



Pharmacist Colleen Teevan reconstitutes the Pfizer-BioNTech vaccine before having it administered to people at the Hartford Convention Center in Hartford, Connecticut, on Jan. 4, 2021. (Joseph Prezioso/AFP via Getty Images)

VACCINES & SAFETY PREMIUM

FDA Authorizes Pfizer COVID-19 Vaccine for Emergency Use in Children Aged 5 to 11

BY JACK PHILLIPS October 29, 2021 Updated: October 29, 2021

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The Food and Drug Administration ([FDA](#)) on Friday issued an emergency authorization to use [Pfizer's](#) COVID-19 vaccine in children aged 5 through 11, coming days after an advisory panel recommended it.

But before the shots can be distributed across the United States, the Centers for Disease Control and Prevention (CDC) must first sign off on the move.

“As a mother and a physician, I know that parents, caregivers, school staff, and children have been waiting for today’s authorization. Vaccinating younger children against COVID-19 will bring us closer to returning to a sense of normalcy,” acting FDA Commissioner Dr. Janet Woodcock said in a [statement](#) Friday.

The FDA’s Vaccines and Related Biological Products Advisory Committee voted overwhelmingly to back a smaller dose of the Pfizer-BioNTech mRNA vaccine for younger children. Children aged 12 and older have been eligible to get the vaccine for months.

In a news release, the FDA said that immune responses in younger children were similar to individuals aged 16 to 25. Based on an ongoing study from the agency, the FDA said that the vaccine was 90.7 percent effective in preventing COVID-19 in kids aged 5 to 11.

About 3,100 children in that age group have not displayed serious side effects in the ongoing study, the agency continued.

“The FDA has determined this Pfizer vaccine has met the criteria for emergency use authorization,” it said. “Based on the totality of scientific evidence available, the known and potential benefits of the Pfizer-BioNTech COVID-19 vaccine in individuals down to 5 years of age outweigh the known and potential risks.”

A news release issued by the FDA said that the agency’s and CDC’s surveillance systems identified higher risks of myocarditis—inflammation of the heart muscle—and pericarditis—inflammation of the tissue surrounding the heart—after males aged 12 to 17 got the Pfizer vaccine.

Based on its own modeling to ascertain the risk-benefit ratio for children aged 5 to 11, the FDA “predicts that overall, the benefits of the vaccine would outweigh its risks in children 5 through 11 years of age.”

Other than heart inflammation, other side effects include headache, fatigue, fever, chills, swollen lymph nodes, loss of appetite, nausea, and a sore arm, the health agency said.

“More children reported side effects after the second dose than after the first dose,” according to the release. “Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.”

The CDC’s Advisory Committee on Immunization Practices will meet next week to discuss the vaccine. Depending on the outcome of the panel’s meeting, CDC Director Rochelle Walensky would then have the final say on when the vaccine can be used for younger children, and also in what circumstances.

Dr. Michael Kurilla, an expert on infectious diseases and pathology who directs a division inside the National Institutes of Health, was the only official on the FDA advisory panel who didn’t support the recommendation earlier this week.

“Because the Pfizer vaccine offers protection against serious disease even after antibody titers have waned, there is some other basis for immunity, but at the lower dose in children, there is no expectation that those same immune processes will behave similarly to the higher adult dose,” he told [The Epoch Times](#).

It came just days after Harvard University professor of medicine Martin Kulldorff told [EpochTV’s “American Thought Leaders”](#) program that he believes children should not get the COVID-19 vaccine.

“I don’t think children should be vaccinated for COVID. I’m a huge fan of vaccinating children for measles, for mumps, for polio, for rotavirus, and many other diseases, that’s critical. But COVID is not a huge threat to children,” said Kulldorff, who has often criticized the federal government’s vaccine mandates on social media.

In the interview earlier this week, Kulldorf pointed to data showing that children have a very low chance of hospitalization, death, or long-term effects from COVID-19.

Children, he added, “can be infected, just like they can get the common cold, but they’re not a big threat. They don’t die from this, except in very rare circumstances. So if you want to talk about protecting children or keeping children safe, I think we can talk about traffic accidents, for example, which they are really at some risk.”

When the vaccines are rolled out for younger children, there is sure to be parental resistance nationwide.

Earlier this week, a poll carried out by the Kaiser Family Foundation discovered that 30 percent of parents said they “will definitely not get the vaccine” for their 5- to 11-year-old. Five percent said they would have their kids get the vaccine only if it was required to attend school, it found.

About 27 percent said they definitely would have their child receive the shot, Kaiser said. Another 33 percent of parents said they would wait and see.

“Parents’ main concerns when it comes to vaccinating their younger children ages 5-11 have to do with potential unknown long-term effects and serious side effects of the vaccine, including two-thirds who are concerned the vaccine may affect their child’s future fertility,” the pollsters [wrote](#).

Zachary Stieber contributed to this report.



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