EXCLUSIVE: Republicans Press FDA on Why COVID-19 Vaccines Would Be Authorized for Young Children

Description

USA: A group of members of Congress is pressing the U.S. Food and Drug Administration (FDA) for answers before the regulator decides whether to authorize COVID-19 vaccines for young children.

All Americans aged 5 and older can get a COVID-19 vaccine. The FDA is scheduled to meet with its advisory panel on June 15 to discuss whether to grant emergency use authorization (EUA) for the Moderna and Pfizer vaccines for children aged 6 months to 4 years old.

A bicameral group of members of Congress, led by Sen. Ted Cruz (R-Texas) and Rep. Bill Posey (R-Fla.), are questioning whether an EUA makes sense, given how little risk COVID-19 poses to young children and how the vaccines have plunged in effectiveness against infection as new virus variants have emerged during the pandemic.

“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,” the members wrote to FDA Commissioner Robert Califf and members of the advisory panel in a June 7 letter obtained by The Epoch Times. “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 members noted that nearly 70 percent of children aged 1 to 4 have recovered from COVID-19, according to the Centers for Disease Control and Prevention (CDC). That recovery gives the children a level of protection against re-infection that studies show is better than the protection from the vaccines. The members also pointed out that children who contract COVID-19 have a high survival rate and have little risk of experiencing severe disease.

The group asked the FDA to answer a series of questions before issuing its decision on the EUA requests from Moderna and Pfizer. They want to know, among other details, the cardiac risk factor for children getting the vaccines; whether the FDA will commit to sticking with a 50 percent effectiveness

threshold it outlined in 2020; and whether there is a possibility children who get the vaccines will face higher risk from future variants of the virus that causes COVID-19, known as SARS-CoV-2 or the CCP (Chinese Communist Party) virus.

“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.”

lawmakers-write-to-fda-vrbpac

VRBPAC stands for the Vaccines and Related Biological Products Advisory Committee. It is the FDA’s advisory panel on vaccines.

The group who wrote the letter also includes 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.).

The FDA did not respond to a request for comment.

“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,” Posey said in a statement.

“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

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Drug Administration (FDA) Commissioner Robert Califf testifies during a Senate Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee hearing on Capitol Hill in Washington on April 28, 2022. (Kevin Dietsch/Getty Images)

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Given the high survival rate of children, the unknown long-term side effects of the shots, and the post-vaccination heart inflammation cases that were only detected after the vaccines were authorized, “the push for vaccine approval seems absolutely reckless,” Gohmert said.

“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,” he added.

After Rep. James Clyburn (D-S.C.) reported being told by Dr. Peter Marks, a top FDA vaccine official, in May that the agency would not withhold authorization solely because a vaccine was not at least 50 percent effective. An FDA spokesperson told The Epoch Times in an email that the agency “will evaluate any data submitted in the context of the ongoing public health emergency and will only authorize vaccines for the youngest children that meet our standards and for which the known and potential benefits outweigh the known and potential risks.”

Experts and parents are divided on whether vaccines are needed for children, especially healthy children.

Based on research and the effect of COVID-19 on youth, “childhood vaccination should not be considered unless a child has significant co-morbidities like cystic fibrosis, severe Type I diabetes, etc.,” Dr. Steven Hatfill, a virologist, told The Epoch Times in an email.

Dr. Moira Szilagyi, president of the American Academy of Pediatrics, said in a statement that U.S. authorities should “move with all possible speed” to review the data on vaccines for young kids, adding, “Children are not immune from COVID, which can cause severe and long-term illness, hospitalizations and even death.”

Correction: A previous version of this article misidentified the state that Sen. Johnson represents. It is Wisconsin. The Epoch Times regrets the error.

Featured image: Sen. Ted Cruz (R-Texas) speaks to reporters in Washington on April 7, 2022. (Drew Angerer/Getty Images)

By Zachary Stieber

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