

Monkeypox Virus (MPV)

Emergency Legal Preparedness Primer

As of September 30, 2022

James G. Hodge, Jr., J.D., L.L.M.

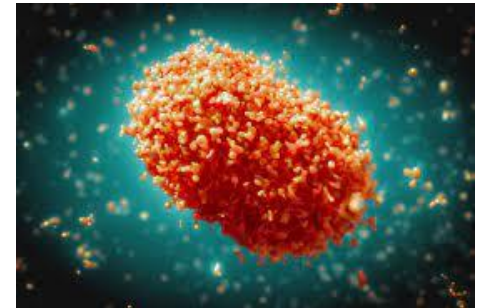
Peter Kiewit Foundation Professor of Law

Director, Western Region Office, Network for Public Health Law

ASU and Day O'Connor College of Law

james.hodge.1@asu.edu

- ☐ **Monkeypox (MPV) Epi Trends**
- ☐ **Emergency Legal Declarations**
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- ☐ **Public Health Surveillance**
- ☐ **Vaccinations**
- ☐ **Testing & Treatment**
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- ☐ **Additional Resources**



Transmission

- Transmissible person-to-person through close, intimate contact (e.g., kissing, sexual contact, skin-to-skin contact) or via direct contact with rash, scabs, or bodily fluids

Symptoms

- Fever, headache, muscle aches, swollen lymph nodes, respiratory symptoms (e.g., sore throat, cough), fatigue
- Rash that progresses from maculopapular lesions to vesicles, pustules, and finally scabs up to 3 weeks after exposure
- According to WHO, “[c]omplications of [MPV] can include secondary infections, bronchopneumonia, sepsis, encephalitis, and infection of the cornea with ensuing loss of vision.”

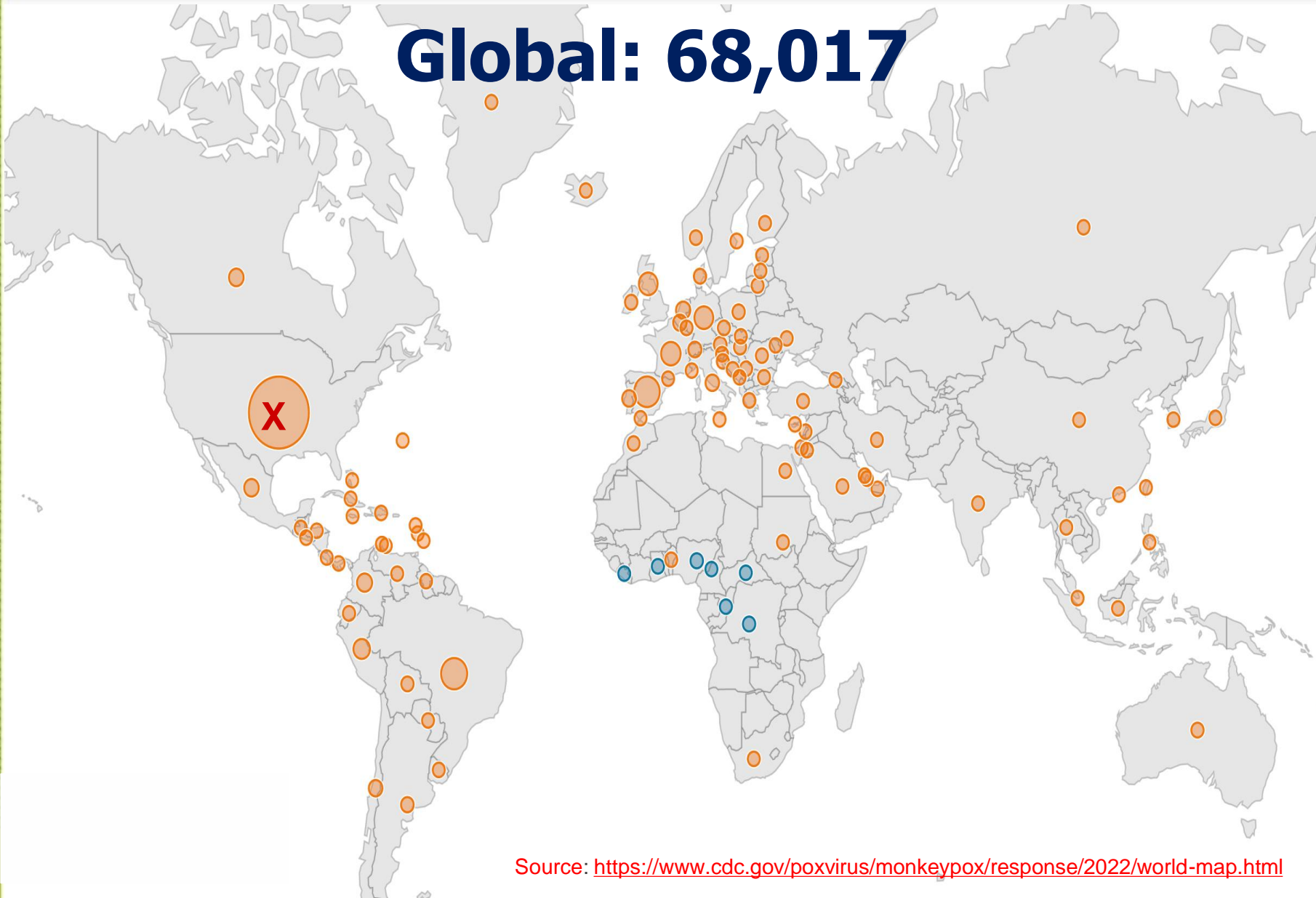
Vaccines & Treatment

- Vaccines are available but in limited supply
- Post-exposure prophylaxis (PEP) is available 4-14 days after the date of exposure



Monkeypox Confirmed Cases

Global: 68,017

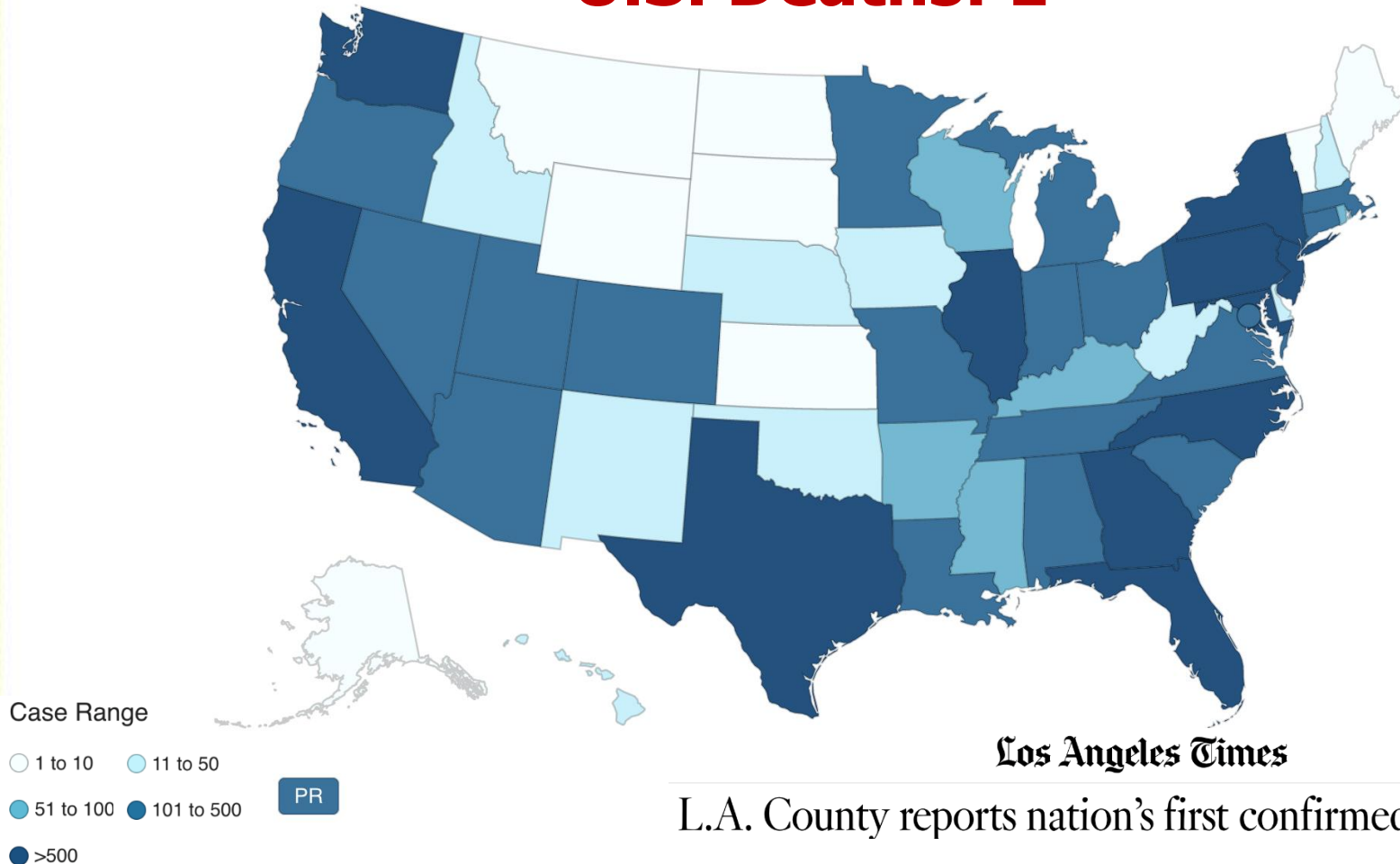


Source: <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>

Monkeypox Confirmed Cases

U.S.: 25,613

U.S. Deaths: 1



Los Angeles Times

L.A. County reports nation's first confirmed MPX death

Source: <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>

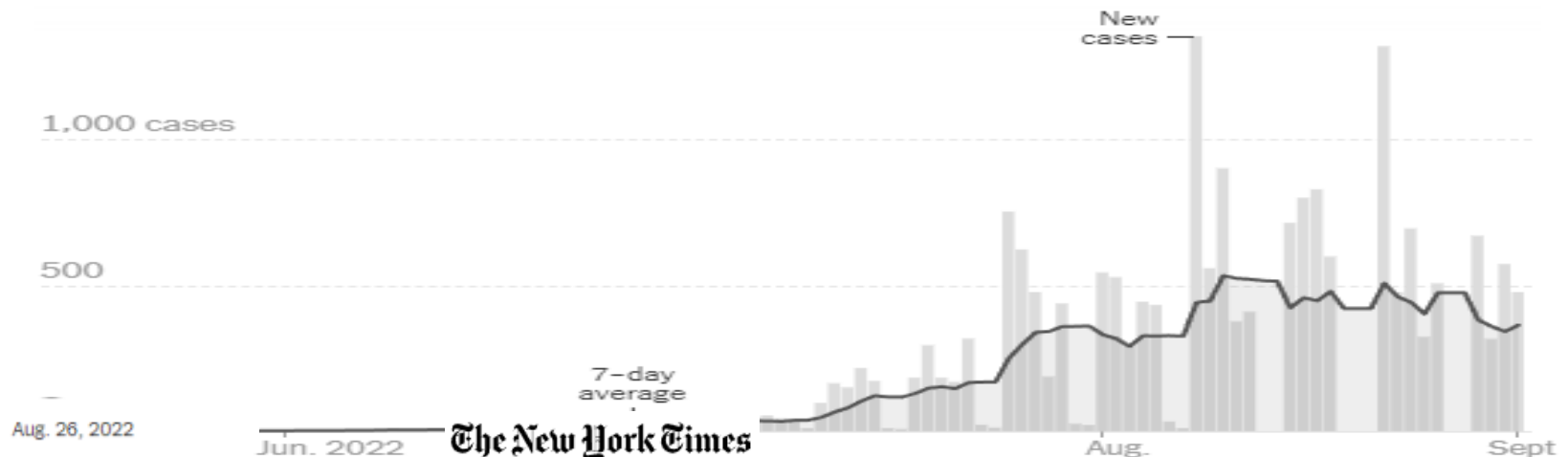
Monkeypox Case Trends

- **Aug. 25:** WHO reported a 21% decline in cases globally, potentially signifying an overall outbreak decline in the West.
- Coextensively, MPV cases are reportedly declining in New York City, California, and other hotspots as cases fall and transmission slows due to **rising vaccination rates** and **individual behavioral responses**, including safer sexual conduct, in part due to targeted messaging.

Confirmed Monkeypox Cases in the U.S.

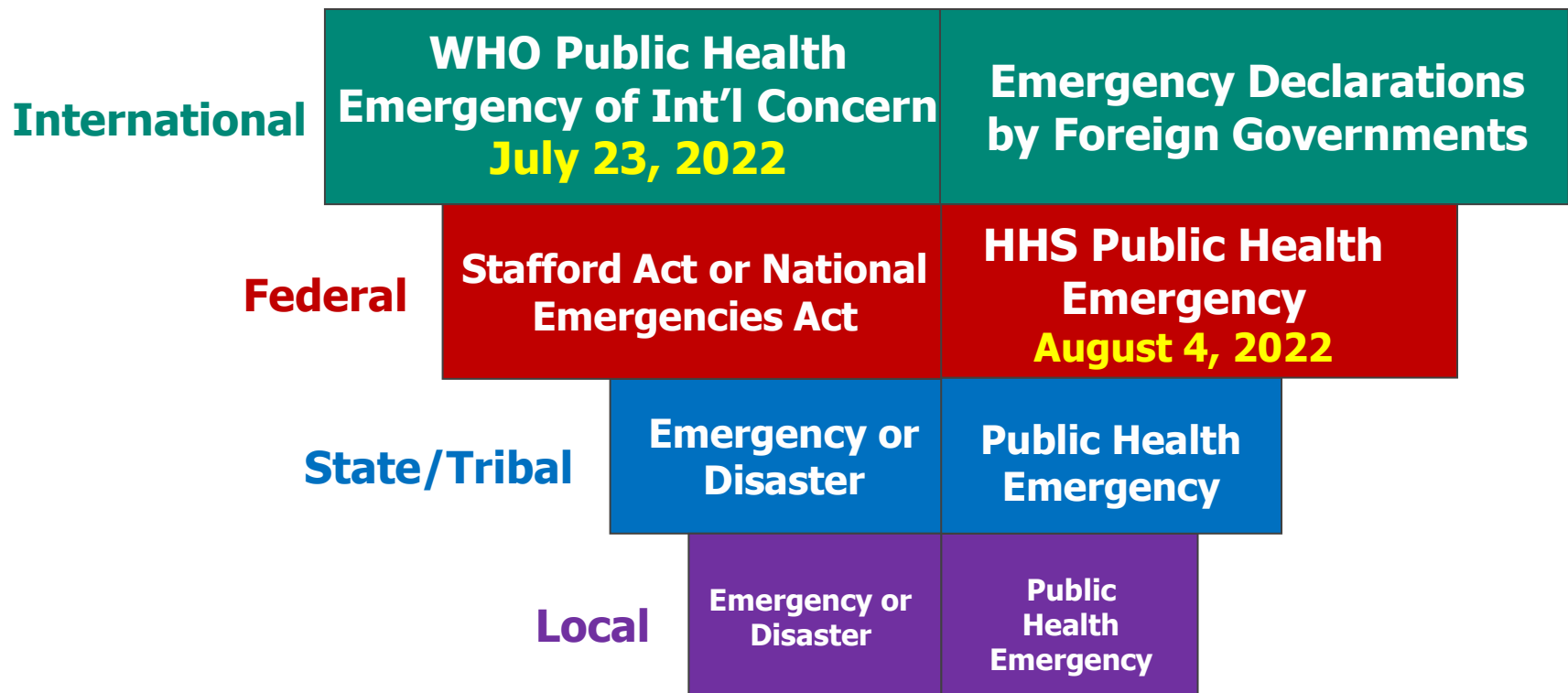
TOTAL	IN PAST TWO WEEKS	DAILY AVERAGE	14-DAY CHANGE
19,465	5,350	363	-24%

Cases by day



Source: Centers for Disease Control and Prevention • Chart shows cases of monkeypox confirmed by the C.D.C. in the 50 states, Washington, D.C., and Puerto Rico.

Public health authorities & powers vary depending on the type of emergency declared at every level of government



July 23, 2022: WHO declares a public health emergency of international concern (PHEIC).



Guidance	Objectives
Organized Responses	Engage in containment, active surveillance, early detection, isolation & contact tracing
Data Sharing	Share data with WHO via IHR legal requirements
Prevention	Focus on reducing human infection/ secondary transmission
Communication	Engage in multi-sectoral communication re: knowledge & research
Restrict Movement	Restricting movement of people/goods may be temporarily useful under limited response capacities or intense cases
Travel	Inform WHO about travel measures as required by the IHR
Discrimination	Avoid actions promoting stigma or discrimination
Developing Countries	Support LMICs to enable their responses & facilitate access to diagnostics, vaccines & therapeutics
Justification	Justify health measures significantly interfering with international traffic

Biden-Harris Administration National Response Efforts

Aug. 2: President Biden names Robert Fenton from the Federal Emergency Management Agency (FEMA) to manage federal MPV response efforts



Robert Fenton, FEMA

Aug. 2: President Biden names Demetre Daskalakis, director of the Division of HIV/AIDS Prevention at CDC, as deputy coordinator of MPV response efforts



Demetre Daskalakis, CDC

HHS Declares Public Health Emergency

July 29: House Oversight Committee Chair, Rep. Carolyn Maloney (D-N.Y.) urges HHS Secretary to immediately declare a public health emergency.

Aug. 4: HHS Secretary Becerra formally declares a **national public health emergency (PHE)**



“Within days of the first confirmed case of [MPV] in the [U.S.], we quickly began deploying vaccines and treatment to help protect the American public and limit the spread of the virus,” . . . While [MPV] poses minimal risk to most Americans, we are doing everything we can to offer vaccines to those at high-risk of contracting the virus . . . [during] the current outbreak.”

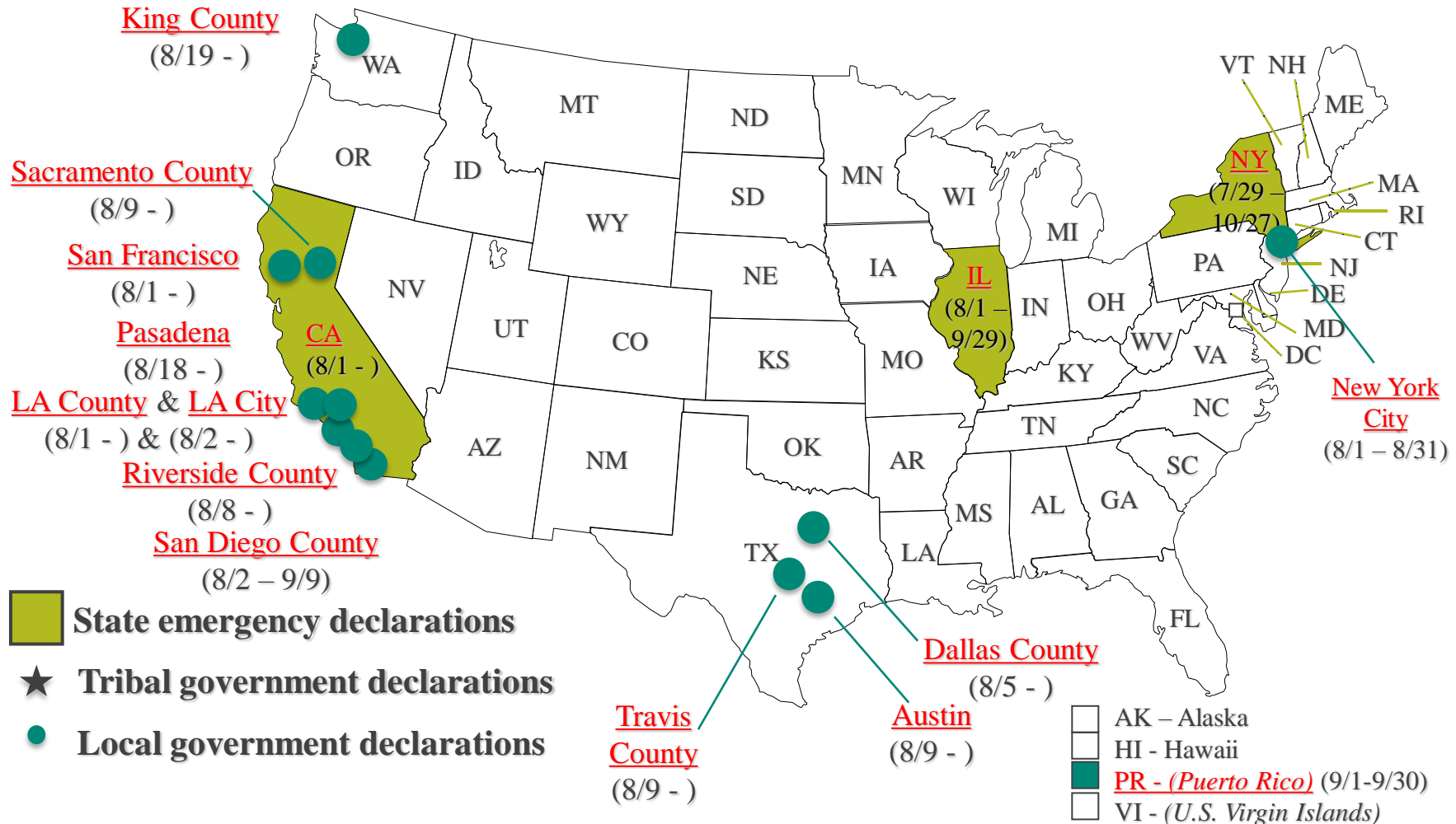
HHS Sec’y Xavier Becerra, **8/4/22**

HHS national PHE declaration authorizes:

- ❖ Enhanced federal contracting & procurement
- ❖ Release of public health emergency funds
- ❖ Interjurisdictional coordination efforts
- ❖ Acquisition, allocation & distribution of vaccines or other medical countermeasures
- ❖ Access to the Strategic National Stockpile
- ❖ Limited licensure reciprocity for health care workers
- ❖ Deployment of emergency management teams
- ❖ Active national public health surveillance efforts
- ❖ CMS testing & hospitalization data assessments

Monkeypox State, Tribal & Local Emergency Declarations

As of September 30, 2022





July 28: New York State Commissioner of Health Dr. Mary T. Bassett declared MPV an Imminent Threat to Public Health

July 29: Governor Kathy Hochul signs an executive order declaring a state of disaster in New York State.

Illinois Public Health Emergency



Aug. 1: Governor Pritzker declares the entire state a disaster area, allowing the Illinois Department of Public Health to *access resources, coordinate across agencies, and rapidly assist in aid vaccine distribution and treatment/prevention.*



Aug. 1: Governor Gavin Newsom declares a **State of Emergency**, taking a “whole-of-government response” approach to enhance vaccination access (incl. via emergency management workers), improve testing, engage contact tracing, support community partnerships, and reduce stigmatization.

State Emergency Declarations – Specific, Express Authorizations

Action	CA 8/1/22 [duration unspecified]	IL 8/1/22 [30 days]	NY 7/29/22 [30 days; extendable]
Altered Contracts Procurements Funding	X	X	X
Emergency Plans ICS Intrastate Coordination	X	X	X
Surveillance Reporting			
Testing Screening Treatment	X	X	X
Isolation Quarantine			
Licensure Reciprocity			
Anti-discrimination		X	
Waivers Suspensions	X		X



Sept. 1: Governor Pedro Pierluisi declared a State of Emergency and signed an executive order facilitating economic allocations and access to the Emergency Fund toward response efforts.



P.R. Department of Health is empowered to implement safeguards to control the outbreak.

San Francisco Public Health Emergency



July 28: Mayor London Breed & San Francisco Department of Public Health announced a local emergency declaration re: MPV to accelerate emergency planning, streamline staffing, and coordinate with agencies.

Aug. 8: The San Francisco Board of Supervisors ratified the city's public health emergency declaration during a special meeting.



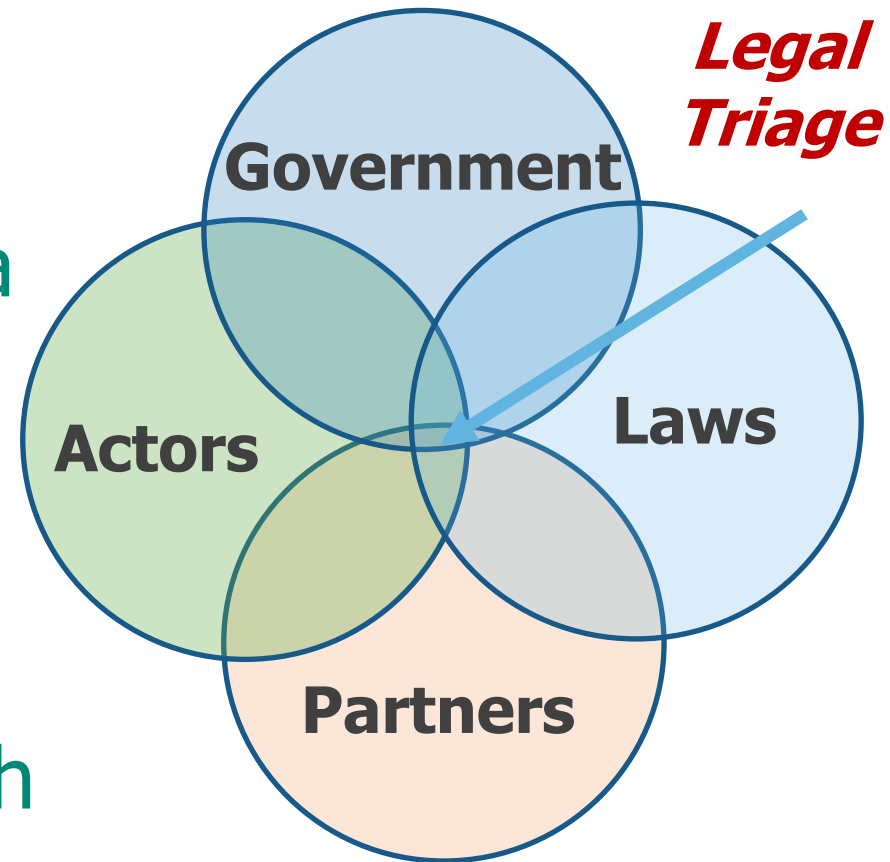
July 30: Mayor Eric Adams declared a state of emergency, allowing the *suspension of specific local laws and enacting new protocols to manage the outbreak*, such as amplifying vaccination and testing efforts across all governments.

Los Angeles County & City Emergency



Aug. 2: The Los Angeles County Board of Supervisors issued a proclamation declaring a local emergency to “*bolster the county’s response and request recovery assistance under the California Disaster Assistance Act.*” That same day **L.A. City** Mayor Garcetti also declared a local emergency.

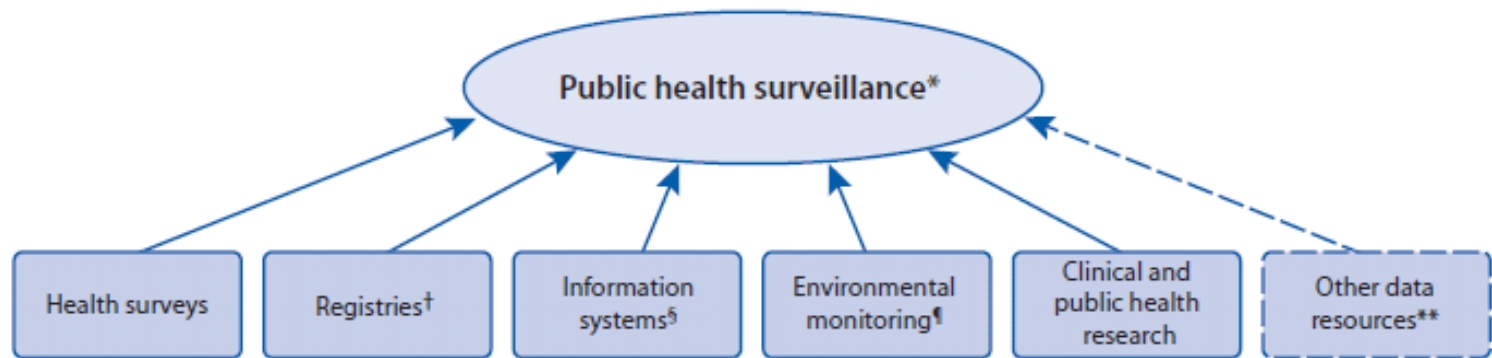
Legal Triage: efforts of legal actors & others during declared emergencies to build a favorable legal environment by prioritizing issues & solutions facilitating legitimate public health responses



Balancing Individual & Communal Interests







- Pursuant to the national PHE, federal agencies have initiated incentives, contracts, and other legal options to improve national surveillance efforts across states.
- HHS reports that over **50 state and local jurisdictions have executed data use agreements** to share MPV surveillance and vaccine administration with CDC.
- CMS and the VA are also collecting their own data on available testing and hospitalization rates.
- Some jurisdictions (e.g., **Missouri**) have issued emergency reporting rules re: MPV.

Testing & Treatment



- Reported MPV cases in the U.S. are significantly undercounted due to sporadic testing and reporting.
- After CDC's Laboratory Response Network proved insufficient, HHS authorized 5 private laboratories on June 22, 2022 to perform testing, upgrading national capacity to 80,000 tests per week.
- On Sept. 7, 2022, HHS Sec. Becerra issued a declaration allowing emergency use authorizations for in vitro diagnostics to enable the development of more validated MPV tests and help further increase testing access.
- TPOXX is designated by FDA to treat MPV as an “investigational drug,” requiring a series of convoluted steps for physicians to acquire it.
- Emergency use authorizations may allow TPOXX to be used more extensively as it remains difficult to access for many providers. A PREP Act declaration could enhance access as well by ushering in greater uses, authorizing licensure reciprocity across states, and providing significant liability protections.
- Sept. 15: New CDC guidance recommends limiting the use of TPOXX to people at high risk for severe cases, citing concerns that broad use could lead to TPOXX resistant mutations.

Monkeypox Vaccines

- **Limited supplies** of Jynneos® vaccine led HHS Sec'y Becerra to declare an emergency via the **Food, Drug & Cosmetic Act § 564** on Aug. 9 allowing FDA to issue emergency use authorizations (EUAs) for the vaccine (and other pharmaceuticals).
- **Aug. 9:** FDA issues EUA allowing intradermal injections to extend vaccine dosages up to 5X despite safety **concerns** expressed by manufacturer, Bavarian Nordic. FDA also allowed specific, at-risk minors to receive the vaccine.
- HHS confirmed **liability shields** for vaccine administration via existing PREP Act declaration for Smallpox MCMs.
- **Sept. 2:** Initial evidence suggests available vaccine may not be as effective as hoped.
- **Sept. 12:** Separate study claims the vaccine produces strong antibody responses.
- **Sept. 28:** CDC data indicated that vaccinated people carry a much lower risk of contracting MPV with a **clinical trial** exploring efficacy of varying doses



Monkeypox Vaccinations: Complications



Public Health
Seattle & King County



- Aug. 18: White House announced sending 1.8 million vaccine doses to jurisdictions that agree to adopt new dosing protocols.
- Some public health agencies seek more flexibility over vaccine administration instead of switching dosing protocols.
- Some agencies (e.g., Boston) have trained providers on intradermal vaccine methods; others did not initially adopt FDA's new approach (e.g., New York).
- Some public health departments struggle to extract the correct number of doses from vials. Seattle/King County Health Department reports only getting 3-4 doses per vial (instead of the prescribed 5).
- Sept. 13: LA announces first infected HCW.

Monkeypox Vaccinations: Allocation Criteria

Jurisdictions' vaccine eligibility criteria vary under new methodologies.

- Harris County (TX) offers the vaccine to individuals that are HIV+, on PrEP, or recently diagnosed with gonorrhea, chlamydia or syphilis (previously only available to MSM).
- Oklahoma expanded eligibility (from those potentially exposed at work) to MSM with 2+ sex partners or in commercial sex work.
- Dallas County (TX) expands eligibility to MSM who had skin-to-skin contact with persons at large venues/events.



Monkeypox Vaccinations: Disparities

- **Aug. 12**: CDC data reveals disparities in MPV vaccine access.
- Despite lessons learned re: vaccine access and allocation during the COVID-19 pandemic initial reporting suggests that those with means & resources (e.g., better access to health care) receive doses first.
- According to the **N.Y. Times**, from the inception of vaccine availability in NYC through mid-Aug. 2022 in NYC:

31% of the population considered at-risk to MPV is Black men but they received only 12% of administered doses

16% of the population considered at-risk to MPV is Hispanic men but they received 23% of doses

Monkeypox Vaccinations: Equitable Distribution

Sept. 1: The White House announced the “equity intervention pilot” program to distribute vaccines to populations in need that face access barriers to online or other appointments and stigma of attending events in person.

- The majority of MPV cases to date are among Black and Hispanic individuals, but these populations have received disproportionately less vaccines. Hispanics have received 2x less and Blacks have received 4x less vaccine doses than Whites.
- 10,000 - 50,000 extra doses are offered to local health departments with additional vaccines to CA, GA, and LA where upcoming events are expected to attract large numbers of vulnerable populations.
- In some states, LGBT+ populations are not consistently prioritized by local health departments.

Sept. 15: CDC announced that local health departments and organizations could begin submitting requests for vaccines through this pilot program.



Stigmatization & Discrimination

- The HIV/AIDS pandemic revealed how public health strategies must avoid stigmatization or discrimination against specific, at-risk communities.
- With current spread of MPV predominantly among MSM and LGBTQIA+ populations, stigmatization is a major concern.
- Specific examples of inappropriate messaging, confusion about targeted communities, event cancellations, and employment-based discrimination have arisen.
- Policy formation & implementation should be accomplished through inclusive participation with affected communities.
- Historic and present-day discrimination experienced among LGBTQIA+ populations tied to disease transmission warrants health privacy protections, supportive messaging, and explicit anti-discrimination practices.



CDC - Reducing Stigma in Monkeypox Communication & Community Engagement

“CDC . . . is working to provide frontline healthcare providers and public health officials with information about what [MPV] looks like and how to manage the illness. Many—though not all—of the reported cases have been among gay and bisexual men. *Given this, CDC is focusing on identifying and using specific channels that will directly reach gay and bisexual men across racial, ethnic, socioeconomic, and geographic backgrounds.* CDC is also providing information to a wider audience about symptoms and the behaviors that can lead to the spread of [MPV].”

Public health messaging must balance raising awareness about MPV spread & providing clear information *against the risk of stigmatization and discrimination.*

Although *anyone can become infected with MPV*, public health data have identified select sub-populations where most cases are saturated. Messaging must reach these groups without alienating them or alarming the public.

How we talk about monkeypox matters.
Experts offer ways to reduce stigma

July 31, 2022 - 5:00 AM ET



U.S. Messaging on Monkeypox Is
Deeply Flawed

Officials seem unwilling to be direct about who is most at risk of the disease.

By Jerusalem Demsas JULY 19, 2022 *The Atlantic*

Higher Education Institutions & Monkeypox Prevention



- Many higher education institutions announced plans to prevent MPV spread as students return to campus for the Fall 2022.
- **CDC** and the **White House** provided guidance through a virtual meeting with school officials to target MPV spread.
- Initially, most schools did not have vaccines available on campus, but many schools started to arrange student appointments and vaccine clinic events in September 2022.
- MPV education provided by colleges varies based on numbers of local cases and presence of active emergency declarations.
- Schools in states with low MPV cases may not offer any guidelines, **despite reported spreads on select campuses.**

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- Special thanks to **Erica N. White, JD**, Research Scholar, and **Cleo Goeckner**, Legal Extern, with ASU's Sandra Day O'Connor College of Law, for their contributions.
- [Ask the Network](#) re: questions/comments
- james.hodge.1@asu.edu | @jghodgejr