No.

In the Supreme Court of the United States

JERI PEARSON, ELIZABETH KLEM, BEN HOMAN, ROB FOWLER,
Petitioners,

v.

SHRINERS HOSPITALS FOR CHILDREN, INC.; SHRINERS HOSPITALS FOR CHILDREN, TEXAS; BEVERLY BOKOVITZ, FRANCES FARLEY, JERRY GANTT, JOHN MCCABE, PHILLIP GRADY, CECILE ERWIN YOUNG,
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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QUESTIONS PRESENTED

Since Congress enacted the 1974 National Research Act, it has been the federal government's policy that no individual can be subjected to a penalty or lose a benefit to which they are otherwise entitled when refusing federally funded, unapproved medical treatments or related research activities. To ensure the congressional mandate was faithfully executed, the Executive Branch established the Federalwide Assurance program in 2001, requiring contracting parties to provide written assurance that they will not place a human under coercion, undue influence, or unjustifiable pressures to participate in such treatments or related activities. Consent to an unapproved medical treatment (*i.e.,* investigational new drugs) in the absence of such coercion, influence, or pressure is known as legally effective informed consent.

QUESTIONS:

1. Is the right to refuse an unapproved medical treatment a fundamental right subject to the Due Process Clause of the Fourteenth Amendment?

2. If a federal program requires a State to obtain legally effective informed consent and the State delegates that duty to a private party, does the private party's deprivation of that consent constitute State action?

LIST OF PARTIES TO THE PROCEEDING

The caption contains the names of all interested parties.

CORPORATE DISCLOSURE STATEMENT

Petitioners are all individuals.

LIST OF DIRECTLY RELATED CASES

Jeri Pearson, et al. v. Shriners Hospitals for Children, et al., No. 24-40436, U.S. Court of Appeals for the Fifth Circuit. Judgment entered April 2, 2025; rehearing denied April 29, 2025.

Jeri Pearson, et al. v. Shriners Hospitals for Children, et al., No. 3:23-cv-387, U.S. District Court for the Southern District of Texas, Galveston Division. Judgment entered June 7, 2024.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Jeri Pearson, Elizabeth Kelm, Ben Homan and Rob Fowler respectfully petition for a writ of *certiorari* to review a judgment of the United States Court of Appeals for the Fifth Circuit.

OPINIONS BELOW

The Fifth Circuit's opinion is published at *Pearson v. Shriners Hosps. for Child.,* 133 F.4th 433 (5th Cir. 2025), and is reproduced at Appendix B. The Fifth Circuit's denial of petitions for panel rehearing and rehearing en banc is reproduced at Appendix A. The District of Southern Texas' opinion is available at *Pearson v. Shriners Hosps. for Child.,* 736 F. Supp. 3d 521 (S.D. Tex. 2024), and is reproduced at Appendix C.

JURISDICTION

The Fifth Circuit issued its opinion on April 2, 2025, and denied petitions for rehearing on April 29, 2025. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, Art. VI, Cl. 2

This Constitution, and the Laws of the United States

which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Fourteenth Amendment, § 1

No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

42 U.S.C. § 1983

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia.

21 U.S.C. § 360bbb-3 (relevant excerpts)

(a) In general.

(1) Emergency uses. Notwithstanding any provision of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product. An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), 512, or 515 of this Act [21 USCS § 355, 360(k), 360b, or 360e] or section 351 of the Public Health Service Act [42 USCS § 262] or conditionally approved under section 571 of this Act [21 USCS § 360ccc] (referred to in this section as an "unapproved product"); ...

(4) Definitions. For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(C) The term "product" means a drug, device, or biological product.

(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A). ...

(b) Declaration of emergency or threat justifying emergency authorized use.

(1) In general. The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of— ...

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; ...

(e) Conditions of authorization.

(1) Unapproved product.

(A) Required conditions. With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and

(III) of the alternatives to the product that are

available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

STATEMENT OF THE CASE

The State of Texas agreed to perform, on behalf of the United States Government ("USG"), the ministerial function of obtaining an individual's legally effective informed consent when offering them an opportunity to use the federally funded CDC COVID-19 Vaccination Program's ("CDC Program") unapproved medical treatments.

Respondent Cecile Erwin Young, the officer of Texas responsible for implementation of the Program, recruited Respondent Shriners Hospital for Children ("Shriners") to perform duties on the state's behalf, which Shriners willfully and contractually agreed to perform. However, Shriners, acting under color of law as a state agent, instituted a policy involving the federal program requiring Petitioners to receive the unapproved medical treatments (i.e.,

drugs not licensed by the FDA) under threat of penalty, depriving Petitioners of their right to withhold legally effective informed consent.[1]

When Petitioners exercised their right to refuse upon learning of the drugs' risks and expected legal conditions of use, Shriners acted upon a state-enforced custom to deprive Petitioners of their right to withhold legally effective informed consent, using employment termination as a form of punishment as a warning to others not to refuse participation in the CDC Program.

The Fifth Circuit's decision that Shriners' policy mandating drugs not approved by the FDA "was not unlawful" nullifies the legally effective informed consent standard, renders the CDC COVID-19 Vaccination Program and Federalwide Assurance Program nonfunctional, vitiates federal statutes, and strips the Secretary of Health and Human Services ("HHS") of his mandate to completely prohibit the nonconsensual use of federally funded unapproved medical treatments.

Notably, although no Respondent directly asserted any authority to compel the use of unapproved medical treatments, the Fifth Circuit, *sua sponte* under Rule 12(b)(6), decreed such conduct lawful — constituting a singular judicial pronouncement among this Nation's circuit courts, one that directly contravenes established federal prohibitions against the nonconsensual administration of unapproved medical products and related activities by authorized HHS agents.

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[1] Legally effective informed consent is consent obtained without coercion, undue influence or unjustifiable pressures. *See* 45 C.F.R. 46.116(1)(a).

I. Legislative background of legally effective informed consent

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 *et seq*.), which vested the federal government with exclusive authority over the introduction of new drugs into interstate commerce and the conditions under which they may be promoted and administered.

In 1957, the world was struck by tragedy when thalidomide — marketed under the trade name Contergan — was promoted as a treatment for morning sickness in pregnant women without undergoing adequate clinical testing for teratogenic effects. What followed has been described as "the biggest man-made medical disaster ever," resulting in over 10,000 children born with a range of severe and debilitating malformations.[2]

In response to the thalidomide tragedy, Congress enacted the Drug Amendments of 1962 — commonly known as the Kefauver-Harris Amendment — Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. § 355), which mandates that manufacturers provide substantial evidence of a new drug's safety and efficacy, derived from adequate and well-controlled clinical investigations, before its introduction into interstate commerce. Specifically, the amendment prohibits the introduction or delivery for introduction into interstate commerce of any new drug unless the FDA has approved an application demonstrating its safety for use and effectiveness

[2] Vargesson, Neil. "Thalidomide-induced teratogenesis: history and mechanisms." *Birth Defects Res C Embryo Today*, 2015 Jun, 105(2):140-56; https://pubmed.ncbi.nlm.nih.gov/26043938/.

according to its labeling.

Notably, the amendment establishes an exemption from these requirements for new drugs intended solely for investigational use, but conditions such exemption upon participants giving informed consent. 21 U.S.C. § 355(i)(4).

The mandate to substantiate both safety and efficacy engendered a surge in the demand for human subjects in clinical trials. Investigators frequently targeted vulnerable populations — such as the indigent, the uneducated, racial and ethnic minorities, incarcerated individuals, and children with intellectual disabilities — who proved particularly susceptible to coercion, undue influence, or unjustifiable pressure in the consent process.

In 1972, the nation recoiled at the revelation of the Tuskegee Syphilis Study, a federally funded research initiative in which investigators deliberately withheld effective treatment from African-American males afflicted with syphilis, permitting them to endure needless suffering and death solely to chronicle the natural progression of the disease. By the study's termination, 128 participants had succumbed to syphilis or its related complications, 40 of their wives had contracted the infection, and 19 of their children were born with congenital syphilis.[3]

Incensed by the abuse, Senator Edward Kennedy presided over congressional hearings in 1973 examining widespread abuses in federally funded medical research.[4] Among the egregious examples

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[3] *See* Curran, W.J. "The Tuskegee Syphilis Study." *New England Journal of Medicine* 289:730 (1973).

[4] U.S. Government Printing Office. "Quality of Health Care — Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public

highlighted was a 15-year hepatitis study (1956–1971) at Willowbrook State School in Staten Island, New York, where researchers deliberately infected over 1,500 intellectually disabled children with the virus by administering extracts from infected feces, often mixed into chocolate milk. Parents, desperate for admission to the overcrowded facility, were coerced into consenting under the false premise that participation was required for enrollment, without full disclosure of the risks or the experimental nature of the infections.

Similarly, the Centers for Disease Control and Prevention ("CDC") conducted Shigella vaccine trials on prisoners and intellectually disabled children at the Sunland Training Center in Fort Myers, Florida, targeting these groups due to the ease and cost-effectiveness of obtaining consent from uneducated inmates and economically disadvantaged families.

In 1971, the U.S. Army exploited the harsh conditions at the Jackson County Courthouse in Kansas City, Missouri — where inmates endured extreme heat, overcrowding, and confinement on upper floors — by recruiting 107 participants for a six-week "Malaria Volunteer" program. Inmates were enticed to participate with incentives including food, ice cream, juice, and a $50 honorarium, culminating in a "Certificate of Merit" for their purported "social responsibility and unselfishness."

In response to Executive Branch medical research abuses, Congress enacted the National Research Act of 1974, Pub. L. No. 93-348, 88 Stat. 342. This pivotal legislation mandated the establishment of Institutional Review Boards pursuant to 42 U.S.C. § 289, charged with providing

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Welfare, United States Senate."

oversight to protect the rights and safety of research participants; it also constituted the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("the Commission"), empowered to formulate guidelines for ethical research practices and to consider "the nature and definition of informed consent in various research settings."

In 1979, the Commission issued the seminal Belmont Report,[5] which outlined fundamental ethical principles for research involving human subjects. The Report emphasized that respect for persons requires honoring their individual autonomy, mandating that informed consent be obtained under conditions free from coercion, undue influence, or unjustifiable pressures.

Guided by the Belmont Report and pursuant to the congressional directive in the National Research Act, the Secretary in 1981 promulgated regulations at 45 C.F.R. Part 46, Subpart A (subsequently known as the Common Rule), binding all federal agencies, departments, and the military to comply with the regulatory framework and the Belmont Report. 45 CFR 46.101(a). When a particular activity is deemed exempt from Common Rule requirements, that activity must still adhere to the principles laid out in the Belmont Report. 45 CFR 46.101(i). The Common Rule established uniform protections for human subjects involved in federally funded or authorized investigational medical products and related activities through a new legal standard known as

[5] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* U.S. Department of Health and Human Services, April 18, 1979.

legally effective informed consent. 45 C.F.R. 46.116(a)(1). Obtaining consent was no longer enough to justify an individual's participation; the researcher had a duty to offer participation in a legally approved environment, ensuring that the potential recipient was *not under pressure to participate* before giving their consent.

The standard for legally effective informed consent reflects the Commission's profound insight, elevating consent beyond a mere affirmative utterance to a deliberative act that must transpire in an environment wholly devoid of coercion — whether manifested as overt threats, excessive inducements, or undue influence.

Additionally, to foster the broad applicability of the Common Rule, the Secretary adopted an expansive definition of "research" as encompassing any systematic investigation — including research development, testing, and evaluation — designed to develop or contribute to generalizable knowledge. 45 CFR 46.102(l). Research, under the Common Rule, can be as straightforward as college students reviewing medical charts to assess the efficacy of a therapeutic product, which requires the patient's legally effective informed consent.

On October 19, 1984, Congress enacted section 1401(c) of the Department of Defense Authorization Act, 1985, Pub. L. No. 98-525, 98 Stat. 2615 (codified at 10 U.S.C. § 980), prohibiting the expenditure of funds appropriated to the Department of Defense ("DoD") for any research involving a human being as an experimental subject unless "the informed consent of the subject is obtained in advance." Under this statute, Congress requires informed consent when federal funds are involved, not specifically when the DoD is involved.

In 1992, the U.S. Senate ratified the International Covenant on Civil and Political Rights Treaty (ICCPR). Article VII of the treaty states, "No one shall be subjected without his free consent to medical or scientific experimentation." *Id.* The legal definition of "experimentation" aligns with the FDA's definition under 21 C.F.R. § 312.3, "Clinical investigation," which states "an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice." "In FDA parlance, experimental drugs that have not yet been approved for public use are deemed 'investigational drugs.' *See* 21 C.F.R. § 312.3(b)." *Abigail Alliance v. Eschenbach*, 495 F.3d 695, n. 1 (D.C. Cir. 2007).

To comply with its legal duties under 42 U.S.C. § 289, 10 U.S.C. § 980 and 45 C.F.R. § 46.122, the Executive Branch, in 2000, under the Office for Human Research Protections ("OHRP") within HHS, established the Federalwide Assurance ("FWA") program, which requires persons engaged in federally supported human subjects research — including activities involving unapproved medical treatments or investigational new drugs — to submit written assurances that they will adhere to the ethical principles enunciated in the Belmont Report and the Common Rule to obtain potential participants' legally effective informed consent. HHS states that "[t]hrough the FWA and the Terms of the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46. The Federalwide Assurance (FWA) is the only type of assurance currently accepted and approved by OHRP."[6] Obtaining FWA authorization is a predicate

[6] https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/index.html

to participating in federal programs such as the CDC Program.

No institution may receive federal funding for, or otherwise possess or administer, unapproved medical treatments, or participate in related research activities, without maintaining an active FWA. Currently, there are an estimated 30,000 active FWA contracts, including all U.S. States, territories, and most major hospitals, universities, and county clinics.

Therefore, it is firmly established in this Nation's jurisprudence and policy that no conscious civilian may be pressured to participate in the administration of an unapproved medical treatment, nor may they be penalized for declining such treatment by persons acting under the FWA program directly or indirectly.

II. Factual background

In 2020, the Executive Branch, through the CDC, established the CDC Program in anticipation of the impending availability of new investigational drugs authorized under Emergency Use Authorization ("EUA"), 21 U.S.C. § 360bbb-3, to mitigate the spread of SARS-CoV-2. In October 2020, the CDC issued the requirements for a U.S. State or territory to participate, as published under the "COVID-19 Vaccination Program Interim Operational Guidance: Jurisdiction Operations," ver. 2.0.[7] The CDC Program was designed to be administered through each State's "immunization cooperative agreement" and FWA. Each State was provided discretionary authority to recruit entities

[7] *See* https://www.cdc.gov/vaccines/imz-managers/downloads/Covid-19-Vaccination-Program-Interim_Playbook.pdf

such as Shriners to administer the investigational drugs to the public under the State's FWA. Because the drugs were federally funded, unapproved medical treatments, the CDC was lawfully bound to obtain the legally effective informed consent of potential participants. The States, therefore, were also bound to obtain legally effective informed consent of potential recipients when presenting them with an opportunity to be administered the CDC Program's investigational new drugs.

The CDC Program imposed multifaceted obligations upon States and their recruited organizations like Shriners, *inter alia*: implementing the Program through the State's immunization cooperative agreement with the federal government, educating the public regarding the salient legal distinctions between a drug introduced into interstate commerce pursuant to EUA and a fully licensed drug under 21 U.S.C. § 355; ensuring that private parties sign the CDC COVID-19 Vaccination Program Provider Agreement, wherein they pledge compliance with "any EUA" and "all applicable" laws relating to the drugs' classification. "State-level personnel must closely monitor activities at the local level to ensure the COVID-19 Vaccination Program is implemented throughout the jurisdiction in adherence with federal guidance and requirements."

States also agreed to conduct post-administration research activities for specific adverse events and to report any adverse events to the CDC. Further, the Secretary informed participating states that HHS would assume the role of "Emergency Response Stakeholder" under any EUA to ensure the "distribution and administration" of the drugs by its recruited agents are "consistent with the terms of this letter and CDC's COVID-19

Vaccination Program" and "instruct [such agents] about the means through which they are to obtain and administer the vaccine under the EUA."[8] The Secretary designated "vaccination provider" as an entity "who has been enrolled in the COVID-19 Vaccination Program." Persons required to sign the Provider Agreement are the "chief executive officer," "chief medical officer," and "Responsible Officers" of the "Organization" agreeing to perform the functions of the program on the State's behalf.[9] Therefore, the executives of Shriners agreed to perform the conditions of authorization on the Secretary's behalf under any EUA letter, and to fully comply with the terms of the CDC Program.

With respect to each individual enrolled in federally funded research, the CDC Program's terms require ongoing monitoring for adverse events and the disclosure of identifiable private health information — such as names, birth dates, addresses, and investigational administration details — to unspecified entities for unknown purposes, without full disclosure of who can access that information, for what purposes, and for what duration. Furthermore, each enrolled individual

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[8] Under each EUA, the Secretary defined Emergency Response Stakeholder as "a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation." FDA Emergency Use Authorization letter to Pfizer, dated August 23, 2021. *See* https://archive.org/details/final-pfizer-loa-to-issue-with-bla-approval-08.23.21-v-2

[9] *See, e.g.,* https://www.nyc.gov/assets/doh/downloads/pdf/imm/covid-19-vaccine-program-agreement-letter.pdf, pp. 5–8.

bears greater than usual risks to their health, safety, and finances, because the Program's EUA products are unlicensed and lack full FDA safety and effectiveness evaluations, while any resulting injuries are shielded from civil liability under the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2818 (2005), codified as amended at 42 U.S.C. § 247d-6d.

The CDC Program vested in prospective participants a property interest in receiving comprehensive disclosures regarding the investigational drugs' potential risks, benefits, and available alternatives, along with affirmation of their programmatic prerogative to accept or decline administration thereof, free from any coercion, undue influence, or unjustifiable pressure, and without incurring any fee, penalty, or forfeiture of entitlements for electing refusal.

In 2020, the USG informed the nation that it had purchased the rights to COVID-19 drugs through advance purchase agreements using DoD-appropriated funding, retaining ownership of them until human administration; that the FDA had authorized these products under EUA as investigational interventions not yet licensed or approved for any legal indication; and that the Secretary had designated them as covered countermeasures, thereby conferring liability immunity pursuant to the PREP Act. These conditions required the Executive Branch to obtain Petitioners' legally effective informed consent when an opportunity to use the Program's unapproved medical treatments was presented to them. The Executive Branch established the CDC Program to distribute and administer these COVID-19 drugs

because they were not licensed by the FDA for any legal indication and operated under a regulatory framework not applicable to licensed drugs.

The State of Texas elected to participate in the CDC Program. and implement the Program through the State's immunization cooperative agreement with the federal government. Pursuant to this arrangement, the Texas Health and Human Services Commission ("HHSC") — encompassing the Department of State Health Services — stood as the sole entity within the state expressly authorized by the CDC to receive, store, distribute, and oversee the administration of the federally owned investigational drugs to the public, while retaining discretionary authority to enlist private parties to assist in executing the state's commitments under the Program. The programmatic duties were vested in Ms. Young, in her capacity as Executive Commissioner of HHSC. Accordingly, and pursuant to her discretionary authority under the CDC Program, Ms. Young enlisted Shriners to help the State perform its promised obligations on behalf of the State of Texas and the USG, to which Shriners voluntarily and contractually agreed.

By creating this collaboration among the federal government, State governments, and recruited parties acting under color of State law, the Executive Branch effectively delegated to Texas its constitutional duties to prospectively obtain legally effective informed consent from individuals considering participation — a governmental obligation — which Texas, in turn, delegated to Shriners in its capacity as a CDC Program provider.

On September 14, 2021, Shriners issued a policy involving the CDC Program, requiring Petitioners to be injected with one of the federally owned

investigational drugs. When Petitioners exercised their right under the CDC Program to refuse the unapproved medical treatments, Shriners first threatened them with loss of benefits (*i.e.,* employment). Upon Petitioners' resolute refusal to relinquish their Fourteenth Amendment protections encompassing bodily integrity, equal protection, and privacy, Shriners inflicted the penalty of employment termination under color of law, contravening Petitioners' right to legally effective informed consent.

III. Proceedings in the District Court

Petitioners commenced an action in the United States District Court for the Southern District of Texas alleging that Respondents, acting on behalf of the State, deprived them of their Fourteenth Amendment fundamental right to refuse an investigational new drug, of their federal benefit to refuse under the CDC Program, of their right to have their option to refuse treated equally with the option to accept, of their right not to have their zone of privacy invaded by a state agent, and to maintain the right to sue if injured by the Program or its products. Importantly, at no juncture did Petitioners challenge the purported authority of Respondents to impose a vaccination requirement using FDA-licensed drugs; rather, their challenge was confined to the permissible scope of a mandate that exclusively relied on unlicensed drugs for compliance and the legality of compelling Petitioners' participation in the CDC Program that was immunized from liability under the PREP Act.

Shriners moved the court to compel Petitioners to abridge their complaint, whereupon the court

ordered a reduction in page count from 80 to 40, notwithstanding the number of issues of first impression presented. The court additionally limited the number of exhibit pages to 75, which constitutes fewer pages than the CDC Playbook, and not counting the State documents detailing the duties Texas required of Shriners. Ironically, Respondent sought leave to file a reply to Petitioners' opposition to the motion to dismiss, requesting twice the customary allotment of pages, which the court granted. Petitioners requested oral argument, given the novel legal questions at stake, but were denied.

Ms. Young and Shriners both filed Rule 12(b)(6) motions to dismiss the complaint on the basis that Petitioners' causes were not actionable because Shriners was allegedly not acting on Texas' behalf when depriving Petitioners of their federally funded benefits under the CDC Program. Respondents did not address their duties under the CDC Program, their Federalwide Assurance agreements, questions of federal preemption, or Petitioners' legally effective informed consent rights. The district court dismissed the case, only accepting *Respondents'* version of facts as true under Rule 12(b)(6), reframing Petitioners' allegations, and offering an analysis in isolation of their claims without explanation.

IV. Proceedings in the Fifth Circuit

Petitioners timely appealed to the Fifth Circuit and moved to consolidate their case with *Bridges v. The Methodist Hospital*, 24-20483 (5th Cir. Jun. 17, 2025), but the Fifth Circuit denied the motion. The two cases share nearly identical legal and factual issues, but the *Bridges* court did not compel the plaintiffs to excise content essential to their causes of

action. Had consolidation been granted, it would have equipped the Fifth Circuit with a complete view of Petitioners' right to refuse federally funded, unlicensed drugs mandated by State actors, while enabling a robust analysis of the pertinent case law cited by Respondents in both cases. The Fifth Circuit affirmed the district court's dismissal of Petitioners' claims under Rule 12(b)(6), only accepting Respondents' version of facts as true, reframing Petitioners' allegations, and offering an analysis in isolation of Petitioners' claims relating to the CDC and FWA programs without explanation of the reasons for its non-consideration of those claims.

The Fifth Circuit began its opinion by stating: "Plaintiffs-Appellants (the 'Former Employees') were terminated from Shriners Hospitals for Children for refusing to get a COVID-19 vaccination" and sued Respondents for their "alleged right to refuse the vaccine." App. 3a–4a. It described the district court's action as "the court dismissed the Former Employees' claims against the Commissioner because she could not be liable for failing to correct Shriners's alleged misconduct when it was not unlawful." App. 8a. Further, the Fifth Circuit stated:

> Shriners was not a state actor when it implemented its mandatory vaccination policy. (App. 9a). …
>
> For the Former Employees' claims, the relevant conduct is Shriners adopting and enforcing its mandatory vaccination policy. Under that policy, it terminated the Former Employees for refusing to get vaccinated. It expressly permitted employees to get vaccinated through Shriners or other

> entities. Thus, Shriners did not implicate its role administering COVID-19 vaccinations by requiring its employees to receive one. … It is commonplace for companies — particularly hospitals — to place such mandates on their employees. (App. 14a).

This petition followed.

REASONS FOR GRANTING THE WRIT

This Court should grant review to restore the constitutional authority of the Legislative and Executive Branches to prohibit the nonconsensual use of unapproved medical products, to affirm that refusing unwanted medical treatment is a fundamental right under the Due Process Clause of the Fourteenth Amendment, and to correct the Fifth Circuit's errors before they spread to the Third, Ninth, and Tenth Circuits, which are considering cases involving similar facts

The Fifth Circuit's holding that Shriners' policy compelling Petitioners to be administered federally owned investigational drugs that lack FDA approval "was not unlawful" is erroneous as a matter of law, particularly in view of Petitioners' well-pled allegations and supporting exhibits.

No Circuit has directly held that any person or State official can mandate unapproved medical treatments; it has always been assumed the right to refuse such treatment was a fundamental right, and because no person can administer such drugs without contractually agreeing not to mandate their administration. Petitioners allege that Ms. Young and Shriners operated under Federalwide Assurance

Nos. FWA00028877 and FWA00025698, respectively, each constituting a solemn assurance to the Executive Branch not to engage in the challenged conduct — punishing individuals who refuse federally funded investigational new drugs. As a matter of law, Shriners is precluded under its FWA from sanctioning any individual who declines federally funded investigational new drugs, irrespective of the relational context, *i.e.,* whether as employee, volunteer, contractor, or patient.

The Fifth Circuit obfuscated the crux of the controversy: the unequivocal prohibition by Congress and the Executive Branch against authorized agents, including States and State contractors, exerting pressure upon individuals to accept unapproved medical treatments or imposing penalties for refusal — a prohibition contractually agreed upon by Respondents under the CDC and FWA programs for Petitioners' benefit. Should this Court not grant *certiorari,* then what is contractually impermissible under the Executive Branch and statutorily prohibited under the Legislative Branch will become permanently justified under judicial preference, nullifying the Secretary's legal obligation and authority to completely prohibit nonconsensual use of federally funded unapproved medical products and procedures.

To underscore the peril, the Fifth Circuit's ruling does not merely abrogate valid enactments of its coequal branches; it supplants them with its own preferences, thereby undermining the democratically informed process of our Republic.

"Under our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *United States*

v. Rutherford, 442 U.S. 544, 555 (1979).

The Fifth Circuit's erroneous ruling impacted another case involving more than 100 surgeons, physicians, nurses, and contractors against Houston's Methodist Hospital, and predicated on analogous factual circumstances. *See Bridges, supra.* In so doing, the *Bridges* panel affirmed the district court's order, which recognized that the COVID-19 drugs were "not approved, licensed, or cleared for commercial distribution," yet deemed the action "foreclosed by … *Pearson v. Shriners Hospitals for Children, Inc*."

Ironically, Shriners administers a multimillion-dollar research program employing investigational drugs, wherein it mandates staff to obtain legally effective informed consent from any individual before administration. Going forward, whom should Shriners heed? The Legislative and Executive Branches, or the Fifth Circuit's unmoored judicial fiat, bereft of any regulatory framework for exempting investigational drugs? The multi-layer federal regulatory framework was designed to protect the bodily integrity rights of Americans against unapproved medical treatments, but the Fifth Circuit ruled as if it doesn't exist.

The self-evident precept that society cannot efficaciously or equitably function amid competing authorities provides ample reason for this Court to expeditiously grant review, lest the erroneous ruling sow profound confusion among FWA agents, Institutional Review Boards and healthcare workers, and inflict irreparable injury upon this nation.

I. Petitioners enjoy a federally guaranteed liberty interest to refuse unapproved medical products, treatments, and related activities without incurring a penalty or losing a benefit to which they are otherwise entitled.

A. The right to refuse unapproved medical products, treatments, and related activities is a fundamental right protected by the Due Process Clause.

Petitioners' liberty interest in exercising their right to refuse unapproved medical treatments is "deeply rooted" in our nation's traditions and "implicit in the concept of ordered liberty," reaching a status so fundamental that "neither liberty nor justice would exist if [it were] sacrificed." *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997).

This Court has been resolute regarding bodily autonomy as constituting fundamental rights. "No right is held more sacred or is more carefully guarded by the common law than the right of every individual to the possession and control of his own person, free from all restraint or interference of others unless by clear and unquestionable authority of law." *Union Pacific Railway Co. v. Botsford,* 141 U.S. 250, 251 (1891).

> On balance, the right to self-determination ordinarily outweighs any countervailing state interests, and competent persons generally are permitted to refuse medical treatment, even at the risk of death. Most of the cases that have held otherwise, unless they involved the interest in protecting

> innocent third parties, have concerned the patient's competency to make a rational and considered choice.

Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261, 273 (1990), citing *In re Conroy*, 98 N.J. 321, 348 (1985).

> The right assumed in *Cruzan*, however, was not simply deduced from abstract concepts of personal autonomy. Given the common-law rule that forced medication was a battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment, our assumption was entirely consistent with this Nation's history and constitutional traditions.

Glucksberg, 521 U.S. 702, 725 (1997).

"The protections of substantive due process have for the most part been accorded to matters relating to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994).

It has been posited that this Court has recognized a liberty interest in refusing FDA-approved medical products and procedures, subject to a circumscribed exception for certain vaccine mandates under exigent circumstances, as described in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). Nonetheless, this Court has yet to expressly designate the right to refuse unapproved medical treatments as a *fundamental* right under substantive due process — an imperative that, by definition, forecloses any imposition of vaccination requirements relying on investigational products, which lack the

safety, efficacy, and legal indication validations attendant to full licensure.

The federal obligation incumbent upon entities offering unapproved medical treatments to prospective recipients — to ensure that treatment is voluntary and untainted by coercion, undue influence, or unjustifiable pressure — is deeply rooted in the legal fabric of American society. Congress mandates that the Secretary ensure entities conducting business with the federal government operate under the review of an "Institutional Review Board" when involving humans with federally funded research activities, *see* 42 U.S.C. § 289, which the Executive Branch promulgates regulations to enforce at 45 C.F.R. Part 46 and 21 C.F.R. Parts 50 and 56. Further, the Executive Branch established the FWAs to contractually bind such entities to the legally effective informed consent standard. Moreover, Congress subjects its annual appropriated budget to Common Rule compliance, demonstrating a strong desire to protect the public from unwanted investigational medical treatments and related research activities. *See* 45 C.F.R. § 46.122.

The federal judiciary has consistently affirmed that individuals do not possess a fundamental right to access or utilize unapproved medical treatments. *See L.W. v. Skrmetti*, 83 F.4th 460, 478 (6th Cir. 2023) ("Neither doctors, adults, nor their children have a constitutional right to use a drug that the FDA deems unsafe or ineffective."); *United States v. Rutherford*, 442 U.S. 544 (1979) (denying terminally ill cancer patients access to drugs not approved for any legal indication); *Abigail Alliance v. von Eschenbach, 495 F.3d 695, 713 (D.C. Cir. 2007), cert. denied, 128 S. Ct. 1069 (2008)* (rejecting an argument

that terminally ill patients hold a fundamental right to access investigational drugs). *The Upjohn Co. v. Finch*, 422 F.2d 944, 954 (6th Cir. 1970) upheld the supreme authority of the Executive Branch to determine when a drug is approved for a legal indication, ("[w]e hold that the record of commercial success of the drugs in question, and their widespread acceptance by the medical profession, do not, standing alone, meet the standards of substantial evidence prescribed by 21 U.S.C. § 355(d))." It engenders an anomalous and untenable outcome to posit, on the one hand, that no such right to access exists, while simultaneously permitting the coercive imposition of these very treatments upon unwilling individuals.

B. Legally effective informed consent was designed to protect the fundamental right to refuse unapproved medical treatments.

The regulatory standard of legally effective informed consent governing unapproved medical treatments stands as a cornerstone of federal policy. It is enshrined within the regulatory frameworks of at least 24 federal departments and agencies, the DoD, the FWA program under which all States and most hospitals and universities operate, and the statutes and regulations of numerous States. It governs every interaction between a potential recipient and the sponsor of the drug's use. This standard also governs the Executive Branch's commitments under international accords, including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use E6 Guidelines, the Council for International Organizations of Medical Sciences

Guidelines, the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and the Indian Council of Medical Research Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

It is difficult to conceive of any other property interest — grounded in the duly enacted measures of the Legislative and Executive Branches — that permeates the societal framework more profoundly than the right to legally effective informed consent. The Fifth Circuit's *sua sponte* decision under Rule 12(b)(6) that the state and its authorized agents can lawfully mandate unlicensed drugs, *a claim made by no Respondent*, has upended a well-settled federal scheme regulating the $600 billion pharmaceutical industry and carefully constructed to protect individuals from medical research abuses.

Legally effective informed consent, as informed by the Belmont Report and 45 C.F.R. § 46.116, can be broken down into a basic formula: (1) individuals must not come under any form of pressure to use unapproved medical treatments, (2) individuals must autonomously consent according to their personal health goals, and (3) the conditions of (1) and (2) are established *before* the individual consents. Administration of unlicensed drugs outside this legal standard nullifies legally effective informed consent.

Accordingly, the Fifth Circuit's decision that "Shriners did not implicate its role administering COVID-19 vaccinations by requiring its employees to receive one" because "[i]t expressly permitted employees to get vaccinated through Shriners or other entities,"[10] violates the legally effective informed consent standard. Whether an employee

[10] App. 14a.

receives the injection from Shriners or another provider, Petitioners' decision is not autonomous because the pressure from Shriners is in effect no matter who administers the shot.

Until this Court grants review, the legally effective informed consent standard now operates under two legally distinct conditions: one guided by the Constitutional powers of the Executive Branch and the other under the Fifth Circuit's preferences. The application of the standard is no longer equally applied within this nation and the Fifth Circuit's ruling will frustrate the Secretary's enforcement of any CDC Program or FWA violation under the Fifth Circuit's jurisdictional authority.

C. Federal preemption protects the right to bodily integrity.

The U.S. Constitution, Art. VI, Cl. 2 provides:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

This Court holds that "a judge, not the jury, must decide the pre-emption question," emphasizing the procedural requirement that judges resolve preemption issues to uphold the supremacy of federal law. *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 310 (2019).

1. EUA Preemption

Under 21 U.S.C. § 360bbb-3, Congress vests exclusive authority in the Secretary to promulgate conditions for EUAs of unlicensed medical products amid a declared public health emergency, and requires that prospective recipients be informed of the product's potential risks, benefits, and alternatives and of their inviolable right to accept or decline administration thereof. To safeguard bodily integrity and autonomy, Congress expressly deprives the Secretary of "any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section." 21 U.S.C. § 360bbb-3(l). Such "activity" includes being injected with EUA unapproved products. By virtue of the Supremacy Clause, neither States, their political subdivisions, nor entities acting as agents of the Secretary may institute legal mandates compelling nonconsensual use of EUA drugs, nor may any governmental actor assert a rational basis for infringing upon an individual's federally conferred prerogative to abstain from such use.[11] *See Arizona v. United States*, 567 U.S. 387, 399 (2012) (explaining the power of Congress to pre-empt State law).

Congress enacted the Project BioShield Act, P.L. 108-276, for the explicit purpose of responding to chemical, biological, radiological, nuclear, and pandemic events by permitting the introduction of

[11] The federal government may not impose upon an entity the obligation to obtain informed consent without concurrently vesting in the prospective participant the correlative right to give or withhold such consent. *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990) ("the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment.")

unlicensed medical products into large populations, predicated upon the strictly voluntary participation of any person involved in any authorized activity. The Fifth Circuit's omission in addressing federal preemption — vis-à-vis Respondents' contractual commitments to execute duties on behalf of the Secretary pursuant to "any EUA" — undermines Congress' manifest intent to introduce EUA products into commerce solely under informed consent conditions. This omission enables the State and its contractors — volunteers enlisted by the Secretary — to effectuate outcomes expressly foreclosed to the Secretary himself.

The Fifth Circuit's intimation that the EUA statute "expressly contemplates that individuals may face consequences for refusing the vaccine"[12] is refuted by the statutory architecture: if Congress withholds from the Secretary the power to mandate use, no adverse repercussions may apply to the option to refuse. Additionally, the Fifth Circuit's assertion that "the 'informational obligation' in the EUA Statute 'falls short of expressing a clear congressional intent to supersede state regulation of private employment'"[13] is specious, inasmuch as Shriners contractually assumed the mantle of a "vaccination provider" on behalf of the State, and cannot mandate nonconsensual use of EUA drugs by any person, irrespective of Shriners' relationship with that person. Shriners, acting on behalf of the Secretary under each EUA, mandated that Petitioners find a state-authorized provider, but informed Petitioners that if they opted to refuse, they would face consequences, thereby frustrating the scheme designed by Congress and regulated by HHS

[12] App. 17a.

to prohibit nonconsensual use of EUA products by any member of society.

EUA medical products are unapproved for their intended use, and because they are authorized solely under the Secretary's authority, they must be administered under the legally effective informed consent doctrine.

2. PREP Act preemption

The PREP Act unambiguously states that no State or political subdivision "may establish, enforce, or continue in effect" a "legal requirement" that involves any matter applicable to the covered countermeasure under the FDCA. 42 U.S.C. § 247d-6d(b)(8). Relevant here, Congress mandates that the Secretary ensure "potential participants are educated" about the "voluntary nature of the program." 42 U.S. Code § 247d-6e(c).

A federal requirement applicable to covered countermeasures under the FDCA in the present action is the Secretary's obligation to ensure that potential recipients are informed "of the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Entities acting under color of law or on the Secretary's behalf are thus expressly preempted from instituting mandates that compel use of EUA drugs designated as covered countermeasures under the PREP Act. As a matter of law, therefore, Shriners — contractually operating on behalf of the Secretary *and* the State of Texas — lacks authority to promulgate requirements coercing Petitioners into nonconsensual use of EUA drugs that are PREP Act countermeasures. Furthermore, the State of Texas, having willfully agreed to execute duties for the USG and to deploy covered

countermeasures amid the declared public health emergency, is expressly preempted from "continu[ing] in effect" its at-will employment doctrine when such law serves as an instrument to sanction individuals for declining EUA/PREP Act countermeasures.

PREP Act preemption further ensures persons are not coerced into surrendering their due process right to bring a cause of action against an EUA product manufacturer, because a person who consents to an EUA product forfeits that right.

D. Recurring Questions

Federal district courts across the nation also refuse to acknowledge the legally effective informed consent standard, or the right to refuse unapproved medical treatments as a fundamental right, or even to address questions of federal preemption. *See Curtis v. Inslee*, 24-1869 (pending Ninth Circuit); *Boysen v. PeaceHealth*, 24-5204 (pending Ninth Circuit); *Sweeney v. UCHA*, 25-1005 (pending Tenth Circuit); *Roberts v. Inslee*, 24-1949 (pending Ninth Circuit); *Timken v. SDCA*, 24-1378 (pending Tenth Circuit); *Horsley v. Aragon*, 24-5812 (pending Ninth Circuit); *Boyd v. Shriners Hospitals for Children*, 25-1183 (pending Third Circuit); *Abrigo v. Kaiser Foundation Hospitals*, 25-2154 (pending Ninth Circuit); *Brock v. City of Bellingham*, 25-1070 (pending Ninth Circuit); *Martinez v. Eastside Fire & Rescue*, 2:24-cv-1706, (pending Rule 59(e), W.D. Wash.); *Wilson v. Kaiser Foundation Hospitals*, 2:24-CV-2142 (pending W.D. Wash.)

II. The Fifth Circuit violated the separation of powers doctrine.

In *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 195 (1978), this Court emphatically defended the separation of powers doctrine:

> We agree with the Court of Appeals that, in our constitutional system, the commitment to the separation of powers is too fundamental for us to preempt congressional action by judicially decreeing what accords with 'common sense and the public weal.' Our Constitution vests such responsibilities in the political branches.

A. Misbranding

The Fifth Circuit held that Shriners "terminated the Former Employees for refusing to get vaccinated."[13] The use of the phrase "vaccinated" denotes a legal indication to achieve a legally identifiable result, as specified in its labeling, which none of the mandated drugs had. Promoting a drug beyond its authorized indication constitutes a misbranding offense under 21 U.S.C. § 352. A biologic achieves licensed status only upon bearing labeling that is compliant with 42 U.S.C. § 262(a)(1). The Secretary mandates that "[a] sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug."

[13] App. 14a.

21 C.F.R. 312.7(a). In light of the Secretary stating that the drugs are "not licensed for any indication,"[14] the Fifth Circuit's holding cannot stand as it tacitly endorses the promotion of products lacking any licensed indication as capable of "vaccinating" individuals. The holding contravenes the Secretary's determination that the investigational vaccines cannot achieve such a result and contravenes the FDCA. Equally problematic is the lower courts' *conflation* of laws relating to "investigational new drugs" with FDA-licensed vaccines, as demonstrated by the court's reframing of Petitioners' cause of action from a fundamental right to refuse an *investigational drug* to the Respondents' claim that Petitioners' cause asserted a fundamental right to refuse a *vaccine*.[15]

B. Federalwide Assurance and Institutional Review Board

The Fifth Circuit's statement that "It is commonplace for companies — particularly hospitals — to place such mandates on their employees"[16] is a false assertion made by no Respondent relating to *unlicensed* drugs. The Secretary binds all entities procuring and administering such unapproved treatments to the public — irrespective of their relational nexus to the individual, whether as employer, contractor, or volunteer — to abstain from imposing external pressures that might compel treatments. Thus apprised of this meticulously forged federal framework — designed to forestall any

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[14] 86 Fed. Reg. 5200 (Jan. 19, 2021), 86 Fed. Reg. 28608 (May 27, 2021).
[15] App. 6a, FN 3.
[16] App. 14a.

recurrence of historical abominations perpetrated through unapproved drugs, biologics, or devices — the Fifth Circuit nonetheless concluded, under Rule 12(b)(6), that Respondents are absolved of these federal imperatives by calling an unapproved medical treatment a "vaccine." Therefore, when the Circuit Court held that Shriners' mandate "was not unlawful," it judicially exempted Shriners from obligations owed to the Executive Branch under its FWA and Institutional Review Board.

III. A State cannot avoid its constitutional obligations by delegating its function without the obligations.

A. State Action

Respondents did not address Petitioners' allegations regarding the terms of the CDC and FWA programs in their lower court filings. The lower courts, in turn, also did not discuss those allegations and ruled in isolation from those facts. The discussion that follows thus focuses on the constitutional obligations owed to Petitioners, Ms. Young's duties under the CDC Program, and Shriners' agreement to perform those duties on behalf of the State — facts that no Respondent disputed.

At bottom, the State of Texas, acting through Ms. Young, owed Petitioners an entitlement under the CDC program to receive comprehensive disclosures regarding the investigational drugs' potential risks, benefits, and alternatives, as well as their prerogative to engage in medical consultation without any fee, penalty, or forfeiture of benefits —

irrespective of whether they elected to accept or refuse the products and per the legally effective informed consent standard. Ms. Young had a duty to ensure all State citizens gave legally effective informed consent when participating in the CDC Program, whether through a State agency or a recruited private party. Administration of the program by the State required adherence to the Fourteenth Amendment's guarantees of equal protection of the laws, due process, privacy, and bodily integrity.

Moreover, the PREP Act compels individuals to relinquish their due process right to pursue a cause of action if injured by a covered countermeasure. This court holds that a cause of action is a property right. See *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982) ("[A] cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause."); accord *Tulsa Prof'l Collection Servs., Inc. v. Pope*, 485 U.S. 478, 485 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985); *Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 313 (1950).

Under the Fourteenth Amendment's Due Process Clause, the State of Texas could not coerce Petitioners to use federally owned investigational drugs, penalize their refusal, compel use of EUA, or divest Petitioners of their federal entitlement to receive disclosures regarding the products' potential benefits and risks while exercising their prerogative to decline the drugs, by employing externally applied consequences. Moreover, Texas could not mandate Petitioners to use a covered countermeasure because such use requires them to surrender their due process rights to a cause of action and the state cannot "compel the surrender of one constitutional

right as a condition of its favor." *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593-94 (1926). Nonetheless, Ms. Young — the official entrusted with knowledge of the Program's terms and the ministerial duty to ensure that recruited entities refrain from mandating non-consensual use of the drugs and punishing refusal — willfully abstained from enforcing these protections, ostensibly to safeguard Texas' influx of over $27 billion in CDC Program revenues. This dereliction fostered a custom whereby state-recruited agents subjected healthcare workers to compelled investigational drug use with impunity. Compounding this, the Texas Workforce Commission perpetuated the custom by withholding unemployment benefits from workers invoking their federal right to refuse, notwithstanding the State's pledge to uphold that entitlement.

This Court holds that:

> [N]o State may effectively abdicate its responsibilities by either ignoring them or by merely failing to discharge them whatever the motive may be. It is of no consolation to an individual denied the equal protection of the laws that it was done in good faith. Certainly, the conclusions drawn in similar cases by the various Courts of Appeals do not depend upon such a distinction. By its inaction, the Authority, and through it the State, has not only made itself a party to the refusal of service, but has elected to place its power, property and prestige behind the admitted discrimination. The State has so far insinuated itself into a position of interdependence with Eagle that it must be

> recognized as a joint participant in the challenged activity, which, on that account, cannot be considered to have been so 'purely private' as to fall without the scope of the Fourteenth Amendment.

Burton v. Wilmington Pkg. Auth, 365 U.S. 715, 725 (1961). The State of Texas is similarly entangled with Shriners respecting the administration or coercion of investigational new drugs under the EUA.

Again, this Court has held that "[s]tates that chose to participate in the [education] program agreed to abide by the requirements of Title I as a condition for receiving funds." *Bennett v. Kentucky DOE*, 470 U.S. 656, 657 (1985). Texas chose to participate in the CDC Program, and is obligated to abide by the terms thereof: Ms. Young lacked the authority to abdicate her responsibility to enforce those terms among the parties she recruited, and her dereliction of duty effectuated an amendment of those terms.

In *West v. Atkins*, 487 U.S. 42, 56 (1988), this Court held:

> Whether a physician is on the state payroll or is paid by contract, the dispositive issue concerns the relationship among the State, the physician, and the prisoner. Contracting out prison medical care does not relieve the State of its constitutional duty to provide adequate medical treatment to those in its custody, and it does not deprive the State's prisoners of the means to vindicate their Eighth Amendment rights. The State bore an affirmative obligation to provide adequate medical care to West; the State delegated

> that function to respondent Atkins; and respondent voluntarily assumed that obligation by contract. …
>
> As the dissent in the Court of Appeals explained, if [contracting out services] were the basis for delimiting § 1983 liability, "the state will be free to contract out all services which it is constitutionally obligated to provide and leave its citizens with no means for vindication of those rights, whose protection has been delegated to 'private' actors, when they have been denied."

Id., at 56 and n. 14.

The instant case mirrors that paradigm: the State of Texas bore an affirmative obligation to obtain Petitioners' legally effective informed consent; Ms. Young delegated that duty to Shriners, and Shriners voluntarily assumed it by contract. The Fifth Circuit's holding that "Shriners had no obligation as an employer, as opposed to as a vaccine provider, to give them the option to refuse the vaccine"[17] creates an exemption from the State's contractual duty to Petitioners. Shriners' executives contractually pledged to discharge obligations on behalf of the State and the Secretary pursuant to the federal program and any EUA, extending to all Texas citizens. Furthermore, in *Bridges*, *supra*, the Fifth Circuit amplified this purported exemption, empowering CDC Program providers to penalize not only employees but also contractors, vendors, and volunteers transacting with the hospital who decline the investigational products. In so doing, the Fifth

[17] App. 8a.

Circuit granted state-recruited entities the authority to achieve indirectly what the State is constitutionally barred from doing directly. *See Bailey v. Alabama*, 219 U.S. 219, 244 (1911).

Ms. Young thus deployed Texas' agent Shriners' employee mandate as a "procedural device" to "produce a result which [she] could not command directly." *Speiser v. Randall,* 357 U.S. 513, 526 (1958).

Neither the district court nor the Fifth Circuit panel undertook to scrutinize Petitioners' claims under these undisputed facts, thereby depriving them of the right "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co.* at 433. Contrary to the Fifth Circuit's erroneous ruling that Respondents' conduct of mandating unlicensed drugs "was not unlawful," it is manifest that Shriners could not and cannot obtain and distribute these drugs outside of the CDC Program voluntarily entered into by the State of Texas — because the authorization, distribution, and administration of unlicensed investigational drugs is an exclusively governmental function of the State under a nationally declared emergency. Texas owes legally effective informed consent to potential participants on behalf of the USG, and its officials cannot avoid that obligation by delegating the federal program's function to Shriners without delegating its concomitant constitutional obligations.

B. Personal Jurisdiction.

The Fifth Circuit also held that "Bokovitz's and Farley's acts — signing the vaccination provider agreement — are insufficient to support specific

jurisdiction."[18] This is a curious statement because the Court was made aware that signing the agreement was a prerequisite for Respondents to access, administer, and bill the USG for rendered services performed in the State when acting on the State's behalf. Therefore, it cannot be reasonably argued for Rule 12(b)(6) purposes that Respondents did not take advantage of the benefits and protection of the State laws, subjecting them to personal jurisdiction. *See Hanson v. Denckla*, 357 U.S. 235, 253 (1958) (personal jurisdiction requires "some act by which the defendant purposefully avails itself of the privilege of conducting activities within the forum State, thus invoking the benefits and protections of its laws"). Further, the Circuit court held that "Gantt's, McCabe's, and Grady's acts — signing Shriners's mandatory vaccination policy — are not sufficiently connected to Texas to support specific jurisdiction" because the policy was not "focused on Texas."[19] While the policy may not have been "focused" on Texas, the signers knew it would be (and was) carried out in their Texas facilities, thus comprising an out-of-state act causing Petitioners' damages within the State. This establishes the "'certain minimum contacts … such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). Jurisdiction over Gantt, McCabe, and Grady is therefore proper "based on the 'effects' of their [out-of-state] conduct in [Texas]." *Calder v. Jones*, 465 U.S. 783, 789 (1984), citing *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 297–298 (1980).

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[18] App. 11a.
[19] App. 12a.

CONCLUSION

Petitioners respectfully urge this Court to grant a writ of *certiorari* for the reasons stated hereinabove.

Respectfully submitted,

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