**No.**

# In the Supreme Court of the United States

SARA BOYSEN, *et al.*,
*Petitioners,*

v.

PEACEHEALTH, *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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## QUESTION PRESENTED

Whether the Due Process Clause of the Fourteenth Amendment, consistent with this Court's precedents in *Jacobson v. Massachusetts,* 197 U.S. 11 (1905), *Berghuis v. Thompkins*, 560 U.S. 370 (2010), and *Board of Regents of State Colleges v. Roth*, 408 U.S. 564 (1972), prohibits a State from conditioning an individual's right to work in a licensed profession upon being injected with an investigational drug and waiving the right to seek judicial remedies for resulting injuries.

## LIST OF PARTIES TO THE PROCEEDING

**Petitioners** are former employees of PeaceHealth: Sara Boysen, Hannah Bernhardt, Alisha Carter, Katherine Derrick, Sarah Guimont, Kathy Murphy, Dale Kingston, Christina O'Harra, Christina Shaneyfelt, Deborah Shaneyfelt, Ann Doreen Waters, and Micaela West.

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**Respondents** are PeaceHealth, a not-for-profit healthcare system headquartered in Clark County, WA; Liz Dunne, President and Chief Executive Officer of PeaceHealth, in her official and personal capacities; Doug Koekkoek, Chief Physician and Clinical Executive of PeaceHealth, in his official and personal capacities; Todd Salnas, Chief Executive of PeaceHealth Oregon Network, in his official and personal capacities; Patrick Allen, in his official and personal capacities as Director of Oregon Health Authority; and Governor Kate Brown, in her official and personal capacities as Governor of the State of Oregon.

## CORPORATE DISCLOSURE STATEMENT

Petitioners have no information to disclose under Rule 29.6. Respondent PeaceHealth has no parent corporation, has no stock ticker, and no publicly held company owns 10% or more of its stock.

## LIST OF DIRECTLY RELATED CASES

*Boysen v. PeaceHealth,* No. 24-5204, U.S. Court of Appeals for the Ninth Circuit. Judgment was entered on December 3, 2025.

*Boysen v. PeaceHealth,* No. 6:23-cv-1229-AA, United States District Court for the District of Oregon. Judgment on motions to dismiss was entered on August 19, 2024.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners Sara Boysen, *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 *Boysen v. PeaceHealth*, 2025 U.S. App. LEXIS 31419 and 2025 WL 3470030; it is reproduced at Appendix A.

The U.S. District Court for the District of Oregon's opinion is unpublished and is available at *Boysen v. PeaceHealth*, 2024 U.S. Dist. LEXIS 147502 and 2024 WL 3888682; it is reproduced at Appendix B.

## JURISDICTION

The Ninth Circuit issued its opinion on December 3, 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 2, 2026, No. 25A910. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional provisions involved are included at Appendix D, App. 64a:

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

The relevant statutory provisions are included at Appendix D, App. 65a–70a:

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

This case concerns whether a State may issue a legal requirement that licensed healthcare workers may no longer work within the State's licensed healthcare industry should they refuse to be injected with investigational new drugs offered under a federally funded program that expressly requires voluntary, informed consent, and that are immunized from liability for resulting damages.

Petitioners were licensed by the State of Oregon as healthcare workers and employed by PeaceHealth. In 2021, the Governor of the State of Oregon and PeaceHealth issued respective health policies requiring Petitioners to receive injections of investigational drugs which were declared covered countermeasures by the U.S. Secretary of Health and Human Services. Petitioners refused the injections, and Respondent PeaceHealth terminated their employment solely for that refusal.

In addition to an individual's constitutional right to bodily autonomy and the prohibition against conditioning governmental benefits on the forfeiture of constitutional rights, Congress, through the National Research Act (1974, Pub. L. No. 93-348), imposed a ministerial obligation on the Executive Branch to protect the rights of individuals offered investigational drugs or invited to participate in federally funded research activities. *See* 42 U.S.C. § 289. In 2000, to comply with its duties under § 289, the Executive Branch implemented the Federalwide Assurance (FWA) program, which requires any entity receiving federal funds or operating under federal authority to provide written assurances that it will obtain legally effective informed consent before administering investigational products or conducting related research. That standard, codified at 45 C.F.R. § 46.116 and rooted in the Belmont Report, prohibits coercion, undue influence, or any penalty for refusal.

In 2020, the Centers for Disease Control and Prevention (CDC) established the CDC COVID-19 Vaccination Program to administer unlicensed COVID-19 vaccines introduced into interstate commerce solely under Emergency Use Authorizations (EUAs) pursuant to 21 U.S.C. § 360bbb-3. These products operated under active Investigational New Drug applications and required strict voluntary use. The State of Oregon, through the Oregon Health Authority, executed Federalwide Assurance No. FWA00000520 with the Department of Health and Human Services, and agreed to execute the CDC COVID-19 Vaccination Program, including incorporating the CDC COVID-19 Vaccination Program Provider Agreement into official state policy, recruiting private parties to assist in the

administration of the drugs, and to monitor the recruited agents for lawful compliance.

These agreements obligated the State and its agents—including private healthcare providers recruited to assist the State—to offer the investigational products under conditions of voluntary informed consent without coercion or punishment.

The State recruited PeaceHealth, a private nonprofit healthcare system, to administer the CDC Program on its behalf. PeaceHealth executed its own FWA (No. FWA00003906) and the required CDC Provider Agreement, binding it to the same federal obligations. Nevertheless, in 2021, the State of Oregon issued a mandate conditioning continued employment in licensed healthcare facilities on acceptance of one of the investigational COVID-19 vaccines (or obtaining a narrow medical or religious exemption). The mandate threatened termination and imposed civil fines of $500 per day per violation on non-compliant workers and facilities. PeaceHealth followed suit and, in defiance of its federal obligations, mandated the use of the investigational drugs by its employees under threat of penalty. Petitioners—licensed healthcare professionals employed by PeaceHealth—were terminated for exercising their constitutional right to bodily autonomy, their federal statutory right to refuse EUA drugs, and their federal statutory right to decline waiving a judicial remedy for injury caused by PREP Act covered countermeasures,[1] and their

[1] The Public Readiness and Emergency Preparedness Act (PREP Act) was enacted as Division C of the Defense Appropriations Act for Fiscal Year 2006, Pub. L. No. 109-148, 119 Stat. 2818 (Dec. 30, 2005). It amends the Public Health Service Act by inserting sections 319F-3 and 319F-4, codified at

federal benefit under the CDC Program to learn of the drugs' risks and then choose to refuse their administration without penalty.

Petitioners filed suit in the United States District Court for the District of Oregon under 42 U.S.C. § 1983, alleging violations of their Fourteenth Amendment rights, including their bodily autonomy right to refuse unwanted medical treatment, freedom from unconstitutional conditions on employment and federally funded benefits, federal statutory rights, procedural and substantive due process, and equal protection. They also asserted Supremacy Clause preemption with respect to the "mandated" COVID-19 investigational drugs, thus negating Respondents' reliance on any rational basis argument appropriate to FDA approved and established vaccines. In the alternative, Petitioners asserted an implied private right of action under 21 U.S.C. § 360bbb-3.

Following Respondents' motions to dismiss under Fed. R. Civ. P. 12(b)(6), the district court granted the motions. App. 5a. It construed facts against Petitioners and held that the Pfizer-BioNTech COVID-19 vaccine was not an investigational drug or unapproved, notwithstanding the Executive Branch's repeated designations to the contrary under each EUA. The court also usurped federal power when it ruled that "the common belief of the people of the state"—rather than the Executive Branch operating under federal law—determines when, where, and how drugs are introduced into interstate commerce. App. 18a. The court also concluded that none of the federal authorities cited by Petitioners created an enforceable § 1983 cause of action. App. 5a.

Petitioners appealed. The Court of Appeals,

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42 U.S.C. §§ 247d-6d and 247d-6e.

acting *sua sponte*, introduced and relied upon several novel legal theories that neither party had briefed or argued in the district court by asserting that *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025) forecloses Petitioners' claims and relying on that opinion to resolve the facts alleged in this case. App. 3a. The *Curtis* panel held that *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), forecloses any substantive due process claim asserting a right to refuse investigational drugs. App. 53a. It further declared that investigational drugs that are "clinically identical" to, or contain the same formulation as, licensed drugs present no material distinction for purposes of an individual's right to refuse. App. 52a. On the equal-protection claim, the *Curtis* court ruled that Article III courts need only ask whether the State's differential treatment is rationally related to a purported legitimate State interest—without first considering whether that treatment intrudes upon the federal domain or conflicts with federal law. App. 54a. The *Curtis* panel also concluded that the federal statutes and regulations cited by Petitioners are mere "suggestions" for States rather than binding obligations (App. 42a, describing statutory provisions as "merely precatory obligation[s]"), and that a State may assert a necessity defense even when Congress has expressly prohibited the challenged conduct. App. 52a–53a.

On the merits, the Court of Appeals refused to address the central question presented: whether a state (or its recruited private agent) may lawfully impose a mandate requiring acceptance of investigational new drugs offered under a federally funded program that expressly demands voluntary informed consent and a waiver of the right to access the courts if injured by the drugs. The Court of

Appeals affirmed the district court's dismissal under Rule 12(b)(6), but did so on grounds the district court never considered.

## REASONS FOR GRANTING THE WRIT

The Court should grant the petition because it presents important and recurring questions of federal procedure, Supremacy Clause preemption, and substantive 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 of 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. Rule 10(c). Both criteria are squarely met. The Ninth Circuit's entire opinion rests on *Curtis v. Inslee*, *supra*, which recast *Jacobson* and failed to apply proper analysis of rational basis review.

Only this Court can correct the lower court's inversion of the Supremacy Clause, restore the proper analysis of *Jacobson*, and safeguard the liberty interest that Congress has strictly enforced through its legislative efforts for the protection of the American people. Although PeaceHealth is a private entity, Petitioners alleged that it was acting on behalf of the state when PeaceHealth deprived Petitioners of their Fourteenth Amendment rights. The panel made clear that it was not addressing

whether PeaceHealth qualified as a state actor or whether qualified immunity applied to any Respondent. App. 4a, n.3. Finally, the *Curtis* court's repeated use of the term "employees" to refer to Petitioners is misleading. They were citizens who were denied meaningful use of their state-issued healthcare licenses because a state policy barred them from entering healthcare facilities unless they participated in the CDC's COVID-19 Vaccination Program.

The Ninth Circuit held that Petitioners' claims were "foreclosed by our recent decision in *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025), which affirmed the district court judgment dismissing claims by similarly situated 'vaccine refusers.'" App. 3a. The court erred in labeling Petitioners as "vaccine refusers" as Petitioners could have proven through discovery that the drugs were not "vaccines" but were unlicensed investigational drugs that did not prevent transmission or infection. Rather, Petitioners were citizens who lawfully exercised their federally protected right to refuse investigational drugs offered under the CDC COVID-19 Vaccination Program. The State of Oregon willfully agreed to administer these products under strict voluntary conditions mandated by Congress in the Federal Food, Drug, and Cosmetic Act (FDCA) Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399i), the State's Federalwide Assurance, and CDC program agreements. It was expressly preempted under 42 U.S.C. § 247d-6d(b)(8) from issuing legal requirements that would deprive Petitioners of their right to refuse without penalty.

## I. The Ninth Circuit violated the party presentation principle by *sua sponte* applying a novel doctrine on a Rule 12(b)(6) motion.

The panel violated the principle of party presentation by citing the *Curtis* ruling. This Court has held, "In our adversarial system of adjudication, we follow the principle of party presentation." *United States v. Sineneng-Smith*, 590 U. S. 371, 375 (2020). The parties "'frame the issues for decision,'" while the court serves as "'neutral arbiter of matters the parties present.'" *Id.* (quoting *Greenlaw v. United States*, 554 U. S. 237, 243 (2008)). As this Court put it in *Clark v. Sweeney*, 607 U.S. 7, 9 (2025), "courts 'call balls and strikes'; they don't get a turn at bat." (quoting *Lomax v. Ortiz-Marquez*, 590 U. S. 595, 599 (2020)). By deciding the case on a theory no party raised, the Ninth Circuit "departed from the principle of party presentation" and committed reversible error. *Sineneng-Smith*, *supra*, at 379.

### A. The Ninth Circuit erred when ruling that *Jacobson* foreclosed any argument of a due process right to refuse unwanted investigational drugs.

The Ninth Circuit's decision rests on a *sua sponte* ruling that *Jacobson* "forecloses" any Fourteenth Amendment right to refuse investigational drugs. In the instant action, neither the district court nor any party claimed that *Jacobson* forecloses such a right with respect to investigational products. The district court discussed *Jacobson* only in the context of approved drugs, and no party argued that it categorically bars claims involving investigational

drugs. Yet the panel below invoked *Jacobson* via *Curtis* to affirm dismissal under Rule 12(b)(6) without permitting Petitioners to develop the factual record or brief the issue. App. 3a. This was error.

The panel below was not bound by *Curtis* on this point. *Curtis*, which is pending before this Court on a Petition for a Writ of Certiorari, No. 25-1119, held only that, as of 1905, *Jacobson* did not recognize a substantive due process right to refuse an investigational drug. App. 39a–40a. That narrow holding did not authorize the *Boysen* panel to decline to consider whether subsequent laws, regulations, treaties, and the deeply rooted nature of the fundamental right to bodily autonomy under *Washington v. Glucksberg*, 521 U.S. 702 (1997). If *Curtis* has such a preclusive effect, then no future panel could ever consider laws enacted *since* 1905 which confer the right to refuse investigational drugs—an absurd and ahistorical result that this Court has never endorsed.

Moreover, the panel fundamentally misapplied *Jacobson*, which was decided long before Congress enacted the modern-day era of drug regulation under its interstate commerce power, and before this Court recognized that substantive due process protects liberties "deeply rooted in this Nation's history and tradition." *Glucksberg*, *supra*, at 721.

In determining whether a right is fundamental, *Glucksberg* requires examining "our Nation's history, legal traditions, and practices." *Id.* at 710. That inquiry is not frozen in 1905. It must account for the comprehensive federal regime Congress and the Executive Branch built over the past century to protect the right to refuse investigational products. Justice Alito has repeatedly emphasized that courts must not "freeze" constitutional rights at some

arbitrary historical point while ignoring subsequent developments. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 250–51 (2022) (Alito, J.). *Jacobson* cannot possibly foreclose a right to refuse that Congress, the Executive Branch, and the States have spent the last eighty years carefully defining and protecting. Under the Ninth Circuit's reasoning, no matter how comprehensively Congress and the Executive Branch have defined and protected that right since 1905, or will ever protect such a right, the Judicial Branch of Government, through *Jacobson*, will always control and foreclose any claim that the right is protected by the Due Process Clause. This Court has never endorsed such a static and ahistorical approach to fundamental rights.

Since 1905, Congress and the Executive Branch have built the following comprehensive federal regime that now protects the right to refuse investigational medical products:

**1.** 1938: The Federal Food, Drug, and Cosmetic Act. In direct response to the Elixir Sulfanilamide disaster of 1937—which killed more than 100 people, many of them children—Congress enacted the FDCA, requiring manufacturers to prove that new drugs were safe before they could be introduced into interstate commerce. *See* 21 U.S.C. § 355(a). This was the first comprehensive federal statute recognizing that the American people have a right to be protected from untested and dangerous medical products.

**2.** 1962: 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.). Following the thalidomide tragedy, which caused thousands of severe birth defects worldwide, Congress enacted the Kefauver-Harris Amendments,

requiring manufacturers to prove both safety *and* effectiveness before a new drug could be marketed. The amendments also established an exemption to 21 U.S.C. § 355(a) permitting sponsors of clinical investigations to expose humans to investigational drugs—*provided* they obtain informed consent. *See* 21 U.S.C. § 355(i)(4). For the first time, Congress expressly conditioned the use of investigational drugs on the individual's informed consent.

**3.** 1972–1974: The Tuskegee scandal and the National Research Act. The nation learned of the Tuskegee Syphilis Study, in which the U.S. Public Health Service allowed hundreds of African-American men to go untreated—even after penicillin became an effective cure—so researchers could observe the disease's natural progression. In response, Congress enacted the National Research Act, which (1) created a National Commission to identify the ethical principles underlying informed consent, (2) required Institutional Review Boards (IRBs) to protect human subjects, and (3) directed the Executive Branch to safeguard the rights of individuals when federal funds or authority are used in research involving investigational drugs, codified at 42 U.S.C. § 289.

The Commission published its findings in the seminal Belmont Report,[2] which established that informed consent can only be legally effective when "no coercion or undue influence is involved" and when "conditions free of coercion and undue influence" are present. The Belmont Report further

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

defined coercion as "an overt threat of harm" and undue influence as "an offer of an excessive, unwarranted, inappropriate, or improper reward" or "manipulating a person's choice through the controlling influence of a close relative" or "threatening to withdraw health services to which an individual would otherwise be entitled." *See* Belmont Report, "Voluntariness."

The Executive Branch established the "Common Rule" (45 C.F.R. Part 46), which requires legally effective informed consent for investigational drugs and federally funded research activities. Notably, there is no exception from complying with 45 C.F.R. Part 46 when involving humans with such activities. *See* 45 CFR 46.101(i), and the expenditure of all federal funding must comply with the consent standard. *See* 45 C.F.R. § 46.122.

**4.** 1984: 10 U.S.C. § 980. Congress prohibited the use of Department of Defense-appropriated funds to involve a human being as an experimental subject in any research project unless the subject has provided prior informed consent. This statute reflects Congress's determination that even in national defense contexts, the right to refuse investigational medical products must be protected.

**5.** 1992: Ratification of the International Covenant on Civil and Political Rights (ICCPR). The United States Senate gave its advice and consent to the ratification of the ICCPR, which President Bush ratified on June 1, 1992. Article VII provides that "no one shall be subjected without his free consent to medical or scientific experimentation." The administration of an investigational new drug during normal medical practice is considered medical experimentation under 21 C.F.R. § 312.3(b). By ratifying this treaty, the United States committed

itself to the principle that informed consent is a fundamental human right.

**6.** 1997: The Food and Drug Administration Modernization Act (FDAMA). Congress enacted expanded-access (compassionate-use) provisions authorizing state-licensed physicians to administer investigational new drugs to patients with serious or life-threatening conditions, provided that a clinical protocol consistent with the informed-consent requirements of 21 U.S.C. § 355(i)(4) is submitted to the Secretary. *See* 21 U.S.C. § 360bbb(b)(4). This statute further embedded the right to refuse into federal law.

**7.** 2000: The Federalwide Assurance (FWA) Program. The Executive Branch established the FWA program to ensure compliance with 42 U.S.C. § 289. The FWA requires any institution, state, or entity that conducts, supports, or engages in human-subjects research involving investigational medical products—when that research is federally funded, conducted, or subject to federal regulation—to provide written assurance that it will obtain legally effective informed consent from every participant. More than 30,000 entities nationwide, including all fifty States, operate under FWA agreements.

**8.** 2004: The Project BioShield Act and the Emergency Use Authorization Statute. Congress enacted the Project BioShield Act of 2004, creating the Emergency Use Authorization (EUA) authority codified at 21 U.S.C. § 360bbb-3. Congress expressly conditioned any such authorization on the requirement that individuals be informed of their right to accept or refuse administration of the product. *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). Congress further protected this right by prohibiting the Secretary from requiring any individual to

participate in any authorized activity, including receiving the product. *See* 21 U.S.C. § 360bbb-3(l). This is the most explicit statutory recognition that the right to refuse investigational medical products is protected by federal law.

The right to refuse investigational drugs meets *Glucksberg's* two-prong analysis of determining whether a right is "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty." *Glucksberg, supra*, at 721. Since 1938, Congress has consistently acted to protect the American people from untested and dangerous medical products. Since 1962, Congress has expressly conditioned the use of investigational drugs on informed consent. Since 1974, Congress and the Executive Branch have built an elaborate regulatory framework—codified in statutes, treaties, contracts, and regulations—designed to ensure that no individual is ever coerced, unduly influenced, or unjustifiably pressured into participating in research involving investigational medical products.

This is not a right created by a single statute or regulation. It is a right that has been consistently recognized, defined, and protected by every branch of the federal government and agreed upon by all U.S. States and territories for nearly a century (*See* FWA agreement). It is a right that reflects the American people's enduring commitment to individual autonomy, bodily integrity, and the principle that no person should be forced to serve as a subject in medical experimentation without their free and informed consent. Therefore, the argument that there is a Fourteenth Amendment due process right to refuse unwanted investigational drugs must have its day in court and should not be foreclosed under Rule 12 (b)(6) dismissal.

### B. The Ninth Circuit judicially implied an exception to 21 U.S.C. § 355(a) not authorized by Congress.

The Ninth Circuit, citing *Curtis*, supplied Respondents with a defense they never argued: 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." App. 52a. This statement is legally and factually flawed in three respects.

First, Congress has created only three narrow exemptions to the prohibition on introducing unapproved drugs and biologics into interstate commerce under 21 U.S.C. § 355(a): 21 U.S.C. §§ 355(i)(4), 360bbb, and 360bbb-3. Every exemption is expressly conditioned on the Secretary ensuring that use is strictly voluntary and that the individual provides legally effective informed consent. There is no statutory exception to the consent requirement for conscious civilians. The Ninth Circuit's ruling effectively creates a fourth, judicially implied exception that Congress has never authorized.

Second, the statement implies that the Ninth Circuit is empowered to determine whether an investigational drug is "clinically identical" to a licensed drug for purposes of the § 355(a) exemption, a phrase not used by any party or the district court. It is not. In *United States v. Rutherford*, 442 U.S. 544 (1979), this Court held that 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 555. This Court further held that "the Act makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective," which "reinforces

our conclusion that no exception … may be judicially implied." *Id.* at 559. The Ninth Circuit's *sua sponte* creation of a "clinically identical" exception is precisely the type of judicial legislation *Rutherford* forbids, and represents a judicial barrier to the vindication of fundamental rights.

Third, the Ninth Circuit has invalidated an Act of Congress. The only means by which Congress has authorized the introduction of drugs into interstate commerce is through the labeling and approval process set forth in 21 U.S.C. § 352 and 42 U.S.C. § 262. Because investigational drugs are not required to maintain a static formulation, it was improper fact-finding at the pleading stage for the Ninth Circuit to conclude that the licensed drugs were "clinically identical" or contained the "same medical formulation" as the investigational drugs at issue. The phrase "clinically identical" appears nowhere in the FDCA, federal regulations, or this Court's precedents. It is a judicial invention that lacks any force of law.

The Ninth Circuit's ruling grants Respondents judicially implied authority to exempt themselves from the laws, regulations, and Executive Agreements governing investigational drugs—authority Congress has never conferred. In doing so, the court violated the separation of powers and this Court's clear instruction in *Rutherford* that courts may not rewrite federal drug safety statutes to suit their own policy preferences.

The Ninth Circuit, citing to *Curtis*, supplied Respondents with a defense they never argued. Even if the *Curtis* ruling was correct, which is denied, Respondents must make the accusation that the drugs were clinically identical and demonstrate by some source of evidence that they were exempt from

their obligations under the CDC and FWA programs, and 21 U.S.C. § 360bbb-3 *et seq*., from obtaining legally effective informed consent when mandating the drugs under their state policy. Even if the drugs in the *Curtis* court had been proven to be "clinically identical" pursuant to FDA standards and authorization, it is up to Respondents to make such argument, not the court.

### C. The Ninth Circuit's reliance on *Jacobson* violates this Court's holdings in *Oakland Cannabis* and *Rutherford*.

Insofar as the panel below relies on *Curtis* for the proposition that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members," and that "a vaccine mandate that has a real or substantial relation to the protection of public health is not in palpable conflict with the Constitution," that reliance is misplaced for two independent reasons. App. 53a.

First, no Respondent argued any authority to mandate the use of investigational drugs or a covered countermeasure under the PREP Act or claimed any necessity to do so. This Court foreclosed precisely that argument in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). There, patients seeking access to marijuana for medical purposes contended that "medical necessity" should be read into the Controlled Substances Act because necessity was a common-law defense. The Court rejected the claim outright, explaining 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. As the D.C. Circuit explained in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (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." *Id.* at 713. 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* 21 U.S.C. § 355(i). Given this Court's conclusion that the common-law defense of necessity cannot override a value judgment already determined by the legislature, the doctrine provides no support for the panel's judicially created exception.

Second, by judicially creating a necessity-based exception to the FDCA's mandatory informed-consent and voluntary-use requirements, the Ninth Circuit directly contravened this Court's holding in *Oakland Cannabis* and impermissibly elevated its own policy preferences over Congress' explicit value-based judgments. The FDCA reflects Congress' deliberate determination that investigational drugs may be used only under strict voluntary conditions, which Respondents contractually agreed to protect. The Ninth Circuit had no authority to override that legislative judgment by judicial fiat.

### D. Petitioners' cited sources of authority are not precatory.

Insofar as the panel below agrees with *Curtis* that Petitioners' cited sources of authority are "merely precatory," that conclusion is incorrect and

constitutes a separation-of-powers violation. App. 42a. *Black's Law Dictionary* (11th ed. 2019) defines "precatory" as "expressing a wish or recommendation, but not a command or direction." The duty to obtain legally effective informed consent is mandatory, not precatory.

The Ninth Circuit engaged in improper fact-finding and premature merits adjudication at the Rule 12(b)(6) stage. The panel dismissed Petitioners' allegations concerning federal statutes, regulations, and binding agreements by recharacterizing them as imposing only "merely precatory obligation[s] on the government" that "do not create enforceable rights." App. 44a. In so doing, the court ignored the expressly mandatory language—"must," "ensure," "shall," "obtain," and "require"—that appears throughout Petitioners' cited authorities. Such language imposes ministerial, nondiscretionary obligations—not mere hortatory suggestions—that can lead to claims of entitlement upon full discovery.

By reframing these expressly mandatory federal mandates as mere precatory suggestions, the Ninth Circuit committed a separation-of-powers violation by judicially implying that such sources of authority are not binding federal mandates but rather mere suggestions for Respondents to consider.

## II. The Ninth Circuit's *sua sponte* reliance on *Curtis* to supply Respondents with a rational-basis defense is error.

The Ninth Circuit now declares that "our only inquiry is whether Employees' treatment is rationally related to the State's objective." App. 57a. That approach directly contradicts this Court's holding in *City of Cleburne v. Cleburne Living Center,*

*Inc.*, 473 U.S. 432, 441 (1985), that rational-basis review applies only to "interests the State has the authority to implement."

Because Petitioners alleged that the challenged mandates are preempted by federal law, the Ninth Circuit, as a matter of law, cannot supply any legitimate State interest at the pleading stage. A policy that violates federal law is not a legitimate exercise of police power; it is void under the Supremacy Clause. The Ninth Circuit's inverted framework—treating federal preemption as irrelevant once a state invokes "public health"—cannot be reconciled with *Jacobson*, *Cleburne*, or the Supremacy Clause.

The panel's opinion effectively casts the State as sovereign and the federal government as subordinate, turning *Cleburne* on its head. It rules that once a State invokes "public health," federal statutes, regulations, and binding agreements governing investigational drugs become irrelevant, and the court's only inquiry is whether the mandate is rationally related to a legitimate State objective.

The Supremacy Clause commands the opposite result. It declares that "the Laws of the United States … shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. As this Court has repeatedly held, "States are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance," and "[t]he State may not pursue policies that undermine federal law." *Arizona v. United States*, 567 U.S. 387, 399, 416 (2012).

For more than eighty-five years, since the FDCA's enactment in 1938, Congress has occupied the entire field of unapproved drug regulation under

its power to regulate interstate commerce, leaving no room for State intrusion. This ruling directly contradicts the federal government's determination that protecting public health requires preserving the unfettered right to refuse investigational medical treatments without penalty or loss of an otherwise-entitled benefit.

*Jacobson* itself is clear that the first inquiry is whether the scope and extent of the statute constitute a legitimate exercise of the State's police powers. "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, or with any right which that instrument gives or secures." *Jacobson*, 197 U.S. at 25.

This principle was illustrated in *Railroad Co. v. Husen*, 95 U.S. 465 (1877), where the Supreme Court struck down a State public-health regulation 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*, 197 U.S. at 25 (citing *Husen*, 95 U.S. at 471–73). The Court emphasized 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." *Husen*, 95 U.S. at 469.

The PREP Act is unambiguous: neither a State nor a political subdivision may establish a legal requirement that conflicts with a PREP Act declaration or any requirement applicable to a countermeasure under the Federal Food, Drug, and Cosmetic Act (FDCA). Respondents' respective mandates violate the FDCA by imposing legal

conditions that conflict with the HHS Secretary's ministerial duty under 21 U.S.C. § 360bbb-3 *et seq*. to ensure that potential recipients are informed of their option to refuse and that the Secretary does not mandate participation in any activity authorized under an EUA, including administration of the product. App. 67a–69a.

Since 1938, no person has had the authority to mandate the use of investigational drugs not approved by the FDA within the meaning of 21 U.S.C. § 355(a). This Court has established that a State may not impose legal requirements that conflict with the FDCA. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (en banc), *cert. denied*, 552 U.S. 1159 (2008) (affirming that "the FDCA's comprehensive scheme" occupies the field).

Moreover, under the FDCA, States are preempted from promoting a drug, biologic, or device for any use not authorized by its approved labeling. *See* 21 U.S.C. § 352. Recipients of EUA products must be informed of the product's known and potential risks and benefits based solely on the Secretary's determinations from incomplete clinical trials. These determinations do not authorize a state to claim that the drug "will," "would," or "can" prevent disease transmission.

Because the FDCA expressly prohibits the promotion of unapproved uses, Respondents' subjective belief that drugs not labeled for any indication will protect public health cannot supply a legitimate State interest for rational-basis review.

Such a claim not only infringes on the FDA's exclusive authority but also constitutes the criminal act of misbranding under 21 U.S.C. § 331. This Court cannot affirm a State interest that directly contradicts the product's FDA-authorized labeling.

Furthermore, for investigational drugs, federal regulations prohibit persons acting under the authority of the HHS Secretary, such as Respondents, from claiming any medical outcome: "A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. § 312.7(a).

Therefore, Respondents cannot issue a health policy mandating the use of an unlicensed drug subject to the voluntary requirements under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), or interfere with the Secretary's duty to refrain from mandating involuntary participation under 21 U.S.C. § 360bbb-3(l). Specifically, Respondents were under contractual obligation to execute on the Secretary's behalf his authorization conditions under each EUA, and Respondents cannot achieve a result on behalf of the Secretary that Congress expressly prohibits—namely, mandating involuntary use of EUA medical products.

Only after confirming that the State has authority to enact the statute may a court proceed to ask whether the means prescribed further a legitimate interest that is not arbitrary, oppressive, or unreasonable. *Jacobson*, 197 U.S. at 31. The Ninth Circuit skipped the first step entirely. Because Petitioners alleged that the mandates are preempted

by federal law, the district court could not, as a matter of federal court procedure, supply a legitimate State interest at the pleading stage. A policy that violates federal law is not a legitimate exercise of police power; it is void under the Supremacy Clause. The Ninth Circuit's refusal to apply the correct *Jacobson* framework rests not on law, but on its own policy preferences. If the mandates infringed upon the federal domain, then they are not within the State's authority to implement, and the court cannot *sua sponte* supply Respondents with a rational basis argument without offending the Supremacy Clause.

The Ninth Circuit cannot simply disregard congressional acts when reviewing Fourteenth Amendment challenges to public health policies. The *Boysen* panel applied a ruling from Washington State to a different set of Oregon facts without considering how the facts in the instant action violated federal law, which is an indisputable fact that ought not be tolerated by this Court.

## III. The Ninth Circuit's *Curtis* decision establishes dangerous precedent that authorizes the coerced waiver of Constitutional rights via State health policies.

The Due Process Clause of the Fourteenth Amendment stands as a bulwark against governmental overreach. It commands that no State shall "deprive any person of life, liberty, or property, without due process of law." U.S. Const. Amend. XIV, § 1. The first inquiry in every due process challenge—whether procedural or substantive—is whether the plaintiff has been deprived of a protected interest in property or liberty. *Am. Mfrs.*

*Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (quoting U.S. Const. Amend. XIV). "To have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." *Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 576 (1972). "Property interests … are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law—rules or understandings that secure certain benefits and that support claims of entitlement to those benefits." *Id.* at 577.

### A. The Due Process Clause prohibits mandating the use of investigational covered countermeasures.

Petitioners alleged that a State cannot constitutionally mandate the use of a covered countermeasure immunized from liability under the PREP Act. Because the Act denies any right to seek judicial remedy for resulting injuries, such a mandate forces Petitioners to surrender a core due process right as the price of continued employment within the State's licensed healthcare industry. This is precisely the type of indirect coercion the Constitution forbids — the State cannot achieve indirectly what it could never command directly.

This Court has long affirmed that access to judicial remedy is a right guaranteed and protected by the Constitution's Due Process Clause.

The right to sue and defend in the courts is the alternative of force. In an organized society, it is the

right conservative of all other rights, and lies at the foundation of orderly government. It is one of the highest and most essential privileges of citizenship, and must be allowed by each State to the citizens of all other States to the precise extent that it is allowed to its own citizens. *Chambers v. Baltimore & Ohio R. Co.*, 207 U.S. 142, 148 (1907).

This Court has also established that a cause of action is a species of property protected by the Due Process Clause. *See Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982) ("The first question, we believe, was affirmatively settled by the *Mullane* [*v. Central Hanover Bank & Trust Co.,* 339 U.S. 306 (1950)] case itself, where the Court held that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause."); *Tulsa Professional Collection Services, Inc. v. Pope*, 485 U.S. 478, 485 (1988); *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 807 (1985).

The PREP Act precludes an individual's due process right to access courts upon using a covered countermeasure resulting in injury: "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).

When a State mandates, under the PREP Act, that workers in a licensed profession surrender, in advance, their right to pursue federal and state tort remedies if injured by a covered countermeasure, the State forces every worker to waive a core due process right as the price of using that license. This is not a voluntary choice. It is an unconstitutional condition and a compelled waiver of constitutional rights that

the Constitution expressly prohibits. *Insurance Co. v. Morse*, 87 U.S. 445, 451 (1874) (A licensed professional may not "barter away his life or his freedom, or his substantial rights" as the price of practicing his state-licensed profession.)

This Court has made clear that any waiver of constitutional rights "must be freely given and shown by 'clear and compelling' evidence." *Janus v. AFSCME*, 585 U.S. 878, 892 (2018) (quoting *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938)). A valid waiver 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). A government mandate of a PREP Act-covered countermeasure, under penalty of loss of employment within a state-licensed industry, places the citizen under moral duress to comply with the mandate, thus surrendering constitutional rights through coercion, not as "a free and deliberate choice." *Id.*

Here, the State has not—and cannot—meet that burden of ensuring a free and deliberate choice. Conditioning continued employment in a state-licensed profession on the surrender of the right to seek judicial remedy if injured by a PREP Act-covered countermeasure is the very definition of coercion. As this Court has long recognized, the government "cannot achieve indirectly what it cannot command directly." *See Speiser v. Randall*, 357 U.S. 513, 526 (1958) (holding that a state may not use a procedural device to necessarily produce a result which the State could not command directly); *see also Bailey v. Alabama*, 219 U.S. 219, 239 (1911). Further, the state cannot evade its constitutional restraints by using private parties to accomplish results it cannot command. *See West v. Atkins*, 487 U.S. 42, 56 (1988) (holding that if a government

bears an affirmative obligation to perform a governmental function to citizens of the state and it contracts with willing private parties, then the private party assumes that Fourteenth Amendment obligation).

This Court has long held that "[i]f the state may compel the surrender of one constitutional right as a condition of its favor, 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. Comm.*, 271 U.S. 583, 593–94 (1926).

> For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests.

*Perry v. Sindermann*, 408 U.S. 593, 597 (1972).

The State's mandate of covered countermeasures conflicts with this Court's longstanding precedent that a State may not require the waiver of constitutional rights—directly or indirectly—as a condition of public benefits and privileges. Petitioners plausibly alleged a deprivation of Fourteenth Amendment guarantees by asserting that Respondents' public health mandate conditioned employment in the State's licensed healthcare industry on the use of a covered countermeasure—a mandate that, if proven unconstitutional, would give

rise to enforceable damages under 42 U.S.C. § 1983. The Ninth Circuit claimed that "Employees' substantive due process claim regarding the PREP Act's grant of immunity also fails," but it failed to address how such a claim is not actionable under § 1983 in light of this Court's precedents. App. 53a.

Petitioners were deprived of their property interest in practicing a State-licensed profession solely because they refused to waive their right to access the courts for judicial remedies if injured by refusing the administration of the mandated countermeasure. The Due Process Clause of the Fourteenth Amendment, as originally understood, protects that interest against governmental deprivation without due process of law.

The Ninth Circuit claimed that "[e]mployees' substantive due process claim regarding the PREP Act's grant of immunity…fails," but it failed to address how such a claim is not actionable under § 1983 in light of this Court's precedent. App. 53a.

### B. The CDC Program provides Petitioners with enforceable property interests.

The *Curtis* ruling, which authorized State power to mandate the administration of investigational drugs on a government official's subjective belief that they "would protect public health," judicially exempts Respondents from federal obligations and deprives Petitioners of their property interests. App. 52a.

The CDC Program, as adopted into official state policy, provided Petitioners with the federally funded benefit of learning the program's risks, benefits, and alternatives, and then being informed of their right to accept or refuse participation without incurring cost or penalty upon refusal. These are property

interests protected by the Due Process Clause. *Roth*, *supra*.

Petitioners' constitutional claims were dismissed because the Ninth Circuit believed it need not inquire whether the challenged policy violated federal law, that the right to refuse investigational drugs is not fundamental, that States may assert a necessity defense even when Congress has preempted the conduct, and that Petitioners possess no property interest in exercising the federally funded option to refuse participation in the CDC Program.

This approach cannot be reconciled with this Court's precedents. Under *Roth* and *Logan*, *supra*, Petitioners' federally funded right to be informed of and exercise their option to refuse investigational products constitutes a protected property interest. Under *Cleburne* and *Arizona*, *supra*, a State policy that violates federal law supplies no legitimate interest for rational-basis review. And under *Glucksberg* and *Dobbs, supra*, the right to refuse investigational medical products is deeply rooted in the Nation's history and tradition.

## IV. The Question Presented warrants this Court's review.

This Court's review is necessary because the Ninth Circuit has invalidated the FDCA's prohibition on the nonconsensual administration of investigational drugs. The Ninth Circuit went further by permitting persons operating under the Federalwide Assurance program to be exempt from federal obligations when they claim the drugs are "clinically identical" to approved products, assert a necessity

defense, or subjectively believe the drugs can help address a public health concern.

As this Court has observed, "[a]s usual when a lower court has invalidated a federal statute, we granted certiorari." *Iancu v. Brunetti*, 139 S.Ct. 2294 (2019). Here, the Ninth Circuit, claiming public and private actors can mandate investigational drugs, invalidates the informed consent requirement under 21 U.S.C. §§ 355(i)(4), 360bbb(b)(4), and §360bbb-3(e)(1)(A)(ii)(III), and denied the Secretary his exclusive authority to determine when, where, and how investigational drugs will be introduced into interstate commerce. Furthermore, the ruling invalidates 42 U.S.C. § 289 by permitting thousands of public and private actors to deny Americans their legally effective informed consent rights, rendering the Executive Branch's authority to protect such rights impotent.

The Ninth Circuit's decision effectively enjoins the Executive Branch from fulfilling its duties under 42 U.S.C. § 289, the FDCA, and their corresponding regulatory enforcement provisions by permitting conduct expressly prohibited by Congress. The President has a constitutional duty to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3. By judicially exempting public and private entities from their federal obligations and refusing to enforce the preemptive effect of federal law, the Ninth Circuit has nullified the President's ability to ensure that the laws are faithfully executed. The harm here is not speculative. The Ninth Circuit's ruling allows State agencies and private contractors operating under FWA agreements to coerce, unduly influence, or unjustifiably pressure individuals into participating in research involving investigational drugs—conduct

that federal law expressly prohibits as discussed herein.

Finally, the Ninth Circuit's declaration that all of Petitioners' cited federal sources of authority are "merely precatory" invalidated the force of law those sources possess. App. 42a. This is no small error of law. Future litigants will be met with immediate dismissal by the Ninth, claiming the *Curtis* panel controls their case, when a person attempts to claim that the laws are more than suggestions.

## V. Cases for consolidated review.

The Ninth Circuit held that Petitioners' claims are foreclosed by its ruling in *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025). According to the Ninth Circuit, the *Curtis* case, pending before this Court as No. 25-1119, is foreclosed by *Jacobson v. Massachusetts* and *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025) pending as No. 25-765. Additionally, *Sweeney v. University of Colorado Hospital Authority*, No. 25-1055, and *Horsley v. Kaiser Foundation Hospitals*, No. 25-5982, are pending before this Court and present a materially similar factual and legal backdrop and identical procedural errors by both the district and circuit courts. The Court may wish to consider these petitions under consolidated review to promote judicial economy and ensure a complete and consistent presentation of the issues.

## 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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