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FDA authorizes Pfizer and Moderna Covid vaccines for infants, toddlers, and preschoolers



By [Matthew Herper](#) June 17, 2022



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The Food and Drug Administration on Friday authorized the Pfizer-BioNTech and Moderna Covid vaccines for use in children as young as 6 months of age, setting the stage for a government push to make the shots available for the youngest children.

The decision comes less than two days after a panel advising the FDA [voted unanimously](#) to recommend authorization, saying their benefits would outweigh any risks for young kids.

The FDA also authorized the Moderna vaccine, which was previously cleared in adults over 18, for older children and adolescents, meaning both vaccines are cleared for all ages over 6 months.

“Those trusted with the care of children can have confidence in the safety and effectiveness of these Covid-19 vaccines and can be assured that the agency was thorough in its evaluation of the data,” FDA Commissioner Robert Califf said in a statement.

Before families can start to avail themselves of the vaccines, though, an advisory committee for the Centers for Disease Control and Prevention needs to recommend the shots, too, and CDC Director Rochelle Walensky must accept the recommendation. The group meets Friday and Saturday, when the votes will be held.

The Biden administration is already prepared to roll out the vaccine. On June 9, the administration said that should the vaccines be authorized and recommended by the CDC, it would be ready with 10 million available doses, with millions more on the way.

Administration officials said that they would work to make sure that a broad range of pediatricians would have the shots, including those at

smaller practices and in rural settings. The vaccines will be available in package sizes of 100 doses and will come with all the supplies needed to administer them, including small needles.

“We know that there are many parents who have been eagerly awaiting the opportunity to vaccinate their youngest kids, and we share their eagerness,” a [senior administration official said](#). “Therefore, you know, every day, all day, right now, we are focusing on getting ready to have this as accessible as possible to as many families as possible.”

Rolling out the shots will pose new logistical challenges because, unlike the vaccines for older children and adults, they have different dosages, dosing schedules, and efficacy and safety profiles.

The Pfizer shot, developed with partner BioNTech, is given in this age group as 3-microgram doses. The first two are given three weeks apart, and the third is given eight weeks after the second dose.

The Moderna vaccine is administered as two 25-microgram doses given a month apart. However, most experts expect that children who receive the Moderna vaccine should also receive a booster either of the original Moderna vaccine, which is not yet authorized, or of a yet-to-be introduced Moderna vaccine more specifically targeting the Omicron variant.

Both vaccines were authorized based on clinical trials showing that they led to the production of antibodies at similar levels as those seen in adults. The Pfizer-BioNTech shot was initially being developed as a two-dose vaccine, but results led the companies to add a third dose to their vaccine regimen. The FDA said that an analysis of the Pfizer/BioNTech vaccine’s efficacy in this age group was not reliable because a low number of Covid cases occurred overall.

“I think we will have to wait a little bit longer for Pfizer to have more mature effectiveness data to have the confidence that we’d like to put out numbers, although we don’t have any concern that there is going to be any significant concern with effectiveness here,” said Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research, at a press conference.

In clinical trials of children 6 through 23 months of age, the Moderna vaccine was 50.6% effective in preventing symptomatic COVID-19, the FDA said. Among participants 2 through 5 years of age, it was 36.8% effective.

Both vaccines can cause symptoms such as fever, fatigue, achiness, irritability, and decreased appetite. The Pfizer vaccine appeared to cause fevers somewhat less often than the Moderna vaccine, although indirectly comparing clinical trials can be misleading and the FDA made no claims in its announcement directly comparing the tolerability of the two vaccines.

“I think with two vaccines that have different dosing regimens it is going to be even more important that the public health education, the education of providers, is done very, very carefully,” said Archana Chatterjee, the vice president of medical affairs at the Rosalind Franklin University of Medicine and Science, at the FDA advisory panel meeting earlier this week. “We are making choices between two different vaccines that have a little bit different profiles.”

Both vaccines have been linked to inflammation of the heart or the lining around it, conditions known as myocarditis or pericarditis, in adolescent males. In 16-17-year-old males, whose risk is highest, myocarditis is reported for about 1 in 13,000 at the second doses of the Pfizer vaccine; some analyses have indicated the risk might be higher for the Moderna

vaccine, but the FDA presented other data at its advisory committee meeting indicating that the risk was similar for both shots.

The FDA said that in analyses it conducted with the CDC, most cases of myocarditis and pericarditis due to the vaccine resolve rapidly with no impact on quality of life 90 or more days after the case was reported. Increased rates of the condition were not detected in younger children.

Uptake of Covid vaccines has been [much lower](#) in children than in adults. According to the CDC, only 29.2% of those aged 5 to 11 were fully vaccinated as of June 1, compared to 74.8% of those aged 40 to 49 and 87.8% of those over age 75.

The CDC emphasized [at the FDA meeting](#) that the risk to children for Covid is very real, even though the risk of hospitalization or death is lower than for adults. In children aged 1 through 4 years old, Covid is the fifth leading cause of death. From January 2020 through May 2022, 202 children in this age group have died from Covid. “Any death of a child is tragic, and should be prevented if possible,” Califf said at the FDA press conference.

Hospitalizations of children in this age group who test positive for Covid surged as the Omicron variant became more prevalent. Hospitalization rates were initially lower than for influenza in this age group, the CDC said at the FDA meeting, but since October 2021 they have been substantially higher. Califf said that hospitalization rates for children with Covid were five times higher during the recent wave than at the worst previous points of the pandemic.

“We have been planning for this moment for months, and as soon as the FDA authorizes these vaccines we’re going to get them distributed across the country,” White House Covid-19 response coordinator Ashish Jha [said](#)

[in a video released Wednesday.](#) “And then as soon as the CDC signs off on this, we’re going to start seeing these vaccines go into arms.”

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