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‘Preposterous’: FDA, CDC Authorize New COVID Boosters for Kids as Young as 5 — With No Data, No Independent Review

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Brian Hooker, Ph.D., called Wednesday’s decision by U.S. public health officials to authorize the untested vaccines for young children “preposterous,” adding, “It is time to stop this criminal experiment on America’s children.”

The U.S. Food and Drug Administration (FDA) on Wednesday amended the Emergency Use Authorizations (EUAs) for the new Pfizer and Moderna COVID-19 Omicron booster shots for children as young as 5 years old — despite having no direct data on the safety or effectiveness of the shots in children.

Within hours, Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention (CDC), signed off on the boosters — without a meeting of the CDC’s independent panel of vaccine experts.

> “FDA’s authorization of updated (bivalent) COVID-19 vaccines for this younger age group, and CDC’s recommendation for use, are critical next steps forward in our country’s vaccination program,” CDC officials said in a statement.

Commenting on the news, Brian Hooker, Ph.D., P.E., told The Defender,

> “It is preposterous to vaccinate these children with untested boosters, especially when the risks of the COVID-19 virus are minimal in this population.”

Hooker, chief scientific officer at Children’s Health Defense, continued:

> “Since the approval of mRNA vaccines for COVID-19 in the U.S., there have been 162 reported deaths attributed to these vaccines in individuals age 17 and under.
>
> “Yet the mortality associated with the COVID-19 virus in this age group is less than one

in 100,000 cases."

"It is time to stop this criminal experiment on America's children," he added.

No clinical trials complete yet, but vaccines ready to ship 'immediately'

Clinical trials of the booster shot in children have yet to be completed, Pfizer admitted.

In an Oct. 12 press release, the company said it "started a clinical trial to evaluate the adapted vaccine based on the BA.4 and BA.5 subvariants in children six months through 11 years of age aiming to offer all age groups the opportunity to immunize against Omicron variants and subvariants."

The Pfizer statement did not include information about the number of participants of the clinical trial or when the trial would be completed.

Pfizer told CNN doses will be shipped immediately.

> "Pfizer has the capacity to ship up to 6 million pediatric doses in the first 7 calendar days following receipt of EUA approval, without any impact to distribution output of the doses for individuals 12 years and old," a Pfizer spokesperson said.

The FDA said prior data on earlier versions of the vaccines — which targeted the original variant from Wuhan and the original Omicron variant BA.1 — sufficed for its decision to authorize the new boosters that target Omicron variants BA.4 and BA.5.

In its announcement, the FDA said it relied on "immune response and safety data" using the original bivalent boosters in adults and data on the original bivalent boosters "in pediatric age groups."

It did not specify the ages or numbers of children in those age groups.

But this presumption does not make scientific sense, according to Dr. Paul Offit, a vaccinologist who directs the Vaccine Education Center and is a member of the FDA's vaccine advisory panel.

> "The BA.1 strain is essentially gone," Offit told MedPage Today in an Aug. 2 interview on why he voted against authorizing the fall boosters for adults.
>
> "It's been replaced by BA.5/BA.4 and now BA.2.12.1, which are just Omicron subvariants that are somewhat distant from BA.1," he added.

Steve Kirsch, executive director of Vaccine Safety Research Foundation, pointed out the significance of Offit's concerns about the fall booster shots.

> "You will not find a bigger proponent of vaccines in general and the COVID vaccines specifically, in American medicine, than Dr. Paul Offit," Kirsch wrote in an Oct. 12 Substack post. "He voted YES to give the COVID vaccines to all children, even babies as young as 6-months."

Yet when the FDA's vaccine advisory panel on June 28 voted on the new COVID-19 boosters, Kirsch said, "Dr. Offit voted no, because (in his own words) 'HELL NO was not a choice!'"

Offit said he felt the panel was led to "vote yes" to reformulate boosters without critical data. In a July 6 interview with ZDoggMD, Offit described the Vaccines and Related Biological Products Advisory Committee's (VRBPAC) meeting as "unusual."

Offit said:

> "I've seen nothing like this. I guess the thing that's most upsetting to me is normally when you get something from the FDA when we have these meetings, you usually get it a few days before you meet. You usually get a couple of hundred pages.
>
> "Here on the other hand, normally you get the EUA [Emergency Use Authorization] submission from the company, which is 85 to 100 pages long, and then you get the FDA's review of all those data. It's a very thorough review. Not here though. Here, it was 22 pages from the FDA, which included a half-page on Pfizer's data and a half-page on Moderna's data."
>
> "You could get that from the press release," Offit said. "In fact, it was no more detail than the press release provided."

The question vaccine advisors are always asked to consider in the end is whether the benefits outweigh the risks — even if the risks are generally small and sometimes unknown, Offit said. "I didn't see the benefits."

Offit said he was surprised that out of 21 voting members, 19 voted "yes" because he "just didn't see the evidence for that."

> "I think this was something that was desired by the Biden administration," he added.

The risks associated with COVID-19 vaccination are real, according to the CDC's own data.

The FDA on Wednesday authorized the Pfizer-BioNTech Omicron BA.4/BA.5-adapted bivalent COVID-19 vaccine for children as young as 5, and Moderna's Omicron BA.4/BA.5-adapted bivalent vaccine for children as young as 6.

When the new bivalent boosters initially received EUA in September, the Pfizer booster was authorized only for individuals ages 12 and older, and the Moderna booster for people 18 and older.

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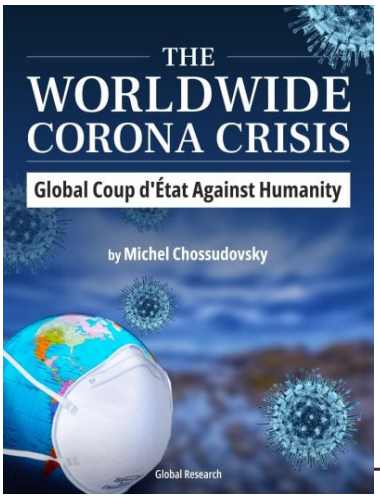

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