FDA Chooses Pfizer Over Kids, Signs Off on Boosters for Children 5 to 11 and Bypasses Advisory Panel

The U.S. Food and Drug Administration (FDA) today authorized a booster dose of the Pfizer-BioNTech COVID vaccine for children ages 5 to 11, without convening its vaccine advisory panel of independent experts to discuss Pfizer's data on 5- to 11-year-olds – and based on a study subset of only 67 children.

The children were only followed for one month, so the FDA has no idea how long "protection" will last, nor was the subset large enough to detect serious adverse events.

The FDA granted Emergency Use Authorization (EUA) for the boosters despite data showing higher infection rates among fully vaccinated children in the 5 to 11 age group compared to unvaccinated children, rapidly waning efficacy and no studies testing the efficacy of the vaccine against the current dominant BA.2 COVID variant.

The vaccine advisory panel for the Centers for Disease Control and Prevention (CDC) is scheduled to meet Thursday. The agency and its director, Dr. Rochelle Walensky, are expected to sign off on the boosters.

Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said data increasingly show protection provided by two shots wanes over time, but the agency determined a third shot could help boost protection for children in the 5 to 11 age group and the "benefits outweigh the risks."

The FDA authorized the third shot after analyzing data from an ongoing Pfizer clinical trial in which a small subset of only 67 children in the age group had higher antibody levels one month after receiving a booster dose. However, antibody levels alone are not indicative of immune protection. When it comes to COVID, T cell and natural killer cell responses are the crucial part of immune protection.

Pfizer has not published its actual data, precluding experts from conducting this analysis.

The authorized booster dose is the same strength as the first two doses and reportedly generated neutralizing antibodies to Omicron and the ancestral Wuhan version of the virus, which are no longer dominant SARS-CoV-2 strains.

The FDA said it did not identify any new safety concerns and found the children in the trial experienced the same mild side effects other people do after receiving a booster.

However, a subset of only 67 children is not large enough to detect potential adverse events like myocarditis, and it is unknown how rapidly any protection provided wanes because trial participants were not followed beyond a 28-day period.

About 8.1 million, or 28%, of children ages 5 to 11, received their primary series of two COVID vaccine doses as of May

11, according to data from the American Academy of Pediatrics.

Millions of children will now be eligible for a third dose five months after their second dose based on data obtained from the 67 children who were followed for only one month.

COVID cases are higher in vaccinated children aged 5 to 11

According to the latest CDC data, higher COVID case rates have been recorded among fully vaccinated children compared to unvaccinated children in the 5 to 11 age group since February.

The CDC on Feb. 12 reported a weekly case rate of 250.02 per 10,000 population in fully vaccinated children ages 5 to 11, compared to 245.82 for unvaccinated children in the same age group. The trend continued through the third week of March, which is the latest week of available data.

"Several factors likely affect crude case rates by vaccination and booster dose status, making interpretation of recent trends difficult," CDC spokesperson Jasmine Reed told The Epoch Times in an email.

"Limitations include higher prevalence of previous infection among the unvaccinated and unboosted groups, difficulty in accounting for time since vaccination and waning protection, and possible differences in testing practices (such as at-home tests) and prevention behaviors by age and vaccination status," Reed said. "These limitations appear to have less impact on the death rates presented here."

According to CDC data, the gap between fully vaccinated and unvaccinated individuals in all age groups has grown increasingly smaller, with the death rate showing the same trend for people over age 50.

For people under age 50, death rates are almost identical

between the vaccinated and unvaccinated since the beginning of the vaccine rollout.

Data show COVID vaccines have a "negligible effect" on people, said Dr. Peter McCullough, a prominent cardiologist and epidemiologist.

"With these results in hand, it is clear the vaccines are having a negligible effect in populations," McCullough told The Epoch Times. "Given the overall poor safety profile and lack of any assurances on long-term safety, Americans should be cautious in considering additional injections of these products."

Efficacy of Pfizer's COVID vaccine wanes rapidly

A study published May 13 in the Journal of the American Medical Association (JAMA) found protection from Pfizer's COVID vaccine turned negatively effective among children and adolescents five months after receiving a second dose — meaning recipients were more likely to get COVID five months after being vaccinated.

Vaccine effectiveness "was no longer significantly different from 0 during month 3 after the second dose," the researchers wrote. They also found protection against hospitalization waned significantly over time.

In adolescents, the authors said, efficacy increased again with boosters.

Most non-randomized studies attempting to determine vaccine efficacy (VE) had "common flaws," including no accounting for baseline prior COVID infection, no reporting for those who received a booster within a six-month time window and no adjudication of hospitalization or death due to COVID-19 or other conditions, McCullough told The Epoch Times.

“As a result, most studies of COVID-19 VE have biases towards overestimating any clinical benefit of vaccination,” McCullough said.

A different study published on May 13 in JAMA showed second and third doses of Pfizer’s COVID vaccine provided protection against the Omicron variant for only a few weeks.

“Our study found a rapid decline in Omicron-specific serum neutralizing antibody titers only a few weeks after the second and third doses of [the Pfizer-BioNTech] BNT162b2,” the authors wrote.

A preprint study released in February showed Pfizer’s two-dose regimen of its COVID vaccine for children was only 12% effective against Omicron in children ages 9 to 11, and the effectiveness of the vaccine “declined rapidly” for children 5 to 11.

Researchers at the New York State Department of Health and the University at Albany School of Public Health examined the effectiveness of the vaccine in children 5 to 11 and adolescents 12 to 17 from Dec. 13, 2021, to Jan. 30, 2022, and determined the effectiveness of Pfizer’s COVID vaccine declined rapidly for children, particularly those 5-11 years.

According to a Danish study of 128 people who had received two or three doses of Pfizer’s COVID vaccine, levels of Omicron-specific “neutralizing” antibodies decline rapidly after a second and third dose of Pfizer’s shot.

Compared to original and Delta variants, researchers found the proportion of Omicron-specific antibodies detected in participants’ blood dropped “rapidly” from 76% four weeks after the second dose to 53% at weeks 8 to 10 and 19% at weeks 12 to 14.

After the third shot, neutralizing antibodies against Omicron fell 5.4-fold between week 3 and week 8.

Last month, Moderna requested EUA for its COVID vaccine for children aged 6 months to 6 years. Pfizer plans to seek EUA for a three-dose regimen for the same age group.

The FDA's top vaccine official told a congressional committee on May 6 that COVID vaccines for children under 6 will not have to meet the agency's 50% efficacy threshold required to obtain EUA.