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FDA Authorizes Pfizer Booster for Kids 5 to 11, Bypasses Advisory Panel

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The U.S. Food and Drug Administration (FDA) today authorized a booster dose of the Pfizer-BioNTech COVID-19 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, CNBC reported.

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, no studies testing the efficacy of the vaccine against the current dominant BA.2 COVID-19 variant and two new studies showing that for vaccinated people who get Omicron, the infection provides better protection against future infections than a second booster dose.

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, The Washington Post reported.

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.

As The Defender reported, antibody levels alone are not indicative of immune protection. When it comes to COVID-19, 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, the same strength as the first two doses, generated neutralizing antibodies to Omicron and the ancestral Wuhan version of the virus, according to The New York Times.

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-19 vaccine doses as of May 11, according to data from the American Academy of Pediatrics.

Those 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 higher in vaccinated children aged 5 to 11, CDC data show

According to the latest CDC data, since February, higher COVID-19 case rates were recorded among fully vaccinated children compared to unvaccinated children in the 5 to 11 age group.

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.
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> "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-19 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 in an email.
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> "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."

Having COVID may be more effective than getting a booster, studies show

Two new studies show, for people who are vaccinated against COVID-19, getting a breakthrough Omicron infection may provide better protection than receiving a second booster, Fortune reported.

One study conducted by German biotechnology company BioNTech SE assessed vaccinated individuals who had breakthrough COVID-19 infection associated with the Omicron variant.

BioNTech found these individuals had a better B-cell response than individuals who had received a booster but had not been infected.

According to MD Anderson Center, B cells are a type of white blood cell that create antibodies that bind to pathogens or foreign substances and neutralize them. B cells bind to a virus and prevent it from entering a normal cell causing infection. They also recruit other cells to help destroy infected cells.

A second study by the University of Washington and Vir Biotechnology investigated the immune responses of various groups based on vaccination and infection status.

The study analyzed blood samples of individuals who had been vaccinated and then caught the Delta or Omicron variants and compared them with those who had COVID-19 first and were then vaccinated, those who had been vaccinated but were not previously infected and those who were infected but had never received a COVID-19 vaccine.

The study found vaccinated individuals with breakthrough Omicron infection produced antibodies that formed a strong defense against other variants of the virus. Unvaccinated people who caught Omicron did not have a similarly robust immune response.

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-19 vaccine turned negatively effective among children and adolescents five months after receiving a second dose — meaning recipients were more likely to get COVID-19 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-19 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.

As The Defender reported on May 13, a different study published in JAMA showed second and third doses of Pfizer's COVID-19 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-19 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-19 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-19 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-19 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 COVID-19 vaccines for children under 6 will not have to meet the agency's 50% efficacy threshold required to obtain EUA.

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