



Pfizer to Ask FDA to Authorize Three Doses of Covid Vax for Tots

Three doses of Pfizer-BioNTech's Covid shot offer strong protection for children between six months and five years of age, the company announced Monday. Pfizer plans to submit the data to the United States regulators later this week, asking them to authorize the shots to be given to some [18 million](#) of the youngest Americans.

Back in early February, Pfizer, following the request of the regulatory agency, [submitted](#) the paperwork to the U.S. Food and Drug Administration (FDA) to request emergency use authorization (EUA) for its two-shot regimen for children between six months and five years old.



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The FDA, however, reversed course and [said](#) it needed to wait for data on how well a third shot works for the age group. Earlier, Pfizer [admitted](#) that while a two-dose regimen was effective in children ages six months to two years, two shots failed to promote a desired immune response in children ages two through four years.

And now the mid-trial data is out, and shows that the three-dose regimen containing 3 µg each, appeared to have an 80.3-percent efficacy based on symptomatic infections counted in a subset of a trial involving 1,678 children. According to the [press release](#), all of them received a third dose during the period when the omicron strain dominated. The children were given an initial two doses three weeks apart, and a third dose at least two months after the second dose.

The company specified that it identified ten symptomatic Covid cases at least seven days after the third dose in the vaccine group. The efficacy rate will be finalized when at least 21 symptomatic cases occur in the vaccine group and then are compared with the number of symptomatic cases in the placebo group.

Pfizer boasted that the shots were “well-tolerated” and that no new safety signals were identified. Pfizer CEO Albert Bourla said the data is “encouraging” and expressed his hopes for the shots to become available to infants and toddlers “as quickly as possible.”

As quoted by the Associated Press, the director of the FDA's Center for Biologics Evaluation and Research (CBER), Peter Marks, pledged the agency to “move quickly” — yet “without sacrificing [its] standards.”

Pfizer's competitor, Moderna Inc., submitted a request to authorize its Covid shots for the same age group in April.

The regulators [set](#) June 14-15 as the meeting date to review both Moderna's and Pfizer's emergency authorization requests.



Written by [Veronika Kyrylenko](#) on May 23, 2022

Notably, the FDA's chief vaccine advisor signaled that he is all in for vaccinating the youngest children with experimental Moderna shots even despite their demonstrating poor protection from the infection.

According to [USSANEWS.com](#), Marks told the House Select Subcommittee on the Coronavirus Crisis that "the agency would not withhold authorization of a pediatric vaccine if it fails to meet the agency's 50% efficacy threshold for blocking symptomatic infections."

Earlier this month, the FDA authorized a third dose of the Pfizer Covid shot for children aged five to 11, with the U.S. Centers for Disease Control and Prevention (CDC) promptly recommending its use.

Is There an "Emergency?"

According to [CDC data](#) — [for what's it worth](#) — as of May 14, infants younger than one accounted for 287, and children aged one to four for 140 out of 1,001,061 total deaths associated with Covid in the United States. [Not a single](#) child has died since March 5.

Multiple studies show Covid poses no danger to children. A Johns Hopkins study [showed](#) a Covid mortality rate of zero among 48,000 healthy children. A major [study](#) in Germany found the case fatality rate among children was three out of a million, with zero deaths reported in children under five.

At the end of December 2021, CDC Director Dr. Rochelle Walensky [acknowledged](#) that a substantial percentage of Covid-positive children were admitted to hospitals for other reasons. It did not prevent Walensky from [claiming](#) just a week later that children were being hospitalized "at their highest rate" compared to any prior point in the pandemic. That, of course, was before a major revelation that the agency was [overcounting](#) Covid pediatric deaths by 24 percent, likely to justify the "emergency" use authorization for children aged five to 11.

While the health authorities and Big Pharma uniformly promote vaccinations among the youngest of Americans, the Vaccine Adverse Event Reporting System (VAERS) shows the shots are far from safe.

[Children's Health Defense](#) (CHD), quoting VAERS data from December 14, 2020 to May 12, 2022 for five- to 11-year-olds, reports that the shots were associated with 10,745 adverse events, including 279 rated as serious and five reported deaths. There were also 43 reports of blood clotting disorders and 22 reports of myocarditis and pericarditis. Yet, noted CHD, that latter number is artificially lowered since the CDC recently excluded from the definition of "myocarditis" cases of cardiac arrest, ischemic strokes, and deaths due to heart problems that occur before patients get to the emergency department.

When the shots for kids aged five to 11 were being [discussed](#) by the FDA's vaccine advisory board, one of the panelists, Dr. Eric Rubin, said, "We're never gonna learn about how safe the vaccine is until we start giving it. That's the way it goes." That, apparently, will also be the case with the youngest children.





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