Correction Needed: Pfizer Vaccine in Children Under 5

Dear Sharon and the Times Correction Editor,

In your June 13, 2022 article “Pfizer’s vaccine is effective in children under 5, the F.D.A. says,” you report that “Pfizer has said only eight children in the placebo group and two in the vaccinated group fell ill.”

However, the FDA source you cite for this claim states:

From Dose 1 through the data cutoff, 1 placebo recipient 6-23 months of age and 7 participants 2-4 years of age (6 BNT162b2 recipients and 1 placebo recipient) met the criteria for severe COVID-19, with only one hospitalization for severe COVID-19 disease in a BNT162b2 recipient 99 days post-Dose 2.

That language is a bit convoluted, but a close read of it shows that 6 children who received the vaccine and 2 who received the placebo experienced a severe case of Covid-19.

This is confirmed by the same FDA document, which also states:

- “Seven cases in participants 2-4 years of age met the criteria for severe COVID-19: 6 in the BNT162b2 group, of which 2 cases occurred post unblinding, and 1 in the placebo group.”
- “The final severe COVID-19 case in a BNT162b2 recipient occurred 99 days post-Dose 2 in a 2-year-old participant who had increased respiratory rate (RR), decreased SpO2 as severe case criteria and was hospitalized due to COVID-19.”

Sincerely,

Jim

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Pfizer’s vaccine is effective in children under 5, the F.D.A. says.

By Sharon LaFraniere

The Food and Drug Administration said on Sunday that three doses of the Pfizer-BioNTech coronavirus vaccine appeared to be effective in preventing Covid illness in children under 5, judging by the level of virus-blocking antibodies the shots induced. …

Pfizer has said only eight children in the placebo group and two in the vaccinated group fell ill. The trial protocol said 21 cases were required to render a judgment on efficacy.

So far, the F.D.A. appears to view both Pfizer’s and Moderna’s requests for pediatric vaccines favorably. Parents are so eager to have a coronavirus vaccine for their youngest children that some have said they would accept even low rates of effectiveness, as long as the vaccines were safe.