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Written by **Veronika Kyrylenko** on July 14, 2022

FDA Authorizes Novavax Covid Shot to Increase Vax Rate, Biden Buys 3.2 Million Doses

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Trying to convince some 100 million unvaccinated Americans to get a Covid shot, U.S. federal regulators have just authorized another Covid vaccine called Novavax. The reasoning behind the move is that if a person is hesitant to take gene-editing mRNA vaccines from Pfizer and Moderna or vector-based Johnson & Johnson, he or she would probably find a vaccine that uses moth cells to grow the most toxic part of the virus — spike protein — a "safer" option.

Commenting on the Emergency Use Authorization (EUA) for Novavax, FDA Commissioner Robert M. Califf said, "Today's authorization offers adults in the United States who have not yet received a COVID-19 vaccine another option that meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality needed to support emergency use authorization."

Despite such claims, FDA-authorized Covid vaccines already in use are associated with more than 1.3 million adverse events and more than 29,000 deaths. Those numbers, apparently, are not significant, and the FDA's sister agency, the U.S. Centers for Disease Control and Prevention (CDC), does not even evaluate them. Moreover, the FDA has been sued to release all documents that it was supposed to review prior to granting full approval to Pfizer-BioNTech. The agency refused, saying it needed at least 75 years to release the documents it reviewed within nine months, although the judge gave the regulators until August 2022 to make them public. Analysis of the data presented to the FDA revealed that the shots are ineffective at preventing Covid and were clinically shown to cause a wide range of severe adverse reactions, including for pregnant women and their babies. Then, there are FDA documents explicitly showing more than 40,000 adverse reactions and 1,200 deaths linked to the Pfizer shot in just two and a half months of its being administered to the public. Yet the FDA finds nothing troubling about that.

Back to Novavax. How does it work?

According to the FDA,

> The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose primary series, three weeks apart. The vaccine contains the SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual. The spike protein in this vaccine is produced in insect cells; the

> Matrix M-adjuvant contains saponin extracts from the bark of the Soapbark tree that is native to Chile.

Novavax describes the steps in the creation of its investigational vaccines, including those for Covid.

An "investigational" medical product means that it is experimental and "is being studied to see if your disease or medical condition improves while taking it," according to the FDA.

The Washington Post produced an instructional video on how Novavax uses moth cells to create its coronavirus vaccine.

The narrator describes how researchers at Novavax "hijack the ovaries of the fall armyworm" and infect them with a genetically-modified baculovirus (a type of insect virus) to contain SARS-CoV-2 spike protein." Then, just like human cells, moths' cells produce spike proteins and then antigen proteins, so "the match is perfect," explained the president of research and development of Novavax, Gregory Glenn, in the video.

Speaking with *The New American* in July of 2021, Dr. Richard Fleming warned against using Novavax, arguing that the spike protein is an actual biological weapon.

Regarding the safety of the shot, it is linked to the increased risk of myocarditis (inflammation of the heart muscle), pericarditis (inflammation of the lining outside the heart), injection-site reactions (pain, redness, swelling, itching), general side effects (fatigue, joint pain, vomiting, muscle pain, etc.), and allergic reactions, according to the FDA. There are no long-term safety studies of the shots. Some of the participants were observed for just four months.

Regulators estimated that the new shot was 90.4-percent effective in preventing mild, moderate, or severe Covid. The figure was lower for those over the age of 65, standing at 78.6 percent. It is not clear how long this immunity lasts, or whether additional doses will be required to maintain this level of protection.

Additionally, unlike the mRNA-based competitor vaccines, Novavax is much more forgiving in terms of storage and does not require storage in subfreezing temperatures. It is also said to have a longer shelf life.

The shot comes in 10-dose vials, which suggests that it would be challenging to get a consistent quantity of the antigen and adjuvant across the 10 different draws from the vial.

The FDA's advisory panel on vaccines, the Vaccines and Related Biological Product Advisory Committee (VRBPAC), endorsed the use of Novavax on June 7.

There are still unanswered questions regarding the studies showing that the Matrix-X adjuvant is safe. It was mentioned during the discussion that there are studies ongoing in West Africa to estimate the safety, though they are not yet concluded. Gregory Glenn told NBC Chicago that each such adjuvant particle is "basically a soap bubble. It's made of stuff that you find in root beer." That may be, but is it safe to mix with moth-produced proteins and inject it into humans?

It also is not clear whether the shot produces sterilizing immunity (meaning, the recipient does not get infected with Covid), and whether it protects against omicron (it was not yet circulating during the clinicals and is not listed on the company's presentation slides).

When considering taking Novavax, one should be aware that there have been unexplained irregularities

during the trials that are described here.

According to Novavax, even before the FDA formally authorized the short, the Biden administration had placed an order for 3.2 million doses of the new shot. However, it won't be available until the CDC's Advisory Committee on Immunization Practices (ACIP) approves it. Currently, the committee is scheduled to meet July 19.