

# Pfizer, BioNTech Seek COVID Biologic Emergency Use Authorization for Infants as Young as Six Months Old

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*Pfizer and BioNTech have requested emergency use authorization (EUA) for doctors to administer two doses of their mRNA COVID-19 biologic to infants as young as six months old. A statement from Pfizer states that the “rolling submission” application was submitted on Feb. 1, 2022 at the request of the U.S. Food and Drug Administration (FDA) “in response to the urgent public health need in this population.”<sup>1</sup> Ten days later the company withdrew the request to gather more data on the vaccine’s effectiveness, which was suboptimal in two to four year olds, and provide evidence for a three dose primary series, rather than two doses.<sup>2</sup>*

## **Pfizer Vaccine Fails to Elicit Robust Immune Response in Younger Children**

Pfizer’s own data<sup>3</sup> demonstrates that the vaccine failed to elicit a strong enough immune response with just two three microgram doses for some within the age group making the EUA process unique from any other age group’s authorization thus far. Pfizer had originally sought authorization for two doses to allow parents of young children to begin the vaccination process while awaiting potential authorization of a third dose. The third dose is scheduled to be administered no earlier than eight weeks after the second dose.<sup>4</sup>

Some physicians and public health officials have expressed concern that such an unusual vaccine approval application will further deter parents from vaccinating their children.<sup>4</sup> As it currently stands, the FDA has granted an EUA to Pfizer for five- to 11-year-olds to receive two 10 microgram doses of the COVID vaccine and also approved a 30-microgram booster dose for ages 12 and up.<sup>5</sup>

## **CDC Data Says Booster Less Beneficial to Younger People**

Newly published data released from the U.S. Centers for Disease Control and Prevention (CDC) confirms that the rationale for booster doses is less compelling in terms of providing benefit to younger populations compared to adults.<sup>6</sup> Dr. Dan Barouch, a virologist at Beth Israel Deaconess Medical Center in Boston, stated:

I'm in favor of boosters, but I don't want to overstate their importance. The benefit of a booster dose is clearly greater in the elderly. It is progressively less in the lower risk groups."<sup>6</sup>

The FDA's Vaccines & Related Biological Products Advisory Committee (VRBPAC) had been scheduled to meet on Feb. 15 to review the vaccine's safety and effectiveness data and discuss Pfizer's request. The FDA authorized the two-dose vaccine for use in children five through 11 years old in October 2021. According to the CDC, approximately one third of children in that age group have received the vaccine.<sup>7</sup>

An article by VOX states that giving COVID vaccines to children will help stop the spread of the virus and relieve stress on hospitals and allow schools to stay open...

[Vaccines for young children] would also provide peace of mind to parents, caregivers, and teachers whose lives have been repeatedly disrupted as the highly transmissible omicron variant continues to rage.

The article continues stating that vaccination of this age group, which makes up more than 20 million children, would help to close one of the biggest remaining gaps in vaccine eligibility.<sup>4</sup>

### **Only 27 Percent of Parents Eager to Vaccinate Children Under 12**

An October survey by the Kaiser Family Foundation<sup>8</sup> found that only 27 percent of parents with children ages five to 11 years old were "eager" to get the vaccine for their children while 30 percent said they will definitely not allow the vaccine to be given to their young children. Parents cited concerns over potential long-term side effects as well as the desire to "wait and see" how the vaccine is working.

### **Some Physician Researchers Urge Caution in Giving COVID Vaccine to Children**

A group of physician researchers who collectively pioneered several vaccines and experimental cancer drugs wrote an opinion piece<sup>8</sup> for *The Washington Times* in October urging the public to apply the brakes in the hastiness of administering the new COVID vaccine to the pediatric population. The article outlines the existing disabling reactions in adults, the use of novel mRNA technology which releases pro-inflammation factors with no built in "off" switch, and the fact that COVID is rarely causing severe illness in children.

The authors also outlined the history of medicine and how we have seen "time and time again" tragic side effects which are not known until decades later. The article concludes:

There is a lot that we don't know about the long-term safety of available COVID-19 vaccines. Bottom line, no health professional in good conscience can look a parent in the eye today and say these vaccines are unequivocally safe. As medical students, we

took the Hippocratic oath, a promise to practice ‘primum non nocere,’ meaning ‘first, do no harm.’ Let us patiently wait for the completion of long-term safety studies before we rush ahead blindly with blanket public health solutions that may cause unintentional and irreparable harm.<sup>8</sup>

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## Notes

<sup>1</sup> Pfizer. [Pfizer and BioNTech initiate rolling submission for emergency use authorization of their Covid-19 vaccine in children 6 months through 4 years of age following request from U.S. FDA.](#) Feb. 1, 2022.

<sup>2</sup> Lovelace B. [Pfizer postpones FDA request for Covid vaccine for kids under five.](#) NBC News Feb. 11, 2022.

<sup>3</sup> Lovelace B. [Pfizer is testing a third Covid vaccine dose in young kids, delaying trial results.](#) NBC News Nov. 4, 2021.

<sup>4</sup> Irfan U. [Why young children have waited so long for COVID-19 vaccines.](#) VOX Feb. 3, 2022.

<sup>5</sup> Pfizer. [Pfizer and BioNTech receive US FDA emergency use authorization of COVID-19 vaccine booster for individuals 12 years of age and older.](#) Jan. 3, 2022.

<sup>6</sup> Mandavilli A. [Younger Americans benefited less from booster shots than older people.](#) The New York Times Feb. 4, 2022.

<sup>7</sup> U.S. Food and Drug Administration. [Coronavirus \(COVID-19\) update: FDA advisory committee meeting request for authorization of Pfizer-BioNTech COVID-19 vaccine for children 6 months through 4 years of age.](#) PR Newswire Feb. 1, 2022.

<sup>8</sup> Hamel L et al. [KFF COVID-19 vaccine monitor: October 2021.](#) Kaiser Family Foundation Oct. 28, 2021.

<sup>9</sup> Kwak L, Rosen S, Shachar I. [Applying brakes on ‘warp speed’ COVID-19 vaccinations for children.](#) The Washington Times Oct. 28, 2021.

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