UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF TEXAS

CHILDREN'S HEALTH DEFENSE, DEBORAH L. ELSE, an individual, and SACHA DIETRICH, an individual, Plaintiffs, v. FOOD and DRUG ADMINISTRATION, and ROBERT CALIFF, Commissioner of FDA Defendants.	**Case No. 6:22-cv-00093** **FIRST AMENDED COMPLAINT**

INTRODUCTION

This case concerns the Defendant Food & Drug Administration's ("FDA") abuse of power leading to Plaintiffs' harm. The FDA abused its emergency powers, eliminated the notice-and-comment process, ignored citizen petitions, abandoned traditional safety mechanisms for assessing drugs injected into interstate commerce and the arms of American children, ignored express legislative limits on their actions, and now claims to be beyond judicial review. Defendants used this emergency power to push dangerous biologics on minors, mislabel and misbrand them to the public, with the express knowledge that their mislabeling would lead to them being coerced on children and infants as young as 6 months old.

SUMMARY

1. Under the pretext of Emergency Use Authorization powers (more than two years into this "emergency"), Defendant FDA authorized two dangerous biologics for minor children as

young as 6 months old to address COVID-19, a disease which poses a lower risk to a young child than the ordinary flu.

2. The FDA recently redefined both Moderna and Pfizer-BioNTech's mRNA COVID-19 biologics as "vaccines" even though they do not meet the century-long definition of the term. The FDA failed to provide for any notice-and-comment period, any citizen petition recognition or redress of petitioner concerns and grievances. The FDA used emergency authorizations, thus claiming unlimited power without legislative approval, and even claimed these emergency powers prevent and preclude judicial review. The FDA has become an agency that declares its own law, enforces its own law, and adjudicates its own law, with children now the sacrificial lambs to this power grab.

3. The FDA is an agency founded on regulating interstate labeling of products, not a supervisory medical or scientific agency. The core of Defendants' work is making sure the marketing of food and drugs conforms to their known qualities. The FDA is meant to highlight a drug's risks, determine the limits on the drug's proven efficacy, and ensure the marketing of any drug conforms to the requirements of informed consent, the universal medical norm and *jus cogens* principle governing all civilized societies, as codified in the Nuremberg Code of 1947.

4. In this case, the FDA shirked its own purpose and rushed an untested product to market, mislabeled this experimental gene therapy a "vaccine", made false statements of safety and efficacy, and facilitated its mandate to minors without parents' or guardians' informed consent. The FDA ignored, violated, and discarded its own laws and rules limiting the marketing of drugs, and pushed them onto minor children with false and manipulative advertising that results in direct marketing to children, resulting in the use of the beloved children's program Sesame Street and Big Bird to promote this mislabeled product.

5. The FDA's unchecked and unbridled reign over COVID-19 pharmaceuticals is the foundation for all vaccination policies and mandates in the United States today.

6. Children now face loss of access to needed organ transplants, medical care, educational programs, travel, and even basic participation in public life based on the FDA's COVID-19 vaccine authorizations. Children who do not have any parental or guardian safeguards against these harmful injections are subjected to FDA's false attestations of safety and effectiveness; as a result, these minors, under pressure from foster care and juvenile systems, may "opt" to take this dangerous biologic. Finally, Texas laws and policies controlling the consent to immunization for minors pose a threat to every child in Texas who is unvaccinated against COVID-19.

7. FDA promised parents honesty in advertising with full disclosure of risks and fair balanced coverage of efficacy limitations, as well as full informed consent before injection. FDA broke that promise in this case, a lie that cost CHD substantial diversion of resources in reeducating the public and continuous risk for CHD member and employee parents in not being able to continually trust the FDA approval and marketing of children's vaccines.

PARTIES

8. Plaintiff CHD is a not-for-profit membership organization headquartered in New Jersey and incorporated under the laws of California. Plaintiff sues in its own capacity and on behalf of its employees and constituent members who have been affected by Defendants' actions. FDA's conduct caused a serious diversion of the organization's resources from its mission to correct this critical error and to try to protect the members from Defendants' illicit actions and the ill effects thereof.

9. Plaintiff Deborah L. Else is a member of CHD and a resident of Bell County, Texas. She is a long-time pharmacist and the parent of R.E., a 10-year-old student at Thomas Arnold

Elementary School in Salado, Texas. Her child is at imminent risk of immediate harm from FDA's action to authorize Pfizer's COVID-19 biologic for children aged 5-11 and is in the class Defendants have targeted with their unlawful authorization and illicit marketing. She is a member of Children's Health Defense.

10. Plaintiff Sacha Dietrich is a resident of Bell County, Texas. She is the parent of H.D. and K.D., who are 11 and 7 years old, respectively. Her children are at imminent risk of immediate harm from this Emergency Use Authorization (EUA) biologic, including but not limited to coercion and pressure to receive the biologic, impending mandates, severe adverse reactions should they receive the drug, and immunization without parental informed consent. Her child is in the class the Defendant FDA targeted with its unlawful authorization and illicit marketing. She is a member of Children's Health Defense.

11. Plaintiff Amy Villella is a resident of Florida. She is the parent four children aged 3, 5, 11, and 13, three of which are subject to the FDA's COVID-19 EUAs at issue. Her children are at imminent risk of harm from FDA's action, including but not limited to coercion and pressure to receive the biologic, potential mandates, severe adverse reactions should they receive the vaccine, and immunization without parental informed consent. She is an employee of Children's Health Defense.

12. Plaintiffs Jonathan Shour and Rebecca Shour are residents of Onslow County, North Carolina. Jonathan Shour is a chaplain in the United States Navy. They have four children aged 2 months, 3 years, 5 years, and 7 years, all of which are threatened by imminent risk from FDA's EUA for pediatric Pfizer-BioNTech and Moderna vaccines. Both are members of Children's Health Defense.

13. Defendant FDA is an agency within the U.S. Department of Health and Human Services. The FDA is primarily a labeling and marketing agency, "responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of human and veterinary drugs, vaccines, and other biological products."

14. Defendant Robert Califf is sued in his official capacity as FDA Commissioner.

JURISDICTION AND VENUE

15. This action arises out of Defendants' misuse of emergency powers under 21 U.S.C. § 360bbb-3 and their non-compliance with the Administrative Procedures Act, 5 U.S.C. § 500 et seq.

16. This lawsuit raises federal questions over which this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361.

17. Pursuant to 28 U.S.C. § 1391(e), venue is proper in the Western District of Texas, where Plaintiffs Deborah L. Else and Sacha Dietrich reside. Under 5 U.S.C. § 703, venue is proper in any court of competent jurisdiction.

18. This lawsuit raises federal questions over which this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361.

19. Pursuant to 28 U.S.C. § 1391(e), venue is proper in the Western District of Texas, where Plaintiffs Deborah L. Else and Sacha Dietrich reside. Under 5 U.S.C. § 703, venue is proper in any court of competent jurisdiction.

20. An actual and justiciable controversy exists between Plaintiffs and Defendants. Plaintiffs are in the class directly injured by the illicit marketing of this vaccine to minor children, and Plaintiff organization must, and has, diverted substantial resources due to it.

STATEMENT OF FACTS

21. We face an unparalleled moment in FDA and public health history: the race to vaccine authorization for infants and very young minor children without adequate clinical trials, without consideration of relevant information, without robust debate, and without even meaningful public participation in the citizen petition process. The FDA's extraordinary emergency authorizations for infants as young as 6 months to minor children up to 11 years old, who face less risk from COVID-19 than from the seasonal flu, endanger their safety, as these biologics lack good manufacturing policies, lack strict safety safeguards, lack accountability, and indeed do not even fit the traditional definition of "vaccine."

22. mRNA vaccines use experimental technology to combat a novel virus from a family of viruses with no history of vaccine success. The human body attempts to attack a virus that continues to mutate in ways prior vaccine studies did not even address. The FDA's unwarranted authorizations endanger vaccine confidence, as they follow a historic path littered with disastrous debacles of unsafe yet sanctioned drugs and biologics that have devastated confidence in public health generally.

23. On October 29, 2021, the FDA granted an Emergency Use Authorization ("EUA") for Pfizer-BioNTech's COVID-19 biologic for children ages 5-11, even though this product poses imminent risk to that portion of the population without proportionate benefit. (Exh. 1)

24. Despite the overwhelming failure of the vaccine, the FDA has continued its crusade: on June 17, 2022, the FDA amended the EUAs for both Pfizer-BioNTech and Moderna vaccines to include children ***as young as six months old***.[1] (Exh. 2)

[1] Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age, June 17, 2022, *FDA News Release,* available at

25. To justify the authorization, the FDA ignored, and even hid, data showing severe short-term risks of COVID-19 vaccination for children and never admitted that the agency's abbreviated studies could not have been long enough in duration to assess long-term severe and irreversible injury. The FDA could not, and did not, arrive at a reasoned explanation of whether benefits outweigh the risk of injury for children aged 5-11, let alone for children aged 6 months through 4 years. If this dangerous rollout is allowed to continue, there are certain to be untold casualties and injuries. Children, expected to have the greatest number of years of life ahead of them, run the greatest risks of vaccine injury, yet have the lowest risk from COVID-19 itself than any other age group.

26. In this, the latest in a series of premature approvals and authorizations, Defendants have abused their emergency powers, denied CHD its procedural right to seek redress via citizen petition for Pfizer's product, redefined the term "vaccine" in violation of procedural due process, failed to satisfactorily articulate standards for assessing the safety, efficacy, and necessity for the vaccine, and promoted the fraudulent marketing of a biologic targeted at children, in violation of the Administrative Procedures Act ("APA").

27. FDA's actions have resulted in injury to Children's Health Defense, which has consistently worked to prevent this abuse of power from occurring and to protect children and their families, such as Plaintiffs in this case, whose children are experiencing coercion to take the vaccine, discrimination if they refuse, and threat of vaccination against their parents' wishes in some circumstances.

FDA's Grant of Emergency Use Authorization for Children

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https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children.

28. Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 360bbb- 3, authorizes the FDA to issue an Emergency Use Authorization ("EUA") for a biologic under certain emergency circumstances, allowing a product to be introduced and administered to the public even when it has not gone through the normal review process necessary for approval and licensure.

29. This is a high burden to meet, as evidenced by the fact that an EUA has never been previously granted for a brand-new vaccine. The only other vaccine to have been authorized for emergency use was an anthrax vaccine, AVA, which had already been formally approved by the FDA for other purposes.[2]

30. In an emergency, the Secretary of Health and Human Services may issue EUAs if he concludes: (1) a serious or life-threatening disease is present; (2) a product "may be effective" in treating or preventing it; (3) there is "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;" (4) a positive risk-benefit analysis that measures both the known and potential benefits of the product against the known and potential risks; and (5) that the patient's option to accept or decline the product is protected through informed consent. 21 U.S.C. § 360bbb-3(c)(1)-(5).

31. As will be set forth below, none of the above factors have been satisfied here.

32. On October 26, 2021, the FDA held a Vaccines and Related Biological Products Advisory Committee ("VRBPAC") meeting to discuss Pfizer's request to amend its EUA to allow for the use of the Pfizer-BioNTech COVID-19 vaccine in children ages 5-11 (Exh. 3).[3]

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[2] Jonathan Iwry, From 9/11 to COVID-19: A Brief History of FDA Emergency Use Authorization, *Harvard Law Petrie-Flom Center* (January 28, 2021), available at https://blog.petrieflom.law.harvard.edu/2021/01/28/fda-emergency-use-authorization-history/.

[3] Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement, *FDA* (October 26, 2021), available at https://www.fda.gov/advisory-

33. On October 29, 2021, in a gross abuse of its discretion under the emergency use statute, the FDA recklessly granted EUA for a pediatric Pfizer-BioNTech COVID-19 vaccine for 5- through 11-year-olds. (Exh. 4)

34. Finally, in their latest abuse of power, the FDA granted two additional EUAs on June 17, 2022, authorizing the use of the Pfizer-BioNTech's COVID-19 vaccine for children 6 months through 4 years and the Moderna vaccine for children 6 months through 11 years of age.[4] (Exh. 5, 6 and 7)

35. The APA limits what drugs and biologics can be authorized, the purposes they can be authorized for, the individuals they can be prescribed for, and the notices and consent required before they can be administered. The EUA statute, 21 U.S.C § 360bbb-3, further codifies these standards, including the obligation of Informed Consent derived from the Nuremberg Code of 1947 to ensure no further medical atrocities.

36. Born of this informed consent, democratically driven process, the FDA biologic authorization and approval process outlines protocols with public input and robust debate, citizen petition and judicial oversight, substantive limits on its methodology and procedural requirements. Only a rigorous scientific review with meaningful public participation, through citizen petitions answered by the FDA, could even authorize the introduction of a novel biologic.

committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement.

[4] Coronavirus (COVID-19) Update: FDA Authorizes Moderna and Pfizer-BioNTech COVID-19 Vaccines for Children Down to 6 Months of Age, June 17, 2022. Last accessed June 27, 2022, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-covid-19-vaccines-children#:~:text=Today%2C%20the%20U.S.%20Food%20and,to%206%20months%20of%20age.

As President Biden advised, no citizen should take a drug without "transparency, transparency, transparency" from the government.[5]

37. The FDA has failed spectacularly to fulfill that promise, and in doing so has also blocked the public from meaningful participation to ensure that the processes through which the FDA conducts its investigations that form the foundation for all public health policies regarding COVID-19 are dependable, accurate, and truthful.

38. Exceptional situations do not give an unelected federal agency the authority to abrogate the people's Constitutional rights.

Vaccine Adverse Events Reporting System: Unprecedented Alarm Signals

39. More than a year and a half after the COVID-19 biologics were introduced to the American public *en masse*, the reports of adverse events and death from the Pfizer-BioNTech and Moderna COVID-19 vaccines are staggering.

40. The input of event reports to VAERS since the COVID-19 vaccines were introduced is *greater than all cumulative adverse event reports to VAERS for the prior thirty years*: an alarming statistic. Death reports for 2021 are also greater than all the deaths reported to VAERS over the preceding 30 years. No public health official has proffered an explanation for this. The CDC, which is charged with investigating every reported death in VAERS, simply waves its hands and claims none are due to vaccination, without providing any data.

41. Data released June 17, 2022 by the Centers for Disease Control and Prevention (CDC) showed that since Dec. 14, 2020, a total of 1,455,346 adverse events following injection were reported to the Vaccine Adverse Event Reporting System (VAERS), with 23,031 deaths and

[5] Biden White House Pledges Data, Transparency, Respect for Free Press, *Reuters* (January 20, 2021), available at https://www.reuters.com/article/us-usa-biden-briefing-idUSKBN29Q08S.

164,324 hospitalizations reported.[6] 859,133 adverse events and 18,814 deaths reported were attributed to the Pfizer-BioNTech COVID-19 vaccine. 495,725 adverse events and 7,627 deaths were attributed to the Moderna vaccine.[7]

42. The Vaccine Adverse Event Reporting System (VAERS) is a 30-year-old voluntary adverse event reporting system for vaccines, jointly managed by FDA and CDC. Injured parties, their healthcare providers and others may file reports. Doctors and vaccine manufacturers are mandated to report severe injuries and deaths that may be linked to vaccination. This is the nation's foremost adverse event reporting system.

43. Past attempts to investigate the VAERS reporting rate have suggested that between 1% and 13% of actual adverse effects get reported; however, because CDC changed VAERS reporting recently to include additional data, it is not possible to estimate the degree of underreporting based on past attempts to do so.[8] All models guarantee that the numbers reported to VAERS are severe underestimates.

44. The CDC has failed to account for this underreporting in its representation of VAERS data, underestimating the number of adverse events to the public and thus ignoring the actual prevalence of COVID-19 biologic harm.

45. Even when strong scientific evidence has been presented of their misconduct, CDC and FDA have refused to issue any corrections, and continue to misrepresent the VAERS data as if VAERS reporting rates reflected accurate adverse event rates.

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[6] Vaccine Adverse Event Reporting System (VAERS), *CDC Wonder*, available at https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=67A4CC1D3E7D207433E5332EABDF.

[7] *Id.*

[8] Varricchio F, Iskander J, Destefano F, Ball R, Pless R, Braun MM, Chen RT. Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. Pediatr Infect Dis J. 2004 Apr;23(4):287-94. doi: 10.1097/00006454-200404000-00002. PMID: 15071280.

46. The VAERS data on myocarditis and pericarditis are especially concerning, with 15,046 and 9,916 cases reported respectively as of June 7, 2022.[9] The absence of data from other FDA- and CDC-accessible databases is alarming. With over 60% of the United States vaccinated, it is inexplicable that we still do not know the actual rates of myocarditis in the population. This information may have been concealed to garner authorizations for the vaccines in the pediatric population, which has experienced the most alarming rates of myocarditis.

47. Although VAERS cannot be used to accurately calculate the rates of any adverse reaction due to the underreporting inadequacy, CDC did exactly that for anaphylaxis, claiming the rate of VAERS reporting was the rate of occurrence, even though it was almost guaranteed to be an underestimate.[10]

48. The FDA has failed to adequately consider data from VAERS. A CHD FOIA interchange with CDC, with which FDA works on VAERS, reveals that the CDC and FDA don't even seriously analyze the VAERS data, further proving that FDA is simply derelict in its duties to protect the American people.[11] (Exh. 8)

COVID-19 Vaccines Have Posed Severe Health Risks that FDA Fails to Address

49. An overwhelming number of case studies and scientific studies emerging since the administration of mRNA COVID-19 vaccines had sufficiently prove that both Pfizer and Moderna's mRNA vaccines pose a significant threat to a recipient's health.

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[9] Vaccine Adverse Event Reporting System (VAERS), *CDC Wonder*.

[10] Meryl Nass, Did CDC Deliberately Mislead Public on Allergic Reactions to Moderna Vaccine?, *The Defender* (January 28, 2021) available at https://childrenshealthdefense.org/defender/did-cdc-mislead-public-allergic-reactions-moderna-vaccine/.

[11] CDC Admits It Never Monitored VAERS for COVID Vaccine Safety Signals, *The Defender*, June 21, 2022, available at https://childrenshealthdefense.org/defender/cdc-vaers-covid-vaccine-safety/.

50. Scientists and health care professionals raised the alarm over the long-term implications of this mRNA gene therapy technology even before the first shots were administered. Their worst fears have come true, and there are myriad vaccine side effects that have been witnessed and reported since the COVID-19 vaccine rollout.

51. We now know that vaccine-induced spike proteins, the putative antigen induced by Pfizer-BioNTech and Moderna COVID-19 vaccines, are toxic. Spike proteins circulate throughout the body and accumulate in large concentrations in organs and tissues, including the spleen, bone marrow, liver, adrenal glands, and especially the ovaries.[12] Since there exists no way to turn off spike production, the actual dose of spike protein may vary by orders of magnitude from person to person, raising grave concerns regarding the FDA's method of determining dosage.

52. In addition, spike proteins logically would be expected to trigger the destruction of cell walls that produce them and present them on their surfaces. Products that induce the production of spike protein should only be used after careful consideration of the individual recipient's risks and benefits. They should not be employed in mass vaccination programs where there is no learned practitioner to weigh appropriate dosage or use, nor in individuals with a very low risk of serious COVID-19 disease as the long-term risks are yet so unfathomable.

53. Strong but not yet conclusive evidence links spike protein in vivo to blood clots, thrombocytopenia, hemorrhages, heart attacks and strokes – the very severe effects of COVID-19 disease itself. The damage the spike proteins may be causing must be fully elucidated. The

[12] SARS-CoV-2 mRNA Vaccine Biodistribution Study, https://www.docdroid.net/xq0Z8B0/pfizer- report-japanese-government-pdf.

toxicity of the spike protein itself means that no vaccine using this design can be assumed to be safe until proven otherwise, and none should continue under an EUA or license.

54. Furthermore, studies have also shown that antibody-dependent enhancement ("ADE") poses a severe threat to vaccinated individuals.[13] "ADE occurs when the antibodies generated during an immune response recognize and bind to a pathogen, but they are unable to provide infection. Instead, these antibodies act as a 'Trojan horse,' allowing the pathogen to get into cells and exacerbate the immune response."[14] Thus, when dealing with different strains of COVID-19, ADE caused by the COVID-19 biologic may accelerate the virus infecting the cells and resulting in more severe illness. Empirical evidence of disease in those already vaccinated confirms this ADE phenomenon. Therefore, children who receive the COVID-19 biologic are likely at risk of increased severity of disease if they are exposed to other COVID-19 variants.

55. In addition, the myocarditis risk immediately after vaccination in older children is considerable, potentially life-threatening, and increases exponentially with decreasing age, suggesting that young children, particularly males, are at high risk.

56. According to the Jerusalem Post on October 7, 2021, the health ministry was considering whether "individuals vaccinated with the Pfizer coronavirus vaccine may be asked to avoid strenuous exercise [including swimming] and other physical activity for one week after receiving each dose due to cases of myocarditis…."[15]

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[13] Infection-enhancing anti-SARS-CoV-2 antibodies recognize both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination? Yahi, Nouara et al. *Journal of Infection*, Volume 83, Issue 5, 607 - 635, doi: https://doi.org/10.1016/j.jinf.2021.08.010.

[14] Antibody-dependent Enhancement and Vaccines, Children's Hospital of Philadelphia, available at https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-safety/antibody-dependent-enhancement-and-vaccines.

[15] Maayan Jaffe-Hoffman, Health Ministry to consider asking newly vaccinated to avoid working out, *The Jerusalem Post* (October 7, 2021), available at https://www.jpost.com/health-and-wellness/health-ministry-to-consider-asking-newly-vaccinated-to-avoid-working-out-681317/.

57. Four Nordic countries recently halted the use of Moderna's vaccine in some age groups due to the risk of myocarditis. It was reported by the Wall Street Journal that FDA paused its review of the Moderna vaccine for teenagers in response to the Nordic countries' action. The article was subtitled, "Agency holds off decision on expanding use of shot to 12-to-17- year-olds while it looks into risk of rare heart condition."[16]

58. Some children have died or been permanently injured from COVID-19 shots authorized to children 6 months through 11 years, and yet the FDA fails to acknowledge these atrocities.

59. For example, Maddie de Garay, aged 12, was healthy when she volunteered to enter Pfizer's pediatric COVID-19 vaccine trial at the University of Cincinnati with her two siblings. She became ill immediately after the second dose with high fever and then a wide range of symptoms. Over the subsequent six months, she had about a dozen emergency room visits and six hospitalizations. She has required a feeding tube and uses a wheelchair. Dr. Frenck, the Principal Investigator for the Pfizer pediatric clinical trial at his hospital, was her physician and is aware of these problems. Yet Maddie de Garay was not reported as a serious adverse event in the trial documents. When her trial data were published in the New England Journal of Medicine, there were no serious vaccine-related adverse events listed for any subject. Dr. Frenck, Maddie's physician, was the first author of the NEJM study. How many other subjects in Pfizer's pediatric trials were similarly injured but went unreported? How many Principal Investigators issued positive reports despite knowing of life-threatening injuries?

60. A number of other serious side effects have been witnessed at alarming rates. Despite this, the public is kept in the dark of these dangerous side effects, in direct violation of informed

[16] FDA Delays Moderna Covid-19 Vaccine for Adolescents to Review Rare Myocarditis Side Effect, *The Wall Street Journal (*October 15, 2021), https://www.wsj.com/articles/fda-delays-moderna-covid-19-vaccine-for-adolescents-to-review-rare-myocarditis-side-effect-11634315159.

consent. When a high-quality study of Massachusetts General Hospital and Brigham Hospital employees showed that anaphylaxis occurred in 250 per million employees,[17] CDC failed to update its website and still claims, as of June 27, 2022, that anaphylaxis occurs only 5 times per million COVID-19 vaccines.[18]

61. FDA actions have buried people in addition to data. The FDA has not shared actual data on efficacy, side effects and all injuries to educate the public on the vaccine risks. Nor have they seemingly utilized this information effectively via risk assessments and safety analyses when granting new EUAs. To grant authorization while failing to inform the public of these egregious health risks is to abet unethical coercion that violates the Nuremberg Code's first principle that informed consent, without coercion or duress, is "absolutely essential."

62. Effective treatments for children injured by COVID-19 shots have not yet been developed, nor has there been an analogous rush to find medical measures against COVID-19 vaccine injury as there were warp speed efforts to invent and push COVID-19 shots onto the market. Realistically, most families will be unable to cover the costs of the potential catastrophic injuries that may occur from COVID-19 shots.

63. The deck is stacked. Current policies assure that we will never fully know the risks of COVID-19 vaccinations nor be apprised of the magnitude of those risks until it is too late.

Vaccination of Children for COVID-19 Was Never Medically Necessary

64. The FDA cannot ignore the fact that there is no COVID-19 emergency for children. (Exh. 9)

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[17] Blumenthal KG, Robinson LB, Camargo CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines. *JAMA*. 2021;325(15):1562–1565. doi:10.1001/jama.2021.3976.

[18] Selected Adverse Events Reported after COVID-19 Vaccination, Centers for Disease Control and Prevention (June 27, 2022) available at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

65. Children have a 99.99% COVID-19 recovery rate, and children under 5 statistically have a 0% chance of dying from the virus. A Johns Hopkins study monitoring 48,000 children diagnosed with COVID-19 shows that children under 18 without comorbidities had a *zero-mortality rate*.[19] Furthermore, a study published in *Nature* yielded the same results: children under 18 with no comorbidities have virtually no risk of death.[20] Studies from other countries also came to the same conclusion.[21]

66. The actual risk of hospitalization and death, or even symptomatic disease, from COVID-19 in young children is the lowest out of all age cohorts. The risk of death and severe illness in children or young adults is exceptionally rare.[22] Children are usually asymptomatic or mildly symptomatic from COVID-19 infections. In fact, according to the CDC's own data, over 75% of American children already have natural immunity to COVID, making vaccination completely

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[19] 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; 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.

[20] 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.

[21] "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.

[22] Clare Smith, David Odd, Deaths in Children and Young People in England following SARS-CoV-2 infection during the first pandemic year: a national study using linked mandatory child death reporting data, (July 7, 2021), doi: https://doi.org/10.21203/rs.3.rs-689684/v1.

superfluous.[23] John Hopkins faculty member Marty Makary published an Op-Ed in the Wall Street Journal detailing the findings when he and a research team reviewed about 48,000 cases of children under 18 reported to have had COVID-19 between April and August of 2020.[24] Their findings were shocking: a mortality rate of zero among children without a pre-existing medical condition.[25]

67. CDC tried to convince the public that there is a real threat to children from COVID-19 through exaggeration and data manipulation. For example, CDC reports 94 COVID-19 deaths with COVID-19 since January 1, 2020 in the 5 through 11 age group. Yet this is misleading since CDC designates these as deaths "involving COVID" or "with COVID" rather than due to COVID-19.[26] It is impossible to separate deaths ***with*** COVID-19 from those ***due to*** COVID-19 in the U.S. because the CDC does not distinguish them.

68. What we do know is that child deaths due to COVID-19 in Germany, according to the BILD newspaper, were a total of 20 by May 2021, in a country with 85 million people. Pediatric deaths were "under 30" through March 2021 according to the UK government, with 60 million people.[27]

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[23] Clarke KE, Jones JM, Deng Y, et al. Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies — United States, September 2021–February 2022. MMWR Morb Mortal Wkly Rep 2022;71:606-608. DOI: http://dx.doi.org/10.15585/mmwr.mm7117e3.

[24] The Flimsy Evidence Behind the CDC's Push to Vaccinate Children, *The Wall Street Journal* (July 19, 2021), available at https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868.

[25] *Id.*

[26] Weekly Updates by Select Demographic and Geographic Characteristics, *CDC National Center for Health Statistics*, https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm.

[27] JCVI Statement on COVID-19 Vaccination of Children and young People Aged 12 to 17 years, UK Department of Health and Social Care (August 4, 2021), available at https://www.gov.uk/government/publications/jcvi-statement-august-2021-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years/jcvi-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-4-august-2021.

69. Since March 2020, it's been well-known that children experience the mildest symptoms from COVID-19. In one report in Hospital Pediatrics,[28] of 146 hospitalized pediatric COVID-19 cases during 5 months in 2020, only 20 (14%) were deemed "significantly symptomatic." Only 24 were admitted to the hospital because of COVID-19. Of those significantly symptomatic, 60% were obese and 35% had asthma. COVID-19 was either incidental or minimally related to the reason for hospitalization in 86% of the admissions. Of the 4 pediatric deaths in this series, the authors attributed only one to COVID-19, in a "medically complex patient admitted for respiratory failure."

mRNA Vaccines Have Been Ineffective at Preventing Transmission or Infection in Children

70. A study published in the March 18th issue of the CDC's Morbidity and Mortality Weekly Review (MMWR) demonstrated an efficacy of a mere 31% among 5- to 11- year-olds, far below the originally promised efficacy of 80%.

71. Recent analysis of the data from Pfizer's clinical trial on children under 5 years old indicates that the 80% estimate of efficacy that Pfizer and the FDA originally promoted was wildly misrepresented from the beginning, as is seen through an analysis of the data published in the FDA's own VRBPAC briefing document regarding the EUA request for the Pfizer-BioNTech COVID-19 vaccine for children 6 months through 4 years of age. For the purposes of calculating efficacy, only SARS-CoV-2 infections that occurred after the *third* dose were counted.[29] However, 97.3% of breakthrough cases occurred before the third dose, and therefore

[28] Webb NE, Osburn TS. Characteristics of Hospitalized Children Positive for SARS-CoV-2: Experience of a Large Center. Hosp Pediatr. 2021 Aug;11(8):e133-e141. doi: 10.1542/hpeds.2021-005919. Epub 2021 May 19. PMID: 34011567.

[29] Vaccines and Related Biological Products Advisory Committee Meeting; FDA Briefing Document, June 15, 2022, available at https://www.fda.gov/media/159195/download.

the efficacy estimate is based on less than 3% of the infections observed in the trial. An accurate calculation therefore yielded an approximate efficacy of merely 20% for children under 5.

72. An analysis of over 1.3 million children (365,000 of whom were vaccinated) from the New York Department of Health demonstrated that the Pfizer shots for children 5-11 yielded very poor efficacy: 31% and then 12% after 7 weeks. The Pfizer shot even had a *negative efficacy* for children 5-11 years of age 8 weeks after receiving the second dose.[30] "By 8 weeks following their second dose, vaccinated children were placed at higher risk of developing COVID-19 than unvaccinated children. Addressing this study, CHD stated in its letter to the FDA regarding the 6 months-4 years EUA:

> "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 ever been vaccinated. Vaccinating children who you know are likely to be placed at higher risk from COVID because of vaccination is not 'public health;' it is a crime. This is an unprecedented proposal not backed by science, logic, or ethics." (Exh. 9)

73. From Moderna's pediatric studies, the FDA found that "efficacy data from 5,476 participants 6 months through 5 years of age show that the vaccine was 36.7% effective . . . in preventing COVID-19," an incredibly weak finding.

74. What's more, on May 6, 2022, the FDA's top vaccine leader, Peter Marks, told a congressional committee that the 50% threshold for efficacy against COVID-19 infections required for adult vaccines, which is already low, will not need to be met for further

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[30] Vajeera Dorabawila, PhD, Dina Hoefer, 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; Vajeera Dorabawila, PhD, Dina Hoefer, 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.

authorizations of the pediatric COVID-19 vaccine, an immediate failure of the FDA's established criteria.[31] Now that the vaccine has been authorized for this youngest age cohort, we can assume that a reasonable threshold of efficacy has not been met.

75. The ineffectiveness of these mRNA vaccines has been further demonstrated by the high rates of breakthrough cases in highly vaccinated communities. However, the CDC has made efforts to underreport the number of breakthrough cases to cover up the vaccine's ineffectiveness. Beginning on May 1, 2021, for CDC to accept a report of a "breakthrough" case, or a case of COVID-19 in a vaccinated individual, the infected person must have required hospitalization or died and had his infection confirmed with a PCR test using 28 or fewer cycles.[32] Other problems with data acquisition of breakthrough cases[33] have further contributed to keeping the official number of such cases much lower than they really are. It's been witnessed that there is a higher rate of COVID-19 cases in the vaccinated compared to the unvaccinated.[34]

76. Pediatric vaccinations cannot be justified as necessary for herd immunity when herd immunity itself is impossible to achieve with COVID-19 vaccines. Given the rapid waning of protection and the inability of current vaccines to prevent transmission of SARS-CoV-2,

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[31] FDA's Peter Marks to Congress: Youngest Kids Vaccines Won't Need to Hit 50% Efficacy Mark, *Endpoints News*, May 11, 2022, available at https://endpts.com/fdas-peter-marks-to-congress-youngest-kids-vaccine-wont-need-to-hit-50-efficacy-mark/.

[32] Ensuring COVID-19 Vaccines Work, *Centers for Disease Control and Prevention* (December 23, 2021) available at https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html.

[33] Erin Banco, Holes in reporting of breakthrough Covid cases hamper CDC response, *Politico* (August 25, 2021) available at https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823.

[34] COVID-19 Vaccine Surveillance Report – Week 42, *UK Health Security Agency*, available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1027511/Vaccine-surveillance-report-week-42.pdf.

admitted by CDC Director Walensky,[35] it is not possible to achieve herd immunity through vaccination. In fact, the U.K.'s head of the Oxford Vaccine Group, Professor Sir Andrew Pollard, told Parliament that herd immunity due to vaccination was "not a possibility."[36]

77. The risk-benefit analysis of COVID-19 vaccines does not support an overall gain from vaccination. A recent study found that the mRNA COVID-19 vaccines yielded an excess risk of serious adverse events of special interest that was greater than the risk reduction for COVID-19 hospitalization witnessed in the Pfizer and Moderna clinical trials (2.3 and 6.4 per 10,000 participants, respectively). In essence: ***the mRNA COVID-19 vaccine is more effective at putting an individual in the hospital than it is at keeping him out of it***.[37]

78. The statistics are clear: healthy children have a miniscule risk of contracting serious COVID-19, 75% already enjoy natural immunity, which is broader and longer lasting than immunity derived from current COVID-19 vaccines, and the vaccines are ineffective at preventing infection or transmission.[38] Vaccinating children exposes them to excess risk without the prospect of benefit.

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[35] Kyle Becker, CDC Director Changes Her Story, Now Admits COVID Vaccines Don't Prevent Virus Transmission, *Becker News* (August 6, 2021), available at https://beckernews.com/walensky-180-40752/.

[36] Mychael Schnell, Herd Immunity 'Not a Possibility' with Delta Variant, Oxford Vaccine Group Head Says, *The Hill* (August 11, 2021), available at https://thehill.com/policy/healthcare/567414-herd-immunity-not-a-possibility-with-delta-variant-oxford-vaccine-group.

[37] Fraiman, J., Erviti, J., Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials, (June 23, 2022) available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4125239.

[38] Kristen Cohen, Susanne Linderman, Zoe Moodie, et al., Longitudinal analysis shows durable and broad immunity memory after SARS -CoV-2 infection with persisting antibody responses and memory B and T cells, *Cell Reports Medicine*, July 14, 2021, DOI: https://doi.org/10.1016/j.xcrm.2021.100354.

79. There is no ethical justification for superfluous vaccination that will put children at elevated risk of harm.[39]

80. Despite this, the CDC has now published its recommended COVID-19 vaccination schedule for children ages 5 through 11 years, suggesting 3 doses of the Pfizer-BioNTech vaccine, and four doses for immunocompromised individuals. For children ages 6 months through 4 years, the CDC recommends 3 doses for all individuals. Alternatively, for children ages 6 months through 11 years, the CDC recommends 2 doses of the Moderna product for most children and 3 doses for immunocompromised children. (Exh. 10)

81. In an act of true salesmanship, the FDA has exaggerated the harms to children from COVID-19 and magnified the benefits of vaccination to allegedly exceed risks. However, when you use more realistic data, such as presented here, the risks undoubtedly exceed the benefits in the 6 months to 11-year age group and no vaccination, and certainly not *this* vaccination, should have ever been aggressively promoted.

82. For all these reasons, local and international governments have begun advising against pediatric COVID-19 shots. Florida also became the first U.S. state to recommend against healthy children receiving a COVID-19 biologic, publishing guidance on March 8, 2022 that "healthy children from ages 5 to 17 may not benefit from receiving the currently available COVID-19 vaccine."[40] Ahead of the latest EUA for infants and toddlers, Florida proclaimed that they would

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[39] Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Announcement, *FDA* (October 26, 2021), available at https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement.

[40] Florida Department of Health Issues New Guidance Regarding COVID-19 Vaccination Recommendations for Children, *Florida Health,* March 8, 2022, available at https://www.floridahealth.gov/newsroom/2022/03/20220308-FDOH-covid19-vaccination-recommendations-

not preorder any COVID-19 vaccines for young children and continued to advise against vaccination for healthy children.

83. Many countries in Europe have encouraged minimal pediatric vaccination. Denmark decided to halt the country's vaccination program following its expansion to include children between 5 and 11, even acknowledging that it was a ***mistake*** to recommend COVID-19 vaccines for all children.[41] Sweden does not offer the vaccine for children under 12 unless they have a severe risk of disease. Finland and Norway refuse to recommend vaccination for healthy kids aged 5-11.

84. These countries all acknowledge what the FDA fails to: vaccination is unnecessary for healthy, young children.

Defendants Falsely and Knowingly Misrepresented these Biologics as "Safe" and "Effective"

85. Defendants have continuously misrepresented these biologics and publicly declared them to be both "safe" and "effective" when they are neither. Many of these misrepresentations were aimed directly at children, while others fostered a public trust in these shots where none should exist.

86. On November 5, 2021, Acting Commissioner Janet Woodcock gave an interview with "Time for Kids," a magazine that provides entertainment and reading material for young children

children.pr.html#:~:text=%E2%80%94%20The%20Florida%20Department%20of%20Health,currently%20available%20COVID%2D19%20vaccine..

[41] Mistake to Recommend COVID-19 for All Children: Top Danish Health Official, *The Epoch Times*, June 23, 2022, available at https://www.theepochtimes.com/mistake-to-recommend-covid-19-vaccines-for-all-children-top-danish-health-official_4553337.html; *see also* Danish National Board of Health Admits Vaccinating Kids for Covid was a Mistake, June 23, 2022, available at https://boriquagato.substack.com/p/danish-national-board-of-health-admits (translated from https://nyheder.tv2.dk/samfund/2022-06-22-set-i-bakspejlet-fik-vi-ikke-meget-ud-af-at-vaccinere-boernene-erkender-brostroem?cid=_soco%3Atw%3A4%3Anews%3A%3A%3A).

to discuss the 5-11 EUA for Pfizer's vaccine. During her exchange with a young child, Woodcock attested that "The FDA is in charge of all medical products . . . *We make sure they're safe and that they work*." (Emphasis added).[42] She continued to promise that "We looked at the data on the pediatric vaccine. We looked at safety. We looked at the effectiveness. We had an advisory committee meeting and got expert input. And those advisers voted very, very positively that kids this age should get the vaccine." Given that the data since the administration of the Pfizer vaccine has proved otherwise, we can only conclude that FDA intentionally misrepresented this vaccine and falsely encouraged young children to take it.

87. Woodcock herself verified the responsibility the FDA bears to ensure safety: "[F]or vaccines, it's really important to do no harm, to make sure that these are very safe. Before we go down into the younger age groups, we want to test them in adults and make sure they're safe." The FDA conclusively failed to meet this burden.

88. When asked about the side effects of the vaccine, Woodcock mentioned only the possibility of a "sore arm or perhaps flu-like symptoms." However, she failed to mention the highly increased risk of myocarditis, pericarditis, blood clots, ADE, neurological damage, and several other serious side effects, including death, that have occurred from this vaccine.

89. During that same interview, Woodcock misrepresented the EUA process, stating: "Emergency use is a special [authority] we have that Congress provided, for when you have a public health emergency like we do with the pandemic. It's to get things out quickly, but with the same level of scrutiny, of carefulness, that we would [use] for a regular approval."

[42] Dr. Janet Woodcock Talks With TIME for Kids, *TIME for Kids*, November 5, 2021, available at https://www.timeforkids.com/g56/dr-janet-woodcock-interview/.

90. In a vaccine informational video published on the FDA's website, an FDA representative explicitly states "The COVID-19 vaccine for children is safe and effective. It has been thoroughly tested."[43]

91. Despite the sheer falsity of these statements, the FDA has continued to double down on the product mislabeling. When the FDA granted the EUA for the Pfizer booster shot for children 5-11, Commissioner Robert Califf promoted that "[v]accination continues to be the most effective way to prevent COVID-19 and its severe consequences, and it is safe."[44]

92. In the FDA's June 17, 2022 press release regarding the expanded EUA for children six months through four years, FDA Commissioner Robert M. Califf stated: "Those trusted with the care of children can have confidence in the safety and effectiveness of these COVID-19 vaccines...." (Exh. 2)

93. Defendants marketed Pfizer's EUA shot to children as if it were a licensed biologic, failing to follow restrictions on marketing biologics to children, or in general, without disclosing it does not fit the traditional and historic medical definition of a vaccine, without disclosing any fair balance between risks and efficacy, and without disclosing the very low risks of the disease for children.

94. FDA's misleading marketing puts Plaintiffs and their children at risk from taking the vaccine.

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[43] COVID-19 Vaccines, *U.S. Food & Drug Administration*, available at https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines; https://www.youtube.com/watch?v=k9ekkC3fhqo.

[44] Coronavirus (COVID-19) Update: FDA Expands Eligibility for Pfizer-BioNTech COVID-19 Vaccine Booster Dose to Children 5 through 11 Years, *U.S. Food & Drug Administration*, May 17, 2022, available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose.

95. Defendants knew that their representations about FDA authorizations of Pfizer and Moderna COVID-19 vaccines were false and misleading. The continuation of their promotion of these products, despite overwhelming detrimental evidence, has destroyed any future public confidence in any FDA-authorized or approved medical product. CHD members, and individual Plaintiffs, are now not able to rely on CDC and FDA representations now and in the future, and CHD must continue to divert resources to try to correct agency lies and accurately inform the public.

96. FDA's misrepresentations have led to continuous coercion, propaganda, and advertisements aimed directly at children, to which Plaintiffs' children are subjected to daily. Plaintiffs' children are bombarded with pro-vaccine messaging encouraging them to take an improperly authorized vaccine.

FDA's Lies Threaten Children Who Lack Parental Safeguards

97. The FDA's false statements of safety and efficacy have put children, including Plaintiffs' children, in direct line of harm from this vaccine. Every child who receives it is threatened with an unreasonable risk that easily outweighs the known benefit.

98. Not only do the FDA's false representations of safety and efficacy mislead parents into unnecessarily and harmfully vaccinating their children, but there are many children who are not safeguarded by parents or guardians who will receive this vaccine. Children are left to decide for themselves whether to take this highly contentious biologic, without sufficient capacity to evaluate the consequences, or to rely on caseworkers who tell them to blindly follow the CDC recommendations.

99. In Texas, children as young as five years old in the Permanent Managing Conservatorship ("PMC") of the Department of Family and Protective Service ("DFPS") who do not have a

parent or assigned advocate to make medical decisions for them, or whose parent cannot be immediately notified of vaccination plans, have been allowed to "choose for themselves" whether to receive the COVID-19 vaccine. (Exh. 11)

100. Guidance issued on May 14, 2021, following the EUA for adolescents aged 12-15, required that a child's consent be given before vaccination. However, the Texas Attorney General addressed a child's incapacity to make his or her own medical decisions in an opinion released February 18, 2022: "Children and adolescents are promised relief and asked to 'consent' to life-altering, irreversible treatment – and to do so in the midst of reported psychological distress, when they cannot weigh long-term risks the way adults do, and when they are considered by the State in most regards to be without legal capacity to consent, contract, vote, or otherwise."[45]

101. The age of majority is eighteen in Texas, Tex. Civ. Prac. & Rem. Code § 129.001, although the Texas Family Code allows circumstances under which a child in state conservatorship who is at least 16 years of age can become her own medical consenter. Tex. Fam. Code § 266.010. No such allowances exist for children under 16, and certainly not for children 6 months to 11 years, who are at risk here.

102. Updated guidance of July 23, 2021 required conservators to notify parents "whose parental rights have NOT been terminated" before vaccination. However, ample support is provided for children willing to take the vaccine, "assuming no known parental objection." In essence, if there is no parent who has legal rights over the child, or the parent has not made an *express objection* to the vaccine, then DFPS's policy is to give consent for any child willing to

[45] *M.D., b/n/f/ Sarah R. Stukenberg, et al. v. Greg Abbott*, Update to the Court Regarding COVID-19 Vaccination Status of Children in the Permanent Managing Conservatorship of DFPS, at fn. 19., Case No. 2:11-cv-00084, Document 1190.

take the vaccine, without full knowledge of the child's medical history and contraindications, including allergies to ingredients in the shots.[46]

103. And even if a parent's rights have not been terminated, the parent is not always named the medical consenter. If the parent could not be located, records indicate that other individuals have served as medical consenters for vaccination on behalf of youth in state custody.

104. DFPS has strongly promoted vaccination of young children. DFPS's policy as of January 15, 2021 made it clear that all eligible children should be strongly encouraged to be vaccinated. "Unless there is a known objection by the parent or person with legal authority over the child, the caseworker should ensure that children in DFPS conservatorship are immunized against infectious diseases, including COVID-19."[47] Furthermore, on August 20, 2021, DFPS Medical Director Dr. Roberto Rodriguez told all staff: "PLEASE' ensure the young people aged 12 and over on your caseload are vaccinated and take those steps TODAY."[48]

105. Following the EUA for children 5-11, DFPS gave caseworkers the ability to consent for children to receive the COVID-19 vaccine: "As the primary medical consenter, the caseworker may provide consent for the COVID-19 vaccine for a youth in conservatorship."[49] Parents whose rights have not been terminated must be notified of the intent to vaccinate their children, but vaccination occurs if the parents fail to timely respond. DFPS guidance tells caseworkers that leaving a voicemail for parents satisfies their "notification" requirement and that they may "proceed with vaccination of the youth if [they] have not heard any objection from a parent within 72 hours" of the voicemail.[50]

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[46] *Id.* at 8.
[47] *Id.*
[48] *Id.* at 9.
[49] *Id.* at 10.
[50] *Id.* at 11.

106. Many young children have been asked to decide for themselves whether to receive a COVID-19 vaccine. In more than 20 cases involving children under age 10, and as young as *five years old,* the child's caseworker documented a conversation during which the child was asked whether he wanted to get the vaccine.[51] Documented conversations demonstrate that the caseworkers consistently use language promoting the shot, stating that it protects the child's health and makes him safe. None of the documented conversations made any mention of potential side effects, nor is there any evidence that a caseworker ever discouraged vaccination.[52]

107. Young children, who are impressionable and cannot conduct a risk-benefit analysis remotely comparable to that of an adult, under state conservatorship have likely been inundated by pro-vaccine messaging since December 2020, including advertising aimed directly at young children through avenues such as *Time for Kids* and *Sesame Street.* One can imagine the impact that seeing Elmo or Big Bird getting vaccinated for COVID-19 would have on a five-year-old child. This messaging, promoted and facilitated by Defendants, will undoubtedly result higher rates of consent.

108. However, many children in the latest EUA cohort, ages 6 months through 4 years, are non-verbal and cannot communicate consent and therefore have no recourse against vaccination. The latest EUA, which has only made vaccines available to young babies for a matter of days, now poses a threat to all those children who are unable to decline. It is not yet clear if DFPS's vaccination policy will be different for children under 5, but under the current policies, these children **will** be vaccinated if a parent or guardian cannot does not decline within 72 hours.

[51] *Id.* at 19.
[52] *Id.*

109. There are currently 34,160 children in DFPS custody in 2022; there are 11,588 children under the age of 11 in the Western District of Texas alone. [53] There are therefore thousands of children who may be vaccinated without proper parental or guardian consent.

110. According to the Texas Department of State Health Services, Texas vaccine providers already have ordered 254,000 doses of the Pfizer and Moderna COVID-19 vaccines for young children.

111. Among the 7,012 PMC children in Texas foster care aged five years or older, the 1,503 children living with relatives or close family friends had the lowest rates of full vaccination (23%), while the children living in congregate care and in foster homes had significantly higher rates of vaccination (49% and 36%, respectively). This suggests that the children in the care of the State are more likely to succumb to the pressure to receive this vaccine and that the rate of vaccination would be much lower if these children were not under the care of conservators who are instructed by DFPS to vaccinate every eligible child. On information and belief, there are financial incentives from the State to deliver these shots to children in foster care.

Texas State Law Supports this Policy Allowing Non-Parents and Non-Guardians to Grant Medical Consent for Minors

112. The Texas Family Code allows for a wide variety of individuals to consent to immunization of a child, without the permission of the child's parent or legal guardian.[54]

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[53] CPS Conservatorship: Children in DFPS Legal Responsibility, *Texas Department of Family and Protective Services*, available at http://www.dfps.state.tx.us/About_DFPS/Data_Book/Child_Protective_Services/Conservatorship/Children_in_Conservatorship.asp.

[54] Sec. 32.101 of the Texas Family Code provides that:

(a) In addition to persons authorized to consent to immunization under Chapter 151 and Chapter 153, the following persons may consent to the immunization of a child:

(1) a guardian of the child; and (2) a person authorized under the law of another state or a court order to consent for the child.

113. Each county within the Western District of Texas has a COVID-19 vaccine consent form that must be completed for a child's receipt of a COVID-19 vaccine. However, for minors, there is no provision on the form that assures that the adult consenting for the minor is indeed the child's parent or legal guardian, or even one of the individuals authorized under Texas statutes to consent. For example, the Waco County consent form requires only the signature of a "consenting adult." (Exh. 12) There is no evidence of additional safeguards put in place in these counties to ensure that children have an advocate who is legally allowed to make those decisions.

114. As a result, children under the age of majority may be receiving EUA COVID-19 vaccines without parental or guardian consent.

115. Therefore, every unvaccinated child in Texas, including Plaintiffs' children, are at risk of being vaccinated against the wishes and consent of their parents, or even without their parents' knowledge. There are no safeguards in Texas law that prevent this from occurring.

116. The children of Plaintiffs Sacha Dietrich and Deborah L. Else face imminent danger of receiving COVID-19 vaccines at the behest of any consenting adult, including those authorized under Texas law. What recourse would Plaintiffs have if this irreversible event were to occur?

(b) If the persons listed in Subsection (a) are not available and the authority to consent is not denied under Subsection (c), consent to the immunization of a child may be given by:

(1) a grandparent of the child; (2) an adult brother or sister of the child; (3) an adult aunt or uncle of the child; (4) a stepparent of the child; (5) an educational institution in which the child is enrolled that has written authorization to consent for the child from a parent, managing conservator, guardian, or other person who under the law of another state or a court order may consent for the child; (6) another adult who has actual care, control, and possession of the child and has written authorization to consent for the child from a parent, managing conservator, guardian, or other person who, under the law of another state or a court order, may consent for the child; (7) a court having jurisdiction of a suit affecting the parent-child relationship of which the minor is the subject; (8) an adult having actual care, control, and possession of the child under an order of a juvenile court or by commitment by a juvenile court to the care of an agency of the state or county; or (9) an adult having actual care, control, and possession of the child as the child's primary caregiver."

117. The only way to protect children in these classes from receiving this improperly tested, mislabeled, misrepresented, and dangerous biologic is to revoke these authorizations that have been granted under a gross abuse of emergency power until such time as the FDA conducts proper safety and efficacy analyses and presents a clear picture of the risks to the American public.

The Attack on Unvaccinated Children

118. For those children who have not received this vaccine, FDA's authorizations for children are leading to egregious discrimination that has the potential to pose far graver health risks than COVID-19.

119. Children in Texas are being denied medical services, including transplants, without vaccination. Cook Children's Medical Center reportedly removed a teenage boy in need of a kidney transplant from the active wait list because he remained unvaccinated against COVID-19.[55] Several other hospitals around the country have similar policies. In the latest example of horror, Tennessee's prestigious Vanderbilt Hospital denied a needed heart transplant to a six-month-old infant because he had not received the COVID-19 vaccine.

120. Texas' Governor Greg Abbott's Executive Order GA 40 does not explicitly address this situation nor has there been any legislative action taken in Texas to prevent these atrocities. Furthermore, vaccine mandates are not prohibited in North Carolina.

121. This medical discrimination is due solely to FDA's authorization and its misleading and false claims that the products available to children are fully licensed and approved. This

[55] Cook Children's Denies Requiring COVID-19 Vaccine for Organ Transplant Patients, *The Texan,* January 24, 2022, available at https://thetexan.news/cook-childrens-denies-requiring-covid-19-vaccine-for-organ-transplant-patients/.

erroneous narrative has led hospitals, medical clinics, and schools to implement COVID-19 vaccination policies for young children.

122. Defendants granted this authorization for an experimental injection knowing full well that their actions are destined eventually to result in nationwide-school vaccine mandates and inclusion on childhood vaccine schedules. States have already set the precedent for compulsory immunizations to attend public and private schools from kindergarten through secondary education; a COVID-19 vaccine mandate for children following authorization is inevitable in some locations. For example, California's Governor Gavin Newsom has already made it clear that students in kindergarten through sixth grade would be phased into the state's vaccine mandate requirement, with all students K-12 required to receive the COVID-19 biologic starting in the 2023 school year. Other schools in California have implemented independent mandates that are stricter than the anticipated state-wide mandate.[56] The harm that may befall a significant number of children in the state of California will occur as a direct result of Defendant FDA's action.

123. Furthermore, young children around the country have been subjected to vaccine mandates to participate in city- or state-funded summer camps or extra-curricular activities.

124. Unless and until all children inject these experimental biologics into their developing bodies – often against the children's wishes and without informed consent – they will slowly be pushed out of society, denied an education, and worse. The precedent has already been set for

[56] As LA Schools Backtrack on COVID Vaccine, Dozens More Districts Push to Mandate It, *ABC10* (January 19, 2022), available at https://www.abc10.com/article/news/local/california/as-la-schools-backtrack-on-covid-vaccine-dozens-more-districts-push-to-mandate-it/103-729bbb6b-1a49-4dbd-8909-9f5573aaa73d.

adults, many of whom already have been denied their livelihoods due to their refusal to take a COVID-19 vaccine. All of this is unprecedented, unwise, unnecessary, and unlawful.

125. In what sane society must a child take an experimental drug that fails to protect her from a virus that has an infinitesimal chance of hospitalizing or killing her, to be able to access the same opportunities as the rest of the society?

126. The risk posed to a child from COVID-19 is not even comparable to the risk posed from not receiving a life-saving transplant or medical service, or even the denial of education or the cultural experience of living life without being asked to show one's papers. The question remains how many children will need to suffer such abuse and discrimination before the FDA will be held accountable.

127. Now, with the FDA's brand-new EUAs for infants and toddlers 6 months old and up, a whole new class of our youngest and most vulnerable children are put at risk from discriminatory treatment and prejudice if they are not vaccinated.

128. Plaintiff Deborah Else attests to recommendations by her child's school for young children to receive the Pfizer-BioNTech biologic, which is available at vaccine clinics on school grounds. Pediatricians have also sent notices to parents exhorting vaccination, despite the almost zero risk of serious symptoms or death in children who contract COVID-19. This societal push toward vaccination has culminated in an inundation of fear mongering and vaccination messaging; advertisements on television, radio shows, announcements, and signage in stores, and even the manipulation of popular children's characters such as Sesame Street's Big Bird have been employed to propagandize the public and the youth.

129. Indeed, on June 28, 2022, Sesame Workshop released a video on the Sesame Street YouTube channel announcing that Elmo had gotten the COVID-19 vaccine for the first time, sending children the message: "you'll get sick if you don't take the COVID-19 vaccine."[57]

130. Plaintiffs Chaplain Shour and Rebecca Shour have children that are especially at risk from these various mandates. As a member of the Navy, Chaplain Shour and his family are often relocated around the country without any say in their state of residence. At any time, Chaplain Shour could be stationed with his children in a state that implements these strict mandates and, as a result, his children could face discrimination and ostracization from certain activities over their vaccination status. Plaintiffs' children are therefore imminently at risk from mandates not only in their state of residence, but in any state where Plaintiffs may be stationed. Plaintiffs have already experienced ostracization and been made to feel unwelcome due to their religious objections to the COVID-19 vaccine.

131. Plaintiff Aimee Villella McBride resides with her young children in North Carolina, a state that does not prohibit vaccine mandates. As such, Plaintiff's children are at direct and imminent risk of being subjected to a mandate for an unsafe, experimental vaccine.

Pfizer's Experimental mRNA Biologic Does Not Conform to the Traditional Definition of "Vaccine"

132. These COVID-19 pharmaceutical drugs do not fall under the traditional definition of "vaccine" because of their composition.

133. Pfizer-BioNTech's and Moderna's experimental mRNA biologics are among the first of their kind, utilizing a brand-new delivery system and gene therapy technology. Unlike vaccines that have come before them, these biologics do not contain SARS-CoV-2, the virus that causes

[57] Sesame Street: Elmo Gets the COVID-19 Vaccine, *Sesame Street*, available at https://www.youtube.com/watch?v=bwimt9n2JEk.

COVID-19, but rather consist of mRNA that infiltrates the body's cells and yields the production of a spike protein that mimics the SARS-CoV-2 coronavirus.

134. The FDA has misled government leaders, health care providers, and the public by branding these COVID-19 mRNA biologics as "vaccines." This is an inaccurate statement that has led to false confidence in the safety of the experimental technology.

135. Originally, a vaccine was "a suspension of attenuated or killed microorganisms (viruses, bacteria, or rickettsiae), administered for prevention, amelioration, or treatment of infectious diseases."[58] Traditional vaccines such as inactivated, attenuated, subunit or protein-based vaccines do not penetrate human cells.

136. The CDC altered the definitions of "vaccine" and "vaccination" to broaden the scope. Prior to the change, a "vaccine" was defined as "a product that stimulates a person's immune system to produce immunity to a specific disease, thereby protecting against that disease." Under the new definition, a vaccine is "a preparation used to stimulate the body's immune response against a specific disease".[59] The original definition of "vaccination" was "the act of introducing a vaccine into the body to produce immunity to a specific disease." Compare that to the new definition, which states that vaccination is "the act of introducing a vaccine into the body to produce protection from a specific disease."[60]

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[58] Vaccine, The Free Dictionary – Medical Dictionary, available at https://medical-dictionary.thefreedictionary.com/vaccine.

[59] Why has the CDC changed the definition of a vaccine?, *Verificat*, September 29, 2021, available at https://www.verificat.cat/vaccines/entry/why-has-the-cdc-changed-the-definition-of-a-vaccine.

[60] The CDC Suddenly Changes the Definition of "Vaccine" and "Vaccination," *Citizens Journal*, September 13, 2021, https://www.citizensjournal.us/the-cdc-suddenly-changes-the-definition-of-vaccine-and-vaccination/.

137. The CDC and FDA have orchestrated a guise under which a product that confers neither immunity nor protection is called a "vaccine." However, while not a "vaccine," this biologic does fall under the FDA Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products." EUAs are particularly risky in the COVID-19 vaccine context as all available vaccines are gene therapies.

138. Moderna, in its 2020 filing to the Securities and Exchange Commission, stated: "Currently, mRNA is considered a gene therapy product by the FDA."[61] Pfizer acknowledged the same in its SEC filing.[62]

139. Gene therapies are defined as "[p]roducts that mediate their effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and that are administered as nucleic acids, viruses, or genetically engineered microorganisms. The products may be used to modify cells in vivo or transferred to cells ex vivo prior to administration to the recipient."[63] Gene therapy COVID-19 vaccines involve a modified virus or an encapsulated segment of RNA entering human cells and utilizing the host cell machinery to produce spike protein.

140. Before COVID-19 injections, gene therapy vaccines were used only in cancer patients and those with inherited metabolic disorders, whose risk profile is radically different from that of healthy children and adults. They have never been used widely in a general population.

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[61] Moderna, Inc., United States Securities and Exchange Commission, Form 10-Q, Quarterly Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934 (for the quarterly period ended June 30, 2020), ttps://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm.

[62] BioNTech SE, United States Securities and Exchange Commission, Form F-1 Registration Statement, filed Sept. 9, 2019, https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330df1.ht m.

[63] Manufacturing of Gene Therapies: Ensuring Product Safety and Quality, *FDA* (2006), available at https://www.fda.gov/media/81682/download.

141. FDA's guidance to industry on gene therapy, issued in January 2020 as COVID-19 vaccine development was commencing, stated: "FDA generally considers human gene therapy products to include all products that mediate their effects by transcription or translation of transferred genetic material or by specifically altering host (human) genetic sequences. Some examples of gene therapy products include nucleic acids (e.g., plasmids, in vitro transcribed ribonucleic acid (RNA)), genetically modified microorganisms (e.g., viruses, bacteria, fungi), engineered site-specific nucleases used for human genome editing (Ref. 2), and ex vivo genetically modified human cells. Gene therapy products meet the definition of "biological product" in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. § 262(i)) when such products are applicable to the prevention, treatment, or cure of a disease or condition of human beings."[64]

142. Because this is a novel technology being used on new populations, it is exceptionally important that the FDA apply both its specific gene therapy scientific criteria and general biologic standards in evaluating safety and efficacy, as the mechanism of gene therapy vaccines differs substantially from all other vaccines as they work on the premise of gene delivery.

143. The gene therapy standards are considerably more stringent than the criteria FDA applies to vaccines generally. Upon information and belief, the FDA did not apply these standards, including long-term safety follow-up, in the EUA approval process.

[64] Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs), U.S. FOOD & DRUG ADMINISTRATION, Guidance Document (Jan. 2020), https://www.fda.gov/regulatory-information/search-fda-guidance- documents/chemistry-manufacturing-and-control-cmc-information-human-gene-therapy- investigational-new-drug.

144. The FDA is required to perform an environmental assessment for gene therapy products.[65] Because gene therapy vaccines may shed or spread genetic material into the environment, manufacturers are required to supply data to FDA for review. There is significant empirical evidence of viral spreading. As such, vaccine negligence has already had life and death consequences to unvaccinated individuals. However, there is no indication that such data was evaluated, nor that the FDA conducted the required environmental assessment as it must according to its own guidelines.

145. The failure to examine and regulate COVID-19 vaccines as gene therapy products, particularly for young children, constitutes arbitrary and capricious action and should have prevented the FDA from issuing EUAs for the children at issue here.

Approving Drugs and Biologics: Citizen Participation

146. After witnessing the clear dangers and ineffectiveness that the COVID-19 mRNA biologics presented to individuals 16 and older, CHD filed a Citizen Petition with the FDA (Exh. 13) on May 16, 2021, asking the FDA to refrain from licensing COVID-19 vaccines and to revoke EUAs for the three existing COVID-19 vaccines (Pfizer-BioNTech, Johnson & Johnson, and Moderna). Individuals submitted over 30,000 comments on this petition.

147. FDA's actions and inactions regarding COVID-19 were and continue to be germane to Children Health Defense's organizational purpose.

148. Despite a dismissive and unsatisfactory response on August 23, 2021 (Exh. 14), the same day the agency approved the Pfizer "Comirnaty" biologic, the FDA has done nothing to assuage the public concerns outlined in the Citizen Petition. Rather, the FDA has forged ahead on its path

[65] Determining the Need for and Content of Environmental Assessments for Gene Therapies, Vectored Vaccines, and Related Recombinant Viral or Microbial Products: Guidance for Industry, *FDA* (March 2015), available at https://www.fda.gov/media/91425/download.

to inject this experimental drug into every American's arm, including those of the most vulnerable. The FDA also approved Pfizer's Comirnaty vaccine for individuals 16 and up on the same day. (Exh. 15) In doing so, the FDA has directly targeted CHD by acting in direct contradiction to its well-reasoned inquiries and concerns. CHD was prepared to engage in an active citizen participation process to address the deficiencies in FDA's decision-making; the FDA acted in direct conflict with CHD's mission.

149. Nothing destroys public confidence in vaccines more than rushing their authorization and approval without addressing public concerns and without the regulatory agencies explaining the standards, if any, used for authorization, approval, and licensure.

150. The FDA Citizen Petition process is meant to prevent this overreach from happening. Citizen participation, through a Citizen Petition, confers some democratic participation in the drug or biologic authorization and approval process, provides for the kind of free discussion and public engagement that imposes the scientific method on the process, and engenders public confidence in the vaccine itself. If you cannot trust the process, you cannot trust the result.

151. A study in May 2021 showed that roughly half the U.S. population did not trust the FDA, CDC, or other major public health organization; this percentage is guaranteed to be higher now, as the FDA has continued expanding eligible pediatric cohorts and authorizing boosters with little to no clinical trial data.[66] Indeed, under 30% of eligible children aged 5-11 have received COVID-19 shots, exemplifying parents justified lack of confidence. If more than half of the population is unprepared to trust the FDA's results and recommendations, the relevance of the Citizen Petition process cannot be understated.

[66] Why America Doesn't Trust the CDC, *Newsweek,* June 10, 2022, available at https://www.newsweek.com/why-america-doesnt-trust-cdc-opinion-1713145

152. CHD has continued to implore the FDA to halt their reckless. In anticipation of the EUA for children ages 6 months through 5 years, CHD again sent a letter to the FDA on June 10, 2022 thoroughly outlining why the EUA would be illicit agency action, with ample scientific evidence in support.[67] Defendants have been well-informed of the dangers of their actions *by CHD alone* that are sufficient to warrant a half of their activity. Yet the FDA did not pause, delay, or even reply in response to CHD's letter.

153. Defendant has continuously denied Plaintiffs their procedural right to participate in the notice and comment process and a satisfactory answer to their concerns in the Citizen Petition.

Children's Health Defense Has Experienced Injury Due to FDA's Overreach of Authority

154. CHD has been injured by FDA's actions beyond the expenditure of resources necessary to bring this litigation.

155. CHD has devoted resources over the past 18 months to investigating the FDA's actions, including its involvement in safety and efficacy studies, clinical trial oversight, interpretation of data, misrepresentation of data, rationale for authorization and approval of COVID-19 related biologics, and public statements and advertising of such biologics. It was through this oversight and investigation that CHD first identified flaws and shortcomings in the EUA reasoning and the FDA's abuse of emergency powers.

156. Independent of this suit, CHD has worked through its newsletters, online video news platforms, and live commentary to educate the public with real information necessary to satisfy *informed* consent.

[67] CHD Letter to FDA, June 10, 2022, available at https://childrenshealthdefense.org/wp-content/uploads/CHD-Letter-to-FDA-VRBPAC_2022-06-10.pdf.

157. CHD has worked with its members to address coercion and pressure to vaccinate, as well as discrimination that members and their children face.

158. CHD has members whose children fall within the age cohorts that are now authorized by the FDA to receive the Moderna and Pfizer-BioNTech vaccines.

159. Drafted in response to the FDA's initial EUA of Pfizer's COVID-19 vaccine for individuals 16 and up, CHD's Citizen Petition assembled and memorialized a tremendous amount of detailed factual findings and research on Pfizer's vaccine regarding the risks to public health and safety, effectiveness of the vaccine (or rather lack thereof), the FDA's misbranding of vaccine authorizations, and the serious consequences and injury to CHD members and their children that FDA's actions spawned. CHD's Citizen Petition was the result of countless hours of work and effort by CHD personnel, including but not limited to Meryl Nass, M.D. (Scientific Advisory Board member) and Robert F. Kennedy, Jr. (Board Chair and Chief Litigation Counsel), requesting that the FDA revoke the EUAs for existing COVID-19 vaccines and refrain from further authorizations and licensure.

160. FDA's further EUAs and approvals of COVID-19 biologics took aim directly at CHD and were done with disregard to CHD's reasonable and legitimate concerns.

161. FDA's illicit activities frustrate CHD's organizational goal to "eliminate harmful exposures, hold those responsible accountable, and to establish safeguards to prevent future harm" to children.[68]

162. CHD, an organization that has tasked itself with protecting and promoting the health and wellbeing of children, has expended considerable resources beyond this lawsuit to combat the FDA's lies and abuses. FDA's actions have directly targeted CHD by not only failing to address,

[68] Children's Health Defense Mission Statement, available at https://childrenshealthdefense.org.

but acting with complete disregard for, the legitimate concerns CHD expressed in its citizen petition and taking the very actions against which CHD warned. In doing so, CHD was denied its right to petition, the chance at notice-and-comment, and its procedural remedies under the Administrative Procedures Act, to which it was legally entitled. Additionally, CHD diverted resources to combat the effect of Defendants' actions by expending resources originally budgeted toward other items to counteract Defendants' deliberate choice to ignore CHD's citizen petition concerning the authorization and marketing of COVID-19 shots to children as young as 6 months old. This follows a pattern of Defendants targeting CHD for adverse actions, by demanding major social media platforms prevent it from reaching the public and preclude it from raising funds for its organizational efforts, because CHD is a principal adversary in these matters. But for Defendants' actions, CHD would have substantially more funds than it does today and better access to educate in the court of public opinion.

The Clinical Trials Used to Justify the FDA's Pfizer and Moderna EUAs Were Inadequate

163. In truth, we know nothing about the long-term risks of administering an mRNA COVID-19 biologic to children from Pfizer and Moderna's clinical trials.

164. COVID-19 vaccines have not gone through testing for genotoxicity, mutagenicity, teratogenicity, and oncogenicity by the FDA's own admission. In plain English, no one can be assured that these products don't cause genetic damage, birth defects, infertility, or cancer; the so-called experts just don't know. This alone should deprive these products of EUA status, especially for children who should have the greatest number of years ahead of them.

165. FDA's press release (Exh. 1) announcing authorization of Pfizer-BioNTech for 5- through 11-year-olds noted that the authorization was based on a trial that included,

"approximately 3,100 children aged 5 through 11 who received the vaccine," and concluded that "no serious side effects have been detected in the ongoing study."[69]

166. The Pfizer biologic was tested on human subjects for less than five months of data collection in Phase II and III clinical trials before being administered to the public under an EUA.[70]

167. Furthermore, the clinical trials performed to test safety and efficacy of the Pfizer COVID-19 vaccine, and the Moderna vaccine, were woefully inadequate and rife with fraudulent error that nullify the reliability of the results. (Exh. 9)

168. Since the Defendant agency's first issuance of an EUA for Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older on December 11, 2020, the FDA has continued to issue EUAs to Pfizer even though its Phase III clinical trials remain, at the time of this filing, incomplete. Pfizer's clinical trial Estimated Primary Completion Date is November 2, 2022, and the Estimated Study Completion Date is May 2, 2023.

169. Furthermore, the FDA did not conduct any clinical trials that properly tested the altered Pfizer formula administered to children. As was stated during the VRBPAC October 26, 2021 meeting, the stabilizer used in the biologic during the trials is different from what was authorized. While manufacturers have claimed that safety studies continue and that they are still following subjects for long-term safety, the absence of any control group makes that claim risible.

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[69] FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age, available at https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age.

[70] About Our Landmark Trial, Pfizer, available at https://www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial. 41 Package Insert – Comirnaty, FDA (8/2021), available at https://www.fda.gov/media/151707/download.

170. This hauntingly echoes the FDA's confirmation in its August 23, 2021 EUA reissuance that vaccine safety and efficacy for the 12-year-old through 15-year-old age group had not been established, acknowledging "unknown benefits and data gaps" in "duration of protection," "effectiveness in certain populations at high risk of severe COVID-19," "effectiveness in individuals previously infected with SARS-CoV-2," "vaccine effectiveness against asymptomatic infection," "vaccine effectiveness against mortality," and "vaccine effects against transmission."[71] Virtually nothing is actually known about the benefits of the Pfizer biologic in the 12- through 15-year-old age group.

171. The pediatric clinical trials are too small to quantify the risk from myocarditis and most other adverse events. Indeed, in the approval for Pfizer's Comirnaty vaccine, the FDA ordered further studies into myocarditis and pericarditis (Exh. 15).[72] As FDA acknowledged when discussing its post-marketing requirements for its Comirnaty vaccine, "[w]e have determined that an analysis of spontaneous post-marketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis. Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks."[73] Pfizer is not required to submit its final reports on myocarditis until 2024 and 2025. It is unacceptable to ponder the inevitability that tens

[71] Letter of Authorization (Reissued), *U.S. Food & Drug Administration*, August 23, 2021. 13 Emergency Use Authorization (EUA) Amendment for an Unapproved Product Review Memorandum, U.S. Food & Drug Administration, available at https://www.fda.gov/media/148542/download.
[72] BLA Approval, U.S. Food and Drug Administration (August 23, 2021), available at https://www.fda.gov/media/151710/download.
[73] *Id.*

or hundreds of millions of the world's children will be vaccinated before BioNTech-Pfizer tells us to what extent their vaccines damage children's hearts.

172. Furthermore, Pfizer willfully ignored health clinical trial concerns and failed to investigate before granting authorization. A Pfizer clinical trial found that the mRNA dosage of the Pfizer vaccine has caused severe fevers in younger children.[74] Children ages 2-5 who received 10 micrograms of mRNA experience fevers that were both more common and more severe than those in other age cohorts.[75] As a result, Pfizer opted to lower the dosage in future tests from 10 micrograms to 3 micrograms for children aged 2-5.[76] However, the same 10-microgram dosage is administered to and authorized for children ages 5-12, with no adjustment for weight. 5-year-olds receive the same dosage that causes severe fevers in children ages 3-4, although many 4 and 5-year-olds are similar in size and robustness.

173. In perhaps the most egregious example of clinical trials in history, Pfizer's clinical trials for babies and young children were shocking. Out of 4526 children aged 6 months to 4 years old, two-thirds of them did not make it to the end of the trial.[77] Pfizer provides no explanation for this drastic drop-off. What the trial data did show is that it is likely that the vaccine is indeed causing COVID-19; children who were vaccinated had a 30% increased chance of catching COVID-19 between the first and second dose. Furthermore, Pfizer was defining "severe COVID" as a child

[74] Analyst and Investor Call to Discuss the First COVID-19 Comprehensive Approach: Pfizer-BioNTech Vaccine and Pfizer's Novel Oral Antiviral Treatment Candidate, Pfizer, December 17, 2021, available at Presentation Title (q4cdn.com).
[75] *Id.*
[76] Pfizer and BioNTech Provide Update on Ongoing Studies of COVID-19 Vaccine, Pfizer (December 17, 2021), available at https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19.
[77] Dr. Clare Craig exposes the twisted Pfizer COVID trial for babies and young children, June 21, 2022, available at https://drjessesantiano.com/dr-clare-craig-exposes-the-twisted-pfizer-covid-trial-for-babies-and-young-children/

with an increased heart rate and breathing. Under that definition, Pfizer could claim that a higher number of trial participants survived "severe COVID," and therefore manipulate a higher ultimate effectiveness. Pfizer manipulated, ignored, and hid data in their clinical trials, making them completely inadequate as a basis for the latest EUA.

174. These are not the first allegations of manipulated and fraudulent data; Pfizer's original trials were fraudulent and riddled with error. On November 2, 2021, the British Medical Journal published alarming information brought forward by whistleblower Brook Jackson, a regional director at the Ventavia Research Group, regarding Pfizer's Phase III clinical trial for the COVID-19 vaccine.[78] Ventavia Research Group is a privately owned clinical research company in Texas responsible for completing a portion of the clinical research upon which Pfizer, the FDA, and the public based their faith on the safety and efficacy of COVID-19 vaccines. Jackson conveyed that "the company falsified data, unblinded patients, employed inadequately trained vaccinators, and was slow to follow up on adverse events reported in Pfizer's pivotal phase II trial." Jackson expressed her concerns regarding "poor laboratory management, patient safety concerns, and data integrity issues" to her supervisors at Ventavia, to no avail. Documentation gathered by Jackson demonstrates that these problems have been continuously occurring since shortly after the clinical trial began. When Jackson was unsuccessful in submitting her concerns to Ventavia, Jackson communicated her observations to the FDA.

175. The email sent to the FDA documents a number of concerning practices Jackson witnessed: "participants placed in a hallway after injection and not being monitored by clinical staff;" "lack of timely follow-up of patients who experienced adverse events;" "protocol

[78] Thacker P D. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial BMJ 2021; 375 :n2635 doi:10.1136/bmj.n2635

deviations not being reported;" "vaccines not being stored at proper temperatures;" "mislabeled laboratory specimens;" and "targeting of Ventavia staff for reporting these types of problems."[79] Although the FDA responded to her email, the agency failed to follow up or inspect Ventavia after she filed the complaint.

176. A former Ventavia employee expressed that the FDA "rarely does anything other than inspect paperwork, usually months after a trial has ended."[80] Indeed, a 2007 Department of Health and Human Services report found that "the FDA inspected only 1% of clinical trial sites" and "inspections carried out by the FDA's vaccines and biologics branch have been decreasing in recent years, with just 50 conducted in the 2020 fiscal year."[81]

177. In the FDA advisory committee meeting held on December 10, 2020, to discuss Pfizer's first application for EUA for its COVID-19 vaccine, Pfizer failed to mention any problems at the Ventavia site. Indeed, the FDA admits in its published summary of inspections of Pfizer's clinical trials that only nine of the trial's 153 sites were inspected; Ventavia was not one of them.[82]

178. The data used to support the Moderna EUAs was no better. The June 17, 2022 authorization of pediatric vaccines for Moderna's biologic was based on data from two *ongoing* studies. The first was a Phase 2/3 trial on 3,726 participants aged 12 through 17 years. The second study is a Phase 2/3 trial involving 6,388 participants ages 6 months through 5 years and 4,002 participants aged 6 years through 11 years. The truth is that the FDA is gambling with

[79] *Ibid.*
[80] *Ibid.*
[81] *Ibid.*
[82] *Ibid.*

children's lives using small, unfinished clinical trials whose long-term results have yet to be determined.

179. The Moderna COVID-19 vaccine also severely lacks clinical trial evidence that it benefits children. In the FDA's BLA approval letter for Moderna's Spikevax for individuals 18 and older, the FDA stated: "We are deferring submission of your pediatric studies because the product is ready for approval for use in adults and *the pediatric studies have not been completed*."[83] (emphasis added) Required studies included trials evaluating the safety and effectiveness in children 12-17 years of age, safety and effectiveness in children 6 months through 11 years of age, and safety and effectiveness in infants younger than 6 months of age. Final data from these studies will not be available until 2024. Other studies evaluated the short- and long-term risk of myocarditis and pericarditis in children and adults. Therefore, at the time of FDA's approval of Spikevax on January 31, 2022, the FDA knew that there were substantial deficiencies in their understanding of Moderna's COVID-19 vaccine risks in young children.

180. FDA should have held off its expansion of the Pfizer and Moderna shots to children until it had completed review on all pediatric COVID-19 vaccines that are known to cause myocarditis. The bottom line is that we have no idea of either the short or long-term risk of the Pfizer and Moderna vaccines in 6 months to 11-year-old children, but it is reasonable to assume the risk of myocarditis is considerable. Other risks have not been quantified but could also be substantial. We do not even know their magnitude in adults, after 6.8 billion COVID-19 vaccinations have been administered throughout the world.[84] It cannot be justified to vaccinate

[83] BLA Approval, *U.S. Food & Drug Administration*, January 31, 2022, available at https://www.fda.gov/media/155815/download.

[84] More than 8.22 Billion Shots Given:Covid-19 Tracker, Bloomberg (December 6, 2021), available at https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/. 50

children with a biologic for which the world's public health professionals have failed to collect and analyze the most rudimentary data on safety during the largest rollout of mostly experimental pharmaceutical products in the history of the world.

Effectiveness of Alternative Treatments

181. Early treatment against COVID-19 is highly effective, but for the FDA to acknowledge this would prevent EUAs from being issued for COVID-19 vaccines.

182. There are well-studied, safe, approved and readily available medical products to prevent and treat COVID-19. Given all the known and unknown risks of existing COVID-19 vaccines, these alternatives are preferable to vaccination, yet the FDA has failed to rigorously evaluate nor recognize them.

183. These alternatives include Ivermectin, Methylprednisolone, Fluvoxamine, Hydroxychloroquine, Vitamin C, Vitamin D3, Zinc, Aspirin, corticosteroids and other accessible therapies. Randomized-controlled trials and observations by front line medical experts have confirmed that COVID-19 is preventable and treatable, especially at early onset stages, with medicines and practices that have been in use for decades, proving their safety.[85]

184. Various treatment methods using combinations of such medications have proven effective. There has been substantial and significant progress on early, ambulatory multi-drug

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Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry, available at https://www.fda.gov/media/139638/download.

[85] McCullough PA, Kelly RJ, Ruocco G, et al. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. *Am J Med*. 2021;134(1):16-22. doi:10.1016/j.amjmed.2020.07.003; McCullough PA, Alexander PE, Armstrong R, et al., Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). *Rev Cardiovasc Med*. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997.

therapy for high-risk COVID-19 patients, resulting in as much as 85% reductions in both hospitalizations and death.[86]

185. Both Ivermectin and Hydroxychloroquine can be taken in a weekly dose to prevent infection from SARS-CoV-2 with great effectiveness.[87]

186. Ivermectin, whose safety has been established with at least a billion doses administered and which is listed on the WHO's list of essential drugs, along with the chloroquine drugs, has been shown to have substantial prophylactic and treatment capabilities.[88]

187. In Africa, Ivermectin is given once or twice yearly to prevent river blindness, and chloroquine or Hydroxychloroquine is taken once weekly to prevent malaria. Thus, they function like vaccines when used in advance of exposure. Rates of COVID-19 cases and deaths in Africa have been only a small fraction of what they are in the US.[89]

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[86] McCullough PA, Alexander PE, Armstrong R, et al., Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). *Rev Cardiovasc Med* (2020) 21:517–530. doi10.31083/j.rcm.2020.04.264.

[87] McCullough PA, Kelly RJ, Ruocco G, et al., Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. *Am J Med*. 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805; McCullough PA, Alexander PE, Armstrong R, et al., Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). *Rev Cardiovasc Med*. 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997.

[88] Kory, Pierre MD, Meduri, Gianfranco Umberto MD; Varon, Joseph MD; Iglesias, Jose DO; Marik, Paul E. MD, Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19, *AMERICAN JOURNAL OF THERAPEUTICS*, May/June 2021 - Volume 28 - Issue 3 - p e299-e318, https://journals.lww.com/americantherapeutics/Fulltext/2021/06000/Review_of_the_Emerging_Evidence_Demonstrating_the.4.aspx.

[89] Guerrero R, Bravo LE, Muñoz E, Ardila EKG, Guerrero E. COVID-19: The Ivermectin African Enigma. *Colomb Med* (Cali). 2020 Dec 30;51(4):e2014613. doi: 10.25100/cm.v51i4.4613; Hisaya Tanioka, Sayaka Tanioka, Kimitaka Kaga, Why COVID-19 is not so spread in Africa: How does Ivermectin affect it?, Europe PMC 2021 Mar 26. doi: https://doi.org/10.1101/2021.03.26.21254377.

188. Many countries and regions have been administering over the counter Ivermectin for COVID-19 with excellent reported treatment success.

189. The probable efficacy of chloroquine drugs for coronaviruses was demonstrated in experiments published by the CDC in 2005 and by Dr. Fauci's National Institute of Allergy and Infectious Diseases (NIAID) in 2014.[90] This prior knowledge, obtained by CDC and NIH regarding these drugs' efficacy and safety at standard doses, while agency officials suppressed their use during the pandemic, is clear evidence of willful misconduct and should nullify liability protection for these officials.

190. In addition, these two inexpensive, readily available drugs are effective regardless of viral variant or strain, and their effects, used weekly, do not wear off after a few months as does vaccine protection, requiring additional booster shots with possible side effects.

191. Yet, the FDA has exhibited bias regarding the effective and safe use of such alternatives, denying their effectiveness and failing to consider them as a viable, and potentially preferential, method to alleviate severe disease and death, nullifying the need for any vaccination scheme. Not only that, but they have also encouraged the vilification of such resources.

192. Many medical professionals suspect FDA's feigned ignorance about ivermectin was a prerequisite to issuing EUAs for COVID-19 vaccines, given the EUA requirement that no approved drug be available for the same indication.

193. If children and adults were treated early with proven drug combinations, very few would progress to the inflammatory and thrombotic stages of COVID-19. While this statement may appear controversial, forest plots of the compiled literature on hydroxychloroquine and

[90] Martin J Vincent, Eric Bergeron, et al., Chloroquine is a potent inhibitor of SARS coronavirus infection and spread, *BMC Virology Journal* (August 22, 2005), available at https://doi.org/10.1186/1743-422X-2-69.

ivermectin for COVID-19 are very compelling, with average efficacy against the different endpoints of 64% to over 80%.

194. There are safer drugs that could be used prophylactically and therapeutically for COVID-19 in children. There is extensive and compelling medical evidence for this assertion; FDA's decision to eschew use of these drugs in favor of a demonstrably dangerous vaccine qualifies as arbitrary and capricious.

195. The law on "authorization for medical products for use in emergencies" requires that the EUA designation be used only when "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." 21 U.S.C. § 360bbb-3(3) (emphasis added).

196. Recognizing and approving hydroxychloroquine, ivermectin, and other successful alternative treatments would have prevented COVID-19 biologics from receiving any emergency use authorization. As such, the FDA's revocation of the EUA for chloroquine phosphate and hydroxychloroquine for use on COVID-19 patients was a de facto attempt to stop doctors from prescribing and treating patients with them, to ensure that the path was clear to grant EUAs for these so-called patented, obscenely lucrative vaccines.[91]

The FDA Abets the Big Pharma Monopoly

197. Pfizer was projected to earn $50 billion dollars in 2021 in COVID-19 vaccine and drug sales, and more than that this year; indeed, Pfizer expects to make almost as much from COVID-

[91] Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine, *U.S. Food & Drug Administration*, available at https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and.

19 vaccines alone as it did for all products in 2020.[92] It is naive to think Pfizer-BioNTech will try to identify the actual rate of myocarditis in children when so much money is at stake. Pfizer is the world's largest drug company. Pfizer has also paid more in fines and settlements to federal and state governments than any other pharmaceutical company. In 2009, Pfizer was ordered to pay a criminal fine of $1.195 **billion** as part of one of the biggest fraud settlements in the US for misbranding a pharmaceutical product with the intent to defraud or mislead; this is the largest criminal fine ordered in the United States ever.[93]

198. Pfizer contracted with the US government, which has possession of all COVID-19 vaccines across the country. An October 19, 2021, Public Citizen report titled Pfizer's Power, discussing Pfizer and its COVID-19 vaccine contracts, notes:

> ". . . neither Pfizer nor the U.S. government can make 'any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Pfizer and the Government hereunder, without the prior written consent of the other.' The contract contains some exceptions for disclosures required by law."

199. Moderna, too, was awarded a multi-billion-dollar contract by the U.S. Department of Defense to produce 200 million doses of its COVID-19 vaccine in June 2021.[94]

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[92] Jake Epstein, Pfizer Expects to Make Nearly as Much Revenue Just From COVID-19 Vaccines in 2021 as it Earned in All of 2020, *Business Insider* (Nov. 2, 2021), available at https://www.businessinsider.com/pfizer-2021-vaccine-revenue-close-to-2020-total-earnings-2021-11.

[93] Justice Department Announces Largest Health Care Fraud Settlement in its History, *US Department of Justice* (September 2, 2009), available at https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history.

[94] Moderna Gets Contract to Produce 200M COVID-19 Vaccines for DOD, *Fox10,* June 21, 2021, available at https://www.fox10phoenix.com/news/moderna-gets-contract-to-produce-200m-covid-19-vaccines-for-dod.

200. Pfizer and Moderna expect a combined $51 billion in vaccine sales alone in 2022, with Pfizer expecting to receive $32 billion and Moderna expecting to receive at least $19 billion.[95]

201. Furthermore, one of the FDA's briefers who failed to find adverse event signals in the Vaccine Safety Datalink (VSD) was Nicola Klein, who is the Principal Investigator (PI) in multiple COVID-19 vaccine studies for Pfizer conducted in both adults and children. Those Pfizer clinical trials have brought many millions of dollars to her institution. Her conflict of interest was undisclosed.[96]

202. In furtherance of a clandestine deal, at to the benefit of monopolistic pharmaceutical companies, FDA has rushed the shots into young children. The FDA's proclivity to curry favor with pharmaceutical companies under the thinly veiled guise of protecting children is obvious.

FDA is Continuing the Inglorious History of Medical Experimentation

203. Born amidst malaria and smallpox pandemics, the Constitution authorized no emergency exception to the liberties secured under it. The Founding Fathers understood the virus of concentrated power posed more of a threat than any biological virus ever could.

204. The Ninth Amendment to the Constitution safeguarded all ancient rights and liberties, including the ancient tort of battery. United States Constitution, *Amendment IX*. The right against battery assured "the right of every individual to the possession and control of his own person, free from all restraint or interference of others," which would be "sacred" and protected under the law. *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). The famed Justice

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[95] What's Next for Pfizer, Moderna Beyond Their Projected $51 Billion in Combined Covid Vaccine Sales This Year, *CNBC*, March 3, 2022, available at https://www.cnbc.com/2022/03/03/covid-pfizer-moderna-project-51-billion-in-combined-vaccine-sales-this-year.html.

[96] Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. *JAMA*. 2021;326(14):1390–1399. doi:10.1001/jama.2021.15072.

Benjamin N. Cardozo defined the doctrine as the universal right of every person "to determine what shall be done with his own body." S*chloendorff v. Society of New York Hospital*, 105 N.E. 92, 93 (1914).

205. This right to informed consent incorporates necessarily the right to refuse treatment: "The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." *Washington v. Harper*, 494 U.S. 210, 229 (1990). The Nuremberg Code enshrines the right of informed consent as a matter of universal law, so widely recognized, that courts consider it a *jus cogens* legal principle enforceable everywhere. *Abdullah v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009). Based on these precepts, courts require clear and convincing evidence that a person poses an imminent, severe risk to others before those individuals may be subject to any forced medical care. *O'Conner v. Donaldson*, 422 U.S. 563 (1975); *Addington v. Texas*, 441 U.S. 418 (1978).

206. We only deviated from this Informed Consent standard of medical care during the Eugenics Era, a diseased doctrine birthed in the medical academies of the United States at the turn of the last century, as a deformed outgrowth of the then in-vogue school of Social Darwinism. A trio of decisions carved out emergency exceptions to Constitutional liberties, including authorizing a criminal fine for not taking a vaccine (*Jacobson v. Massachusetts*, 197 U.S. 11 (1905)), forced sterilization of poor and politically unprotected populations (*Buck v. Bell*, 274 U.S. 200 (1927)), which relied exclusively on expanding *Jacobson*, and the decisions culminated in the kind of "emergency exception" logic that led the Supreme Court to authorize forced detention camps based on race alone. *Korematsu v. United States*, 323 U.S. 214 (1944). This trilogy of infamy sees its corpses rise again as "precedents," seemingly permitting governments to reinstate Eugenics-Era logic across the legal landscape.

207. Reeling from the moral horror of the Nazi regime, and its enthusiastic embrace of eugenics, American jurists led the way in reestablishing the Constitutional order by invalidating eugenics-era precedents and by instituting the Nuremberg Code of 1947, whose governing principles of Informed Consent for all medical matters form a *jus cogens* principle of universal, internationally recognized law, enforceable amongst all civilized nations. The right to bodily autonomy has guided the standards governing all matters of medical care concerning the state. Only clear and convincing evidence of an imminent danger to others justifies any forced medical care. *Washington v. Harper*, 494 U.S. 210, 229 (1990); *Addington v. Texas*, 441 U.S. 418 (1978). Only business necessity warrants a place of public accommodation or an employer to discriminate against someone based on her perceived medical status. 42 U.S.C. § 12101. The Nuremberg Code-derived governance of medical authority in the U.S. and elsewhere reversed the eugenics-era precedents, empowered individuals with a meaningful participatory role in their own medical care, and empowered democratic oversight, judicial supervision, and procedural safeguards on the medical regulatory process. It enshrined informed consent as the ethical foundation of modern medicine and a fundamental human liberty so universal that courts acknowledge it as a peremptory norm.

208. Concern over uninformed, nonconsensual, and pharmacological failures haunts the history of rushed drugs, biologics and negligent courts. From Tuskegee to the military, from the foster homes of young women to Indian health care services on reservations, from facilities for the mentally ill to jails for women, the least powerful and most trusting have been horrendously victimized by government medical experimentation, without recourse or remedy. Deceptive denial of syphilis treatment, forced sterilizations, testing of radioactive ingredients on unwitting patients, psychological experimentation on unsuspecting students (such as the MK-Ultra type

testing on Ted Kaczynski at Harvard), the LSD testing on government employees, the chemical testing over San Francisco or in New York City subways, the mustard gas secret tests on drafted soldiers – history has taught us that government must be reined in lest it treat its citizenry as rats in a cage or guinea pigs for experimentation.

209. In 1955, regulators rushed approval of a polio vaccine that caused an outbreak of polio in hundreds of children, known as the Cutter Incident. Later scholars attributed the blame to the federal government's failures in rushing the product to market. In 1959, the Belgian Congo rushed the development of another polio vaccine. Twenty-five years later, a new virus emerged in the population: Acquired Immune Deficiency Syndrome or AIDS. Detailed journalistic investigations have attributed it to the use of contaminated monkey kidneys in the development of polio vaccines.[97] In 1963, Americans discovered that the polio vaccine from monkey kidneys contained the Simian Virus 40 that could cause cancer in humans.[98] In 1976, the Ford Administration rushed a vaccine for swine flu. The virus proved less deadly than anticipated, but the vaccine proved far more dangerous, causing thousands of Americans to develop a serious neurological disorder known as Guillain-Barre Syndrome, causing paralysis. As the "60 Minutes" report from the time identified, the FDA was again the source of failure because of the rushed, pressured political environment of the time.[99]

[97] Edward Hooper, *The River: A Journey to the Source of HIV and AIDS* (1999).
[98] Debbie Bookchin and Jim Schumacher, *The Virus and the Vaccine* (July 1, 2005). 72 60 Minutes: Swine Flu (1976), available at https://www.youtube.com/watch?v=4bOHYZhL0WQ.
[99] The Swine Flu Fraud of 1976, https://www.youtube.com/watch?v=ae1TJi5zw84.

210. Most recently, in 2018, the World Health Organization rushed approval of a vaccine against Dengue Fever, despite warnings from dissident doctors, which left hundreds of children dead and thousands more injured.[100]

211. These examples pale in comparison to the mass experimentation that the FDA is currently facilitating on infants, toddlers, and young children globally with an experimental mRNA vaccine.

CAUSE OF ACTION I:
VIOLATION OF THE ADMINISTRATIVE PROCEDURES ACT

212. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

213. The Administrative Procedures Act (APA) requires "[e]ach agency [to] give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e).

214. The APA does not set fixed timelines for agency action and, instead, requires agency action within a "reasonable" time by providing judicial review to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(2). A "reasonable time for agency action is typically counted in weeks or months, not years," *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) and an agency action's exigent context may demand expedited review. *Fund for Animals v. Norton*, 294 F.Supp.2d 92, 114 (D.D.C. 2003) ("pressing human health concerns…demand prompt review").

215. Congress requires that courts "shall hold unlawful and set aside" any agency "action," "finding," or "conclusion" whenever the agency failed to follow the necessary process for reasoned decision-making. 5 U.S.C. § 706(2)(A). The traditional judicial protocol is to vacate the

[100] Michaeleen Doucleff, Rush to Produce, Sell Vaccine Put Kids In Philippines At Risk, *NPR* (May 3, 2019), available at https://www.npr.org/sections/goatsandsoda/2019/05/03/719037789/botched-vaccine-launch-has-deadly-repercussions

agency action and remand the matter to the agency for compliance with the requisite process before taking any further action.

216. The Administrative Procedures Act protects the public from arbitrary and capricious executive branch action by imposing the rule of reason and the rule of law through judicial oversight. An agency is "required to engage in reasoned decision making." *Michigan v. EPA*, 576 U.S. 743, 750 (2015). This requires that the agency "examine the relevant data." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983). This also requires that the agency "articulate a satisfactory explanation for its action." *Id.* An agency action is considered "arbitrary and capricious" if it fails to comply with the rules of reason articulated in *Motor Vehicle.*

The FDA Abused Its Power Under the Emergency Use Authorization Statute

217. The emergency use authorization statute requires that an actual emergency exist. This is an essential prerequisite to a legislative loophole that removes barriers to authorization that are in place to ensure safety and effectiveness.

218. To support an EUA declaration, certain circumstances must exist to justify it. § 564(b)(1). As the FDA admits, "a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020, does not enable FDA to issue EUAs."[101]

219. The FDA here has failed to justify its conclusion that children ages 6 months through 11 years face an emergency that warrants subjecting them to life-threatening short-term adverse effects and untold long-term adverse effects.

[101] Emergency Use Authorization, *U.S. Food & Drug Administration* (December 3, 2021), available at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

220. Young children are the most protected from SARS-CoV-2. Children that do contract COVID-19 typically do not become as sick as adults, with most children having mild or no symptoms.[102] Those few that have experienced severe symptoms or death from COVID-19 have almost exclusively had comorbidities or other underlying health conditions.[103] The survival rate of children who have tested positive for COVID-19 is exceptionally high.

221. Even assuming that children are at risk from SARS-CoV-2, given that the Pfizer-BioNTech and Moderna COVID-19 biologics have only been marginally effective at reducing severe symptoms hospitalization, or death, it is medically contraindicated for children to receive this biologic.

222. Meanwhile, the adverse effects from the COVID-19 vaccines in children can be serious and deadly. The FDA has failed to properly address these risks and is still analyzing them through clinical trials that are not scheduled to be completed until these biologics have been marketed to young children for several years.

223. As the risk of COVID-19 to babies, toddlers, and children ages 6 months through 11 years cannot be categorized as an emergency, the FDA is not at liberty to utilize the emergency use authorization statute to carry out its agenda to vaccinate every American against COVID, no matter the cost.

224. The FDA further denied CHD its procedural right to seek redress via citizen petition, a right conforming to the right to petition under the First Amendment.

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[102] COVID-19 (coronavirus) in babies and children, *Mayo Clinic*, available at https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-in-babies-and-children/art-20484405.

[103] Clare Smith, David Odd, Rachel Harwood, et al., Deaths in Children and Young People in England following SARS-CoV-2 infection during the first pandemic year: a national study using linked child death reporting data, *Research Square* (July 7, 2021), DOI: 10.21203/rs.3.rs-689684/v1, available at https://www.researchsquare.com/article/rs-689684/v1.

225. The First Amendment guarantees the right to petition one's government and the necessity of robust debate following strict scientific standards. "A private citizen exercises a constitutionally protected First Amendment right anytime he or she petitions the government for redress." *Fregia v. Bright*, No. 1:16-CV-187, 2017 U.S. Dist. LEXIS 179667, *11 (E.D. Tex. Aug. 15, 2017). Citizens are guaranteed by the First Amendment "the right of access to all branches of the government for the redress of wrongs." *Noles v. Dial*, No. 3:20-CV-3677-N-BK, 2021 U.S. Dist. LEXIS 178694, *17 (N.D. Tex. Aug. 25, 2021).

226. Plaintiff CHD exercised that right by filing a citizen petition requesting that the FDA halt licensing of COVID-19 until such time as the concerns outlined in the petition had been alleviated and the proper scientific and administrative processes followed.

227. Defendants failed to adequately address the concerns in their response, which did nothing to ameliorate the legitimate and grave grievances in the petition.

228. The FDA's pattern of administering EUAs is a continuation of the violative and harmful actions Defendants have taken earlier.

229. Unless and until Defendants properly allow for citizen engagement, follow the laws governing their role as an administrative agency, and address the underlying concerns presented by Plaintiff CHD in the original citizen petition, Defendants' unbridled contempt for citizens and their abuse of power must be stopped.

The FDA Redefined the Term "Vaccine" in Violation of Procedural Due Process

230. The FDA and CDC have altered the traditional definitions of "vaccine" and "vaccination" to encompass the COVID-19 biologics and be able to market and administer them as vaccines, although they do not fit the century-long definition of the word.

231. Defendants failed to provide a citizen participation or notice-and-comment process when it labeled the COVID-19 biologics as vaccines. This erroneous labeling has misled the public and created an unfounded trust. By promoting it as a "vaccine," which comes with a connotation of a medical miracle, rather than its true label of an experimental pharmaceutical gene therapy, Defendants have been able to propagate a national vaccination campaign based on the public's erroneous beliefs.

232. Plaintiffs Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour, on behalf of their children, and Plaintiff CHD, on behalf of its members and employees, have experienced the harm that has come from this false designation, as well as the pressure, coercion and discrimination that has resulted.

Defendants Failed to Articulate Any Standard for Assessing Risk

233. This agency process requires Defendants to articulate a clear standard for assessing the safety, efficacy, and necessity of any drug or biologic, whether for an EUA or license. This is especially so when the product is likely to be mandated to millions of people around the world. *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962). This also requires that the agency "articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

234. The FDA failed to articulate any standard for assessing an individualized, stratified risk for children between the ages of 6 months and 11 years from the various COVID-19 vaccines, including any risk assessment specific to the variants of the virus, the efficacy of the vaccines to variants of the virus, or the risks of the vaccines themselves by any statistical measurement to these children. The FDA's failure violated its obligation to create such a standard, provide the

individualized, stratified analysis, and give some measurable assessment for children, and their parents, to assess for themselves the risks of each option.

235. This is further demonstrated by Defendants' failure to investigate credible allegations of fraud in Pfizer's clinical trials. Defendants turned a blind eye to falsified data, ignoring adverse reported adverse events, failing to follow protocols, revealing confidential participant information, and adverse actions taken against staff who spoke out against these issues. As such, without a widespread investigation into Pfizer's clinical trial practices, Defendants have failed to explain how and why their findings from these studies should be relied upon to justify the issuance of EUAs for children ages 6 months through 11 years.

236. Since the launch of the first COVID-19 biologic in 2020, the FDA's method for assessing risk for all individuals, but especially for children, has been wholly inadequate and shrouded in mystery.

237. The FDA also failed to examine and regulate mRNA COVID-19 vaccines as gene therapies. The failure to apply these required criteria, which are more stringent than those for vaccines generally, and the complete lack of an assessment standard for these gene therapies in FDA's EUA assessment, is arbitrary and capricious.

Defendants Failed to Examine Relevant Data

238. As part of "reasoned decision making," an agency is required to "examine the relevant data." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)

239. Defendants failed to address the inadequacies regarding clinical trials. Most importantly, the clinical trials did not address adverse effects that, if serious, would be borne by children/adolescents for potentially decades."[104]

240. In addition, the FDA ignored data on the high recovery rate of children diagnosed with COVID-19 and the high rates of natural immunity. The FDA cannot grant an emergency use authorization when there is no emergency for this age group.

241. Defendants have furthermore ignored adverse events that have been documented through the VAERS database, even though the input of event reports to VAERS since the COVID-19 vaccines were rolled out is greater than all cumulative adverse event reports to VAERS for the prior thirty years. The failure to investigate this data before administering this experimental injection to our nation's children goes beyond arbitrary and capricious action; it is an abhorrent neglect that shocks the conscience. Massive numbers of independent reports and case studies of vaccine side effects have accumulated, which the FDA continues to ignore.

242. Meanwhile, Defendants have dismissed the effectiveness of alternative treatments, which have the potential to significantly reduce hospitalizations and death to the extent that any vaccination program may have been unnecessary. Such treatments, had the FDA recognized them, would have threatened the agency's ability to issue EUAs.

243. Defendants' hype is outweighed by tidbits of truth that the public must ferret out from an ever-increasingly censored media. These experimental and prematurely licensed vaccines are not only dangerous and defective, but their efficacy has also been grossly exaggerated. There is substantial evidence that vaccine effectiveness wanes substantially after mere months, hence the

[104] Why are we vaccinating children against COVID-19?, *Science Direct*, available at https://www.sciencedirect.com/science/article/pii/S221475002100161X?via%3Dihub.

narrative that booster shots are necessary. Defendants have willfully ignored data critical of the Pfizer and Moderna biologics, inviting children to be victims of a consistent schedule of COVID-19 injections that are inadequately tested and dangerous. In so doing, Defendants have demonstrated that they are willing to arbitrarily and capriciously gamble with millions of children's lives.

244. This lawsuit simply asks the FDA to follow its own rules and hit the pause button on this rush to pharmapocalypse. It seeks vacatur of the authorizations for infants 6 months to children aged 11, as well as remand for Defendants to abide by their legal obligations, statutory duties, and scientific processes.

245. The FDA has failed to engage in a pluralistic, critical, open, transparent, and scientific dialogue with the public based on careful, deliberative evaluation of all relevant research and experience. On the contrary, it recklessly rushed these shots without proper evaluation in violation of the APA.

246. Plaintiffs bring this action because the FDA is failing to carry out its mission and is once again shamelessly displaying its true colors as a captured agency that ignores health and safety while granting favors to pharma. Plaintiffs seek this Court’s intervention to put the FDA back on the path to lawful protection of the public in these precarious times.

247. Defendants' arbitrary and capricious actions warrant a stay, a vacatur and remand.

CAUSE OF ACTION II: DECLARATORY RELIEF

248. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

249. Plaintiffs seek a declaratory judgment that Defendants cannot use the emergency authorization statute to mislabel drugs as vaccines, mislabel drugs that have not been thoroughly tested as safe and effective, mislabel drugs as permitted to be compelled without informed

consent, and to mislabel drugs to children that result in mandates being issued concerning those children's access to basic services, including medical and educational services. Plaintiffs seek Defendants' return to the regular biologic licensure process that incorporates citizen participation, including the right of a citizen petition and response thereto.

250. Congress expressly created this remedy of declaratory relief for federal courts as a critical check on abuse of power by executive branch agencies and thereby authorized by law that this Court "may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Children's Health Defense, Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour respectfully ask this Court:

i. To enjoin any further marketing or promotion of the Pfizer-BioNTech and Moderna COVID-19 vaccines to children;

ii. To stay the FDA's decision to grant Emergency Use Authorization for Pfizer-BioNTech's COVID-19 vaccine for children aged 5-11;

iii. To stay the FDA's decision to grant Emergency Use Authorization for Pfizer-BioNTech's COVID-19 vaccine for infants and toddlers ages 6 months through 4 years of age;

iv. To stay the FDA's decision to grant Emergency Use Authorization for Moderna's COVID-19 vaccine for infants and toddlers ages 6 months through 4 years of age;

v. To vacate and remand these decisions to the agency;

vi. To award attorneys' fees and costs, as authorized under 28 U.S.C. § 2412; and

vii. To grant all other appropriate relief as necessary.

Dated: July 1, 2022

Respectfully submitted,

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