No.

# In the Supreme Court of the United States

JANE ELIZABETH ROBERTS, *et al.*,
*Petitioners,*

v.

JAY ROBERT INSLEE,
GOVERNOR OF THE STATE OF WASHINGTON,
in his individual capacity, *et al.,*
*Respondents.*

.

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

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

**1.** Whether the Fourteenth Amendment prohibits a State from mandating that an individual accept the administration of a drug that is exempt from 21 U.S.C. § 355(a) — on penalty of losing benefits — where the Federal Food, Drug, and Cosmetic Act expressly requires the Secretary to ensure such administration is the product of voluntary, informed consent.

**2.** Whether a State mandate for an individual to accept the administration of a covered countermeasure is consistent with the Fourteenth Amendment insofar as the PREP Act's immunity clause of 42 U.S.C. § 247d-6d(a)(1), upon administration, extinguishes the right to access courts if injured by the countermeasure.

## LIST OF PARTIES TO THE PROCEEDING

**Petitioners** are former employees of Shriners Hospitals for Children: Jane Elizabeth Roberts, Jon Alleman, Michelle Andrews, Ginger Bennett, Lani Laganowski, Inga Miller, Francisco Oquendo, Erin Palmer, Michelle Richardson, Peter Springs, Kathy Wold, and Julia Zelepukhin.

**Respondents** are Jay Robert Inslee, Governor of the State of Washington, in his individual capacity; Shriners Hospitals for Children, a network of not-for-profit hospitals incorporated in Colorado and licensed to do business in Washington; Shriners Hospitals for Children – Spokane, a 30-bed hospital operated by Shriners Hospitals for Children; Beverly Bokovitz, Chief Nursing Officer for Shriners; Frances Farley, M.D., Chief Medical Officer for Shriners; Jerry Gantt, President and Chairman of the Board of Trustees for Shriners; John McCabe, Executive Vice President and Chief Operating Officer for Shriners; Phillip Grady, Vice President of Hospital Operations for Shriners; and Peter Brewer, Administrator of Shriners Children's Spokane.

## CORPORATE DISCLOSURE STATEMENT

Petitioners have no information to disclose under Rule 29.6. Respondent Shriners Hospitals for Children — Spokane is a subsidiary of Shriners Hospitals for Children, a nonprofit with no stock ticker, and no publicly held company owns 10% or more of its stock.

## LIST OF DIRECTLY RELATED CASES

*Roberts v. Inslee,* No. 24-1949, U.S. Court of Appeals for the Ninth Circuit. Judgment was entered on December 10, 2025.

*Roberts v. Inslee,* No. 2:23-cv-00295-TOR, United States District Court for the Eastern District of Washington. Judgments on motions to dismiss were entered on February 8, 2024 for Shriners Hospitals for Children, and on March 18, 2024 for Jay Inslee.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners Jane Elizabeth Roberts, *et al.* respectfully seek a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Ninth Circuit, which affirmed orders granting Respondents' Rule 12(b)(6) motions to dismiss.

## OPINIONS BELOW

The Ninth Circuit's opinion is unpublished and is available at *Roberts v. Inslee*, 2025 U.S. App. LEXIS 32287 and 2025 WL 3539135; it is reproduced at Appendix A.

The U.S. District Court for the Eastern District of Washington's opinion dismissing Respondent Jay Inslee is unpublished and is available at *Roberts v. Inslee*, 2024 U.S. Dist. LEXIS 47503 and 2024 WL 1160895; it is reproduced at Appendix B.

The U.S. District Court for the Eastern District of Washington's opinion dismissing Respondent Shriners Hospitals for Children is unpublished and is available at *Roberts v. v. Shriners Hosps. for Child.*, 2024 U.S. Dist. LEXIS 235070 and 2024 WL 5517091; it is reproduced at Appendix C.

## JURISDICTION

The Ninth Circuit issued its opinion on December 10, 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 Kagan until Saturday, May 9, 2026, No.

25A911. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional provisions involved are included at Appendix E, App. 80a:

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

The relevant statutory provisions are included at Appendix E, App. 81–86a:

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.

## STATEMENT OF THE CASE

### I. The federal framework

Since 1938, federal law has prohibited the introduction of any new drug into interstate commerce unless the FDA has approved the drug as safe and effective. 21 U.S.C. § 355(a). Congress created exactly three pathways by which a drug not approved under § 355(a) may lawfully be

administered to a human. Each requires the U.S. Secretary of Health and Human Services to promulgate regulations ensuring they are administered under the condition of voluntary, informed consent of the human recipient. § 355(i)(4); 21 C.F.R. § 50.20. Section 360bbb authorizes expanded access for patients with serious or life-threatening conditions, likewise conditioned on informed consent. 21 C.F.R. § 312.310(b)(2). Congress could have provided that patients facing death may be required to accept investigational treatments. It did not. Section 360bbb-3 authorizes emergency use of unapproved drugs during declared emergencies — and imposes the most explicit anti-mandate conditions in the entire FDCA. It requires that individuals be informed of "the option to accept or refuse administration of the product." § 360bbb-3(e)(1)(A)(ii)(III). It provides that "[n]othing in this section provides the Secretary any authority to require any person to carry out any activity" under the authorization, which includes the activity of receiving the product. § 360bbb-3(l). And it limits the section's legal effect to persons who voluntarily participate. *Id.*

Congress established a parallel requirement to the informed consent requirement in 1947, under the National Research Act. 42 U.S.C. § 289. This Act imposed a ministerial obligation on the Executive Branch to protect the rights of the American people when involving them in investigational drugs or related research activities. In 2000, the Executive Branch instituted the Federalwide Assurance program, which requires persons operating under federal authority or using federal funding to involve humans in investigational drugs to provide written assurance that they will obtain the potential

participants' legally effective informed consent. This consent standard requires the presentation of opportunity to use such drugs to ensure the recipient is under no coercion, undue influence, or unjustifiable pressure to accept the administration of the drugs. The State of Washington operated under Federalwide Assurance No. FWA00000327. Respondent Shriners operated under FWA00025698. These agreements are activated whenever Respondents are engaged in federal programs subject to 42 U.S.C. § 289 requirements.

In 2005, Congress enacted the PREP Act, 42 U.S.C. § 247d-6d, granting covered persons near-total immunity from suit under federal and state law for claims arising from administration of a covered countermeasure. § 247d-6d(a)(1). The sole exception is a willful misconduct action filed exclusively in the U.S. District Court for the District of Columbia under a clear-and-convincing-evidence standard. § 247d-6d(c)(3), (d)(1). The immunity attaches upon administration, extinguishing the individual's state tort claims by operation of statute and access to state courts. The Act's express preemption provision prohibits States from establishing or enforcing any requirement "different from, or in conflict with" the FDCA framework. § 247d-6d(b)(8). This includes legal requirements that would otherwise render the FDCA's informed consent requirement inapplicable.

## II. Factual background

In December 2020 and February 2021, the FDCA issued Emergency Use Authorizations for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines pursuant to 21 U.S.C. § 360bbb-3. None was approved for marketing under 21 U.S.C. § 355(a).

The FDA-authorized fact sheets for each product expressly informed recipients that they had "the option to accept or refuse" administration. Each vaccine was designated a covered countermeasure under the PREP Act. The FDCA regulates drugs according to their labeling, not their formulation. 21 U.S.C. § 352. At the time Respondents imposed and enforced their mandates, no product bearing the labeling required for FDA approval under § 352 was available to Petitioners. Each EUA required the manufacturer to maintain an active Investigational New Drug application.

In 2020, the Centers for Disease Control and Prevention established the CDC COVID-19 Vaccination Program on the express premise that the incoming COVID-19 would be introduced into interstate commerce solely under 21 U.S.C. § 360bbb-3, as an exemption from *Id.* § 355(a) and would be administered only with voluntary informed consent. The CDC issued jurisdictional guidance for State participation. The only drugs made available under the program to the public were FDA-classified as investigational and designated as covered countermeasures under the PREP Act.

The State of Washington voluntarily joined the Program and agreed to recruit private entities to assist in administering the vaccines to the public while monitoring those entities for full compliance with all federal requirements. That compliance included adherence to the conditions of each EUA and all applicable provisions of the FDCA governing the classification and use of the investigational products. Washington recruited Respondent Shriners, which agreed to perform these federal functions on the State's behalf. The CDC also informed participants that it retained ownership of

the vaccines until the moment of administration. Accordingly, from the Executive Branch through Governor Jay Inslee to Respondent Shriners, every actor was subject to a ministerial obligation to ensure the voluntary, informed consent of potential recipients and was expressly prohibited from implementing any policy that penalized individuals for refusing administration of the investigational drugs.

In 2021, Respondent Jay Inslee issued Proclamation 21-14.1, requiring licensed healthcare professionals to accept administration of the investigational drugs or forfeit the right to practice their profession. Respondent Shriners then imposed its own mandate, conditioning Petitioners' continued employment on acceptance of the drug. Petitioners were offered information concerning the drugs' risks, benefits, and alternatives, and the right to accept or refuse administration. Petitioners exercised their right to refuse after learning of the drugs' risks. Respondent Shriners terminated Petitioners' employment under color of State law pursuant to official State policy and custom solely for exercising a benefit that Respondents agreed to protect under the federal program.

## III. Procedural background

In 2023, Petitioners filed suit in the District Court for the Eastern District of Washington alleging that the Supremacy Clause preempted the mandate because it required consent under coercion, a prohibited requirement under the FDCA, and that the requirement to accept administration of a PREP Act countermeasure was prohibited under the Fourteenth Amendment because the Act vitiates the

right to access courts upon product administration — a relinquishment of rights that States are constitutionally forbidden to compel. Petitioners alleged several violations of their Fourteenth Amendment due process and equal protection rights, as well as unlawful termination of employment under State law.

Respondents did not allege authority to mandate the use of investigational drugs or covered countermeasures in their motions to dismiss. The district court grounded its dismissal of all claims by primarily finding that the COVID-19 vaccines were "effectively FDA approved," App. 38a, notwithstanding numerous judicially noticeable documents from the Executive Branch that expressly required Respondents to conspicuously state that the drugs were neither FDA-licensed nor approved.

Petitioners timely appealed, and on December 10, 2025, the Ninth Circuit panel affirmed the district court solely on the grounds that its decision in *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025) foreclosed this case, without informing the parties how the ruling in *Curtis* applied to the facts alleged in the instant action. App. 53a.[1]

## REASONS FOR GRANTING THE WRIT

The Court should grant the petition because it presents important and recurring questions of

[1] The exact panel of Ninth Circuit judges who decided *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025) — McKeown, Paez, and Sanchez — also decided *Boysen v. PeaceHealth* (petition for *cert.* submitted May 4, 2026) and the instant case based on their *Curtis* decision. Accordingly, they are referred to as the "*Curtis* panel" at times in this petition.

federal procedure, Supremacy Clause preemption, and due process that only this Court can authoritatively resolve. Review is necessary to protect the comprehensive federal framework Congress has carefully constructed over more than eight decades to safeguard public health, drug safety, and the fundamental liberty interests in informed consent and bodily integrity. This Court may grant *certiorari* when "a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court." Sup. Ct. R. 10(c). Both are squarely met in this petition.

## I. STATE MANDATES[2] REQUIRING INVOLUNTARY USE OF INVESTIGATIONAL DRUGS VIOLATE THE SUPREMACY CLAUSE.

### A. Congress conditioned every form of public access to investigational drugs under the Federal Food, Drug, and Cosmetic act on voluntary informed consent.

"The Laws of the United States … shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2.

[2] There is no previously established legal definition for the term "mandate" which includes an executive branch order directed to the public. During the COVID-19 pandemic, however, the press began repeatedly describing executive branch orders or regulations (or even orders of public and private institution directors) to be "vaccinated" with emergency use drugs as "mandates." Petitioners use the word here to mean these types of orders.

When a State law, regulation, or executive order conflicts with a valid federal statute, the State action yields because the Constitution commands it. *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 480 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011). Section 505(a) of the FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" unless the Secretary of Health and Human Services has approved a marketing application for that drug. 21 U.S.C. § 355(a). That prohibition has been the law of the United States since 1938 and establishes a single, unqualified rule: unapproved drugs may not be introduced into interstate commerce except on terms prescribed by Congress.

Congress created exactly three statutory pathways by which a drug not approved under § 355(a) may lawfully be administered to a human being. Each is conditioned on voluntary, informed consent.

### *1. Investigational Use: 21 U.S.C. § 355(i).*

Congress exempts drugs intended for investigational use from § 355(a)'s prohibition on the condition that the Secretary "promulgates regulations" governing such exemptions. 21 U.S.C. § 355(i)(1). Congress directed that those regulations "shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation … [who] will obtain the consent of such human beings or their representatives." *Id.* § 355(i)(4).

The implementing regulations require that "no investigator may involve a human being as a subject in research" 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. Consent must be obtained "under circumstances that provide the prospective subject … sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." *Id*. "Legally effective informed consent," 45 C.F.R. § 46.116(b)(8), requires that the person presenting an individual with an opportunity to accept the administration of an investigational drug funded by the federal government, *Id*. § 46.122, ensure the individual is not under "coercion," "undue influence," or "unjustifiable pressure" to accept the drug's administration or to participate in any related research activity before or after the product's administration. *See* 45 C.F.R. § 46.101(c). External pressure, whether positive or negative, invalidates legally effective informed consent.

### *2. Expanded Access: 21 U.S.C. § 360bbb.*

Congress authorizes the Secretary to permit expanded access to investigational drugs for patients with serious or life-threatening diseases or conditions. 21 U.S.C. § 360bbb(a), (b). This exemption requires submission of a "clinical protocol consistent with the provisions of section 355(i)," *id*. § 360bbb (b)(4), thereby incorporating the same informed consent requirements that govern investigational use. The implementing regulations require that "in all cases of expanded access … investigators are responsible for … ensuring that the informed consent requirements of part 50 of this chapter are met." 21 C.F.R. § 312.305(c)(4). Congress also permits "widespread" access to investigational drugs for

"eligible patients" on the condition that the "protocol submitted" is consistent with the informed consent requirement under "section 355(i)" and the regulations promulgated thereunder. 21 U.S.C. § 360bbb(c)(7). Under 21 U.S.C. § 360bbb-0a, Congress provides a separate pathway for "eligible patients" to access investigational drugs, exempting them from certain § 355(i)(4) requirements — but only on the condition that the "eligible patient" provides the "treating physician written informed consent regarding the eligible investigational drug." *Id.* § 360bbb-0a(a)(1). The expanded access provisions demonstrate that even when Congress authorized access to unapproved drugs for patients facing death, it did not permit compulsion. If Congress preserved the right to refuse for individuals confronting terminal illness, it did not silently authorize a State to override the right to refuse unapproved drugs for healthy professionals as a condition of practicing their State-licensed profession.

### *3. Expanded Access: 21 U.S.C. § 360bbb.*

The Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, is codified in part at 21 U.S.C. § 360bbb-3. That provision authorizes the Secretary to introduce unapproved drugs into interstate commerce during declared emergencies, "[n]otwithstanding section[] 355 … of this title." *Id.* § 360bbb-3(a)(1). Such emergencies include historic chemical, biological, or nuclear terrorist events and pandemics. Congress imposed several conditions on the exercise of this authority.

*First*, Congress structured the Emergency Use Authorization (EUA) framework around disclosure and individual choice rather than compulsion.

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.* § 360bbb-3(e)(1)(A). For healthcare professionals who administer the product, Congress required that they be informed of the product's EUA status and of its known and potential risks, benefits, and available alternatives. *Id.* § 360bbb-3(e)(1)(A)(i)(I)–(III). For individuals to whom the product is administered, Congress imposed the same disclosure requirements and added one critical protection: the individual must be informed of "the option to accept or refuse administration of the product." *Id.* § 360bbb-3(e)(1)(A)(ii)(III). In defining what it means "to protect the public health" in the EUA context, Congress chose disclosure and autonomy over compulsion. The statutory scheme requires that individuals receive information about the product's unapproved status, its risks, and available alternatives — and then be given the opportunity to decide for themselves whether to accept or refuse. Congress placed the final decision with the informed individual and did not authorize the Secretary, healthcare providers, or any other actor to override that choice. A State cannot, consistent with the Supremacy Clause, insert itself into this federal scheme and compel individuals to accept an investigational product that Congress has conditioned on the individual's informed consent.

*Second,* 21 U.S.C. § 360bbb-3(l) states 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." Such "person" and

"activity" includes the individual considering accepting the product's administration. Congress prohibited the Secretary — the federal official who declares the emergency, issues the authorization, and administers the entire EUA framework — from requiring any person to participate. The word "require" is unqualified. It encompasses every form of compulsion, and Congress prohibited even the requirement that an individual *explain* their refusal.

*Third,* Congress expressly limited the statute's reach. Section 360bbb-3(l) provides that "[t]his section only has legal effect on a person who carries out an activity for which an authorization under this section is issued." By its terms, the statute's framework applies only to those who voluntarily elect to participate in an authorized activity. If an individual does not voluntarily participate in such an activity, the statute imposes no legal obligations on that person. The statutory scheme is therefore structured as an opt-in framework. A State cannot, consistent with the Supremacy Clause, compel individuals to participate in the statute's framework and then impose conditions that deprive them of the federally secured option to refuse that Congress attached to that framework

### B. By statute, Congress requires the Executive Branch to ensure that no investigational drug is administered to any person without voluntary, informed consent.

Congress enacted a framework — rooted in the National Research Act, Pub. L. No. 93-348 (1974) and

implemented through the Common Rule[3] — which independently requires voluntary, informed consent when federal funds or federal authority are used to involve humans with investigational drugs.

In 1972, the American public learned of the Tuskegee scandal — a decades-long study in which U.S. Public Health Service-funded researchers allowed hundreds of African-American men to remain untreated for syphilis, even after effective treatment became available, so researchers could observe the disease's natural progression. Congress responded by enacting the National Research Act, which directed the Secretary to require that every entity receiving federal research funding establish an institutional review board to protect the rights of human subjects. *See* 42 U.S.C. § 289.

Section 289 mandates that the Secretary "shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit … assurances satisfactory to the Secretary that it has established … a board … to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research." *Id.*

The Executive Branch primarily implemented this mandate through the Common Rule, 45 C.F.R. Part 46, which provides 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

[3] 45 C.F.R. Part 46, Subpart A.

legally authorized representative." 45 C.F.R. § 46.116(a)(1). The regulations require that potential subjects be informed that "participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled." 45 C.F.R. § 46.116(b)(8). Whether the research activity is exempt or nonexempt, it "shall be exercised consistent with the ethical principles of the Belmont Report" (45 C.F.R. § 46.101(c), (i)), which report established that informed consent can be legally effective only when "no coercion or undue influence is involved" and "conditions free of coercion and undue influence" are present. The regulation further requires that any expenditure of federal funds subject to that regulation comply with that consent requirement. 45 C.F.R. § 46.122.

To ensure compliance with 42 U.S.C. § 289, the Federalwide Assurance program, administered by the Office of the Assistant Secretary of Health, was implemented in 2000. It requires entities administering investigational medical products — including drugs exempted under 21 U.S.C. § 355(a) — to provide written assurance that they will comply with the legally effective informed consent standard under the Common Rule.

This Court has held that "[i]t is [the President's] responsibility to take care that the laws be faithfully executed." *Free Enterprise Fund v. Public Company Accounting Oversight Bd.*, 561 U.S. 477, 484 (2010). Congress directed the President, through the Secretary, to ensure that no person is subjected to an investigational drug without voluntary, informed consent. 42 U.S.C. § 289. The Ninth Circuit's holding — that State and private actors may mandate investigational drugs whenever they believe doing so will protect public health — strips the Executive

Branch of its capacity to faithfully execute that statutory command.

### C. The PREP Act's express preemption clause precludes States from mandating investigational drugs designated as covered countermeasures.

The preemption provision of 42 U.S.C. § 247d-6d(b)(8) provides, in pertinent part:

> During the effective period … 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 — (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the … administration … of the covered countermeasure, or 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*.]

The drugs at issue are covered countermeasures and were introduced into interstate commerce under 21 U.S.C. § 360bbb-3, a provision of the FDCA. The federal requirements applicable to these drugs under the FDCA and incorporated by the PREP Act's preemption clause are:

- 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III): requires that individuals to whom the product is

administered be informed of "the option to accept or refuse administration of the product"; and

- 21 U.S.C. § 360bbb-3(l): provides 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."

A State mandate that conditions the practice of a state-licensed profession on the acceptance of a covered countermeasure authorized under 21 U.S.C. § 360bbb-3 relates to the "administration" of that countermeasure and to "matters included in a requirement applicable to the covered countermeasure" under the FDCA within the meaning of § 247d-6d(b)(8)(B) — and is "different from" and "in conflict with" the requirements of § 360bbb-3(e)(1)(A)(ii)(III) and § 360bbb-3(l) because it:

- eliminates the option to refuse that § 360bbb-3(e)(1)(A)(ii)(III) requires;

- requires the activity of using a covered countermeasure, which § 360bbb-3(l) prohibits;

- overrides the consent requirement for obtaining a statutory exemption from 21 U.S.C. § 355(a);

- maximizes coercion rather than minimizing it as 45 C.F.R. § 46.116 demands; and,

- imposes a severe penalty — career destruction — despite 45 C.F.R, § 46.116(b)(8) requiring "no penalty or loss of benefits …"

The Supremacy Clause requires the state to yield to the authority of the federal government, which alone declares national emergencies under the PREP Act and determines the conditions under which the Act will be executed. States are expressly preempted from mandating the use of a emergency drug authorized under 21 U.S.C. § 360bbb-3 that is also designated as a covered countermeasure under the PREP Act.

### D. The Ninth Circuit's reliance on *Jacobson* fails as a matter of federal preemption.

The *Curtis* panel relied exclusively on *Jacobson v. Massachusetts* , 197 U.S. 11 (1905); *Zucht v. King*, 260 U.S. 174 (1922); and *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025), to conclude that State actors can mandate investigational drugs when they believe doing so will protect public health. App. 68a. None of these decisions considered a public health mandate that relies exclusively on investigational drugs administered through a federal program requiring voluntary, informed consent.

*Jacobson* did not authorize States to override federal law in the name of public health. It held the opposite: "a local enactment or regulation, even if based on the acknowledged police powers of a State, must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution." *Jacobson,* at 25. Citing its earlier decision in *Railroad Company v. Husen*, 95 U.S. 465 (1877), a case in which the State's legitimate interest extended to slowing the spread of the Texas or Spanish fever, the *Jacobson* Court

acknowledged States' rights to enact sanitary laws for the protection of life, liberty, health, or property. Yet the *Husen* Court struck down a public health policy because it "went beyond the necessity of the case and under the guise of exerting a police power invaded the domain of Federal authority, and violated rights secured by the Constitution." *Jacobson*, at 25 (citing *Husen*, at 471–73); *see also Husen* at 469 ("It seems hardly necessary to argue at length that unless the statute can be justified as a legitimate exercise of the police power of the state, it is a usurpation of the power vested exclusively in Congress.") *See also City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 441 (1985) (legitimate interests of the State are only those "interests the State has the authority to implement.") The *Curtis* panel extended *Jacobson*, *Zucht*, and *Health Freedom* into a categorical rule those cases were never intended to establish: that a State may mandate any medical product, subject only to rational basis review, without considering whether the mandate conflicts with federal law.

When a State and its state actor condition the continued practice of a licensed profession on accepting an investigational drug, they introduce precisely the form of coercion that federal law was designed to prevent, and thus render any resulting "consent" invalid. Further, 21 U.S.C. § 355's implementing regulations are explicit: informed consent for investigational products must be obtained "under circumstances that provide the prospective subject … sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." 21 C.F.R. § 50.20. *See also* 45 C.F.R. § 46.116 ("General Requirements For Informed Consent"). The operative

word is *minimize* — the regulatory framework presumes that coercion is incompatible with valid consent and demands affirmative steps to eliminate it. A State mandate that ties a professional's livelihood to acceptance of an investigational drug does the opposite. It maximizes coercive pressure.

As this Court explained in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261,269 (1990), the common-law doctrine of informed consent is rooted in the principle that "even the touching of one person by another without consent and without legal justification was a battery." A person who submits to a medical procedure only because refusal would mean professional ruin has not consented — they have capitulated. The federal government mandates voluntary conditions as a prerequisite to exemption from 21 U.S.C. § 355(a); a State mandate overrides that requirement. The two legal requirements conflict, and thus the Supremacy Clause resolves that conflict in favor of the federal government, requiring the State and its actors to yield to the informed consent requirement under the FDCA for drugs not approved for their marketing label within the meaning of 21 U.S.C. § 355(a) and § 352.

In *United States v. Rutherford*, 442 U.S. 544, (1979, this Court unanimously held that § 355(a) allows no implied exceptions. The Court stated that "the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied," and that courts may not create one because "federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *Id.* at 559,

555. Since *Rutherford*, Congress has provided several exemptions from 21 U.S.C. § 355(a), but none outside the voluntary, informed consent framework. A State actor's "belief" that an investigational drug can protect public health is not listed as an exemption under the FDCA. If Congress does not permit terminally ill patients to access investigational drugs outside the prescribed exemption to § 355(a), it most certainly does not grant State actors the power to mandate such drugs for healthy individuals who do not need nor want the experimental treatment.

The provision under 21 U.S.C. § 360bbb-3 is an extraordinary exemption Congress created for nationally declared emergencies involving catastrophic events. Congress authorized it "[n]otwithstanding sections 355, 360(k), and 360e" — language that acknowledges the gravity of temporarily overriding § 355(a)'s prohibition. Congress conditioned acceptance of a product authorized only for emergency use on the individual's right to refuse, and prohibited the Secretary from mandating involuntary participation. In *Rutherford*, this Court affirmed that Congress does not create implied exceptions to § 355(a) outside its express authorization. Sections 360bbb-3(e) and (l) tell us that Congress expressly prohibited the involuntary use of drugs authorized for emergency use during a declared public health emergency.

Congress has not imposed a general federal informed consent requirement for drugs approved under 21 U.S.C. § 355. Yet every exemption that permits the use of *unapproved* drugs requires the individual's voluntary, informed consent. This distinction is legally significant and demonstrates that Congress intended access to investigational drugs to remain voluntary. States and State actors

may not override this by coercing participation.

The Ninth Circuit's precedent dismantles the federal framework governing investigational drugs at every level. It strips the Secretary of his exclusive authority to determine the conditions under which investigational drugs enter interstate commerce. It renders the FDCA's informed consent requirements — which Congress attached to every exemption from 21 U.S.C. § 355(a) — unenforceable against any State that invokes its police power. It nullifies the Federalwide Assurance program, under which every State in the Union contractually promised the federal government that it would never subject individuals to investigational drugs under coercive conditions. It eliminates the function of Institutional Review Boards, whose sole purpose is to ensure that no administering entity pressures individuals to accept investigational treatments. And it renders 42 U.S.C. § 289 — Congress' post-Tuskegee command that the Executive Branch protect the rights of every person involved in federally funded research — inoperative whenever a State or private actor determines that an investigational drug will serve the public health. No single provision survives. The Ninth Circuit's holding invalidates the entire federal scheme designed to protect the American people from unwanted investigational treatments.

### E. The Ninth Circuit's "clinically identical" exception has no basis in law.

The *Curtis* panel held that "there is no material distinction between the refusal of a vaccine and … refusal of administration of an investigational drug that is clinically identical to a vaccine." The panel

neither defined "clinically identical" nor identified any provision of the FDCA that recognizes such a category. It also failed to explain which legal standard governs whether an investigational drug qualifies as "clinically identical" to an approved product, who makes that determination, or under what procedures. The term appears nowhere in the FDCA nor any other federal law.

21 U.S.C. § 355(a) draws a single, binary distinction: a drug is either approved for marketing, or it is not. If not approved, it is prohibited from interstate commerce unless it is statutorily exempted. The practical consequences of the panel's creation of this *ultra vires* definition are dangerous. Under the panel's rule, any person — a pharmaceutical manufacturer, a hospital administrator, a school nurse — may conclude that an investigational drug is "clinically identical" to a licensed product and administer it outside the framework Congress designed to protect the American people from nonconsensual participation. No federal standard governs such a determination, reviews it, or provides a process that constrains it.

The panel's holding permits State actors to exempt themselves from the FDCA's informed consent requirements through a self-serving, undefined, and unreviewable determination of clinical similarity — usurping the Secretary's exclusive authority to establish the conditions under which investigational drugs reach the public.

The *Curtis* panel invented a legal definition, and then applied its own law as the basis for dismissal under Rule 12(b)(6). The *Curtis* panel did not interpret the statute. It rewrote it — creating an exemption Congress never authorized and giving that judicial invention the force of federal law.

As this Court has repeatedly held, it is a "fundamental principle of statutory interpretation that 'absent provision[s] cannot be supplied by the courts.'" *Rotkiske v. Klemm*, 589 U.S. 8, 12 (2019) (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 94 (2012)). *See also Dodd v. United States*, 545 U.S. 353, 359 (2005) ("We are not free to rewrite the statute that Congress has enacted.").

There are no exemptions from 21 U.S.C. § 355(a) that permit involuntary administration, even if drugs are "clinically identical," because Congress regulates drugs by their labeling, not their formulation. A drug is investigational, unapproved, or licensed based entirely on its labeling, in accordance with 21 U.S.C. § 352 and its implementing regulations under 21 C.F.R. § 201. For biologics, a label must meet the exacting requirements under 42 U.S.C. § 262(a) to be considered a licensed vaccine. Sponsors of investigational drugs "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). Presenting an investigational drug as having an approved legal indication for safety and efficacy constitutes a misbranding violation under 21 U.S.C. §§ 331 and 352, with penalties enforced under § 333(a)(2). See *United States v. Marschall*, 82 F.4th 774 (9th Cir. 2023) (upholding conviction for misbranding violation).

The claim that an investigational drug is clinically identical to a licensed product is statutorily baseless. The Ninth Circuit has established competing standards for regulating drugs in the marketplace — whether based on their labeling or on

the personal beliefs of public and private actors mandating them — under the undefined term "clinically identical." This ruling sows confusion in an industry that requires strict protocols for the nation's safety and health.

### F. The necessity defense does not override Congress' value judgment under the FDCA

The *Curtis* panel held that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members, [so] a vaccine mandate that has a real or substantial relation to the protection of public health is not in palpable conflict with the Constitution." (quoting *Jacobson* at 27). App. 68a–69a. The panel treated this language as a necessity defense — the proposition that the urgency of the public health emergency justified overriding the FDCA's informed consent requirements.

This Court foreclosed the *Curtis* panel's reasoning in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), and the argument that an "emergency" allows states and state actors to ignore the requirements of the *Emergency* Use Authorization statute is absurd.

In *Oakland Cannabis*, patients seeking access to marijuana for serious medical conditions argued that "medical necessity" should be read into the Controlled Substances Act as an implied defense. This Court rejected the argument, holding that "[u]nder any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a determination of values." *Id.* at 491.

The FDCA embodies exactly such a legislative value judgment. Congress weighed the public interest in accessing investigational drugs against the individual's right to decide whether to accept them and resolved the balance in favor of the individual in every statutory exemption, without exception. As the D.C. Circuit recognized in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (en banc):

> Congress may limit or even eliminate a necessity defense that might otherwise be available. That is precisely what the FDCA has done. 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, see *id*. § 355(i). Given the Supreme Court's conclusion that the common law defense of necessity remains controversial and cannot override a value judgment already determined by the legislature, the common law doctrine of necessity provides little support to the Alliance's proposed right.

The *Curtis* panel did what *Oakland Cannabis* prohibits. Congress determined that investigational drugs may be administered only upon the condition of voluntary, informed consent. *Oakland Cannabis* holds that courts may not override that judgment on the basis of necessity. *Jacobson*'s recognition that States possess police powers to address epidemics does not alter this conclusion — because *Jacobson* itself held that the police power "must always yield

in case of conflict with the exercise by the General Government of any power it possesses under the Constitution." *Jacobson* at 25. The police power justifies State action, but only within the bounds of federal law. It does not authorize State action that violates federal law on the basis of necessity

## II. The Ninth Circuit's holding permits States to condition professional licensure on the surrender of property, liberty, and the privileges of citizenship, without due process and in violation of federal law.

U.S. Const. Amend. XIV, § 1 provides:

> 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

No court has ever held that a State may require the administration of an investigational drug as a condition of practicing a licensed profession. The Ninth Circuit's decision in *Curtis*, upheld by the same panel in this case, is the first such holding. If it stands, every licensed professional in the country is subject to the loss of livelihood, tort remedies, access to courts, and bodily autonomy — by executive order, without a hearing, and without judicial review — whenever a State invokes public health. The question is whether the Constitution permits that result. It does not.

Respondents issued and enforced their respective mandates in direct violation of their binding federal agreements and controlling federal law. Governor Jay Inslee issued Proclamation 21-14.1, which required licensed healthcare professionals to accept administration of investigational drugs or forfeit their right to practice their profession. Respondent Shriners, acting under color of state law, followed with its own coercive requirement, which it enforced pursuant to the Governor's proclamation, which purportedly permitted any public or private entity to disregard the terms of its federal and State contracts with impunity. Because the State of Washington was itself under a federal obligation to monitor and ensure compliance by all recruited agents in the CDC COVID-19 Vaccination Program, this custom of non-enforcement was the direct product of Respondent Jay Inslee's abuse of the federal program.

Both Respondents, however, had long maintained active Federalwide Assurance agreements with the U.S. Department of Health and Human Services. Those agreements — executed well before the pandemic — expressly conditioned their participation in any federally funded program, including the CDC COVID-19 Vaccination Program, on obtaining the legally effective informed consent of every potential recipient. This informed-consent obligation was, and remains, a foundational requirement of both federal law and standard practice among State health departments and hospitals nationwide, until the Ninth Circuit's ruling judicially created exceptions to those standards.

This Court's jurisprudence requires courts to first determine whether a State health policy intrudes upon the federal domain before assessing its rationality. The panel collapsed this analysis into a

single inquiry — "whether [the] treatment is rationally related to the State's objective," App. 73a — and never reached the threshold question. The panel nevertheless concluded that Respondents' conduct "easily survives rational basis review," asserting that it need not consider whether the mandates violated federal law. That holding is fundamentally flawed. A State cannot assert a legitimate governmental interest in conduct that is itself unlawful under federal statutes, regulations, and binding contractual agreements to which it is a party.

No Respondent ever claimed that mandating the use of investigational drugs — products expressly immunized from liability under the PREP Act — constituted a legitimate State interest. Because the challenged mandates directly contravened federal law, the Ninth Circuit's entire rational-basis analysis collapses. The panel's refusal to address the Supremacy Clause, Respondent Inslee's violation of the State's federal agreements, and Shriners' violation of its State and federal agreements render the panel's analysis of Petitioner's constitutional claims untenable.

The Ninth Circuit panel held — solely by citing its decision in *Curtis* — that none of the sources of federal authority Petitioners invoked supplied a viable cause of action under 42 U.S.C. § 1983. Even if that were correct, such a ruling cannot justify dismissal at the pleading stage. This Court has squarely held that "pleading rules call for 'a short and plain statement of the claim showing that the pleader is entitled to relief,'" and that they "do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *Johnson v. City of Shelby*, 574 U.S. 10, 11

(2014) (per curiam) (quoting Fed. R. Civ. P. 8(a)(2)). Here, Petitioners alleged that Respondents' mandates were unlawful under federal law. If those underlying state actions were in fact unlawful — as the complaint and judicially noticeable documents establish — then the resulting termination of Petitioners' employment was arbitrary, unequal, and in direct violation of their Fourteenth Amendment due-process rights. Such deprivations are actionable under § 1983 because Petitioners possessed a protected property interest in continuing their licensed professional careers free from abusive governmental interference. The panel's refusal to recognize this is the very kind of pleading-formalism error this Court has repeatedly rejected.

### A. The Ninth Circuit invalidated protected property interests

This Court has made clear that "Property interests … 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). *See also Perry v. Sindermann*, 408 U.S. 593, 597 (1972) ("this Court has made clear that … the government … may not deny a benefit to a person on a basis that infringes his constitutionally protected interest."). The "root requirement" of the Due Process Clause is "that an individual be given an opportunity for a hearing before he is deprived of any significant property interest." *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985) (quoting *Boddie*

*v. Connecticut*, 401 U.S. 371, 379 (1971)); *see also Bell v. Burson*, 402 U.S. 535, 542 (1971).

### *1. The CDC COVID-19 Vaccination Program*

The CDC COVID-19 Vaccination Program, as incorporated into Washington state policy, conferred upon Petitioners a state and federally protected entitlement: the right to receive accurate information concerning the investigational drugs' risks, benefits, and alternatives, and the right to accept or refuse administration of those drugs without incurring any cost, penalty, or loss of the federally funded benefit itself. In other words, Petitioners held the right to choose freely, and Respondents were under a ministerial. Obligation to accept the choice with no strings attached. This is the legally effective informed consent standard required by Congress under 42 U.S.C. § 289 as implemented by the executive branch under 45 C.F.R. § 46.116 and contractually enforced pursuant to the Federalwide Assurance agreement. These explicit "rules" and "understandings" created a legitimate claim of entitlement protected by the Due Process Clause. *Roth*, *supra*. By wielding their governmental authority to punish Petitioners solely for exercising that federally conferred right to refuse, Respondents effected an arbitrary deprivation of a protected property interest. That deprivation is actionable under 42 U.S.C. § 1983 as a violation of the Equal Protection and Due Process Clauses. Moreover, because the State had agreed to abide by the Program's terms as a condition of receiving federal funds, any state policy or custom inconsistent with

those terms is invalid. *King v. Smith*, 392 U.S. 309, 333 (1968).

***2. The cause of action.***

A cause of action is a species of property protected by the Due Process Clause. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982); *Tulsa Professional Collection Services, Inc. v. Pope*, 485 U.S. 478, 485 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985). By conditioning Petitioners' continued employment on acceptance of a PREP Act-covered countermeasure, Respondents triggered the Act's sweeping immunity provisions and thereby extinguished Petitioners' protected property interest in any federal or state cause of action for injuries caused by the drug or its administration. The government may not force an individual to surrender one constitutionally protected property interest in order to preserve another. Petitioners were thus forced to choose between retaining their right to practice their licensed profession by forfeiting valuable causes of action or preserving that right by forfeiting their livelihoods. That coercive dilemma is the very definition of an unconstitutional condition. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) ("The unconstitutional conditions doctrine vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up.").

***3. The professional license.***

A professional license constitutes protected property under the Due Process Clause. *Barry v.*

*Barchi*, 443 U.S. 55, 64 (1979); *Bell v. Burson* at 539. Petitioners were deprived of that protected property interest solely because they exercised their federally conferred right to refuse participation in the CDC COVID-19 Vaccination Program and to decline administration of a PREP Act-designated covered countermeasure — a product that would require them to prospectively waive valuable judicial remedies for any resulting injuries. By imposing termination of their licensed practice as the direct penalty for refusing to surrender these rights, the State violated the Fourteenth Amendment. *See Lefkowitz v. Turley*, 414 U.S. 70, 83 (1973) (disqualification from pursuing one's chosen occupation as a penalty for asserting a constitutional privilege is unconstitutional). The government may not force licensed professionals to choose between their livelihood and the exercise of a fundamental constitutional right. *Home Ins. Co. v. Morse*, 87 U.S. (20 Wall.) 445, 451 (1874) ("[A] man may not barter away … his substantial rights.").

## B. The State mandate infringes fundamental rights.

### *1. The right to refuse.*

The right to refuse unwanted investigational medical treatment is a fundamental liberty interest. *Washington v. Glucksberg* 521 U.S. 702, 720–21 (1997); *Washington v. Harper*, 494 U.S. 210, 221–22 (1990); *Cruzan* at 269, 278 (1990). This Court has never held that a State may compel the administration of an investigational drug under penalty. Under *Glucksberg*, determining whether an asserted right qualifies as fundamental requires

examining "this Nation's history, legal traditions, and practices." *Glucksberg*, at 710. The panel conducted no such inquiry. It held that *Jacobson* forecloses any substantive due process claim to refuse an investigational drug in private and public health contexts.

But *Jacobson* involved a century-old vaccine, a monetary fine, and a legal framework that predated every modern protection for human subjects. The panel did not examine the 120 years of legal development that followed — the FDCA (1938), the National Research Act (1974), the Common Rule (1991), informed consent exemptions from 21 U.S.C. § 355(a), and the ICCPR treaty — each codifying the principle that individuals may not be compelled to accept investigational medical products. These are a portion of the "history, legal traditions, and practices" that *Glucksberg* commands courts to examine. The panel examined none of them. It is untenable to recognize a substantive due process right to refuse unwanted medical treatment on one hand while denying that same right when the treatment is investigational and unlicensed. If anything, the constitutional protection against compelled administration of investigational products is stronger, not weaker, than the protection against compelled administration of approved products. The American people possess a fundamental right to refuse unwanted investigational drugs, biologics, and devices.

### *2. The right of access to courts.*

The PREP Act strips nearly all State-law remedies from individuals who receive a covered countermeasure. The Act provides that a "covered

person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). Immunity reaches losses having "a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.* § 247d-6d(a)(2)(B). The only exception is a narrow federal cause of action for death or serious physical injury proximately caused by willful misconduct, which must be filed exclusively in the District Court for the District of Columbia. *Id.* §§ 247d-6d(d), (e)(1).

When the State mandated the countermeasure, it compelled petitioners to surrender access to State courts and virtually all State tort claims as the price of continued employment. The right of access to courts is among the oldest and most deeply rooted rights in the Anglo-American tradition. Clause 40 of Magna Carta (1215) declared: "To no one will we sell, to no one deny or delay right or justice." The Virginia Ratifying Convention, proposing amendments to the federal Constitution on June 27, 1788, declared:

> That every freeman ought to find a certain remedy by recourse to the laws for all injuries and wrongs he may receive in his person, property or character. He ought to obtain right and justice freely without sale, completely and without denial, promptly and without delay, and that all establishments or regulations contravening these rights, are

oppressive and unjust.

Jonathan Elliot, *The Debates in the Several State Conventions on the Adoption of the Federal Constitution*, Vol. 1, p. 327 (2d ed. 1836).

This Court has recognized the right to a remedy's constitutional dimension, describing access to courts as "the alternative of force," "the right conservative of all other rights," and "one of the highest and most essential privileges of citizenship." *Chambers v. Baltimore & Ohio R. Co.,* 207 U.S. 142, 148 (1907) grounded the privilege in Article IV's Privileges and Immunities Clause. The Fourteenth Amendment extended that protection against a citizen's *own* State. *See McDonald v. City of Chicago*, 561 U.S. 742, 819–50 (2010) (Thomas, J., concurring) (the Privileges or Immunities Clause protects rights understood at ratification as fundamental to citizenship, drawing on *Corfield v. Coryell*, 6 F. Cas. 546, 551–52 (E.D. Pa. 1823), which expressly included access to State courts); *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002) (the right of access has been grounded in the Article IV Privileges and Immunities Clause, the First Amendment, the Fifth Amendment, and the Fourteenth Amendment).

The right to remedy in the courts is substantive. In *Boddie v. Connecticut*, the Court struck down filing fees that denied access — holding that the State could not bar access to the adjudicatory mechanism itself. *Id.* at 380–381. In *Wolff v. McDonnell*, 418 U.S. 539, 576 (1974), the Court held that prisoners retain a right of access that the State may not obstruct. In neither case did the Court say the State must provide a better process before denying access. In both cases, the Court said the State may not deny access, directly or through

obstruction. That is the hallmark of a substantive right.

Congress understood the constitutional stakes. The PREP Act's companion provision expressly required the Secretary to ensure that "potential participants are educated with respect to … the voluntary nature of the program." 42 U.S.C. § 247d-6e(c). An individual who *voluntarily* accepts a countermeasure thus consents to a limited executive branch remedy for any harm that results.

This Court has spoken with unmistakable clarity on this issue. A waiver of rights 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). As this Court held in *Janus v. AFSCME*, 585 U.S. 878, 930 (2018), such a waiver "must be freely given and shown by 'clear and compelling' evidence," and "such a waiver cannot be presumed." (quoting *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938), and *Curtis Publishing Co. v. Butts*, 388 U.S. 130, 145 (1967) (plurality opinion)).

The State, by mandating the use of an investigational drug immunized under the PREP Act, achieves indirectly what it can never command — direct waiver of due process rights. *See Speiser v. Randall*, 357 U.S. 513, 526 (1958); *Bailey v. Alabama*, 219 U.S. 219, 239 (1911). If the state could condition the benefit of state privileges on the surrender of one constitutional right, then "it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence." *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583, 593–94 (1926).

The Ninth Circuit's rejection of Petitioners'

procedural due process, substantive due process, equal protection, and unconstitutional conditions claims rests on a single foundational error: the panel refused to recognize that the challenged conduct is prohibited under federal law. That refusal not only distorted the constitutional analysis of the presented claims, but it also altered the FDCA by permitting conduct expressly prohibited by federal authority. Until the threshold question of federal authority is resolved, the constitutional inquiry cannot proceed.

## CONCLUSION

For the reasons discussed hereinabove, Petitioners respectfully request that the Court grant their petition for a writ of *certiorari*.

Respectfully submitted,

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