

# FDA authorizes rationing of the vaccine against monkeypox

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Given the rising rates of monkeypox infections across the US and the limited available doses of the Jynneos vaccine (Imvanex in Europe) made by Bavarian Nordic, the only authorized vaccine against the orthopoxvirus, last week the US Food and Drug Administration (FDA) issued an emergency use authorization (EUA) to ration the vaccine through the use of intradermal injections.

FDA Commissioner Dr. Robert M. Califf said, "In recent weeks, the monkeypox virus has continued to spread at a rate that has made it clear our current vaccine supply will not meet the current demand. The FDA quickly explored other scientifically appropriate options to facilitate access to the vaccine for all impacted individuals. By increasing the number of available doses, more individuals who want to be vaccinated against monkeypox will now have the opportunity to do so."

What the commissioner is explaining is called fractional monkeypox vaccine dosing, or a dose-sparing measure. Instead of giving the vaccine deep into the muscle, one-fifth of the standard dose is injected between the layers of skin. Evidence for the intradermal route was obtained based on a 2015 clinical study conducted by the government which demonstrated it could provide a similar immune response to intramuscular injection. As a result, the total number of available doses has been expanded by five-fold or five doses per vial.

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, speaking during the Centers for Disease Control and Prevention (CDC) seminar to inform clinicians of the change in the interim guidance on the new practice, estimated that approximately 1.7 million Americans were at risk of contracting monkeypox. At least 3 million doses would be needed, although only half that amount would be available by year's end.

The fractional dosing offered the only viable alternative as the ACAM2000 smallpox vaccine, which is available in abundance, carries a significant risk of myocarditis and rare but known complications of death. Specifically, ACAM2000 is contraindicated in immunocompromised individuals.

Yet even as an intradermal injection, the Jynneos vaccine (a smallpox vaccine) still requires two doses to be given 28 days apart to complete the series. It has also not been approved for children under the age of 18. Jynneos has also never been verified to be effective against monkeypox, and little is known about its role as postexposure prophylaxis.

In a letter dated August 9, 2022 sent to Food and Drug Administration (FDA) Commissioner Robert Califf, with copies to White House National Monkeypox Response Coordinator Robert Fenton and his deputy Dr. Demetre Daskalakis, Bavarian Nordic CEO Paul Chaplin wrote: "Bavarian Nordic is dedicated to assisting governments around the globe to control the monkeypox outbreak and is fully supportive of dose-sparing approaches, such as delaying the second vaccination. However, we do have some reservations on the intradermal (ID) approach due to the very limited safety data available (less than 200 people), the higher reactogenicity [adverse reaction] compared to the Jynneos standard dose ... and the fact that there was a relatively high percentage of subjects (20 percent) that failed to receive the second vaccination during a controlled clinical study."

These raise serious concerns about the impact that the intradermal injection approach will have on vaccine uptake and coverage. Additionally, Chaplin criticized the FDA's EUA for not including an implementation protocol to track and gather safety data on the route of administration that would be essential for safe practices. Other questions raised included the duration of the vials remaining open, whether remaining doses could be refrigerated again, the sizes of needles and dosing for pre-and post-exposure prophylaxis.

As of August 12, 2022, global monkeypox cases have reached almost 35,500. The global seven-day rolling average of daily new cases has reached close to 1,400 cases per day. Ninety-four non-endemic countries and territories have reported monkeypox cases, of which nearly one-third have been reported in the United States (11,130). The seven-day rolling average in the US is around 650 cases per day. Only Wyoming remains monkeypox-free thus far.

However, Spain, with 5,719 cases, leads globally per capita. Two of the five deaths related to monkeypox outside non-endemic regions occurred in two previously healthy men in their 30s and 40s, each developing encephalitis, the swelling and inflammation of the brain, which led to their demise. The other three deaths have happened in Brazil, India and most recently, Ecuador. Europe, however, continues to be the epicenter of the monkeypox pandemic.

Little is mentioned by the mainstream press of monkeypox's impact on Africa. The African CDC noted in the last week of July that since the beginning of 2022, more than 2,000 confirmed and suspected cases had been reported among nine endemic and two non-endemic African Union (AU) member states. At least 75 deaths have been documented for a case fatality rate (CFR) of 3.7 percent. During the COVID-19 pandemic, nearly 12,500 monkeypox infections and 365 deaths have been reported, for a CFR of 2.9 percent, underscoring the infection's deadliness and the need to access the vaccines that have been hoarded for more than a decade by the US and EU.

The African CDC noted in its recent press release: "For the last three years (2020-2022), the monkeypox outbreak in Africa continued to grow from one country to another with little international attention. To date, the critical tools required in outbreak preparedness and response, including diagnostics, therapeutics, and vaccines, have not yet been made readily available to AU Member States ... the inequity and delayed access to COVID-19 tools in Africa should not be repeated with monkeypox, which has been a public health emergency since 2020."

In 2013, the US had more than 20 million doses of Jynneos vaccines in its strategic national stockpiles, with another 8 million doses added in 2015. Yet, these vaccines were allowed to expire because of the preferred investment in bulk freeze-dried quantities of the vaccines. These could have been made available to the African CDC at the time to combat the evolving monkeypox outbreak there.

Prior to a major outbreak in 2017, the Nigerian CDC had reported only one monkeypox case in the country dating back to 1971, in a four-year-old child in the southeastern part of the country. On October 13, 2017, the Nigerian CDC received confirmation of a human monkeypox case, and by November 17, 2017, there were 146 suspected cases reported from 22 of the 36 states. Women made up a third of cases, and one immunocompromised person died from complications. Many of the cases were in urban centers, implying the likelihood that the disease would spread internationally. In 2018, Nigerian scientists led by Adesola Yinka-Ogunleye warned of a growing outbreak of monkeypox infections spreading among people in the country.

Madhukar Pai, director of McGill University's global health programs in Montreal, told *Quartz*, "I don't expect rich nations to do anything different with monkeypox. They will do exactly what they did with COVID: corner the vaccine supplies, hoard them, and block vaccine manufacturing in low- and middle-income countries. And just like we are seeing no end to COVID, monkeypox will be kept alive and well because of the myopia and greed of rich nations."

In his estimates of the number of people at risk, Marks' projections fail to account for the inevitability that monkeypox will spread to other communities, upending the false narrative that the virus is a sexually transmitted disease that only affects men who have sex with men.

Though the number of children that have contracted monkeypox remains comparatively small, on August 9, 2022, the Robert Koch Institute, Germany's leading health authority, reported a case of monkeypox in a four-year-old girl living with two infected adults in Pforzheim, according to *Deutsche Welle*. Other countries with cases in children include the US, France, the Netherlands and Spain. Of the 98 documented infections globally in children, 25 cases have been in children four years and younger, who also happen to be the most susceptible to severe disease and death.

Meanwhile, five US colleges have already reported monkeypox cases this summer, even with most students away. Recently, Clark County School District in Washington state identified a case at Palo Verde High School, and last week a daycare worker in Champaign County, Illinois, was diagnosed with the infection. These raise the specter of a growing outbreak as K-12 schools and colleges reopen across the US and internationally in the coming weeks.

With nearly 2,000 cases, California is seeing hundreds waiting in lines for vaccines only later to be turned away. Meanwhile, there is too little testing and treatment despite the recent declaration of a public health emergency. Despite the claims of increased testing capacity, on August 2, the California health department received only 6,682 monkeypox test results, with a positivity rate of around 19 percent, highlighting that there is nowhere near enough testing being performed.



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