No.

In the Supreme Court of the United States

BETH BOYD, JANET NOLAND, MICHELLE PECK, AND CARLY ROBSON,
Petitioners,

v.

SHRINERS HOSPITALS FOR CHILDREN, SHRINERS HOSPITAL FOR CHILDREN-ERIE, BEVERLY BOKOVITZ, FRANCES FARLEY, JERRY GANTT, JOHN MCCABE, PHILLIP GRADY, and MARY ANTOON,
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Federal Food, Drug, and Cosmetic Act ("FDCA"), the National Research Act ("NRA"), the Public Readiness and Emergency Preparedness Act ("PREP Act"), and the Project BioShield Act of 2004 together form a comprehensive federal framework governing investigational drugs. Together with their implementing regulations and Executive Branch agreements, those Acts require that the administration of such drugs be the product of voluntary, informed consent, a requirement not imposed on drugs approved for their marketing application under 21 U.S.C. § 355 *et seq*. The questions presented are:

1. Whether the Fourteenth Amendment prohibits a State, or its delegated agent, from mandating that an individual accept the administration of a drug that is exempt from 21 U.S.C. § 355(a), under threat of penalty, where federal law conditions that exemption on consent obtained free of coercion, undue influence, and unjustifiable pressure.

2. Whether the Fourteenth Amendment prohibits a State or its delegated agent from mandating that an individual accept the administration of a covered countermeasure, where the PREP Act's immunity provision, 42 U.S.C. § 247d-6d(a)(1), extinguishes the recipient's right to access the courts for a resulting injury.

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees of Shriners Hospitals for Children: Beth Boyd, Janet Noland, Michelle Peck, and Carly Robson.

Respondents are Shriners Hospitals for Children, a not-for-profit healthcare corporation incorporated in Colorado and headquartered in Tampa, Florida; Beverly Bokovitz, Chief Nursing Officer of Shriners, in her official and individual capacities; Frances Farley, MD, Chief Medical Officer of Shriners, in her official and individual capacities; Jerry Gantt, Chairman of the Board of Shriners, in his official and individual capacities; John McCabe, Executive Vice President and Chief Operating Officer of Shriners, in his official and individual capacities; Phillip Grady, Vice President of Hospital Operations of Shriners, in his official and individual capacities; and Mary Antoon, Hospital Administrator of Shriners' hospital facility in Erie, Pennsylvania, in her official and individual capacities.

CORPORATE DISCLOSURE STATEMENT

Petitioners have no information to disclose under Rule 29.6.

Respondent Shriners Hospitals for Children is a Colorado nonprofit corporation. It does not have a parent corporation. No publicly held corporation owns 10 percent or more of Shriners Hospitals for Children. "Shriners Hospitals for Children – Erie" is a fictitious name registered and used by Shriners to refer to and operate the facility in Erie, Pennsylvania.

LIST OF DIRECTLY RELATED CASES

Boyd v. Shriners Hosps. for Children, No. 25-1183, U.S. Court of Appeals for the Third Circuit. Judgment was entered on April 14, 2026.

Boyd v. Shriners Hosps. for Children, No. 1:23-cv-00342, United States District Court for the Western District of Pennsylvania. Judgment on motion to dismiss was entered on December 30, 2025.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Beth Boyd, *et al.* respectfully seek a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Third Circuit, which affirmed an order granting Respondents' Rule 12(b)(6) motion to dismiss.

OPINIONS BELOW

The Third Circuit's opinion is unpublished and is available at *Boyd v. Shriners Hosps. for Child.*, 2026 U.S. App. LEXIS 10558 and 2026 WL 1005549; it is reproduced at Appendix A.

The U.S. District Court for the Western District of Pennsulvania's opinion is unpublished and is available at *Boyd v. Shriners Hosps. for Child*, 2024 U.S. Dist. LEXIS 234521 and 2024 WL 5263009; it is reproduced at Appendix B.

JURISDICTION

The Third Circuit issued its opinion on April 14, 2026. 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 Wednesday, August 12, 2026, No. 25A1455. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional provisions involved are included at Appendix C, App. 17a:

Fourteenth Amendment, § 1
U.S. Constitution, Art. VI, Cl. 2

The relevant statutory provisions are included at Appendix C, App. 18a–23a:

42 U.S.C. § 1983
21 U.S.C. § 355
21 U.S.C. § 360bbb
21 U.S.C. § 360bbb-3
42 U.S.C. § 247d-6d(a)(1)
42 U.S.C. § 247d-6d(b)(8)
42 U.S.C. § 247d-6e(c)
42 U.S.C. § 289.

INTRODUCTION

The Third Circuit announced that it "will not distinguish between 'investigational drugs' and vaccines." App 3a, n1. In so ruling, the court erased the bright line Congress drew between the Pfizer-BioNTech COVID-19 Vaccine—placed into interstate commerce under Investigational New Drug ("IND") Application No. 19736 and an Emergency Use Authorization ("EUA") under 21 U.S.C. § 360bbb-3—and COMIRNATY, the product the FDA licensed under 42 U.S.C. § 262(a) for ordinary commercial distribution but which Pfizer, Inc. never introduced into interstate commerce.

The Federal Food, Drug, and Cosmetic Act ("FDCA") allows an unlicensed drug to enter interstate commerce only on one explicit condition: its administration must be the product of voluntary, informed consent. 21 U.S.C. §§ 355(i)(4), 360bbb(b)(4), 360bbb-3(e)(1)(A)(ii)(III). The PREP Act

reinforces that condition by preempting any state requirement that would undermine it for covered countermeasures. 42 U.S.C. § 247d-6d(b)(8).

Congress went further still: 42 U.S.C. § 289 conditions federal funding for investigational drugs on the administering entity's written assurance that an independent board will protect the subjects' rights. Those rights—including legally effective informed consent—are spelled out in the regulations. 45 C.F.R. § 46.116; 21 C.F.R. § 50.20. They apply only to drugs exempt from § 355(a), and they categorically forbid the administration of an investigational drug as a product of coercion or permit punishment for those who refuse to accept them. The Executive Branch implemented that command through the Federalwide Assurance ("FWA") program as the basis of its compliance with federal law, binding Respondents by contract to the specific assurance that they will never place an individual under coercion, undue influence, or an unjustifiable pressure to accept the administration of an investigational drug.

The Commonwealth of Pennsylvania ("State") agreed to administer investigational drugs on behalf of the Executive Branch under the CDC COVID-19 Vaccination Program ("CDC Program") and enlisted Shriners Hospitals for Children to assist in discharging the governmental duty of securing the public's legally effective informed consent—consent that the Fourteenth Amendment's Due Process Clause requires. Under that arrangement, the Executive Branch's obligation to obtain legally effective informed consent was transferred to the State, and from the State to Respondent Shriners. Both the State and Shriners held FWA agreements and knew or should have known that they could not

coerce the involuntary administration of the CDC Program's investigational drugs.

The Third Circuit ignored all of this. Without accepting Petitioners' allegations as true under Rule 12(b)(6), it embraced Respondents' conclusory premise: if an investigational drug is "functional[ly] equivalent" to a licensed product, the statutory consent requirement evaporates and administering entities may threaten economic ruin to coerce administration. That is not interpretation; it is judicial rewriting. The condition for exemption from § 355(a) and the condition for administration are one and the same—voluntary, informed consent. Coercing acceptance of an unlicensed drug is precisely the unauthorized introduction into interstate commerce that § 355(a) prohibits.

This Court has already rejected such judicial freelancing. In *United States v. Rutherford*, 442 U.S. 544, 559 (1979), the Court reversed the Tenth Circuit's attempt to create an extra-statutory exception for the terminally ill, holding "[t]hat "§ 505(i) of the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated to be safe and effective reinforces the conclusion that no exception for terminal patients may be judicially implied." The *en banc* D.C. Circuit reached the identical conclusion in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007): "Congress has prohibited general access to experimental drugs … and has prescribed in detail how experimental drugs may be studied and used by the scientific and medical communities." As that court correctly observed, "In FDA parlance, experimental drugs that have not yet been approved for public use are deemed 'investigational drug[s].'" *Id.* at 713 n.1. Informed

consent is therefore an integral condition of the statutory exemption itself—not a detail left to the discretion of lower courts, state actors, or private parties.

The Third Circuit's error is not isolated. The Ninth Circuit committed the same abuse of discretion in *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025), inventing the phrase "clinically identical" as a judicial override of § 355(a). *Id.* at 691. These two courts of appeals, in addition to the Fifth and Tenth Circuits, have now nullified the informed-consent requirements of the FDCA and the Federalwide Assurance agreements, gutted the PREP Act's express preemption clause, and obstructed the President's constitutional duty via the Secretary of Health and Human Services to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3; *see Free Enterprise Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 484 (2010). An investigational drug carries a higher risk of injury for a reason: its manufacturer is under no obligation to lock in a fixed formulation, guarantee purity, or disclose every ingredient, as required of a licensed drug. By creating an atextual exception for any drug a member of society labels "functionally equivalent," the Third Circuit—like the Ninth—has effectively invalidated the informed-consent safeguards Congress enacted for every product introduced under an exemption from § 355(a), and stripped the Secretary of Health and Human Services ("Secretary") of his exclusive statutory authority to determine the market conditions of such drugs. That result cannot stand. "[A]s usual when a lower court has invalidated a federal statute, we granted certiorari." *Iancu v. Brunetti,* 588 U.S. 388, 391 (2019).

The circuit courts have no warrant to rewrite the clear conditions that Congress attached to the interstate shipment of investigational drugs to protect the American people. When circuits invent atextual exceptions that nullify informed-consent protections passed by Congress, they simultaneously override the Executive's duty to take care that the laws be faithfully executed, and this Court must intervene. The alternative is to leave standing a judicial amendment of the FDCA that Congress never authorized and that the Constitution does not permit.

STATEMENT OF THE CASE

Petitioners are state-licensed healthcare workers and former employees of Shriners Hospitals for Children in Pennsylvania. In 2021, Shriners Hospitals for Children was recruited by the Commonwealth of Pennsylvania to distribute the COVID-19 injections approved for emergency use authorization ("EUA") under the Project Bioshield Act of 2004. Subsequently, Shriners required Petitioners to be injected with these EUA drugs or lose their employment. Petitioners refused, lost their employment, and sued.

Petitioners' claims against Respondents were and are narrowly defined. They only assert the right to refuse administration of an investigational drug, to refuse participation in federally funded research, to refuse public disclosure of private health information to medical researchers, and to refuse to waive their Fourteenth Amendment right of access to the courts for resulting injuries. They contend that the State owed them a due-process right to legally effective informed consent when the State offered

them investigational COVID-19 drugs under the CDC Program, a governmental obligation the State delegated to Respondents, who voluntarily assumed that function under contract. Respondents punished Petitioners for declining to participate by terminating their employment—punishment that itself breached the state and federal agreements under which Respondents had undertaken the duty to protect the right of individuals to refuse EUA drugs without consequence. The State compounded the injury by denying Petitioner Carly Robson unemployment benefits solely because she withheld consent, a statutory and programmatic right the State and Respondents agreed to protect.

A. Legal Background

The federal protections under which Petitioners rely are the product of many decades of Congressional action and development of informed consent rights.

1. Federal Food, Drug, and Cosmetic Act

Congress enacted the FDCA in direct response to the 1937 Elixir Sulfanilamide disaster and has since expanded it through a series of amendments to regulate the use, sale, labeling, and administration of drugs, biologics, and devices, thereby protecting the American people from irreparable harm. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i).

As originally enacted, the Act categorically prohibited introducing an unlicensed drug into interstate commerce unless the FDA had approved a new drug application for it. 21 U.S.C. § 355(a). Since

1938, Congress has provided three primary pathways by which an individual may access an unlicensed drug.

In response to the thalidomide tragedy, Congress enacted the Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (Oct. 10, 1962) (codified as amended in scattered sections of 21 U.S.C.), which required manufacturers to demonstrate a drug's safety and efficacy through clinical investigation before FDA approval. 21 U.S.C. § 355(i) exempts investigational drugs from the prohibition in § 355(a), conditioned on the Secretary's promulgating regulations, § 355(i)(1), that require the clinical investigator to "obtain the consent" of the human subject, § 355(i)(4). The implementing regulation, 45 C.F.R. § 46.116(a)(1), requires that "[b]efore 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."

Congress enacted the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997), which, in part, authorizes licensed health practitioners to administer investigational drugs to a patient facing a life-threatening situation, conditioned on the physician submitting a medical protocol consistent with the informed consent requirements of 21 U.S.C. § 355(i). 21 U.S.C. § 360bbb(a), (b)(1)–(4). The implementing regulation requires that "[n]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative." 21 C.F.R. § 50.20.

Congress enacted the Project BioShield Act of

2004, Pub. L. No. 108-276, 118 Stat. 835, as codified in part at 21 U.S.C. § 360bbb-3, to provide broad population access to drugs, biologics, and devices not licensed for their intended emergency use during chemical, biological, radiological, nuclear, or pandemic[1] events. Section 360bbb-3(e)(1)(A) imposes on the Secretary a mandatory duty to establish conditions on all persons carrying out authorized activities "to protect the public health." *Id*. For individuals to whom the product is offered, Congress imposed a unique disclosure requirement not found anywhere else in the FDCA: the individual must be informed of "the option to accept or refuse administration of the product." *Id*. § 360bbb-3(e)(1)(A)(ii)(III). Congress further ensured that the statute could not be used to compel involuntary acceptance by declaring that "Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity"—language that expressly includes the decision to refuse the product. *Id.* § 360bbb-3(l). Congress also requires the Secretary to "appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product." *Id*. § 360bbb-3(e)(1)(A)(iii).

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[1] Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, 127 Stat. 161 (2013), added emerging infectious disease threats, including pandemic influenza, to the Secretary's emergency-use authority under 21 U.S.C. § 360bbb-3(b)(1).

2. The PREP Act

Congress enacted the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d, to shield manufacturers and administering entities from liability for covered countermeasures during a declared public health emergency. App. 22a. That immunity operates alongside an express preemption clause that reserves the governing terms to federal law. The clause preempts states and political subdivisions from establishing a legal requirement that is "different from," or "in conflict with," a requirement under the "FDCA" applicable to the countermeasure. 42 U.S.C. § 247d-6d(b)(8), App. 22a. The FDCA's informed consent requirements are subject to the PREP Act's express preemption clause when the Secretary designates an investigational drug as a covered countermeasure.

Further, the Act provides near-absolute immunity to "covered persons" with respect to all claims for loss resulting from the administration to or use by an individual of a "covered countermeasure."[2] *Id.* § 247d-6d(a)(1). It permits judicial remedy only for the tort of willful misconduct. *Id.* § 247d-6d(d)(1). And even that narrow exception forecloses access to any state court: any such action "shall be filed and maintained only" in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1).

3. National Research Act

Following the public disclosure of the Tuskegee

[2] "Covered countermeasure," in the case of COVID-19 injections, is also an investigational drug.

tragedy[3] in 1972, Senator Edward Kennedy conducted hearings into federally funded research abuse. *See* "Quality of Health Care — Human Experimentation, 1973: Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare; United States Senate; Ninety-Third Congress." Congress responded by enacting the National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974) ("NRA"). The NRA required a Commission to study, among other requirements, "the nature and definition of informed consent in various research settings." *Id*. § 202(a)(1)(B)(iv), 88 Stat. 342, 348–49.

The Commission published its findings in the seminal Belmont Report. *National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Apr. 18, 1979). The Report found that consent to participate in research is valid only if given voluntarily, and that voluntariness "requires conditions free of coercion and undue influence." Coercion occurs "when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance," while unjustifiable pressure occurs "when persons in positions of authority or commanding influence — especially where possible sanctions are involved — urge a course of action for a subject." *See Belmont Report*, "Voluntariness."

The NRA also requires the establishment of review boards to provide independent, third-party review of research conducted by authorized persons, thereby protecting human subjects. It also produced

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[3] *See* U.S. Dep't of Health, Educ. & Welfare, "Final Report of the Tuskegee Syphilis Study Ad Hoc Advisory Panel," April 28, 1973.

42 U.S.C. § 289, which requires the Secretary to ensure that any entity applying for a federal grant, contract, or cooperative agreement for a project involving humans in biomedical research submits "assurances" that it has established a "board" to review the research activity "to protect the rights of the human subjects."*Id*. § 289(a). App. 23a.

4. The Common Rule

Building on the Commission's findings, the NRA directed the Secretary to issue regulations, which were promulgated at 45 C.F.R. Part 46 (the "Common Rule"). Most relevant here, the regulation provides that "[f]ederal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied." 45 C.F.R. § 46.122. It further requires that persons conducting such research comply with the Belmont Report, *id*. § 46.101(c), even when the activity is otherwise exempt from the policy, *id*. § 46.101(i). The Secretary defined "research" broadly, as any activity "designed to develop or contribute to generalizable knowledge."*Id*. § 46.102(l). Compliance requires that potential participants give their "legally effective informed consent." *Id*. § 46.116(a)(1). The potential participant must be made aware that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." *Id*. § 46.116(b)(8).

Importantly, each exemption from 21 U.S.C. § 355(a) is conditioned on research. *Id*. § 355(i)(4) (see title, "Exemptions of drugs for research"); *id*. §

360bbb(b)(4) (requiring submission of a medical protocol, including research activities, consistent with *id.* § 355(i)); *id.* § 360bbb-3(e)(1)(A)(iii) (Secretary must establish "appropriate conditions for the monitoring and reporting of adverse events"). "Activities that meet the[] definition [of research] constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes." 45 C.F.R. § 46.102(l). Administration of an investigational drug is, by the terms of its own exemption, a research activity.

5. Federalwide Assurance

The Executive Branch established the FWA program within the Health and Human Services agency as the basis of its compliance with the NRA and 42 U.S.C. § 289. The FWA contractually binds institutions to the legally effective informed consent and Common Rule requirements. The State executed such an agreement under contract No. FWA00028491, and Respondents executed one under contract No. FWA00025698. See 45 CFR 46.103(a) (entities "shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy.")

B. Factual Background

Petitioners are state-licensed healthcare workers and former employees of Shriners Hospitals for Children in Pennsylvania. They are registered nurses, physical therapists, and medical assistants whose employment with Respondents ranged from three to twenty-eight years.

Respondents are a state-licensed medical facility located in Erie, Pennsylvania, and executives of Shriners Hospitals for Children, incorporated in the State of Colorado. Respondents knew, or should have known, the legal requirements governing drug labeling laws and the administration of investigational drugs as they operate a multi-million-dollar research program that administers investigational drugs on an ongoing basis. JA-096.[4]

1. CDC COVID-19 Vaccination Program

In 2020, the Executive Branch established the CDC COVID-19 Vaccination Program ("CDC Program") to administer investigational drugs to the public. In October 2020, the CDC issued program requirements to states considering participation. See "COVID-19 Vaccination Program Interim Operational Guidance Jurisdiction Operations." JA-209–210. The CDC required states to (1) "help the public to understand key differences in FDA emergency use authorization and FDA approval (i.e., licensure)"; (2) "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"; and (3) "ensure provider agreement, profile form, and redistribution agreement (if applicable) are thoroughly and accurately completed by each enrolled provider [and] retained on file for a minimum of 3 years." Each recruited "vaccination provider must agree to the Provider Agreement whereby they promise to comply with FDA's

[4] Citations to "JA-" are to the Joint Appendix filed in the Third Circuit, No. 25-1183 (JA1–JA376, two volumes).

requirements, including EUA-related requirements described in FDA's Letter of Authorization, as applicable. Providers must also administer COVID-19 vaccine in compliance with all applicable state and territorial vaccine laws." *Id.*

Under the CDC Program, the State's health agency served as the "Emergency Response Stakeholder" for each EUA, responsible for identifying and recruiting entities to administer investigational drugs in compliance with federal and state laws governing EUAs. JA-141. The manufacturer would conduct medical research activities, including monitoring and reporting serious adverse events and cases of multisystem inflammatory syndrome, and, based on agreed-upon study designs, conducting post-authorization studies to determine the nature of adverse events related to the drug's administration, including hospitalizations and deaths. JA-140–141. Recruited agents like Shriners are likewise be required to conduct research activities and report adverse events to the Vaccine Adverse Event Reporting System (VAERS). JA-142.

As a recruited vaccination provider, Respondents were required by the State to sign and comply with the CDC COVID-19 Vaccination Program Provider Agreement, incorporated into official state policy, as a condition of assisting in the State's own federal obligations under the program. Section 12(a) of that agreement states: "Organization must 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." JA-095.

In February 2020, the Secretary issued a PREP Act declaration covering all drugs administered through the CDC Program. JA-073. On December 11,

2020, the FDA issued an EUA for the Pfizer-BioNTech COVID-19 Vaccine, affirming that the drug was "an investigational vaccine not licensed for any indication." JA-063–064. Under the EUA, the Secretary required Pfizer to submit research data collected through the drug's EUA administration to Investigational New Drug Application No. 19736. JA-051. On August 23, 2021, after the FDA approved COMIRNATY, a "legally distinct" product, the agency continued to place Respondents under a ministerial obligation to "conspicuously" state that the Pfizer-BioNTech COVID-19 Vaccine "has not been approved or licensed by FDA." JA-204. COMIRNATY, however, was never available to the public; the Secretary continued issuing EUAs for the Pfizer-BioNTech COVID-19 Vaccine drug on its determination that COMIRNATY was not available for distribution. JA-136 n. 9

The program required providers to inform potential participants of the drug's risks, benefits, and alternatives; of their option to participate and their right to refuse; to offer medical counseling free of charge; and, for those who elected to receive the drug, to furnish administrative visit time and all ancillary supplies at no cost. Participants who accepted administration under the program were required to assume greater physical risk from the investigational drug; to become human subjects in ongoing medical research, including perpetual monitoring for adverse events; to publicly disclose their identifiable private information to medical researchers; and to forfeit their right of access to the courts for any injury caused by the drug, its administration, or any activity causally connected to it. JA-097, JA-113.

The CDC informed the nation that the drugs

"remain[] U.S. government property until administered to the recipient." JA-082. The CDC further stated that "Other … administration … 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." *Id.*

2. Shriners' Policy

Respondents executed an agreement with the State to perform the State's duties under the federal program. On September 14, 2021, however, they issued a corporate policy requiring "employees, contract employees, vendors, and volunteers" to participate in the CDC Program under threat of penalty—receiving an initial dose of one of the program's investigational drugs no later than October 11, 2021, and completing the multi-dose series no later than December 6, 2021. Exemptions were limited to medical or religious grounds. Those who refused faced termination of employment or contract, or denial of facility access. JA-146–152.

C. Procedural History

1. Petitioners Sue Respondents

After the policy's compliance deadline passed, Respondents terminated Petitioners' employment solely because they refused administration of one of the CDC Program's investigational drugs. JA-061, ¶ 185. On November 30, 2023, Petitioners filed suit in the United States District Court for the Western District of Pennsylvania. They alleged that the State had agreed to offer the CDC Program to the public

under voluntary conditions and thereby owed Petitioners an affirmative duty to obtain their legally effective informed consent to the program's research activities and to the administration of the investigational drugs—an obligation the State delegated to Respondents, who voluntarily undertook to discharge it. Petitioners further alleged that the State's failure to monitor its agents' compliance with that consent requirement matured into a pervasive custom that operated as official state policy, which the Department of Labor & Industry then enforced by denying unemployment benefits to those terminated for withholding consent. Because the State itself owed the duty of obtaining Petitioners' legally effective informed consent, a purely governmental function under the CDC Program, Respondents were under the same duty to obtain such consent, that is, Petitioner's property interest subject to the Fourteenth Amendment's Due Process Clause.

Petitioners asserted claims for substantive due process, procedural due process, and equal protection under 42 U.S.C. § 1983, together with a claim for wrongful discharge under Pennsylvania's public-policy exception to at-will employment. Respondents moved to dismiss under Federal Rule of Civil Procedure 12(b)(6), asserting as fact that "a fully approved vaccine was available for Shriners Children's employees" and that Petitioners "accordingly were not required to receive 'experimental' or 'investigational' vaccines to comply with Defendants' policy." JA-178.

Petitioners alleged that, by signing the CDC Provider Agreement, Respondents had agreed to comply with the Secretary's conditions of authorization under each EUA, and that on August

23, 2021—after the FDA licensed the unavailable COMIRNATY—the Secretary continued to require them to "conspicuously" state that the Pfizer-BioNTech COVID-19 Vaccine "has not been approved or licensed by FDA, but has been authorized for emergency use by FDA." JA-204. Respondents offered no analysis of the state-action doctrine as it applies to the CDC Program, the PREP Act, or the legally effective informed-consent requirements imposed by federal law.

On December 31, 2024, the District Court granted the motion. Citing seven decisions from courts outside the Third Circuit—most still pending further review—the court stated that it found "Defendants' arguments and the other courts' decisions persuasive and will dismiss Plaintiffs' claims for essentially the same reasons." App. 11a. The District Court examined the state-action question without regard to the duties the State and Respondents owed by reason of the drugs' investigational classification, the significance of Respondents' PREP Act immunity in abrogating Petitioners' Fourteenth Amendment rights, or Petitioners' protected interest in exercising the federally funded benefit of learning of the drugs' risks and declining their administration without coming under external pressure to accept them or being punished for such refusal. It dismissed the § 1983 counts with prejudice.

Petitioners timely appealed on January 29, 2025. The Third Circuit did not accept Petitioners' well-pleaded allegations as true under Rule 12(b)(6). On April 14, 2026, it affirmed. The court adopted Respondents' conclusory assertion that the Pfizer-BioNTech COVID-19 Vaccine was "functionally equivalent" to the unavailable COMIRNATY and

declared that it "will not distinguish between 'investigational drugs' and vaccines and instead refer to publicly available COVID-19 immunizations as vaccines" because the two products were "functional[ly] equivalent." App. 2a–3a. It then analyzed the state-action claim without reference to Petitioners' allegations concerning the legally effective informed-consent requirement. App. 6a–7a.

REASONS FOR GRANTING THE WRIT

I. Four circuits have decided an important first-impression question of federal law in a manner that conflicts with relevant decisions of this Court.

A. Circuit courts subordinate the FDCA's informed consent requirement to State actors' mandates.

Where federal laws are enacted pursuant to the limited powers granted Congress, "[t]he Laws of the United States … shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2.

Since 1938, the FDCA has prohibited any person from introducing an unlicensed drug into interstate commerce. 21 U.S.C. § 355(a); *see id.* § 321(e) ("The term 'person' includes individual, partnership, corporation, and association.") For every exemption Congress has created from that prohibition, it has attached a single, unqualified condition: access to an investigational drug must rest on the recipient's informed, voluntary consent. This Court and the *en banc* D.C. Circuit have both held that a person may not obtain an unlicensed drug outside the FDCA's

express statutory exemptions. *Rutherford*, *supra*; *Abigail Alliance, supra.* Administering an investigational drug outside those express exemption requirements therefore constitutes the introduction of a new drug into interstate commerce in violation of § 355(a)—a prohibited act under § 331(d).

In the decision below, the Third Circuit rested its judicially implied exemption from 21 U.S.C. § 355(a) on two premises. First, it declared that it would no longer distinguish between an investigational drug and a licensed vaccine, thereby declining to apply federal laws governing investigational products. App. 3a, n1. Second, it treated a state actor's assertion of "functional equivalence" as sufficient to render the statutory legal distinctions between investigational drugs and licensed biologics null and void, while simultaneously making an apparently scientific and medical finding in order to dismiss Petitioners' claims. App. 2a–3a.

Congress has never recognized the term "functionally equivalent," and the panel cited no statutory provision authorizing its use. A biologic is licensed only when it is labeled in accordance with 42 U.S.C. § 262(a). Treating an unlicensed drug as licensed constitutes misbranding in violation of federal law; any communication to that effect is labeling and is misleading. *See* 21 U.S.C. §§ 352(a)(1), 333; *see also Kordel v. United States*, 335 U.S. 345 (1948) (communications outside the labeling affixed to the drug constitute labeling for purposes of misbranding). Moreover, 21 C.F.R. § 312.7(a) prohibits a sponsor, investigator, or any person acting on their behalf from representing in a promotional context that an investigational new drug is safe or effective for the purposes under investigation, or from otherwise promoting the drug.

By permitting a private entity acting under color of State law such as Shriners Hospitals for Children to define and apply the atextual concept of "functional equivalence" to investigational drugs—the Third Circuit judicially created an exception to 21 U.S.C. §§ 352 and 355, 42 U.S.C. § 262, and 21 C.F.R. § 312.7(a). In doing so, it engaged in improper fact finding; a finding based on nothing more than other circuit courts' similar improper fact finding despite Rule 12(b)(6).

In *Children's Health Defense, Inc. v. Rutgers, The State University of New Jersey*, 93 F.4th 66 (3d Cir. 2024) (precedential decision), *cert. denied*, 144 S. Ct. 2688 (2024), the Third Circuit held that "there is no unqualified right to decide whether to 'accept or refuse' an EUA product without consequence." Congress, however, requires the Secretary only to establish conditions informing a recipient "of the consequences, if any, of refusing administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). That disclosure obligation alerts the recipient to consequences that may already exist independently of the statute—the natural course of an untreated condition, for example. It does not authorize the Secretary, the State, or any recruited agent to create a civil penalty as punishment for refusal. Congress expressly withheld that power from the Secretary. *Id*. § 360bbb-3(l). If the Secretary may not mandate acceptance of an authorized product, then, under the Supremacy Clause, States are impliedly preempted from achieving, through delegation of State action, a result that the federal statute itself does not authorize. The Third Circuit transformed a disclosure requirement into a grant of coercive authority Congress never conferred—converting a statute that demands voluntary acceptance into a

vehicle for punishing refusal and thereby nullifying informed consent as a statutory condition of an EUA drug's exemption from § 355(a).

In *Norris v. Stanley*, 73 F.4th 431 (6th Cir. 2023), *cert. denied*, 144 S. Ct. 1353 (2024), the Sixth Circuit recognized that "[t]he [EUA] statute is meant to ensure patients' consent to the pharmaceutical they are receiving," and that the option to refuse "addresses the interaction between the medical provider and the person receiving the vaccine, not the interaction between an employer and an employee receiving a vaccine." *Id.* at 437. Recognizing the purpose of the statutory informed consent requirement, the court proceeded to override that purpose by declaring that "this does not mean that [MSU, a public employer] cannot require [vaccination] as a term of … employment." *Id.*

This Court has held that States may not regulate a field Congress has chosen to occupy exclusively and "may not pursue policies that undermine federal law." *Arizona v. United States*, 567 U.S. 387, 402, 406 (2012). It has likewise held that "the relationship between a federal agency and the entity it regulates is inherently federal in character" because that relationship "originates from, is governed by, and terminates according to federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). The Secretary's regulation of an EUA product — who may manufacture, distribute, and administer it, and to whom, when, where, and how — is federal in exactly that sense. An EUA may issue only upon the establishment of conditions that inform potential recipients of their option to refuse and 21 U.S.C. § 360bbb-3(l) withholds from the Secretary any authority to compel acceptance. Once a product enters commerce under those conditions, a State may

not override them by requiring the very involuntary use Congress has excluded. The Third Circuit below joined the *Norris* court in subjecting the FDCA's informed-consent requirement to state authority—thereby inverting the Supremacy Clause.

In *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025), *cert. denied*, 608 U.S. ___ (June 1, 2026), the Ninth Circuit judicially implied an exemption from § 355(a) by ruling that "there is no material distinction between the refusal of a vaccine and Employees' refusal of administration of an investigational drug that is clinically identical to a vaccine." The judicially manufactured term "clinically identical" results in the same overreach as in the case below. This Court has two pending petitions dismissed under Rule 12(b)(6) by the Ninth Circuit on the "clinically identical" claim in which it has issued a call for a response in both: *Boysen v. PeaceHealth*, No. 25-1280 (call for response issued June 17, 2026; response due Aug. 31, 2026); *Roberts v. Ferguson,* No. 25-1327 (call for response issued July 12, 2026; response due August 13, 2026).

In *Timken v. South Denver Cardiology Assocs., P.C.*, 155 F.4th 1227 (10th Cir. 2025) (Nos. 24-1378 & 25-1005) (consolidated with *Sweeney v. University of Colorado Hospital Authority*), *cert. denied sub nom. Sweeney v. University of Colorado Hospital Authority*, No. 25-1055 (U.S. June 1, 2026), and *Pearson v. Shriners Hosps. for Child., Inc.*, 133 F.4th 433 (5th Cir. 2025), both the Tenth and Fifth Circuits declined to give effect to statutes, regulations, and contracts prohibiting defendants from compelling individuals to accept the administration of an investigational drug. Each court instead examined the challenged conduct in isolation from those governing authorities, thereby nullifying the

decades-long development of the federal laws governing legally effective informed consent.

This Court held in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), that it is the legislature, not the courts, that determines the measures best suited to protect public health. Congress has already made that determination with respect to drugs distributed in interstate commerce: whether in a clinical trial, under single-patient emergency use, or during a national emergency, an individual retains the unqualified right to refuse administration of an investigational drug introduced into commerce under an exemption from 21 U.S.C. § 355(a). The appellate courts discussed above have substituted their own policy preferences for the clear judgment of Congress, in violation of this Court's instruction that "federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *Rutherford,* 442 U.S. at 555, 559. Such revision of the informed consent requirement will result in irreparable harm to the American people without this Court's intervention.

B. Circuit courts are judicially implying an exception to FDCA's informed consent requirement.

In *Rutherford*, this Court held that "§ 505(i) of the [FDCA] makes explicit provision for carefully regulated use of certain drugs not yet demonstrated to be safe and effective [and thereby] reinforces the conclusion that no exception for terminal patients may be judicially implied." 442 U.S. at 559. Whether an exemption should exist "is a question for legislative judgment, not judicial inference." *Id*. This

Court therefore reversed the Tenth Circuit's holding that terminally ill patients could obtain unlicensed drugs outside the FDCA's framework, confirming that the Act—not the judiciary—controls access to unlicensed treatment. The *en banc* D.C. Circuit reached the same conclusion in *Abigail Alliance* after surveying the Nation's history of drug regulation: "Congress has prohibited general access to experimental drugs, see 21 U.S.C. § 355(a), and has prescribed in detail how experimental drugs may be studied and used by the scientific and medical communities." 495 F.3d at 713.

The Third, Sixth, Ninth, and Tenth Circuits—in *Rutgers*, *Norris*, *Curtis*, *Roberts*, *Boysen*, *Sweeney*, and the decision below—have departed from those holdings. Where *Rutherford* and *Abigail Alliance* establish that access to an investigational drug rests solely on explicit congressional authorization (which presently requires strict voluntary consent), those circuits have implied a new coercion exemption from § 355(a). They permit States, state agents, private parties, and political subdivisions to mandate administration of an investigational drug as a condition of compliance with their own policies, in a manner Congress has never authorized. This Court should resolve the conflict and reaffirm that, under current law, an investigational drug introduced under an exemption from § 355(a) may be administered only with the voluntary, informed consent of the recipient.

C. Circuit courts refuse to accept well-pleaded informed-consent allegations as true under Rule 12(b)(6).

In *Brock v. City of Bellingham*, 25-1070 (9th Cir,

May 26, 2026); *Bridges v. The Methodist Hospital*, No. 24-20483 (5th Cir. June 17, 2025); *Horsley v. Kaiser*, No. 24-5812 (9th Cir. Nov. 17, 2025); *Pearson*, *Sweeney*, *Curtis*, *Roberts*, *Boysen*, *Timken*, and the case below, plaintiffs alleged that defendants operated under Federalwide Assurance and CDC Program agreements, promising pressure-free administration of investigational drugs to the public. No defendant claimed authority to mandate an investigational drug, or disputed that they operated under such agreements. Still, the Circuits declined to accept those allegations as true under Rule 12(b)(6) and dismissed the cases on rationales no party had advanced — effectively holding that the defendants, acting under color of State law to administer a federal program, may engage in conduct that the federal government expressly prohibits.

In other words, despite pleading these facts with the specificity *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) demand, no Circuit court has permitted a single case—involving the very statute, regulations, and contracts that guarantee legally effective informed consent for the Nation's protection—to survive past the pleadings and reach summary judgment, even though each case presented matters of first impression in its circuit. The only such cases capable of reaching this Court, then, are those dismissed on procedural grounds — precisely the posture of the case below. This Court has never abandoned the rule that "when ruling on a defendant's motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint." *Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *see Twombly* at 555; *Iqbal* at 678.

The federal courts are using Rule 12(b)(6) to

issue a substantive ruling—one that tells states, their recruited agents, political subdivisions, and an estimated 30,000 entities operating under FWA agreements that they may coerce the use of investigational drugs and punish individuals who refuse. This Court is called upon to correct rulings that rest on the policy preferences of the Judicial Branch rather than on any interpretation of federal law.

II. The decision below is wrong: the Fourteenth Amendment prohibits this mandate and punishment

A. Congress created a protected property interest in legally effective informed consent.

Property interests protected by the Due Process Clause "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."*Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). A statutory entitlement is one such source. *Goldberg v. Kelly*, 397 U.S. 254, 262 & n.8 (1970). So are a program's own binding terms. *Perry v. Sindermann*, 408 U.S. 593, 601 (1972).

The rules here could not be more definite. The FDCA conditions every exemption from 21 U.S.C. § 355(a) on the recipient's consent. *Id.* §§ 355(i)(4), 360bbb(b)(4), 360bbb-3(e)(1)(A)(ii)(III). The Common Rule defines that consent as "legally effective" only when sought "under circumstances … that minimize

the possibility of coercion or undue influence." 45 C.F.R. § 46.116(a)(2). The CDC Program promised participants the option to accept or refuse without penalty or fee, and the FWA agreements bound the State and Respondents to those terms by contract. These are precisely the "rules or understandings" *Roth* describes: they secure a specific benefit — pressure-free choice — and they support a claim of entitlement to it. Petitioners therefore held a protected property interest in that choice. Respondents' duty to obtain consent necessarily includes Petitioners' corresponding authority to grant or withhold it. *See Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 270 (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.")

B. The Constitution independently protects the liberty interest at stake.

The entitlement Congress created runs alongside a liberty interest this Court has already recognized: "'The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Cruzan* at 278. The interest in avoiding the unwanted administration of a drug is "significant" even inside a prison's walls. *Washington v. Harper*, 494 U.S. 210, 221–22 (1990). If the Constitution protects a prisoner against an unwanted antipsychotic drug, it protects a nurse against an unwanted investigational drug — a product whose formulation the law does not require to be fixed, disclosed, or free of contamination. The investigational classification does not weaken the

liberty interest; it is the reason Congress fortified it with an explicit consent requirement.

C. A mandate backed by PREP Act immunity requires a waiver the Constitution forbids.

When a State, or its recruited agent, mandates the use of a covered countermeasure under threat of penalty, it mandates a waiver of the right to access the courts for a judicial remedy if injured. The PREP Act, by its terms, extinguishes any State or federal cause of action for injuries caused by a covered countermeasure, subject only to the willful misconduct exception. 42 U.S.C. § 247d-6d(a), (d). The mandate and the waiver are inseparable. The individual may not comply with the former without suffering the latter. The State's agent has thus achieved, on the State's behalf, through the leverage of economic survival (losing one's job), what the state may never achieve by direct command: the extinguishment of a constitutional guarantee. *See Speiser v. Randall*, 357 U.S. 513, 526 (1958); *Bailey v. Alabama*, 219 U.S. 219, 239 (1911) (a State may not achieve a result indirectly that it may not command directly).

This Court has long held that a cause of action is a protected property interest subject to the Due Process Clause. "A cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause." *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). *See Tulsa Prof. Collection Svcs. v. Pope*, 485 U.S. 478 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797 (1985). This Court has also long held that "the right to sue and defend in the courts is the alternative of force … the right conservative of all other rights, and … the

highest and most essential privileges of citizenship ...." *Chambers v. Baltimore & Ohio Railroad Co.*, 207 U.S. 142, 148 (1907); *Ryland v. Shapiro*, 708 F.2d 967, 971 (5th Cir. 1983) ("The right of access to the courts is basic to our system of government, and it is well established today that it is one of the fundamental rights protected by the Constitution."); *Grannis v. Ordean*, 234 U.S. 385, 394 (1914) ("the fundamental requisite of due process of law is the opportunity to be heard."); *Christopher v. Harbury*, 536 U.S. 403, n.12 (2002) ("Decisions of this Court have grounded the right of access to courts in the Article IV Privileges and Immunities Clause … the First Amendment Petition Clause … the Fifth Amendment Due Process Clause … and the Fourteenth Amendment Equal Protection … and Due Process Clauses."). To mandate the use of a liability-shielded product is to demand a waiver of the right to access courts upon injury.

Courts across the nation have wrongly extended PREP Act immunity, which is a *product liability* provision, even to constitutional injuries arising from the administration of a countermeasure over the individual's express refusal to consent. *See Hogan v. Lincoln Medical Partners*, 2025 ME 22 (2025); *Politella v. Windham Se. Sch. Dist.*, 2024 VT 43 (2024). *See also Happel v. Guilford Cnty. Bd. of Educ.*, 387 N.C. 186 (2025) (holding that the PREP Act forecloses state tort remedies for an involuntary injection, but does not foreclose a state constitutional claim arising from the same conduct — in tension with *Politella* and *Hogan*, which extend PREP Act immunity to bar all state-law claims, tort and constitutional alike).

The Ninth Circuit in *Curtis* rejected the claim that a state mandate conditioning a public benefit on

acceptance of a covered countermeasure — on pain of forfeiting the right to access the courts — states a substantive due process violation. 154 F.4th 678, 692 (9th Cir. 2025) ("Employees' substantive due process claim regarding the PREP Act's grant of immunity also fails.").

In *Brock*, *Pearson*, *Bridges*, *Horsley*, *Sweeney*, *Roberts*, *Boysen*, *Timken*, and the case below, no appellate court would address plaintiffs' claim that states and/or their recruited agents cannot mandate the use of a covered countermeasure, because such mandates indirectly waive an individual's right to judicial remedy upon injury. This Court has long held that a waiver of any constitutional right must be "voluntary, knowing, and intelligently made," and it must be "an intentional relinquishment or abandon-ment of a known right or privilege." *D.H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185–86 (1972); *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938). It must be "the product of a free and deliberate choice rather than intimidation, coercion, or deception." *Berghuis v. Thompkins*, 560 U.S. 370, 382–83 (2010). In *Janus v. AFSCME*, 585 U.S. 878 (2018), the Court reaffirmed that a waiver of a constitutional right must be freely given, shown by clear and compelling evidence, and never presumed.

Here, the CDC Program carried out by Respondents on behalf of the State required a waiver of the right to sue for injury. Neither the State nor Respondents had authority under governing federal law to compel that waiver by mandating participation in the federal program, still less to use the loss of employment as the instrument of coercion and intimidation.

This Court should hold that the right of access to the courts is a fundamental right subject to strict

scrutiny. Alternatively, the right is secured by the Fourteenth Amendment's Privileges or Immunities Clause—an argument that full briefing would permit Petitioners to develop. In either event, this Court should hold that no State or State actor may compel the use of a PREP Act covered countermeasure in order to exact a waiver of that right.

D. Respondents' mandate deprived petitioners of liberty interests without process, and by coerced waiver.

"[T]he Due Process Clause provides that certain substantive rights — life, liberty, and property — cannot be deprived except pursuant to constitutionally adequate procedures." *Cleveland Board of Education v. Loudermill*, 470 U.S. 532, 541 (1985). Petitioners received no procedure at all. The State delegated to Respondents the governmental function of obtaining legally effective informed consent under the CDC Program, and a private party who voluntarily performs a governmental function the State owes to an individual acts under color of law in performing it. *West v. Atkins*, 487 U.S. 42, 54–56 (1988). Rather than perform the function delegated to them, Respondents inverted it: accept the drug's administration or be punished by losing employment. Punishment, no matter the form, is the dispositive fact of this case. Respondents claimed the right to terminate Petitioners' at-will employment, but notably avoided asserting any right to coercively terminate employment to compel acceptance of the administration of investigational drugs. The former is an employer/employee dispute whereas the latter, under the CDC Program, is a Fourteenth Amendment violation.

A waiver of a constitutional right must be "an intentional relinquishment or abandonment of a known right," *Johnson*, 304 U.S. at 464, "voluntary, knowing, and intelligently made," *D.H. Overmyer Co.*, 405 U.S. at 185–86, and "the product of a free and deliberate choice rather than intimidation, coercion, or deception," *Berghuis, supra,* at 382. A choice required on pain of termination satisfies none of these standards.

Nor may the government purchase what it cannot command. The unconstitutional-conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Management District*, 570 U.S. 595, 604 (2013). The government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests," *Perry*, 408 U.S. at 597, and it may not use its leverage to compel the surrender of constitutional rights as the price of a privilege. See *Frost & Frost Trucking Co. v. Railroad Commission*, 271 U.S. 583, 593–94 (1926). Permitting state agents to condition continued employment on acceptance of an investigational drug — with PREP Act immunity foreclosing any remedy for resulting injury — is that forbidden exchange in its starkest form.

The Third Circuit reached none of this. By refusing to distinguish investigational drugs from licensed vaccines, and failing to address PREP Act immunity, it erased the statutory and programmatic sources of the entitlement and never asked the constitutional question Petitioners presented. Restore the terms and rules of understanding enacted by the Executive and Legislative Branches for Petitioners' benefit, then the complaint survives dismissal under Rule 12(b)(6).

III. Respondents acted under color of State law.

The Fourteenth Amendment binds States, not private persons — but for over a century this Court has recognized that private persons sometimes stand in the State's place, and when they do, the Amendment's obligations follow them. *Lugar v. Edmondson Oil Co.*, 457 U.S. 922, 941 (1982); *United States v. Price*, 383 U.S. 787, 794 (1966); *Blum v. Yaretsky*, 457 U.S. 991, 1004 (1982).

Two independent paths establish state action here, and Petitioners' complaint pleads both. *First, delegation.* When a State owes an individual a duty grounded in the Constitution, and a private party voluntarily contracts to perform that duty on the State's behalf, the private party acts under color of law in carrying it out. *West*, 487 U.S. at 54–56. The State agreed to offer the CDC Program under voluntary conditions and thereby owed Petitioners an affirmative obligation to obtain their legally effective informed consent — an obligation it delegated to Respondents, who voluntarily agreed to perform that governmental function. A State cannot shed the obligation by handing off the function, and Respondents could not accept the duty without accepting the Fourteenth Amendment obligations that came with it.

Second, custom. A custom or usage is enforceable under § 1983 when it carries the force of law by virtue of the persistent practices of State officials, and a private party who acts pursuant to such a state-enforced custom acts under color of law. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144 (1970). The State breached its monitoring obligation twice over: it failed to enforce the consent requirement against its recruited agents, and it violated the requirement

directly — Governor Wolf mandated involuntary use for certain members of the State, and the Department of Labor & Industry denied Petitioner Robson unemployment benefits solely for exercising the Program's guarantee of refusal. That persistent practice was a custom having the force of law, and it clothed Respondents with the power of the State. State action exists in the punishment itself, whatever form it takes. The Third Circuit erred by severing the State-action inquiry from the Commonwealth's constitutional obligation to obtain Petitioners' legally effective informed consent—an obligation the Commonwealth delegated to Respondents. It compounded that error by treating the terminations as an ordinary exercise of private employment authority, rather than as punishment for exercising a right to refuse investigational drug administration that federal law expressly protects and bars State or private override.

Because "a judge must accept as true all of the factual allegations contained in the complaint," *Erickson*, 551 U.S. at 94, that recharacterization was error. Restore the State's informed-consent obligation to the analysis, and Petitioners' state-action allegations survive Rule 12(b)(6).

IV. This case serves as an ideal vehicle to resolve these important questions.

The right to bodily integrity and the importance of complying with legal requirements protecting against involuntary administration of investigational drugs rank "among the highest public policy concerns one could articulate." *Doe v. Rumsfeld,* 297 F. Supp. 2d 119, 134 (D.D.C. 2003). The right of access to the courts is likewise "one of the highest and most

essential privileges of citizenship." *Chambers, supra*. Yet the Third Circuit—joined by its sister circuits in *Sweeney*, *Curtis*, and *Pearson*—has declined to apply the statutes Congress enacted to protect these rights. Instead, each court has substituted its own policy preferences, in plain disregard of the separation of powers. With no health emergency now present, the moment is ripe to resolve a question that Respondents themselves did not contest: whether they may mandate an investigational drug or covered countermeasure, or compel its acceptance by imposing punishment for refusal. This case, together with *Roberts* and *Boysen*, now pending before this Court, provides this Court with an ideal vehicle to settle these recurring questions of the highest public policy concern, potentially involving irreparable harm.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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