

**Pfizer**

## FDA to debate authorizing Pfizer's Covid vaccine for kids aged five to 11

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Independent experts with the Food and Drug Administration (FDA) will debate whether to recommend the **Pfizer** Covid-19 vaccine for children aged five to 11 on Tuesday. The vaccine is currently authorized for children 12 years of age and older.

Vaccine authorization for young children has been widely anticipated by parents in the US, as a wave of Covid-19 fueled by the Delta variant took hold across the country just as many students were returning to classrooms. The **Biden administration** also sees it as an important next step in the vaccine rollout program, which has slowed considerably.

The advisory committee is hearing evidence from Pfizer and regulators, debating whether to recommend emergency authorization of kid-sized vaccines, and will vote on a recommendation by the end of the day. Regulators do not always follow independent committees' advice, but they usually do.

The debate has hinged largely around whether the benefits of the vaccine - including the social and physical health of children during the pandemic - outweigh the risks of rare side effects like myocarditis, an inflammation of the heart muscle.

Advisers and officials have also pointed to the importance of vaccinating children in order to halt community spread of the virus.

According to seroprevalence data, “infections in children are less likely to be reported compared with adults, but children are at least as likely as adults to be infected with SARS-CoV-2,” said Fiona Havers, a medical officer at the CDC.

This meeting is the first of four steps. Next, the FDA will weigh the advisers' recommendations to make a decision on authorizing the vaccine in the next few days. Then, independent advisers with the CDC will meet next week to form their own recommendations, which would inform the CDC's decision.

If authorized, a campaign to vaccinate roughly 28 million elementary school-aged children will begin, with vaccines distributed through pharmacies, community clinics, pediatricians' offices and some school-based clinics.



▲ 'Get it today': Biden urges Americans to get Pfizer vaccine after FDA approval - video

While hospitalization and death rates are lower among young children as compared to adults, kids have made up an increasing share of cases amid a Delta-driven summer surge, especially as in-person school has resumed.

Children between five and 11 have one of the highest case rates of any age group, accounting for about one in 10 of all Covid cases in the country.

Five-to-11 year-olds have had more than 1.9m infections, 8,300 hospitalizations, and 2,500 cases of multisystem inflammatory disorder from Covid-19.

Nearly 100 children in this age group have died, making it the eighth leading cause of death in the past year for this group.

But the effects of the pandemic are unequal among children, as they are among adults. Black, Hispanic and Native American children have a greater risk for developing severe illness like MIS-C or dying from Covid-19.

Although children with underlying medical conditions such as asthma, diabetes and obesity made up the majority of severe Covid cases, about one-third had no known health conditions, Havers said on Tuesday.

Illness and death are not the only risks, officials said.

“There are many other adverse outcomes on children from the pandemic, including worsening emotional and mental health, decreased physical activity and loss of caregivers,” Havers said. “Lost in-person learning is another potential adverse outcome of Covid-19.”

Children may also spread Covid-19 to adults even if they are not themselves severely ill.

“Children likely play an important role in transmission, and vaccinating children can help reach herd immunity,” said William Gruber, head of vaccination development at Pfizer.

The Pfizer-BioNTech vaccine among kids was roughly as effective against the Delta variant as against the original virus, Gruber said.

To study the safety and efficacy of vaccines in kids, the Pfizer-BioNTech trial included 1,518 children who received the vaccine beginning in June, as well as an additional 1,591 children who were vaccinated beginning in August, when the FDA asked the company to expand the trial in order to identify any safety concerns.

Each participant received two shots spaced three weeks apart, and were followed for two months afterward.

The study found Pfizer's vaccines were about 91% effective in children, based on 16

The study found Pfizer's vaccines were about 91% effective in children, based on 16 cases of Covid-19 in the placebo group and three cases in the vaccinated group.

Most side effects kids experienced occurred within a couple of days and included pain at the injection site, fatigue, headache, muscle pains and chills. The study did not find any cases of myocarditis, or heart inflammation, though the size of the study makes it unlikely for the condition to have presented itself.

There is probably a link between messenger RNA vaccines, such as the vaccine developed by Pfizer, and heart inflammation, the CDC has said.

Myocarditis cases after vaccination tend to happen within a week, and boys between the ages of 16 and 17 have the highest rate, at 0.007%, said Matthew Oster, a medical officer for the CDC. "Testosterone and hormones play a big role in this, which is part of why you may see a really high peak in adolescence and young adulthood, especially among males," Oster said.

While rare cases of myocarditis are important adverse events to continue following, Oster said, "not all myocarditis is the same". Vaccine-induced myocarditis tends to be more mild than myocarditis caused by viral infections, for instance, and patients usually return to normal "within a few days".

About one-third of parents said they would get their young children vaccinated "right away", and another one-third said they would "wait and see" whether to vaccinate their children, according to the [Kaiser Family Foundation](#). Last week, the White House announced an education campaign targeted at parents.

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