

Pfizer asks FDA to allow COVID-19 vaccine for kids under 5

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Nurse Lydia Holly prepares a child's COVID-19 vaccine dose, on Nov. 3, 2021, at Children's National Hospital in Washington. U.S. regulators are urging drugmaker Pfizer to apply for emergency authorization for a two-dose regimen of its COVID-19 vaccine for children ages 5 and under while awaiting data on a three-dose course, aiming to clear the way for the shots as soon as late February. Credit: AP Photo/Carolyn Kaster, File

Pfizer on Tuesday asked the U.S. to authorize extra-low doses of its COVID-19 vaccine for children under 5, potentially opening the way for the very youngest Americans to start receiving shots as early as March.

In an extraordinary move, the Food and Drug Administration had urged Pfizer and its partner BioNTech to apply earlier than the companies had planned—and before it's settled if the youngsters will need two shots or three.

The nation's 19 million children under 5 are the only group not yet eligible for vaccination against the coronavirus. Many parents have been pushing for an expansion of shots to toddlers and preschoolers, especially as the omicron variant sent record numbers of youngsters to the hospital.

"I would say the parents in my office are desperate" to get young kids vaccinated, said Dr. Dyan Hes, who runs a pediatrics practice in New York City, where vaccination rates are high. For many, "that's the first thing they ask when they walk through the door: 'When do you think the shot is going to come out?'"

Pfizer aims to give children as young as 6 months shots that contain one-tenth of the dose given to adults. The company said it had started submitting its data to the FDA and expects to complete the process in a few days.

An open question is how many shots those children will need. Two of the extra-low doses turned out to be strong enough for babies but not for preschoolers in early testing. Pfizer now is testing a third shot, data that's expected in late March.

That means the FDA may consider whether to authorize two shots for now, with potentially a third shot being cleared later if the study supports

it.

Pfizer CEO Albert Bourla said in a statement that company scientists believe this age group ultimately will need three of the extra low-dose shots but that FDA action now could let parents begin the vaccination process while awaiting a final decision.

The FDA said it will convene a panel of independent researchers and physicians in mid-February to help review the Pfizer data. The agency isn't required to follow their advice, but the input is a key step in publicly vetting vaccine safety and effectiveness.

The question of how long to wait for new vaccine data—and how much to require—is a concern for FDA regulators, who face pressure to be more proactive against a virus that has repeatedly confounded health experts.

The FDA asked Pfizer to begin submitting its application now due to omicron's "greater toll on children," an agency spokeswoman said, citing a peak in cases among children under 5.

"In light of these new data and the rise in illnesses and hospitalization in this youngest age group, FDA believed that it was prudent to request that Pfizer submit the data it had available," agency spokeswoman Stephanie Caccamo said in an emailed statement.

The FDA's ultimate decision could come within the month, but that isn't the only hurdle. The Centers for Disease Control and Prevention also has to sign off.

The Biden administration has been trying to speed the authorization of COVID-19 shots for children, contending vaccinations are critical for opening schools and day care centers and keeping them open, and for

freeing up parents from child care duties so they can go back to work.

Yet vaccination rates have been lower among children than in other age groups. As of last week, just 20% of kids ages 5 to 11 and just over half of 12- to 17-year-olds were fully vaccinated, according to the American Academy of Pediatrics. Nearly three-quarters of adults are fully vaccinated.

Young children are far less likely than adults to get severely ill from the coronavirus, but it can happen, and pediatric COVID-19 infections are higher than at any other point in the pandemic.

"What we're seeing right now is still a lot of hospitalizations and unfortunately some deaths in this age group," said Dr. Sean O'Leary of the University of Colorado, who is on the AAP's infectious disease committee. If the FDA clears vaccinations for these youngsters, "that's going to be really important because all of those hospitalizations and deaths essentially are preventable."

For kids under 5, Pfizer's study is giving participants two shots three weeks apart, followed by a third dose at least two months later. The company is testing whether the youngsters produce antibody levels similar to those known to protect teens and young adults.

In December, Pfizer announced that children under 2 looked to be protected but that the antibody response was too low in 2- to 4-year-olds. It's not clear why, but one possibility is that the extra-low dose was a little too low for the preschoolers.

Since the preliminary results showed the shots were safe, Pfizer added a third dose to the testing in hopes of improving protection.

A Kaiser Family Foundation poll found just 3 in 10 parents of children

under 5 would get their youngster vaccinated as soon as shots were authorized, while about a quarter said they definitely would not. Results of the survey of 1,536 adults, conducted in mid-January, were released Tuesday.

Chicago health officials have been trying to prepare parents for months for the day the shots are available, said Dr. Nimmi Rajagopal, a family medicine physician for Cook County Health, which oversees the public hospital system. Some parents wonder how rigorously the shots will be evaluated or have other questions that she said are critical to address.

Rajagopal is excited about getting her own 2-year-old son vaccinated if FDA clears the way, so it will be safer for him to play with other children.

"I have been waiting and waiting and waiting," she said.

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