Republicans Question FDA Over Imminent 'Reckless' Authorization of COVID-19 Vaccines for Kids Under 5

A group of Republican lawmakers led by Rep. Ted Cruz (R-Texas) and Rep. Bill Posey (R-Fla.) are questioning why the U.S. Food and Drug Administration (FDA) would authorize COVID-19 vaccines for young children when the virus poses little risk to kids, vaccines are not effective and long-term risks of vaccination are unknown.

The FDA is scheduled to meet with its vaccine advisory panel, the Vaccines and Related Biological Products Advisory Committee (VRBPAC), on June 15 and is expected to recommend Emergency Use Authorization (EUA) to Pfizer and Moderna COVID-19 vaccines for children aged 6 months to 5 years.

Ten million pediatric vaccine doses have been made available for pre-order in anticipation of vaccinations for kids ages 5 and younger beginning before the end of the month, the White

House announced Thursday.

To date, jurisdictions have already ordered 58% of available Pfizer doses and 34% of available Moderna doses even though the FDA and Centers for Disease Control and Prevention (CDC) have not signed off on vaccines for this age group and their advisory panels have not met to discuss the data.

Although the CDC would have to sign off on the FDA's decision, White House officials say they anticipate vaccines will begin in earnest on June 21.

In a letter obtained June 7 by The Epoch Times, lawmakers wrote:

> *"The broad approach of the CDC and FDA to date has been a one-size-fits-all policy – get the vaccine regardless of age, risk factors, the underlying health of the individual, or previous infection. Yet, to date there remain many unanswered questions about these EUA-approved COVID-19 vaccines and only a small percentage of the safety data about these vaccines that are in the possession of the FDA and the manufacturers has been released for review."*

The congressional members noted nearly 70% of children aged 1 to 4 have natural immunity from having had COVID-19 – and this percentage was determined by the CDC prior to the last two waves.

Natural immunity has been shown to provide longer-lasting, robust and more durable protection against re-infection than vaccines.

The group asked the FDA to answer a series of questions before authorizing COVID-19 vaccines for young children:

They asked why the FDA has been slow to release "hundreds of thousands of pages of data pre-approval manufacturer studies, post-approval adverse events data and other post-approval

manufacturer data submitted to the FDA as required by law; whether the FDA will release within 14 days the data that served the basis of the FDA's EUA approval should it be granted for children under 5, what the cardiac risk factor is in administering COVID vaccines to kids, why the FDA lowered its 50% efficacy threshold requirement for the nation's youngest children, whether COVID vaccines cause antibody-dependent enhancement, whether there's an increased risk of disease to future variants if vaccinated, how many lives will be saved through vaccination over the next year and how many children have died from COVID age 5 and under had pre-existing conditions.

The group also asked the agency for examples of medical emergencies for children ages 4 and under that would allow it to use its "emergency use authorization" and further questioned the data being used to justify EUA of COVID-19 vaccines for kids.

"The data show that the risks of serious adverse outcomes for COVID for children five and under is very low and as such the standard for evaluating EUA interventions must be very high," the group wrote.

"We believe each question raised above is not just important, but essential questions for the FDA, VRBPAC and the CDC when it comes to doing a thorough job of evaluating the potential benefits and potential risks of the vaccines for which you have been asked to consider granting an Emergency Use Authorization," the letter states.

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Posey said in a statement:

> *"I am concerned that in a rush to mandate a 'one-size-fits-all' policy, the FDA is failing to consider that this age group is least at risk for complications from COVID and that the CDC estimates 68% of those under five have already had*

> *COVID. Common sense would suggest that VRBPAC members have already asked these questions, so we would expect a response by the time they meet. If we don't receive answers, it is right to assume they haven't asked basic benefit and risk questions about using this vaccine for millions of children who are at very little risk from COVID."*

Cruz said:

> *"We are in our third year with COVID-19, and we know vastly more about the virus now than we did in 2020. One of the most important things we know is that this virus poses minimal risk for children. Before the FDA approves an Emergency Use Authorization for a children's vaccine, parents should be able to see the data and paperwork they would use to justify this decision. This is the least the FDA can do for families in Texas and across the country so parents can make the best decisions for their children."*

Louie Gohmert (R-Texas) questioned the unknown long-term side effects of the shots, post-vaccination heart inflammation cases that weren't detected until after the vaccines were authorized and the high survival rate of COVID-19 in children.

"The push for vaccine approval seems absolutely reckless," Gohmert said.

He added:

> *"Just last month, the FDA essentially announced that people should no longer take the Johnson and Johnson vaccine due to dangerous blood clotting side effects. This, after telling us the J&J vaccine was safe and effective for over a year. As Americans, we have every right to demand that the utmost safety and efficacy standards be implemented and rigorous studies and testing be performed before these injections are approved for anyone, especially innocent children."*

Lawmakers who signed on to the letter also include Sen. Ron Johnson (R-Wis.), Rep. Louie Gohmert (R-Texas), Rep. Ralph Norman (R-S.C.), Rep. Mary Miller (R-Ill.), Rep. Andy Biggs (R-Ariz.), Rep. Chip Roy (R-Texas), Rep. Dan Bishop (R-N.C.), Rep Lauren Boebert (R-Colo.), Rep. Andrew Clyde (R-Ga.), Rep. Thomas Massie (R-Ky.), Rep. Warren Davidson (R-Ohio), Rep. Jeff Duncan (R-S.C.), Rep. Diana Harshbarger (R-Tenn.), Rep. Matt Rosendale (R-Mont.), Rep. Vicky Hartzler (R-Mo.) and Rep. Bob Good (R-Va.).

As The Vault Project reported on May 10, a top vaccine official told a congressional committee COVID-19 vaccines for kids under six will not have to meet the agency's minimum 50% efficacy requirement to obtain EUA.

The FDA's top vaccine official, Dr. Peter Marks, told a congressional committee the agency would not withhold authorization of a pediatric COVID-19 vaccine for kids under six if it failed to meet the agency's 50% efficacy requirement for blocking symptomatic infection.

"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 vaccine to obtain EUA, it must "prevent disease or decrease its severity in at least 50% 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 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.