FDA advisers back Novavax COVID shots as 4th US option

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In this image provided by the Serum Institute of India, vials of freshly manufactured Novavax COVID-19 vaccines wait to be labeled in 2022, in Pune, India. The more traditional kind of COVID-19 vaccine moved a step closer to the U.S. market Tuesday, June 7, 2022. Advisers to the Food and Drug Administration voted to back shots made by Novavax for U.S. adults. If the FDA ultimately agrees, Novavax's option could become the nation's fourth COVID-19 vaccine. Credit: Serum Institute of India for Novavax via AP, File

American adults who haven't yet gotten vaccinated against COVID-19 may soon get another choice, as advisers to the Food and Drug Administration on Tuesday backed a more traditional type of shot.

Next, the FDA must decide whether to authorize the protein vaccine made by latecomer Novavax as the nation's fourth coronavirus shot for adults. It's made with more conventional technology than today's dominant Pfizer and Moderna shots and the lesser-used Johnson & Johnson option.

N ovavax shots are already available in Australia, Canada, parts of Europe and multiple other countries, either for initial vaccinations or as mix-and-match boosters. But U.S. clearance is a key hurdle for the Maryland-based company.

FDA's vaccine chief Dr. Peter Marks said another choice in the U.S. may entice at least some vaccine holdouts—whatever their reason—to consider rolling up their sleeves.

"We do have a problem with vaccine uptake that is very serious in the United States," Marks said. "Anything we can do to get people more comfortable to accept these potentially life-saving products is something that we feel we are compelled to do."

A final FDA decision isn't expected immediately, as the agency finishes combing through the data.

Nor is it clear how widely a Novavax vaccine would be used, at least right away. Only about 27 million U.S. adults remain unvaccinated, according to the Centers for Disease Control and Prevention. Eventually, Novavax hopes also to become a choice for the millions more who haven't yet had a booster dose of today's vaccines, regardless of which shot people got originally.

The FDA advisory panel voted that the benefits of two primary Novavax doses outweigh its risks—but they had a lot of questions about the shots' role at this point in the pandemic.

"This vaccine does indeed fill some unmet needs," such as an option for people with allergies to competing shots, said Dr. Michael Nelson of the University of Virginia.

But the FDA is considering two adult doses for now, when other COVID-19 vaccines have needed a third dose, he said.

And while "this vaccine has incredible potential," there's no clear evidence yet of how well it works against the more contagious omicron variant and its siblings, added fellow adviser Dr. Bruce Gellin of the Rockefeller Foundation.

Large studies in the U.S., Mexico and Britain found two doses of the Novavax vaccine were safe and about 90% effective at preventing symptomatic COVID-19. One complication: Those studies were done far earlier in the pandemic.

Novavax chief medical officer Dr. Filip Dubovsky said tests of a booster dose revved up virus-fighting antibodies that could tackle the omicron mutant, data that FDA will have to consider later.

This type of vaccine "we think generates a broad immune response against a broad array of variants," he told the FDA advisory panel.

Trial participants generally experienced only mild reactions such as injection-site pain or fatigue, but the FDA did highlight a possible concern: six cases of heart inflammation, known as myocarditis, found among the 40,000 people who received the vaccine in studies.

COVID-19 vaccines are coming under close scrutiny for the possibility of heart inflammation after the Pfizer and Moderna shots were linked to that rare risk.

Novavax argued there were other potential causes for the reports. Other infections including COVID-19 also can cause heart inflammation. The company said more than 744,000 vaccinations in other countries so far support the shots' safety.

Several of FDA's advisers said the Novavax vaccine should come with a warning until more is known but cautioned against comparisons with the Pfizer and Moderna shots' estimated rate of the rare side effect.

"I don't want to stigmatize this vaccine inappropriately," said Dr. Cody Meissner of Tufts University.

The Novavax vaccine is made of copies of the spike protein that coats the coronavirus, packaged into nanoparticles that to the immune system resemble a virus. Then an immune-boosting ingredient, or adjuvant, that's made from the bark of a South American tree is added that acts as a red flag to ensure those particles look suspicious enough to spark a strong immune response.

Protein vaccines have been used for years to prevent hepatitis B, shingles and other diseases.

That's very different than the vaccines currently used in the U.S. The most widely used Pfizer and Moderna vaccines deliver genetic instructions for the body to produce its own copies of the spike protein. J&J uses a cold virus to deliver those instructions.

Manufacturing problems held up Novavax's vaccine but the company said those problems have been resolved. Novavax, a small biotech

company, created the vaccine in its research lab. But the Serum Institute of India, the world's largest vaccine maker, produces most of its shots including those slated for the U.S.