


No. \_\_\_\_\_

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**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.*

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

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**PETITION FOR A WRIT OF CERTIORARI**

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## 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

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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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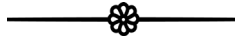
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## OPINIONS BELOW

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)<sup>1</sup>. 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?<sup>2</sup> 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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<sup>1</sup> “Rule” refers herein to the Rules of the Supreme Court of the United States.

<sup>2</sup> *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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