Children's Health Defense™

February 9, 2022

VIA FEDERAL EXPRESS and EMAIL

Dear Dr. Woodcock, Dr. Walensky, Sec. Becerra, Dr. Marks & VRBPAC Members:

I write to you on behalf of Children's Health Defense (CHD), a non-profit organization devoted to the health of people and the planet. We have actively followed your work to evaluate, authorize and approve vaccines for the American public, and particularly children.

We are aware that you are likely to grant Emergency Use Authorization (EUA) of Pfizer's BioNTech SARS-CoV-2 vaccine for children aged six months up to five years old following your upcoming meeting on February 15, 2022. We are writing to put you on notice that should you recommend this pediatric EUA vaccine to children under five years old, CHD is poised to take legal action against you. CHD will seek to hold you accountable for recklessly endangering this population with a product that has little, no, or even negative net efficacy but which may put them, without warning, at risk of many adverse health consequences, including heart damage, stroke and other thrombotic events and reproductive harms.

We briefly outline why such a recommendation would be reckless for nearly 20 million children in the United States, and millions more around the world.

1. **There is no COVID emergency for children under five years old.** Children have a 99.995% recovery rate and a body of medical literature indicates that almost zero healthy children under five years old have died from COVID.

    - A **Johns Hopkins study** monitoring 48,000 children diagnosed with COVID showed a zero mortality rate in children under 18 without comorbidities.[1,2]
    - A **study** in *Nature* demonstrated that children under 18 with no comorbidities have virtually no risk of death.[3]
    - Data from England and Wales, published by the **UK Office of National Statistics** on January 17, 2022, revealed that throughout 2020 and 2021, only one (1) child under the age

[1] Audrey Unverferth, "Johns Hopkins Study Found Zero COVID Deaths Among Healthy Kids," The Federalist (Jul. 21, 2021). https://thefederalist.com/2021/07/21/johns-hopkins-study-found-zero-covid-deaths-among-healthy-kids/

[2] FAIR Health, West Health Institute & Marty Makary, MD, MPH, "Risk Factors for COVID-19 Mortality among Privately Insured Patients" *FAIR Health* (Nov. 11, 2020). https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf

[3] Smith, C., Odd, D., Harwood, R. *et al.* "Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year," *Nat Med* **28** (2022): 185–192. https://doi.org/10.1038/s41591-021-01578-1

of 5, without comorbidities, had died from COVID in the two countries, whose total population is 60 million.[4]

- A large **study** conducted in Germany showed zero deaths for children 5-11 and a case fatality rate of three out of a million in children without comorbidities.[5]
- Another **study** in *Nature* from April, suggests children's bodies clear the virus more easily than adults.[6]
- This **study** published in December in *Nature* demonstrated how children efficiently mount effective, robust and sustained immune responses.[7]

2. **Over one third of all children are estimated to have natural immunity to COVID, according to CDC's own data.**[8] There is no ethical justification for superfluous vaccination that will put children at elevated risk of vaccine harm.

3. **The risks demonstrably outweigh the benefits of COVID vaccination in young children**. A study out of Hong Kong,[9] showed one out of every 2,700 12-17 year old boys being diagnosed with myocarditis following the 2nd dose of Comirnaty vaccine, or 37 per 100,000 vaccinated. A study from Kaiser found the same rate of myocarditis in 12-17 year old American boys, 1/2700.[10]

4. While the CDC is saying that myocarditis is a mild disease, cardiologists know otherwise. CDC's own preliminary data, reported at the February 4 ACIP meeting, revealed that nearly half of the young people diagnosed with myocarditis still had symptoms 3 months later, and 39% had their activity restricted by their physician.[11] We know this serious adverse event occurs frequently in teenagers. But no one knows how often it occurs in younger children. This is of major concern for babies and younger children.

5. **The clinical trials for children 2 through 4 years old failed**.[12,13] You're proposing to use a product and schedule that *failed* in its clinical trials, and you may potentially add a third dose later in the

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[4] Office for National Statistics, "COVID-19 deaths and autopsies Feb 2020 to Dec 2021, Table 1: Number of deaths where COVID-19 was the only cause mentioned on the death certificate, 1 February 2020 to 31 December 2021, by sex and age group, England and Wales," (Jan. 17, 2022). https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/covid19deathsandautopsiesfeb2020todec2021

[5] AL Sorg et al, "Risk of Hospitalization, severe disease, and mortality due to COVID-19 and PIMS-TS in children with SARS-CoV-2 infection in Germany," *MedRxiv* preprint (Nov. 30, 2021). https://www medrxiv.org/content/10.1101/2021.11.30.21267048v1

[6] Kevin J. Selva et al, "Systems serology detects functionally distinct coronavirus antibody features in children and elderly," *Nature Communications* (Apr. 1, 2021). https://doi.org/10.1038/s41467-021-22236-7

[7] Dowell, A.C., Butler, M.S., Jinks, E. *et al.* "Children develop robust and sustained cross-reactive spike-specific immune responses to SARS-CoV-2 infection," *Nat Immunol* 23 (2022): 40–49. https://doi.org/10.1038/s41590-021-01089-8

[8] CDC, "Estimated COVID-19 Burden-February 2020–September 2021," *CDC* (Updated Nov. 16, 2021). https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden html

[9] Gilbert T. Chua, Mike Yat Wah Kwan, et al., "Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination," *Clinical Infectious Diseases*, ciab989 (Nov. 28, 2021). https://doi.org/10.1093/cid/ciab989

[10] Katie A Sharff, David M Dancoes, et al, "Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods," *medRxiv* 2021.12.21.21268209; doi: https://doi.org/10.1101/2021.12.21.21268209

[11] Ian Kracalik, PhD, MPH, "Myocarditis Outcomes Following mRNA COVID-19 Vaccination," *Advisory Committee on Immunization Practices* (Feb. 4, 2022). https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04-COVID-Kracalic-508.pdf

[12] Sharon LaFraniere and Noah Weiland, "Pfizer Asks F.D.A. to Clear 2 Vaccine Doses for Young Children as a Start," *NYT* (Feb. 1, 2022). https://www nytimes.com/2022/02/01/us/politics/pfizer-vaccine-kids html

[13] Kristina Fiore, "FDA Advisors Face Difficult Decision on COVID Vaccine for Youngest Kids," *MedPage Today* (Feb. 3, 2022). https://www medpagetoday.com/special-reports/exclusives/97011

spring. This is an unprecedented proposal not backed by science. It does not meet the risk-benefit standard of 21 U.S. Code § 360bbb–3[14] *"the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product."*

6. **Some children likely will die and others will be permanently injured from these vaccines based on reporting to the current VAERS database.**[15] The latest data shows a total of **1,088,560** reports of adverse events from all age groups following COVID vaccines, including **23,149 deaths** and **183,311 serious injuries**[16] between Dec. 14, 2020, and Jan. 28, 2022.

7. **The pediatric clinical trials for the COVID vaccines were too small to detect safety signals–especially** for a population in the tens of millions.

8. **There are a) no long-term safety data for COVID vaccination of young children,** and b) the proposal is to vaccinate children under the Emergency Use Authorization. Both a) and b) establish that vaccinating small children for COVID will be an experiment, not a standard medical procedure.

9. **Unethical coercive pressure will be applied to children and their parents**, as has occurred with older children and adults.[17] To grant authorization is to abet this unethical coercion that violates the Nuremberg Code's first principle.

10. **There is no available care for children injured by COVID shots.** There is no way to remove the spike protein and other toxic byproducts of vaccination, which may be produced for a considerable period of time following inoculation of messenger RNA. The science and medicine have not yet developed, and most families will be unable to cover the costs of potential catastrophic injuries.

11. **First, do no harm. You are a physician who owes a duty to patients and medical ethics.** If you recommend these shots to this age group, given all you know, will you be upholding your oath? If not, is it possible that your acts could later be seen as reason to remove your medical licenses?

12. **The liability-free nature of your deliberations may not stand the test of time.** In the fullness of time, your decisions may not have the liability protection that they currently enjoy. Under the PREP Act of 2005, all actors advancing an EUA agenda for medical countermeasures enjoy liability protection, absent willful misconduct.[18,19] Nonetheless, if at a later point these shots are deemed non-therapeutic gene products that you knowingly and recklessly recommended, and which were then distributed to children as a direct result of your decision, it is possible that liability could later attach.

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[14] "21 U.S. Code § 360bbb–3 - Authorization for medical products for use in emergencies," *Legal Information Institute (LII).* https://www.law.cornell.edu/uscode/text/21/360bbb-3

[15] VAERS, "From the 1/28/2022 release of VAERS data: Found 1,088,560 cases where Vaccine is COVID19," *MedAlerts* (Feb.7, 2022). https://www medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19

[16] VAERS, "From the 1/28/2022 release of VAERS data: Found 183,311 cases where Vaccine is COVID19 and Serious," *MedAlerts* (Feb. 7, 2022). https://www medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&SERIOUS=ON

[17] Minnesota Department of Health, "Kids Deserve a Shot vaccine incentive program," *Got Your Shots? News*, (Jan. 22, 2022). https://www health.state mn.us/people/immunize/hcp/gys/jan22.pdf

[18] Public Health Emergency, "PREP Act Q&As," *U.S. Department of Health & Human Services* (Dec. 22, 2021). https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#q3

[19] Kevin J. Hickey, "The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures," *Congressional Research Service* (Jan. 13, 2022). https://crsreports.congress.gov/product/pdf/LSB/LSB10443

13. **There are safer drugs that could be used prophylactically and therapeutically for COVID in children.** There is extensive and compelling medical evidence for this assertion; and the choice to eschew use of these drugs in favor of a demonstrably dangerous vaccine is arbitrary and capricious.

14. **The vaccines do not prevent transmission. They do not prevent infection.** There is no statistically valid evidence that they prevent severe disease or deaths in children.[20] Which begs the question: what are you actually trying to accomplish by vaccinating small children? What is your goal?

15. On August 23, 2021, **FDA's letter to BioNTech**[21] explained that neither the VAERS nor the VSD surveillance systems were adequate for FDA to determine the risk of myocarditis resulting from the Pfizer vaccine. Therefore, Pfizer and BioNTech were instructed by FDA to carry out a series of studies on myocarditis to ascertain the risk in different groups, including children. These studies were scheduled to produce final reports to FDA over the next five years. If the FDA is willing to wait until 2027 to learn the actual risks of myocarditis from the vaccine for children, shouldn't it be required to wait until 2027 before inoculating millions of small children with a vaccine anticipated to provide them no benefit and possibly substantial risks?

16. An important *Cell* article in press,[22] written by **scientists from Stanford**, has shown that based on lymph node sampling after mRNA vaccination, spike protein and its mRNA remain present in the germinal centers of draining lymph nodes for up to 60 days, which is when sampling ceased. This was not supposed to happen. The demonstration of vastly prolonged spike protein production has revealed that the dose of spike protein produced *in vivo* by mRNA vaccines is unpredictable. FDA, however, requires uniformity of dosing. This fact alone should disqualify all authorizations and approvals of mRNA COVID vaccines.

We ask that you carefully consider all the information above before making any recommendation for Pfizer's vaccine in the 6 months to under 5 year age group at your meeting on February 15, 2022.

Sincerely,

Robert F. Kennedy, Jr.

[20] Wang R, Chen J, Hozumi Y, Yin C, Wei GW. Emerging Vaccine-Breakthrough SARS-CoV-2 Variants. ACS Infect Dis. 2022 Feb 8. doi: 10.1021/acsinfecdis.1c00557. Epub ahead of print. PMID: 35133792. https://pubmed ncbi nlm nih.gov/35133792/

[21] FDA, "Biologics License Application (BLA) Approval for COVID-19 Vaccine, mRNA-Pfizer/BioNTech," *U.S. Food & Drug Administration* (Aug. 23, 2021). https://www fda.gov/media/151710/download

[22] Katharina Röltgen, Sandra C.A.et al., "Immune imprinting, breadth of variant recognition and germinal center response in human SARS-CoV-2 infection and vaccination," *Cell* (2022), ISSN: 0092-8674. https://doi.org/10.1016/j.cell.2022.01.018 https://www.cell.com/cell/pdf/S0092-8674(22)00076-9.pdf