No.

In the Supreme Court of the United States

JENNIFER BRIDGES, *et al.*,
Petitioners,

v.

THE METHODIST HOSPITAL, *doing business as* THE METHODIST HOSPITAL SYSTEM; METHODIST HEALTH CENTERS, *doing business as* HOUSTON METHODIST THE WOODLANDS HOSPITAL, *et al.,*
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

This case presents similar questions as No. 24-40436, *Jeri Pearson, et al., Petitioners v. Shriners Hospitals for Children, Incorporated*, *et al.*, and arises from the same court of appeals, which is being circulated for conference on October 17, 2025. In the case at bar, both the district court and the Fifth Circuit relied on facts presented in *Pearson* to resolve disputed facts and issues of law under Rule 12(b)(6). The Court may wish to consider the two petitions together.

Since the passage of the 1974 National Research Act, federal policy has ensured that no individual faces penalties or loss of benefits for refusing unapproved medical treatments.

QUESTIONS:

1. Whether a State's obligation under federally funded programs to obtain legally effective informed consent for unapproved medical treatments creates an individually enforceable liberty interest under the Due Process Clause to give or withhold such consent, actionable under 42 U.S.C. § 1983 upon violation?

2. Whether a State can evade its federal obligation to obtain legally effective informed consent for unapproved medical treatments through private delegation, and whether the private party's deprivation of Fourteenth Amendment rights in performing that function constitutes state action under 42 U.S.C. § 1983?

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees, contractors and vendors of The Methodist Hospital and Methodist Health Centers and are Jennifer Bridges, Ceranise Alcindor, Rosemarie Aldaya, Sandra Altamirano, Dina Amaya, Scott Anderson, Judith Andriko, Mary Apacway, Dajuana Armstrong, Kim Bane, Edna Barrera, Debra Baugh, Latricia Blank, James Borje, Laura Bowden, Savannah Brazil, John Brockus, Katherine Brol, Monika Bury, Amanda Castro, Patrick Charles, Tameka Clark, Brian Clegg, Sherry Colbert, De'Anna Conway, Brett Cook, JoAnn Crump-Creamer, Zoretta Curry, Julie DeTorre, Sierra Dockray, Stephanie Dunlap, Manuel Elizondo, Celina Elvir, Breann Emshoff, Brian Felgere, Elizabeth Flores, Rebekah Fontenot, Michelle Fuentes, Gerardo Garza, Aquarius Grady, Cedrick Green, Ashton Hanley, Tara Hansen, Stacey Hanzelka, Tanisha Hatchet, Starla Haugenater, Philip Herin, Shauna Herin, Jade Hernandez, Luz Hernandez, Sharon Hollier, Walter Infantes, Dana Janoch, Jason Jimenez, John Lasseigne, Ashlee Leon-Lewis, Shayna Lincoln, Amanda Lofton, Bennie Lopez, Stacey Martinez, Stefanie Martinez, Brian Matthews, James McCann, Becky Melcer, Rogelio Mendez, Jr., Kimberly Mikeska, Norma Miller, Yolunda Milton, Ahmed Montgomery, Robert Morin, Thomas Mulkey, Bob Nevens, Linda Pickard, McKenli Pinkney, Jonae Powell, Juan Ramirez, Averi Reed, Kimberly Rensi, Amanda Rivera, Peejayé Robins, Maria Rodriguez, Betty Samuel, Diana Sanchez, Giovanni Savans, Leevetra Seals, Maria Serrano, Kara Shepherd, Mandy Sisto, Nicole Smith, Talisha Smith, Anna Luz Soberano-Hathorn, Mary Louise Stephens, Freenea Stewart, Karene

Tanner, Kelly Tate, Shelby Thimons, Paige Thomas, Kaylan Timmons, Kathy Tofte, Derek Trevathan, Maria Trevino, Terah Trevino, Charles Varghese, Brandi Vincent, Mathea Volesky, Jennifer Warren, Alexandra Williams, Karen Witt, Kidist Woldergabriel, Latasha Woods, Katie Yarber, and Ricardo Zelante.

Respondents are The Methodist Hospital, *doing business as* The Methodist Hospital System; Methodist Health Centers, *doing business as* Houston Methodist The Woodlands Hospital, *doing business as* Houston Methodist Willowbrook Hospital, *doing business as* Houston Methodist Sugarland Hospital, and *doing business as* Houston Methodist Baytown Hospital; Marc L. Boom, M.D., Robert A. Phillips, M.D., Bryan Daniel, and Cecile Erwin Young.

CORPORATE DISCLOSURE STATEMENT

Petitioners are all individuals.

LIST OF DIRECTLY RELATED CASES

Jennifer Bridges, et al. v. The Methodist Hospital, et al., No. 24-20483, U.S. Court of Appeals for the Fifth Circuit. Judgment entered June 17, 2025.

Jennifer Bridges, et al. v. The Methodist Hospital, et al., No. 4:23-CV-1699*,* U.S. District Court for the Southern District of Texas, Houston Division. Judgment entered September 30, 2024.

Jennifer Bridges, et al. v. The Methodist Hospital, et al., No. 23-04-05209, 284th Judicial District Court, Montgomery County, Texas. Removed from state court to federal district court on May 8, 2023.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Jennifer Bridges, *et al.* 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 unpublished opinion appears at Appendix A and can be found at *Bridges v. Methodist Hospital,* 2025 U.S. App. LEXIS 14964 and 2025 WL 1693074. The District of Southern Texas' opinion is reproduced at Appendix B and can be found at *Bridges v. Methodist Hosp.,* 2024 U.S. Dist. LEXIS 176790 and 2024 WL 4354816.

JURISDICTION

The Fifth Circuit issued its opinion on June 17, 2025. Petitioners requested an extension of time in which to file the instant petition for a writ of *certiorari*, and were granted an extension by Justice Alito until October 15, 2025, No. 25A257. 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.

INTRODUCTION

Brought under 42 U.S.C. § 1983, this case arises from the federal government's response to the COVID-19 pandemic. In 2020, the Centers for Disease Control (CDC) established the CDC COVID-19 Vaccination Program (CDC Program) to administer investigational drugs to willing members of the public.

Federally funded unlicensed drugs must comply with the legally effective informed consent standard derived from the 1974 National Research Act, which standard ensures that individuals considering use of such drugs are never placed under coercion, undue influence, or unjustifiable pressure to use them. External pressure, negative or positive, nullifies the

consent standard. The Executive branch purchased the drugs, placing them under a congressional mandate to obtain legally effective informed consent of individuals in accordance with the Fifth Amendment's due process clause. The CDC delegated the informed consent requirement to Texas, which had a ministerial duty to obtain such consent from Petitioners. Through the CDC Program, Texas delegated to Respondent Houston Methodist the ministerial duty of obtaining legally effective informed consent, denying it any right to list the drugs under a mandate, which it violated by mandating the use of drugs and punishing Petitioners for exercising their programmatic option to refuse.

This case presents novel questions of significant national importance concerning when, where, and how an individual can be subjected to investigational drugs while simultaneously being deprived of the right to sue when injured by such drugs or related activities. Petitioners allege that the State of Texas and respondent Houston Methodist voluntarily and contractually assured the United States Government, under the FWA program, that they would not subject individuals to threats of penalty for refusing unlicensed drugs administered through the federally funded CDC Program—a factual assertion that no Respondent disputed.

This case does not challenge whether Respondent Houston Methodist may generally impose a vaccination requirement relying upon FDA-licensed drugs; rather, it is narrowly tailored to determine whether Houston Methodist, performing under a state obligation, can mandate Petitioners to use unapproved medical treatments under threat of penalty despite contractual commitments to

voluntariness — commitments that preempt conflicting state actions under the Supremacy Clause.

Because of the effect this case and No. 24-40436, *Jeri Pearson, et al., Petitioners v. Shriners Hospitals for Children, Incorporated*, *et al*., have on the power of the Executive branch and the health of the American public, Petitioners suggest that the Court should grant *certiorari* in both cases and call for the views of the Solicitor General.

STATEMENT OF THE CASE

I. Legal Background

Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301 *et seq*.), which vested the federal government with exclusive authority to determine when, where, and how a drug, biologic, or device will be introduced into commerce and the conditions under which they may be labeled, marketed, and administered. No State or political subdivision may establish a legal requirement that is different from or conflicts with the requirements under the FDCA. See *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341 (2001); *Riegel v. Medtronic, Inc*., 552 U.S. 312 (2008); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013).

Secretary's exclusive authority

Congress empowers the Secretary of Health and Human Services ("Secretary") with the exclusive authority to establish expanded access protocols for unlicensed drugs. He can authorize access to such

drugs for purposes of research and education under 21 U.S.C. § 355(i), conditioned on potential recipients being informed that the drugs are investigational (*i.e.,* not licensed for any indication) and on the sponsor of the research obtaining informed consent. § 355(i)(4). The Secretary may also introduce unlicensed drugs into commerce for emergency medical purposes under 21 U.S.C. § 360bbb(a) for single administration or for small groups, so long as the administration of the drug is consistent with the informed consent protocols under 21 U.S.C. § 355(i).

During a nationally declared emergency, the Secretary is authorized to introduce unlicensed drugs into commerce for large populations, provided he believes the product "may be effective in diagnosing, treating, or preventing" the life-threatening emergency condition. § 360bbb-3(c)(2)(A). However, Congress requires the Secretary to ensure that informed consent is obtained by establishing appropriate conditions informing the medical community that he has authorized the use of the unlicensed drug (temporary exemption from 21 U.S.C. § 355(a)) and ensuring that conditions are established to inform potential recipients of their "option to accept or refuse administration of the product." § 360bbb-3(e)(1)(A)(ii)(III). Importantly, Congress denies the Secretary authority to mandate persons to participate in authorized activities, including the use of EUA products. § 360bbb-3(l). Therefore, the Secretary may authorize Pfizer, Inc. to manufacture an Emergency Use Authorization ("EUA") drug, but he cannot require Pfizer to manufacture it, nor mandate a doctor to administer it, nor a person to receive it.

When determining the legal meaning of the "option to accept or refuse administration of the

product" under an EUA, it is helpful to understand the context of that statement within the congressional mandate under 42 U.S.C. § 289, as regulated under 45 C.F.R. Part 46, which requires an Institutional Review Board ("IRB") to oversee the uses of federally funded unlicensed drugs, even during a nationally declared emergency, to ensure that the "rights" of the individual are protected. Congress, desiring to ensure that Americans were no longer subjected to medical research abuses as exposed by Senator Edward Kennedy,[1] enacted the National Research Act of 1974 to prevent further abuses. This Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research ("the Commission"), which is empowered to consider "the nature and definition of informed consent in various research settings."

In 1979, the Commission issued the seminal Belmont Report,[2] 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 pressure. Guided by the Belmont Report and pursuant to the congressional directive in the National Research Act and 42 U.S.C.

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[1] 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

[2] 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.

§ 289, the Secretary in 1981 promulgated regulations at 45 C.F.R. Part 46, Subpart A ("Common Rule"), binding all federal agencies, departments, and the military to comply with the regulatory framework and the Belmont Report. 45 C.F.R. § 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 C.F.R. § 46.101(i).

The Common Rule established uniform protections for individuals subjected to federally funded unlicensed drugs through a new legal standard known as legally effective informed consent. 45 C.F.R. § 46.116(a)(1). Obtaining consent was no longer enough to justify an individual's use of such drugs; the researcher had a duty to offer the drugs in a legally approved environment, ensuring that the potential recipient was *not under pressure* before giving their consent. If an individual is under external pressure, whether positive or negative, consent is not legally effective.

The requirement 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, or the Secretary issuing a requirement among EUA-authorized agents to monitor for specific adverse reactions and to report those events to add to the "generalizable knowledge of the product." *Id*.

To comply with the congressional mandate under 42 U.S.C. § 289 relating to federally funded unlicensed drugs, the Executive branch established the Federalwide Assurance ("FWA") program under the authority of the Assistant Secretary of Health. The FWA program requires persons conducting business with the federal government to provide HHS with written assurance that they will comply with 45 C.F.R. Part 46, the Belmont Report, and the legally effective informed consent doctrine when involving humans with unlicensed drugs. There are an estimated 30,000 active FWA contracts, including all U.S. States, territories, and most major hospitals (including Houston Methodist and Shriners), universities, and other entities. There are no exceptions to the legally effective informed consent standard relating to conscious civilians.

Additionally, persons requesting an investigational drug authorization must promise to comply with the legally effective informed consent standard as a condition of authorization. 21 CFR § 312.60. The United States Food and Drug Administration ("FDA") requires legally effective informed consent in clinical investigations, as meticulously outlined under 21 CFR § 50.24, in accordance with 21 CFR § 50.20. An IRB has a ministerial duty to ensure that legally effective informed consent is obtained at all times. 21 CFR 56.111(a)(4). Although not all of these provisions

apply to Petitioners' arguments, they demonstrate the full intent of the Legislative and Executive branches to completely prohibit an individual from being pressured to use unlicensed drugs or being penalized for refusing such drugs.

45 C.F.R. § 46.122, mandated under 42 U.S.C. § 289, and enforced via the FWA program, requires compliance with 45 C.F.R § 46.116(a)(1) as a condition of the activity being funded by the government. That regulation states, "Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative." All manufacturers of EUA drugs are subject to this requirement. 45 C.F.R. § 46.116 *et seq*. outlines what legally effective informed consent entails. The language in 21 U.S.C. §360bbb-3(e)(1)(A)(ii) corresponds with the legally effective informed consent requirements outlined in 45 C.F.R. § 46.116 and 21 U.S.C. § 355(i)(4). The duty of the Secretary to ensure that the potential recipient receives full disclosure of the EUA product's potential risks, benefits, and alternatives directly corresponds with Common Rule requirements under 45 C.F.R. §§ 46.116(b)(2-4). Therefore, the congressional mandate of the Secretary to ensure that potential recipients are informed of their EUA option to accept or refuse, while denying the Secretary authority to mandate involuntary use, ensures that the legally effective informed consent conditions are met, as any offer to use the drug is not influenced by external pressure. The primary difference between obtaining informed consent under an EUA and under 45 C.F.R. § 46.116 is that EUA consent is verbal rather than written, unless the Secretary states otherwise.

PREP Act's express preemption clause

All of the drugs offered under the CDC Program were listed as covered countermeasures under the Public Readiness and Emergency Preparedness Act ("PREP Act"), codified at 42 U.S.C. § 247d-6d and § 247d-6e.

> No State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that … relates to … any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301, *et seq*.]

42 U.S.C. § 247d-6d(b)(8)(B).

One such requirement applicable to the CDC Program's countermeasures is the FDCA's option to refuse an EUA drug under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). Therefore, State and local governments are expressly preempted from establishing legal requirements mandating individuals to use an EUA drug listed as a countermeasure because such a requirement would conflict with the FDCA's option to refuse. Moreover, use of a PREP Act-covered countermeasure requires the user to willfully surrender their fundamental due process right to sue when injured by the countermeasure or related activities. Governments cannot mandate a person to surrender their constitutional guarantees. Thus, they cannot use the PREP Act as a "procedural device" to "produce a result which the State could not command directly."

Speiser v. Randall, 357 U.S. 513, 526 (1958).

Therefore, whether by the express preemption clause relating to EUA drugs or by the Constitution's Due Process Clause for any countermeasure, licensed or unlicensed, governments cannot compel use of a covered countermeasure through threats of penalties because such conduct manipulates an individual's constitutional guarantees out of existence. *See Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593–94 (1926), (affirming that a State "may not impose conditions which require the relinquishment of constitutional rights.)

II. Factual background and procedural history

This case is about how the federal government requires persons acting under its authority or using its funding to obtain an individual's legally effective informed consent when involving them with unlicensed drugs. As relevant here, the Centers for Disease Control ("CDC") informed the nation in 2021:

> At this time, all COVID-19 vaccine in the United States has been purchased by the U.S. government (USG) for administration exclusively by providers enrolled in the CDC COVID-19 Vaccination Program and remains U.S. government property until administered to the recipient. Only healthcare professionals enrolled through a health practice or organization as vaccination providers in the CDC COVID-19 Vaccination Program (and authorized entities engaged in shipment for the Program) are authorized to

> lawfully possess, distribute, deliver, administer, receive shipments of, or use USG-purchased COVID-19 vaccine. Other possession, distribution, delivery, administration, shipment receipt, or use of COVID-19 vaccine outside the parameters of the Program constitutes, at a minimum, theft under 18 U.S.C. § 641, and violation of other federal civil and criminal laws. Violators are subject to prosecution to the full extent of the law.[3]

The Secretary informed the nation that the drugs are "an investigational vaccine not licensed for any indication" and only introduced into commerce under an EUA and are listed as covered countermeasures under a declaration made pursuant to the PREP Act. *See* 86 Fed. Reg. 5200 (Jan. 19, 2021), 86 Fed. Reg. 28608 (May 27, 2021), and 85 Fed. Reg. 15198 (March 17, 2020).

In 2020, the CDC established the federally funded COVID-19 Vaccination Program to administer the unlicensed drugs to the public in accordance with federal law. The CDC, operating under FWA00001413, established the federal program as a cooperative agreement in accordance with 42 U.S.C. § 289 and its corresponding legally effective informed consent standard at 45 C.F.R. § 46.116. The CDC was bound to ensure that potential recipients were informed of their right to refuse without consequence. The CDC only recruited U.S. States and territories directly to help it administer the drugs to the public because those entities held active

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[3] CDC, "How to Enroll as a COVID-19 Vaccination Provider," https://web.archive.org/web/20211031192200/https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html

FWA agreements, which bound them to the exact legal requirements that Congress requires of the Executive branch regarding unlicensed drugs. The CDC required participating States to assume the role of "Emergency Response Stakeholder" to ensure that the Secretary's conditions of authorization were implemented, including the requirement to inform potential recipients of their option to refuse EUA products.

Texas, on its own prerogative, agreed to perform on behalf of the CDC in accordance with the Program's terms. Operating under FWA00028877, Texas knew that it could not mandate individuals to use federally funded unlicensed drugs. Moreover, the State was preempted under the Supremacy Clause from establishing legal requirements conflicting with the Secretary's conditions of authorization for any EUA, and the PREP Act expressly preempted the State from mandating involuntary EUA use, *see infra*. Finally, as a governmental function in accordance with the Fourteenth Amendment, the State was required to obtain legally effective informed consent from every potential recipient, which fact prevents the State from listing the drugs under a mandatory requirement.

The CDC did not provide Texas with discretionary authority to amend the terms of the program so as to allow any person to come under the threat of penalty or incur a penalty or lose a benefit to which they were otherwise entitled when refusing. However, the CDC did permit Texas to recruit public and private parties to assist it in fulfilling its promised functions to the federal government, predicated upon the State incorporating the terms of the CDC Program Provider Agreement ("Provider Agreement") into official state policy, ensuring that

recruited agents sign the agreement, and monitoring agents for compliance.

The Provider Agreement stated, "This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC."[4] The persons required to sign the agreement are the Chief Executive and Medical Officers, or their equivalents, and "Responsible Officers" as designated by the participating "Organization." However, only State-authorized organizations could act on the State's behalf in the CDC Program. Importantly, the Organization promised to "comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine." Under each EUA, the Organization assumed the role of "Vaccination Provider," promising to act on the Secretary's behalf to execute his conditions of authorization.

Texas recruited Respondent Houston Methodist. Operating under FWA00000438, Houston Methodist knew that it could not place individuals under the threat of penalty to use federally funded unlicensed drugs, a claim undisputed by Respondent. At all times material, the CDC Program required Texas to obtain legally effective informed consent, which in turn, delegated that duty to Houston Methodist, who owed that duty to all Texas' residents in accordance with the Fourteenth Amendment, as a delegated agent of the State, irrespective of any relationship it

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[4] *CDC COVID-19 Vaccination Program Provider Agreement*. (11/10/2020). *See, e.g.,* https://www.nyc.gov/assets/doh/downloads/pdf/imm/covid-19-vaccine-program-agreement-letter.pdf, pp. 5–8.

may have had with any individual (e.g., employee, contractor, vendor, volunteer).

On April 1, 2021, years before any such licensed drug existed in commerce, Respondent Houston Methodist enacted a policy placing employees, contractors, vendors, and volunteers under coercive external pressure to be injected with one of the CDC Program's investigational drugs or face employment termination should they refuse. When Petitioners refused to surrender their Fourteenth Amendment rights, Respondent, acting under a state-enforced custom, penalized them by terminating their employment, conduct they are contractually prohibited from engaging in under their FWA agreement and in violation of their duties owed to the State and Petitioners under the CDC Program.

Proceedings in the state court

Petitioners sued Respondents in state court on April 10, 2023, for the violation of their rights and termination of their employment. Respondents removed to federal district court on May 8, 2023.

Proceedings in the federal district court

Petitioners amended their complaint to sue Respondents under 42 U.S.C. § 1983 for deprivation of Petitioners' Fourteenth Amendment rights, alleging that they held a Fourteenth Amendment due process right to refuse the drugs. Petitioners also alleged that they held a statutory entitlement under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III) to refuse such drugs without consequence, the deprivation of which is enforceable under 42 U.S.C. § 1983 pursuant to *Health and Hospital Corp of Marion Cty. v. Talevski*, 599 U.S. 166 (2023).

Petitioners also claimed liberty and property

rights under the CDC Program to refuse administration of the drug.

Texas, having paid out unemployment benefits to Petitioner Bob Nevens, required him to repay them after Respondent Houston Methodist informed the State that Mr. Nevens violated the company policy by refusing to be injected with a COVID-19 drug. Petitioners sought a ruling from the district court that States may not deny unemployment benefits to a person who exercised their right to refuse the CDC Program's drugs.

Respondents filed Rule 12(b)(6) motions to dismiss. In granting the motions, the district court stated that Petitioners "were let go for refusing to inoculate themselves against COVID-19," which is the court's insertion of a fact: that the FDA licensed the drug to inoculate a person from the coronavirus. This contradicts the FDA's determination that the drug was *not* licensed for any such indication.

The district court concealed the alleged material facts through omission, disregarding the CDC Program, the drugs' classification as investigational, the State's duties owed to Petitioners, and Houston Methodist's obligation to obtain legally effective informed consent from Petitioners on the State's behalf.

Aware of the explicit prohibitions on the nonconsensual use of federally funded investigational drugs, the district court nevertheless erroneously applied *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), and stated, "Plaintiffs do not have a fundamental right to refuse vaccination."

Proceedings in the federal appellate court

Petitioners appealed. The Fifth Circuit upheld the district court's decision. The Circuit started its

ruling stating that none of the Petitioners "allege that any defendant directly administered the vaccine to them[.]" Petitioners' claims had nothing to do with being administered the investigational drug at all (since all refused to be injected); they claimed injury from the deprivation of their Fourteenth Amendment right to refuse the unlicensed drugs, in the face of a legal environment requiring them to publicly disclose their identifiable private and health information and to forfeit their due process right to sue for injury from PREP Act countermeasures.

The Circuit court concealed the alleged material facts through omission, disregarding the CDC Program, the drugs' classification as investigational, the State's duties owed to Petitioners, and Houston Methodist's obligation to obtain legally effective informed consent from Petitioners on the State's behalf.

Further reframing Petitioners' allegations, the Circuit court stated that Petitioners claimed a "substantive due process right to refuse a vaccine," when Count One stated that Petitioners were subjected to investigational drug use, not vaccines. The Fifth Circuit stated that the Petitioners alleged violation of their "equal protection right not to be classified on the basis of vaccination status."[5] Petitioners actually claimed that the right to refuse participation in the CDC Program and its applicable laws is equal to the right to accept, and their chosen option to refuse was treated differently from the option to accept.

The court asserted that Petitioners' alleged a "procedural due process right to a hearing prior to depriving them of their right to refuse a vaccine

[5] App. 7a.

without penalty,"[6] when they claimed a right not to be deprived of their statutory and constitutional rights by a State actor when refusing unlicensed drugs or refusing to surrender their due process rights to sue if injured by a PREP Act countermeasure. Finally, the Fifth Circuit asserted that Petitioners claim a "right to refuse a vaccine under the Spending Clause of the Constitution, and various statutes, treaties, and administrative actions." However, Petitioners claimed specific rights to refuse participation in the CDC Program, EUA medical products, PREP Act-covered counter-measures, and federally funded investigational new drugs based on specific rules of understanding.

The Fifth Circuit fundamentally distorted the gravamen of Petitioners' claims, reframing them from a challenge to compelled use of unlicensed drugs—rooted in federal laws, regulations, and Executive directives on unapproved products—to a routine workplace vaccination dispute. This Court holds that plaintiffs are "masters of their complaint," controlling their legal theories and facts. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). By reframing Petitioners' claims as attacking a private policy, rather than Fourteenth Amendment violations tied to the COVID-19 Vaccination Program and rules on unlicensed drugs and coerced treatments, the Fifth Circuit denied Petitioners' due process right to have their merits fairly judged.

The panel erred further by noting that a "private organization's vaccination policy is not a 'power[] traditionally exclusively reserved to the State.'"[7] Though abstractly true, this ignores the facts: Texas agreed to administer federally funded, unlicensed

[6] App. 7a.
[7] App. 9a.

interventions as an emergency public function for the federal government, an exclusive traditional power of the State, then delegated its obligations under the emergency program to Respondent Houston Methodist, imposing the same constitutional duties on it as on the State. If courts can arbitrarily reframe Petitioners' allegations of state action as unrelated to the governmental program, Petitioners become "master[s] of nothing." *Id.* As this Court stated in *Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913), "the party who brings a suit is master" of its pleadings, and the Fifth Circuit cannot rewrite them to evade review.

REASONS FOR GRANTING THE WRIT

I. The legally effective informed consent standard is a liberty interest subject to the Due Process Clause.

Legally effective informed consent.

The Due Process Clause of the Fourteenth Amendment prohibits any State from depriving "any person of life, liberty, or property, without due process of law." U.S. Const. amend. XIV, § 1. This safeguard encompasses the fundamental liberty interest in refusing unapproved medical treatment, including injections of drugs neither labeled for any indication nor approved for safety. The Legislative branch firmly established the right to refuse such treatment as described herein. Persons offering the treatment have a duty to obtain the potential recipient's legally effective informed consent via 45 C.F.R. § 46.116, which regulation derives its authority from 42 U.S.C. § 289; 42 U.S.C. 300v-1(b).

Legally effective informed consent can only be obtained under conditions free of coercion, undue influence, or unjustifiable pressure.[8] This consent doctrine is both "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 (1997). Being deeply rooted is evidenced by the fact that all U.S. States and an estimated 30,000 additional entities have agreed to the consent standard through their FWA contracts. This Court's precedence relating to the fundamental right to refuse *unwanted* medical treatment extends to the right to refuse *unapproved* medical treatments, because unapproved drugs carry inherent risks of depriving a person of their life, liberty, and property. See *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) (affirming that "competent persons generally are permitted to refuse medical treatment"); *Union Pacific Railway Co. v. Botsford*, 141 U.S. 250 (1891) (affirming the "right of every individual to the possession and control of his own person); *Washington v. Glucksberg*, 521 U.S. 702 (1997) (recognizing the "long legal tradition [of the courts] protecting the decision to refuse unwanted medical treatment"); *Albright v. Oliver*, 510 U.S. 266, 272 (1994) (recognizing the "right to bodily integrity" is a fundamental right).

Vaccine mandates are issued to treat, cure, or prevent a known disease. But unlicensed drugs are not legally indicated for such purposes. Only the FDA has the authority to designate a drug's legal indications; any individual or entity assigning such

[8] *See* Belmont Report, "Voluntariness" and 45 C.F.R. § 46.116.

an indication outside of FDA oversight, with the intent of inducing others to use the drug under the false belief that it is legally indicated, engages in misbranding under 21 U.S.C. § 352, which violates federal law.[9]

Each use of an unapproved medical treatment must be reviewed by an IRB and require legally effective informed consent of the participant, without exception. Moreover, "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." (21 C.F.R. § 312.7(a)). Any person administering EUA drugs is acting on behalf of the drug's sponsor.

Congress was so moved by the past human rights atrocities exposed by Senator Kennedy, as mentioned above, that when it authorized the Secretary to establish expanded access protocols and conditions of authorization for the administration of investigational drugs, it was only on the condition that informed consent must always be obtained. The duty to obtain such consent confers upon the potential recipient a property right to grant or withhold that consent, which right is subject to the Due Process

[9] "Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – i.e., any use not specified in an application and approved by FDA." U.S. Department of Justice, Office of Public Affairs. "Justice Department announces largest health care fraud settlement in its history." (September 2, 2009). https://www.justice.gov/archives/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history

clause.

This Court holds that "[t]o have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Board of Regents of State Colleges v. Roth,* 408 U.S. 564, 577 (1972).

> Property interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law — rules or understandings that secure certain benefits and that support claims of entitlement to those benefits. Thus, the welfare recipients in *Goldberg v. Kelly*, 397 U.S. 254 (1970), had a claim of entitlement to welfare payments that was grounded in the statute defining eligibility for them.

Id.

The CDC Program defined Respondents' duties to provide Petitioners full disclosure of the products' risks, benefits, and alternatives, and of their right to refuse such products without coming under pressure to participate or incurring a fee or penalty for refusing. These federally funded entitlements are analogous to the welfare recipient in *Goldberg*. These benefits are subject to the Due Process Clause, which Texas owed Petitioners, as a governmental function under the CDC Program, delegated to Respondent Houston Methodist to perform on the State's behalf.

Moreover, Congress may not impose upon an entity the obligation to obtain an individual's legally

effective informed consent without concurrently vesting in the potential recipient 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.") Such consent is a liberty interest, subject to the Due Process Clause, because it stems from rules, understandings, and expected entitlements when involved in federally funded, unlicensed drugs. Correspondingly, Congress mandating the Secretary to ensure that Petitioners are informed of their option to accept or refuse the administration of an EUA product means they have been granted a liberty interest to choose, without penalty. The option is subject to the Due Process Clause and cannot be taken without procedural due process. This Court held in *Dennis v. Higgins*, 498 U.S. 439, 445 (1991) that "we have given full effect to its broad language, recognizing that §1983 'provide[s] a remedy, to be broadly construed, against all forms of official violation of federally protected rights,'" and "'we refused to limit the phrase to 'personal' rights, as opposed to 'property' rights.'" *Id*., *citing Lynch v. Household Finance Corp.,* 405 U.S. 538 (1972).

Whenever a human is presented with an opportunity to use federally funded unlicensed drugs, legally effective informed consent must be the key that unlocks their use.

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).

In *The Upjohn Co. v. Finch*, 422 F.2d 944, 954 (6th Cir. 1970), the Sixth Circuit 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 States and political subdivisions to mandate such treatments, implying that they do hold the fundamental right to access them and to provide them to persons under such mandate.

EUA statute

Under the EUA statute, the Secretary may authorize a manufacturer's unapproved medical treatments for emergency use, but only by imposing stringent requirements for voluntary use. Critically, the Secretary bears a non-discretionary duty to ensure that potential recipients receive comprehensive information about the treatment's emergency status, its known and potential benefits and risks, and—most salient here—their unqualified option to accept or refuse. This obligation survives delegation: the Secretary authorizes a manufacturer

to introduce an EUA treatment into commerce under voluntary conditions, with which no State or political subdivision may interfere. Those volunteering to administer the treatment are bound to the statute's prohibitions and must faithfully execute the Secretary's conditions of authorization. Therefore, where Congress bars the Secretary from mandating EUA treatments,[10] then the Supremacy Clause dictates that persons who volunteer or contract to administer such treatments on his behalf are also subject to that prohibition.

The Secretary's duty to ensure that Petitioners are informed of their option to refuse EUA products means Congress fully expects them to effectively exercise that option without consequence. In *Talevski, supra*, the Court held that the "right to be free from … any physical or chemical restraints" and the right to advanced notice of discharge provisions of the FNHRA[11] statute "meet this test," stating, "This framing is indicative of an individual's rights-creating focus. *Gonzaga*, 536 U.S., at 284." *Id*., at 184.

21 U.S.C. §360bbb-3(e)(1)(A)(ii) "unambiguously confers" the right to be informed of the option to accept or refuse administration of the product. Also, it speaks in terms of "individual rights upon a class of beneficiaries" to which the plaintiff belongs. The provision actually uses the word "individuals" when describing to whom the right is conferred. The class of beneficiaries is those contemplating the "administration of the product." *Id.* By describing the right the way it did, Congress intended to create a federal right for the identified class.

The Fifth Circuit's ruling that Respondents' role

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[10] 21 U.S.C. § 360bbb-3(l).

[11] Federal Nursing Home Reform Act.

under the EUA "does not apply at all' to those acting in their role as 'private employers like the hospital in this case'"[12] is misleading because Respondent Houston Methodist, the "Organization," signed an agreement to perform on the Secretary's behalf with regard to the EUA treatments. Respondent is expressly preempted from accomplishing a result on behalf of the Secretary that the Secretary cannot accomplish himself.

CDC COVID-19 Vaccination Program

The CDC Program was subject to the legally effective informed consent standard. Investigational drugs are subject to the Common Rule when a federal agency using federal funding engages in research activities using private identifiable information, and the activity will use the individual's data to "contribute to generalizable knowledge" of the product or determine the effectiveness of a federal program. 45 C.F.R. §§ 46.101, 46.102(e)(1)(ii), 46.102(l), 46.122. The CDC Program, and its corresponding Provider Agreement, was a legally distinct set of requirements in addition to those under any EUA. States agreed to collect participants' private identifiable information, conduct research activities (*i.e.,* monitoring for specific adverse reactions), and report such adverse reactions to the Executive branch so it could add that data to the generalizable knowledge of the product, subjecting the CDC Program to the Common Rule's requirements, FWA obligations, and the prohibition of coercion or undue influence in obtaining consent. 45 C.F.R. § 46.116 (a)(1)-(8).

When offering individuals the opportunity to

[12] App. 10a.

participate in the CDC Program, the Executive branch was obligated to secure legally effective informed consent, as mandated under 42 U.S.C. § 289 through the Common Rule. Moreover, it could not compel the use of the drugs conditioned on any public benefit, given that these products were designated as covered countermeasures under the PREP Act; such mandates would unconstitutionally condition access to governmental benefits on the waiver of Fifth Amendment due process rights to pursue remedies for harm. See *Perry v. Sindermann*, 408 U.S. 593, 597 (1972) (the government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests"). These prohibitions and obligations were delegated to Texas via the CDC Program, without discretionary authority to alter the prohibitions and obligations.[13] Texas, under an obligation to administer the program in accordance with the Fourteenth Amendment, delegated its obligations to Respondent Houston Methodist. At the same time, the Executive branch retained ownership of the investigational drugs until physical administration. This unbroken chain — Executive branch to Texas to Respondent — prohibited all parties from mandating the drugs or penalizing refusal. The constitutional duties flowed downward, rendering Respondent's deprivation of Petitioners' informed consent rights a quintessential state action under the Fourteenth Amendment, actionable via § 1983.

Certiorari is essential to vindicate the safeguards designed by the Executive and Legislative branches over the past 50 years to prevent the kind of human

[13] *Bennett v. Kentucky* DOE, 470 U.S. 656, 657 (1985), affirming that states choosing to participate in federal programs to receive funding must abide by the program's conditions.

rights atrocities the U.S. Senate sought to end when enacting the National Research Act.

II. A State cannot evade constitutional obligations by delegating its functions to private parties without delegating its obligations.

When a State delegates its governmental functions to private entities, it cannot evade its constitutional duties or strip individuals of their liberty interests through that private delegation.

As one court aptly observed: "If a state government must satisfy certain constitutional obligations when carrying out its functions, it cannot avoid those obligations and deprive individuals of their constitutionally protected rights by delegating governmental functions to the private sector. … The delegation of the function must carry with it a delegation of constitutional responsibilities." *Giron v. Corrections Corp. of Am.*, 14 F. Supp. 2d 1245, 1249 (D.N.M. 1998), *citing Terry v. Adams*, 345 U.S. 461 (1953). This principle echoes in this Court's precedents, such as *West v. Atkins*, 487 U.S. 42, 54–57 (1988), holding that if a State bears an obligation to perform a function and delegates that function to a private party voluntarily agreeing under contract to perform it, then the private party's deprivation of the obligation constitutes state action for purposes of 42 U.S.C. § 1983 enforcement. Further, the *Atkins* court took note of the circuit court's dissenting opinion, stating that a State cannot contract out its constitutional obligations to "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 n. 14. *See also*

Bailey v. Alabama, 219 U.S. 219, 244 (1911) ("What the state may not do directly it may not do indirectly.")

A national public health emergency delegated to the State is unequivocally a power traditionally reserved for the State. The CDC COVID-19 Vaccination Program conferred on Petitioners a federally funded benefit: comprehensive disclosure of the investigational drugs' risks, benefits, and alternatives, coupled with a guarantee against coercion by the State of Texas or its delegated agents. Bound by its FWA contract, Texas pledged not to pressure individuals into using federally funded investigational products, ensuring compliance with the legally effective informed consent standard. Thus, neither the State nor its recruits could mandate the drugs or leverage them as conditions for unrelated benefits. While Houston Methodist retains broad discretion to terminate at-will employees, it cannot wield that power to compel nonconsensual participation in the CDC Program without implicating state action.

Texas owed Petitioners a federal obligation to obtain legally effective informed consent, and Houston Methodist voluntarily contracted to discharge that duty on the State's behalf, rendering it a State actor under the Fourteenth Amendment. Texas bore a ministerial duty to prevent its recruited delegates from coercing participation, yet it failed to discharge this responsibility. This Court has made clear 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. … By its inaction, the [state entity], and through it the State, has not only made itself a party to the [discrimination], but has elected to place its power,

property and prestige behind [it]." *Burton v. Wilmington Parking Auth.*, 365 U.S. 715, 725 (1961).

When Respondent contested Petitioner Bob Nevens' unemployment claims based on his refusal to take the drugs, the State enforced that denial of a benefit, establishing a state-enforced custom and engaging in joint action with Houston Methodist to deny Petitioners their Due Process right to withhold legally effective informed consent. These facts establish Houston Methodist's state action when depriving Petitioners of their right to withhold consent (a liberty interest). As the Ninth Circuit explained, a defendant "subjects" another to a constitutional deprivation within § 1983's ambit through "an affirmative act, participat[ion] in another's affirmative acts, or omit[ting] to perform an act which he is legally required to do that causes the deprivation." *Johnson v. Duffy*, 588 F.2d 740, 743 (9th Cir. 1978) (*citing Sims v. Adams*, 537 F.2d 829 (5th Cir. 1976)).

This Court holds that "[Congress's] intent to displace state law altogether can be inferred from a framework of regulation 'so pervasive … that Congress left no room for the States to supplement it' or where there is a 'federal interest … so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.'" *Arizona v. United States*, 567 U.S. 387, 399 (2012), quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

As described in *Arizona,* Congress enacted a complete scheme of regulation and provided a standard for the administration of federally funded unlicensed drugs that States and political subdivisions cannot conflict or interfere with, or curtail or complement, or enforce additional or

auxiliary regulations, because such infringement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

The State cannot avoid preemption through delegation. This case exemplifies how emergency delegations to private parties led to unlawful coerced deprivations of liberty interests without due process.

III. Justice demands review

The Fifth Circuit's ruling exemplifies a disturbing judicial trend in sister circuits and district courts alike: the arrogation of powers constitutionally reserved to the federal government under the FDCA and PHSA, followed by their improper delegation to States, political subdivisions, and private executives — all in blatant defiance of federal supremacy. This power grab manifests in no fewer than 17 parallel federal lawsuits, each contesting identical abuses by similarly situated defendants, and all now advancing toward this Court.

Boysen v. PeaceHealth, No. 24-5204, was filed in the Ninth Circuit August 22, 2024 on appeal from *Boysen v. PeaceHealth,* No. 6:23-cv-01229-AA, (D. Or., August 19, 2024). The appeal was filed after the case was dismissed for failure to state a cause of action. The court effectively held that the federal government does not determine the when, where, and how a drug will be introduced into commerce and/or labeled for its safety and indication, but rather, it is the "common belief of the people of the state … and members of the medical profession" who shall make such determinations, vitiating the FDCA

entirely.[14] The court arrogated powers unto the State of Oregon that Congress exercises under the commerce power. Even if Congress had not so acted, however, abrogating the liberty interest in refusing experimental medical treatments is not within state power.

Roberts v. Shriners Hosps. for Child., No. 24-1949, was filed in the Ninth Circuit March 26, 2024, on appeal from *Roberts v. Shriners Hosps. for Child*, No. 2:23-CV-0295-TOR (E.D. Wa., February 02, 2024). The appeal was filed after the case was dismissed for failure to state a cause of action. Shriners argued the drugs were not unapproved drugs, which Plaintiffs contested with a judicially noticeable document from Secretary Becerra placing defendants under a ministerial duty to conspicuously state that the Pfizer-BioNTech COVID-19 Vaccine drug "has not been approved or licensed by the FDA." The district court disregarded Executive branch determinations and held that the drug was "effectively FDA approved," a legally meaningless phrase, and that "Plaintiffs' claims that Defendants' vaccination policy was unlawful because an FDA-approved vaccine was unavailable falls short."[15] The court, arrogating power to Shriners to determine the drug's classification, implicated the Secretary of violating the EUA statute by issuing EUAs when an FDA drug was approved for the intended emergency use.

Martinez v. Eastside Fire and Rescue, No. 25-5982, was filed in the Ninth Circuit September 18, 2025, on appeal from *Martinez v. Eastside Fire and*

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[14] *Boysen v. PeaceHealth*, 2024 U.S. Dist. LEXIS 147502, at *3 (*citing Jacobson*).

[15] *Roberts v. Shriners Hosps. for Child.*, 2924 U.S. Dist. LEXIS 235070, at *14.

Rescue, No. 2:24-cv-01706-TL (W.D. Wa., June 10, 2025). The appeal was filed after the case was dismissed for failure to state a cause of action. The court was provided with a judicially noticeable document that the Pfizer-BioNTech COVID-19 Vaccine was under investigational new drug application 19736, and that COMIRNATY® was not available in commerce for use. Plaintiffs informed the court that an EUA cannot be issued if a licensed drug exists in the marketplace that is licensed for the intended emergency use. The court dismissed the case, ruling that when COMIRNATY® was approved, "the Pfizer vaccine was no longer an 'investigational drug,'" and although the court agreed the drug was under EUA, it held that "the informed consent requirements of the EUA statute do not apply to the Pfizer vaccine" under the EUA statute.[16] This vitiates Executive branch determinations and effectively "amends" the EUA statute.

In *Curtis v. Inslee*, No. 24-1869, filed in the Ninth Circuit Oct. 6, 2025, plaintiffs challenged the State of Washington's purported authority to mandate that its licensed medical facilities employ only individuals who receive the CDC Program investigational drugs. In this consolidated set of appeals, plaintiffs allege that the FDA classified the COVID-19 drugs as investigational; that Washington had entered into Contract No. FWA00000327 with the federal government, promising never to coerce such drugs; and that under the CDC Program, the State had contractually committed to administering the drugs on a purely voluntary basis. Plaintiffs further contend that the EUA statute and PREP Act effectively preempt state mandates compelling use of

[16] *Martinez v. Eastside Fire & Rescue*, 2025 U.S. Dist. LEXIS 109981, *17–*18.

the drugs, and that conditioning a state healthcare license on receipt of PREP Act countermeasures coerces individuals into forfeiting their property rights to sue for injuries caused by the drugs.

Disregarding the State's federal obligations under the CDC and FWA programs, as well as preemption issues and the Secretary's exclusive authority to set conditions for investigational drug authorizations, the Ninth Circuit held that "[t]he court in *Jacobson* was crystal clear that, because 'a community has the right to protect itself against an epidemic of disease which threatens the safety of its members,' a vaccine mandate that has a 'real or substantial relation to the protection of public health' is not"in palpable conflict with the Constitution.'"

The Ninth Circuit cannot invoke *Jacobson* to nullify 21 U.S.C. § 355(a), which prohibits introducing drugs into commerce without FDA approval, or outside agency-authorized conditions. Further, the PREP Act demands individuals forfeit their fundamental property and due process rights to sue for injuries as a condition of participating in countermeasures. In sum, the Ninth Circuit wielded *Jacobson* to eviscerate enactments of Congress, deprive the public of core property rights, nullify the CDC and FWA programs' terms, divest the Secretary of his sole authority over the introduction of unapproved medical treatments into commerce, and improperly arrogate those powers to the State of Washington—a profound violation of the dual sovereignty of our federal system.

In *Pearson v. Shriners Hosps. for Child.,* 133 F.4th 433 (5th Cir. 2025) — appeal pending in this Court, No. 25-204 — the Fifth Circuit affirmed that the drugs were not licensed for any indication, but ruled Shriners' conduct of subjecting individuals to

investigational drug use "was not unlawful" and that "[i]t is commonplace for companies—particularly hospitals—to place such mandates on their employees." *Id.* at 441, 444.

The Circuit arrogated powers to hospital executives, denied to them under the FWA program, and affirmed that hospitals routinely introduce unlicensed drugs into commerce in violation of the FDCA, but sanctioned such conduct.

In *Children's Health Defense, Inc. v. Rutgers, State University of New Jersey,* 93 F.4th 66 (3d Cir. 2024), *cert. denied*, 144 S. Ct. 2688, the Third Circuit—applying precedential rules without regard to the facts of the instant case, except insofar as they illuminate the EUA statute's application—held that "there is no unqualified right to decide whether to 'accept or refuse' an EUA product without consequence," and that, to the contrary, "being advised of the consequences is precisely what § 360bbb-3(e)(1)(A)(ii)(III) requires, providing explicitly that the recipient of an EUA product shall be informed 'of the consequences, if any, of refusing administration of the product.'" The Circuit used the word consequence to mean a penalty for choosing the option to refuse. The EUA's term "consequence" at 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III)), however, was erroneously interpreted. It corresponds with 45 C.F.R. § 46.116(c)(4) to mean health consequences. This holding arrogates to a state university authority to impose consequences for exercising the statutory option to refuse. But Congress vests the Secretary with exclusive power to prescribe conditions of authorization under the EUA statute, not Rutgers University. And as detailed *supra*, Congress expressly prohibits the Secretary from mandating participation, rendering any penalty for refusal

impermissible.

If Article III courts are repeatedly permitted to disregard allegations plainly demonstrating that dismissal is unwarranted, to reframe arguments, to amend federal statutes by judicial fiat, to nullify duly enacted federal programs, and to divest coequal federal branches of their constitutional authority, then due process itself will surely be crucified.

IV. This case is a suitable vehicle for deciding the question presented

This case and *Pearson* present ideal vehicles for resolving the questions presented, as both involve analogous deprivations of liberty, property and due process rights amid emergency delegations of public health functions to private employers. Lower Article III courts have uniformly dismissed such claims at the pleading stage, foreclosing discovery and preventing the development of a factual record for this Court's review.

Petitioners here and in *Pearson* include subject matter experts who possess specialized expertise in the relevant laws, regulations, and constitutional safeguards against coerced administration of unapproved medical products—insights absent in other petitions, ensuring a fully informed adjudication.

V. This Court should consider calling for the views of the Solicitor General

The federal government's interest in this case is profound, warranting this Court's invitation for the views of the Solicitor General. The Fifth Circuit's ruling effectively curtails the authority Congress

delegated to the Secretary to prohibit nonconsensual administration of unlicensed drugs, conduct the Circuit sanctions in *Pearson*, thereby foreclosing this case.

CONCLUSION

This Court should grant *certiorari* in this case or in *Pearson*, or, in the alternative, call for the views of the Solicitor General in one or both cases.

Respectfully submitted,

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