

FDA authorizes 1st COVID-19 shots for infants, preschoolers

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Syringes and colorful bandages are prepared as children from local schools prepare to get COVID-19 vaccines in Pittsfield, Mass., on Monday Dec. 13, 2021. Credit: Ben Garver/The Berkshire Eagle via AP, File

U.S. regulators on Friday authorized the first COVID-19 shots for

infants and preschoolers, paving the way for vaccinations to begin next week.

The Food and Drug Administration's action follows its [advisory panel's unanimous recommendation](#) for the shots from Moderna and Pfizer. That means U.S. kids under 5—roughly 18 million youngsters—are eligible for the shots. The nation's vaccination campaign began about 1 1/2 years ago with older adults, the hardest hit during the coronavirus pandemic.

There's one step left: The Centers for Disease Control and Prevention recommends how to use vaccines. Its independent advisers began debating the two-dose Moderna and the three-dose Pfizer vaccines on Friday and will make its recommendation Saturday. A final signoff is expected soon after from CDC Director Dr. Rochelle Walensky.

At a Senate hearing Thursday, Walensky said her staff was working over the Juneteenth federal holiday weekend "because we understand the urgency of this for American parents."

She said pediatric deaths from COVID-19 have been higher than what is generally seen from the flu each year.

"So I actually think we need to protect young children, as well as protect everyone with the vaccine and especially protect elders," she said.

The FDA also authorized Moderna's vaccines for school-aged children and teens; CDC's review is next week. Pfizer's shots had been the only option for those age groups.

For weeks, the Biden administration has been preparing to roll out the vaccines for little kids, with states, tribes, community health centers and pharmacies [preordering millions of doses](#). With FDA's emergency use

authorization, manufacturers can begin shipping vaccine across the country. The shots are expected to start early next week but it's not clear how popular they will be.

Without protection for their tots, some families had put off birthday parties, vacations and visits with grandparents.

"Today is a day of huge relief for parents and families across America," President Joe Biden said in a statement.



This photo provided by Pfizer shows the production of Pfizer's COVID-19 vaccine for children under 5 on May 2022 in Puurs, Belgium. U.S. regulators on Friday, June 17, authorized the first COVID-19 shots for infants and preschoolers, paving the way for vaccinations to begin next week. Credit: Pfizer via AP

While young children generally don't get as sick from COVID-19 as older kids and adults, their hospitalizations surged during the omicron wave and FDA's advisers determined that benefits from vaccination outweighed the minimal risks. Studies from Moderna and Pfizer showed side effects, including fever and fatigue, were mostly minor.

White House COVID-19 coordinator Dr. Ashish Jha predicted the pace of vaccinations for kids under 5 to be far slower than it was for older populations and said the administration doesn't have any internal targets for the pace of vaccinations.

"At the end of the day, our goal is very clear: We want to get as many kids vaccinated as possible," Jha told The Associated Press.

In testing, the littlest children developed high levels of virus-fighting antibodies, comparable to what is seen in young adults, the FDA said. Moderna's vaccine was about 40% to 50% effective at preventing infections but there were too few cases during Pfizer's study to give a reliable, exact estimate of effectiveness, the agency said.

"Both of these vaccines have been authorized with science and safety at the forefront of our minds," Dr. Peter Marks, FDA's vaccine chief, said at a news briefing.

Marks said parents should feel comfortable with either vaccine, and should get their kids vaccinated as soon as possible, rather than waiting until fall, when a different virus variant might be circulating. He said adjustments in the vaccines would be made to account for that.

"Whatever vaccine your health care provider, pediatrician has, that's what I would give my child," Marks said.

The two brands use the same technology but there are differences.

Pfizer's vaccine for kids younger than 5 is one-tenth of the adult dose. Three shots are needed: the first two given three weeks apart and the last at least two months later.

Moderna's is two shots, each a quarter of its adult dose, given about four weeks apart for kids under 6. The FDA also authorized a third dose, at least a month after the second shot, for children who have immune conditions that make them more vulnerable to serious illness.



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via AP

Both vaccines are for children as young as 6 months. Moderna next plans to study its shots for babies as young as 3 months. Pfizer has not finalized plans for shots in younger infants. A dozen countries, including China, already vaccinate kids under 5, with other brands.

Immediately upon hearing of the FDA's decision, Dr. Toma Omofoye, a Houston radiologist, made appointments for her 4-year-old daughter and 3-year-old son. Without the shots, her family has missed out on family gatherings, indoor concerts, even trips to the grocery store, she said. During a recent pharmacy stop, Omofoye said her daughter stared and walked around like it was Disneyland, and thanked her.

"My heart broke in that moment, which is why my heart is so elated now," Omofoye said.

But will other parents be as eager to get their youngest vaccinated? By some estimates, [three-quarters of all U.S. children](#) have already been infected. And only about 30% of children aged 5 to 11 have gotten vaccinated since Pfizer's shots opened to them last November.

The FDA officials acknowledged those low rates and said the government is committed to getting more older kids vaccinated and having better success with younger kids.

"It's a real tragedy, when you have something free with so few side effects that prevents deaths and hospitalization," said FDA Commissioner Robert Califf.

Roughly 440 children under age 5 have died from COVID-19, federal

data show.

Dr. Beth Ebel of the University of Washington School of Medicine in Seattle, said the tot-sized vaccines would be especially welcomed by parents with children in day care where outbreaks can sideline parents from jobs, adding to financial strain.

"A lot of people are going to be happy and a lot of grandparents are going to be happy, too, because we've missed those babies who grew up when you weren't able to see them," Ebel said.

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