

Monkeypox: Legal & Policy Conundrums Underlying America's Newest Public Health Emergency

September 7, 2022

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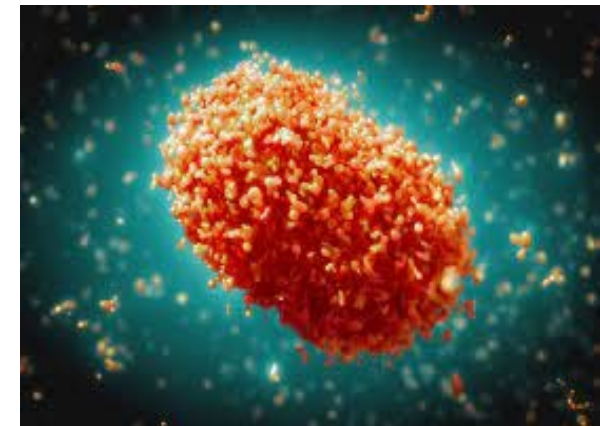
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- ❑ **Monkeypox Epi Trends**
- ❑ **Emergency Legal Declarations**
- ❑ **Public Health Emergency Powers**
- ❑ **Legal Conundrums**
 - ❑ Public Health Surveillance
 - ❑ Testing & Treatment
 - ❑ Vaccinations
 - ❑ Stigmatization & Discrimination
- ❑ **Higher Education Institutes**



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 monkeypox can include secondary infections, bronchopneumonia, sepsis, encephalitis, and infection of the cornea with ensuing loss of vision.”

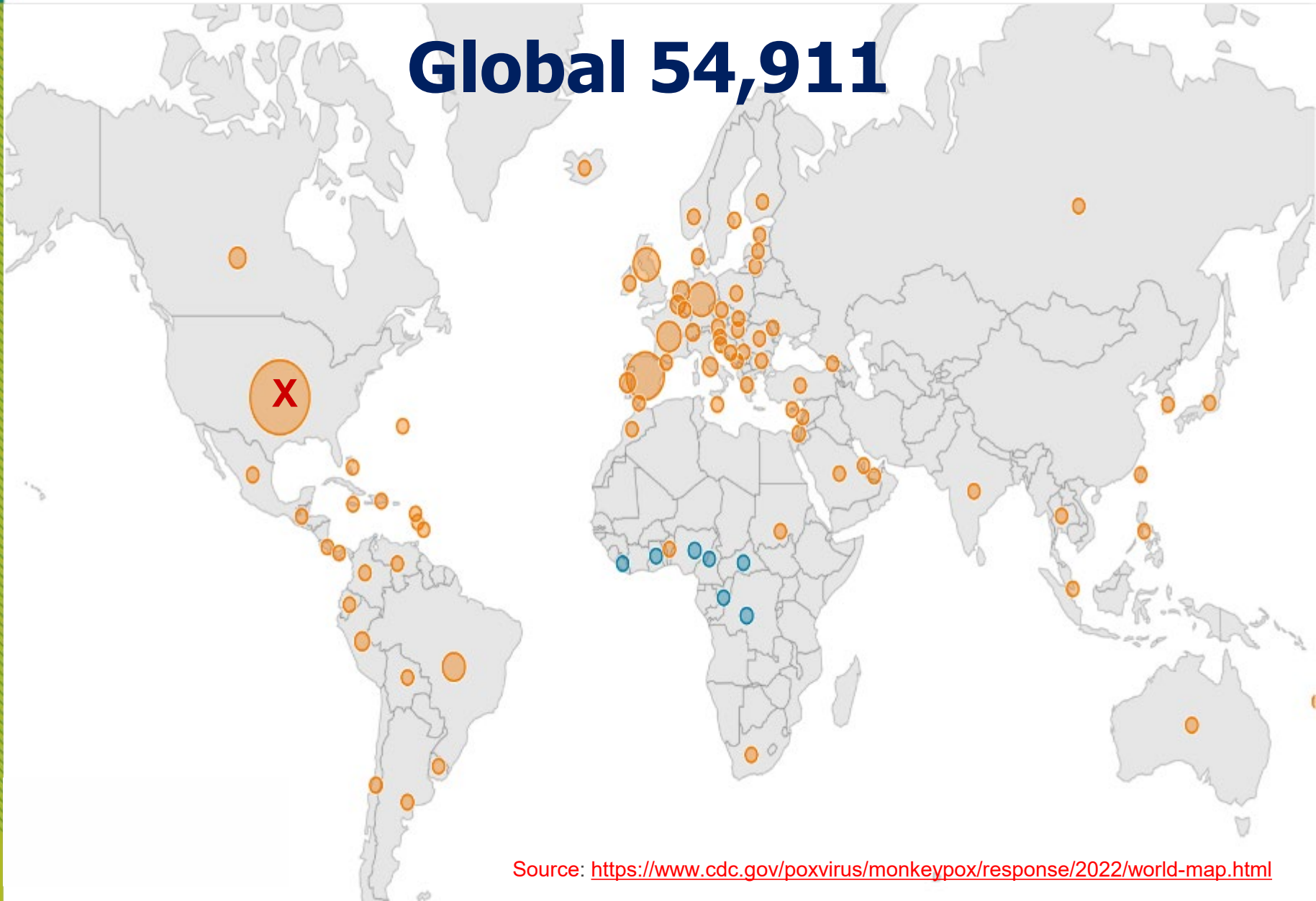
Vaccines & Treatment

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



Monkeypox Confirmed Cases

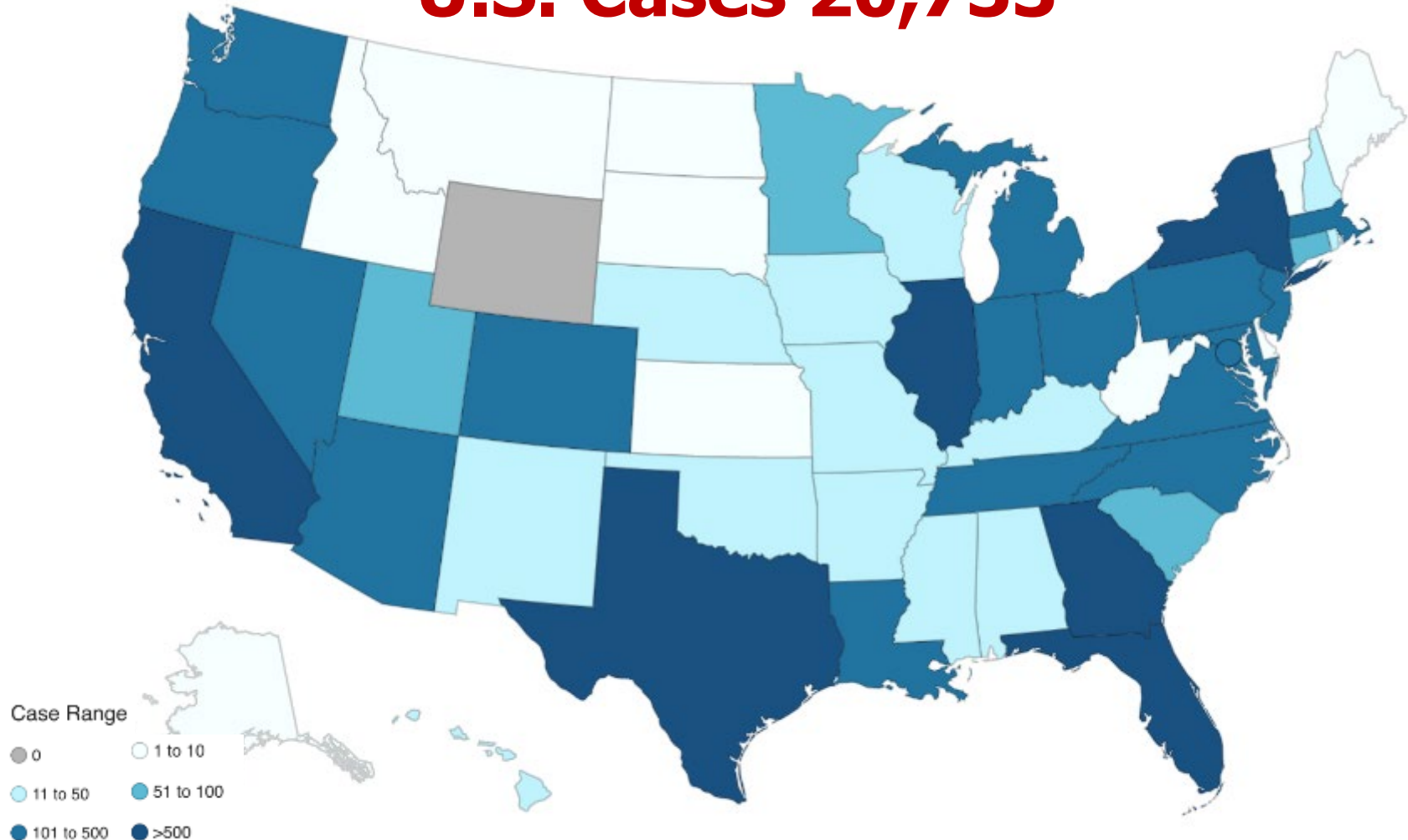
Global 54,911



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

Monkeypox Confirmed Cases

U.S. Cases 20,733



Territories

PR

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



Monkeypox Confirmed Cases

State	Confirmed Cases
California	3,833
New York	3,526
Florida	2,126
Texas	1,859
Georgia	1,512
Illinois	1,128
...	
Nebraska	28

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).



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 monkeypox 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 monkeypox 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

Biden-Harris Administration National Response Efforts

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



Robert Fenton, FEMA

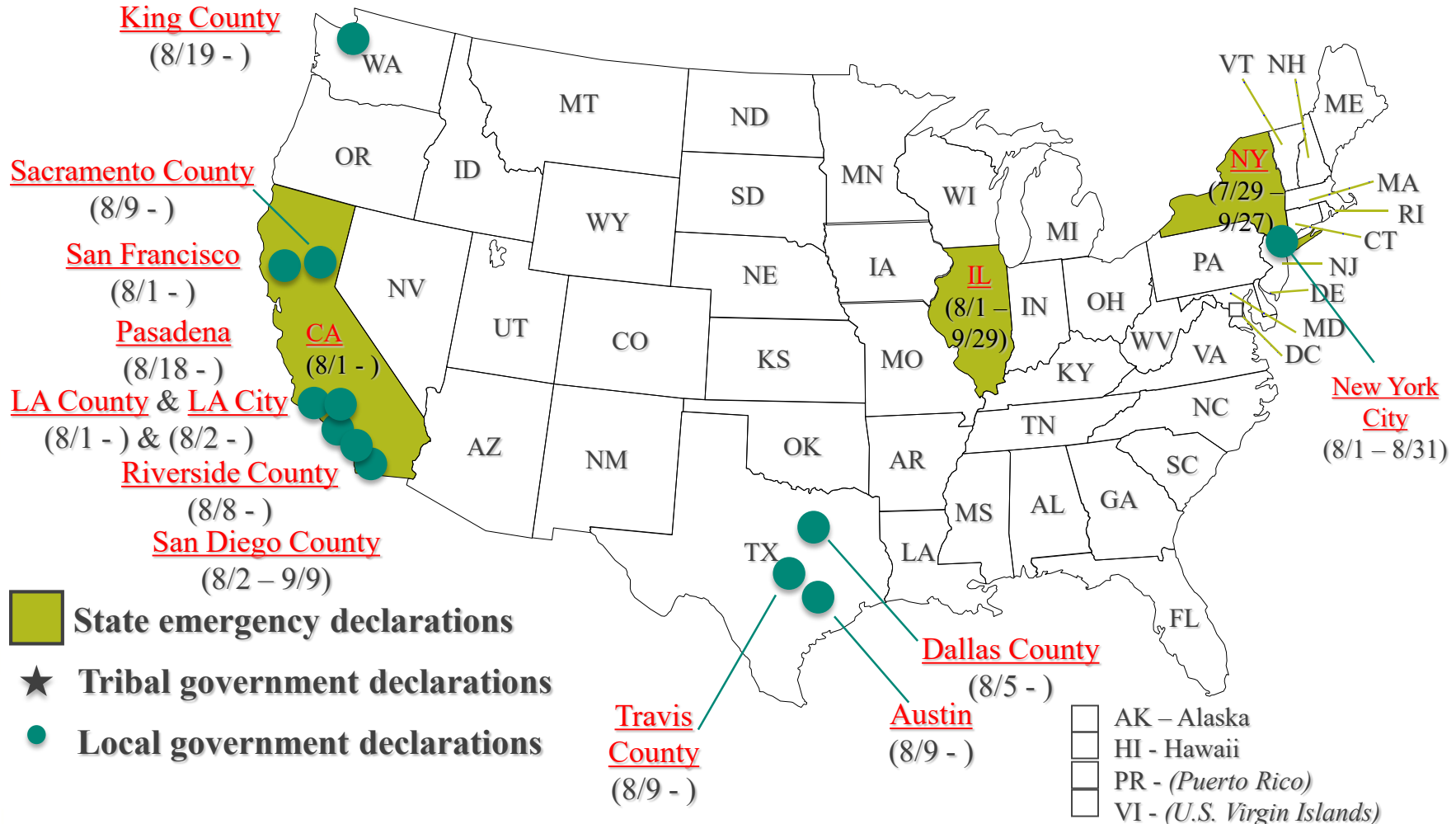
Aug. 2: President Biden names Demetre Daskalakis, director of the Division of HIV/AIDS Prevention at CDC, as deputy coordinator of monkeypox response efforts



Demetre Daskalakis, CDC

Monkeypox State, Tribal & Local Emergency Declarations

As of September 7, 2022





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

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



Aug. 1: Governor J.B. 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.*

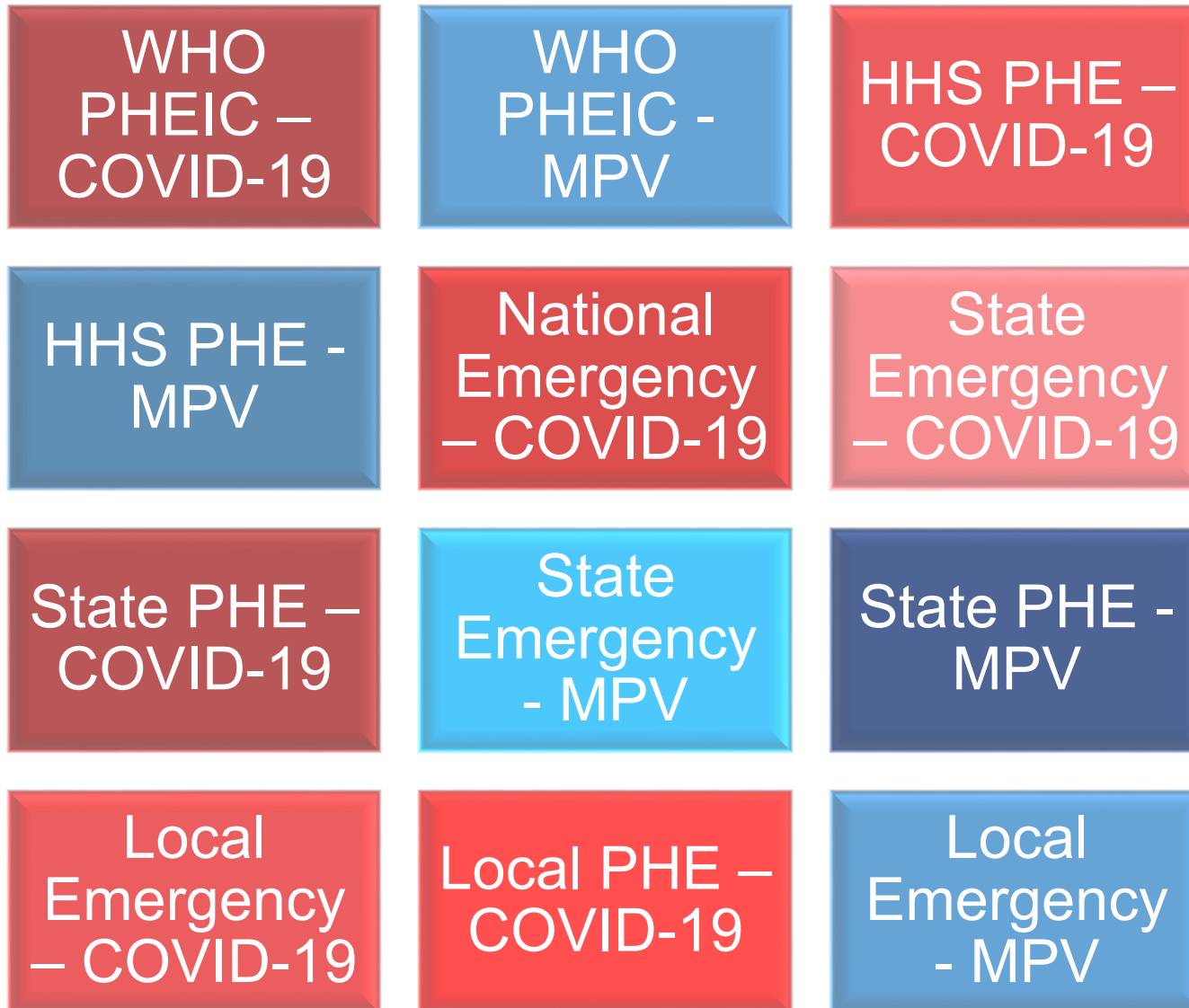


Aug. 1: Governor Gavin Newsom declares a **State of Emergency**, taking a “whole-of-government response” approach to enhance vaccination access (incl. via emergency management workers), improve testing, engage contact tracing, support community partnerships, and reduce stigmatization.

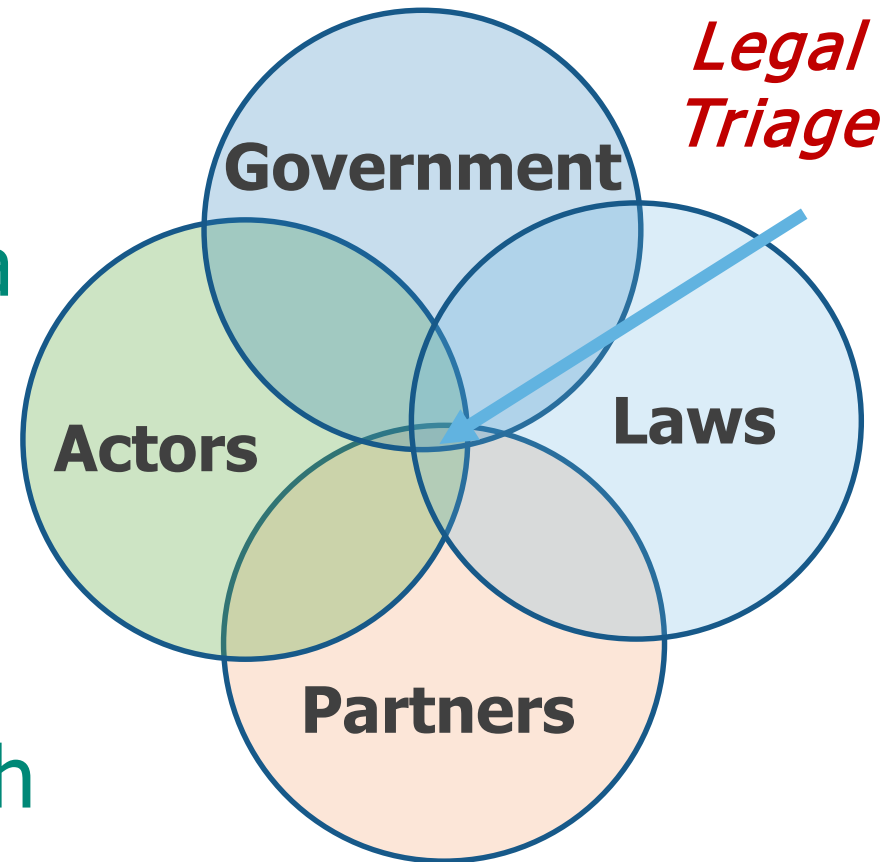
State Monkeypox Emergency Declarations – Specific, Express Authorizations

Action	CA 8/1/22 [duration unspecified]	IL 8/1/22 [30 days]	NY 7/29/22 [30 days]
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

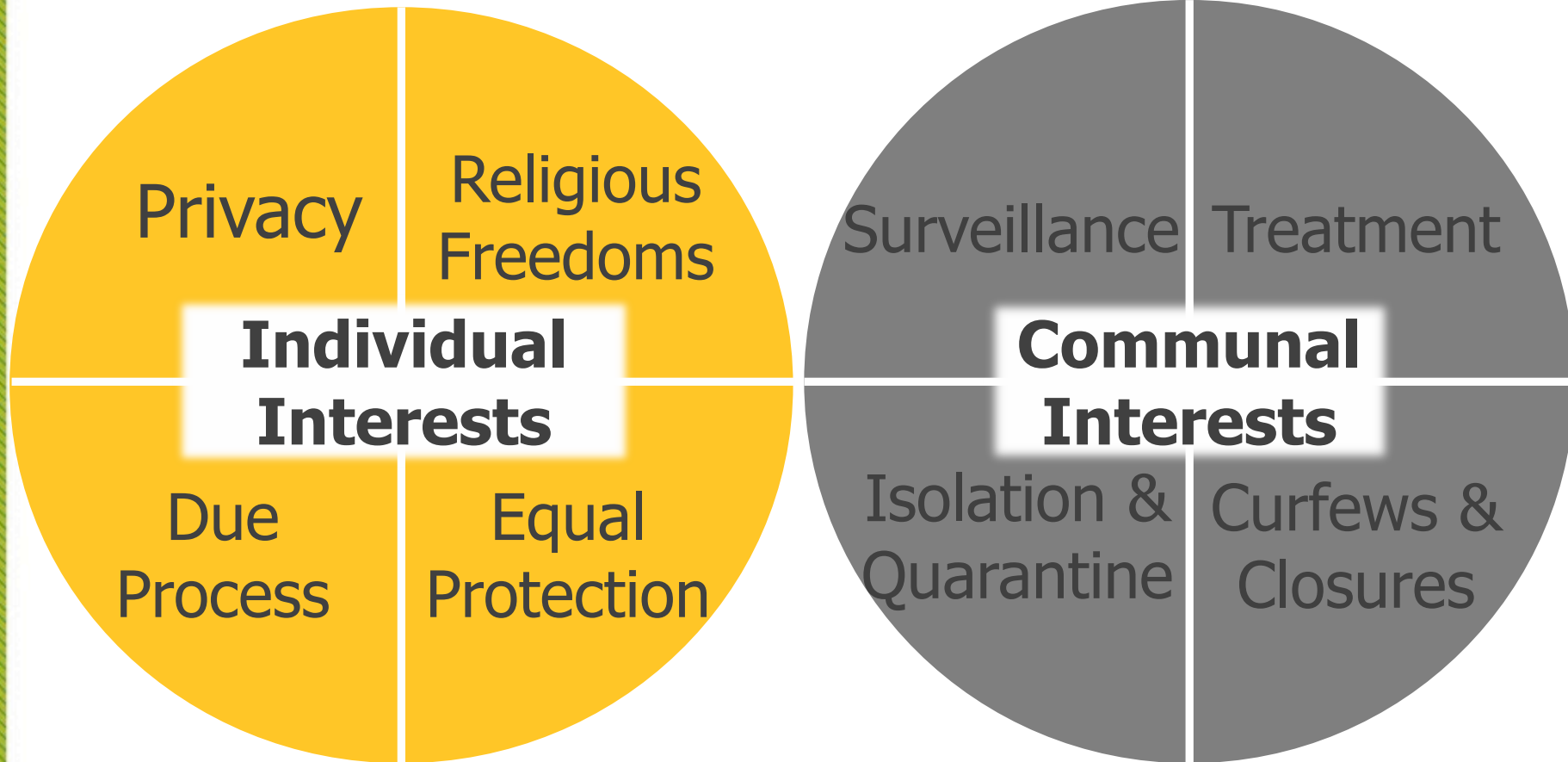
Layered Emergency Declarations



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



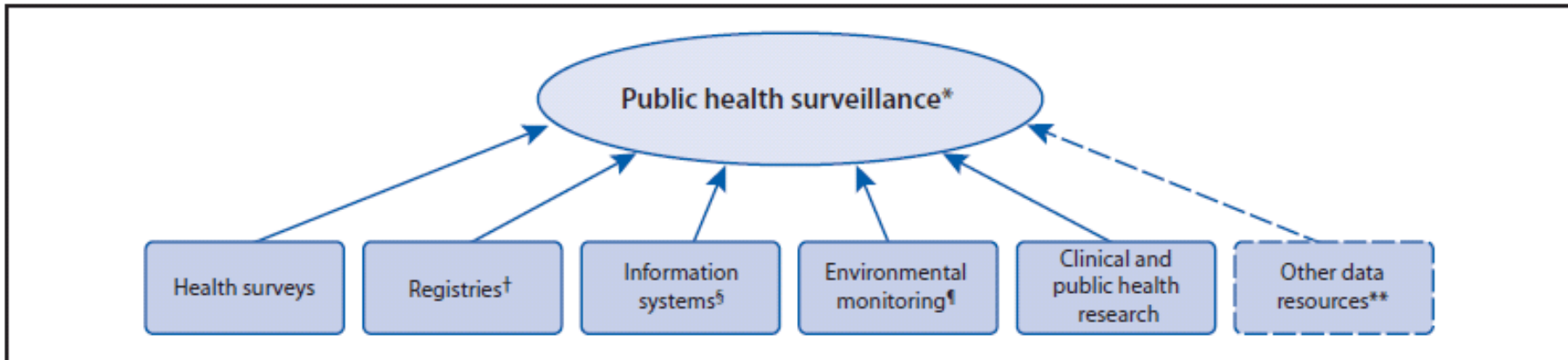
Balancing Individual & Communal Interests



Emergency Preparedness & Response



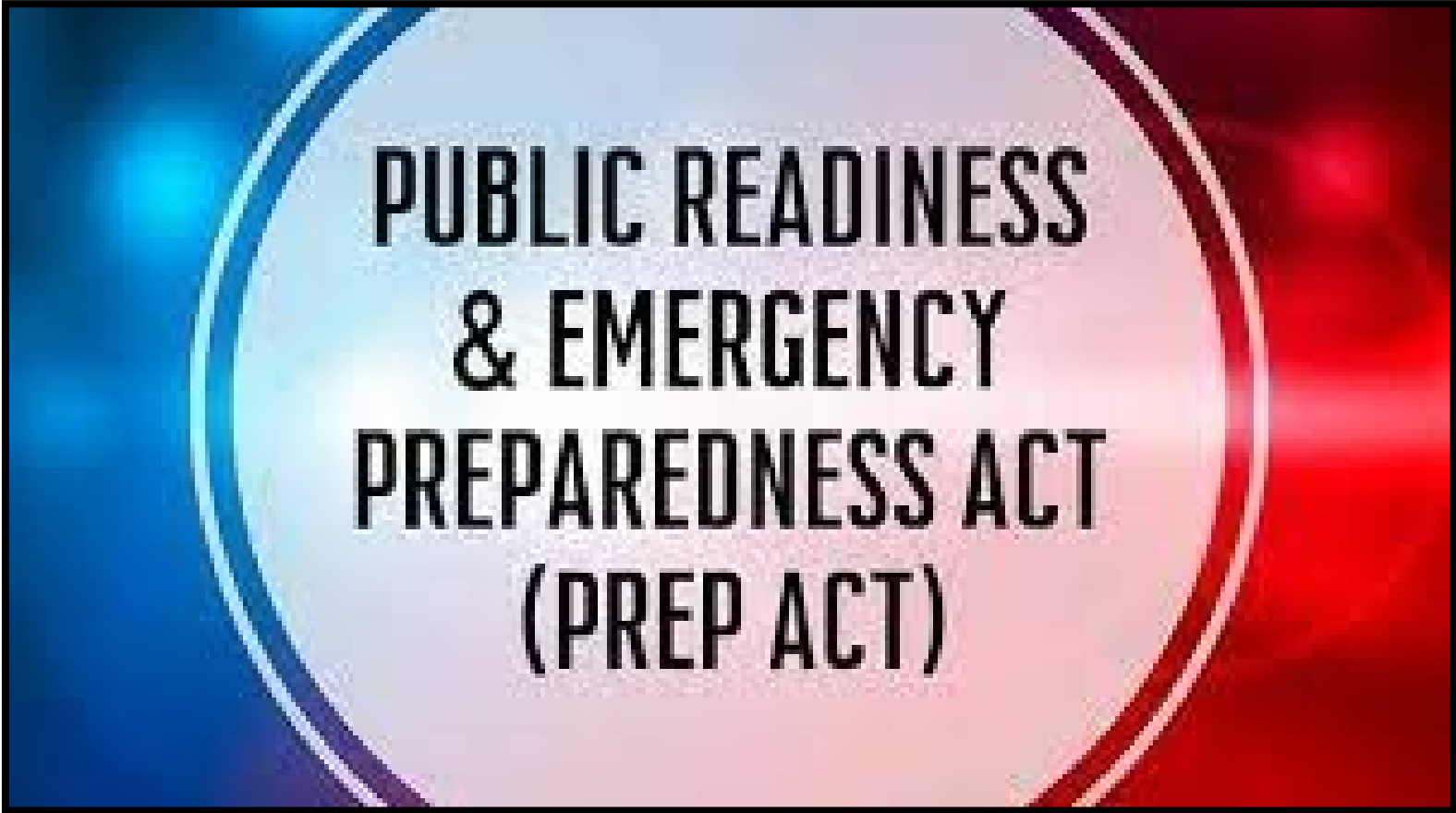




- Pursuant to the national PHE, federal agencies have initiated incentives, contracts, and other legal options to improve national surveillance efforts across states.
- HHS reports that over **50 state and local jurisdictions have executed data use agreements** to share monkeypox surveillance and vaccine 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: monkeypox.



- Reported monkeypox 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.
- **TPOXX** is designated by FDA to treat monkeypox 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.



**PUBLIC READINESS
& EMERGENCY
PREPAREDNESS ACT
(PREP ACT)**

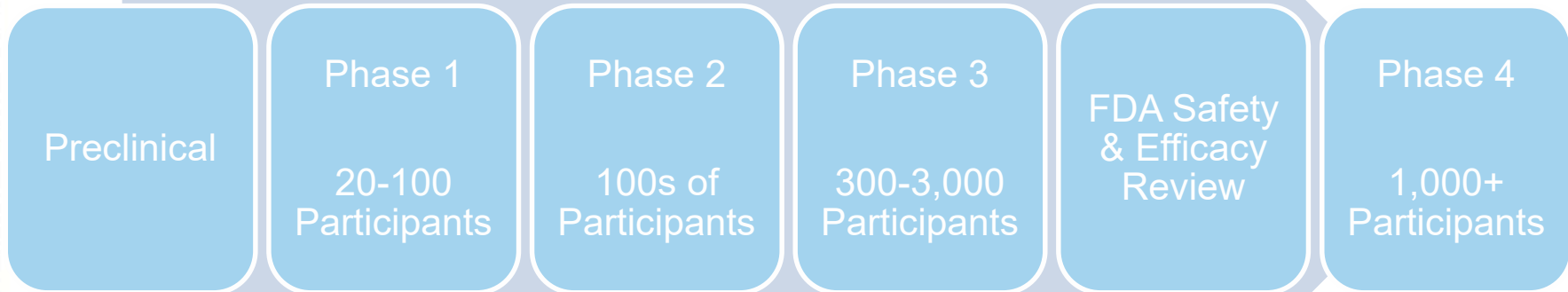


Monkeypox Vaccines

- **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.



FDA Approval & EUA Authorizations



Emergency Use Authorization (EUA):

FDA evaluates evidence available, balancing known risks with known benefits, to determine whether the product “may be effective” and subsequently authorized.



Monkeypox Vaccinations: Complications



- **Aug. 18**: The 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).

Public Health
Seattle & King County



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 monkeypox 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 monkeypox is Black men but they received only 12% of administered doses

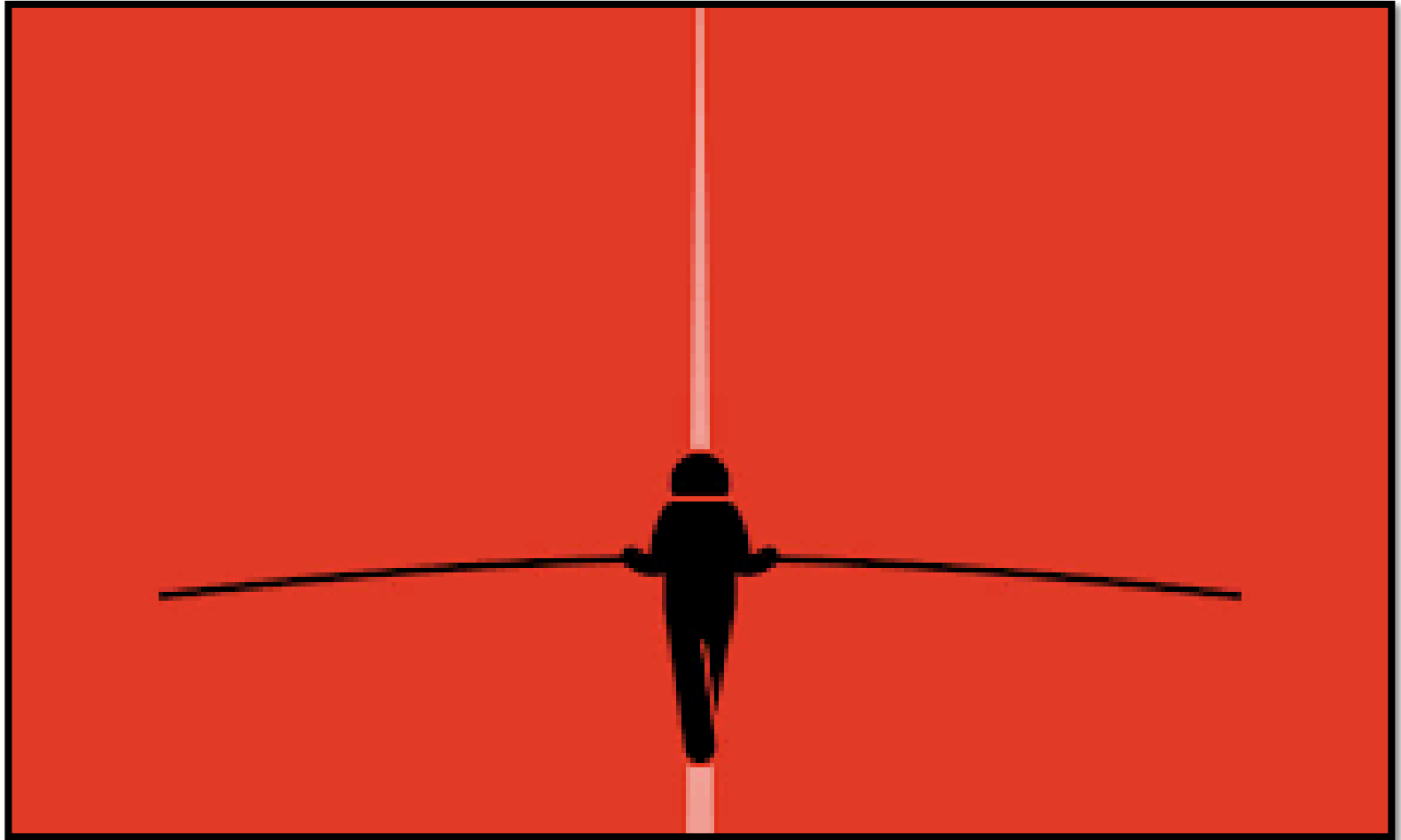
16% of the population considered at-risk to monkeypox is Hispanic men but they received 23% of doses

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 monkeypox 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.





- The HIV/AIDS pandemic revealed how public health strategies must avoid stigmatization or discrimination against specific, at-risk communities.
- With current spread of monkeypox 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 monkeypox 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 monkeypox.”

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

Although *anyone can become infected with monkeypox*, 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



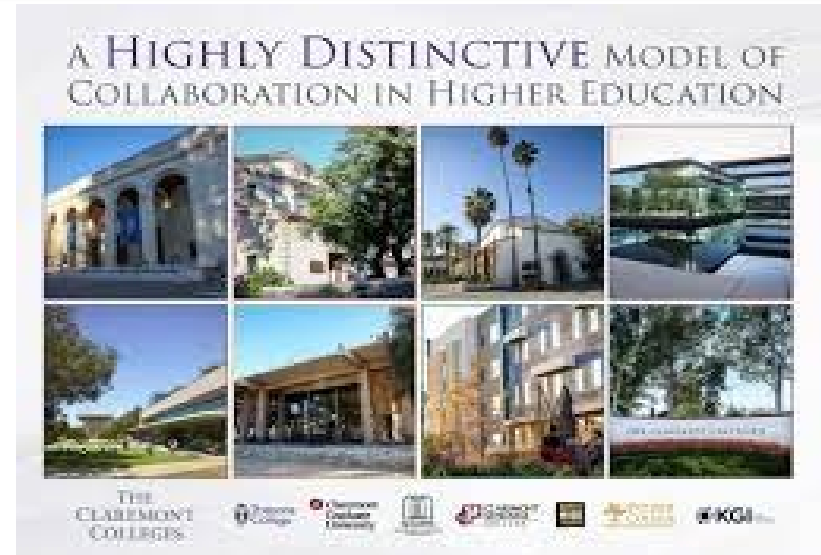
- Many higher education institutions announced plans to prevent monkeypox spread as students return to campus for the Fall 2022.
- Monkeypox infections identified as originating from college campuses could implicate liability concerns.
- **CDC** and the **White House** provided guidance through a virtual meeting with school officials to target monkeypox spread.
- Most schools *do not have vaccines available on campus* but are directing students and faculty to local health departments.
- Monkeypox education provided by colleges varies based on numbers of local cases and presence of active emergency declarations.
- Schools in states with low monkeypox cases may not offer any guidelines.

Monkeypox Policies – Select California Institutions



U. California- Berkeley

- Testing and limited vaccine appointments available on campus for students.
- UC statewide guidance *comporting with state and local emergency orders* and guidance recommends isolation for those with symptoms or testing positive.



Claremont Institutions

- Students with monkeypox infection not required to isolate (despite LA County Department of Health recommendations)
- Contact isolation (covering of rash and wearing mask) is required.

Monkeypox Policies – Select Florida Institutions

Florida International University:

Despite local area case numbers in Miami-Dade (& surrounding) counties that are highest in the state, brief information is posted on the [Student Health & Wellness webpage](#), minimizing risk of infection and lacking express guidance or recommendations.

University of Florida: [University health webpage](#) suggests prevention techniques but does not require isolation. Only CDC guidance is referenced. Vaccines are unavailable or difficult to access.





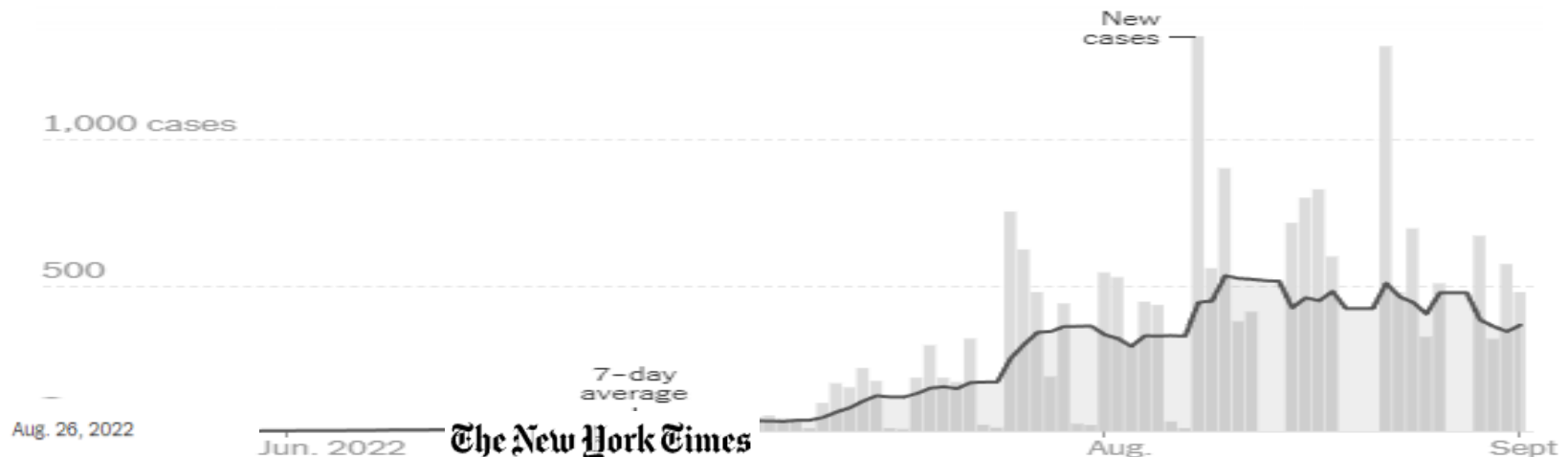
Monkeypox: A “Glancing Blow”?

- **Aug. 25:** WHO reported a 21% decline in cases globally, potentially signifying an overall outbreak decline in the Western hemisphere.
- Coextensively, monkeypox 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.

Access these and other Network materials by clicking [here](#)

[Latest Resources](#)

[Federal Public Health Emergencies](#)

[Social Distancing Powers](#)

[Liability of Health Care Workers and Entities](#)

[Hospital Emergency Legal Preparedness](#)

[State and Local Preparedness](#)

[Emergency Declarations and Powers](#)

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[Public Health Emergency Ethics](#)

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Questions & Comments



Ask the Network re: additional questions/comments

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