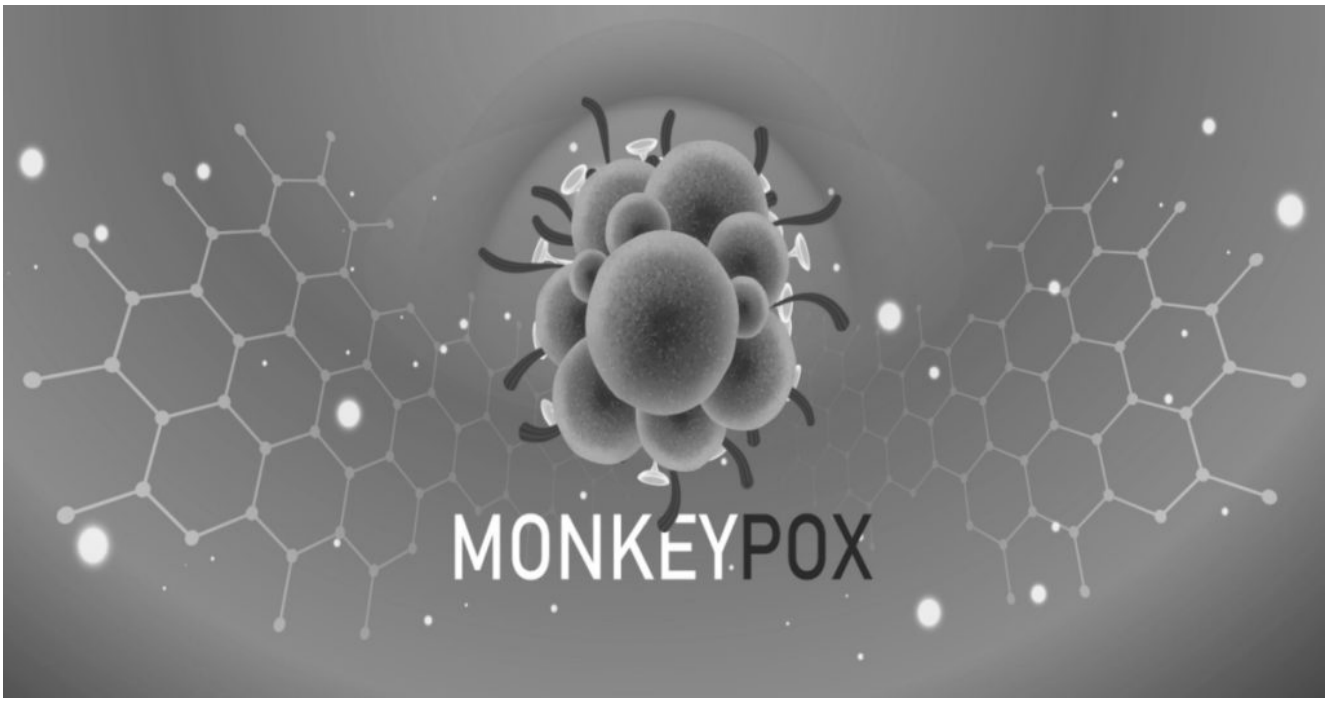
Monkeypox Declared a Public Health Emergency as FDA Gives Vaccine to Kids Despite No Clinical Trials



Department of Health and Human Services Secretary Xavier Becerra on Thursday declared monkeypox a national public health emergency to raise awareness and allow for additional funding to fight the spread.

“We’re prepared to take our response to the next level in addressing this virus, and we urge every American to take monkeypox seriously and to take responsibility to help us tackle this virus,” Becerra said.

Becerra said he is also considering a second declaration that would allow federal officials to expedite medical countermeasures – such as potential treatments and vaccines – designed to ensure drugs are safe and effective.

President Biden said in a tweet later on Thursday that he

remained “committed to our monkeypox response: ramping-up vaccine distribution, expanding testing and educating at-risk communities.”

“That’s why today’s public health emergency declaration on the virus is critical to confronting this outbreak with the urgency it warrants,” Biden said.

The last time the U.S. declared a public health emergency was with COVID-19 in January 2020.

According to the Centers for Disease Control and Prevention (CDC), more than 7,100 cases of monkeypox have been reported in the U.S., including five cases in children.

Symptoms of monkeypox infection are usually mild and include fever, rash and swollen lymph nodes, and occasionally intense headache, back pain, muscle aches, lack of energy and skin eruptions that can cause painful lesions, scabs or crusts.

The virus is rarely fatal and no deaths have been reported in the U.S.

Monkeypox is primarily spread through skin-to-skin contact during sex and affects mostly gay and bisexual men, public health officials say, although the virus can affect anyone.

According to the CDC, about 98% of monkeypox patients who provided demographic information to clinics identified as men who have sex with men.

“Public health emergency” paves way to use vaccine for kids

Monkeypox needed to be deemed a “public health emergency” to pave the way for emergency use authorization (EUA) of the monkeypox vaccine for kids. Only through EUA can a vaccine bypass the years of testing it would otherwise have to undergo

to prove it is safe and effective.

Now that the Biden administration has declared the monkeypox outbreak a public health emergency, the U.S. Food and Drug Administration (FDA) can move to issue an Emergency Use Authorization for the JYNNEOS vaccine for children under 18.

If the agency does so, JYNNEOS would have the special liability protections COVID-19 vaccines enjoy for injuries children experience from the vaccine.

There are currently two vaccines that may be used "for the prevention" of monkeypox virus infection: JYNNEOS – also known as Imvamune or Imvanex – and ACAM2000, which is licensed by the FDA for use against smallpox and "—made available for use against monkeypox under an "Expanded Access Investigational New Drug application."

Moderna is currently looking into developing an mRNA vaccine for monkeypox due to the demand for the shot.

The FDA told ABC News on Thursday that while the current monkeypox vaccine, JYNNEOS, is approved only for adults ages 18 and older, it will be available for kids on a case-by-case basis.

The JYNNEOS vaccine, delivered in a two-dose series, has not been tested through clinical trials in children.

However, the FDA confirmed to ABC News that "numerous" children have been granted access to the vaccine through a special permission process, but declined to state exactly how many children have received the vaccine to date through this process.

"If a doctor decides a person under 18 was exposed to monkeypox and the benefit of the vaccine is greater than any potential risk, they can submit a request to the FDA," ABC News reported.

According to the CDC, the "immune response" takes "14 days after the second dose of JYNNEOS and 4 weeks after the ACAM2000 dose for maximal development."

The CDC's website also states, "No data are available yet on the effectiveness of these vaccines in the current outbreak."

According to the latest data from the Vaccine Adverse Event Reporting System (VAERS), between June 14, and July 21, 2022, 31 adverse events were reported following vaccination with JYNNEOS – manufactured by Bavarian Nordic.

The World Health Organization (WHO) declared monkeypox a global health emergency after more than 26,000 cases were reported across 87 countries.

A global emergency is the WHO's highest level of alert, but the designation does not necessarily mean a disease is particularly transmissible or lethal.

The U.S. makes up 25% of confirmed cases globally although the UK was the first to alert the world to the outbreak in May after confirming several cases.

Like the "Event 201" simulation that was held just weeks before the COVID-19 outbreak – that mirrored what later followed with the COVID-19 pandemic – a similar simulation was held for monkeypox.

According to the Nuclear Threat Initiative, the monkeypox exercise, which was "developed in consultation with technical and policy experts," brought together "19 senior leaders and experts from across Africa, the Americas, Asia, and Europe with decades of combined experience in public health, biotechnology industry, international security and philanthropy."

The fictional start date of the monkeypox pandemic during the exercise was May 15, 2022. The first European case of

monkeypox was identified on May 7, 2022.

Key participants in the simulation included Johnson & Johnson and Janssen, the Bill & Melinda Gates Foundation, the Chinese Centers for Disease Control and Prevention, the Nuclear Threat Initiative, GAVI – the Vaccine Alliance, Merck and the World Health Organization. Several of the participants listed above also “participated” in Event 201.