FDA Experts Recommend Emergency Authorization of Novavax COVID Vaccine, Ignore Risk of Heart Inflammation

The U.S. Food and Drug Administration's (FDA) vaccine advisors recommended the Novavax COVID-19 vaccine for emergency use authorization on Tuesday, paving the way for a fourth U.S. vaccine.

The panel's vote was 21 in favor of authorizing Novavax and one abstention. However, FDA authorization could be delayed because the company informed the agency just four days before its experts met that it had changed its manufacturing process.

During the panel's discussions, Dr. Eric Rubin, editor in chief of The New England Journal of Medicine, said data for the Novavax vaccine look a lot like mRNA vaccines Moderna and Pfizer-BioNTech – which is not even remotely reassuring.

Of course, we can't confirm Rubin's statement for ourselves

because we don't have Moderna's data and the FDA wants to wait at least 75 years to disclose data underlying its approval of Pfizer's COVID-19 vaccine.

Before the shots can be used, the FDA would need to sign off on the company's manufacturing practices and accept the panel's recommendation, which it is not required to do. The Centers for Disease Control and Prevention (CDC) must also recommend the shots before they can be used.

Novavax is an original recipient of $1.8 billion in taxpayer funding from Operation Warp Speed. The company has never brought a product to market and has had numerous issues with its manufacturing process.

Prior to the pandemic, Novavax failed two vaccine trials in less than 3 years and the firm's shares had plunged to less than $1 for 30 straight days, triggering a warning by NASDAQ prior to landing its gig to produce a COVID-19 vaccine.

According to The New York Times, the U.S. government agreed to buy 110 million doses of Novavax if the vaccine is authorized, but "flushed with effective vaccines," [that rapidly wane, do not prevent COVID-19 or transmission and are not safe] has little need for more.

The Novavax vaccine is a protein subunit vaccine that does not use mRNA or adenovirus vector technologies. Instead, it contains nanoparticles made up of proteins from the surface of the coronavirus and uses moth cells to produce spike protein.

According to SCIENCE, baculoviruses loaded with the gene for the coronavirus spike protein invade moth cells. The moth cells then express the coronavirus spikes on their cell membranes. Scientists harvest the proteins and mix them with a delivery vehicle: synthetic particle.

Each "nanoparticle" ends up studded with up to 14 spike

proteins. Then Novavax adds its saponin adjuvant – a compound found in soap bark trees that stimulates the immune system.

"Having a protein-based alternative may be more comfortable for some, in terms of their acceptance of vaccine," said Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. "We do have a problem with vaccine uptake that is very serious in the United States, and anything that we can do to get people more comfortable to be able to accept these potentially life-saving medical products is something we feel we are compelled to do."

In clinical trials, the Novavax vaccine was found to have an efficacy of 90.4% at preventing mild, moderate or severe infection with older variants of the virus that are essentially gone. Because none of the clinical trial participants who got the vaccines experienced moderate to severe infection, the company claims its efficacy is 100%.

In FDA briefing documents scientists identified six cases of myocarditis and pericarditis, types of heart inflammation, in 40,000 volunteers.

"Multiple events of myocarditis/pericarditis were reported in temporal relationship to NVX-CoV2373 [the Novavax vaccine used during the trials] administration, similar to myocarditis following mRNA COVID-19 vaccines and raising concern for a causal relationship to NVX-CoV2373," the documents state.

The FDA said the cases raise concern Novavax was the cause and that rates of heart inflammation could be higher than with mRNA vaccines. Novavax denied the claim stating, "data showed that overall the rate of myocarditis was balanced between the vaccine and placebo arms."

"We believe that the totality of the clinical evidence here is not enough to establish an overall causal relationship with the vaccine," said Dr. Denny Kim, Novavax's chief safety officer.

According to Dr. Lucia Lee, an official with the FDA's division of vaccine research, the myocarditis cases that occurred in young males are "concerning" because they were recorded within days of vaccination, and because there is already an established connection between other COVID-19 vaccines and heart inflammation.

However, advisers on the FDA committee ignored the above assessment in voting to recommend the Novavax vaccine.

Novavax said their vaccine had a "reassuring safety profile" and the most common adverse events were headache, nausea or vomiting, myalgia, arthralgia, injection site tenderness/pain, fatigue and malaise.

FDA briefing documents show:

> *"Events of lymphadenopathy were infrequent but reported by a higher proportion of participants in the NVX arm, with the highest rate observed after Dose 2 (0.2%).*
>
> *"Review of the data also identified small imbalances in certain thromboembolic events, including cardiac and neurovascular events, hypersensitivity events, cholecystitis, uveitis, cardiac failure, and cardiomyopathy.*
>
> *"Data from passive surveillance during post-authorization use in other countries also indicate a higher-than-expected rate of myocarditis and pericarditis (mainly pericarditis) associated with the vaccine."*

The Novavax vaccine has already been authorized in India, South Africa and Britain, and has also received clearance from the European Union and World Health Organization.

FDA approval for the Novavax vaccine had previously been

expected as early as February. The company submitted its final trial data to the FDA on Dec. 31, 2021, and applied for emergency authorization in the U.S. and nine other countries.