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Pfizer to Ask FDA to Allow 3rd COVID Shot for Healthy 5- to 11-Year-Olds, Based on Study of 140 Kids

By Megan Redshaw
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The companies also plan to request authorization from the European Medicines Agency and other regulatory agencies around the world as soon as possible.

Pfizer said in a press release the third dose of its vaccine produced significant protection against the Omicron variant in children 5 to 11 in a small Phase 2/3 clinical trial.

The study was based on data from only 140 children 5 through 11 years old who received a booster dose six months after the second dose of Pfizer-BioNTech's COVID vaccine as part of the primary series.

A closer look at 30 children showed a 36-fold increase in virus-fighting antibodies — levels high enough to fight the Omicron variant, ABC News reported.

Pfizer claimed the third dose was "well tolerated with no new safety signals observed."

Although Pfizer said more than 10,000 children under the age of 12 have participated in clinical trials investigating Pfizer's COVID vaccine, only 140 were selected for the study forming the basis for the company's EUA request.

Commenting on the news, Dr. Brian Hooker said,

> "The clinical trial used to support the notion of a COVID-19 booster for 5- to 11-year-olds is entirely inadequate to make any such recommendation."

Hooker, chief science advisor at Children's Health Defense (CHD), added:

> "This small-scale, limited-time trial contains only 140 patients, which is not sufficiently sized to assess vaccine adverse events at all, especially rarer injuries such as the devastating medical maladies sustained by Maddie de Garay — an adolescent injured in the original Pfizer clinical trial."

Hooker said he was also concerned there are "no data on the prevention of COVID-19 infection, only neutralizing antibody titers, which are not necessarily predictive of transmission and severity of the disease."

Dr. Liz Mumper, a pediatrician, said, "Once again, Pfizer does science by press release." Mumper said the rise in antibody titers is just one small piece of the story of kids and COVID.

> "The more important issue is that, on the basis of careful risk-versus-benefit analysis, healthy children do not need a COVID vaccine," Mumper said, because many kids already had COVID and developed robust and durable antibodies.

CHD President Mary Holland accused Pfizer of reaching "a new low" by seeking authorization of booster shots for children based on an "unpublished, non-peer-reviewed study of 140 children."

Holland said:

> "Following the science on COVID vaccination shows that the risks outweigh the benefits for COVID shots for kids, let alone boosters. One suspects this is simply a misguided ploy to use up Pfizer's vaccine inventory before its expiration."

Pfizer tested its booster dose while Omicron was the dominant variant this winter. In recent weeks, BA.2 has become the dominant COVID variant. It has not been determined whether a third dose provides any protection against the new variant.

The U.S. Food and Drug Administration (FDA) in October 2021 authorized the Pfizer-BioNTech COVID vaccine for children 5 through 11 and recently authorized a booster dose for teens 12 through 15 and older and also immunocompromised children 5 and older.

According to a study published late last month in The New England Journal of Medicine, Pfizer's vaccine showed "reduced effectiveness" against the Omicron variant among children 12 and older.

According to an analysis of Centers for Disease Control and Prevention (CDC) data by theAmerican Academy of Pediatrics, as of April 6, 2022, 9.7 million U.S. children ages 5 to 11 had received at least one dose of a COVID vaccine — representing 34% of 5- to 11-year-olds.

Approximately 7.8 million U.S. children ages 5 to 11 completed the 2-dose primary vaccination series — representing 28% of 5- to 11-year-olds.

About 18.7 million children 5 to 11 had yet to receive their first COVID vaccine dose.

Seventeen million U.S. adolescents ages 12 to 17 have received at least one dose of a COVID vaccine — representing 68% of 12- to 17-year-olds.

Only 58% completed the 2-dose vaccination series and 8.1 million adolescents in this age group have yet to receive a COVID vaccine.

There are 72.8 million children under age 18 in the U.S., which is 22% of the U.S. population. Children aged 5 to 11 represent 8.6% of the U.S. population.

The FDA has not authorized any COVID vaccines for use in children under 5.

According to the latest data from the CDC's Vaccine Adverse Events Reporting System (VAERS), between Oct. 1, 2021, and April 1, 2022, 10,157 adverse events, including 239 rated as serious and 5 reported deaths after COVID vaccines, were reported in the 5- to 11-year-old age group.

Although reports submitted to VAERS require further investigation before a causal relationship can be confirmed, the system has been shown to report only 1% of actual vaccine adverse events.

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