



June 10, 2022

VIA EMAIL

Dear Dr. Califf, 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, 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 ages 6 months through 5 years old, and Moderna's COVID-19 mRNA vaccine for infants and children ages 6 months through 5 years and 6 years through 17 years of age following your upcoming meetings on June 14-15, 2022. We are writing to put you on notice that should you recommend these pediatric EUA vaccines to children 6 months through 17 years old, CHD is poised to take legal action against you. CHD will seek to hold you accountable for recklessly endangering our children with products that have 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 future reproductive harms.

We briefly outline why such a recommendation would be reckless for nearly 74 million children in the United States and millions more around the world.

1. **There is no COVID emergency for children.** 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

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, and 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 Clare Smith, David Odd, Rachel Harwood, 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>.

- 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 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 ages 5-11 and a case fatality rate of three per million in all 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
- The [CDC](#) published data stating that 203 children aged 6 months through 4 years have died “with” COVID since the start of the pandemic, averaging 85 deaths in this age group “with” COVID yearly.⁸

We know that only a fraction of these children's deaths were due to COVID. They do not accord with pediatric COVID death rates from other countries. CDC has chosen to conceal the number of Americans who died due to COVID, even though the data are found on death certificates.

Yet you propose to vaccinate 18 million babies through preschoolers with an initial 54 million doses of Pfizer vaccine (or 36 million doses of Moderna), and we can probably anticipate further booster doses after several months since you authorized boosters starting 5 months after being “fully vaccinated” for 5-11-year-olds last month.

2. **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.⁹ Current mRNA injections were formulated based on the original Wuhan strain and were not tested for benefits against current variants in clinical trials. Which begs the question: what are you actually trying to accomplish by vaccinating small children? What is your goal?

⁴ “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, *Office for National Statistics*, <https://www.ons.gov.uk/aboutus/transparencyandgovernance/freedomofinformationfoi/covid19deathsandautopsiesfeb2020todec2021>.

⁵ A.L. Sorg, M. Doenhardt, N. Diffloth 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, Carolien E. van de Sandt, Melissa M. Lemke, et al., “Systems Serology Detects Functionally Distinct Coronavirus Antibody Features in Children and Elderly,” *Nature Communications* 12, no. 2037 (2021), <https://doi.org/10.1038/s41467-021-22236-7>.

⁷ Alexander C. Dowell, Megan S. Butler, Elizabeth Jinks, 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 “Provisional COVID-19 Death Counts by Age in Years, 2020-2022,” Centers for Disease Control and Prevention, updated Jun. 2, 2022, <https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Age-in-Years-3apk-4u4f>.

⁹ Rui Wang, Jiahui Chen, Yuta Hozumi et al., “Emerging Vaccine-Breakthrough SARS-CoV-2 Variants,” *ACS Infect Dis.* 8, no. 3 (2022), [www.doi.org/10.1021/acsinfecdis.1c00557](https://doi.org/10.1021/acsinfecdis.1c00557).

3. Most children are already immune. Natural immunity is superior to vaccine-induced immunity, and vaccinating the already immune is [superfluous and potentially harmful](#).¹⁰ **CNBC reported in April 2022, “An estimated 95% of the U.S. population ages 16 and older had developed antibodies against the virus either through vaccination or infection as of December, according to a CDC survey of blood donor samples.”**¹¹ CDC earlier said over 75% of children already have partial or full immunity to COVID. There is no ethical justification for unnecessary vaccination that will put children at elevated risk of vaccine harm when it appears that most are already immune and will obtain NO benefit.

Furthermore, multiple [studies have suggested](#) that vaccinating after infection [increases the risk](#) of vaccine-induced side effects such as **myocarditis**.^{12,13}

4. **The risks demonstrably outweigh the benefits of COVID vaccination in children.** A study out of [Hong Kong](#)¹⁴ showed one out of every 2,700 12-17-year-old boys are diagnosed with myocarditis following the 2nd dose of Comirnaty vaccine (37 per 100,000 vaccinated). A study from [Kaiser](#) found the same rate of myocarditis in 12-17-year-old American boys, 1/2700.¹⁵
5. While CDC is saying that myocarditis is a mild disease, cardiologists know otherwise. The 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.¹⁶ We know this serious adverse event frequently occurs in teenagers. **But no one knows how often it occurs in younger children.** This is of significant concern for babies and younger children.
6. **The Pfizer clinical trials for children 2 through 4 years old failed to meet FDA-specified requirements for COVID vaccine EUAs. The vaccines did not show 50% efficacy nor meet the required 30% lower bound with a 95% confidence interval.**^{17,18} You’re proposing to use a product and schedule that *failed FDA’s established criteria* in its clinical trials. You propose to add

¹⁰ “COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021,” Centers for Disease Control and Prevention, Jan. 28, 2022, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm>.

¹¹ Spencer Kimball, “CDC director says high immunity in U.S. population provides some protection against omicron BA.2,” CNBC, Apr. 5, 2022, <https://www.cnbc.com/2022/04/05/cdc-director-says-high-immunity-in-us-population-provides-some-protection-against-omicron-bapoint2.html>.

¹² A.S. Etuk, I.N. Jackson, H. Panayiotou, “A Rare Case of Myocarditis After the First Dose of Moderna Vaccine in a Patient With Two Previous COVID-19 Infections,” *Cureus* 14, no. 5 (2022):e24802. <https://doi.org/10.7759/cureus.24802>. PMID: 35676986; PMCID: PMC9169579.

¹³ Muhammed Z. Khan, Scott Janus, Sona Franklin, et al., “COVID-19 Vaccination-Induced Cardiomyopathy Requiring Permanent Left Ventricular Assist Device,” *Cureus* 14, no. 4 (2022): e24477, www.doi.org/10.7759/cureus.24477.

¹⁴ Gilbert T. Chua, Mike Yat Wah Kwan, Celine SL Chui, et al., “Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination,” *Clinical Infectious Diseases* ciab989 (2021), <https://doi.org/10.1093/cid/ciab989>.

¹⁵ Katie A Sharff, David M Dancoes, Jodi L Longueil, 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,” *Pharmacoepidemiology & Drug Safety* (2022), <https://doi.org/10.1002/pds.5439>.

¹⁶ 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-Kracalik-508.pdf>.

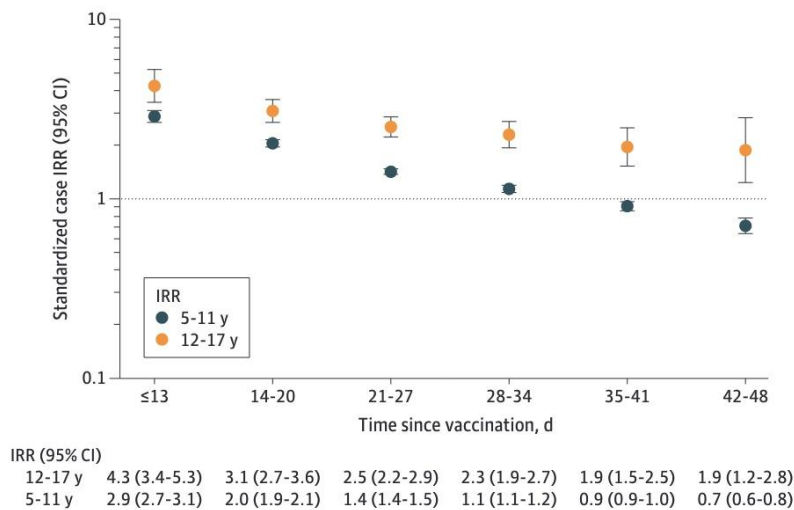
¹⁷ Sharon LaFraniere and Noah Weiland, “Pfizer Asks F.D.A. to Clear 2 Vaccine Doses for Young Children as a Start,” *NYT*, Feb. 1, 2022, <https://www.nytimes.com/2022/02/01/us/politics/pfizer-vaccine-kids.html>.

¹⁸ 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>.

a third dose later in order to provide a fleeting efficacy boost to the Pfizer vaccines for preschoolers.

Yet you must be well aware that the Pfizer shots in the 5-11 year range led to very poor efficacy; 31% [according to the CDC](#)¹⁹ and [12% after 7 weeks](#) according to a massive database comprising over 1.3 million children (365,000 of whom were vaccinated) from the NY Department of Health.²⁰ Five to 11-year-old children dropped into the negative efficacy range by 8 weeks after receiving the second dose. See [Figure](#) below.²¹

Figure. New COVID-19 Cases Among Unvaccinated Children vs Fully Vaccinated Children by Time Since Vaccination and Age Group



Time since full vaccination was defined as days subsequent to 14 days after completion of the primary 2-dose series. Incidence rate ratio (IRR) values less than 1 observed in later times likely reflect estimator instability, residual confounding, or both as opposed to true relative increased risk for those vaccinated.

Let us be crystal clear about what this study shows. It is the largest COVID vaccine efficacy study in children ever published, using the highest quality, official data from NY state. There was a large, linear drop in efficacy seen with each successive week following full vaccination. Extremely narrow confidence intervals confirm the validity of these data.

By 8 weeks following their second dose, vaccinated children were placed at higher risk of developing COVID than unvaccinated children. By 9 weeks, their risk was even higher. Despite data-free theories offered to minimize this finding, the indisputable fact is that being vaccinated placed these children in a higher risk category for a COVID infection than if they had never been vaccinated. Vaccinating children who you know are likely to be placed at higher risk from COVID

¹⁹ Ashley L. Fowlkes, ScD, Sarang K. Yoon, DO, Karen Lutrick, PhD, et al., “Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5–11 Years and Adolescents Aged 12–15 Years—PROTECT Cohort, July 2021–February 2022,” Centers for Disease Control and Prevention (MMWR), Mar. 18, 2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7111e1.htm?s_cid=mm7111e1_w.

²⁰ Vajeera Dorabawila, PhD, Dina Hoefler, PhD, Ursula E. Bower, PhD et al., “Effectiveness of the BNT162b2 Vaccine among Children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant,” *medRxiv*, Feb. 28, 2022, <https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full.pdf>.

²¹ Vajeera Dorabawila, PhD, Dina Hoefler, PhD, Ursula E. Bower, PhD et al., “Risk of Infection and Hospitalization among Vaccinated and Unvaccinated Children and Adolescents in New York After the Emergence of the Omicron Variant,” *JAMA* (2022), [www.doi.org/10.1001/jama.2022.7319](https://doi.org/10.1001/jama.2022.7319).

as a result of vaccination is not “public health;” it is a crime. This is an unprecedented proposal not backed by science, logic, or ethics.

It does not meet the risk-benefit standard of [21 U.S. Code § 360bbb-3](#)²² “*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.*”

7. **Some children likely will die and others will be permanently injured from these vaccines based on reporting to the current [VAERS database](#).**²³ The latest data shows a total of **1,287,595** reports of adverse events from all age groups following COVID vaccines, including **28,532 deaths** and **235,041 serious injuries**²⁴ between Dec. 14, 2020, and May 27, 2022.
8. **The [pediatric clinical trials](#) for the COVID vaccines were too small (the booster trial for 5-to-11-year olds had 140 participants)²⁵ to detect safety signals for serious adverse events—especially** for a recipient population in the tens of millions. It is difficult to understand how FDA allowed trials to be conducted with so few children enrolled, knowing they were inadequate to assure safety.
9. **There are no long-term safety data for COVID vaccination of young children,** and the proposal is to vaccinate children under an Emergency Use Authorization. These facts establish that vaccinating small children for COVID will be an experiment, not a standard medical procedure. If we miss significant side effects that occur in babies and toddlers, the health trajectories of their lives could be changed.
10. **Unethical coercive pressure to vaccinate will be applied to children and their parents, [as has occurred](#)** with older children and adults.²⁶ To grant authorization is to abet this unethical coercion that violates the Nuremberg Code’s first principle.^{27,28}
11. **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

²² “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>.

²³ VAERS, “From the 5/27/2022 Release of VAERS Data: Found 1,287,595 Cases Where Vaccine is COVID19,” *MedAlerts*, May 27, 2022, <https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=CAT&EVENTS=ON&VAX=COVID19>.

²⁴ VAERS, “From the 5/27/2022 Release of VAERS data: Found 235,041 Cases Where Vaccine is COVID19 and Serious,” *MedAlerts*, May 27, 2022, <https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&SERIOUS=ON>.

²⁵ “Pfizer and BioNTech Announce Data Demonstrating High Immune Response Following a Booster Dose of their COVID-19 Vaccine in Children 5 Through 11 Years of Age,” *Pfizer*, press release, Apr. 14, 2022, <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-data-demonstrating-high-immune>

²⁶ 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>.

²⁷ John Cádiz Klemack, “Mom Says Son Vaccinated in Exchange for Pizza at LAUSD Without Her Consent,” *NBC-LA*, Dec. 7, 2021, <https://www.nbclosangeles.com/news/local/mom-says-son-vaccinated-in-exchange-for-pizza-at-lausd-without-her-consent/2773619/>

²⁸ Howard Blume, “LAUSD to End Weekly COVID Tests and Spend \$5 Million on Prizes to Encourage Vaccinations,” *Los Angeles Times*, Nov. 17, 2021, <https://www.latimes.com/california/story/2021-11-17/lausd-to-spend-5-million-for-gift-cards-to-incentivize-students-to-get-covid-19-vaccine>.

period of time following inoculation of [messenger RNA](#).²⁹ The science and medicine have not yet developed, and most families will be unable to cover the costs of potential catastrophic injuries.

The federal government's [Countermeasures Injury Compensation Program](#) has not compensated a single person injured by COVID vaccines.³⁰

12. **First, do no harm. You are a physician or health official 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?
13. **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](#)."^{31,32} Nonetheless, if at a later time 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.
14. **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.^{33,34}
15. On August 23, 2021, **FDA's letter to BioNTech [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.³⁵ 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 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?

²⁹ Katharina Röltgen, Sandra C.A. Nielsen, Olivia Silva, et al., "Immune Imprinting, Breadth of Variant Recognition and Germinal Center Response in Human SARS-CoV-2 Infection and Vaccination," *Cell* 185, no. 6 (2022): 1025-1040, [www.doi.org/10.1016/j.cell.2022.01.018](https://doi.org/10.1016/j.cell.2022.01.018).

³⁰ "Countermeasures Injury Compensation Program (CICP) Data," *Health Resources & Services Administration*, May 1, 2022, <https://www.hrsa.gov/cicp/cicp-data>.

³¹ 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>.

³² 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>.

³³ Eveline Hürliemann, Ladina Keller, Chandni Patel, et al., "Efficacy and Safety of Co-Administered Ivermectin and Albendazole in School-Aged Children and Adults Infected with *Trichuris Trichiura* in Côte d'Ivoire, Laos, and Pemba Island, Tanzania: A Double-Blind, Parallel-Group, Phase 3, Randomised Controlled Trial," *Lancet Infect Dis.* 22, no. 1 (2022): 123-135, [www.doi.org/10.1016/S1473-3099\(21\)00421-7](https://doi.org/10.1016/S1473-3099(21)00421-7).

³⁴ D. Morgado-Carrasco, J Ibaceta-Ayala, and J Piquero-Casals, "Hydroxychloroquine: An Essential Drug in Dermatology and Its Controversial Use in COVID-19," *Actas Dermosifiliogr.* 113, no. 2 (2022): T166-T175, [www.doi.org/10.1016/j.ad.2022.01.012](https://doi.org/10.1016/j.ad.2022.01.012).

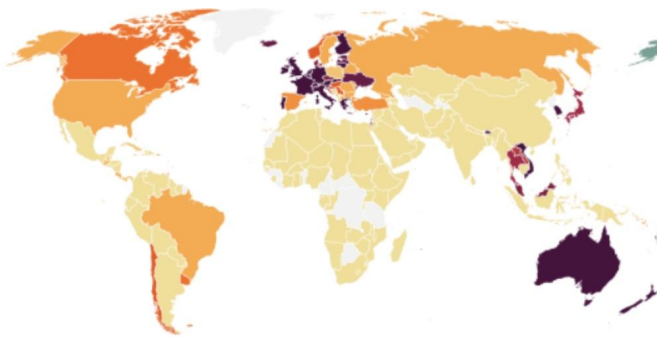
³⁵ FDA, "Biologics License Application (BLA) Approval for COVID-19 Vaccine, mRNA-Pfizer/BioNTech," *U.S. Food & Drug Administration*, Aug. 23, 2021, <https://www.fda.gov/media/151710/download>.

16. An important [Cell](#) article 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.³⁶ 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.

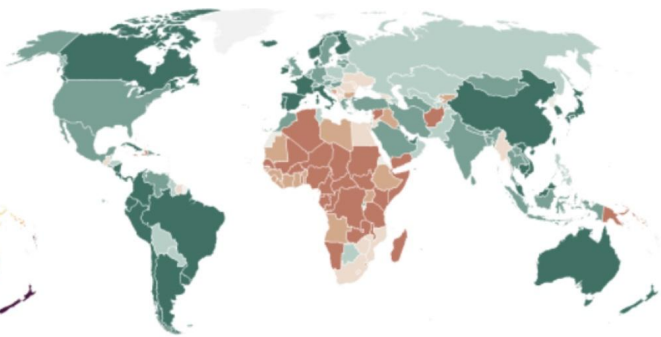
FDA, however, requires uniformity of dosing. This fact alone should disqualify all authorizations and approvals of mRNA COVID vaccines.

17. The June 8, 2022 *New York Times* reveals that the most vaccinated regions in the [US](#) and [the world](#) are also those regions with the highest current case counts.^{37,38} This provides additional supportive evidence that several months after being vaccinated, efficacy becomes negative and vaccination increases the likelihood of developing a COVID infection.

Global hot spots >



Global vaccinations >



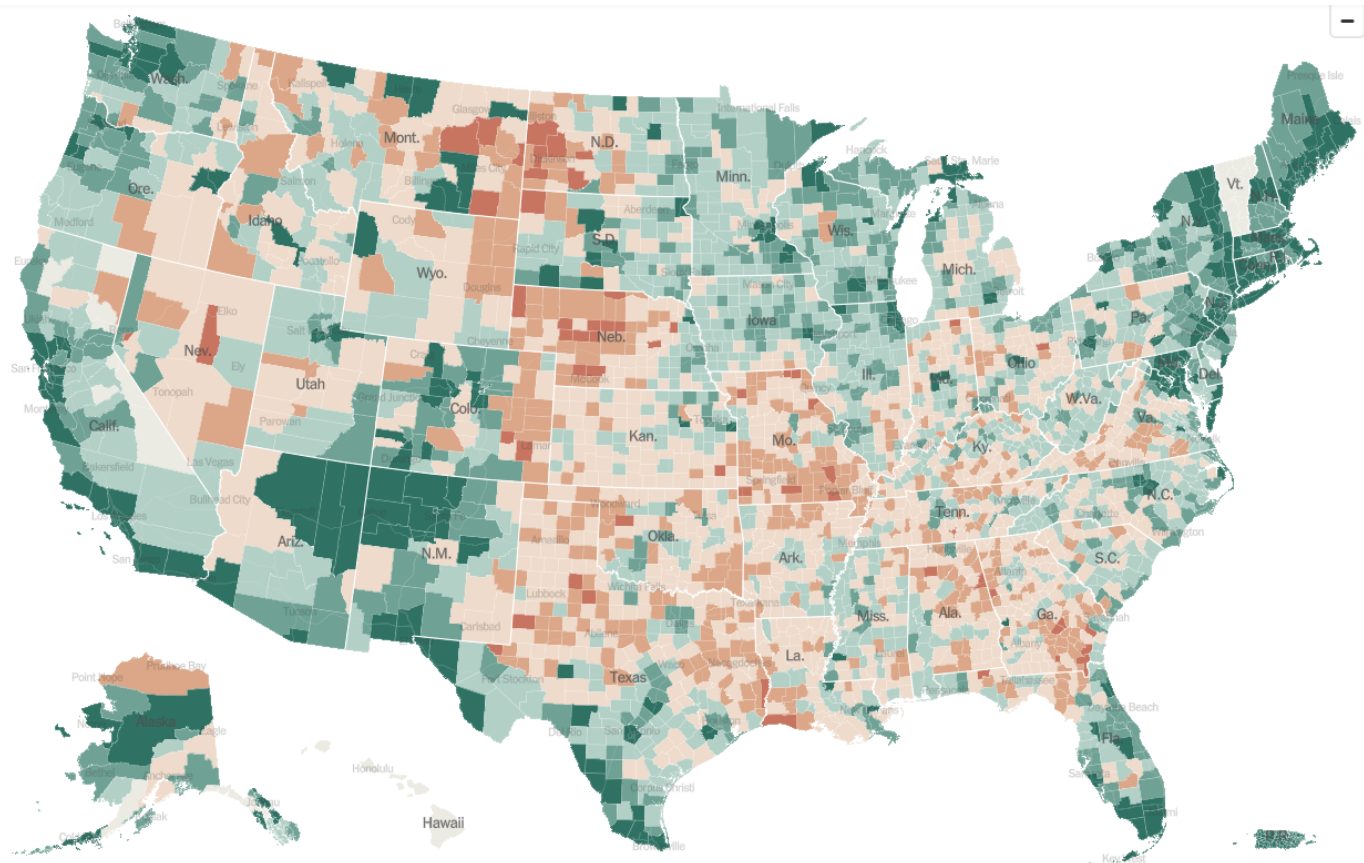
³⁶ Katharina Röltgen, Sandra C.A. Nielsen, Olivia Silva, et al., “Immune Imprinting, Breadth of Variant Recognition and Germinal Center Response in Human SARS-CoV-2 Infection and Vaccination,” *Cell* 185, no. 6 (2022): 1025-1040, [www.doi.org/10.1016/j.cell.2022.01.018](https://doi.org/10.1016/j.cell.2022.01.018).

³⁷ “Coronavirus in the U.S.: Latest Map and Case Count,” *New York Times*, updated Jun. 8, 2022, <https://www.nytimes.com/interactive/2021/us/covid-cases.html>.

³⁸ “Coronavirus World Map: Tracking the Global Outbreak,” *New York Times*, updated Jun. 8, 2022, <https://www.nytimes.com/interactive/2021/world/covid-cases.html>.

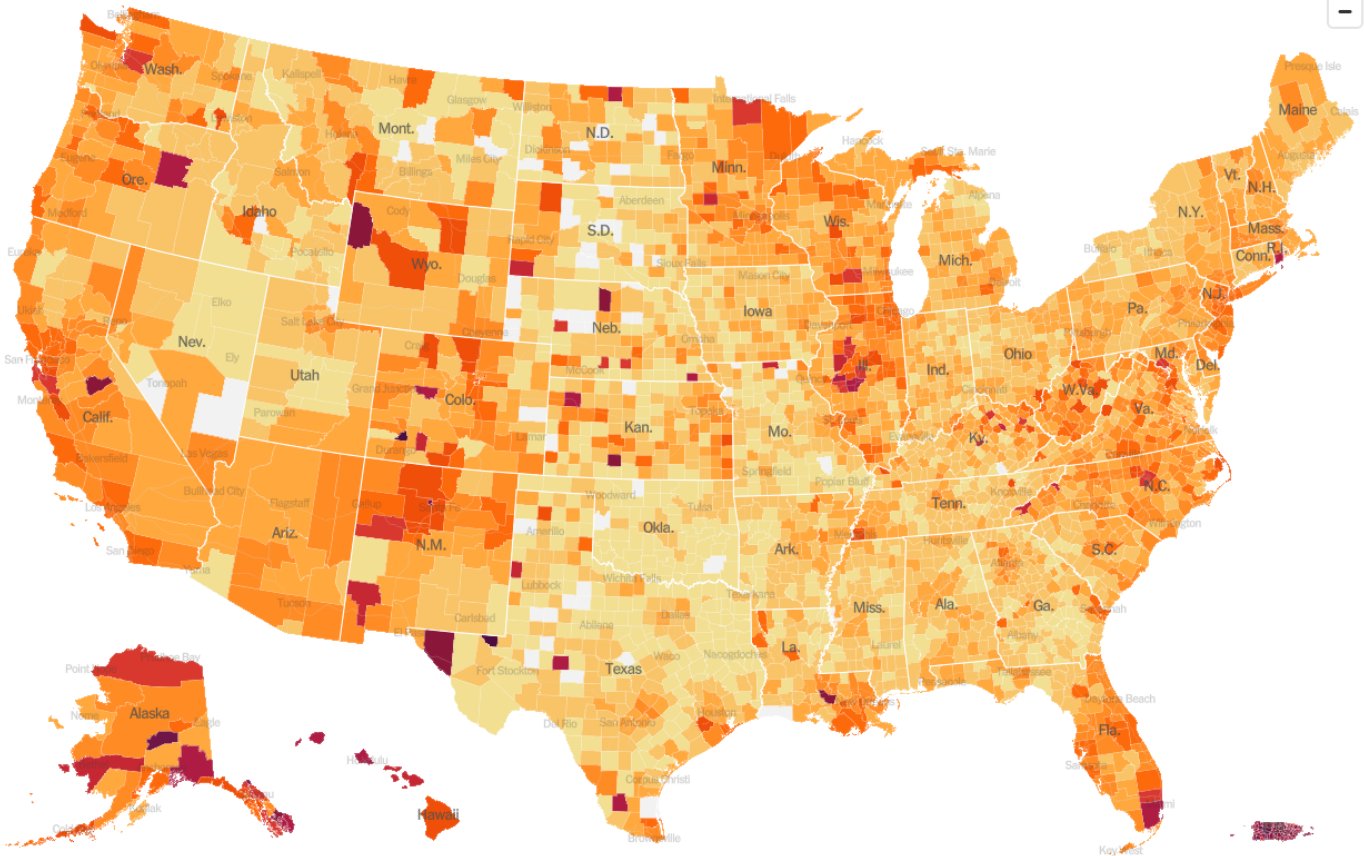
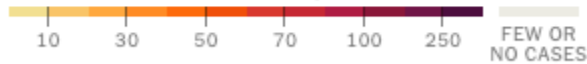
Vaccinations

PCT. OF RESIDENTS THAT ARE FULLY VACCINATED



Hot spots

AVERAGE DAILY CASES PER 100,000 PEOPLE IN PAST WEEK



18. Three weeks ago, [FDA authorized](#) booster doses of Pfizer vaccine for 5-11-year-olds without convening a VRBPAC meeting or providing any public discussion of the evidence supporting the booster.³⁹ Dr. Peter Marks, the Director of FDA’s Center for Biologics told the VRBPAC in April that the FDA’s issuance of an EUA for a second booster in adults was a “[stopgap measure](#)”--the implication being there was no scientific evidence to support that booster.⁴⁰ Has FDA given up even the appearance of a scientific evaluation before issuing more EUAs for COVID vaccines?

³⁹ US Food and Drug Administration, “Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years,” news release, May 17, 2022, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose>.

⁴⁰ Scott Hensley, “Advisers to FDA weigh in on updated COVID boosters for the fall,” NPR, Apr. 6, 2022, <https://www.npr.org/sections/health-shots/2022/04/06/1091242252/advisers-to-fda-weigh-in-on-updated-covid-boosters-for-the-fall>.

19. It is well known that hospitalizations and deaths **with** COVID have been misattributed as hospitalizations and deaths **due to** COVID by federal health agencies, leading to numbers of severe cases and deaths that have been disputed by US physicians investigating them, and which do not accord with the mortality rates for children in other nations. CDC now publishes its [COVID mortality data](#) as deaths **with** COVID, blatantly exaggerating COVID-caused morbidity and mortality.⁴¹
20. According to CDC and the [New York Times](#), it has been over 3 months (since February 28, 2022) during which there has been fewer than one US child per 100,000 children hospitalized daily for COVID.⁴²
21. According to the [CDC data tracker](#), less than 0.1% of all US deaths that have occurred “with” COVID have occurred in children aged 0 through 4.⁴³
22. Strong evidence that newer variants of COVID-19 (Omicron) pose dramatically reduced risks to young children was published in the April 1, 2022, [JAMA Pediatrics](#) by Wang et al.⁴⁴ Using a huge US medical database, they were able to match children aged under 5 who were infected with an Omicron variant with those who were infected with a Delta variant. Children with Omicron were only 35% as likely to require an ICU admission and only 15% as likely to require mechanical ventilation as same-aged children who had been sick due to earlier delta variants.

⁴¹ “Provisional COVID-19 Death Counts by Age in Years, 2020-2022,” Centers for Disease Control and Prevention, updated Jun. 2, 2022, <https://data.cdc.gov/NCHS/Provisional-COVID-19-Death-Counts-by-Age-in-Years-/3apk-4u4f>.

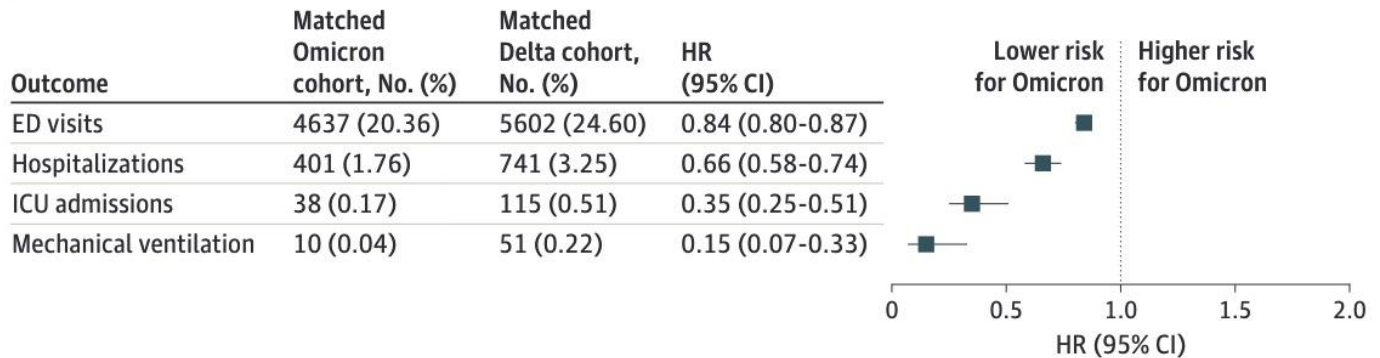
⁴² “Coronavirus in the U.S.: Latest Map and Case Count,” *New York Times*, updated Jun. 8, 2022, <https://www.nytimes.com/interactive/2021/us/covid-cases.html>.

⁴³ “COVID Data Tracker: Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC,” Centers for Disease Control and Prevention, updated Jun. 7, 2022, https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html#demographics.

⁴⁴ Lindsey Wang, Nathan A. Berger, MD, David C. Kaelber MD, PhD, et al., “Incidence Rates and Clinical Outcomes of SARS-CoV-2 Infection With the Omicron and Delta Variants in Children Younger Than 5 Years in the US,” *JAMA Pediatrics*, Apr. 1, 2022, doi.org/doi:10.1001/jamapediatrics.2022.0945.

Figure. Comparison of Risks of Clinical Outcomes of SARS-CoV-2 Infection in Children Younger Than 5 Years

A Omicron vs Delta cohorts



23. The original [Moderna clinical trial data](#), which should have been available to regulatory agencies at least since the Moderna package was presented for licensure, reveals that while **93% of unvaccinated controls** produced detectable SARS-CoV-2 anti-nucleocapsid antibody after infection, only **40% of the vaccinated** produced this antibody after infection. Most of the vaccinated failed to mount the expected immune response.⁴⁵

This is probably why [Dr. Marco Cavaleri](#) of the European Medicines Agency "warned that frequent Covid-19 booster shots could adversely affect the immune response and may not be feasible. Repeat booster doses every four months could eventually weaken the immune response and tire out people, according to the European Medicines Agency."⁴⁶

It is probable that the more doses of these vaccines you receive, the less broad immunity you will develop, even after getting infected. Why subject children to the long-term risk of damaging their immunity to coronaviruses by authorizing vaccines for the youngest children?

24. Below are the June 8, 2022, *New York Times* graphs for the current number of US patients in hospitals, ICUs, and suffering deaths attributed to COVID.

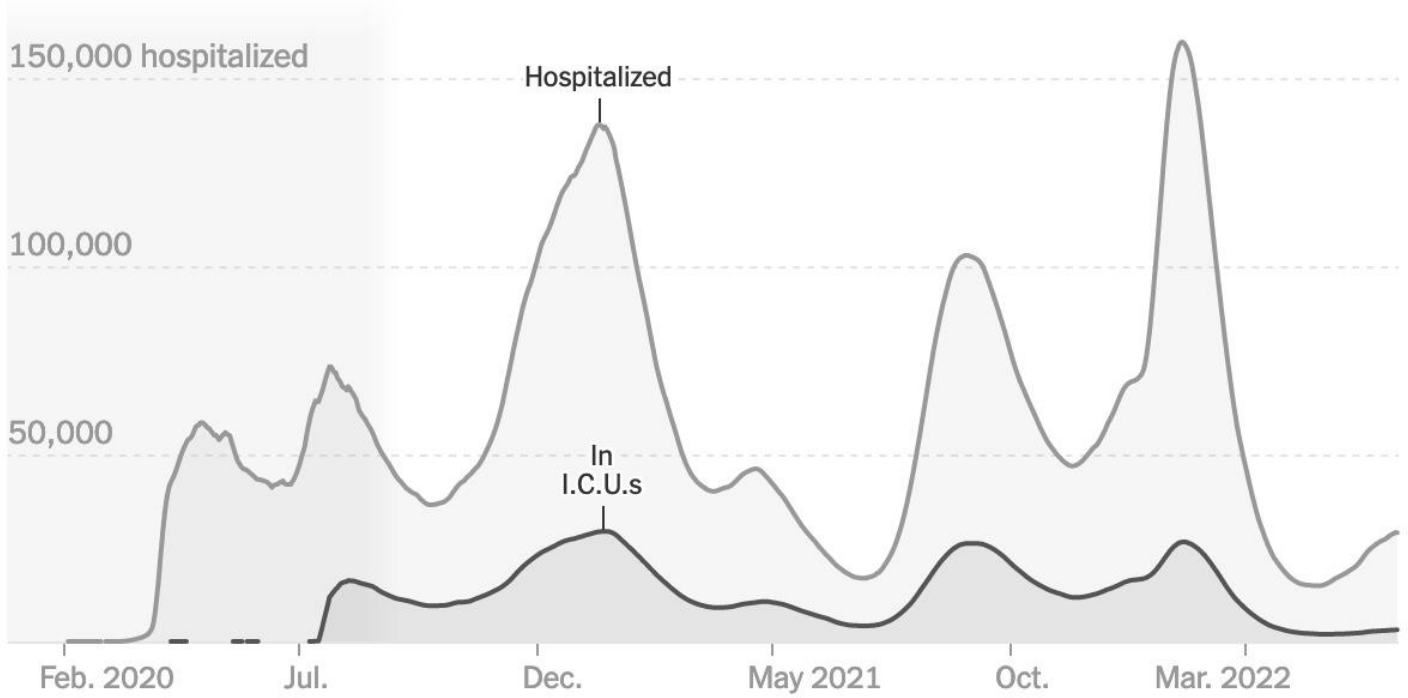
The numbers of patients in ICUs and dying each day ascribed to COVID are close to **the lowest numbers since the start of the pandemic**. Given that CDC extrapolated that 95% of Americans already have partial to complete immunity, while we are at historic low levels for severe COVID disease, it should be clear that there is no need to vaccinate anyone now.

⁴⁵ Dean Follmann, Holly E. Janes, Olive D. Buhule, et al., "Anti-Nucleocapsid Antibodies Following SARS-CoV-2 Infection in the Blinded Phase of the mRNA-1273 Covid-19 Vaccine Efficacy Clinical Trial," *medRxiv* preprint, Apr. 19, 2022, <https://doi.org/10.1101/2022.04.18.22271936>.

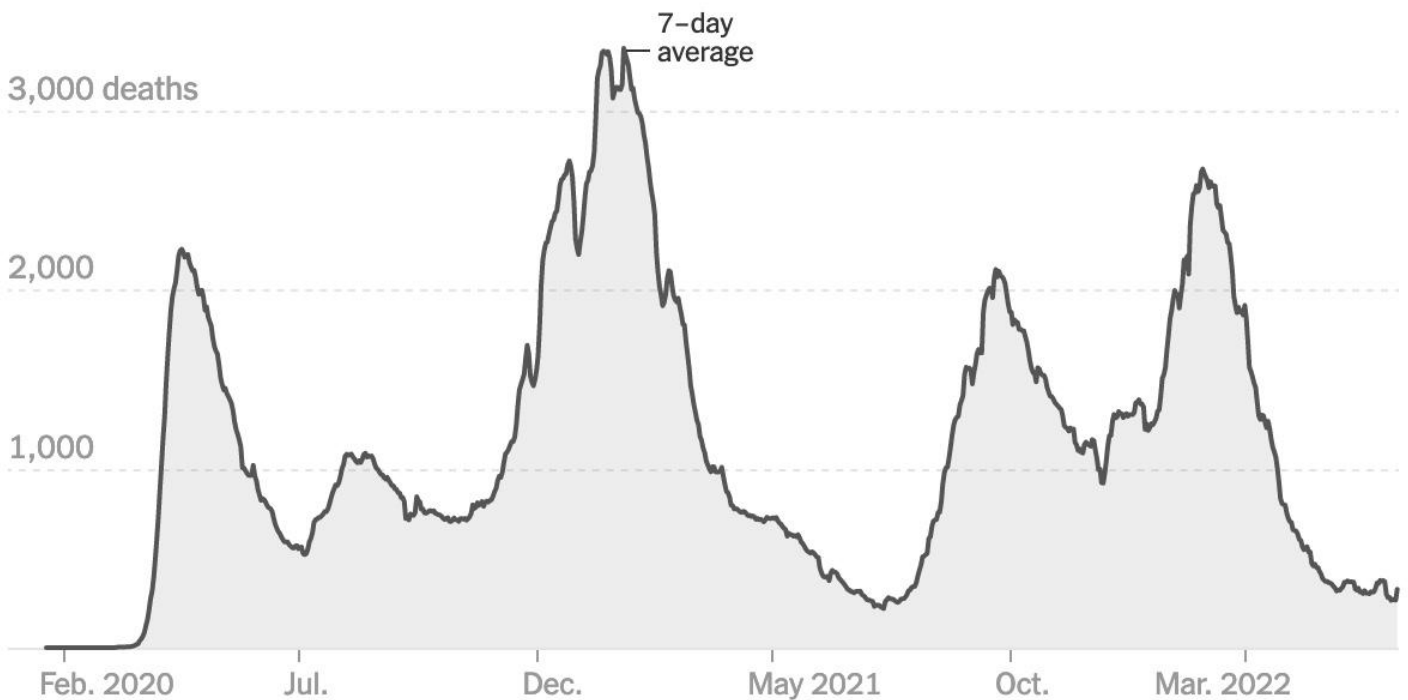
⁴⁶ Irina Anghel, "Frequent Boosters Spur Warning on Immune Response," *Bloomberg*, Jan. 11, 2022, <https://www.bloomberg.com/news/articles/2022-01-11/repeat-booster-shots-risk-overloading-immune-system-ema-says>.

Covid patients in hospitals and I.C.U.s

Early data may be incomplete.

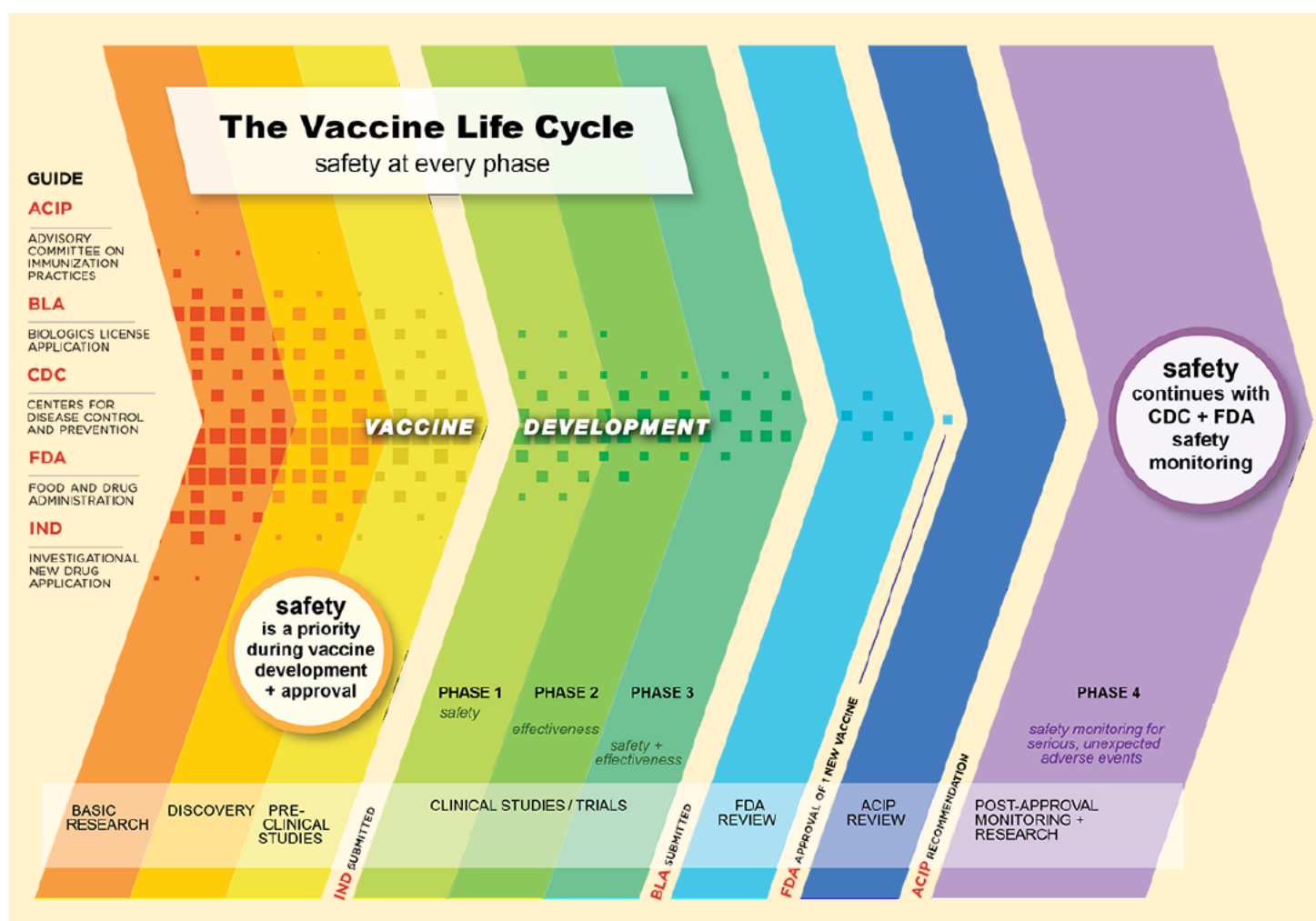


New reported deaths by day



25. The [CDC](#) says, “*Vaccine licensing is a lengthy process that can take 10 years or longer.*”⁴⁷ Yet FDA has managed to compress this into mere months, by omitting most of the preclinical requirements, overlapping the Phase 1-3 trials, using so few pediatric subjects that serious safety issues are missed, and failing to review the vast majority of Phase 4 safety and efficacy data available to it in FDA’s B.E.S.T. databases and elsewhere. Under what authority has FDA jettisoned 50 years of vaccine regulatory science and standards to compress a ten-year process into only months?

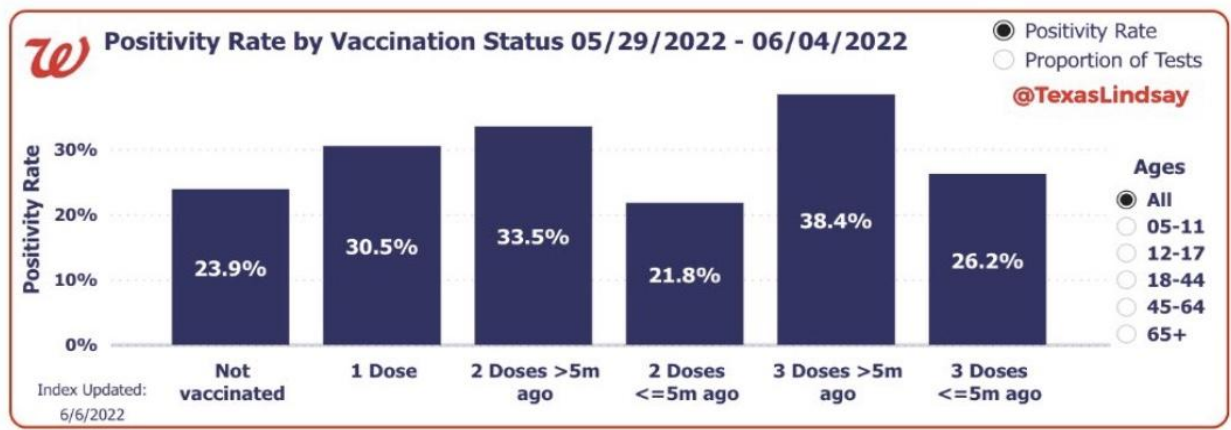
CDC: The Vaccine Life Cycle: Safety at Every Phase



⁴⁷ “US Vaccine Safety: Overview, History, and How the Safety Process Works,” Centers for Disease Control and Prevention, last reviewed Sep. 9, 2020, <https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html>.

26. Walgreens pharmacies perform rapid antigen COVID tests and report weekly on the results, based on the number of vaccine doses received and the date the most recent vaccination was obtained. The results reveal that receiving a 2nd or 3d dose within the past 5 months leads to a comparable positivity rate as being unvaccinated (21.8-26.2%). However, receiving 2 or 3 doses more than 5 months ago leads to the highest positivity rates (33.5-38.4%). This is further supportive evidence that efficacy falls into negative territory several months after vaccination. See the chart below.

Covid-19 Index: May 29th–June 4th 2022



We ask that you carefully consider all the information above before making any recommendations for infants and children regarding Moderna’s vaccine for ages 6 through 17 years old, 6 months through 5 years old, and Pfizer’s vaccine for 6 months through 4 years old at your meetings on June 14-15, 2022.

Sincerely,

Robert F. Kennedy, Jr.



Emergency Use Authorization

Overview and Considerations for COVID-19 Vaccines

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December 10, 2020

The seven slides included here come from a [presentation](#) to the Vaccines and Related Biological Products Advisory Committee (VRBPAC) by FDA’s Dr. Doran Fink on December 10, 2020. Dr. Fink laid out the requirements for issuing EUAs for COVID vaccines, and also discussed criteria for revoking EUAs later if the vaccines failed to meet the required standards as more information about them accrued.

Criteria for FDA Issuance of EUA



- The agent referred to in the EUA declaration can cause a serious or life-threatening disease or condition
- The medical product may be effective to prevent, diagnose, or treat the serious or life-threatening condition caused by the agent
- The known and potential benefits of the product outweigh the known and potential risks of the product
- No adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition
 - Only FDA-approved product for COVID-19 is remdesivir (for treatment, not prevention)
 - Additional products have EUA but not FDA approval (none for prevention of COVID-19)

5

Slide #5 lists two of the [statutory requirements for an EUA](#) established by Congress: that the known and potential benefits of the product outweigh the known and potential risks, and that there must be no adequate, approved (in FDA parlance this means already licensed) and available product to prevent or treat the medical condition. FDA repeats this language in presentations, guidance to industry, and in all the EUA authorization documents.

This statutory language is the reason FDA cannot admit that hydroxychloroquine, ivermectin, fluvoxamine, or other licensed drugs have efficacy against COVID. To admit this would mean that FDA had acted illegally to issue EUAs for vaccines and drugs for COVID.

COVID-19 Vaccine EUA - FDA Expectations



- Discussed at October 22, 2020, VRBPAC meeting and in FDA Guidance, [Emergency Use Authorization for Vaccines to Prevent COVID-19](#)
 - Data to demonstrate manufacturing quality and consistency
 - Clear and compelling safety and efficacy data to support favorable benefit-risk of the vaccine when rapidly deployed for administration to millions of individuals, including healthy people
 - Plans for further evaluation of vaccine safety and effectiveness, including in ongoing clinical trials, active and passive safety monitoring during use under EUA, and observational studies

6

Slide #6 says manufacturing should be of good quality and yield a uniform product. We know that under the best of circumstances, the intact mRNA used in COVID vaccines varied from about 50% to 75%, and the so-called degradation products or visible particulates seen in vials were not characterized by Pfizer, based on its response to FDA's Query 8 in the *Comirnaty* licensure package. Thus the product was not uniform and its quality is at issue.

Slide #6 also says there should be "clear and compelling" safety and efficacy data, sufficient to permit using the product in hundreds of millions of people. And that the collection of these data should be ongoing.

FDA Expectations for Clinical Data



- Efficacy data from at least one well-designed Phase 3 trial demonstrating protection against SARS-CoV-2 infection or disease:
 - Point estimate of least 50% vs. placebo comparator
 - Appropriately alpha-adjusted confidence interval lower bound >30%
- Safety data from throughout clinical development to evaluate reactogenicity, serious AEs, and AEs of special interest
 - Including a high proportion of Phase 3 study subjects followed for at least 1 month after completion of the full vaccination regimen
- Sufficient cases of severe COVID-19 to assess for signals of enhanced disease (and preliminary evidence of protection against severe disease)

7

Slide #7 specifies that efficacy should be at least 50%. Furthermore, FDA required that a sufficient number of cases of severe COVID disease must be studied, in order to determine whether vaccine-enhanced disease is occurring. In other words, FDA was concerned about the possibility that being vaccinated might lead to a worse COVID outcome when infected, as had happened in animal studies of older coronavirus vaccine prototypes, in an RSV vaccine trial in infants, and in a very early, licensed measles vaccine around 1960. Vaccine-enhanced disease also happened recently, during the 2017 rollout of the *Dengvaxia* vaccine in the Philippines. [*Dengvaxia* was subsequently licensed in the US](#) in 2019 despite the [Philippines debacle](#).

FDA Expectations for Further Evaluation



- Following issuance of an EUA, further vaccine evaluation would be needed:
 - For ongoing benefit/risk assessment to support continuation of the EUA
 - To accrue additional data to support licensure as soon as possible and/or to inform labeling
- Further vaccine evaluation following issuance of an EUA would include:
 - Longer-term follow-up for safety, including in larger numbers of vaccine recipients and in populations with lower representation in clinical trials
 - More precise estimation of vaccine effectiveness in specific populations
 - More robust assessment of effectiveness against aspects of SARS-CoV-2 infection or disease
 - Characterization of duration of protection
 - Investigation of immune biomarkers that might predict protection
 - Ongoing monitoring for signals of enhanced disease

9

FDA Expectations for Further Evaluation



- Issuance of an EUA for a COVID-19 vaccine would be contingent upon the ability to conduct further vaccine evaluation through a combination of:
 - Active follow-up of vaccine recipients under the EUA
 - Passive monitoring for clinically significant adverse reactions using established reporting mechanisms (e.g., VAERS)
 - Observational studies, including those that leverage healthcare claims databases
 - Continuation of blinded, placebo-controlled follow-up in ongoing clinical trials for as long as is feasible and strategies to handle loss of follow-up
- FDA does not consider issuance of an EUA for a COVID-19 vaccine to necessitate immediate unblinding of ongoing clinical trials or offering vaccine to all placebo recipients
 - Trial participants may choose to withdraw from follow-up for any reason, including to receive vaccine made available under EUA

10

Issuance of EUA for a COVID-19 Vaccine



- EUA may be revised or revoked if:
 - Circumstances justifying the EUA no longer exist
 - Criteria for issuance are no longer met
 - Other circumstances arise that warrant changes necessary to protect public health or safety, e.g. based on new information concerning:
 - Vaccine safety or effectiveness
 - Vaccine manufacturing or quality
 - COVID-19 epidemiology or pathogenesis

12

Slides 9, 10, and 12 include what FDA said would be needed for its ongoing assessment.

- There needs to be ongoing evaluation of the risk vs. benefit for the vaccine.
- There must be continued safety follow-up using real-world data.
- There must be more precise and robust assessments of vaccine effectiveness.
- The duration of protection must be characterized.
- There must be ongoing monitoring for vaccine-enhanced disease.
- Both active and passive monitoring for adverse effects must continue, to include insurance claims databases such as those FDA has obtained with its BEST initiative.
- The double-blinded, placebo-controlled studies should be continued for as long as feasible. But paradoxically, a week after this presentation, FDA allowed the vaccine manufacturers to unblind their trials and offer vaccines to all placebo subjects, effectively ending the placebo-controlled safety studies.
- **EUAs can be revoked (slide 12), if the circumstances justifying them no longer exist, or if the issuing criteria are no longer met.** It would seem that since the Omicron variants have largely escaped vaccine-induced immunity, because the illness is now much less severe, and because 95% of the population has partial to complete immunity, following these FDA guidelines, the EUAs should all be revoked, not expanded.