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AUGUST 15, 2024



Stock prices for mpox vaccine maker Bavarian Nordic surged after the World Health Organization (WHO) on Wednesday declared mpox a **global public health emergency**.

The company's share prices jumped 17% in early trading in Copenhagen today, **Forbes reported**, after climbing 12% yesterday when the WHO made its announcement. In the U.S., shares were up 33% this morning.

The WHO cited recent outbreaks in the Democratic Republic of Congo (DRC) and neighboring nations in its declaration.

In the first known infection of its kind outside Africa, **Sweden today confirmed a case** of the highly contagious strain of mpox, according to NBC News. The WHO's European regional office in Copenhagen said it was discussing with Sweden how best to manage the newly detected case, according to **Medical Xpress**.

This is the second time in two years the WHO has declared mpox a "public health emergency of international concern" PHEIC — **pronounced "fake"** — which is its highest form of an alert.

The announcement follows a **declaration Tuesday** by the Africa Centres for Disease Control and Prevention that mpox is a continent-wide public health emergency.

Last week, the **WHO triggered the process** to grant **Emergency Use Listing** to two mpox vaccines, although it didn't name which ones it would list. The agency also **invited manufacturers of mpox vaccines** to submit an "expression of interest" for Emergency Use Listing.

The DRC, where the outbreak is concentrated and most severe, has **approved two vaccines** — Japan's LC16 and Bavarian Nordic's Jynneos, which is also marketed as Imvamune and Imvanex.



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Bavarian Nordic is one of the few companies in the world with an already-approved mpox vaccine that is also available in large quantities. Other contenders, such as Emergent BioSolutions' **ACAM2000** have been available under special investigational protocols. Others, like **Tonix Pharmaceuticals**, have experimental shots that are in earlier stages of development.

LC16 is a smallpox vaccine licensed in 1980 in Japan and **approved in July 2022 for mpox**. It isn't commercially available, but there are large supplies in Japan's national stockpile, the **Center for Infectious Disease Research and Policy** reported. Like Jynneos, it is a third-generation mpox vaccine that uses **attenuated virus strains**.

Jynneos and ACAM2000 can cause myocarditis, pericarditis and other serious side effects at high rates, Dr. Meryl Nass told The Defender last week, as the **labels** for both drugs indicate.

The **Japanese LC16 vaccine** also has been linked to encephalitis, Nass reported on her Substack today.

"The WHO is using the monkeypox outbreak in Africa to fast-track, under emergency use, two monkeypox vaccines," **Dr. Kat Lindley**, a senior fellow at FLCCC Family Medicine and president of the **Global Health Project** told **The Defender**.

"We need to use discernment and evaluate risks and benefits before recommending any experimental new product to a vulnerable population," she said.

The African CDC in a **LinkedIn post** said it needed 10 million doses to control the outbreak and called for global support for its vaccination efforts.

Bavarian Nordic's CEO Paul Chaplin told Bloomberg the company can provide 10 million doses of its vaccine to African countries over the next year and a half.

In an interview Wednesday — before today's stock price surge — Chaplin said, "We have inventory and we have the capabilities. What we're missing are the orders."

In May 2022, the WHO announced it would phase out the name "monkeypox" and rename the disease "mpox" to avoid the stigma generated by associating the disease with monkeys.



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WHO process for issuing PHEIC declarations 'non-transparent and contradictory'

WHO Director-General Tedros Adhanom Ghebreyesus said in his press announcement that the agency decided to declare a PHEIC because:

"The detection and rapid spread of a new clade of mpox in eastern DRC [**Democratic Republic of Congo**], its detection in neighboring countries that had not previously reported mpox, and the potential for further spread within Africa and beyond is very worrying."

The WHO declaration signals a public health risk requiring an international coordinated response. It can lead to WHO member countries and private investors pouring substantial resources into countries with outbreaks to facilitate sharing of vaccines, treatments and testing.

The declaration also **grants the WHO authority** to issue travel warnings or restrictions, to review and critique the validity of public health measures by member countries and to help persuade people that they ought to follow public health recommendations.

This is the eighth public health emergency the WHO has declared since 2007, when it substantially revised its International Health Regulations (IHR). Critics have called the process for designating such an emergency "**non-transparent and contradictory**."

In July 2022, the **WHO declared mpox a global emergency** after reporting the disease had spread to **more than 70 countries**, mostly affecting gay and bisexual men. At the time, Tedros made the declaration unilaterally, in direct contradiction to independent review panel advice.

At that time, the Jynneos vaccine was licensed in the U.S. and ACAM2000 was "made available for use against mpox in the current outbreak [2022] under an **Expanded Access** Investigational New Drug (EA-IND) protocol." Jynneos received emergency use authorization in the U.S. for children under 18 considered to be at high risk.

Although in the U.S. monkeypox has appeared to be a mild illness, several lucrative **government contracts** in 2022 paid the vaccine makers **hundreds of millions** to stockpile the vaccines.

The **2022 outbreak** reportedly affected nearly 100,000 people, primarily gay and bisexual men, in 116 countries and about 200 people died.

Despite media hype and hundreds of thousands of dollars spent to stockpile mpox vaccines in the U.S., the designation was quietly withdrawn in May 2023, “given the **sustained decline in cases.**”

On Aug. 8, the Biomedical Advanced Research and Development Authority renewed its **contract with Bavarian Nordic**, committing \$156.8 million to manufacture and store Jynneos doses to partly replenish the inventory used to manufacture vaccines in response to the mpox outbreak in 2022.

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Critics suggest ‘common sense mitigation measures’

Mpox was first detected in humans in 1970 in the DRC, **according to the WHO**, and is considered endemic to countries in central and west Africa, with the number of cases rising and falling periodically.

The disease causes flu-like symptoms and pus-filled lesions. It is usually mild but can be serious, particularly in people with weakened immune systems, **Reuters reported.**

In its announcement Wednesday, the WHO said the DRC is experiencing a severe **outbreak of mpox**, with 15,600 cases and 537 deaths. It said the current outbreak is caused by a virus strain, or “clade” — clade 1b — that is more severe than clade 2, which was responsible for the global outbreak in 2022.

It “appears to be spreading mainly through sexual networks,” and it has been detected in neighboring countries of Burundi, Kenya, Rwanda and Uganda, with 100 “laboratory-confirmed cases of clade 1b” in total in those countries.

Lindley said health officials are most likely using PCR tests, which were shown during the COVID-19 pandemic to generate false positive results.

“We really have no idea,” she said, if the alleged deaths are “complications of people who have depressed immune systems and are dying of other things.”

“Why would we start mass vaccination with a new product for which we know nothing about the safety profile when common sense mitigation measures can work?” she asked. “If it is sexually transmitted, use a condom or abstain from sex. If it can be transmitted through secretions, wash your hands and don’t touch people with clinical presentation.”

Nass expressed similar skepticism on her **Substack**:

“If this generally mild viral illness is killing people, what is the cause of death? Does it only cause death in severely immune suppressed patients? Are babies dying due to dehydration? Do we need to treat babies with fluids rather than give them a vaccine that was never tested in babies? Lots of unanswered questions.”



Brenda Baletti, Ph.D.

Brenda Baletti, Ph.D., is a senior reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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