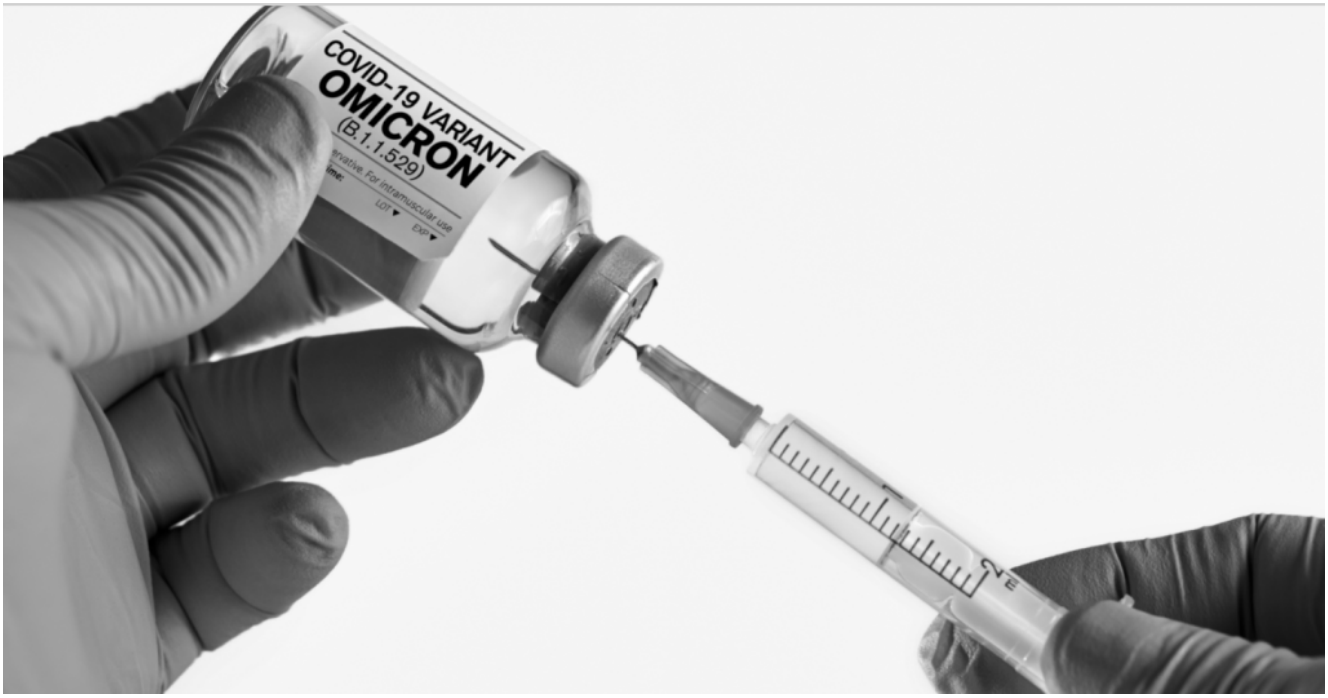
FDA Authorizes Bivalent COVID Booster as Fourth Shot for Kids Under Five With Almost No Data



The U.S. Food and Drug Administration (FDA) on Tuesday authorized a booster dose of Pfizer-BioNTech's bivalent COVID-19 vaccine for kids under five years old who previously received the three-dose primary series.

"Today's authorization provides parents and caregivers of children 6 months through 4 years of age who received the three-dose primary series with the monovalent Pfizer-BioNTech COVID-19 vaccine an opportunity to update their children's protection by receiving a booster dose with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent," Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research, said in a press release.

"Currently available data show that vaccination remains the best defense against severe disease, hospitalization and

death caused by COVID-19 across all age groups," he added.

Responding to the FDA's news, civil rights attorney Aaron Siri tweeted:

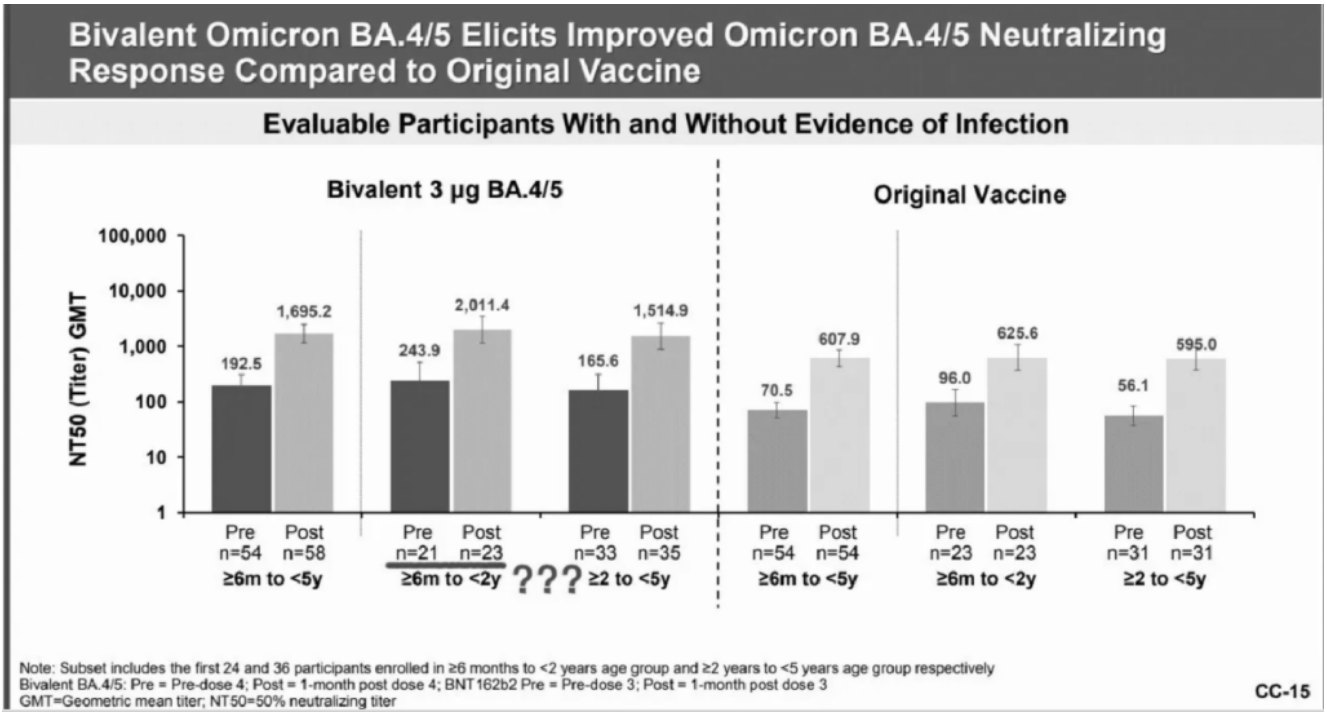
> *Breaking: This may be a new low, even for FDA. It just authorized new bivalent C19-V for babies/toddlers and only trial of this vaccine for those ages had "24 participants 6 months through 23 months" and "36 participants 2 years through 4 years of age." https://t.co/FwbAd136rv*
>
> *— Aaron Siri (@AaronSiriSG) March 15, 2023*

The FDA said its decision to authorize a fourth dose was based on previous analyses of earlier vaccine data and a new clinical trial in only 60 children ages 6 months through 4 who, after completing the primary series and receiving the bivalent booster, "demonstrated an immune response" to both the original SARS-CoV-2 strain and the BA.4/BA.5 Omicron subvariants.

The agency did not clarify what the immune response was, whether they were looking at anything other than increased antibody level, which they've said at previous meetings is not an accurate indicator of efficacy, and how long any immune response lasts.

The results of the new clinical trial have not been published but were presented to the FDA's vaccine advisors during a Jan. 26 meeting. According to writer Igor Chudov, the data included "the strangest count of participants."

For example, slide 16 of the presentation showed 21 babies in the clinical trial before the fourth shot and 23 babies after. None of the vaccine advisors questioned the discrepancy.



Chudov pointed out that under the new authorization, the four-dose vaccination series could be completed by the time a child is 10 months old if starting at age 6 months. As COVID-19 vaccines are shed via breast milk and cross the placenta, a 10-month-old baby could have eight exposures to COVID vaccines in their lifespan, including pre-birth, he said.