

October 19, 2022

CDC Advisory Committee on Immunization Practices

Center for Disease Control and Prevention

U.S. Department of Health and Human Services

**Docket No. CDC-2022-0111**

Members of the Committee:

The notice for your October 2022 meeting advises the public that you will be considering the child/adolescent immunization schedule and you are to vote on Covid-19 vaccines for children. I would respectfully request that you reject any proposal to recommend that the Covid-19 vaccines be added to the standard childhood immunization schedule.

Covid-19 vaccines, developed under an emergency use authorization, were designed to cope with a national medical emergency. Though the public health emergency is still in force, the pandemic is receding, as President Biden himself recently indicated; and that is a blessing to those who were most threatened by Covid-19: Americans over 65 and those with multiple comorbidities, such as obesity, cardiovascular disease, and respiratory conditions.

The inclusion of the Covid-19 vaccines in the standard immunization schedule for children is neither necessary to combat the pandemic nor medically appropriate for an entire class of persons who are indisputably the least susceptible to serious illness, hospitalization, and death. While a child with a serious underlying condition would be an appropriate candidate for Covid vaccination, there is no evidence that it would either be medically necessary or appropriate for an entire class of young, healthy children. Though there is no appreciable benefit for such a mass vaccination, there is an unnecessary risk.

**The recommendation is unnecessary.** As a rule, younger and healthier people have faced relatively minor risk from COVID-19, and healthy children 17 years of age and younger have faced hardly any risk at all. For example, the accumulated CDC data through October 12, 2022,

estimate a total of just over one million deaths in the United States associated with COVID-19. Of those deaths, only 1,310 were children under the age of 18.<sup>1</sup>

Not only is COVID-associated severe illness and death among children extremely rare in the U.S., but the international experience also follows this pattern. A June 2022 study conducted in the United Kingdom found that most children who died with COVID between March 2020 and December 2021 had serious underlying medical conditions. The British study identified 81 COVID-related deaths among persons under the age of 20. Of those, 61 had an underlying condition, with severe neurodisability and immunocompromised conditions as the most prevalent.<sup>2</sup>

Children, except for those who suffer a serious comorbidity, are not only less likely to suffer severe illness or death, but most have been infected and evidence suggests that this has not significantly affected community transmission. The national experience concerning school closures is directly relevant to the wisdom of mass COVID-19 vaccination for children. Drs. Sandro Galea and Michael Stein, professors of public health at Boston University, noted that many decisions concerning school closures, for example, did not reflect the scientific evidence: “The science showed relatively quickly that children were at low risk from the virus, and did not much influence transmission of COVID-19 in the general populations.”<sup>3</sup> As early as the summer of 2020, Drs. Galea and Stein observed that the data showed that children were “less likely” to contract the coronavirus, and when they did become infected their symptoms were “mild” and their capacity for transmission of COVID 19 was low.<sup>4</sup>

**The recommendation will further undermine public trust in our public health institutions.** Though the FDA has already authorized COVID vaccines for infants as young as six months, policymakers should be mindful that only a small percentage of these children are vaccinated.

The FDA first authorized vaccines for children aged 5-11 in October 2021. During the FDA’s Vaccines and Related Biological Products Advisory Committee (VRBPAC) consideration of that proposed authorization, the possibility was raised of limiting the authorization to only children with comorbidities that put them at higher risk. One member of the committee, noting the uncertainties around safety issues and the low expected benefit to healthy children, stated, “I’m just worried that, if we say yes, that the states are going to mandate the administration of this vaccine to children in order to go to school, and I do not agree with that.”<sup>5</sup>

In response, the VRBPAC committee member from the CDC noted role of the CDC’s Advisory Committee on Immunization Practices (ACIP), stating, “...if FDA authorizes a product more

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<sup>1</sup> Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. [https://www.cdc.gov/nchs/nvss/vsrr/covid\\_weekly/index.htm#SexAndAge](https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge).

<sup>2</sup> Marta Bertran, “COVID-19 Deaths in Children and Young People: Active Prospective National Surveillance, March 2020 to December 2021, England,” Social Science Research Network, SSRN, posted June 20, 2022. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4125501](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125501).

<sup>3</sup> Sandro Galea MD and Michael Stein, MD, “The Limits of Our Science,” *The Public Health Post*, July 15, 2021.

<sup>4</sup> Sandro Galea, MD, and Michael Stein, MD, “Why Did We Keep Our Schools Closed,” *Public Health Post*, October 14, 2021.

<sup>5</sup> Food and Drug Administration, “Transcript of 170th Vaccines and Related Biological Products Advisory Committee Meeting,” October 26, 2021, pp. 326-328, <https://www.fda.gov/media/154950/download>.

broadly, then ACIP can look at which specific populations may benefit and will benefit from the vaccine and can make more focused or nuanced recommendations if they choose, or they can recommend that the entire population that FDA authorized the product for is recommended to receive it...”<sup>6</sup>

The FDA granted the authorization on October 29, 2021, and on November 2, 2021, the CDC’s ACIP approved a recommendation of the vaccine for children ages 5 to 11 years that did not include any caveats or limitations.<sup>7</sup>

Nearly a year later, fewer than one-third of children in this age group have received two shots.<sup>8</sup> Only 39 percent had received their first dose. And the rate has slowed to a trickle. Just 40,000 children got their first inoculation in the week ending June 22, 2022, compared with a peak of 1.6 million for the week ending November 24, 2021. After an initial surge, parental interest in the vaccine for school-aged children appears to have plummeted, even though the American Academy of Pediatrics has endorsed the COVID vaccines. When it comes to vaccinating children, it does not appear that parents (and family physicians perhaps) are very enthusiastic about administering the COVID-19 vaccines to their children.

Any compulsion, such as vaccination as a condition for public school attendance, that emerges from the adoption of the proposed COVID vaccine recommendation will surely sow further popular distrust. Given the likelihood of future pandemics, the last thing America can afford is a further weakening of public confidence in our public health institutions.

Apparent parental concerns about the wisdom of vaccinating young children are also shared by Members of Congress. Representative Bill Posey of Florida and Senator Ted Cruz of Texas, along with 16 other Members of Congress, posed 19 specific questions to FDA Commissioner Robert M. Califf on the rationale for vaccinating children under five, especially since 68 percent of children between 1 and 4 years of age, according to CDC data, -had already been infected with COVID 19: “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. 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.”<sup>9</sup>

**The recommendation does not appropriately balance risk with benefit.** The benefits of the Covid-19 vaccines are widely acknowledged, especially in reducing the likelihood of serious illness, hospitalization, and death among older persons. Nonetheless, the legitimate public and congressional concerns about risk, especially among young and healthy children, must not be

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<sup>6</sup> Ibid. pp. 342-343.

<sup>7</sup> Centers for Disease Control, “Meeting of the Advisory Committee on Immunization Practices, November 2-3, 2021, Summary Minutes,” March 16, 2022, p. 48, <https://stacks.cdc.gov/view/cdc/118730>.

<sup>8</sup> “Summary of Data Publicly Reported by the Centers for Disease Control and Prevention,” American Academy of Pediatrics, updated August 10, 2022, <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-vaccination-trends/#:~:text=About%2018.2%20million%20children%205.67%25%20receiving%20their%20first%20dose.>

<sup>9</sup> Rep. Bill Posey and Sen. Ted Cruz, et al, Letter to the Hon. Robert M. Califf, MD, Commissioner, US Food and Drug Administration, June 7, 2022, p. 1.

ignored. A June 2022 preprint study by Joseph Fraiman, et al. examined safety and efficacy data in the Phase III trials of the Pfizer and Moderna mRNA vaccines.<sup>10</sup> The authors found that both vaccines were associated with an increased risk of serious adverse events, when compared against the placebo group. Not surprisingly, they called for a “more formal harm-benefit analyses especially in individuals at low risk of COVID-19 hospitalization and death.”

Not only are children at minimal risk for serious illness, let alone hospitalization and death, public officials cannot discount the strength of childhood natural immunity. Writing in a March 2022 edition of *Lancet Child and Adolescent Health*, a team of British medical researchers found that COVID-19 reinfection is “uncommon” in adults, but even more uncommon in children.<sup>11</sup> The researchers found that in England, between January 2020 and July 2021, there were 688, 419 primary infections in children 16 years or younger, and just 2343 reinfections. Of the 109 children hospitalized with the reinfection, 78 of them (72 percent) had comorbidities. Over this period, of the entire cohort there were 44 deaths among children testing positive for the coronavirus. All childhood deaths occurred among children with a primary infection; none after reinfection. In the study, only 4 children were admitted to an intensive care unit following a COVID-19 reinfection: “All four children had multiple and severe multisystem comorbidities and, despite detailed case note review, ascertaining the contribution of SARS-CoV-2 infection to the illness that eventually led to the intensive care admission was not possible.”

Thank you for your consideration of these comments and observations.

Sincerely,

Robert Emmet Moffit, PhD  
Senior Fellow, The Heritage Foundation  
Former Chairman, The Maryland Health Care Commission

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<sup>10</sup> Joseph Fraiman, et al., “Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials, *SSRN*, posted June 23, 2022, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4125239](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239).

<sup>11</sup> Anna A Mensah, Helen Campbell, Julia Stowe, Giulia Seghezze, Ruth Simmons, Joanne Lacy, Antoaneta Bukasa, Shennae O’Boyle, Mary E. Ramsay, Kevin Brown, Shamez N. Ladhani, “Risk of SARS-COV-@ Reinfections in Children: A Prospective National Surveillance Study Between January 2020, and July, 2021, in England,” *Lancet Child and Adolescent Health*, March 28, 2022, <https://pubmed.ncbi.nlm.nih.gov/35358491/>.