EMBARGOED UNTIL 7PM ET, 6/28

FACT SHEET: Biden-Harris Administration' Monkeypox Outbreak Response

For years, the United States has invested in research on monkeypox and in tools to effectively respond to the disease. Monkeypox is a virus that is generally spread through close or intimate contact, with symptoms that include a rash and fever. It is much less transmissible than fast-spreading respiratory diseases like COVID-19, and this outbreak has not caused any deaths in the United States. The virus, however, is spreading in the United States and globally, and requires a comprehensive response from federal, state, local, and international governments and communities. Since the first United States case was confirmed on May 18, President Biden has taken critical actions to make vaccines, testing, and treatments available to those who need them as part of its whole-of-government monkeypox outbreak response.

Today, the Biden-Harris Administration announced the first phase of its national monkeypox vaccine strategy, a critical part of its monkeypox outbreak response. The vaccine strategy will help immediately address the spread of the virus by providing vaccines across the country to individuals at high risk. This phase of the strategy aims to rapidly deploy vaccines in the most affected communities and mitigate the spread of the disease.

This announcement is a critical component of the Administration's broader public health response, which includes rapidly scaling up and decentralizing testing alongside continued provider education and community engagement across the country. The Administration's monkeypox outbreak response is also informed by the multiple times over the last twenty years that the United States has effectively responded to the virus. The United States government's response is coordinated by the National Security Council Directorate on Global Health Security and Biodefense – more commonly known as the White House Pandemic Office – which President Biden restored on day one of his presidency, in collaboration with the Department of Health and Human Services (HHS).

Collectively, the Administration's efforts aim to **expand vaccination for individuals at risk** and **make testing more convenient for healthcare providers and patients across the country**. The Biden-Harris Administration remains committed to working with urgency to detect more cases, protect those at risk, and respond rapidly to the outbreak.

> **Scaling and Delivering Vaccines to Mitigate New Infections**: Thanks to prior investments in health security and the nation's prior experience responding to the monkeypox virus, the United States has effective vaccines and treatments that can be used against monkeypox. To date, HHS has received requests from 32 states and jurisdictions, deploying over 9,000 doses of vaccine and 300 courses of antiviral smallpox treatments. **With today's national monkeypox vaccine strategy, the United States is significantly expanding deployment of vaccines, allocating 296,000 doses over the coming weeks, 56,000 of which will be allocated immediately. Over the coming months a combined 1.6 million additional doses will become available.**
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> **Making Testing Easier**: The new national monkeypox vaccine strategy builds on the Administration's efforts to make testing more widely available and easier to access. On day one of this outbreak, providers had access to a high-quality, FDA-cleared test to detect

monkeypox. The CDC has since scaled testing capacity to 78 sites in 48 states, primarily at state public health laboratories, with spare capacity to conduct nearly 10,000 tests per week nationwide. **Last week, CDC began shipping tests to five commercial laboratory companies, including some of the nation's largest reference laboratories, to further increase monkeypox testing capacity and access in every community. This action will dramatically improve convenience for patients and health care providers across the nation.**

Activating Community Leaders and Stakeholders: The response to monkeypox requires a whole-of-society effort between federal, state, territorial, and local governments and communities. The Biden-Harris Administration is communicating with healthcare providers, public health officials, and affected communities on a daily basis to share information on what the virus is, how to treat it, and which communities are most at risk. The Administration is also sharing information on how to access testing, treatments, and vaccines, and how to prevent transmission with local, government, and community leaders in geographies and communities where transmission rates have been the highest. The Administration is grateful for the leadership and activism of advocates in the LGBTQI+ community who have thus far been most affected and have quickly mobilized to promote information and awareness.

The Biden-Harris Administration is providing vaccines to protect high-risk groups across America.

As part of the monkeypox outbreak response, the Biden-Harris Administration is launching a national strategy to provide vaccines for monkeypox for individuals at higher risk of exposure. The strategy aims to mitigate the spread of the virus in communities where transmission has been the highest and with populations most at risk. This plan distributes the two-dose JYNNEOS vaccine, which the Food and Drug Administration (FDA) approved for protection against smallpox and monkeypox in individuals 18 years and older determined to be at high risk for smallpox or monkeypox infection. States will be offered an equitable allotment based on cases and proportion of the population at risk for severe disease from monkeypox, and the federal government will partner with state, local, and territorial governments in deploying the vaccines.

The goal of the initial phase of the strategy is to slow the spread of the disease. HHS will immediately allocate 56,000 vaccine doses currently in the Strategic National Stockpile to states and territories across the country, prioritizing jurisdictions with the highest number of cases and population at risk. To date, vaccines have been provided only to those who have a confirmed monkeypox exposure. With these doses, CDC is recommending that vaccines be provided to individuals with confirmed monkeypox exposures and presumed exposures. This includes those who had close physical contact with someone diagnosed with monkeypox, those who know their sexual partner was diagnosed with monkeypox, and men who have sex with men who have recently had multiple sex partners in a venue where there was known to be monkeypox or in an area where monkeypox is spreading.

In the coming weeks, HHS expects to receive an additional 240,000 vaccines, which will be made available to a broader population of individuals at risk. HHS will hold another 60,000 vaccines in reserve.

As additional doses are received from the manufacturer, HHS will make them available to jurisdictions to expand availability to the vaccine for individuals with elevated risk. HHS is increasing the availability of doses by leveraging its long-standing partnership with the manufacturer of JYNNEOS to expand vaccine supply and by accelerating completion and shipment of doses to the United States. HHS expects more than 750,000 doses to be made available over the summer. An additional 500,000 doses will undergo completion, inspection, and release throughout the fall, totaling 1.6 million doses available this year.

To supplement the supply of JYNNEOS, states and territories may also request a second vaccine, ACAM2000. ACAM2000 is FDA-approved for protection against smallpox, caused by the variola virus. ACAM2000 is also believed to confer protection against monkeypox, and is available under an expanded access investigational new drug protocol sponsored by CDC for vaccination of individuals at risk of monkeypox infection. However, ACAM2000 carries greater risk of certain serious side effects than JYNNEOS and cannot be provided to individuals who are immunocompromised or who have heart disease. The CDC will work with state, territorial, and local health departments requesting the ACAM2000 vaccine to ensure that individuals are fully informed on the benefits and the risks before receiving the vaccine.

HHS will work closely with local and state partners and health providers to continuously evolve and strengthen its vaccine strategy to ensure that vaccines are being made available to communities most at risk and where transmission has been highest.

The Administration is expanding testing supply and availability.

Last week, CDC began shipping its FDA-cleared orthopox test to five major commercial laboratory companies to rapidly increase monkeypox testing access across the country. This action will dramatically expand testing capacity nationwide and convenience for patients and health care providers. These laboratories will begin to come on board for testing in early July and increase capacity through the month.

This expansion reflects the latest, most significant increase in testing accessibility, building on the capacities already available within the Laboratory Response Network (LRN). CDC has worked with the LRN to increase public health testing capacity by more than 50% since the start of the outbreak, increasing testing capacity from 6,000 tests per week to approximately 10,000 test per week. This network continues to provide spare testing capacity to jurisdictions across the country. CDC is working with state, territorial, and local health departments to make the monkeypox testing process more accessible to health care providers.

To further expand access to testing early in the outbreak, CDC published its protocol from their FDA-cleared test on June 9, 2022 for any laboratory to test for monkeypox. The FDA is exercising enforcement discretion regarding CDC's tests, which permits the use of tests beyond the current network. FDA has also authorized the use of additional reagents and automation to increase the capacity of laboratories using the CDC test.

Since the start of the monkeypox outbreak, the number of days from average symptom onset to test has decreased by approximately 35%, enabling patients to more quickly learn their diagnosis, access care, and prevent spread to others. The expansion of testing aims to facilitate further reductions in the gap between symptom onset and test result, maximizing access to treatment and vaccines for patients and high-risk contacts early in the course of disease.

The Administration has launched a robust community and stakeholder engagement strategy.

The most effective response to infectious disease outbreaks is a community-based response. The Biden-Harris Administration is communicating with healthcare providers, public health officials, and communities on a daily basis to raise awareness of the monkeypox outbreak and educate the public and local and community leaders about what the virus is, how it is transmitted, and which populations are most at risk of the virus. As part of its robust engagement strategy, the Administration is facilitating access to vaccines, treatments, and tests. The Administration will also continue to engage directly with leaders and stakeholders in the LGBTQI+ community to work together to prevent and combat stigma and bias, and promote testing and vaccine access and health equity for LGBTQI+ communities. Through its comprehensive stakeholder engagement strategy, the Administration is also creating a critical feedback loop - learning from the experiences of those most at risk and responding based on their insights and needs.

HHS has provided a range of public health information to inform providers and high-risk communities, including:

- Updating and expanding the monkeypox case definition by June 1st to encourage health care providers to consider testing for all rashes with clinical suspicion for monkeypox;
- Releasing emergency information on May 20th and June 14th covering clinical testing, treatment, contact tracing, and other topics to health providers, sexual and community health centers, and public health officials across the nation;
- Providing over 570 case consultations to healthcare providers and health departments;
- Clarifying how to transport and dispose of medical waste that allowed healthcare facilities and waste management companies to operate confidently and safely; and,
- Regularly speaking with global, community, clinical, and public health stakeholders to solve challenges and answer questions.

HHS and CDC will continue to engage with the public and communities most impacted and at risk on a daily basis throughout the response.

The Administration is leading efforts to combat monkeypox globally

There is no domestic-only response to a global outbreak. The Biden-Harris Administration is committed to combatting monkeypox in the United States and around the world, including in countries where it has been historically endemic. The United States has also supported international efforts to combat monkeypox in endemic countries for years, including in Nigeria and the Democratic Republic of the Congo. The Biden-Harris Administration is dedicated to assisting endemic and non-endemic countries combat their outbreaks and is exploring options to further support the international response.

The Administration is also developing key U.S. monkeypox research and evidence priorities, led by the White House Office of Science and Technology Policy, to drive efforts to improve our arsenal of medical countermeasures, strengthen real-time monitoring, enhance our understanding of the monkeypox virus, and energize the broader U.S. and global scientific community around urgent monkeypox research and evidence challenges.

The Biden Administration has been responding to the outbreak since the first domestic case was identified with urgency, humility, and transparency, adapting our approach as we learn more about how this virus is spreading. It will continue to ensure a whole-of-government response to the

monkeypox outbreak moving forward, and will lead the government in adapting our response as the situation develops.

To learn more about monkeypox, signs and symptoms, treatments, and prevention, please visit the CDC page here.