

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

By [Megan Redshaw](#)

Global Research, May 18, 2022

[Children's Health Defense](#) 17 May 2022

Region: [USA](#)

Theme: [Law and Justice](#), [Science and Medicine](#)

All Global Research articles can be read in 51 languages by activating the “Translate Website” drop down menu on the top banner of our home page (Desktop version).

To receive Global Research’s Daily Newsletter (selected articles), [click here](#).

Visit and follow us on [Instagram](#), [Twitter](#) and [Facebook](#). Feel free to repost and share widely Global Research articles.

\*\*\*

*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 [waned 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.

“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.

“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.

\*

Note to readers: Please click the share buttons above or below. Follow us on Instagram, Twitter and Facebook. Feel free to repost and share widely Global Research articles.

*Megan Redshaw is a staff attorney for Children’s Health Defense and a reporter for The Defender.*

*Featured image is from CHD*

The original source of this article is [Children's Health Defense](#)  
Copyright © [Megan Redshaw](#), [Children's Health Defense](#), 2022

---

[Comment on Global Research Articles on our Facebook page](#)

[Become a Member of Global Research](#)

Articles by: [Megan Redshaw](#)

**Disclaimer:** The contents of this article are of sole responsibility of the author(s). The Centre for Research on Globalization will not be responsible for any inaccurate or incorrect statement in this article. The Centre of Research on Globalization grants permission to cross-post Global Research articles on community internet sites as long the source and copyright are acknowledged together with a hyperlink to the original Global Research article. For publication of Global Research articles in print or other forms including commercial internet sites, contact: [publications@globalresearch.ca](mailto:publications@globalresearch.ca)

[www.globalresearch.ca](http://www.globalresearch.ca) contains copyrighted material the use of which has not always been specifically authorized by the copyright owner. We are making such material available to our readers under the provisions of "fair use" in an effort to advance a better understanding of political, economic and social issues. The material on this site is distributed without profit to those who have expressed a prior interest in receiving it for research and educational purposes. If you wish to use copyrighted material for purposes other than "fair use" you must request permission from the copyright owner.

For media inquiries: [publications@globalresearch.ca](mailto:publications@globalresearch.ca)