NO. _____

In the Supreme Court of the United States

CHILDREN'S HEALTH DEFENSE, ET AL,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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April 22, 2024 *Counsel for Petitioners*

QUESTION PRESENTED

Whether a Constitutionally cognizable case or controversy exists under Article III when agency action causes substantial resource diversion of an organization and exposes children they represent to an unvetted and unsafe "vaccine", in light of this Court's conflicting injury-in-fact standards set forth in *United States v. Students Challenging Regulatory Agency Procedures,* 412 U.S. 669 (1973) and *TransUnion LLC v. Ramirez,* 495 U.S. 413 (2021)?

PARTIES TO THE PROCEEDINGS

Petitioners and Plaintiffs-Appellants below

- Children's Health Defense
- Deborah L. Else
- Sacha W. Cayce Dietrich
- Aimee Villella McBride
- Jonathan Shour
- Rebecca Shour

Respondents and Defendants-Appellees below

- United States Food and Drug Administration
- Robert M. Califf, Commissioner of the FDA

RULE 29.6 STATEMENT

None of the petitioners are nongovernment corporations. Consequently. None of the petitioners have a parent corporation or shares held by a publicly traded company.

LIST OF PROCEEDINGS

U.S. Court of Appeals for the Fifth Circuit

No. 23-50167

Children's Health Defense, et al v. United States Food And Drug Administration

Date of Final Opinion: January 23, 2024

U.S. District Court, Western District of Texas (Waco)

No. 6:22-cv-00093-ADA

Children's Health Defense, et al v. United States Food And Drug Administration

Date of Final Order: January 12, 2023

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The Opinion of the United States Court of Appeals for the Fifth Circuit ("Court of Appeals" or "Fifth Circuit"), dated January 12, 2023 is included in the Appendix ("App.") App.1a-14a. The Order of Dismissal of the U.S. District Court, Western District of Texas at Waco (the "District Court") is included at App.15a-34a. These opinions and orders were not designated for publications.

JURISDICTION

The Court of Appeals entered its Opinion on January 23, 2024. App.1a-14a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Const. art. III, § 2

> The judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority;—to all Cases affecting Ambassadors, other public Ministers and Consuls;—to all Cases of admiralty and maritime Jurisdiction;—to Controversies to which the United States shall be a Party;—to

> Controversies between two or more States;—between a State and Citizens of another State,—between Citizens of different States,—between Citizens of the same State claiming Lands under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects . . .

5 U.S.C. § 553(e)

> Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

5 U.S.C. § 706

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;
>
> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

STATEMENT OF THE CASE

Petitioner Children's Health Defense ("CHD") is a nonprofit "organization that has tasked itself with protecting and promoting the health and wellbeing of children." App.3a. The remaining petitioners are parents of children whose ages range from 2 months to 13 years old. App.38a-39a. (hereinafter along with CHD collectively "Petitioners"). Respondents are the Food & Drug Administration an agency within the U.S. Department of Health and Human Services (hereinafter the "FDA"), and its Commissioner, Robert M. Califf. App.2a.

On April 1, 2020, the Secretary of the U.S. Health and Human Services determined that circumstances surrounding the COVID-19 outbreak justified "the authorization of emergency use of drugs and biological

products." App.2a. In December 2020, the FDA issued two emergency use authorizations ("EUAs") for administering COVID-19 vaccines to people over age 16. App.2a-3a. From May 2021 through to June 2022, the FDA expanded those EUAs to authorize vaccinations to children from 17 years down to 6 months old. App.3a.

In May 2021, petitioner CHD filed a citizen petition with the FDA (the "Citizen Petition"), demanding FDA to revoke the existing EUAs, because the COVID-19 vaccines authorized by them were ineffective and lacked proper vetting. App.3a. The Citizen Petition requested that FDA stay its issuance of EUAs until proper scientific and administrative procedures had been followed first. App.3a. On August 23, 2021, FDA responded to the Citizen Petition with a denial of the relief requested therein. App.3a.

A. Proceedings In The District Court Below

Following the FDA's denial of the Citizen Petition, Petitioners filed a civil action against FDA on January 24, 2022. On July 1, 2022, Petitioners filed a First Amended Complaint (the "Amended Complaint"), alleging two causes of action, the first under the Administrative Procedures Act codified in 5 U.S.C. §§ 553(e) and 706(2) (the "APA"), and the second for declaratory relief. App.108a-118a. The Amended Complaint alleged that FDA violated the APA by failing to grant citizen redress and judicial review of the EUAs prior to unleashing improperly vetted vaccinations upon children nationwide, and further that FDA's inadequate assessment of the adverse effects of the vaccines authorized by the EUAs posed a substantial risk of harm and even death to children who received them. App.36a-38a, App.41a-43a, App.46a-54a. and App.89a-97a.; App.3a-4a and 6a. The Amended Complaint further

alleged that FDA affirmatively misrepresented the safety, and omitted to disclose the risks and dangers, of the COVID-19 vaccines authorized by the EUAs. App.64a-68a. Finally, the Amended Complaint alleged that the EUAs issued by the FDA, combined with the FDA's aforementioned misrepresentations and omissions regarding the subject vaccines, had the effect of spawning tremendous public and social pressure on parents and their children to get vaccinated, even leading to vaccinations absent parental consent. App. 67a-68a; App.3a-4a.

On January 12, 2023, the District Court granted Respondents' motion to dismiss the Amended Complaint with prejudice for lack of subject-matter jurisdiction, finding that Petitioners lacked Article III standing to bring their claims against FDA (the "Order of Dismissal"). App.15a-34a.

B. Proceedings in the Court of Appeals Below

On March 3, 2023, Petitioners filed a timely Notice of Appeal, seeking review by the Fifth Circuit Court of Appeals (the "Fifth Circuit") of the District Court's Order of Dismissal.

On January 23, 2023, the Fifth Circuit entered its unpublished opinion affirming the District Court's Order of Dismissal (the "Fifth Circuit Opinion"). App.1a-14a. The basis for the Fifth Circuit's affirmance of the District Court's Order of Dismissal, was that Petitioners' pleadings failed to sufficiently allege the injury-in-fact element of associational Article III standing. App.6a-12a. On February 14, 2024, the Fifth Circuit issued a Judgment as the mandate in the matter.

REASONS FOR GRANTING THE PETITION

Review on writ of certiorari may be granted for compelling reasons, which include that a "United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court, . . . ". Rule 10(c)[1]. This case asks a question this Court's own Justices recently asked at oral argument: who can sue the FDA when the FDA violates the law, misrepresents the safety and efficacy of a drug, and endangers the public?[2] The lower courts answered: no one can. Is that the law?

To the ordinary person, this matter is a "case or controversy" within the plain language and original intent of Article III of the United States Constitution. Yet the lower courts determined that a federal agency lying to the public in a manner costing the petitioner substantial resources and endangering the lives of toddlers wasn't a "case or controversy" at all in the language of the law. The law may have its linguistic roots in Latin, but that makes our own Constitutional words written in a language foreign to our founders.

The lower courts have stretched the doctrine of standing to justify abdication of judicial obligation,

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[1] "Rule" refers herein to the Rules of the Supreme Court of the United States.

[2] *U.S. Food and Drug Administration, et al., v. Alliance For Hippocratic Medicine, et al.*; Docket No. 23-235: "Is there anybody who can sue and get a judicial ruling on whether what FDA did was lawful? And maybe what they did was perfectly lawful, but shouldn't somebody be able to challenge that in court?" Justice Alito asked the government's lawyer at oral argument.

excusing emergency exceptions to our Constitutional liberties for rogue, wayward, conflicted administrative agencies, at the expense of our most vulnerable population: toddler, foster children, and children in institutional care. The last time this Court tolerated such conduct? A case called *Buck v. Bell*, 274 U.S. 200 (1927). Is that ignominious, infamous tradition what this Court wants to return to?

It is time for this Court to clarify the meaning of Article III in a manner that gives meaningful predictability and consistent Constitutional conformity for all. A standard currently missing from the conflicting and confusing lower court decisions across the Circuits concerning this most critical and foundational question: who has access to the judicial branch of government to petition for redress of grievances?.

I. THE INJURY-IN-FACT ELEMENT OF ARTICLE III STANDING IS UNSETTLED BY DECISIONS OF THIS COURT.

Forty years ago in one of its most seminal decisions on Article III standing, *Allen v. Wright,* 468 U.S. 737, 751 (1984), this Court held that the injury-in-fact element of Constitutional Article III jurisdictional standing requires the courts to draw a line between injuries that confer standing because they are "distinct and palpable", and those which it characterized as "abstract", "conjectural", or "hypothetical". This Court in *Allen* stated that the absence of precise and mechanical rules " . . . hardly leaves courts at sea in applying the law of standing." (*Id.,* at 751). Yet, the underlying case that gave rise to this Petition reveals that the District and Circuit Courts indeed remain very much "at sea" in regards to whether plaintiffs that suffer

a risk of future harm arising from the actions of a defendant, have Article III standing.

Clarity by this Court over this most important principle and its ramifications for separation of powers is thus crucial at this juncture. This Petition grants this Court the opportunity to do just that.

A. One Line of Decisions Holds That Standing Exists So Long as an "Identifiable Trifle" of Injury Is Suffered by The Plaintiff.

On one end of the spectrum regarding standing is the case of *United States v. Students Challenging Regulatory Agency Procedures,* 412 U.S. 669 (1973) ("*SCRAP*").

In *SCRAP*, this Court rejected an argument that standing should be accorded only to persons "significantly" affected by agency action. Instead, this Court ruled that the plaintiffs in *SCRAP* sufficiently alleged standing by contending that a rail freight surcharge could discourage use of recyclable goods, encourage greater use of virgin materials, and thus impair the future pleasures of outdoor activities that comprised the injury to the plaintiffs in that case. In determining that the *SCRAP* plaintiffs' aesthetic-based injury comprised standing, this Court held: "'an identifiable trifle is enough for standing to fight out a question of principle; the trifle is the basis for standing and the principle supplies the motivation' [citation omitted]." *Id.,* at 689, fn. 14. The *SCRAP* decision still remains as authority by this Court supporting that injury-in-fact may be found despite the plaintiff not suffering any present or even imminent injury.

Recent Circuit Court decisions in other Circuits remain faithful to that very "identifiable trifle" standard set forth in *SCRAP*.

In *Natural Resources Defense Council, Inc. v. U.S. Food and Drug Admin.,* 710 F.3d 71 (2nd Cir. 2013), the Second Circuit found standing where the plaintiffs' claim was that the FDA failed to appropriately determine whether a substance contained in antibacterial soap called triclosan should be approved for use by the public, despite the uncertainty of risk of injury to a person's thyroid or liver. *Id.,* at 84 [rejecting the government's contention that the absence of "quantitative evidence of the 'precise risk'" was necessary to show standing].

Similarly, in *In re Paoli R.R. Yard PCB Litig.,* 916 F.2d 829, 850 (3rd Cir. 1990), the Third Circuit held that: " . . . courts have begun to recognize claims like medical monitoring, which can allow plaintiffs some relief even absent present manifestations of physical injury" and that "in the toxic tort context, courts have allowed plaintiffs to recover for emotional distress suffered because of the fear of contracting a toxic exposure disease."

The Sixth Circuit followed suit. In *Sutton v. St. Jude Medical S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005), plaintiffs had standing to bring claims against the defendant hospital arising from exposure to an increased risk of future harm arising from a defective device that was implanted into their body, despite no symptoms arising from the subject devices being exhibited.

The Ninth Circuit followed suit as well. In *Natural Resources Defense Council v. U.S. E.P.A.,* 735 F.3d 873, 878-879 (9th Cir. 2013), the Circuit

found standing where an environmental organization challenged conditional registration of a pesticide that would be used on many forms of manufactures textiles, on the grounds the parents could not control the risk that their children would be exposed to the pesticide in various ways.

Decisions in the D.C. Circuit did so as well. *Cutler v. Kennedy,* 475 F.Supp. 838, 848 (D.D.C. 1979) [consumers can bring suit against the FDA when the agency has "increased the risk that they will purchase and consume unsafe or ineffective drugs. . . . [the] risk and deprivation itself constitutes a distinct and palpable injury . . . "].

As did the Third Circuit in *Cottrell v. Alcon Laboratories*, 874 F.3d 154 (3rd Cir. 2017) ("*Cottrell*"). In *Cottrell*, the plaintiffs brought claims against the manufacturers of an allegedly defective eye medication. In holding that those plaintiffs had standing pursuant to this Court's "identifiable trifle" standard the Third Circuit held:

> "The injury-in-fact requirements is 'very generous' to claimants, demanding only that the claimant 'allege[] some specific, 'identifiable trifle' of injury." (citing *Bowman v. Wilson,* 672 F.2d 1145, 1151 (3rd Cir. 1982) (quoting *SCRAP,* 412 U.S. at 686-90 n. 14). It 'is not Mount Everest.' (citing *Danvers Motor Co., Inc. v. Ford Motor Co.,* 432 F.3d 286, 288 (3rd Cir. 2005))."

Cottrell, supra, 874 F.3d at 162-163.

Finally, in *Massachusetts v. United States Dept. HHS,* 923 F.3d 209, 222 (1st Cir. 2019), the First Circuit held: "[i]t is bedrock proposition that a relatively small

economic loss – even an 'identifiable trifle' – is enough to confer standing." (citing among other authority, *SCRAP, supra,* 412 U.S. at 690 n. 14).

B. A Separate Line of Decisions Holds That Standing Cannot Exist Unless "Materialized" Risk of Future Harm Is Suffered by The Plaintiff.

On the other end of the spectrum, is the case of *Clapper v. Amnesty International USA,* 568 U.S. 398 (2013) ("*Clapper*"). In that case, this Court held that: "'allegations of *possible* future injury are not sufficient' (quoting *Whitmore v. Aransas,* 495 U.S. 149, 158 (1990))." (emphasis original). Indeed, *Clapper* was both cited and heavily relied upon by the Fifth Circuit below in affirming the District Court's Order of Dismissal of Petitioner's claims for lack of standing. App.6a-7a, and 11a.

Similarly, in another case relied upon by the Fifth Circuit below to affirm dismissal of Petitioners' claims, this Court's recent decision in *TransUnion LLC v. Ramirez,* 495 U.S. 413, 437-438 (2021) ("*TransUnion*") held that the plaintiffs in that case failed to show injury-in-fact because "plaintiffs did not demonstrate that the risk of future harm materialized" and such risk was "too speculative". *Compare* Fifth Circuit's Opinion affirming Order of Dismissal, at App.8a-11a.

The Fifth Circuit thus diverted from the First Circuit, the Second Circuit, the Third Circuit, the Sixth Circuit, the Ninth Circuit, and the Tenth Circuit– reflecting a divide found in this Court's own conflicting directions on the fundamental question of: who can petition the judicial branch for redress?

II. THIS COURT SHOULD SETTLE THE TWO CONFLICTING INJURY-IN-FACT STANDARDS TO PRESERVE UNIFORMITY OF COURT DECISIONS OVER THIS IMPORTANT PUBLIC AND CONSTITUTIONAL ISSUE.

We face an unparalleled moment in the history of public health: the race to rush a vaccine authorization and approval without robust debate or meaningful citizen participation. Forced vaccination onto unwilling citizens without strict safety safeguards, with no manufacturer liability, using experimental technology to combat a novel virus from a viral family with no history of vaccine success.

The FDA misled caretakers and guardians of children as young as six months old into believing that what they are receiving is a biologically licensed, fully vetted and completely approved vaccine, when such a product was not even available. Despite the overwhelming evidence to the contrary, the FDA continuously misrepresented the biologic as a "safe," "effective," "vaccine," when it is neither safe nor effective, nor even a vaccine under the colloquial and common definition of a vaccine – to actually prevent infection and transmission.

If Petitioners cannot sue, who can? As Justices of this court effectively asked at recent oral argument, can no one sue the FDA? Is that what Article III means? If that is the law, then Article III is empty and the judicial branch legally impotent from rogue agencies exercising extraordinary emergency powers at the direct expense of the people they were obligated to protect. If CHD, drained of resources fighting the lies of the FDA to protect children, have no right of redress

from the judicial branch, then the FDA is both above the law and beyond the Constitution.

The basis for Constitutional standing is a simple one: a "case or controversy." If those subject to forced vaccines, and an organization whose mission it is to protect our country's most vulnerable groups against medical harm, cannot be said to have a "case and controversy" against the government agency tasked with maintaining transparency and honesty in pharmaceutical labeling, then there is no plaintiff who could. As discussed above, the District and Circuit Courts lack uniformity of decisions from this Court in determining whether standing arising from the plaintiff's exposure to risk of future harm requires an "identifiable trifle" (*SCRAP, supra,* 412 U.S. at 690 n. 14), or "materialized" "future harm" (*TransUnion, supra,* 495 U.S. at 437-438).

The Fifth Circuit below went with the far more exacting standard set forth in *TransUnion*, essentially ignoring the deferential standard set forth in *SCRAP*. It is imperative for this Court to clarify which standard applies, in order for uniformity of decisions over this most important issue of separation of powers to exist going forward.

Ultimately, the FDA asks this Court to declare itself powerless, the judiciary empty of remedy, the balance of powers imperfectly imbalanced, and the Constitutional check on executive power mute. That is not the law, and this Court should say so.

III. THIS COURT SHOULD ALSO RESOLVE THE UNSETTLED ISSUE OF WHEN AN ORGANIZATION HAS STANDING TO SUE WHERE ITS RESOURCES ARE DIVERTED BY AGENCY ACTION.

The Fifth Circuit also diverted from sister Circuits on the question of organizational standing. Unlike the decision below, decisions of sister Circuit Courts affirm an organization's standing under Article III, where its pre-litigation efforts to evaluate and challenge government acts result in a drain on the organization's resources. *See e.g.*, *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 469 F.3d 129 (D.C. Cir. 2006); *Hooker v. Weathers*, 990 F.2d 913, 915 (6th Cir. 1993); *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991); *Public Citizen v. Foreman,* 631 F.2d 969, fn. 12 (D.C.Cir.1980); *Natural Resources Defense Council, Inc. v. SEC,* 606 F.2d 1031 (D.C. Cir. 1979); *Am. Acad. of Pediatrics v. FDA*, 379 F.Supp.3d 461 (D. Md. 2019).

For example, the DC Circuit Court found an organization need not show an "overly burdensome" injury to satisfy standing. *Public Citizen v. Foreman,* 631 F.2d 969, fn. 12 (D.C. Cir. 1980) ("*Public Citizen*"). In *Public Citizen*, the court held that a nonprofit public interest group and two of its members had standing against the government to seek a declaratory judgment that nitrates used in curing bacon are an "unsafe" food additive under the Federal Food, Drug, and Cosmetic Act. The Court found that because nitrite-free bacon "was not readily available at a reasonable price", plaintiffs sustained an injury, even though they could abstain from eating bacon or purchase the more

expensive nitrite-free bacon and the injury was not "overly burdensome." *Id.* at fn. 12.

The Fifth Circuit diverted from these sister Circuits, requiring a direct, immediate, intended injury beyond foreseeable resource diversion, that reflects a continued confusion in this critical area of law governing judicial access. For that reason as well, this Petition should be granted by this Court in order to clarify this unsettled area of the law of organizational standing.

CONCLUSION

For the reasons set forth above, this petition for a writ of certiorari should be granted.

Respectfully submitted,

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April 22, 2024

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OPINIONS AND ORDERS

OTHER DOCUMENTS

OPINION, U.S. COURT OF APPEALS FOR THE FIFTH CIRCUIT (JANUARY 23, 2024)

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

CHILDREN'S HEALTH DEFENSE; DEBORAH L. ELSE; SACHA DIETRICH; AIMEE VILLELLA MCBRIDE; JONATHAN SHOUR; REBECCA SHOUR,

Plaintiffs–Appellants,

v.

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF,

Defendants–Appellees.

No. 23-50167

Appeal from the United States District Court
for the Western District of Texas
USDC No. 6:22-CV-93

Before: JONES, HAYNES, and DOUGLAS, Circuit Judges.

PER CURIAM:*

Five parents and one organization challenged the Food and Drug Administration's issuance of emergency use authorizations covering COVID-19 vaccines for children. Specifically, the parents allege fears of a third party vaccinating their children without parental consent, harassing or marginalizing their children for their unvaccinated status, and pushing pro-vaccine messaging. After finding that Plaintiffs lacked standing, the district court dismissed the suit. For the reasons that follow, we AFFIRM.

I. Background

The Food and Drug Administration ("FDA"), an agency within the U.S. Department of Health and Human Services ("HHS"), and FDA Commissioner Califf are tasked with protecting the public's health by ensuring the safety, efficacy, and security of drugs and biological products, among other things. In February 2020, the Secretary of HHS declared a "public health emergency . . . that involves a novel (new) coronavirus," known as SARS-CoV-2, the virus that causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). Subsequently, the Secretary of HHS determined that the circumstances surrounding the COVID-19 pandemic justified "the authorization of emergency use of drugs and biological products." 85 Fed. Reg. 18250, 18250–51 (Apr. 1, 2020); *see* 21 U.S.C. § 360bbb-3 (authorizing the use of medical products in emergencies and justified threats).

In December 2020, FDA issued two emergency use authorizations ("EUAs") for administering COVID-

* This opinion is not designated for publication. *See* 5th Cir. R. 47.5.

19 vaccines to individuals over age 16.[1] In May 2021, October 2021, and June 2022, FDA revised the Pfizer EUA to expand the authorization to include additional age groups: first, individuals 12 through 15 years old; second, individuals 5 through 11 years old; and third, individuals 6 months through 4 years old. And in June 2022, FDA revised the Moderna EUA to authorize administration of the vaccine to those between 6 months and 17 years old.[2]

In May 2021, Plaintiff Children's Health Defense ("CHD ") filed a petition with FDA asking the agency to revoke the existing EUAs for the COVID-19 vaccines. The FDA denied the petition, and the instant lawsuit followed in January 2022.

CHD is a nonprofit "organization that has tasked itself with protecting and promoting the health and wellbeing of children." The remaining Plaintiffs are

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[1] Specifically, the vaccines manufactured by Pfizer, Inc. and BioNTech Manufacturing GmbH were authorized for use in individuals 16 years of age and older and one manufactured by ModernaTX, Inc. was authorized for use in individuals 18 years of age and older. *See* 86 Fed. Reg. 5200, 5200, 5204, 5214 (Jan. 19, 2021) (providing notice of EUA issuance).

[2] *See* FDA, Emergency Use Authorization, https://perma.cc/XKQ8-GUBN (listing EUAs). While the FDA has issued EUAs for an updated bivalent formula of both the Pfizer-BioNTech and Moderna vaccines, the monovalent formulas remain licensed but are no longer authorized for emergency use in the United States; they are thus only approved for use in individuals 12 years and older (Pfizer) or 18 years and older (Moderna). *See generally* FDA, FDA COVID-19 Vaccine News and Updates, https://perma.cc/E3VU-JDWF; FDA News Release, Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines (Apr. 18, 2023), https://perma.cc/WY2V-YLYU.

parents that do not want their children to receive a COVID-19 vaccine. Some of the parents allege that they are at risk because their children may be coerced to receive the vaccine, may be forced to take the vaccine due to allegedly impending mandates, may receive the vaccine without parental consent, or may suffer adverse reactions should they be given the vaccine. Moreover, they complain of a "societal push toward vaccination" evidenced by, for example, "Sesame Workshop" which released a YouTube video announcing that Elmo had gotten the COVID-19 vaccine.[3] Plaintiffs claim that FDA failed to comply with the Administrative Procedure Act's ("APA") reasoned decision making requirements when it approved the COVID-19 vaccine for children and, as a result, request a stay, vacatur, and remand. Plaintiffs also seek an injunction against the marketing or promotion of the vaccines.

The district court dismissed the initial complaint, which included only the plaintiff parents from Texas. Plaintiffs filed an amended complaint, adding the

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[3] Plaintiffs allege that Elmo sent the message that children will "get sick if [they] don't take the COVID-19 vaccine." In doing so, Plaintiffs rely on a video that suggests otherwise. *See* Sesame Street: Elmo Gets the COVID-19 Vaccine, Sesame Street, available at https://www.youtube.com/watch?v=bwimt9n2JEk. In the video, Elmo's father states that: "I had a lot of questions about Elmo getting the COVID vaccine. Was it safe? Was it the right decision? I talked to our pediatrician so I could make the right choice. I learned that Elmo getting vaccinated is the best way to keep himself, our friends, neighbors and everyone else healthy and enjoying the things they love." *Id.* Further, the video explains that "it's okay to have questions about the COVID-19 vaccine for your kids. Get the latest facts by speaking with your pediatrician or healthcare provider." *Id.*

plaintiff parents from North Carolina and Florida, who likewise do not want their children to receive COVID-19 vaccines. The district court again dismissed Plaintiffs' complaint for lack of standing, concluding that no plaintiff had adequately pled an injury in fact. This appeal followed. "We have jurisdiction to determine our own jurisdiction. *" Martin v. Halliburton,* 618 F.3d 476, 481 (5th Cir. 2010).

II. Discussion

We review standing de novo. *See Shemwell v. City of McKinney,* 63 F.4th 480, 483 (5th Cir. 2023). We may affirm a dismissal "'on any basis supported by the record.'" *Collins v. Dep't of the Treasury,* 83 F.4th 970, 978 (5th Cir. 2023) (quoting *Asadi v. G.E. Energy U.S., L.L.C.,* 720 F.3d 620, 622 (5th Cir. 2013)).

A. Article III Standing

"'The law of Art. III standing is built on a single basic idea—the idea of separation of powers.'" *TransUnion LLC v. Ramirez,* 594 U.S. 413, 422-23 (2021) (quoting *Raines v. Byrd,* 521 U.S. 811, 820 (1997)). "Under Article III, federal courts do not adjudicate hypothetical or abstract disputes" and "do not exercise general legal oversight of the Legislative and Executive Branches." *Id.*

Plaintiffs argue that the district court erred in its analysis of Article III standing on three grounds, including organizational standing, associational standing, and the APA. To begin, we must consider whether Plaintiffs satisfy the first requirement for Article III standing. Then, we consider whether CHD itself has standing.

1. Injury in Fact

"[T]o establish standing, a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion,* 594 U.S. at 423 (citing *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-561(1992)).

For an injury to be "'concrete,'" it must be "'real, and not abstract.'" *Id.* at 424 (quoting *Spokeo, Inc. v. Robins,* 578 U.S. 330, 340 (2016)). When evaluating whether a harm is "concrete," we consider "whether the alleged injury to the plaintiff has a 'close relationship' to a harm 'traditionally' recognized as providing a basis for a lawsuit in American courts." *Id.* (quoting *Spokeo,* 578 U.S. at 340). To be "imminent," "there must be at least a 'substantial risk' that the injury will occur." *Stringer v. Whitley,* 942 F.3d 715, 721 (5th Cir. 2019) (quoting *Susan B. Anthony List v. Driehaus,* 573 U.S.149,158 (2014)).

Moreover, "allegations of *possible* future injury are not sufficient." *Clapper v. Amnesty Intl USA,* 568 U.S. 398, 409 (2013) (quoting *Whitmore v. Arkansas,* 495 U.S. 149, 158 (1990)). Instead, "to ensure that the alleged injury is not too speculative," a plaintiff who wishes to rely on a threatened injury to establish standing must demonstrate that a concrete injury is "certainly impending." *Id.*

Plaintiffs contend that the injury-in-fact element is satisfied because a third party might vaccinate their children over their objections, and that such vaccine could allegedly injure them and their children. Additionally, Plaintiffs argue that any alleged advertis-

ing or disseminated information regarding the vaccine constitutes harm. In doing so, Plaintiffs note that "general factual allegations of injury" "may suffice" where, as here, the district court granted a motion to dismiss based on the pleadings. Be that as it may, we agree with the district court that Plaintiffs fail to demonstrate an injury in fact because the alleged injury is neither concrete nor imminent. "The party invoking federal jurisdiction bears the burden of establishing" the elements of standing, which "are not mere pleading requirements but rather an indispensable part of the plaintiff's case[.]" *Lujan,* 504 U.S. at 561.

Nothing in Plaintiffs' amended complaint or briefs suggest that the alleged injuries are nonspeculative or "certainly impending." *Clapper,* 568 U.S. at 409. To begin, it is insufficient that Plaintiffs allege that some hypothetical third party might, at some hypothetical point in the future and through some hypothetical means, will vaccinate their children against their wishes.

We are not persuaded by the out-of-circuit cases that Plaintiffs rely on to establish injury in fact. Take *Booth v. Bowser,* 597 F.Supp.3d 1 (D.D.C. 2022), which concluded that two sets of parents had sufficiently alleged an impending injury to establish standing. The parents in *Booth* challenged the District of Columbia's law permitting children at least eleven years old to get vaccinated without parental consent. *Id.* at *9. To determine whether the parents had standing, the court considered whether the complaint detailed allegations regarding the likelihood that the parents' children would soon seek vaccines. *Id.* For example, one child said he would take the vaccine if

offered, and another child repeatedly told her parents that she needed the vaccine to participate in various school activities, so she wanted to get the vaccine. *Id.* at *6 (finding that the child "made it clear that he is on the cusp of getting vaccinated"). Thus, the imminent injury for the parents in *Booth* arose from the D.C. law allowing children to seek vaccines absent parental consent, particularly when D.C. mandated vaccines for most students. *Id.* at *13.

In contrast, the parents in this case do not allege any facts establishing a similar likelihood that their children will seek or obtain a vaccine without parental consent. The parents do not allege that their children are or will be subject to any vaccine mandates that might be imposed by third parties. Nor do they allege that their children wish to receive a COVID-19 vaccine or have the means or opportunity to get it despite their parents' wishes. The parents' allegations are particularly speculative because there are no COVID-19 vaccine mandates, state or federal, and their states generally *prohibit* administering vaccines absent parental consent.[4] *See e.g., Biden v. Feds for*

[4] State laws establish vaccination requirements for school children. *See* Fla. Stat. 1014.06(1); N.C. Gen. Stat. § 90-21.5(a1); Tex. Family Code Ann. § 151.001(a)(6); *see also* Tex. Family Code Ann. § 32.101(b) (permitting certain specified non-parents to consent to immunization in limited circumstances where, among other things, the parents are "not available."). To be sure, the Texas-based parents have alleged fears of a third-party authorizing vaccines to their children but, as they have noted, this occurs in limited circumstances. The parents neither identify any specific third party able to provide that authorization, nor do they allege that a third party wants to vaccinate their children, or that their children would consent on their own. Even if they did, the claim still fails for lack of imminency. As the district court explained, under Texas and Florida law, vaccination cannot be mandatory.

Med. Freedom, No. 23-60, 2023 WL 8531839, at *1 (U.S. Dec. 11, 2023) (explaining that an order granting a preliminary injunction against a vaccine mandate is moot because such mandate does not exist). By extension, there is also no "impending injury" arising from the parents' fear of moving to another state that might have a vaccine mandate in the future, as such a mandate has not materialized.[5] *See e.g., TransUnion,* 594 U.S. at 437-38 (explaining that plaintiffs did not establish a concrete harm because "plaintiffs did not demonstrate that the risk of future harm materialized" and such risk was "too speculative").

Moreover, information in the public domain related to vaccines and general "pressure to receive the COVID-19 [vaccine] . . . from the media and other children" do not constitute a concrete injury. Plaintiffs rely on cases that find standing on similar theories as *Booth,* such as where a government agency allegedly exposed the plaintiff to, or increased the risk that the plaintiff would be exposed to, harmful products or drugs;[6] where an agency allegedly increased health-

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Tex. Executive Order GA-40 (Oct. 11, 2021); Fla. Stat. § 381.00319. Moreover, under North Carolina law, individuals other than parents are not permitted to vaccinate a child. N.C. Gen. Stat. § 90-21.5(a1).

[5] To be clear, Plaintiffs fail to point to any states that require COVID-19 vaccines for children or adults. Even if they did, nothing in the amended complaint suggests that a vaccine mandate would present a threat to the parent or child that chooses not to seek the vaccine. Further, if a mandate existed, plaintiffs would need to bring a cause of action against the mandating entity (*i.e.*, schools, employers, businesses), not FDA.

[6] *See Baurv. Veneman,* 352 F.3d 625 (2d Cir. 2003); *Cutler v. Kennedy,* 475 F.Supp. 838 (D.D.C. 1979); *Center for Food Safety*

related uncertainty;[7] and where a parent's medical control over her children's care was allegedly impaired.[8] As the district court explained, however, those cases are neither binding, nor persuasive. To illustrate, in *Baur,* the plaintiff described how the alleged threat of harm *directly* arose from the agency's action. *See Baur,* 352 F.3d at 634 (finding that enhanced risks in the "context of food and drug safety suits . . . are cognizable for standing purposes, where the plaintiff alleges exposure to potentially harmful products."). *Baur* clarifies that the injury must nonetheless be a "discrete, individual risk of personal harm from exposure[.]" *Id.* at 635.

Unlike the plaintiffs in *Baur,* the Plaintiffs do not have a concrete or particularized injury. Instead, Plaintiffs merely allege that a third party may vaccinate their children without their consent, that a third party might harass their children for being unvaccinated, and that their children may be exposed to pro-vaccine messaging. These hypothetical dangers are untethered to the law. Even if the alleged harms were plausible, each are the result of a third-party action, not the FDA. *See e.g., TransUnion,* 594 U.S. at 438 (finding that plaintiffs failed to establish a future risk of harm by not showing "a sufficient likelihood that their individual credit information would be requested by third-party businesses and provided by

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v. Price, No. 17-cv-3833, 2018 WL4356730 (S.D.N.Y. Sept. 12, 2018).

[7] *See New York Public Interest Research Grp. v. Whitman*, 321 F.3d 316 (2d Cir. 2003).

[8] *See Tummino v. Torti,* 603 F.Supp.2d 519 (E.D.N.Y. 2009) (explaining that under the challenged FDA action, parents are unable to legally obtain Plan B on behalf of their children).

[defendant] . . . [or] that there was a sufficient likelihood that [defendant] would otherwise intentionally or accidentally release their information to third parties."). In other words, the EUAs do not put the parents at an imminent risk of harm or exposure because the parents are free to choose whether to consent to their children receiving the COVID-19 vaccine, and whether to restrict their children's access to information related to the vaccine.[9] Thus, the parents fail to display any nonspeculative risk of harm based on a "possible future injury." *Clapper,* 568 U.S. at 409.

In addition, Plaintiffs fail to argue how being marginalized by society and media campaigns based on vaccination status constitutes an injury in fact to sue FDA. Plaintiffs simply point to a Sesame Street video saying that Elmo received the COVID-19 vaccine.[10] Because they do not explain on appeal how media or even societal norms may constitute an injury-in-fact, they forfeit any challenge to the district court's

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[9] "Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care." *See e.g.,* Food & Drug Admin. Fact Sheet for Recipients and Caregivers about Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) which has Emergency Use Authorization (EUA) to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 6 Months through 11 Years of Age; 21 U.S.C. § 360bbb-3(c)(1)-(5). www.covidvaxoption.com.

[10] Misleadingly, Plaintiffs also allege that a federal vaccine mandate for students exists. The falsity of that allegation is demonstrated by Plaintiffs failure to cite any legal or factual support. Indeed, Plaintiffs do not identify any specific factual allegations that would support their claim of harassment related to their vaccination status.

conclusion that plaintiffs have not suffered an injury in fact at the hands of unidentified third parties or the media. *See Owens v. Circassia Pharm., Inc.,* 33 F.4thth 814, 824 n.4 (5th Cir. 2022); *see also TransUnion,* 594 U.S. at 424 ("[U]nder Article III, a federal court may resolve only 'a real controversy with real impact on real persons.'") (quoting *American Legion v. American Humanist Assn.,* 139 S. Ct. 2067, 2103 (2019). Even if challenged, the district court correctly explained that Plaintiffs have not suffered an injury in fact because they have merely alleged a "psychological consequence" "produced by observation of conduct with which one disagrees." *Valley Forge Christian Coll. v. Am. United for Separation of Church & State, Inc.,* 454 U.S. 464, 485 (1982).

2. Organizational and Associational Standing

We next consider whether CHD, as an organization or association, establishes standing. CHD first suggests that it has spent resources working with its members, addressing societal pressures, and educating the public regarding alleged dangers of vaccines. Then CHD asserts that it spent resources investigating FDA's action to prepare for litigation and file a citizen petition.

Organizations can satisfy injury-in-fact for standing under two theories: organizational standing and associational. *OCA-Greater Houston v. Texas,* 867 F.3d 604, 610 (5th Cir. 2017). "[A]n organization may establish injury in fact by showing that it had diverted significant resources to counteract the defendant's conduct." *N.A.A. C.P. v. City of Kyle,* 626 F.3d 233, 238 (5th Cir. 2010). Thus, any diversion must be a specific response to the challenged law or action. It

is not fairly traceable to defendants if the diversion responded not only to the defendants' conduct but also to other forces. *Texas State LULAC v. Elfant,* 52 F.4th 248, 254 (5th Cir. 2022). "A "setback to [an] organization's abstract social interests" is insufficient. *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 379 (1982).

Associational standing is derivative of an organization's members. *OCA-Greater Houston,* 867 F.3d at 610. To have associational standing, the organization must show: (1) that its members independently possess Article III standing, (2) "the interests the association seeks to protect are germane to the purpose of the organization," and (3) the claim and the relief requested does not require participation of the individual members. *Ctr. for Biological Diversity v. U.S. EPA,* 937 F.3d 533, 536 (5th Cir. 2019).

We find that CHD has not established standing as it has not "diverted significant resources to counteract" the FDA's EUAs. *City of Kyle,* 626 F.3d at 238. In particular, CHD has failed to show how the diversion of resources in response to the EUAs has "concretely and 'perceptibly impaired'" CHD's ability to carry out its purpose. CHD "ha[s] not identified any specific projects that [it] had to put on hold or otherwise curtail in order to respond to" the EUAs; instead, it has "only conjectured that the resources that [it] had devoted to" the EUAs "could have been spent on other unspecified [CHD] activities." *City of Kyle,* 626 F.3d at 238-39. Furthermore, an organizational plaintiff—like any other plaintiff—cannot spend its way to standing through a lawsuit; instead, the organization must show that the injury increases the resources devoted to programs, "independent of its suit challenging the action." *Online Merchs. Guild v.*

Cameron, 995 F.3d 540, 547 (6th Cir. 2021) (quotation omitted); *see also Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 107 (1998) ("Obviously, . . . a plaintiff cannot achieve standing to litigate a substantive issue by bringing suit for the cost of bringing suit."). CHD fails to show how such previously incurred costs are redressable. Further, because the parents have not demonstrated an injury in fact, CHD has not established associational standing.

III. Conclusion

Because Plaintiffs fail to show that they have standing, we AFFIRM the district court and DISMISS the suit for lack of jurisdiction.

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS, U.S. DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, WACO DIVISION (JANUARY 12, 2023)

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

CHILDREN'S HEALTH DEFENSE, DEBORAH L. ELSE, SACHA DIETRICH, AIMEE VILLELLA MCBRIDE, JONATHAN SHOUR, AND REBECCA SHOUR,

Plaintiffs,

v.

FOOD & DRUG ADMINISTRATION AND ROBERT M. CALIFF,

Defendants.

No. 6:22-CV-00093-ADA

Before: Alan D. ALBRIGHT, U.S. District Judge.

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Before the Court is Defendants Food & Drug Administration ("FDA") and FDA Commissioner Robert M. Califf's Motion to Dismiss for Lack of Subject-

Matter Jurisdiction and Failure to State a Claim filed on July 29, 2022. ECF No. 29. Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour filed a response to Defendants' Motion on August 26, 2022. ECF No. 30. Defendants filed a reply in support of their Motion on September 16, 2022. ECF No. 31. The Court held a hearing on the Motion on November 18, 2022. ECF No. 33.

After considering the parties' briefing, the arguments at the hearing, the relevant facts, and the applicable laws, the Court GRANTS Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction. The Court concludes that Plaintiffs lack standing to sue. The Court does not reach the other issues in Defendants' Motion.

I. Background

On March 27, 2020, the Secretary of the Health and Human Services determined that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." Emergency Use Authorization Declaration, 85 Fed. Reg. 18250, 18250-51 (Apr. 1, 2020). In December 2020, FDA issued emergency use authorizations (EUAs) for the COVID-19 vaccines produced by Pfizer-BioNTech and ModernaTX, Inc. Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic, 86 Fed. Reg. 5200, 5201 (Jan. 19, 2021). On October 29, 2021, FDA revised the EUA to authorize administration of the Pfizer vaccine to children ages five to eleven. ECF No. 26-1 at 106 n.12. On June 17, 2022, the FDA further revised the EUA to authorize the administration of the

Pfizer vaccine to children ages 6 months to 4 years. *Id.* at 107. The FDA states on its website that "there is an option to accept or refuse receiving the vaccine." ECF No. 29 at 3. The FDA also states that "[s]hould you decide for your child not to receive it, it will not change your child's standard medical care." *Id.*

In May 2021, CHD filed a petition with the FDA asking the agency to revoke the existing EUAs for the COVID-19 vaccine. *Id.* at 3-4. The FDA denied this petition. *Id.* at 4. On January 24, 2022, Plaintiffs filed this action against Defendants. ECF No. 1. In its first Complaint, Plaintiffs alleged that the FDA failed to comply with the Administrative Procedures Act (APA) when it approved the COVID-19 vaccine for children. *Id.* ¶ 18. On April 25, 2022, Defendants filed their first Motion to Dismiss Plaintiffs' Complaint for lack of jurisdiction and for failure to state a claim. ECF No. 18. Defendants argued that this Court lacked subject-matter jurisdiction because no Plaintiff has standing to sue and sovereign immunity bars Plaintiffs' cause of action. *Id.* at 6. In the alternative, Defendants argued that the case should be dismissed for failure to plausibly state a claim for relief. *Id.* at 15. The Court held a hearing on Defendants' first Motion to Dismiss on May 17, 2022. ECF No. 25. At the hearing, the Court granted Defendants' Motion to Dismiss for lack of subject matter jurisdiction without prejudice. *Id.* Based on Plaintiffs' first Complaint, the Court found that Plaintiffs lacked standing to sue and did not rule on the other grounds for Defendants' Motion to Dismiss. The Court granted Plaintiffs leave to amend their complaint.

Plaintiffs filed their Amended Complaint on July 1, 2022. ECF No. 26. In their Amended Complaint,

Plaintiffs reallege that the FDA failed to comply with the APA when it approved the COVID-19 vaccine for children. *Id.* ¶¶ 212-46. The individual Plaintiffs, Deborah L. Else, Sacha Dietrich, Aimee Villella McBride, Jonathan Shour, and Rebecca Shour, claim that they are in imminent risk of immediate harm because of the authorization and advertising of the COVID-19 vaccine for their children. *Id.* ¶¶ 9-12. Some of the individual Plaintiffs claim that they are at risk because their children may be coerced to receive the vaccine, may be forced to take the vaccine due to impending mandates, may receive the vaccine without parental consent, or may suffer adverse reactions should they be given the vaccine. *Id.* ¶¶ 10-11. Plaintiffs claim that "Defendants' arbitrary and capricious actions warrant a stay, a vacatur and remand." *Id.* ¶ 247. Plaintiffs also 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." *Id.* ¶ 249. Plaintiffs further ask the Court to order the FDA to use "the regular biologic licensure process that incorporates citizen participation." *Id.*

Defendants filed the present Motion in response to Plaintiffs' Amended Complaint. ECF No. 29. Defendants argue that Plaintiffs' Amended Complaint should be dismissed because the Court lacks subject-matter jurisdiction over Plaintiffs' claims. *Id.* at 5. Defendants argue that no Plaintiff has standing to sue. *Id.* at

6. Defendants argue that the individual Plaintiffs lack actual imminent risk of injury sufficient to meet the injury-in-fact requirement for standing. *Id.* at 6. Defendants argue that CHD lacks organizational and associational standing because none of its members possess standing. *Id.* at 11. Defendants further argue that if the Plaintiffs have standing, sovereign immunity bars the suit. *Id.* at 5-6. Lastly, Defendants argue that even if this Court has subject-matter jurisdiction over the claim, Plaintiffs' Amended Complaint should be dismissed for failure to plausibly state a claim for relief. *Id.* at 16. The Court held a hearing on this motion on November 18, 2022. ECF No. 33. The Court took Defendants' Motion under advisement. *Id.*

II. Legal Standard

The law of standing is built around "the idea of separation of powers." *Trans Union LLC v. Ramirez,* 141 S. Ct. 2190, 2203 (2021). For a federal court to have subject-matter jurisdiction, the plaintiff must present a case or controversy under Article III of the Constitution. *Id.* In other words, the plaintiff must have standing. *Id.* To establish standing, the plaintiff must show: (1) the plaintiff has suffered an injury in fact, (2) there is a casual connection between the injury and the defendant's conduct, and (3) the plaintiff s injury would likely be redressed through judicial relief. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560-61 (1992).

"Under Article III, federal courts do not adjudicate hypothetical or abstract disputes." *Trans Union,* 141 S. Ct. at 2203. The plaintiff must show an "injury in fact that is concrete, particularized and actual or imminent." *Id.* For an injury to be "concrete," it must

be "real, and not abstract." *Id.* at 2204. An injury-in-fact cannot be "'conjectural' or 'hypothetical.'" *Susan B. Anthony List v. Driehaus,* 573 U.S. 149, 158 (2014) (quoting *Lujan,* 504 U.S. at 560). When evaluating whether a harm is "concrete," courts consider "whether the asserted harm has a 'close relationship' to a harm traditionally recognized as providing a basis for a lawsuit in American courts—such as physical harm, monetary harm, or various intangible harms." *Trans Union,* 141 S. Ct. at 2204. Mental angst from an alleged violation that impacts the public at large is typically not considered a concrete harm. *See Hein v. Freedom From Religion Foundation, Inc.,* 551 U.S. 587, 633 (2007) (Scalia, J., concurring) (concluding that a taxpayer's mental angst is merely a generalized grievance and is not an injury-in-fact); *Lujan,* 504 U.S. at 573-574 (concluding that a "generally available grievance about the government" is not sufficient for standing). The Supreme Court has held that "the psychological consequence presumably produced by observation of conduct with which one disagrees" is "not injury sufficient to confer standing under Art. III." *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.,* 454 U.S. 464, 485 (1982). The Sixth Circuit has held that "the purported indignity of receiving a letter" is a "psychic injury [that] falls well short of a concrete harm needed to establish Article III standing." *Glennborough Homeowners Assn v. U.S. Postal Serv., 21* F.4th 410, 415 (6th Cir. 2021).

For an injury-in-fact to be "imminent," "there must be at least a 'substantial risk' that the injury will occur." *Stringer v. Whitley,* 942 F.3d 715, 721 (5th Cir. 2019) (quoting *Susan B. Anthony List,* 573 U.S. at 158). "[A]llegations of possible future injury are not

sufficient." *Clapper v. Amnesty Int'l USA,* 568 U.S. 398, 409 (2013). An injury is not "imminent" where "the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control." *Lujan,* 504 U.S. at 564 n.2.

An organization can have associational or organizational standing. To have associational standing, the organization must show: (1) that its members independently possess Article III standing, (2) "the interests the association seeks to protect are germane to the purpose of the organization," and (3) the claim and the relief requested does not require participation of the individual members. *Ctr. for Biological Diversity v. U.S. EPA,* 937 F.3d 533, 536 (5th Cir. 2019). To have organizational standing, the organization must show a "concrete and demonstrable injury to [its] activities with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 379 (1982). "Not every diversion of resources to counteract the defendant's conduct, however, establishes an injury in fact." *NAACP v. City of Kyle,* 626 F.3d 233, 238 (5th Cir. 2010). "For example, the mere fact that an organization redirects some of its resources to litigation and legal counseling in response to actions or inactions of another party is insufficient to impart standing upon the organization." *Louisiana ACORN Fair Housing v. LeBlanc,* 211 F.3d 298, 305 (5th Cir. 2000) (quotations omitted).

With respect to procedural injuries, the Supreme Court has "consistently held that a plaintiff raising only a generally available grievance about government—claiming only harm to his and every citizen's

interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him that it does the public at large—does not state an Article III case or controversy." *Lujan,* 504 U.S. at 573-574. Further, "Congress's creation of a statutory prohibition or obligation and a cause of action does not relieve courts of their responsibility to independently decide whether a plaintiff has suffered a concrete harm." *Trans Union,* 141 S. Ct. at 2205. "[A] bare procedural violation, divorced from any concrete harm" does not satisfy the injury-in-fact requirement of Article III. *Spokeo, Inc. v. Robins,* 578 U.S. 330, 341 (2016).

The plaintiff has the burden of showing that it has standing. *Trans Union,* 141 S. Ct. at 2207. When considering standing at the motion-to-dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice" and the court presumes that "general allegations embrace those specific facts that are necessary to support the claim." *Lujan,* 504 U.S. at 561.

III. Analysis

The Court first considers whether it has subject-matter jurisdiction over this case. Defendants argue that both the individual Plaintiffs and CHD lack standing to sue. The Court considers whether each group of Plaintiffs has standing below.

A. The Individual Plaintiffs Lack Standing to Sue

Defendants argue that the individual Plaintiffs lack standing to sue because they have not suffered an injury in fact. ECF No. 29 at 6. The individual Plain-

tiffs have alleged the following injuries: (1) imminent risk of harm from the vaccine EUAs and (2) harm from vaccine advertising and loss of confidence in the FDA. The Court considers whether either of the individual Plaintiffs' alleged injuries meet the injury-in-fact requirement below.

1. Imminent Risk of Harm from the Vaccine EUAs

With respect to the individual Plaintiffs' allegation of harm from the vaccine EUAs, Defendants argue that Plaintiffs fail to allege a "substantial risk that the injury will occur." *Id.* at 6-7 (quoting *Stringer,* 942 F.3d at 721). Defendants argue that the FDA does not require children, or the public at large, to receive the vaccine. *Id.* at 7. Defendants argue that the individual Plaintiffs allege "an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiffs own control." *Id.* (quoting *Lujan,* 504 at 564 n.2). Defendants further argue that the individual Plaintiffs do not plead an imminent injury from any particular source. *Id.* at 8.

For the individual Plaintiffs in Texas, Deborah Else and Sacha Dietrich, Defendants point out that Texas law permits parents to consent or not to consent to receiving the vaccine. *Id.* (citing Tex. Fam. Code. § 151.001(6)). While Else and Dietrich fear that another adult may authorize immunization of their children against their wishes, Defendants argue that Texas law prohibits this possibility. *Id.* Defendants further argue that Else and Dietrich's alleged imminent risk of harm from social pressure and impending mandates does not meet the injury-in-fact requirement. *Id.*

Defendants point out that the Governor of Texas has prohibited any entity of Texas from requiring individuals to receive the vaccine. *Id.* (citing Executive Order GA-40 (Oct. 11, 2021)). With respect to the allegation that children in Texas are being denied medical services, Defendants argue that the Amended Complaint fails to provide facts demonstrating that Else and Dietrich's children face an imminent risk that they will be denied medical treatment. *Id.* at 9. Defendants argue that this remote possibility of harm does not meet the injury in fact requirement. *Id.*

For the individual Plaintiff in Florida, Aimee Villella McBride, Defendants argue that McBride fails to allege an imminent risk of harm. *Id.* Defendants argue that because Florida law prohibits educational institutions from requiring the COVID-19 vaccine for any student, McBride does not face an imminent risk of impending mandates. *Id.* Finally, for the individual Plaintiffs in North Carolina, Jonathan and Rebecca Shour, Defendants also argue that the Shours fail to allege an imminent risk of harm. *Id.* Defendants argue that because North Carolina law prohibits a health care provider from administering the vaccine to children without written consent from a parent or guardian, there is no imminent risk of harm that the Shour children will be given the COVID-19 vaccine without their consent. *Id.* at 9-10. While the Shours claim that they face imminent risk of harm because they may be moved elsewhere in the country for work and that state may have a vaccine mandate, Defendants argue that this hypothetical harm is too speculative to meet the injury-in-fact requirement. *Id.* at 10.

In response, Plaintiffs argue that exposure to potentially harmful products can satisfy the injury-in-

fact requirement. ECF No. 30 at 12 (citing *Baur v. Veneman,* 352 F.3d 625 (2d Cir. 2003)). Further, Plaintiffs argue that agency actions that create health-related uncertainty satisfy the injury-in-fact requirement. *Id.* (citing *New York Pub. Int. Rsch. Grp. v. Whitman,* 321 F.3d 316 (2d Cir. 2003)). Plaintiffs also argue that impairing parents' medical control over their children has been found to satisfy the injury-in-fact requirement. *Id.* (citing *Tummino v. Torti,* 603 F. Supp.2d 519 (E.D.N.Y. 2009)).

Additionally, Plaintiffs argue that all of the individual Plaintiffs have shown that they are directly threatened by the FDA's EUAs. Plaintiffs argue that the individual Plaintiffs' children "face the risk of expanding vaccine mandates, including those preventing them from receiving lifesaving transplants and medical treatment." *Id.* at 13-14. And while the Governor of Texas has banned vaccine mandates by executive order, Plaintiffs claim that this "executive order has not prevented discriminatory and cruel treatment towards the unvaccinated—particularly children." *Id.* at 14. Plaintiffs also argue that the Shours are at risk from mandates around the country because the family may move to any state in the future due to Chaplain Shour's employment in the U.S. Navy. *Id.* Plaintiffs also claim that under Texas law, adults other than a child's parent can consent to vaccination. *Id.* Lastly, Plaintiffs argue that they have also been harmed because they can no longer rely on the FDA's representations in the future. *Id.* at 15.

The Court finds that the individual Plaintiffs have not suffered an injury in fact as a result of the vaccine EUAs. The individual Plaintiffs have failed to show that they face imminent harm due to the FDA's

EUAs. The individual Plaintiffs merely allege a speculative threat of harm from vaccination by a non-parent or impending vaccine mandates. But this type of speculative harm is insufficient to meet the injury-in-fact requirement. None of the individual Plaintiffs meet their burden of showing that the risk of future harm is "imminent." To plead an imminent future harm, Plaintiffs must show that "there is a substantial risk that the injury will occur." *Stringer,* 942 F.3d at 715. The individual Plaintiffs claim that there is a risk that someone will authorize a vaccine for their children sometime in the future. However, under at least Texas and Florida law, vaccination cannot be mandatory. Tex. Executive Order GA-40 (Oct. 11, 2021); Fla. Stat. § 381.00319. Further, under at least Texas and North Carolina law, individuals other than the child's parent are not permitted to vaccinate a child. Tex. Fam. Code § 32.101(b)—(c); N.C. Gen. Stat. § 90-21.5(a1). Because the applicable state laws prevent mandatory vaccination and vaccination without parental consent, the individual Plaintiffs have failed to allege a substantial risk that injury will occur.

Further, with respect to the Shours, Plaintiffs have alleged that the Shours are at risk because they may be subject to mandates in another state if the Navy requires the family to move. Plaintiffs allege that the Shour children may be discriminated against or ostracized from certain activities if they move to a state with a vaccine mandate. ECF No. 30 at 14. But here, Plaintiffs merely assert "allegations of possible future injury." *Clapper,* 568 U.S. at 409. Such allegations are insufficient to confer standing. *Id.* Plaintiff have failed to show that there is a substantial risk that

the Shours will move to a state with a vaccination mandate that will require the Shour children to be vaccinated to participate in certain activities.

Many of the cases cited by Plaintiffs are distinguishable and nonbinding. In *Baur v. Veneman,* the plaintiff alleged a credible threat of harm from exposure to potentially unsafe food products. *Baur,* 352 F.3d at 641. In *Baur,* the plaintiff provided data showing that the threat of harm arising from the agency action. *Id.* at 629. The plaintiff's data was confirmed by the agency's research. *Id.* at 638-640. Further the threat of harm was directly tied to the agency action. *Id.* at 640. Here, the Court has found that the individual Plaintiffs have failed to allege a credible threat of harm. The individual Plaintiffs merely allege that there is a chance that their children may be vaccinated against without their consent. Further, even if this threat were credible, it would be the direct result of independent third-party action, not the FDA's EUAs. Further, in *New York Public Interest Research Group v. Whitman,* the plaintiffs alleged that the EPA's failure to enforce the Clean Air Act caused health effects and uncertainty. 321 F.3d at 325. In *Whitman,* the court focused on the fact that the plaintiff s members lived near facilities that may be releasing excess pollutants, which presented specific personal and economic harms. *Id.* at 325-326. However, in that case, the individual Plaintiffs are not in any particular danger of exposure. The FDA's EUAs do not put the individual Plaintiffs at an imminent risk of exposure because parents are free to choose whether to consent to their children receiving the COVID-19 vaccine. The FDA has stated that "there is an option to accept or refuse receiving the vaccine." ECF No. 29

at 3. In *Tummino v. Torti,* the FDA's regulations *prohibited* parents from making a decision for their children's medical care. *Tummino,* 603 F.Supp.2d at 540 (explaining that under the challenged FDA action, parents are unable to legally obtain Plan B on behalf of their children). Here, the FDA, and relevant state laws, provide parents the choice of whether to consent to their children receiving the vaccines authorized by the FDA's EUAs.

For the foregoing reasons, the Court concludes that the individual Plaintiffs allegations that they are imminent risk of harm due to the FDA's EUAs fail to meet the injury-in-fact requirement under Article III.

2. Harm from Vaccine Advertising and Loss of Confidence in the FDA

With respect to the individual Plaintiffs' allegation of harm from vaccine advertising, Defendants argue that Plaintiffs "cursorily allege that their children have been exposed to so called 'pro vaccine messaging.'" ECF No. 29 at 6 n.2. Defendants argue that "'the purported indignity of receiving a' message with which one disagrees is 'a psychic injury [that] falls well short of a concrete harm needed to establish Article III standing.'" *Id.* (quoting *Glennborough Homeowners Ass'n,* 21 F.4th at 415). Defendants argue that the psychological toll of pro vaccine messaging has "no 'close historical or common-law analogue for their asserted injury.'" ECF No. 31 at 3 (quoting *Trans Union,* 141 S. Ct. at 2204). Defendants claim that such psychological toll is not sufficient to confer standing. *Id.* With respect to Plaintiffs' allegations that they have suffered a loss of confidence in the FDA, Defendants argue that Plaintiffs have failed to allege a "real

and immediate threat of future harm." *Id.* at 4 (quoting *Funeral Consumers All, Inc. v. Serv. Corp. Int'l,* 695 F.3d 330, 343 (5th Cir. 2012)). Defendants assert that no plaintiff has claimed that it will refrain from using an FDA-approved products in the future and no plaintiff has explained how court-ordered relief would redress this alleged injury. *Id.*

Plaintiffs argue that they have suffered an injury from the "false advertising of COVID-19 shots." ECF No. 30 at 1. Plaintiffs also allege that the EUAs and false advertising caused the individual Plaintiffs to have a "complete collapse of confidence in the FDA." *Id.* at 3. Plaintiffs claim that the "FDA's misrepresentations have led to continuous coercion, propaganda, and advertisements aimed directly at children, to which Plaintiffs' children are subjected daily." *Id.* at 13. The individual Plaintiffs allege that such advertisements "harras[es]" and "pressure[s]" the Plaintiffs' children. *Id.* Plaintiffs claim that "coercive pressures, false advertising, and propaganda aimed at young children" presents an injury. *Id.* at 14. Plaintiffs allege that due to the FDA's EUAs and allegedly false advertising, the individual Plaintiffs "are no longer able to rely on FDA representations now or in the future." *Id.* at 15.

The Court finds that the individual Plaintiffs have not suffered an injury in fact as a result of vaccine advertising. Plaintiffs have merely alleged a "psychological consequence" "produced by observation of conduct with which one disagrees." *Valley Forge,* 454 U.S. at 485. The Supreme Court has found such an injury is not sufficient to confer standing. *Id.* The Court finds that any injury suffered as a consequence of the vaccine advertising is not sufficient to confer standing because it is not the type of harm that is "tra-

ditionally recognized as providing a basis for a lawsuit in American courts—such as physical harm, monetary harm, or various intangible harms." *Trans Union,* 141 S. Ct. at 2204.

As to Plaintiffs' allegations that it has suffered a harm due to its loss of confidence in the FDA, the Court also finds that this injury does not give rise to Article III standing. Because Plaintiffs have failed to allege that this loss of confidence will alter their purchasing decisions in the future, any loss of confidence that the individual Plaintiffs have suffered does not present a real and immediate risk of future harm. *See Funeral Consumers,* 695 F.3d at 342 (determining that the plaintiff lacked standing where there was no "real or immediate threat" that the plaintiff would purchase the allegedly overpriced product). Because the individual Plaintiffs have not alleged that the loss of confidence presents a real and immediate risk of harm, the allegation that Plaintiffs have suffered a loss of confidence in the FDA does not give Plaintiffs standing to sue.

For the foregoing reasons, the Court finds that the individual Plaintiffs lack standing to sue under Article III.

B. CHD Lacks Standing to Sue

Defendants argue that CHD lacks both associational standing and organizational standing. ECF No. 29 at 11. To have associational standing, the organization must show that its members independently possess Article III standing. *Ctr. for Biological Diversity,* 937 F.3d at 536. Because the Court has determined that the individual Plaintiffs, the only identified members of CHD, failed to show that they independently possess

Article III standing, the Court finds that CHD lacks associational standing.

As for organizational standing, CHD must show a "concrete and demonstrable injury to [its] activities– with the consequent drain on [its] resources," not "simply a setback to [its] abstract social interests." *Havens Realty Corp.,* 455 U. S. at 379. Defendants argue that CHD merely alleges a vague and conclusory claim that the FDA's conduct has caused a serious diversion of CND's resources. ECF No. 29 at 11. Defendants argue that CHD has failed to show any specific projects that CHD had to put on hold to respond to the FDA's conduct. *Id.* at 12. Defendants argue that the actions taken by CHD in response to the FDA's conduct are routine activities for the organization, which exists to protect and promote the health and wellbeing of children. *Id.* Defendants point to Fifth Circuit law, which states that "an organization does not automatically suffer a cognizable injury in fact by diverting resources in response to a defendant's conduct." ECF No. 31 at 5 (quoting *El Paso Cnty. v. Trump,* 982 F.3d 332, 343 (5th Cir. 2020)). Further, Defendants point to Fifth Circuit law, which states that the organization must show that any diversion of resources "concretely and 'perceptibly impaired'" its "ability to carry out its purpose." *Id.* (quoting *City of Kyle,* 626 F.3d at 239).

In response, CHD argues that it has organizational standing based on the concrete and demonstrable injury that the organization's activities have suffered due to "a consequent drain on the organization's resources." ECF No. 30 at 5 (quoting *Havens Realty Corp.,* 455 U.S. at 378). CHD complains that the FDA's actions have required CHD to "undergo a complete

revamping of its budgeted plans." *Id.* at 3. CHD argues that the diversion of its resources, on its own, is sufficient to meet the injury in fact requirement under Article III. *Id.* at 7. CHD argues that it diverted resources in response to the FDA's conduct by: (1) investigating the FDA's actions and conducting its own studies on the vaccines, (2) working with its members to deal with the coercion and pressure to vaccinate, and (3) publishing newsletters, online video news, and live commentary to educate the public on the FDA's alleged misinformation. *Id.* at 9.

With respect to CHD's claim for organizational standing, the Court finds that CHD has not alleged a drain on its resources due to the FDA's conduct that would give rise to standing. The Fifth Circuit has stated that "[n]ot every diversion of resources to counteract the defendants conduct . . . establishes an injury in fact." *City of Kyle,* 626 F.3d at 238. In *City of Kyle,* the plaintiff organization claimed that its prelitigation studies and correspondence on the impact of the government conduct diverted the organization's resources. *Id.* However, the Fifth Circuit concluded that the plaintiff organization failed to explain how these activities "differ from the [organization's] routine lobbying activities." *Id.* The Fifth Circuit determined that the organization lacked standing because "Plaintiffs have not demonstrated that the diversion of resources here concretely and 'perceptibly impaired' the [organization's] ability to carry out its purpose." *Id.* at 239. Here, CHD has similarly failed to show how its efforts in response to the FDA's EUAs differ from its ordinary activities. Further, CHD has failed to show how the diversion of resources in response to the FDA's conduct has "concretely and 'perceptibly

impaired'" CHD's ability to carry out its purpose. *Id.* Thus, the Court determines that CHD has failed to show that it has organizational standing based on the diversion of its resources in response to the FDA's conduct.

CHD also argues that it has standing to enforce the APA. *Id.* at 7. CHD argues that the APA creates standing for "a person suffering legal wrong because of agency action." *Id.* at 9 (quoting 5 U.S.C. § 702). In response, Defendants argue that a bare procedural violation does not give rise to Article III standing. ECF No. 29 at 12. Defendants argue that CHD has failed to show that its procedural injury is "concrete and particular, as opposed to an undifferentiated interest in the proper application of the law." *Id.* at 12-13 (quoting *Sierra Club v. Glickman,* 156 F.3d 606, 613 (5th Cir. 1998)).

With respect to CHD's claim to standing under the APA, the Court concludes that CHD's procedural injury is merely a generalized grievance. The Supreme Court has "consistently held that a plaintiff raising only a generally available grievance about government—claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him that it does the public at large—does not state an Article III case or controversy." *Lujan,* 504 U.S. at 573-574. The procedural harm allegedly suffered by CHD is not concrete and particularized to CHD-it is the same procedural harm suffered by the public at large. Thus, CHD's alleged procedural harms do not give rise to standing under Article III.

IV. Conclusion

For the foregoing reasons, the Court GRANTS Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction. The Court concludes that all Plaintiffs lack standing to sue. The Court does not rule on Defendants' Motion to Dismiss for Failure to State a Claim. This case is hereby DISMISSED with prejudice.

SIGNED this 12th day of January, 2023.

/s/ Alan D. Albright
United States District Judge

FIRST AMENDED COMPLAINT
(JANUARY 12, 2023)

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 M. CALIFF, COMMISSIONER OF FDA,

Defendants.

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 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 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)

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

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

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

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]

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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/.

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]

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,

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[3] 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.

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

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[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.

[5] Biden White House Pledges Data, Transparency, Respect for Free Press, *Reuters* (January 20, 2021), available at https://www.

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 un-elected 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

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reuters.com/article/us-usa-biden-briefing-idUSKBN29Q08S.

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 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.

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[6] Vaccine Adverse Event Reporting System (VAERS), *CDC Wonder*, available at https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=67A4CC1D3E7D207433E5332EA BDF.

[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

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.

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]

J. 2004 Apr;23(4):287-94. doi: 10.1097/00006454-200404000-00002. PMID: 15071280.

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

[10] Meryl Nass, Did CDC Deliberately Mislead Public on Allergic

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.

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

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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/.

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 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

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

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

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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.

one week after receiving each dose due to cases of myocarditis. . . . "[15]

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

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[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/.

[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.

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 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

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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):1562–15 65. 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.

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)

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

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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/covid19d eathsandautopsiesfeb2020todec2021.

[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.

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 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

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21203/rs.3.rs-689684/v1.

[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.

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]

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."

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[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.

[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.

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 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

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

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 com-

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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.

mittee 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 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

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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.

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, 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

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[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.

[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.

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.

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

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[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.

[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.

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 not preorder any COVID-19 vaccines for young children

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

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

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[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).

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 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,

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[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/.

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."

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]

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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.

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.

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 bomb-

arded 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 take the vaccine, without full knowledge of the child's medical

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[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.

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

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[46] *Id.* at 8.

[47] *Id.*

[48] *Id.* at 9.

[49] *Id.* at 10.

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]

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

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[50] *Id.* at 11.

[51] *Id.* at 19.

[52] *Id.*

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.

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

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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/Conservatorshi p/Children_in_Conservatorship.asp.

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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[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.
>
> (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:

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.

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(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."

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?

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 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

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[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/.

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 statewide 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 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

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[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.

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.

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

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 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

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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/

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]

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]

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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/.

[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), https://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.htm.

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.

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

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

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.

144. The FDA is required to perform an environmental assessment for gene therapy products.[65] Be-

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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.

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.

cause 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 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.

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.

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[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

[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.

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.

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, 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

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

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

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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.

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.

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

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[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.

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 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

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[73] *Id.*

[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.*

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 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.

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[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/

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;"

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[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

"protocol 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

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[79] *Ibid.*

[80] *Ibid.*

[81] *Ibid.*

[82] *Ibid.*

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 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

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

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 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.

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

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 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]

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[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.

[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.

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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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

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[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.

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 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-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]

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[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.

[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.

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]

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]

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[94] Moderna Gets Contract to Produce 200M COVID-19 Vaccines for DOD, *Fox10,* June 21, 2021, available at https://www.fox10-phoenix.com/news/moderna-gets-contract-to-produce-200m-covid-19-vaccines-for-dod.

[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.

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.*

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[96] Klein NP, Lewis N, Goddard K, et al. Surveillance for Adverse Events After COVID-19 mRNA Vaccination. *JAMA*. 2021;326 (14):1390–139 9. doi:10.1001/jama.2021.15072.

Botsford, 141 U.S. 250, 251 (1891). The famed Justice 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

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97 Edward Hooper, The River: A Journey to the Source of HIV

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]

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

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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.

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

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 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.

220. Young children are the most protected from SARS-CoV-2. Children that do contract COVID-19

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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.

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

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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.research-square.com/article/rs-689684/v1.

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.

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

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

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 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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