Pfizer Seeks FDA Authorization of Experimental COVID Bivalent Booster Shot for Kids Under 5

Pfizer and German partner BioNTech announced on Monday they submitted an application to the U.S. Food and Drug Administration (FDA) for emergency use of their Omicron bivalent COVID-19 booster vaccine for children under the age of 5.

If authorized, children would receive a three-dose primary series consisting of two doses of the original Pfizer/BioNTech vaccine and an additional dose of the bivalent booster, which contains both the original Wuhan strain that's no longer circulating and a strain tailored to the BA.4 and BA.5 omicron subvariants that will soon be obsolete.

Pfizer said Monday a third dose may help prevent severe illness and hospitalizations in children. Yet, there is no clinical data to support that assertion.

According to the Centers for Disease Control and Prevention (CDC), only 2% of children under two and 4% of 2- to 4-year-olds have been vaccinated against COVID-19.

The FDA has already authorized the modified bivalent COVID-19 shots by Pfizer and Moderna for everyone ages 5 and older. The CDC rolled out the shots for children aged 5 to 11 mid-October, despite the absence of any human clinical trials showing the vaccine was safe or effective.

CDC claims bivalent booster is effective based on inferior 'data'

In a report published by the CDC on Dec. 2 providing the first "real-world data" on the bivalent booster, the agency claimed the shot is effective in protecting people from severe COVID-19.

The relative effectiveness among people ages 18 to 49 who received the bivalent booster compared to those who only received two shots ranged from 30% if their last primary vaccine dose was two to three months prior, to 56% if their last original vaccine dose was more than eight months prior to the new one.

The effectiveness was lower for people aged 50 years or older—ranging from 28% to 48% and was 43% among persons 65 years and older.

Researchers claimed a third dose was "effective" because antibody levels slightly increased, despite the fact the FDA's vaccine advisory panel acknowledged during previous meetings that antibody levels are not an accurate indicator of whether a COVID-19 "vaccine" provides "protection."

According to data released Friday by the CDC, as of Nov. 25, there were a total of 10,547 reports of adverse events following the new COVID-19 bivalent booster, with 45%

attributed to Moderna's booster and 55% attributed to Pfizer/BioNTech's booster. The data included a total of 90 deaths and 627 serious injuries.