



October 19, 2022

Centers for Disease Control and Prevention  
1600 Clifton Road NE  
MS H24-8,  
Atlanta, GA 30329-4027

Attn: October 19-20, 2022, ACIP Meeting,  
Docket No. CDC-2022-0111  
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The COVID-19 messenger mRNA biological product developed by Pfizer/BioNTech (Comirnaty) and Moderna/NIAID (Spikevax) is currently being distributed for administration to children between the ages of six months and 12 years (Pfizer) and between six months and 18 years (Moderna) under an Emergency Use Authorization (EUA) granted to the companies by the U.S. Food and Drug Administration (FDA).<sup>1</sup> Currently, these vaccines are being recommended by the U.S. Centers for Disease Control (CDC) for children under the interim guidance within the scope of an Emergency Use Authorization (EUA).<sup>2</sup> Pfizer's COVID vaccine has been fully licensed by the FDA for use in individuals over age 12, while the Moderna COVID vaccine is fully licensed for individuals over age 18.<sup>3 4</sup>

On Oct. 12, 2022, the FDA amended the EUA to approve distribution of a new COVID bivalent booster for children as young as five years old (Pfizer) or as young as six years old (Moderna) containing the original strain of SARS-CoV-2 and a mutated form of the spike protein found in the BA.4 and BA.5 variants of the Omicron strain. FDA officials stated that the EUA approval for the bivalent booster to be given to young children was based on "immune response and safety data that it had previously evaluated from a clinical study in adults of a booster dose of a bivalent COVID-19 vaccine that contained a component of the original strain of SARS-CoV-2 and a component lineage BA.1."<sup>5</sup>

CDC officials immediately recommended the new mRNA COVID bivalent booster be administered to young children, despite the fact that the Pfizer and Moderna COVID vaccines have not been officially licensed by the FDA for use in young children and the ACIP had not yet publicly discussed the scientific evidence for that recommendation.<sup>6</sup>

Since the Pfizer and Moderna mRNA COVID vaccines were approved for distribution under an EUA in December 2020, there have been over 1.3 million mRNA COVID vaccine-related adverse event reports filed with the federal Vaccine Adverse Event Reporting System (VAERS), including more than 46,000 reports involving children

between the ages of six months and 17 years.<sup>7</sup> Although not every adverse event report made to VAERS can be assumed to be vaccine-related, it is of great concern to the public, especially parents of minor children, that mRNA COVID vaccine adverse event reports comprise over half of all vaccine adverse event reports made to VAERS for all vaccines since the system became operational in 1990 under the National Childhood Vaccine Injury Act of 1986.

The development of mRNA COVID biological products manufactured and marketed by Pfizer and Moderna were fast-tracked and distributed under an EUA before full scientific evaluation of the ability of the product to prevent symptomatic or asymptomatic infection and transmission of SARS-CoV-2,<sup>8</sup> and without full scientific evaluation of the vaccine's complications, including inflammation of the heart (myocarditis/pericarditis) and other complications that can affect immune and brain function in people of all ages and may lead to sudden death.<sup>9 10 11</sup> With regard to children, there has been widespread acknowledgment that SARS-CoV-2 infections in the majority of healthy children are asymptomatic or mildly symptomatic and infrequently cause serious complications or death, with most complications occurring in children with certain chronic health conditions similar to those that raise SARS-CoV-2 infection risks in adults.<sup>12 13</sup>

Historically, after ACIP makes a universal use recommendation for a new vaccine for children, there has been an immediate push to mandate the vaccine in the states as a requirement for daycare and school attendance.<sup>14</sup> The mRNA COVID vaccines have been made available under an EUA to parents, who may choose to give the vaccine to their children. There is no need for ACIP to recommend the mRNA COVID vaccines for universal use in all children, which predictably will lead to lobbying efforts to mandate the vaccine without exemptions as a condition for children to get an education or participate in other activities.<sup>15</sup>

For the above reasons, the National Vaccine Information Center (NVIC.org) opposes the addition of mRNA COVID vaccines to the CDC's childhood vaccine schedule and encourages the ACIP to call for more scientific research into the biological mechanisms for mRNA COVID vaccine reactions and identification of individuals at higher risk for suffering COVID-19 vaccine complications.

Sincerely,  
Barbara Loe Fisher  
Co-founder & President

## References:

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<sup>1</sup> U.S. Food and Drug Administration (FDA). [Coronavirus \(COVID-19\) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age.](#) June 17, 2022.

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- <sup>2</sup> U.S. Centers for Disease Control. [Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States 2022](#). In: Child and Adolescent Immunization Schedule. Notes Pg 5. Accessed Oct. 18, 2022.
- <sup>3</sup> U.S. Food and Drug Administration (FDA). [Pfizer-BioNTech COVID-19 Vaccines](#). Oct. 18, 2022.
- <sup>4</sup> U.S. Food and Drug Administration (FDA). [Moderna COVID-19 Vaccines](#). Oct. 17, 2022.
- <sup>5</sup> U.S. Food and Drug Administration (FDA). [Coronavirus \(COVID-19\) Update: FDA Authorizes Moderna and Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose in Younger Age Groups](#). Oct. 12, 2022.
- <sup>6</sup> U.S. Centers for Disease Control. [CDC Expands Updated COVID-19 Vaccines to Include Children Ages 5 Through 11](#). Oct. 12, 2022.
- <sup>7</sup> [MedAlerts.org](#).
- <sup>8</sup> U.S. Center for Disease Control. [COVID-19 after Vaccination: Possible Breakthrough Infection](#). June 23, 2022.
- <sup>9</sup> Mascarenhas L. [FDA adds a warning to COVID-19 vaccines about risk of heart inflammation](#). *CNN* June 26, 2021.
- <sup>10</sup> Oster JE, Shay DK, Su JR et al. [Myocarditis Cases Reported After mRNA-Based COVID-19 Vaccination in the U.S. From December 2020 to August 2021](#). *JAMA* 2022; 327(4): 331-340.
- <sup>11</sup> Choi S, Lee SH, Seo JW et al. [Myocarditis-induced Sudden Death after BNT162b2 mRNA COVID-19 Vaccination in Korea: Case Report Focusing on Histopathological Findings](#). *J Korean Med Sci* 2021; 36(40).
- <sup>12</sup> U.S. Centers for Disease Control. [Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Professionals](#). June 15, 2022.
- <sup>13</sup> Forrest CB, Burrows EK, Mejias A et al. [Severity of Acute COVID-19 in Children under 18 Years Old March 2020 to December 2021](#). *Pediatrics* 2022; 149(4).
- <sup>14</sup> National Conference of State Legislatures. [State Immunization Policy Overview: School Requirements](#). Feb. 26, 2021.
- <sup>15</sup> Fisher BL. [Guide to Reforming Vaccine Policy and Law](#). *National Vaccine Information Center (NVIC)*. 2014 (Rev. 2017, 2022).