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 young children than the ordinary flu.

2. The FDA recently redefined both Moderna and Pfizer's 21 CFR § 601.2 and COVID-19 ³YDFFLQHV´ HYHQ WKRXJK WKH GHIL QRW PHH 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 VXSHUYLVRU\ PHGLFDO RU VFLHQWLILF DJHQF\ 7KH FRUH F marketing of food and drugs conforms to their known qualities. The FDA is meaningless right to GUXJ¶V UL VNV GHWHUPLQH WKH OLPLWV RQ WKH GUXJ¶V S drug conforms to the requirements of informed consent, the universal medical nojus and 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, PLVODEHOHG WKLV H[SHULPHQWDO JHQH WKHUDS\ D ³YDFFL 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 resulted in direct marketing to children, resulting in the use of WKH EHORYHG FKLOGUHQ¶V SUR and Big Bird to promote this mislabeled product.

5. The FDA's unchecked and unbalanced reliance on Big Pharma officials has led to a COVID-19 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 COVID-19 vaccine authorizations. Children who do not have any parental or guardian safeguards against these harmful influences are subjected to the FDA's ill-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 members and employees, 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 the organization's conduct, as well as in the public's interest. Plaintiff CHD's members, employees, and constituents have been affected by the illegal and wrongful actions of the Defendants as well as the effects of Defendants' actions thereof.

9. Plaintiff Deborah L. Else is a member of CHD and a resident of Bell County, Texas. She is a longtime 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

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Defendants have targeted with their unlawful authorization and illicit marketing. She is a

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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

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11. Plaintiff Amy Villella is a resident of Florida. She is the parent of four children aged 3, 5,

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to receive the biologic, potential mandates, severe adverse reactions should they receive the vaccine, and immunization without parental informed consent. 6 K H L V D Q H P S O R \ H H R I &

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 old. 2 O O R I Z K L F K D U H W K U H D W H Q H G E \ L

EUA for pediatric Pfizer-BioNTech and Moderna vaccines. % R W K D U H P H P E H U V R I & K L

Health Defense.

13. Defendant FDA is an agency within the U.S. Department of Health and Human Services. The FDA is primarily labeling and marketing agency that claims to protect 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 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 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 GR QRW HYHQ ILW WKH WUDGLWLRQDO GHILQLWLRQ RI ³YDF

22. mRNA vaccines use experimental technology to combat a novel virus and a family of viruses with no history of vaccine success. The human body attempts to attack a virus that FRQWLQXHV WR PXWDWH LQ ZD\V SULRU YDFFLQH VWXGLHV 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-% L R 1 7 H F K ¶V 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 addressed long-term risks. The 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 11-15, 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 in violation of the Administrative Procedure Act, and violated Plaintiffs' due process rights. The FDA has failed to satisfactorily articulate standards for assessing the safety, efficacy, and necessity for the vaccine, and promoted the fraudulent marketing of a vaccine based on illogic targeted at children, in violation of the Administrative Procedure Act ("APA").

27. FDA's actions have resulted in irreparable harm to Children's Health Defense and its members, which CHD has consistently worked to prevent this abuse of power from occurring and to protect children and their families, such as Plaintiffs in this case, who are experiencing coercion to take the vaccine, discrimination if they refuse, and threat of vaccination against their will 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.

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.

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.