Pfizer to Seek Emergency Use Authorization of COVID Vaccine for Ages 5-11 Based on Small Study of 140 Kids

Pfizer and BioNTech said Thursday they plan to apply for Emergency Use Authorization (EUA) of a booster dose of their COVID vaccine for healthy 5- to 11-year-olds based on the results of a small study that has not been published or analyzed by independent experts.

The companies also plan to request authorization from the European Medicines Agency and other regulatory agencies around the world as soon as possible.

Pfizer said in a press release a third dose of its vaccine produced significant protection against the Omicron variant in children 5 to 11 in a small Phase 2/3 clinical trial.

The study was based on data from only 140 children 5 through 11 years old who received a booster dose six months after the

second dose of Pfizer-BioNTech's COVID vaccine as part of the primary series.

Pfizer said 30 children who participated in the study revealed a 36-fold increase in virus-fighting antibodies – levels high enough to fight the Omicron variant. What Pfizer didn't acknowledge is the fact antibody titers are not necessarily predictive of the transmission or severity of the disease.

Pfizer claimed a third dose was "well tolerated with no new safety signals observed," although this doesn't explain much considering the severe adverse events reported with the original two doses include things like heart damage and paralysis.

Although Pfizer said more than 10,000 children under the age of 12 have participated in clinical trials investigating its COVID vaccine, only 140 were selected for the study forming the basis for the company's EUA request for a third dose. Apparently, the company believes that a sample size of 140 children is sufficient to make a sweeping recommendation that all U.S. children in the younger age group receive a booster dose.

This is the equivalent of doing a study to determine if smoking is safe for millions of people, including only 140 people in the study, and concluding smoking doesn't cause cancer because nobody developed cancer from smoking a few cigarettes over the two-week period they were followed for adverse events.

"The clinical trial used to support the notion of a COVID-19 booster for 5 to 11-year-olds is entirely inadequate to make any such recommendation," said Dr. Brian Hooker, chief science advisor at Children's Health Defense.

"This small-scale, limited-time trial contains only 140 patients, which is not sufficiently sized to assess vaccine adverse events at all, especially rarer injuries such as the

devastating medical maladies sustained by Maddie de Garay – an adolescent injured in the original Pfizer clinical trial."

Maddie de Garay suffered severe injuries during Pfizer's clinical trial for 12 to 15-year-olds that left her paralyzed, unable to eat, with seizures and no bladder control. Her extensive injuries have been ignored by the pharma giant.

Dr. Liz Mumper, a pediatrician, said, "Once again, Pfizer does science by press release." Mumper said the rise in antibody titers is just one small piece of the story of kids and COVID.

"The more important issue is that, on the basis of careful risk-versus-benefit analysis, healthy children do not need a COVID vaccine," Mumper said, because many kids already had COVID and developed robust and durable antibodies.

CHD President Mary Holland accused Pfizer of reaching "a new low" by seeking authorization of booster shots for children based on an "unpublished, non-peer-reviewed study of 140 children."

"Following the science on COVID vaccination shows that the risks outweigh the benefits for COVID shots for kids, let alone boosters," Holland said. "One suspects this is simply a misguided ploy to use up Pfizer's vaccine inventory before its expiration."

Pfizer tested its booster dose while Omicron was the dominant variant this winter; however, Omicron is no longer the dominant variant. In recent weeks, BA.2 has become the dominant COVID variant. It has not been determined whether a third dose provides any protection against the new variant.

Requesting EUA based on a tiny sample size where a third dose was tested against a variant that is becoming obsolete is absurd – but U.S. health agencies have proven the bar is low. The U.S. Food and Drug Administration (FDA) and CDC recently bypassed their vaccine safety advisors to approve a second

booster for adults aged 50 and up based on non-peer-reviewed Israeli data in adults 60 and up.

The FDA authorized the Pfizer-BioNTech COVID vaccine for use in children 5 through 11 years of age in October 2021 and recently authorized a booster dose in individuals 12 through 15 years of age and older and immunocompromised children 5 years of age and older.

According to an analysis of CDC data by the American Academy of Pediatrics, as of April 6, 2022, 9.7 million U.S. children ages 5 to 11 have received at least one dose of a COVID vaccine – representing 34% of 5- to 11-year-olds.

Approximately 7.8 million U.S. children ages 5 to 11 completed the 2-dose primary vaccination series – representing 28% of 5- to 11-year-olds.

About 18.7 million children aged 5 to 11 had yet to receive their first COVID-19 vaccine dose.

Seventeen million U.S. adolescents ages 12 to 17 have received at least one dose of a COVID vaccine – representing 68% of 12- to 17-year-olds. Only 58% completed the 2-dose vaccination series and 8.1 million adolescents in this age group have yet to receive a COVID vaccine.

There are 72.8 million children under age 18 in the U.S., which is 22% of the U.S. population. Children aged 5 to 11 represent 8.6% of the U.S. population.

The FDA has not authorized any COVID vaccines for use in children under 5.

According to the latest data from the CDC's Vaccine Adverse Events Reporting System (VAERS), between Oct. 1, 2021, and April 1, 2022, 10,157 adverse events, including 239 rated as serious and 5 reported deaths were reported in the 5- to 11-year-old age group after receiving a COVID vaccine.

Although reports submitted to VAERS require further investigation before a causal relationship can be confirmed, the system has been shown to report only 1% of actual vaccine adverse events.