TESTIMONY

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Stopping the Spread of Monkeypox: Examining the Federal Response

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Chair Murray, Ranking Member Burr, and distinguished members of this Committee, it is my honor to appear before you today to discuss the Centers for Disease Control and Prevention's (CDC) response to the global outbreak of monkeypox. The world is experiencing an unprecedented outbreak of monkeypox, with tens of thousands of cases reported worldwide, predominantly in countries where this disease is not endemic. We are still learning more about this outbreak every day but are relying on the tools we have – diagnostics, vaccines, therapeutics, and community education and outreach – to continue our public health response efforts.

State of the Outbreak

On May 17, 2022, the Massachusetts Department of Public Health contacted CDC about a case of suspected monkeypox in the United States. CDC's Laboratory Response Network (LRN) testing confirmed orthopoxvirus infection and, the next day, testing at CDC confirmed the patient was infected with monkeypox virus. The case was identified as Clade II (formerly known as the West African strain), which is associated with less severe disease than Clade I (formerly known as Congo Basin strain). This case, and many of the first cases identified in the United States in this outbreak, were among persons with a history of international travel to Europe or Canada, countries that were also reporting clusters of cases. From detection of the first case, CDC immediately began enhancing surveillance and testing to identify additional cases; supporting jurisdictions in post-exposure prophylactic vaccination of close contacts; educating clinicians, public health partners, and the public; conducting outreach to LGBTQ+ organizations, and advocates to share information and amplify messaging; and preparing for community spread of monkeypox within the United States. On June 28, 2022, CDC elevated its response to monkeypox by activating its agency-wide Emergency Operations Center. On July 23, 2022, the World Health Organization declared the current outbreak and Public Health Emergency of International Concern, and Department of Health and Human Services (HHS) Secretary Xavier Becerra declared a U.S. Public Health Emergency on August 4. In the United States, as of September 12, there have been 21,985 reported monkeypox cases, one confirmed death, and two additional deaths currently under investigation. Globally, there have been 57,016 cases reported with 19 deaths.

Monkeypox can be transmitted through close, personal contact. This is often skin-to-skin-contact, including hugging and intimate activity, but also through respiratory secretions

during prolonged face-to-face contact and skin contact with fabrics and surfaces used by persons with monkeypox—although respiratory droplet and indirect transmission do not appear to be significant drivers of the current outbreak. While anyone who comes into close contact with an infected person or contaminated items like bedding or clothing could contract monkeypox, the current outbreak is disproportionately affecting gay, bisexual, and other men who have sex with men. The characteristic rash of monkeypox can initially look like pimples or blisters and can appear on the hands, feet, chest, face, mouth, or anogenital region, and may sometimes occur with other flu-like symptoms. Monkeypox is transmissible from the time symptoms begin until the rash has healed, all scabs have fallen off, and a fresh layer of skin has formed. Infection typically lasts for two- to four-weeks. CDC recommends people with monkeypox isolate at home, keep rashes covered until they have fully healed, and notify close contacts, including sexual partners. The clinical presentation in this outbreak is atypical. The characteristic rash is still common, but lesions associated with this outbreak have often occurred in the anogenital region or in the mouth, and rash may be confined to only a few lesions or even a single lesion. In addition, prior to and after the rash, other symptoms may be mild or non-existent.

Similar to COVID-19 and many other public health challenges before it, the burden of monkeypox is not distributed equitably. In this outbreak, and based on available data, over 90 percent of U.S. cases have occurred among gay, bisexual, and other men who have sex with men. Although case data for race and ethnicity are incomplete, Hispanic/Latinx and Black men have represented more than 50 percent of cases in recent weeks among those case reports for which we have data on race and ethnicity. Where the data is clear, we know that we must act to address the monkeypox outbreak in communities that are disproportionately impacted. And where a lack of complete data constrains our ability to understand the full extent of these disparities, we are working to better understand these impacts.

The monkeypox response is impacted by one of the fundamental constraints CDC faces in its response to public health threats – we are often limited in our ability to quickly and reliably access the data we need to maximize the impact of our public health response. We need to bring the nation's public health data infrastructure into the 21st century so that CDC and state, Tribal, local and territorial health agencies may review, analyze, and report data in real time. The public health workforce is stretched thin, and sustained investment in the workforce is needed to

provide Americans with a data-fluent, pandemic-ready public health system. Our nation's public health laboratories are essential to early detection, and equipping these labs with the best available resources enables a faster response. Committing to rebuilding public health infrastructure through a revitalized public health workforce, modern data pathways, and strong laboratories supports the foundation for an immediate and robust response to public health emergencies like monkeypox.

Diagnostic Testing

Since 2003, CDC's LRN has provided state and local health departments with a way to test and identify orthopoxvirus cases, including monkeypox. CDC has a Food and Drug Administration-cleared test capable of detecting non-variola orthopoxviruses like monkeypox pre-positioned within the LRN due to previous work in smallpox public health preparedness supported by investments from Congress. These nearly 70 laboratories that are part of the LRN could test about 6,000 specimens per week at the start of the outbreak, a capacity which CDC worked quickly to expand to about 10,000 tests per week. A positive orthopoxvirus test result is enough for clinicians and patients to act to prevent additional spread. States may also send samples to CDC for further viral characterization and genomic sequencing.

Even while testing capacity through LRN labs greatly exceeded demand, CDC and FDA began working with five U.S. commercial laboratory companies to improve the accessibility of orthopoxvirus testing to the nation's providers. In June 2022, CDC began shipping orthopoxvirus tests to these five commercial laboratories. By July, testing capacity in the United States increased to 80,000 tests per week. As ofSeptember 7, orthopoxvirus testing throughput is at about 14 percent of total capacity. This Administration is preparing for potential increased demand for testing in the future and is exploring all available avenues to make testing more accessible.

Vaccines and Therapeutics

Through federal investments in public health preparedness, the U.S. supported the development of vaccines and therapeutics for orthopoxviruses, like monkeypox, before detection of the first U.S. case associated with the 2022 outbreak. The FDA-cleared non-variola

orthopoxvirus test, antiviral tecovirimat (also known as TPOXX), and ACAM2000 and JYNNEOS vaccines were all developed as part of the Smallpox Research Agenda. Under this ongoing U.S. smallpox preparedness work, CDC has collaborated with other U.S. public health officials to work to ensure medical countermeasure tools are available in the event of a smallpox outbreak. Unlike COVID-19, the monkeypox virus is not a novel pathogen, and our response benefited from our ability to mobilize existing countermeasures and move swiftly to acquire more.

From the beginning of the outbreak, CDC has worked closely with the Administration for Strategic Preparedness and Response and its Strategic National Stockpile to make vaccines available quickly, efficiently, and equitably. CDC's role in the monkeypox response vaccine strategy is to prioritize the allocation of our limited supply of the JYNNEOS vaccine to maximize public health impact. Allocations to jurisdictions are based on two factors: recent population-adjusted case incidence and the number of people who have the highest risk for disease in the current outbreak, as estimated by the number of gay, bisexual, and other men who have sex with men who are living with HIV or are eligible for HIV pre-exposure prophylaxis within a jurisdiction.

In light of FDA's August 9, 2022 Emergency Use Authorization for the JYNNEOS vaccine allowing for intradermal administration for individuals 18 years of age and older who are determined to be at high risk for monkeypox infection, CDC released interim clinical considerations with relevant information on how to administer the JYNNEOS vaccine intradermally. This approach provides a level of immune response comparable to that achieved by subcutaneous administration without compromising safety and can extend the vaccine supply by administering 0.1mL doses, allowing multiple doses to be administered from one 0.5mL vial.

Equitable allocation of vaccines and therapeutics for those at greatest risk of monkeypox is not possible without robust data. Vaccine and therapeutic administration data are important to verify that vaccines and therapeutics are going to the populations most affected by this outbreak. Other data, such as race and ethnicity data or HIV status, are also important to contextualize the distribution and administration. For example, we know that in the current monkeypox outbreak, more than one third of U.S. cases are occurring in people living with HIV. CDC has published Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People

with HIV and, with additional data, will continue to share treatment and prophylaxis considerations with clinicians. CDC is building on the approach and infrastructure established for COVID-19 to receive monkeypox vaccine administration data, including race and ethnicity, and has a data use agreement in place with every state to receive these data. On August 15, 2022, we began receiving vaccine administration data from high-burden jurisdictions andcurrently, a total of 35 jurisdictions are reporting these data to CDC.

CDC also is committed to increasing access to therapeutics for monkeypox patients. We acted quickly on reports from our state, local, and territorial health partners to reduce the burden of administering the FDA-approved smallpox treatment, tecovirimat or TPOXX, through the Expanded Access Investigational New Drug protocol. We did this because TPOXX has shown promising efficacy in preventing serious illness from monkeypox based on animal studies. To balance the need for safety and efficacy information with the need for timely administration, we worked closely with FDA to revise the protocol to allow for telemedicine check-ups, make laboratory sample collection optional, and streamline regulatory reporting.

Community Outreach and Public Awareness

While anyone – irrespective of age, gender identity, or sexual orientation – can contract monkeypox if they are exposed, engaging with populations currently disproportionately affected by the monkeypox outbreak is a cornerstone of the government-wide response. CDC is committed to collaborating and sharing timely knowledge with members of the LGBTQ+ community, especially gay and bisexual men. We know that successful public health efforts depend on authentic collaboration where the community is at the table, leading discussions, informing and grounding decisions based in the reality of those affected, and otherwise making vital contributions to our public health response. We are working closely with partner organizations and offices like AIDS United, UnidosUS, the Ryan White HIV/AIDS Program, Southern AIDS Coalition, and event organizers who bring LGBTQ+ people together across the country. Trusted community leaders are providing a voice to amplify messages for prevention, testing, and treatment. We are also working with our core public health partners at the local and state level to provide technical assistance on engaging local community partners to support prevention, vaccination, and testing. HHS launched pilot programs to provide additional vaccine allocations to state and local health departments in jurisdictions that are hosting large events that

attract gay, bisexual, and other men who have sex with men and to ensure more vaccines reach populations that face additional barriers to access through support for equity interventions. CDC will continue to provide technical assistance and support to jurisdictions for these large events and equity interventions, such as helping to develop testing and vaccine strategies, providing messaging and communication resources, and developing tools for information-gathering from event participants.

Stigmatization of diseases and groups of people hinders public health efforts and contributes to poorer health outcomes. CDC is drawing on what we have learned through decades of work in sexually transmitted infections (STIs) and HIV to ensure that CDC messaging does not contribute to the stigmatization of gay, bisexual, and other men who have sex with men. CDC is conducting community listening sessions and working closely with LGBTQ+, sexual health, and HIV advocacy organizations to take our fight against stigma to the next level by creating messaging that is sex-positive and LGBTQ-affirming. We will work with healthcare providers, organizations of all kinds, and public health partners to support better approaches that reach affected communities.

CDC uses a variety of mechanisms including the *Morbidity and Mortality Weekly Report* to disseminate information to public health partners and healthcare providers about outbreaks of rare pathogens like monkeypox. Our monkeypox clinical considerations have received hundreds of thousands of page views. On May 20, 2022, CDC released the first Health Alert Network Health Advisory on the monkeypox outbreak, and we have issued three subsequent advisories, each reaching over 1 million people. CDC regularly hosts Clinician Outreach and Communication Activity calls where subject matter experts provide the latest information and considerations for tens of thousands of clinicians. The agency continues to work closely with clinical and core public health partners to amplify messaging to their members, including the American Medical Association, Infectious Disease Society of America, American Academy of Pediatrics, American Academy of HIV Medicine, Council of State and Territorial Epidemiologists, Association of State and Territorial Health Officials, National Association of County and City Health Officials, Association of Public Health Laboratories, National Coalition of STD Directors, Big Cities Health Coalition, and National Indian Health Board.

CDC is also providing information to a wider U.S. audience about the symptoms of monkeypox and how to mitigate the spread of the disease. Because of how monkeypox is transmitted, CDC recognizes that individuals may be concerned about the spread of monkeypox in group settings. CDC has developed recommendations for reducing infection risk in group settings and will continue to adapt and refine these recommendations based on what we learn about virus transmission. A priority of our response to monkeypox is to support early identification of monkeypox spread in congregate living settings, like dormitories, correctional facilities, shelters, and others. Informational resources for populations that could be at increased risk continue to be developed. CDC has also posted responses to frequently asked questions from facilities serving children to provide administrators, parents, and caregivers with information as their students return to school.

Looking Ahead

There is much more research to be done to better understand this unique monkeypox outbreak and other diseases with pandemic potential. Flexible, disease-agnostic investments are critical to inform our efforts to respond to emerging public health threats. Additionally, sustained support for core capabilities – such as modernized data systems, public health infrastructure, and a diverse public health workforce – are critical for an effective and equitable disease response at the national, state, Tribal, local, and territorial levels. Epidemiologic studies on the characteristics of monkeypox and spread in this outbreak can provide better understanding to improve the efficacy of prevention and intervention efforts.

Access to timely and actionable data has been a challenge during the initial stages of the monkeypox outbreak given our nation's fragmented streams of data collection and reporting. The COVID-19 pandemic demonstrated and the monkeypox outbreak has reaffirmed that nothing about public health data in the United States is easy – it is a complex, de-centralized landscape with many points of friction that can keep data from getting from its source to where it is needed to inform public health action. CDC's new Center for Forecasting and Outbreak Analytics is already enabling timelier, more effective decision-making in responding to monkeypox, but its work in modeling and analytics hinges on our ability to collect and integrate high-quality data.

CDC has deep collaborative partnerships with state and local jurisdictions to help navigate these challenges, but the fact remains that ongoing modernization and support from Congress is needed to provide CDC additional policy levers to enable timely reporting of actionable data before the next threat arrives. In particular, COVID-19 and monkeypox have showed the importance of timely and comprehensive data to support decision making at federal, state, and local levels. This data is most effective when collected before and during an outbreak to mount a fully effective response. To achieve this goal, CDC will need support from Congress for an updated authority to set a common framework for how data is reported to support federal, state, and local decision making. In the absence of this authority, CDC must spend precious time negotiating bespoke data use agreements with many dozens of jurisdictions and rely on voluntary data reporting – a process that took months for both the COVID-19 and monkeypox responses for key data elements.

As COVID-19 demonstrated, and as we see again now with monkeypox, the American public health system is fragile due to years of underinvestment in national preparedness and in state, Tribal, local, and territorial public health agencies. And yet, our nation's security depends on the strength of its public health system. It is for this reason that long-term, foundational investments must be made to ensure we are prepared to respond rapidly and effectively to future pandemics and other public health threats. Moving from reliance on unpredictable supplemental resources to reliable multi-year funding will enable us to transition the infrastructure built for the COVID-19 response to a sustained core infrastructure – including data, workforce, and laboratories – capable of addressing current and future public health challenges. Investment in laboratory capacity and standards across the country, regardless of the diseases they are used for, ensures that laboratories can process tests quickly and effectively when a health threat arrives. Workforce funding gives health departments the personnel they need to pivot and respond to new threats, untethered to a specific funding line or program activity. The FY 2023 President's Budget included a five-year request for $88 billion for pandemic preparedness, including $28 billion for CDC to transform our public health capacities nationwide, which is urgently needed to ensure we are prepared for *any* infectious disease threat that comes our way.

Conclusion

As CDC continues to contribute to a robust whole-of-government response to this outbreak, we are working with governmental and non-governmental partners to ensure easy, safe, and equitable access to diagnostic tests, vaccines, and therapeutics. We will continue to educate healthcare providers and the American public on monkeypox, with a particular emphasis on the disproportionately impacted community of gay, bisexual, and other men who have sex with men. We are working to share scientific findings and data faster; to translate science into practical, easy-to-understand policy; and to optimize public communications. The current outbreak demonstrates that the work of public health is never done and that we must continue to make investments and structural changes now to address the long-standing vulnerabilities in our public health system. We must stay vigilant in global disease surveillance and efforts to modernize the public health data landscape. Resources to support public health preparedness and infrastructure, including at the state, Tribal, local, and territorial levels, remain as necessary as they have been during and prior to the COVID-19 pandemic. I am committed to working with Congress to advance these efforts and build a more resilient public health system that contributes to a healthier, safer, and more secure future for all Americans.

Thank you, and I look forward to your questions.