NO. 22-_____

In the Supreme Court of the United States

CHILDREN'S HEALTH DEFENSE
AND AMY MILLER,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION
AND JANET WOODCOCK, M.D.,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

ROBERT E. BARNES, ESQ.
COUNSEL OF RECORD
BARNES LAW
700 SOUTH FLOWER STREET
SUITE 1000
LOS ANGELES, CA 90017
(310) 510-6211
ROBERTBARNES@BARNESLAWLLP.COM

DECEMBER 21, 2022 *COUNSEL FOR PETITIONERS*

SUPREME COURT PRESS ♦ (888) 958-5705 ♦ BOSTON, MASSACHUSETTS

QUESTIONS PRESENTED

1. Whether a Constitutionally cognizable case or controversy exists under Article III when agency action is a substantial factor in the actions of an independent third party that inflicts the injury?

2. Whether a Constitutionally cognizable case or controversy exists under Article III when agency action increases the risk of injury?

3. Whether a Constitutionally cognizable case or controversy exists under Article III when agency action causes an organization to divert resources for pre-litigation investigation of the agency's action?

PARTIES TO THE PROCEEDINGS

Petitioners and Plaintiffs-Appellants below

- Children's Health Defense
- Amy Miller

Respondents and Defendants-Appellees below

- United States Food and Drug Administration
- Janet Woodcock, M.D.

RULE 29.6 STATEMENT

Neither Petitioner Children's Health Defense, nor Petitioner Amy Miller, are nongovernment corporations. Consequently, said Petitioners do not have a parent corporation or shares held by a publicly traded company.

LIST OF PROCEEDINGS BELOW

United States District Court for the Eastern District of Tennessee (Chattanooga)

No. 1:21-CV-00200-DCLC-CHS

Children's Health Def., et al., *Plaintiffs,* v.
Food and Drug Admin., et al., *Defendants*

Date of Final Opinion: November 30, 2021
(Order Granting Defendants' Motion To Dismiss and Dismissing Plaintiffs' Complaint (the "Order of Dismissal") and Judgment Dismissing Plaintiff's Amended Complaint (the "Judgment of Dismissal")

United States Court of Appeals for the Sixth Circuit

No. 21-6203

Children's Health Defense; Amy Miller,
Plaintiffs-Appellants, v.
United States Food and Drug Administration;
Janet Woodcock, MD, *Defendants-Appellees*

Date of Final Opinion and Judgment: July 12, 2022
(The "Opinion" affirming district court)

Date of Rehearing Denial: September 22, 2022

TABLE OF CONTENTS

TABLE OF CONTENTS – Continued

TABLE OF CONTENTS – Continued

Page

APPENDIX TABLE OF CONTENTS

OPINIONS AND ORDERS

REHEARING ORDER

TABLE OF CONTENTS – Continued

Page

OTHER DOCUMENTS

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES – Continued

Page

STATUTES

TABLE OF AUTHORITIES – Continued

TABLE OF AUTHORITIES – Continued

Page

OPINIONS BELOW

The Opinion of the United States Court of Appeals for the Sixth Circuit dated July 12, 2022, is found in the Appendix (hereinafter "App.") at App.1a-12a. The Memorandum Opinion and Order of the United States District Court for the Eastern District of Tennessee, dated November 30, 2021, is included at App.15a-31a. The district court judgment, also dated November 30, 2021, is included at App.31a-32a. These opinions were not designated for publication.

JURISDICTION

The Court of Appeals entered its Opinion on July 12, 2022. App.1a-12a. Its Order Denying Rehearing was entered September 22, 2022. App.33a-34a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

5 U.S.C. § 706(2)(A)

> 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—

[. . .]

(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;

STATEMENT OF THE CASE

A. Proceedings in the District Court Below

On September 23, 2021, Petitioners filed an Amended Complaint, alleging a single cause of action under the Administrative Procedures Act codified in 5 U.S.C. § 706(2)(A) (the "Amended Complaint"). App. 47a-276a. The Amended Complaint alleged that Respondents United States Food and Drug Administration and Janet Woodcock (collectively "Respondents" and "Respondent") violated 5 U.S.C. § 706(2)(A), when it performed a bait-and-switch with COVID-19 vaccines, that led the Department of Defense to mandate the vaccine on its members, when no licensed vaccine was then available to be mandated, and when the EUA (Emergency Use Authorized) vaccine could not be legally mandated on members.

On October 14, 2021, Respondents filed a Motion to Dismiss Plaintiffs' Amended Complaint pursuant to Federal Rules of Civil Procedure, Rule 12(b)(1) (the "Motion to Dismiss"). App.2a. On November 30, 2021, the District Court granted Respondents' Motion to Dismiss and entered the Judgment of Dismissal without leave to amend. App.5a. The grounds for dismissal

asserted by the District Court, were that it lacked subject matter jurisdiction because Petitioners lacked Article III standing to bring the claims alleged in their Amended Complaint. *Ibid.*[1]

On December 16, 2021, Petitioners filed a timely Notice of Appeal, seeking review by the Seventh Circuit Court of Appeals of the District Court's Order of Dismissal and Judgment of Dismissal. App.5a.

B. Proceedings in the Court of Appeals Below

On December 17, 2021, the Court of Appeals docketed Petitioners' appeal. App.2a. On June 1, 2022, the cause was submitted on the briefs to a panel consisting of Judges Gibbons Rogers and Murphy. App.1a-12a. On July 12, 2022, the Court of Appeals entered the Opinion, affirming the District Court's rulings. App.1a-12a. On September 22, 2022, the Court of Appeals entered its Order Denying Rehearing (App.33a-34a), and issued the Mandate on September 30, 2022.

---

[1] The Judgment of Dismissal also denied Petitioners' separate motions to stay Respondents' licensure of the Pfizer *Comirnaty* COVID-19 vaccine under 5 U.S.C. § 705, without consideration of the merits of those motions, in light of the District Court's dismissal of the entire action without leave to amend. The District Court's rulings on said motions to stay are not at issue on this Petition. App.5a.

REASONS FOR GRANTING THE PETITION

There are two fundamental reasons to grant this petition: first, the clear conflict between the Circuits on the important matter of defining what constitutes a Constitutionally cognizable case or controversy sufficient to give an injured party standing to seek judicial redress of injury from agency action; and second, this critical question of Constitutional law in a matter of great public importance concerning emergency power exceptions to legislative limit or judicial review governing a drug coerced to millions without informed consent—warrants this Court settling the matter with clarity.

I. THE CIRCUITS SPLIT ON WHETHER A CONSTITUTIONALLY COGNIZABLE CASE OR CONTROVERSY EXISTS FOR INJURIES INVOLVING INDEPENDENT THIRD PARTIES.

The Court of Appeals' aforementioned analysis of Petitioners' associational standing and causation of third-party injury conflicts with decisions by other Circuit Courts.

The Court of Appeals held that Petitioners' alleged injuries are not "fairly traceable" to the Respondent agency's actions, because an independent third party, another federal agency, directly caused the injury, regardless of the substantial role the Respondent agency's action played in causing the other federal agency to take the action it did. App.8a-10a. This holding directly conflicts with several other circuits.

Specifically, the Sixth Circuit's ruling in this matter conflicts with decisions issued by the D.C. Circuit, the Second Circuit, the Fifth Circuit, and the Ninth Circuit. In contrast with the Sixth Circuit's decision in this case, each of those other Circuits adopted the same "substantial factor" or "causal connection" test for independent third parties causing the injury, requiring only that a party allege that the agency action was a link in the chain of the injury, not the only or last link in the chain, as the Court of Appeals found here.

The D.C. Circuit conflicts with the decision below by the Sixth Circuit as well. In the D.C. Circuit, the defendant's action needs only be a "substantial factor" in the plaintiff's alleged injury. *Tozzi v. HHS*, 271 F.3d 301, 308 (D.C. Cir. 2001) ("*Tozzi*"). In *Tozzi,* the D.C. Circuit held: "Where, as here, the alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties, we have required only a showing that the agency action is at least a substantial factor motivating the third parties' actions." *Tozzi, supra,* 271 F.3d 301, 308 (D.C. Cir. 2001).

Equally, the Second Circuit disagreed with the Sixth Circuit's decision below. In *Oneida Indian Nation v. United States Dep't of the Interior,* 336 F.Supp.3d 37, 47 (N.D.N.Y. 2018), *aff'd,* 789 F. App'x 271 (2nd Cir. 2019), the Second Circuit adopted the same standard articulated in *Tozzi*: "Where an 'alleged injury flows not directly from the challenged agency action, but rather from independent actions of third parties,' the plaintiff must show 'that the agency action is at least a substantial factor motivating the third parties' actions.' [citing *Tozzi, supra,* 271 F.3d at 308]."

The Third Circuit, citing this Court's warnings, also disagrees with the decision below by the Sixth Circuit. In the context of Constitutional standing, "the Supreme Court has cautioned against 'wrongly equating injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation.'." *Constitution Party of Pennsylvania v. Aichele*, 757 F.3d 347, 366 (3rd Cir. 2014) (brackets and ellipsis omitted) (quoting *Bennett v. Spear*, 520 U.S. 154, 168-69, 117 S.Ct. 1154, 137 L.Ed.2d 281 (1997) ("*Bennett*")).

The Fifth Circuit also disagrees with the decision by the Sixth Circuit below. In *Inclusive Communities Project, Inc. v. Department of Treasury,* 946 F.3d 649, 655 (5th Cir. 2019), the Fifth Circuit held that "[e]ven though Article III requires a causal connection between the plaintiff's injury and the defendant's challenged conduct, it doesn't require a showing of proximate cause or that 'the defendant's actions are the very last step in the chain of causation.'." (citing *Bennett, supra,* 520 U.S. at 169).

The Ninth Circuit also disagrees with the decision below of the Sixth Circuit. The Ninth Circuit held the causation necessary for a Constitutionally cognizable case or controversy "may be found even if there are multiple links in the chain connecting the defendant's unlawful conduct to the plaintiff's injury, and there's no requirement that the defendant's conduct comprise the last link in the chain." *Mendia v. Garcia,* F.3d 1009, 1013 (9th Cir. 2014); *see also Renee v. Duncan,* 623 F.3d 787, 797 (9th Cir. 2010), *opinion supplemented on reh'g,* 686 F.3d 1002 (9th Cir. 2012) (holding that there was a causal connection between the promulgation of the federal regulation challenged in this

case and the later promulgation of a state regulation which were adopted as a result).

The Sixth Circuit affirmed the District Court's order granting Respondents' motion to dismiss under Rule 12(b)(1). App.1a-12a. The Court of Appeal's holding was on the grounds that an insufficient causal connection between Respondents' actions and the alleged injury to Petitioners, existed. This holding by the Court of Appeals was in conflict with the holdings of this Court and Circuit Courts discussed above. Without the Respondent agency's improper "bait and switch" approval of Pfizer's *Comirnaty* biologic, and the illicit extension of the emergency use authorization of Pfizer-BioNTech's biologic, none of Petitioners' injury would or even could occur. But for Respondent United States Food and Drug Administration's ("FDA's") emergency authorization of an experimental biologic and its illicit concurrent biologic approval, the Department of Defense would, and legally never could, mandate the vaccine for all military service members.

In the instant case, Petitioners' Amended Complaint adequately pled that the FDA was aware that its approval would trigger mandates for the COVID-19 vaccine not only for military members but across the country. There is a clear causal link between Respondents' action and the injury alleged as all injury stems directly from Respondents, without whom the injury at issue necessarily could not occur. The Court of Appeal's Opinion affirming the District Court's Order of Dismissal and Judgment of Dismissal directly conflicts with the above-discussed decisions by this Court (*Bennett, supra*, 520 U.S. at 154), as well as no less than five Circuit Courts (*Tozzi, supra,* 271 F.3d at 301; *Oneida, supra,* 336 F.Supp.3d at 37; *Constitution*

Party, supra, 757 F.3d at 347; *Inclusive Communities Project, supra,* 946 F.3d at 649; *Mendia, supra,* F.3d at 1009). This Court should grant review accordingly, pursuant to Rule[2] 10(a).

II. THE CIRCUITS SPLIT ON WHETHER A CONSTITUTIONALLY COGNIZABLE CASE OR CONTROVERSY EXISTS WHEN THE AGENCY ACTION INCREASES THE RISK OF INJURY.

The Sixth Circuit Court of Appeal's holding below also conflicts with other Circuits' standards for evaluating standing when agency actions increase the risk of injury to the public.

In *New York Public Interest Research Group v. Whitman*, 321 F.3d 316 (2nd Cir. 2003), the Second Circuit held that agency actions that increase health-related uncertainty constitute a remediable injury for a Constitutionally cognizable case or controversy. The grounds are that merely increasing the exposure to potentially harmful products constitutes a remedial injury that satisfies standing. In *Baur v. Veneman*, 352 F.3d 625, 636 (2nd Cir. 2003), the court recognized "exposure to enhanced risk as injury-in-fact" when the plaintiff alleged an increased risk of contracting a food-borne illness when the United States Department of Agriculture failed to ban the use of downed livestock as food for human consumption.

The D.C. Circuit Court similarly found injury when government agencies merely allowed potentially harmful drugs to enter the United States in *Beaty v. Food & Drug Administration,* 853 F.Supp.2d 30 (D.D.C.

---

2 All references to "Rule" herein, are to the Rules of the Supreme Court of the United States.

2012). In *Beaty*, the court found that death row inmates had Article III standing to pursue their claims against Food and Drug Administration and other agencies that alleged the FDA violated the Administrative Procedure Act by improperly allowing shipments of a misbranded and unapproved new drug to enter United States for use in state lethal injection protocols.

When the risk of a biologic is only possible due to the FDA's actions, then that risk constitutes a clearly cognizable case or controversy for those affected. Similarly, consumers can bring suit against the FDA when the agency has "increased the risk that they will purchase and consume unsafe or ineffective drugs." *Cutler v. Kennedy,* 475 F.Supp. 838, 848 (D.D.C 1979). If the FDA authorizes a biologic in violation of federal laws, and in doing so increases the risk that plaintiffs will be exposed to those drugs and deprives them of regulation to which they are entitled, this "risk and deprivation itself constitutes a distinct and palpable injury to plaintiffs' statutory interests as drug consumers." *Id.*

Indeed, under the standards articulated by the Second Circuit (*New York Public, supra,* 321 F.3d at 316; *Baur, supra*, 352 F.3d at 625) and the D.C. Circuit (*Beaty, supra,* 853 F.Supp.2d at 30; *Cutler, supra,,* 475 F.Supp. at 838), the FDA clearly injured Petitioners by not only enhancing, but initiating, the risk of individuals taking a harmful and experimental biologic. The Sixth Circuit's decision below thus conflicts with the D.C. and Second Circuits on when a Constitutionally cognizable case or controversy exists. Review by this Court should be granted for that reason as well pursuant to Rule 10(a).

III. THE CIRCUITS SPLIT ON WHETHER A CONSTITUTIONALLY COGNIZABLE CASE OR CONTROVERSY EXISTS FOR PRE-LITIGATION INVESTIGATION COSTS THAT DRAIN AN ORGANIZATION'S RESOURCES.

The Sixth Circuit rejected the idea that an organization pleads a Constitutionally cognizable case or controversy, where the injury alleged reflected the organization's pre-litigation costs investigating the agency action and seeking legal remedy therefore. App. 5a-6a. As pled and attached to their Amended Complaint, Petitioners' pre-litigation investigatory efforts included the research, drafting and filing of a 19-page Citizen Petition that assembled and memorialized a tremendous amount of detailed factual findings and research regarding: (i) the risks to public health and safety of Respondents' actions; (ii) effectiveness of vaccines (or rather lack thereof); (iii) Respondent FDA's misbranding of the vaccine authorizations; and (iv) the serious injuries and consequences spawned by the FDA's actions upon U.S. military service members and children. *See generally*: App.63a-94a.[3] The Court of Appeal's holding conflicts with the decisions of this Court, as well as decisions by the Second, Seventh, District of Columbia and Ninth Circuits.

In *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378 (1982), this Court held that an organization's pleading satisfies Article III standing, where it alleges

---

[3] In addition, as discussed more fully in the Petitioners' briefing to the Court of Appeals, Petitioners' pre-suit resources devoted to its programs and activities that were drained by Respondent's conduct, also included the additional man hours required to review Respondent's 52-page response to Petitioners' Citizen Petition. App.131a-240a.

a: "concrete and demonstrable injury to the organization's activities – with the consequent drain on the organization's resources . . . " Decisions of other Circuit Courts have expanded on the standard set forth in *Havens,* affirming that an organization's standing exists in its own right under Article III, where its pre-litigation efforts to evaluate and challenge government acts results in a drain on the organization's resources. *See*: *Maya v. U.S. Dept. Homeland Security*, 975 F.3d 120, 129-130 (2nd Cir. 2020); *Sierra Club v. Marita*, 46 F.3d 606, 612-613 (7th Cir. 1995); *Spann v. Colonial Village, Inc.*, 899 F.2d 24, 27 (D.D.C. Cir. 1990); *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review*, 959 F.2d 742, 748 (9th Cir. 1991).

The Sixth Circuit's holding that Petitioners lacked organizational standing under Article III conflicts with the above-discussed decisions by this Court and the Circuit Courts. Review by this Court should be granted for this reason as well.

IV. THIS CASE IS OF GREAT PUBLIC IMPORTANCE.

The Constitutional consequence of the Sixth Circuit's holding below, parallels the public impact of this case.

The Court of Appeals' decision would ensure that government agencies such as the FDA can operate unchecked and with no limits on its power. Emergency powers such as the one that allowed this biologic to be rushed to market should be limited to the most severe and unconventional circumstances and, as such, should be used reservedly. However, COVID-19 normalized the dangerous use of emergency powers and the dismissal of protocols designed to ensure the safety of products prior to introducing them to the public.

By claiming emergency powers, the FDA abandoned safety mechanisms for assessing drugs injected into interstate commerce, ignored express legislative limits on their actions, and now have been placed beyond judicial review.

We face an unparalleled moment in the history of the FDA and 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. These vaccines attempt to attack a virus that continues to mutate in ways prior vaccine studies did not even address. We are destroying American society over a virus whose current Delta variant poses a case fatality rate, for most young, healthy working adults, that approaches that of the common seasonal flu, despite more vaccine-related deaths and severe adverse results reported in both U.S. and European government databanks from COVID vaccines, than all previous vaccines combined.

The FDA toyed with the labels of "authorization" and "approval" to guarantee that the largest number of people possible could be forced to take the Pfizer-BioNTech and *Comirnaty* COVID-19 vaccines. Promises of safety and effectiveness and the massive push for vaccination has had catastrophic societal implications. "Job or jab" ultimatums, denial of life-saving treatment in hospital settings[4], discrimination against students,

---

[4] Maureen Mackey, *Teen Denied Kidney Transplant Because She's Not Vaccinated for COVID, Say Parents*, FOX NEWS, December

societal coercion, and shaming all commonplace experiences.

After two years of being administered to the public as the first mRNA vaccine, data and studies show that the COVID-19 biologic is undoubtedly the most dangerous and harmful "vaccine" ever put to market. From its inception, the alarming number of reports to the Center for Disease Control's Vaccine Adverse Event Reporting System (VAERS) and Pfizer's own data from the initial administration of the vaccine, which the FDA had in its possession, shows a safety profile unlike any we've seen for any vaccine in history. This should come as no surprise given the vaccine was rushed through the emergency use authorization process challenged by Petitioner's Amended Complaint, with virtually no safety or efficacy testing.

Per the VAERS data, there have been 32,534 deaths, 35,182 life threatening events, and 184,943 hospitalizations from COVID-19 vaccines reported to the VAERS database as of the time of this filing. Given the limitations of self-reporting systems, this is likely a gross underestimation and could represent as little as 1% of the total numbers.[5] Indeed, recent estimates suggest that the rate of injury for vaccinated individuals is at least one out of twenty Americans.[6] Serious

---

10, 2022, available at https://www.foxnews.com/lifestyle/teen-denied-kidney-transplant-not-vaccinated-covid-parents.

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

6 Daniel Horowitz, *Horowitz: German Insurance Claims Hint at Millions of Unreported COVID Vaccine Injuries*, CONSERVATIVE

side effects from vaccination such as myocarditis, pericarditis, blood clots[7], thrombosis, stroke, Guillain-Barre syndrome, and "sudden death" have been witnessed at alarming rates.

The safety data mirrors the efficacy data. Indeed, a senior Pfizer executive in the European Union admitted that Pfizer did not know whether the vaccine stopped transmission of SARS-CoV-2 prior to administering it to the public.[8] This is consistent with the emerging efficacy data, which has shown that the vaccine even has a negative effectiveness and could even increase the risk of infection.[9] Studies conclude that any negligible benefit of taking the COVID-19 vaccine does not outweigh the abundance of risk.

REVIEW, August 15, 2022, available at https://www.conservativereview.com/horowitz-german-insurance-claims-vaccine-injury-2657863726.html.

7 De Michele et al., *Evidence of SARS-CoV-2 Spike Protein on Retrieved Thrombi from COVID-19 Patients*, JOURNAL OF HEMATOLOGY & ONCOLOGY, (2022) 15:108, https://doi.org/10.1186/s13045-022-01329-w.

8 Frank Chung, *Pfizer Did Not Know Whether Covid Vaccine Stopped Transmission Before Rollout, Executive Admits*, NEWS.COM.AU, October 13, 2022, available at https://www.news.com.au/technology/science/human-body/pfizer-did-not-know-whether-covid-vaccine-stopped-transmission-before-rollout-executive-admits/news-story/f307f28f794e173ac017a62784fec414

9 Altarawneh, H., Chemaitelli, H., et al. *Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections,* N. ENGL. J. MED. 2022; July 7, 2022, DOI: 10.1056/NEJMoa2203965; Florentino, P., Millington, T., *Vaccine Effectiveness of Two-Dose BNT162b2 Against Symptomatic and Severe COVID-19 Among Adolescents in Brazil and Scotland Over Time: a Test-Negative Case-Control Study,* THE LANCET, August 8, 2022, DOI: https://doi.org/10.1016/S1473-3099(22)00451-0

The FDA misled members of the public 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. But furthermore, 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.

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. The Nuremberg Code enshrines the right of informed consent as a matter of universal law, so widely recognized, courts consider it a *jus cogens* legal principle enforceable everywhere. *Abdullah v. Pfizer, Inc.*, 562 F.3d 163 (2nd Cir. 2009).

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, 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 fine for not taking a vaccine (*Jacobson v. Massachusetts*, 197 U.S. 11 (1905)), forced sterilizations of poor and politically unprotected populations (*Buck v. Bell*, 274 U.S. 200 (1927), (which relied exclusively on expanding *Jacobson*), and culminated in the kind of "emergency exception" logic that led a court to authorize forced detention camps of American citizens convicted of no crime (*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 leap across the legal landscape.

The 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 the Indian health care services on reservations, from facilities for the mentally ill to jails for women, the least powerful and most trusting have been victimized by government medical experimentation, too often without recourse or remedy. Deceptive denial of syphilis treatment, forced sterilizations, testing of radioactive ingredients on unwitting patients, psychological experimentation on unsuspecting students (like 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 teaches us that we cannot afford to carve out emergency or public health exceptions to Constitutional liberty, lest governments be authorized and approved to treat its citizenry as rats in a cage or guinea pigs for experimentation.

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 another polio vaccine. Twenty-five years later, a new virus emerged in the population: AIDS. Detailed journalistic investigations attributed it to the use of contaminated monkey kidneys in the development of polio vaccines.

In 1963, Americans discovered that the polio vaccine from monkey kidneys contained the Simian Virus 40 that could cause cancer in humans.

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.

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. Journalistic inquiry revealed that the vaccine disaster was due to a "rush to produce, sell vaccine" that put the children at unnecessary risk.

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

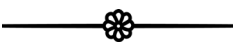
Born of this post-Nuremberg, informed consent, democratically-driven process, the FDA biologic approval process defined protocols with public input and robust debate, citizen petition and judicial oversight, substantive limits on agency reasoning, and procedural requirements for any drug's biologic approval. Only a rigorous scientific review, with meaningful public participation through citizen petitions answered by the FDA, could even legally authorize the introduction of

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

In this case, the FDA eviscerated all those procedural protections and substantive limits, under the guise of emergency powers, proclaiming neither legislative limit nor judicial review could apply to them. The emergency powers of Pandora's Box then legitimated the bait-and-switch the FDA used to greenlight forced vaccines by the DOD on military members.

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. This Sixth Circuit decision, in conflict with so many other Circuits, enables agencies to continue to abuse emergency powers, play bait-and-switch and hide-the-ball amongst the agencies to avoid legislative limit or judicial oversight, and empower the FDA's most egregious abuse of emergency power, as the deaths, disabilities, and injuries mount daily, all while public confidence in our public health agencies continually collapses.

This case shapes more than confidence in the public health agencies; this case shapes the confidence in the Constitutional separation of powers that compel judicial oversight, redress and remedy rather than judicial abandonment of its citizens in a matter of such great public import.



CONCLUSION

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

Respectfully submitted,

ROBERT E. BARNES, ESQ.
COUNSEL OF RECORD
BARNES LAW
700 SOUTH FLOWER STREET
SUITE 1000
LOS ANGELES, CA 90017
(310) 510-6211
ROBERTBARNES@BARNESLAWLLP.COM

COUNSEL FOR PETITIONERS

DECEMBER 21, 2022