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# U.S. Domestic Response to the 2022 Monkeypox Outbreak

## Background

On August 4, 2022, the Department of Health and Human Services (HHS) Secretary declared a Public Health Emergency for the monkeypox outbreak. Countries in Africa have reported monkeypox since the first human case of monkeypox was identified in 1970 (endemic spread). There have been limited outbreaks in countries outside of Africa. Starting in May 2022, clusters of monkeypox cases were reported in Europe and the United States. Since then, case counts have increased in non-endemic countries—representing the largest outbreak in non-endemic countries in recent history. According to the Centers for Disease Control and Prevention (CDC), as of August 4, 2022, over 26,800 cases of monkeypox have been confirmed globally, with over 26,500 cases in countries that have not historically reported endemic spread of the virus; over 7,000 cases have been confirmed in the United States.

### 2022 Outbreak

Monkeypox is a disease caused by infection with the monkeypox virus, which is part of the same family of viruses that causes smallpox. There are two types (or clades) of monkeypox virus: West African and Congo Basin. The case fatality rate for those infected with the West African clade is roughly 1%; the case fatality rate of the Congo Basin clade is approximately 10%. All cases in the 2022 outbreak have been linked to the West African clade. The 2022 outbreak is distinct from prior monkeypox outbreaks in non-endemic countries in two key ways.

**Transmission.** Monkeypox is typically transmitted from animals to humans with limited human-to-human spread. In prior outbreaks in non-endemic countries, cases were mostly linked to travel. In the 2022 outbreak, there is significant person-to-person spread with no links to travel.

**Clinical Presentation.** Monkeypox usually begins with a fever, swollen lymph nodes, malaise, and headache. Following this, patients develop a rash, which usually spreads throughout the body. In the 2022 outbreak, clinical presentations have varied widely among patients. Some report no fever or initial symptoms; some report smaller and more localized rashes. This may result in misdiagnosis and delays in testing.

Scientists are still learning the specifics of this outbreak. Researchers in Portugal found that the strain of monkeypox virus causing the 2022 outbreak shows a significant number of genetic mutations from the closest known strain detected in Nigeria in 2018-2019. Waning smallpox immunity in the population and changes in behavior following pandemic restrictions may be contributing to this outbreak.

The majority of initial cases were reported among men who have sex with men (MSM). However, MSM are not the only population susceptible to the disease. Several countries have reported cases in children and other populations. According to CDC, monkeypox is most commonly spread through close personal contact, contaminated materials, and animals. While scientists are still studying if the current monkeypox virus strain can be sexually transmitted, close interpersonal contact, including during sexual activity, with an infected person can facilitate transmission.

Most monkeypox cases are self-limited and resolve in two to four weeks. According to a study of 528 patients in the current outbreak, about 13% were hospitalized. At least 10 deaths have been reported globally in Nigeria, Ghana, Spain, Brazil, and India. No deaths have been reported in the United States.

## 2022 Outbreak Domestic Response

On June 28, 2022, CDC activated its Emergency Operations Center for monkeypox response. On August 2, 2022, the White House appointed a Federal Emergency Management Agency (FEMA) official as the lead coordinator for the monkeypox response and assigned a CDC official as his deputy. Other HHS agencies, such as the Administration for Strategic Preparedness and Response (ASPR; formerly Office of the Assistant Secretary of Response) and the Food and Drug Administration (FDA) are also actively engaged in response efforts.

The White House and HHS agencies have initiated response activities, including supporting education and awareness and defining federal research priorities. Some key response activities include the following:

### Testing

HHS reports testing capacity of 80,000 tests per week through public health and CDC-designated commercial laboratories as of July 21, 2022. In 2018, CDC developed a test that detects, but does not distinguish between, non-variola orthopoxviruses (NVO), the genus that includes monkeypox virus. This test received FDA clearance only for use in the Laboratory Response Network that involves state, local, and federal laboratories. In June 2022, a new clearance was issued allowing for expanded use of the test, although its use is still "limited to Centers for Disease Control and Prevention designated laboratories." Positive specimens are sent to CDC for characterization as monkeypox virus (response activities begin with the orthopox result). Some clinical laboratories are also developing laboratory-developed tests for monkeypox generally using CDC's recently published non-variola PCR testing procedure. Separate from testing capacity, issues have been reported with access to testing. CDC reports efforts to inform clinicians about test availability and referral.

### Tracking, Surveillance, and Contact Tracing

CDC has developed case definitions, or uniform clinical criteria, for reporting monkeypox cases. Requirements for reporting monkeypox cases are under state and subfederal law. The Council of State and Territorial Epidemiologists voted to make monkeypox a nationally notifiable disease, meaning there is formal consensus to collect state data and report to CDC (reporting is voluntary). CDC advises that when an NVO test result returns positive, public health authorities should initiate contact tracing and investigation.

### Medical Countermeasures: Vaccines and Therapeutics

**Vaccines.** The Strategic National Stockpile (SNS) hosts two vaccines that may be used for monkeypox: JYNNEOS (which is FDA approved for both smallpox and monkeypox) and ACAM2000 (which is FDA-indicated for smallpox, but is allowed for use against monkeypox under a CDC Expanded Access Investigational New Drug protocol). While the SNS hosts a greater supply of ACAM2000, there are significant side effects associated with that vaccine; therefore, HHS has prioritized distribution of JYNNEOS. In addition to the existing JYNNEOS doses stockpiled and scheduled to be distributed over the first weeks of the response, HHS has announced the purchase of an additional 5 million JYNNEOS doses (2.5 million on July 1 and 2.5 million on July 15), which are to be delivered at the end of 2022 through early 2023. This would bring the total available supply of the vaccine to 6.9 million doses. As of August 4, 2022, ASPR had delivered over 602,000 doses of JYNNEOS to state, local, tribal, and territorial jurisdictions.

While the FDA determined the JYNNEOS vaccine is safe in humans, the efficacy trials relied on animal studies. Thus, exactly how well it prevents monkeypox in humans remains undetermined. Based on observational data from those who received the JYNNEOS vaccine in Africa, CDC estimates that the vaccine is 85% effective.

State, tribal, territorial, and select local health jurisdictions are currently able to order vaccines through ASPR. The ASPR sets a maximum number of doses available for order through an algorithm that takes into account variables such as total population, at-risk population, case counts, and vaccine uptake. As circumstances change, ASPR may modify the algorithm. Authorities are permitted to redistribute their vaccines to other health jurisdictions, health care entities, and other appropriate recipients for administration to eligible populations.

Currently, CDC recommends the use of available vaccines as pre-exposure prophylaxis (PrEP) for those whose jobs, such as laboratory positions, could expose them to orthopoxviruses. For the 2022 outbreak response, CDC also recommends use of vaccines post-exposure (PEP) for certain individuals at high risk or are presumed exposed. Individual jurisdictions can set their own criteria for determining eligibility for their allocated vaccines.

**Therapeutics.** There are no therapeutic products specifically indicated for use in monkeypox. CDC has identified some anti-viral and antibody medical countermeasures for which evidence of efficacy for use in monkeypox is limited, but that may provide patients with clinical benefit. One of these medical countermeasures, Tecovirimat (TPOXX), has demonstrated effectiveness against orthopoxviruses in animal studies, but there is limited efficacy data for its use in human monkeypox. Clinical trials of TPOXX have shown minor side-effects in humans. These medical countermeasures can be requested by state and territorial health authorities from the CDC Emergency Operations Center. The SNS has over 1.7 million TPOXX courses available.

## Selected Considerations for Congress

### Funding

It is uncertain whether the President will submit a formal supplemental appropriations request for the monkeypox response. HHS agencies, such as CDC and APSR, are using available appropriations to respond to the outbreak. CDC has access to an Infectious Diseases Rapid Response Reserve Fund (IDRRRF), with funding available based on an HHS Secretarial determination of an infectious disease emergency (42 U.S.C. §247d-4a), which can be activated without a PHE declaration. As of July 29, 2022, The IDRRRF had a balance of $609 million. CDC can transfer the funding to ASPR and the National Institutes of Health. The PHE Declaration (42 U.S.C. §247d(b)) also activated a Public Health Emergency Fund; that fund currently has a balance of $56,000.

### Equity

Given that reported monkeypox cases have been concentrated among the MSM population, some have expressed concern about potential stigmatization or mischaracterization of the disease as sexually transmitted. Further, some have expressed equity concerns around access to testing and the limited supply of vaccines. For Coronavirus Disease 2019 (COVID-19) response, the federal government supported community-based testing and vaccination sites to target underserved populations. The Government Accountability Office (GAO) has reviewed these efforts (GAO-22-104457). Congress might consider lessons learned and whether to support similar programs for the monkeypox response.

### Data Reporting

CDC Director Rochelle Walensky has remarked that CDC lacks authority to require data collection on monkeypox cases. Instead, CDC relies on data shared by state and local health departments. For COVID-19, Congress enacted a federal laboratory reporting requirement on test results as a part of the CARES Act (P.L. 116-136; §18115). Through guidance, HHS still mostly directed labs to report through state and local channels. Separate data modernization efforts helped enable real-time reporting on COVID-19 results from laboratories to CDC. Congress may consider whether a similar reporting requirement for monkeypox is appropriate, and whether the data infrastructure for COVID-19 can be leveraged for monkeypox response.

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