

Congress of the United States
House of Representatives
Washington, DC 20515-4606

January 26, 2021

Peter Marks, M.D., Ph.D.
Director, Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dr. Peter Marks:

I write to you today with concerns regarding your recent comments about the need to vaccinate infants and toddlers with a COVID-19 vaccine and the potential approval of a COVID-19 vaccine for children under 5-years-old.

On a January 3, 2022 media call with Acting Commissioner Woodcock, you responded to a journalist's question on approving a COVID-19 vaccine for infants and toddlers saying:

“As for the zero- to five-year age range, although we can't talk about our actions, we can say that we certainly understand that there is a pressing need [to vaccinate] in that age range, that we understand the hospitalizations that may be occurring in that age range, and we will move with appropriate speed with the appropriate data in hand.”¹

This is in line with a recent comment made by Dr. Anthony Fauci. On January 19, 2022, Dr. Fauci explained that it his hope for a three-dose COVID-19 vaccine to be approved for children under five “in the next month or so.”²

Sadly, according to the CDC, there have been 368 (0%) COVID-19 deaths among the 0-4 age group since the onset of the pandemic. Comparatively, there have been 5,662 (0.8%) COVID-19 deaths among the 18-29 age group, 192,918 (26%) among the 75-84 age group, and 204,578 (27.6%) among the 85 and older age group.³

As you know, the Center for Biologics Evaluation and Research (CBER) is charged with assuring the safety and effectiveness of vaccines and other biological products, which is why your comment is deeply

¹ <https://youtu.be/zBRfXk5xvLw?t=957>

² <https://www.cnn.com/2022/01/19/fauci-says-fda-could-authorize-pfizers-covid-vaccine-for-kids-under-5-in-the-next-month.html>

³ <https://covid.cdc.gov/covid-data-tracker/#demographics>

concerning. As the CDC data shows, there is no “pressing need” for infants and toddlers to get vaccinated as COVID-19 poses an extremely low risk of death or hospitalization to children. In fact, some scientific literature suggests that the rare heart side effects from the vaccine may pose a greater risk to certain age groups of children than hospitalization from COVID-19.^{4,5}

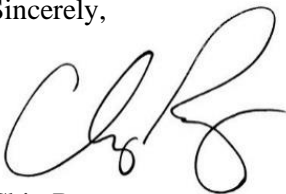
Further, the lack of transparency of your agency has offered throughout the pandemic is concerning. As recently displayed in the Freedom of Information Act (FOIA) suit involving the Public Health and Medical Professionals for Transparency, the FDA requested around 75 years to fully publish the requested documents for the approval of the Pfizer-BioNTech COVID-19 vaccine. As a victory for transparency, the court rightly concluded that “this FOIA request is of paramount public importance” and ordered the documents to be released at a rate of 55,000 pages per month, rather than the FDA’s requested rate of 500 pages per month.⁶

It is of the utmost importance that the FDA is completely transparent to the American public, especially regarding medical products for children. Due to the recent history of your agency’s lack of transparency, please provide full and separate responses to each question below as well as the requested documents by February 26, 2022.

1. What communication, if any, have you received from Pfizer personnel regarding the potential approval of a COVID-19 vaccine for the 0-4 age group or trials for this age group? For the approval of booster vaccine doses for other age groups under 18? Please provide copies of that correspondence.
2. To date, have you received any correspondence or documentation that shows any adverse effects of a COVID-19 vaccine for the 0-4 age group? Please provide copies of that correspondence.
3. Is the 0-4 age group at risk of cardiac adverse events (CAE), such as myocarditis, from a COVID-19 vaccine? How does this risk compare to other age groups?
4. What communication, if any, have you received from any member of the Vaccine and Related Biological Products Advisory Committee regarding a COVID-19 vaccine for the 0-4 age group? For the approval of a booster vaccine for the 12-15 age group? Please provide copies of that correspondence.

Thank you for your clarification.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chip Roy', with a stylized, flowing script.

Chip Roy
Member of Congress

⁴ <https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1.full.pdf>

⁵ <https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1>

⁶ <https://fingfx.thomsonreuters.com/gfx/legaldocs/gdvzykdllpw/Pittman%20FOIA%20Order.pdf>