

FDA approves Pfizer COVID vaccine for kids 5-11

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(HealthDay)—The U.S. Food and Drug Administration on Friday

approved the emergency use of a smaller dose of Pfizer's coronavirus vaccine for children ages 5 to 11, paving the way for 28 million kids across the country to get their shots.

These youngest Americans can now receive one-third of the adult dose, with two injections given three weeks apart. If the U.S. Centers for Disease Control and Prevention signs off on the approval after its advisory panel meets Tuesday, young children could start getting shots as early as Wednesday.

"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 an agency [statement](#) announcing the approval. "Our comprehensive and rigorous evaluation of the data pertaining to the vaccine's safety and effectiveness should help assure parents and guardians that this vaccine meets our high standards."

"We are confident in the safety, effectiveness and manufacturing data behind this authorization. As part of our commitment to transparency around our decision-making, which included our public advisory committee meeting earlier this week, we have posted documents today supporting our decision and additional information detailing our evaluation of the data will be posted soon. We hope this information helps build [the] confidence of parents who are deciding whether to have their children vaccinated," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in the same statement.

Infectious disease experts welcomed the approval.

"It's an incredibly important tool in the return to normalcy," Dr. Larry

Corey, a virologist at the Fred Hutchinson Cancer Research Center in Seattle and a leader of the COVID-19 Prevention Network, told the *New York Times*. "To be able to know that your child is protected and not going to get severely ill by going to school is an incredible psychological relief."

Earlier in the week, the FDA's vaccine advisory panel voted to recommend the approval. The vote was nearly unanimous at 17-0, with one abstention.

Despite the vote count, some panel members noted at the time that they struggled with the decision.

"This is a much tougher one, I think, than we had expected coming into it," panel member Dr. Eric Rubin, editor-in-chief of the *New England Journal of Medicine*, said during the meeting, *NBC News* reported. "The data show that the vaccine works and it's pretty safe ... [yet] we're worried about a side effect that we can't measure yet," he said, referring to a heart condition called myocarditis that has cropped up in rare cases in some younger recipients of COVID vaccines.

Another panel member questioned whether the vaccinations were needed at all for these youngest Americans.

"It just seems to me that in some ways, we're vaccinating children to protect the adults, and it should be the other way around," committee member Dr. James Hildreth, president and CEO of Meharry Medical College in Tennessee, told *NBC*. "I do believe that children at highest risk do need to be vaccinated. But vaccinating all of the children ... that seems a bit ... much for me."

Panel member Dr. Paul Offit, a vaccine researcher at Children's Hospital of Philadelphia, said, "It's always nerve-racking, I think, when you're

asked to make a decision for millions of children based on studies of only a few thousand children."

But he stressed that the potential threat from a pediatric infection with COVID-19 is real.

"The question is, when do you know enough?" Offit added. "And I think we certainly know that there are many children between 5 and 11 years of age who are susceptible to this disease who could very well be sick and are hospitalized or die from it."

Panel member Dr. Amanda Cohn, chief medical officer at the U.S. Centers for Disease Control and Prevention, saw the decision similarly.

"When I look at this question, it is pretty clear to me that the benefits do outweigh the risk, when I hear about children who are being put in the ICU, who are having long-term outcomes after their COVID, and children are dying," Cohn said. "We vaccinate routinely against a couple of vaccine-preventable diseases for which far fewer deaths and hospitalizations and ICU admissions occur."

In fact, more than 1.9 million children aged 5 to 11 have tested positive for the coronavirus over the course of the pandemic, and more than 8,400 have been hospitalized, said Dr. Fiona Havers, a medical officer with the CDC, *NBC News* reported. And when hospitalized with COVID-19, children are more likely to be admitted to the intensive care and more likely to need a ventilator than children hospitalized with the flu are, she added.

Children who contract COVID-19 are also at risk for a rare inflammatory condition called multisystem inflammatory syndrome (MIS-C). As of Oct. 4, more than 5,200 children of all ages have developed MIS-C, and 46 have died, Havers said, adding that the

condition was most common in [younger children](#).

Two doses of the Pfizer vaccine is nearly 91% effective in preventing symptomatic illness in [young children](#) and brings no unexpected safety issues, according to a [study](#) posted last Friday by the FDA.

"Overall, it is very promising news that the FDA has decided to approve the vaccine, allowing parents to collectively breathe a sigh of relief. The bottom line is that they can now extend this much needed protection to their children and families as a whole," said Dr. Robert Glatter, an emergency medicine physician with Lenox Hill Hospital in New York City.

Now, the Biden administration's plans to roll out the vaccine through pediatricians' offices, community clinics and pharmacies will begin, as U.S. health officials hope to reassure hesitant parents that the jab will protect their kids from COVID-19.

The White House has decided that pediatric COVID-19 shots will be delivered in settings that parents know and trust, rather than mass vaccination sites.

More than 25,000 pediatric and family doctor clinics will provide vaccinations to children, along with tens of thousands of pharmacies, children's hospitals and community health centers, according to the White House plan.

"Our planning efforts mean that we will be ready to begin getting shots in arms in the days following a final CDC recommendation," a White House [statement](#) on the plan said.

The [federal government](#) has already bought enough vaccine to fully cover all 28 million American kids aged 5 to 11, and it will be

distributed in smaller packages of about 100 doses each, to make things more manageable for doctors' offices and community health centers, the White House added.

And there will be takers for the pediatric version of the [vaccine](#): Two-thirds of U.S. parents of kids aged 5 to 11 plan to get their [children](#) vaccinated once the shots are approved, according to a recent [poll](#) by the COVID-19 Vaccine Education and Equity Project.

More information: The U.S. Centers for Disease Control and Prevention has more about [COVID vaccination for children ages 5 to 11](#).

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