Congress of the United States
Washington, DC 20515

May 3, 2022

Dr. Rochelle P. Walensky
Director
Centers for Disease Control and Prevention
395 E Street S.W., Suite 910
Washington, D.C. 20201

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf and Director Walensky:

We write regarding Food and Drug Administration (FDA) emergency use authorization (EUA) of COVID-19 vaccines for our youngest population, our children. Our greatest duty is to ensure the safety of America's youngest generation, to ensure that their health is considered and protected accordingly. This generation is the population at least risk for serious adverse complications from COVID-19, therefore we should take caution when promoting a vaccine for their developing bodies.

We would like to bring forth concerns regarding the COVID-19 vaccines and our children as the FDA considers meeting with the Vaccine and Related Biological Products Advisory Committee (VRBPAC) to consider Emergency Use Authorization (EUA) of Pfizer's COVID-19 vaccine for children 6 months to 4 years old. Moderna has also announced that it will seek EUA from the FDA for a COVID-19 vaccine for children 6 months old to 6 years old.

We understand that following authorization, the Advisory Committee on Immunization Practices (ACIP) will outline guidelines on COVID-19 immunization practices for these children just as ACIP did for vulnerable children ages 5-to-11years old.

We believe in the need for a very high standard for safety and efficacy, especially in the younger populations. There are many extremely important questions regarding the safety of mRNA COVID-19 vaccines that must first be answered, many of which have not been answered by the FDA. These mRNA vaccines are unprecedented, were created rapidly, lack long-term studies made available to the public, and have been causing myocarditis – especially in children and young adults.

We're sure the FDA is aware of the prevalence of myocarditis, as the CDC recently announced that they may consider experimenting with spacing out the time between vaccine doses so as to attempt to prevent the many myocarditis cases that have come about in children.

The FDA has also reportedly ordered Pfizer to investigate the risk of heart inflammation following COVID-19 vaccination, and accepted Pfizer's suggestion of reporting this information as late as October 31, 2025.

The lack of concern with experimenting on our children is extremely shocking, especially because there has been a rapid decline in the prevalence of COVID-19 cases, with the high having been 1,335,349 cases on January 10, 2022, and the current low at 23,358 new cases as of April 24, 2022. The CDC states that the Omicron variant causes less severe disease than infection with prior variants, and can spread through those who are vaccinated.

As of March 30, 2022, the CDC has reported 363 deaths in 0-to-4-year-olds from 2020 to 2022, and has not indicated if these were directly caused by COVID-19 infection, and if any were directly from Omicron. According to the CDC, the largest spikes in COVID-19 cases in 0-to-4-year-olds occurred September 18, 2021, for a total of 15 COVID-19 deaths.

Pfizer has stated that it believes three doses of its COVID-19 vaccine will be needed for young children, because two doses were not sufficient to induce an immune response. A study released in February 2022 found that the Pfizer vaccine

was only 12% effective in children 5-to-11-years-old after 30 days. How will a third dose boost this large of a decline in efficacy, and what is the decline in efficacy for 0-to-4-year-olds?

Children have been found to develop strong and robust antibody responses to the spike protein after having been infected with COVID-19. The antibody response against the spike protein was found to be higher in children than in adults, and remained high over a period of 6 months post infection while antibody waning was observed in adults.

A German study published in November of 2021 found a low hospitalization and fatality rate due to COVID-19 in young children, approximately 0.2 ICU hospitalizations in 5-to-11-year-olds per 10,000. A study published in January of 2022 concluded that 99.995% of children under 18 years of age with a positive COVID-19 test survived.

A competing study, completed in November 2021, argues that the COVID-19 vaccine is safe for children ages 5-to-11, an age group for which 10,157 adverse reactions have been reported from December 14, 2021, to April 1, 2022. But this study was funded by BioNTech and Pfizer, the same companies manufacturing the vaccine they claim is safe for children who are at a low risk of severe infection from COVID-19.

Does the FDA believe this to be a conflict of interest? Why are the companies who are producing unprecedented mRNA vaccines for children the same companies that are funding the study for safety and efficacy?

Moderna is also pursuing EUA authorization for children under 6 years old, and stated that its two-dose COVID-19 vaccine reduced cases of symptomatic infection by 43.7% in children 6 months to 2 years old, and by 37.5% in children 2-to-6-years-old. Only 6,700 children were enrolled in the trial's study of children 6-years-old and younger. Concerningly, Moderna failed to meet 50% efficacy for EUA standards, and failed to enroll enough participants. Moderna reportedly also admitted that they used immunobridging, a practice of taking the efficacy results from one population to predict the efficacy in another population.

This does not accurately predict the vaccine's effectiveness or safety in our youngest children. Moderna is treating our children as statistical numbers that they can manipulate, not the developing and vulnerable children that they are.

Given the low risk that COVID-19 poses to children, and the robust strength of their immune systems, it is concerning that the FDA is considering a vaccine that has an extremely low efficacy rate in children and comes with risks such as myocarditis – something that can be fatal or pose chronic health issues. Furthermore, no one knows the potential long-term adverse effects of COVID-19 mRNA vaccines, especially in young and rapidly developing children.

Given these facts, we are very concerned that FDA approval of these vaccines for healthy children – who have a 99.995% survival rate against COVID-19 – may pose significantly more risk than benefit.

We believe this issue deserves the greatest attention and we would like to hear directly from the FDA about the details of the risks and benefits should the FDA consider broad approval of these vaccines for the youngest of children.

Sincerely,

Bill Posey
Member of Congress

Ted Cruz
U.S. Senator

Louie Gohmert
Member of Congress

Jeff Duncan
Member of Congress

Andy Biggs
Member of Congress

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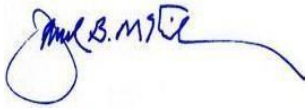

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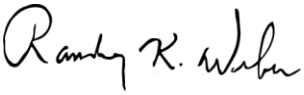

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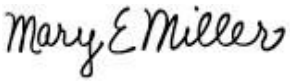

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