

The Virgin Islands Consortium

FDA Advisers Approve Pfizer's Covid-19 Vaccine For Children Ages 5-11, Setting the Stage for Availability in November

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Experts on a panel called the Vaccines and Related Biological Products Advisory Committee, which has been advising the Food and Drug Administration, on Tuesday voted 17-0, with one abstention to recommend that the FDA approve Pfizer's Covid-19 vaccine for children ages 5-11, setting the stage for use as early as next week.

The panel concluded that the benefits outweighed any risks, and U.S. health officials have said widespread availability is expected in November.

About 28 million children in the U.S. and its territories would be eligible. “Severe pediatric Covid is not nearly as common as in adults, but it does happen and it’s not negligible,” said Dr. Ofer Levy, a panel member and director of the Precision Vaccines Program at Boston Children’s Hospital (via the Wall Street Journal). “I think this vaccine will likely be effective in reducing pediatric Covid in this age group, and may also help reduce transmission.”

The FDA must clear a vaccine before it can be used outside of testing. A greenlight from the FDA is followed by guidance from the Centers for Disease Control and Prevention to facilities such as pharmacies and vaccination sites as well as doctors. The CDC also sets policy for vaccine use.

In a study of 2,268 children 5 to 11 years, the Pfizer-BioNTech vaccine was generally well-tolerated and generated levels of neutralizing antibodies comparable to those seen in subjects who were 16 to 25 years, according to the companies. Pfizer is also the furthest ahead in advancing shots for children.

The panel held discussions on the risk of myocarditis, a heart-inflammation condition found in a small number of young men and male teenagers who have received mRNA vaccines. The Pfizer-BioNTech and Moderna Inc. shots use mRNA technology. There were not cases of myocarditis found in the children’s study, however the study was too small to detect the potential risk, according to Pfizer and BioNTech.

While some panel members shared concerns about the risk of myocarditis and other potential side effects, they wanted to make sure that the vaccine was available for children with the highest risk of becoming ill. According to WSJ, earlier in the meeting, U.S. health officials told the panel that two-thirds of hospitalized children have underlying medical conditions.

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While children are generally at low risk of severe Covid-19 disease or death, there was a marked increase in hospitalization among that age group as a result of the Delta variant. Additionally, physicians and doctors have said vaccination in children is important not only to protect the youngsters, but also those around them. The V.I. Dept. of Health [said late Sept.](#) that infections at daycare centers and school-age children represented a majority of the positive cases during that time period.