

US gives final clearance to COVID-19 shots for kids 5 to 11

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U.S. health officials on Tuesday gave the final signoff to Pfizer's kid-size COVID-19 shot, a milestone that opens a major expansion of the nation's vaccination campaign to children as young as 5.

The Food and Drug Administration already authorized the shots for [children](#) ages 5 to 11—doses just a third of the amount given to teens and adults. But the Centers for Disease Control and Prevention formally recommends who should receive FDA-cleared vaccines.

The announcement by CDC director Dr. Rochelle Walensky came only hours after an advisory panel unanimously decided Pfizer's shots should be opened to the 28 million youngsters in that age group.

The decision marks the first opportunity for Americans under 12 to get the powerful protection of any COVID-19 [vaccine](#).

"As a mom, I encourage parents with questions to talk to their pediatrician, school nurse or local pharmacist to learn more about the vaccine and the importance of getting their children vaccinated," Walensky said Tuesday night, in a statement.

In remarks earlier in the day, she said while the risk of severe disease and death is lower in young children than adults, it is real—and that COVID-19 has had a profound social, mental health and educational impact on youngsters, including widening disparities in learning.

"There are children in the second grade who have never experienced a normal school year," Walensky said. "Pediatric vaccination has the power to help us change all of that."

President Joe Biden called the decision "a turning point."

"It will allow parents to end months of anxious worrying about their kids, and reduce the extent to which children spread the virus to others," he said in a statement. "It is a major step forward for our nation in our fight to defeat the virus."

The American Academy of Pediatrics welcomed the decision as its members get ready to start the first injections into little arms, which the CDC said could begin "as soon as possible." The 5- to 11-year-olds will receive two low doses, three weeks apart, of the vaccine made by Pfizer and its partner BioNTech—the same schedule as everyone else, but using a smaller needle.

Pfizer over the weekend began shipping millions of the pediatric shots to states, doctors' offices and pharmacies—in orange caps, to avoid mix-ups with purple-capped vials of adult vaccine.

Many parents have clamored for vaccine protection for youngsters so they can resume normal childhood activities without risking their own health—or fear bringing the virus home to a more vulnerable family member. But CDC's advisers said they recognize many parents also have questions, and may be fearful of the vaccine because of rampant misinformation.

Members of the [advisory panel](#) said they want parents to ask about the shots—and understand that they're far better than gambling that their child will escape a serious coronavirus infection. As for safety, more than 106 million Americans have safely gotten two doses of Pfizer's full-strength shots—including more than 7 million 12- to 15-year-olds.

"I have vaccinated my kids," said CDC adviser Dr. Helen Keipp Talbot of Vanderbilt University, saying she wouldn't recommend something for other families unless she was comfortable with it for her own. "We have seen the devastation of this disease."

In the U.S., there have been more than 8,300 coronavirus-related hospitalizations of kids ages 5 to 11, about a third requiring intensive care, according to government data. The CDC has recorded at least 94 deaths in that age group, with additional reports under investigation.

And while the U.S. has seen a recent downturn in COVID-19 cases, experts are worried about another uptick with holiday travel and as winter sends more activity indoors where it's easier for the coronavirus to spread.

Pfizer's study of 2,268 youngsters found the kid-size vaccine is nearly 91% effective at preventing symptomatic COVID-19—based on 16 diagnoses among kids given dummy shots compared to just three who got the real vaccination.

The FDA examined more children, a total of 3,100 who were vaccinated, in concluding the shots are safe. The [younger children](#) experienced similar or fewer reactions—such as sore arms, fever or achiness—than teens or young adults get after larger doses.

That study wasn't large enough to detect any extremely rare side effects, such as the heart inflammation that occasionally occurs after the second full-strength dose, mostly in young men and teen boys. Regulators ultimately decided the benefits from vaccination outweigh the potential that younger kids getting a smaller dose also might experience that rare risk.

Some of CDC's advisers said for some parents, deciding to get their children vaccinated may hinge on that small but scary risk.

"The risk of some sort of bad heart involvement is much higher if you get COVID than if you get this vaccine," Dr. Matthew Oster, a pediatric cardiologist at Emory University, told the panel. "COVID is much riskier to the heart."

Last week, FDA's advisers struggled with whether every young child needed a vaccine. Youngsters hospitalized with COVID-19 are more likely to have high-risk conditions such as obesity or diabetes. But

otherwise healthy children can get seriously ill, too, and the CDC's advisers ultimately recommended the shots for all of them—even children who've already recovered from a bout of COVID-19.

CDC officials calculated that for every 500,000 youngsters vaccinated, between 18,000 and 58,000 COVID-19 cases—and between 80 and 226 hospitalizations—in that age group would be prevented, depending on the pandemic's trajectory. And CDC officials noted that COVID-19 has caused more deaths in this age group than some other diseases, such as chickenpox, did before children were routinely vaccinated against them.

What about younger children? Pfizer is testing shots for babies and preschoolers and expects data around the end of the year. The similarly made Moderna vaccine also is being studied with [young children](#). But the FDA still hasn't cleared its use in teens, and the company is delaying its application for younger children pending that review.

A few countries have begun using other COVID-19 vaccines in children under 12, including China, which just began vaccinations for 3-year-olds. But many that use the Pfizer-BioNTech vaccine are watching the U.S. decision, and European regulators just began considering the companies' kid-size doses.

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