were Hispanic
- 12.0% were Black
- 10.3% were Asian Pacific Islander
- 8.8% were Other. (The race and ethnicity language is NYC Health's).<sup>115</sup>

These New York City data document a striking racial and ethnic disparity between disease burden and vaccine uptake. Other states and cities have also reported racial and ethnic disparities in vaccine uptake. The North Carolina Department of Health and Human Services recently reported that while 70% of those diagnosed with MPX in the state are Black, 67% of those accessing the JYNNEOS vaccine to date there are White.<sup>116</sup> A Kaiser Family Foundation analysis found that in Philadelphia, 28.1% of cases have occurred among White people, while White people have gotten 57.3% of the vaccinations. Black

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<sup>113</sup> Philpott D, Hughes CM, Alroy KA, et al. Epidemiologic and Clinical Characteristics of Monkeypox Cases – United States, May 17-July 22, 2022. *MMWR Morb Mortal Wkly Rep*. August 12, 2022;71:1018-1022.

<https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e3.htm> DOI: <http://dx.doi.org/10.15585/mmwr.mm7132e3>

<sup>114</sup> NYC Health. Monkeypox: Data. As of August 26, 2022. Data published on August 29, 2022. Accessed August 29, 2022. <https://www1.nyc.gov/site/doh/data/health-tools/monkeypox.page#surveillance>

<sup>115</sup> Ibid.

<sup>116</sup> North Carolina Department of Health & Human Services. Monkeypox Response Update: Equity Data Report on Cases, Vaccines and Testing. August 10, 2022. <https://www.ncdhhs.gov/media/17508/open>.

people represented 57.1% of the MPX cases in Philadelphia, but Black people only received 23.2% of MPX vaccinations.<sup>117</sup>

CDC data on the demographics of a small number (288) of those accessing TPOXX indicate that 98.9% were male sex at birth and 1.1% were female sex at birth. A plurality, 40.2%, were White, non-Hispanic, 35.2% were Hispanic, 15.6% were Black, non-Hispanic, 3.1% were Asian, non-Hispanic, 2.3% were Unknown Race, non-Hispanic, 2.0% were Multiple Races, non-Hispanic, and 1.6% were Other, non-Hispanic (language used is CDC's). The median age is 37 years.<sup>118</sup>

California reported August 11, 2022, that it “has distributed 2,687 oral treatment courses and 303 IV treatment doses of Tecovirimat (TPOXX).”<sup>119</sup> It did not publish demographic data on those who received the treatment.

### *People living with HIV (PLWH)*

People living with HIV in the U.S. and Europe appear to be disproportionately burdened by the current MPX outbreak. According to the U.S. Centers for Disease Control and Prevention (CDC):

Available summary surveillance data from the European Union,<sup>120,121,122</sup> England<sup>123</sup>, and the United States<sup>124</sup> indicate that among gay, bisexual,

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<sup>117</sup> Ndugga N, Haldar S, Pillai D, Hill L and S Artiga. *Monkeypox (MPX) Cases and Vaccinations by Race/Ethnicity*. Kaiser Family Foundation. August 24, 2022. Accessed August 30, 2022. <https://www.kff.org/racial-equity-and-health-policy/issue-brief/monkeypox-mpx-cases-and-vaccinations-by-race-ethnicity/>

<sup>118</sup> Centers for Disease Control and Prevention (CDC). Demographics of Patients Receiving TPOXX for Treatment of Monkeypox. Updated August 22, 2022. Accessed August 29, 2022. <https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics-TPOXX.html>

<sup>119</sup> California Department of Public Health. State Public Health Officials Provide Monkeypox (MPX) Update. August 11, 2022. Number NR22-122. Accessed August 29, 2022. [https://www.cdph.ca.gov/Programs/OPA/Pages/NR22-122.aspx?TSPD\\_101\\_R0=087ed344cfab200014bc110bcd3a9922600afd13b076a22257ccbd16e94aa35b40141a3bcb6419408ee4130b5143000f41bea51307eaaac73fcd49a95905f434960386d4ca80d1c8221ea5da87cc76d7b1222f6f74602359d43cb73080a9834](https://www.cdph.ca.gov/Programs/OPA/Pages/NR22-122.aspx?TSPD_101_R0=087ed344cfab200014bc110bcd3a9922600afd13b076a22257ccbd16e94aa35b40141a3bcb6419408ee4130b5143000f41bea51307eaaac73fcd49a95905f434960386d4ca80d1c8221ea5da87cc76d7b1222f6f74602359d43cb73080a9834)

<sup>120</sup> European Centers for Disease Prevention and Control; World Health Organization Regional Office for Europe. Joint ECDC-WHO Regional Office for Europe monkeypox surveillance bulletin. Stockholm, Sweden: European Centers for Disease Prevention and Control; 2022. Accessed August 3, 2022. <https://monkeypoxreport.ecdc.europa.eu>.

<sup>121</sup> Perez Duque M, Ribeiro S, Martins JV, et al. Ongoing monkeypox virus outbreak, Portugal, 29 April to 23 May 2022. *Euro Surveill.* 2022;27(22):2200424. doi:10.2807/1560-7917.ES.2022.27.22.2200424

<sup>122</sup> Iñigo Martínez J, Gil Montalbán E, Jiménez Bueno S, et al. Monkeypox outbreak predominantly affecting men who have sex with men, Madrid, Spain, 26 April to 16 June 2022. *Euro Surveill.* 2022 Jul;27(27). doi: 10.2807/1560-7917.ES.2022.27.27.2200471. PMID: 35801519.

<sup>123</sup> UK Health Security Agency. Investigation into monkeypox outbreak in England, Technical Brief #3, updated July 8, 2022. Available at: <https://www.gov.uk/government/publications/monkeypox-outbreak-technical-briefings>.

<sup>124</sup> Centers for Disease Control and Prevention (CDC). Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV. Updated August 17, 2022. Accessed August 26, 2022. <https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>



and other men who have sex with men (MSM) with monkeypox for whom HIV status is known, 28%–51% have HIV infection.

Regarding infection risk, it is currently unknown whether an HIV infection alters (e.g., increases) a person's risk of acquiring monkeypox disease after exposure. Regarding illness after infection, the available data indicate that people with advanced and uncontrolled HIV can be at a higher risk of severe or prolonged monkeypox disease.<sup>125</sup>

### *Gender identity, sex, and sexual orientation data*

CDC data indicate that that 0.7% of 1,195 individuals diagnosed with MPX from May 17 to July 22 were transgender—0.4% were transgender women and 0.3% were transgender men. Among 2,891 cases reported through July 22, “99% of cases were among men; among men with available information, 94% reported male-to-male sexual or close intimate contact during the 3 weeks before symptom onset.”<sup>126</sup>

NYC Health data indicate that, among MPX cases through August 25, 2022, for whom: gender identity and sex are know:

- 96.0% were [cisgender] men
- 1.4% were non-binary/gender-queer
- 1.0% were transgender women
- 0.8% were [cisgender] women
- 0.2% were transgender men
- 0.5% were unknown (language is NYC Health's).

Among MPX cases through August 25, 2022, for whom sexual orientation is known:

- 68.9% were LGB+
- 5.1% were straight
- 25.9% were unknown (language is NYC Health's).

NYC Health data indicate that, among individuals vaccinated through August 25, 2022, for whom gender identity and sex is known:

- 86.0% were [cisgender] men
- 6.3% were non-binary/gender-queer
- 2.4% were [cisgender] women

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<sup>125</sup> Ibid.

<sup>126</sup> Philpott D, Hughes CM, Alroy KA, et al. Epidemiologic and Clinical Characteristics of Monkeypox Cases – United States, May 17-July 22, 2022. *MMWR Morb Mortal Wkly Rep*. August 12, 2022;71:1018-1022. <https://www.cdc.gov/mmwr/volumes/71/wr/mm7132e3.htm>

- 1.5% were transgender women
- 0.7% were transgender men
- 2.5% were unknown (language is NYC Health's).

NYC Health data indicate that, among individuals vaccinated through August 25, 2022, for whom sexual orientation is known:

- 92.3% were LGBTQ+
- 2.0% were straight
- 5.6% were unknown (language is NYC Health's).<sup>127</sup>

We have significant concerns about the lack of equitable access to vaccination, treatment, and testing. Individuals who are not in routine preventive care and those who are not located in major metropolitan areas may face significant barriers to testing. Those who do not live near large academic medical centers can find it challenging to access treatment for MPX. And while vaccinations have been made available in many cities across the U.S., there are substantial class and racial equity concerns. For example, until recently vaccinations were available in Montgomery County, Maryland but not in Baltimore.<sup>128</sup> Earlier this summer there were few vaccination sites in the South, but not enough, and none in rural areas. Medical mistrust related to racism, anti-transgender and anti-lesbian and bisexual discrimination, undocumented status, and other factors likely limits access for many marginalized communities.<sup>129,130,131,132</sup> Gay and bisexual men in rural America are less likely to disclose their sexual behavior and orientation to a health care provider,

Individuals who are not in routine preventive care and who live outside of major metropolitan areas likely face significant barriers to testing and treatment for MPX.

<sup>127</sup> NYC Health. Monkeypox: Data. As of August 26, 2022. Data published on August 29, 2022. Accessed August 29, 2022. <https://www1.nyc.gov/site/doh/data/health-tools/monkeypox.page#surveillance>

<sup>128</sup> Roth, Grant, "Monkeypox Vaccination Access Project," updated July 30, 2022, [https://docs.google.com/document/d/1QO55TTeO6ZKrC0yw\\_LvIrKU56wb1r7rX9kAW\\_WsLLtQ/edit](https://docs.google.com/document/d/1QO55TTeO6ZKrC0yw_LvIrKU56wb1r7rX9kAW_WsLLtQ/edit).

<sup>129</sup> Cahill S, Taylor SW, Elsesser SA, Mena L, Hickson D, Mayer KH. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. *AIDS Care*. 2017 Nov;29(11):1351-1358. doi: 10.1080/09540121.2017.1300633. Epub 2017 Mar 12.

<sup>130</sup> Brenick A, Romano K, Kegler C, Eaton LA. Understanding the Influence of Stigma and Medical Mistrust on Engagement in Routine Healthcare Among Black Women Who Have Sex with Women. *LGBT Health*. 2017 Feb;4(1):4-10.

<sup>131</sup> D'Avanzo PA, Bass SB, Brajuha J, Gutierrez-Mock L, Ventriglia N, Wellington C, Sevelius J. Medical Mistrust and PrEP Perceptions Among Transgender Women: A Cluster Analysis. *Behav Med*. 2019 Apr-Jun;45(2):143-152. .

<sup>132</sup> L. P. Oakley, D. F. López-Cevallos, and S. M. Harvey, "The Association of Cultural and Structural Factors with Perceived Medical Mistrust Among Young Adult Latinos in Rural Oregon," *Behav Med* 45, no. 2 (Apr-Jun 2019), <https://doi.org/10.1080/08964289.2019.1590799>.

potentially increasing their risk of being infected and not accessing treatment.<sup>133</sup>

In addition, it is crucial to remember that GBMSM communities are influenced by over 40 years of experience with regards to infectious disease surveillance. This means that their ability to identify and address outbreaks of MPX may not be easily replicated in other vulnerable communities. We should be proactive in identifying groups who may be at risk for viruses borne by close contact (for example, incarcerated individuals, unhoused individuals, families living in communal settings) to get ahead of the virus before it's too late.

## SOLUTIONS

**Get a better picture of the affected populations through demographic data and increase awareness nationwide:** Monkeypox is currently impacting a population (GBMSM) which has extensive experience dealing with infectious diseases (HIV and syphilis in particular), but we have little insight as to whether other communities are experiencing outbreaks.

The CDC should strongly advise public health authorities to collect data on race/ethnicity, sexual orientation, gender identity, sex, and other demographic factors to better understand health equity issues in the MPX outbreak and rapidly identify new outbreaks.<sup>134</sup>

The forms patients must complete to access TPOXX should be translated into Chinese, Haitian, and other widely-used languages in the United States (they were recently made available in Spanish). Forms should also be inclusive of all gender identities and seek to meet best practice standards for collecting data on gender.

Outreach efforts should not be limited to GBMSM. HHS and the CDC should work with public health authorities to develop outreach campaigns to reduce potential stigma associated with MPX and to limit the risk of outbreaks in congregate settings like prisons and homeless shelters.<sup>135</sup> Sex workers could also be at elevated risk, and harm reduction prevention education approaches with this population should be deployed.

Federal, state, and local health agencies should work with community-based organizations and influencers in communities of color to ensure creative, effective outreach to Black and Hispanic GBMSM and transgender and nonbinary people, and broader communities of color, to ensure equitable vaccine uptake proportional to the disproportionate burden of monkeypox on Black and Hispanic communities.

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<sup>133</sup> Dani E. Rosenkrantz et al., "Health and health care of rural sexual and gender minorities: A systematic review," *Stigma and Health* 2, no. 3 (2017), <https://doi.org/10.1037/sah0000055>.

<sup>134</sup> Infectious Diseases Society of America, "HHS Monkeypox Letter," July 22, 2022.

<sup>135</sup> Prep4All, "Monkeypox," 2022, <https://www.prep4all.org/monkeypox>.

**Congress must act to provide funding for the MPX response and research:**

While executive branch agencies have scrambled to address the MPX outbreak, Congress has thus far failed to appropriate funding to support the MPX response. Congress must step up and make funding available for testing, vaccination, treatment, public education and prevention, and research on MPX. Federal agencies have creatively reallocated existing funding, but substantial new funding is needed to pay for all of the care that has been provided since May 2022 on an emergency basis. Funding is also needed for critically important research to better understand MPX and the biomedical interventions at our disposal to prevent and treat it. President Biden requested \$26 billion in a continuing resolution for the COVID-19 and MPX response. Most of this funding would support COVID-19 efforts, with \$3.9 billion for MPX. Republicans in Congress expressed opposition, claiming that the funding would exacerbate inflation.<sup>136</sup> GOP leaders must stop this

Congress must act to appropriate funding for the MPX response, including critically needed research. It should include the President's \$3.9 billion ask for the MPX response in a continuing resolution.

obstructionism and join others in Congress to take urgent action to address this critical public health threat. Funding is needed to support the health care providers and community organizations that have led the MPX response for the past four months and are now working to address equity issues in the response. Funding is also urgently needed to support the research necessary to better reduce MPX transmission and plan for its control and elimination.

**Share MPX tools worldwide:** While the MPX outbreak is now global, we must also ensure that people living in places where MPX outbreaks have been occurring for decades, such as central and western Africa, are also prioritized for testing, vaccination, and treatment programs. We cannot afford to delay and deny access to effective tools to prevent and treat an outbreak such as MPX when there are scientifically proven vaccines, treatments, and test protocols which, when used together and equitably, can bring this virus under control everywhere. President Biden should rally world leaders and work with the World Health Organization, Bavarian Nordic, and other companies to dramatically scale up vaccine production. We must ensure equitable access to this important health technology, and ensure that we do not repeat the failures of COVID-19 vaccine access in the global south.

The August 4, 2022, declaration by the Health and Human Services Secretary Xavier Becerra that monkeypox is a public health emergency is welcome, as is

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<sup>136</sup> Muoio, Dave. "GOP lawmakers throw cold water on White House's latest \$26B COVID, monkeypox ask." *Fierce Healthcare*. September 8, 2022. <https://www.fiercehealthcare.com/providers/biden-administration-asks-congress-include-over-26b-covid-monkeypox-fy23-budget-stopgap>

the August 2022 appointment of Robert Fenton and Demetre Daskalakis as White House National Monkeypox Response Coordinator and Deputy Coordinator.<sup>137</sup> Congress must appropriate significant emergency funding to support the beleaguered health system's efforts to contain the outbreak. Emergency use authorizations could enable more testing options, ramped up vaccine production, and easier access to treatment.

President Biden should lead a global effort in collaboration with the WHO and allies to scale up vaccine production, and to eliminate monkeypox from the world as we did with smallpox forty years ago.

President Biden should speak to the nation about the importance of coming together to defeat this virus here in the U.S. and in Africa, where people have been suffering and dying of it for more than 50 years. He should lead a global effort in collaboration with the World Health Organization and allies to scale up vaccine production, and to eliminate monkeypox from the world as we did with smallpox forty years ago. As it has done with HIV and Ebola, the U.S. government should lead a global effort to leverage resources to address MPX in central and western Africa. Controlling MPX in the part of the world where it has afflicted people for at least 52 years, causing immense human suffering and death, will make us safer in the U.S. and around the world.

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<sup>137</sup> Diamond, Dan. "Monkeypox Is 'a Public Health Emergency,' U.S. Health Secretary Declares." *The Washington Post*, August 7, 2022. <https://www.washingtonpost.com/health/2022/08/04/monkeypox-public-health-emergency-united-states-becerra/>.



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