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COVID Vaccines for Kids Under 6 Won't Have to Meet 50% Efficacy Standard, FDA Official Says

By Megan Redshaw
Global Research, May 11, 2022
Children's Health Defense 10 May 2022

Region: USA
Theme: Science and Medicine

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The U.S. Food and Drug Administration's (FDA) top vaccine official told a congressional committee on Friday that COVID-19 vaccines for kids under 6 will not have to meet the agency's 50% efficacy threshold required to obtain Emergency Use Authorization (EUA).

The FDA is reviewing data from Moderna's two-shot vaccine for infants and toddlers 6 months to 2 years old, and for children 2 to 6 years old.

The agency is awaiting data on Pfizer and BioNTech's three-dose regimen for children under age 5 after two doses of its pediatric vaccine failed to trigger an immune response in 2-, 3- and 4-year-olds comparable to the response generated in teens and adults.

According to Endpoints News, **Dr. Peter Marks**, director of the Center for Biologics Evaluation and Research at the FDA, told the House Select Subcommittee on the Coronavirus Crisis the agency would not withhold authorization of a pediatric vaccine if it fails to meet the agency's 50% efficacy threshold for blocking symptomatic infections.

COVID-19 vaccines for adolescents, teens and adults had to meet the requirement.

> "If these vaccines seem to be mirroring efficacy in adults and just seem to be less effective against Omicron like they are for adults, we will probably still authorize," Marks said.

The FDA on June 30, 2020, issued guidance that in order for an experimental COVID-19 vaccine to obtain EUA, it must "prevent disease or decrease its severity in at least 50 percent of people who are vaccinated."

The guidelines were issued during a briefing with the Senate Committee on Health, Education, Labor and Pensions, during which senators sought assurances from former FDA Commissioner **Stephen Hahn, Dr. Anthony Fauci** and other top health officials that the expedited speed of development of COVID-19 vaccines wouldn't compromise the integrity of the final product.

All previously authorized COVID-19 vaccines and boosters for all age groups were required to meet the FDA's 50% requirement prior to obtaining EUA.

Vinay Prasad, a hematologist-oncologist and associate professor of Epidemiology and Biostatistics at the University of California, San Francisco posted a video responding to the news the FDA would bypass its own standard to authorize pediatric COVID-19 vaccines for kids.

Prasad said:

> "Peter Marks from the FDA — he's the defacto regulator-in-chief when it comes to vaccines — is saying that kids' vaccines don't need to hit the target. They don't need to hit the 50% vaccine efficacy against symptomatic SARS-CoV-2 target. That was the target that the FDA themselves came up with in the original pandemic.
>
> "They came up with this target 50% point estimate above, and the lower bound to the 95% confidence interval has to be above 30%. That was their minimum efficacy standard for vaccination. That was the standard they themselves set and that was the standard initial vaccine trials did clear for adults.
>
> "But the pediatric vaccine trials — both the Pfizer and Moderna — appear not to have cleared that bar, and Peter Marks is talking to congressional officials and he is saying that it's okay, we'll probably authorize it anyway."

> US FDA drops Kids Vax 50% Efficacy Requirement □□
>
> My Takehttps://t.co/sk3JVTW86d
>
> — Vinay Prasad, MD MPH □□ (@VPrasadMDMPH) May 10, 2022

Prasad said it was "incredible" that Marks would sign off on a pediatric vaccine if it seems to be mirroring efficacy in adults but is less effective against Omicron.

> "We have standards for a reason," Prasad said. The standard chosen by the FDA was "arbitrary and if anything I'd argue it was on the low side — 50% isn't as good as what we wanted," Prasad said.
>
> "Fifty percent is quite low, and if you have a very low vaccine efficacy […] you can have compensatory behavior that actually leads to a lot more viral spread," he added.

Prasad said when it comes to kids, it's "kind of a moot point" because estimates from the Centers for Disease Control and Prevention from a few months ago showed 75% of children had seroprevalence — and it's "probably higher now."

> "Taking a child under the age of 5 who already had and recovered from COVID and trying to make them better off with a vaccine against the original Wuhan ancestral strain — that's an uphill battle," Prasad said.
>
> "The absolute upper bound, absolute risk reduction, has got to be super super low because once kids have it and recover from it they generally do pretty well. If they get it again they do even better than the first time."

Lowering the regulatory standards for vaccine products is not the direction FDA should go, Prasad said. "They need to be upholding the standards they've set and raising the standards."

Prasadd raised concerns over what the standard will be moving forward if the agency doesn't abide by its own minimum requirement.

> "At what point will vaccine efficacy arrive at something the agency doesn't accept?" He asked.

Prasad said once the FDA does away with EUA, many preschools will immediately mandate COVID-19 vaccines, and they won't make exceptions for natural immunity or provide any exceptions at all.

> "And so what he's talking about is authorizing a vaccine in a setting where you have 75% minimum seroprevalence and the vaccine efficacy could be less than 50%," Prasad said. "How much less?"

Pointing to a Moderna press release stating one arm of its trial showed its pediatric vaccines were only 37% and 23% effective, Prasad asked, "How much lower can it go — 10%? How low before Peter Marks says that's too low?"

Prasad said if the adult vaccine becomes less effective over time, "tell me why that means you should accept the less effective kids' vaccine?"

Prasad explained:

> "If a therapy loses efficacy over time, why does that mean the bar to be a therapy is lower? It should mean that we need new therapies. We need a new mRNA construct.
>
> "You need to kind of aim at the thing that's actually out there now and not the original thing from two years ago. Maybe you want to rejigger your process. Try something new but it doesn't mean we keep lowering the bar. This is ridiculous."

Moderna reports concerning efficacy data for pediatric COVID-19 vaccines

As The Defender reported, Moderna on April 28 asked the FDA to approve its COVID-19 mRNA-1273 vaccine for children 6 months to 6 years old, citing different efficacy numbers than it disclosed in March.

The company conducted separate trials for two versions of the vaccine, one for infants and toddlers aged 6 months to 2 years, and one for children 2 to 6 years, and claimed data showed "a robust neutralizing antibody response" and "a favorable safety profile."

Yet, Moderna's KidCOVE study showed the company's COVID-19 vaccine failed to meet the FDA's minimum efficacy requirements for EUA in the 2- to under-6 age group, and barely surpassed the agency's 50% efficacy requirement in the 6-month to 2-year age group — even after the vaccine maker changed its analysis of the study to meet the threshold.

Moderna also did not follow trial participants beyond 28 days, so vaccine effectiveness after that time is unknown. Data from New York state show vaccine effectiveness for the 5-to-11 age group plummets within seven weeks to 12%.

> "Here, we're looking only at the first four weeks," **Dr. Madhava Setty** told The Defender. "Although data from New York were in a different age group using a different mRNA vaccine, the effectiveness was remarkably similar after four weeks. Why wouldn't we expect that the same thing is going to happen?"

The House Select Subcommittee on Coronavirus Crisis on April 26 asked the FDA for a status update on COVID-19 vaccines for children under 5.

The agency said it was considering holding off on reviewing Moderna's request to authorize its COVID-19 vaccine for children under 5 until it has data from Pfizer and BioNTech on their vaccine for children, pushing the earliest possible authorization of a vaccine from May to June.

When asked on Friday whether the FDA's vaccine advisors would slow-roll Moderna's applications and wait to review Pfizer's and Moderna's applications together, Marks said the meetings set for next month could move up if necessary.

> "Obviously if we get through reviews faster, then we will send them to committees sooner," Marks said.

According to **Rep. Jim Clyburn**'s (D-S.C.) account of the meeting, Marks said the FDA's vaccine advisory committee has reserved earlier dates, enabling the agency to potentially "move dates up even by a week for any of these reviews."

> "At the end of the day, we want people to have confidence in getting vaccinated," Marks said. "We need to get more kids vaccinated, not just in the younger than 5 age range, but also older than 5."

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