No.

In the Supreme Court of the United States

BRENDA HORSLEY, *et al.*,
Petitioners,

v.

KAISER FOUNDATION HOSPITALS, *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

DAVID J. SCHEXNAYDRE
SCHEXNAYDRE LAW FIRM, LLC
2895 Hwy 190, Ste. 212
Mandeville, LA 70471
(985) 292-2020
david@schexnaydre.com

Counsel for Petitioners

QUESTIONS PRESENTED

Question 1:

Whether *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), forecloses a substantive due process claim under the Fourteenth Amendment that an individual has a right to refuse unwanted investigational drugs without incurring a penalty or losing a public benefit to which the individual is otherwise entitled.

Question 2:

Whether the Federal Food, Drug, and Cosmetic Act and the Public Readiness and Emergency Preparedness Act preempt states from conditioning employment in a state-licensed healthcare facility on an individual's receipt of investigational drugs.

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees of Kaiser Foundation Hospitals: Brenda Horsley, Cynthia Anderson, Vincent Lanchinebre, Justin Rawson, Daniel Ruvalcaba, Patricia Underhill, Courtney Wolfenstein, Kristi Shepherd, Janet Manning, Maria Samantha De La Cruz, Jeff Folkes, Michael Jang, Joshua Pacheco, and Michelle Massa.

Respondents are Kaiser Foundation Hospitals, Inc.; Gavin Newsom, Governor of California; Thomas J. Aragon, Greg Adams, and Andrew Bindman.

CORPORATE DISCLOSURE STATEMENT

Petitioners have no information to disclose under Rule 29.6. Respondent Kaiser Foundation Hospitals, Inc. 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

Horsley v. Kaiser Foundation Hospitals, No. 24-5812, U.S. Court of Appeals for the Ninth Circuit. Judgment entered November 17, 2025.

Horsley v. Kaiser Foundation Hospitals, No. 3:23-cv-05628-AMO, United States District Court for the Northern District of California. Judgment on motions to dismiss was entered on August 26, 2024.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Brenda Horsley, *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 *Horsley v. Kaiser Found. Hosps., Inc.*, 2025 U.S. App. LEXIS 29935 and 2025 WL 320587; it is reproduced at Appendix A.

The U.S. District Court for the Northern District of California's decision dismissing Respondents is reported at *Horsley v. Kaiser Found. Hosps., Inc*, 746 F. Supp. 3d 791 (N.D. Cal. 2024), and is reproduced at Appendix B.

JURISDICTION

The Ninth Circuit issued its opinion on November 17, 2025. Petitioners requested an extension of time in which to file the instant petition for a writ of *certiorari*, and were granted an extension by Justice Kagan until April 16, 2026, No. 25A880. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional provisions involved are included at Appendix C, App. 29a:

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

The relevant statutory provisions are included at Appendix C, App. 30a–35a:

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-6e(c)
42 U.S.C. § 247d-6d(b)(8)
42 U.S.C. § 289.

INTRODUCTION

This Petition presents a profound constitutional crisis that strikes at the very heart of our federal system and the fundamental liberties secured by the Fourteenth Amendment. During the pleading stage, under Federal Rule of Civil Procedure 12(b)(6), the Ninth Circuit continues to dismiss cases based on invented novel doctrines that empower state governments to compel American citizens to submit to the administration of investigational new drugs, to disclose their identifiable private health information to medical researchers, and to prospectively waive their fundamental right to seek judicial redress if injured by those drugs — all as a condition of working within a state-licensed industry.

In what has become a tangled mess of interdependent rulings, the Ninth Circuit used cases now pending before this Court to dismiss Petitioners' claims, stating that Petitioners' substantive due

process claims are foreclosed by *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025) (Supreme Court No. 25-1119). *Curtis* relied, in part, on *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025) (Supreme Court No. 25-765). Meanwhile, Petitioners in *Carvalho* expressly refer to *Curtis* as an example of the harmful consequences of the Ninth Circuit's *Carvalho* ruling. The Ninth Circuit dismissed this case by also relying on *Curtis*.

The Tenth Circuit case *Sweeney v. University of Colorado Hospital Authority* (Supreme Court No. 25-1055), presents an identical factual and legal backdrop and the same procedural errors as those at issue here and cites to *Curtis* as partial justification for its ruling. This Court may wish to consider the instant petition together with *Carvalho*, *Curtis*, and *Sweeney*, to ensure a complete and consistent treatment of the recurring constitutional questions raised by these cases.

The Ninth Circuit dismissed this case under Rule 12(b)(6), holding that Petitioners' constitutional challenge to the mandatory use of investigational drugs is foreclosed by *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025). This holding affirms the unconstitutional judicial doctrine it first announced in *Curtis*: that when reviewing Fourteenth Amendment challenges to state health policies, "the only inquiry is whether [the policy] is 'rationally related to the State's objective.'" *Id.*, at 692. This holding is profoundly ironic. Both *Curtis* and the decision below rest heavily on *Jacobson v. Massachusetts,* 197 U.S. 11 (1905). Yet *Jacobson* itself requires a two-step analysis. The threshold inquiry is whether the challenged state policy lies within the legitimate bounds of the state's police power or instead invades the domain of federal authority. *Id.*, at 25.

Drawing directly from its earlier decision in *Railroad Company v. Husen*, 95 U.S. 465 (1877), the *Jacobson* Court made clear that a state health measure exceeds the police power if 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 28. *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.")

Only after confirming that the policy is a valid exercise of state authority does the court proceed to the second inquiry: whether the means selected are reasonable and not arbitrary, oppressive, or an unreasonable exercise of the police power. By collapsing *Jacobson* into a single rational-basis test and skipping the threshold federal-authority inquiry altogether, the Ninth Circuit has fundamentally distorted this Court's precedent. The question of authority is dispositive. If the mandates were facially unlawful under federal law, then the penalties imposed for refusing to comply were likewise unconstitutional.

Respondents in this case were under clear federal obligations—imposed by the Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301–399i) (FDCA), the Federalwide Assurance program (FWA), and the CDC COVID-19 Vaccination Program—to ensure that Petitioners faced no external pressure to accept an investigational drug and would suffer no penalty for exercising their statutory right to refuse. Despite these obligations, the courts below dismissed

the action under Rule 12(b)(6) solely because the Ninth Circuit now refuses to consider federal supremacy or preemption when reviewing Fourteenth Amendment challenges to state health mandates.

This inversion of constitutional authority undermines the very protections Congress designed for the American people and is spreading to other Circuits. The Tenth Circuit has already embraced a parallel approach. In *Sweeney v. University of Colorado Hospital Authority*, No. 25-1005 (10th Cir. Oct. 21, 2025), published as *Timken v. South Denver Cardiology Associates*, *P.C.,* 155 F.4th 1227 (10th Cir. 2025), that court, without explanation, disregarded the federal obligations and executive agreements that bind the governmental entity and upheld the alleged power of state actors to penalize individuals for refusing investigational drugs.

However, a far more profound constitutional crisis lies beneath the surface. When an Article III court presumes to "sit as councils of revision, empowered to rewrite legislation in accord with [its] own conceptions of prudent public policy," *United States v. Rutherford*, 442 U.S. 544, 555 (1979), it usurps the legislative function and undermines the constitutional structure of our Republic. In our system of separate powers, it is the people—acting through their elected representatives in Congress—who make the fundamental value-based judgments regarding the conditions under which investigational drugs may be introduced into interstate commerce and administered to the public. For more than eighty years, We the People have consistently required informed consent and voluntary participation as essential conditions for any such use. The Ninth Circuit offers no justification for transferring to

governors, hospital administrators, and other state officials an authority that Congress has expressly withheld even from the Secretary of Health and Human Services (Secretary) and all other governments. *See* 21 U.S.C. § 355(a). By disregarding the informed-consent requirements enacted by the people's representatives, the court has not only nullified federal law—it has denied the American people their representative form of government.

Petitioners respectfully submit that the time has come for this Court to safeguard the safety, health, and fundamental liberties of the American people by restoring the constitutional order and proper standards governing Federal Rule of Civil Procedure 12(b)(6). The petition for a writ of certiorari should be granted, the judgment of the Ninth Circuit reversed, and the case remanded for further proceedings consistent with this Court's precedents.

STATEMENT OF THE CASE

Factual Background

In 2020, the federal government established the CDC COVID-19 Vaccination Program to facilitate the nationwide distribution and administration of unlicensed COVID-19 vaccines authorized for emergency use under 21 U.S.C. § 360bbb-3, as an exception to the general prohibition on the introduction of unapproved new drugs into interstate commerce set forth in 21 U.S.C. § 355(a).

The State of California agreed to participate in this federal program on behalf of the United States. As part of its ministerial duties, California was required to recruit and oversee public and private

entities to administer the vaccines to the public. The State was obligated to ensure that participating providers executed the CDC COVID-19 Vaccination Program Provider Agreement, under which those providers committed to complying with all conditions imposed by the Secretary in each Emergency Use Authorization. California was further contractually required to monitor those providers to ensure lawful compliance and to protect the public's rights and safety. The federal government retained ownership of the investigational vaccines until the moment of administration to an individual, and any administration outside the authorized conditions constituted fraud against the United States.

California specifically recruited Kaiser Permanente to act as its agent in presenting members of the public with the opportunity to accept the EUA-authorized investigational drugs. Kaiser's discretionary authority was limited to offering the product to the public at times, places, and dates of their choosing. Kaiser's ministerial obligations were to inform the potential recipient of (1) the benefits, risks, and alternatives of the program's investigational drugs, and (2) their option to accept or refuse and accept the individual's chosen option without interference.

In 2021, the state and its agent, Kaiser, issued policies mandating the involuntary use of investigational drugs, subject to penalties, in violation of their respective agreements. When Petitioners exercised their constitutional and federal statutory right to refuse the investigational drugs, Kaiser, acting under state policy and custom, punished Petitioners by denying them access to work within the state's licensed healthcare industry, resulting in economic, emotional, and other damages.

Procedural Background

The underlying action challenged mandatory health policies promulgated and enforced by Respondents. Petitioners filed suit on October 31, 2023, and amended their complaint to add additional plaintiffs. In their Second Amended Complaint, Petitioners asserted Fourteenth Amendment claims under 42 U.S.C. § 1983 for the deprivation of their right to: (1) refuse the administration of EUA investigational drugs; (2) refuse the administration of covered countermeasures shielded from liability under the PREP Act;[1] (3) refuse disclosure of private health information to medical researchers, and (4) refuse participation in the CDC COVID-19 Vaccination Program; and not have these rights withheld as a condition of continued employment in the state's licensed healthcare industry, among other claims. Respondents filed motions to dismiss, which the district court granted on August 26, 2024 (App. 7a) on the ground that Respondents failed to state a cause of action under Federal Rule of Civil Procedure 12(b)(6).

Petitioners filed a timely Notice of Appeal on September 24, 2024, to the Ninth Circuit. The Ninth Circuit affirmed the district court's dismissal because Petitioners two § 1983 claims relating to investigational drugs "are foreclosed by our decision in *Curtis*."

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[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 42 U.S.C. §§ 247d-6d and 247d-6e.

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 in informed consent and bodily integrity.

The Ninth Circuit has informed American citizens that their constitutional right to enjoy public benefits now hinges upon whether they are willing to submit to the administration of investigational drugs, disclose identifiable private health information to medical researchers for undisclosed purposes, prospectively waive their right to seek judicial remedies if injured by those unlicensed drugs or any activities causally connected to their administration, and forfeit federally funded benefits to which they are otherwise entitled.

Although Kaiser is a private entity, Petitioners allege that it was acting on behalf of official state policy when it deprived Petitioners of their Fourteenth Amendment rights — a contention the Ninth Circuit expressly acknowledged. App. 2a. The panel made clear that it was not addressing whether Kaiser qualified as a state actor or whether qualified immunity applied to any Respondent. App. 4a. Additionally, the panel referred to Petitioners as "at-will employees," a characterization that has no bearing on this case. The Court acknowledged that Kaiser was acting under official state policy when applying punishment to Petitioners after refusing to

accept the administration of investigational drugs. App. 2a.

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 criteria are squarely met. The Ninth Circuit's entire opinion rests on *Curtis*' radical recasting of *Jacobson*, to hold that lower courts need not inquire whether federal law—including the FDCA and more than 120 years of subsequent congressional enactments—establishes a substantive due process right to refuse investigational drugs, or prohibits states from mandating the use of such drugs under threat of penalty.

I. The Ninth Circuit's claim that *Curtis* forecloses the substantive due process argument of the right to refuse investigational drugs conflicts with this Court's required framework for analyzing claims of fundamental rights.

It should be noted at the outset that no Respondent asserted any authority to mandate investigational drugs, nor did any Respondent claim a rational basis for issuing a health policy that relied exclusively on such products. Nevertheless, the Ninth Circuit, in violation of the principle of party presentation, *sua sponte* crafted and supplied that defense on behalf of Respondents. *See United States v. Sineneng-Smith*, 590 U.S. 371, 375 (2020) (parties frame the issues for decision; the court serves as neutral arbiter of matters the parties present).

The Ninth Circuit stated that "Plaintiffs' two Section 1983 claims pursuant to the Fourteenth Amendment fare no better because they are foreclosed by our decision in *Curtis*." App. 3a. However, the panel does not inform *which* two § 1983 claims they refer to, Petitioners believe that one of the claims is the Fourteenth Amendment right to refuse an investigational drug.

The *Curtis* opinion rested on the *en banc* decision in *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025), and this Court's 120-year-old decision in *Jacobson*. Considering that this case involves matters of first impression at the pleading stage, the Ninth Circuit's opinion that *Jacobson* forecloses any substantive due process argument of the right to refuse investigational drugs without pressure or penalty is irrational and an abuse of discretion. Moreover, it cannot be reconciled with this Court's settled precedent governing the identification and protection of fundamental liberty interests under the Due Process Clause of the Fourteenth Amendment.

The panel's sole explanation for permitting a state to violate both federal law and a 120-year-old judicial precedent—while foreclosing any modern substantive due process argument to refuse a class of drugs unknown to the *Jacobson* Court—was the bare assertion that "the penalties imposed … were amply justified by public health concerns." App. 4a. With that single sentence, the panel concluded its analysis.

This approach is fundamentally incompatible with this Court's longstanding and recently reaffirmed methodology for substantive due process claims. This Court has made clear that the Due Process Clause "specially protects those fundamental

rights and liberties which are, objectively, 'deeply rooted in this Nation's history and tradition,' and 'implicit in the concept of ordered liberty,' such that 'neither liberty nor justice would exist if they were sacrificed.'" *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997) (citations omitted). The Court has likewise insisted on a "careful description" of the asserted right so that the historical inquiry remains disciplined and objective rather than subjective or policy-driven. *Id.* at 721. These "crucial 'guideposts for responsible decisionmaking' … direct and restrain our exposition of the Due Process Clause." *Id.*

The Ninth Circuit's decision ignored these guideposts. Neither the panel opinion nor the *Curtis* decision, which it slavishly followed, engaged in any historical analysis of the specific liberty interest Petitioners assert: the right of an individual to refuse unwanted investigational drugs without incurring a penalty or losing a public benefit to which the individual is otherwise entitled. The courts below conducted no examination of this Nation's history and tradition concerning bodily integrity, informed consent, or the refusal of investigational or conditionally authorized medical interventions. They cited no common-law authorities, no historical statutes, and no longstanding governmental practices addressing the precise right at issue. Worse, both *Curtis* and the decisions below were resolved at the pleading stage under Rule 12(b)(6). No discovery was permitted. No factual record was developed concerning the investigational status of the products, the scope and effect of mandating drugs not labeled by the FDA for their safety and efficacy, or the concrete penalties imposed. Petitioners were never given the opportunity, through discovery, to present evidence or historical materials that this

Court's precedents require before a lower court may declare an asserted liberty interest non-fundamental. By short-circuiting the *Glucksberg* inquiry and simply declaring the claims "foreclosed" by prior circuit precedent, the Ninth Circuit prevented the very record development and careful historical analysis that this Court demands. That is the antithesis of the disciplined methodology this Court has prescribed.

The panel's reflexive reliance on *Jacobson* only compounds the constitutional error. *Jacobson* addressed a traditional smallpox vaccine administered more than a century ago during a deadly epidemic thirty-three years before Congress enacted the FDCA. *Jacobson* does not insulate every conceivable mandate of investigational or emergency-authorized products—from substantive due process scrutiny. *Jacobson* predates the modern substantive due process framework by nearly a century and applied a highly deferential standard to a different factual and legal context. It cannot substitute for the rigorous historical inquiry this Court requires when a petitioner asserts a distinct and previously unaddressed liberty interest.

The conflict with this Court's precedent is clear and intolerable. The Ninth Circuit has effectively converted *Jacobson* and circuit precedent decided on the pleadings into a *per se* rule that forecloses any substantive due process challenge to mandates involving investigational medical products. That rule cannot coexist with *Glucksberg*. This Court's intervention is necessary to reaffirm that lower courts may not evade the disciplined historical analysis required to determine whether an asserted right is fundamental.

A. The right to refuse investigational drugs is firmly established by Congress.

In 1938, Congress enacted the FDCA in direct response to the Elixir Sulfanilamide disaster of 1937. That tragedy killed more than 100 people—many of them children—after a manufacturer marketed an untested liquid medicine containing the toxic solvent diethylene glycol. The disaster exposed serious deficiencies in existing federal law and created overwhelming public demand for stronger oversight of drug safety. Congress responded swiftly by requiring manufacturers to prove that new drugs were safe before they could be introduced into interstate commerce. *See* 21 U.S.C. § 355(a).

In 1962, Congress enacted the Kefauver-Harris Amendments (Pub. L. No. 87-781, 76 Stat. 780 (Oct. 10, 1962)) (codified as amended in scattered sections of 21 U.S.C.) in response to the thalidomide tragedy, which caused thousands of severe birth defects worldwide after the drug was marketed without adequate proof of safety or effectiveness. The amendments strengthened federal drug regulation by requiring manufacturers to prove that new drugs are both safe and effective before they may be introduced into interstate commerce. The amendments established an exemption to 21 U.S.C. § 355(a) by permitting sponsors of clinical investigations to expose humans to investigational drugs, provided they obtain their informed consent. *See* 21 U.S.C. § 355(i)(4).

In 1972, the nation learned of the Tuskegee Syphilis Study, a profound human rights tragedy in which the U.S. Public Health Service allowed hundreds of African-American men suffering from syphilis to go untreated—even after penicillin

became an effective and available cure—so researchers could observe the disease's natural progression. In response to this scandal and other documented abuses in medical research, Senator Edward M. Kennedy convened congressional hearings in 1973.[2] Congress responded by enacting the National Research Act of 1974, Pub. L. No. 93-348. This statute (1) created a National Commission to identify the basic ethical principles underlying informed consent, (2) required the establishment of Institutional Review Boards (IRBs) to protect the rights and welfare of human subjects participating in research involving investigational drugs and medical procedures, and (3) directed the Executive Branch to safeguard the rights of individuals when federal funds or authority are used in such research, as codified at 42 U.S.C. § 289.

The Commission published its findings in the seminal Belmont Report.[3] The Commission determined that informed consent can only be legally effective when:

> Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for

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

[3] 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.

informed consent are satisfied.

The Commission determined that the adequate standards of informed consent are met when no coercion or undue influence is involved:

> An agreement to participate in research constitutes valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence; …
>
> Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance; …
>
> Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable; ...
>
> Unjustifiable pressures usually occur when persons in positions of authority or commanding influence — especially where possible sanctions are involved — urge a course of action for a subject, and …
>
> undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be

entitled.

Id.

Pursuant to the National Research Act, the Secretary of Health and Human Services codified the ethical principles of the Belmont Report into federal regulations at 45 C.F.R. Part 46, Subpart A—commonly known as the "Common Rule." The Common Rule governs all research involving human subjects, including research with investigational medical products or activities related to their administration. It applies whenever an investigation is designed to develop or contribute to generalizable knowledge and involves a human subject through intervention, interaction, or the collection of identifiable private information. See 45 C.F.R. § 46.102. Examples of activities that qualify as "research" under the Common Rule include clinical trials, retrospective medical chart reviews conducted by college students to determine patient outcomes, and the Secretary issuing an Emergency Use Authorization (EUA) to a manufacturer while simultaneously requiring the manufacturer to monitor and study participants for adverse events. Whether the activity is exempt or non-exempt from full Institutional Review Board review, it must comply with the core ethical principles. *See* 45 C.F.R. §§ 46.101(c),(i).

The Common Rule requires the sponsor, or persons acting on the sponsor's behalf, to prospectively obtain an individual's "legally effective informed consent." 45 C.F.R. § 46.116(a)(1). The consent is specified in detail under 45 C.F.R. § 46.116. Legally effective informed consent, according to the Common Rule, can be summarized as:

> (1) the individual must not be under external pressure to participate;
> (2) the only reason an individual participates is that they believe the product may benefit their personal health goals; and
> (3) the conditions of 1 and 2 are established before the individual participates in the investigational activity.

Any person acting under federal authority or participating in a federally funded program must ensure that potential participants are not subject to external pressure when deciding whether to participate in research involving investigational medical products or related activities. The application of any external pressure, at any time, violates the informed consent standard.

In 1981, the Department of Health and Human Services issued a major revision to Subpart A of 45 C.F.R. Part 46 (46 Fed. Reg. 8386). In 1991, fifteen federal departments and agencies formally adopted the Federal Policy for the Protection of Human Subjects—commonly known as the "Common Rule"—within their own regulatory frameworks (56 Fed. Reg. 28,003). This coordinated adoption has since expanded to nineteen federal agencies. Nevertheless, 45 C.F.R. § 46.101(a) ensures that the Common Rule applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department, agency, or the military.

Congress enacted 10 U.S.C. § 980 on October 19, 1984, as § 1401(a) of the Department of Defense Authorization Act for Fiscal Year 1985, Pub. L. No. 98-525, 98 Stat. 2485. The statute prohibits 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.

On April 2, 1992, the United States Senate gave its advice and consent to the ratification of the International Covenant on Civil and Political Rights (ICCPR) treaty, which President Bush ratified on June 1, 1992. Article VII affirms 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. *See* 21 C.F.R. § 312.3(b).

In 1997, Congress enacted the Food and Drug Administration Modernization Act (FDAMA), Pub. L. No. 105-115, which added expanded-access (compassionate-use) provisions to the Federal Food, Drug, and Cosmetic Act. These provisions authorize 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).

In 2004, Congress enacted the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835. This legislation created the Emergency Use Authorization (EUA) authority, codified at 21 U.S.C. § 360bbb-3, which permits the Secretary of Health and Human Services to authorize the emergency use of unapproved drugs, biologics, or devices for the general population during a declared public health emergency. 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).

The State of California affirms that individuals must "be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision." *See* Cal. Health & Safety Code § 24172(j) (2013).

In 2000, the Executive Branch established the Office for Human Research Protections; Federalwide Assurance for the Protection of Human Subjects, 65 Fed. Reg. 37136-37137 (June 13, 2000). The FWA is the mechanism the Executive Branch uses to ensure its compliance with 42 U.S.C. § 289. The FWA requires any institution, state, or entity that conducts, supports, or otherwise engages in human-subjects research involving investigational medical products — when that research is federally funded, conducted, or subject to federal regulation — to provide a written assurance that it will obtain legally effective informed consent from every participant. California, for example, operates under FWA No. FWA00000681, expressly committing the State to these protections. More than 30,000 entities nationwide—including all fifty States, U.S. territories, virtually every major hospital, and nearly all universities—currently maintain active FWAs.

B. The right to refuse investigational drugs is deeply rooted in the nation's history and tradition.

Since *Jacobson*, this Court and lower courts have issued a long line of opinions recognizing that the right to informed consent involving investigational drugs and the right to refuse unwanted medical treatment which are "deeply rooted in this Nation's history and tradition" and so "implicit in the concept of ordered liberty" that "neither liberty nor justice would exist if they were sacrificed." *See, e.g., Glucksberg*, at 721.

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

Glucksberg, at 725; *See also Washington v. Harper*, 494 U.S. 210, 221–222 (1990) (the significant liberty interest in avoiding unwanted administration of antipsychotic drugs); *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261, 269, 277 (1990) (the constitutionally protected right to refuse lifesaving hydration; "The principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions."); *Youngberg v. Romeo*, 457 U.S. 307, 316 (1982) (freedom from bodily restraints); *Ingraham v. Wright*, 430 U.S. 651,

673 (1977) (freedom from unjustified intrusions on personal security); *Vitek v. Jones*, 445 U.S. 480, 495–96 (1980) (involuntary transfer to a mental hospital, coupled with mandatory behavior modification treatment implicated liberty interests); *Parham v. J.R.*, 442 U.S. 584, 600 (1979) ("[A] child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment."); *Rennie v. Klein*, 653 F.2d 836, 844 (3d Cir. 1981) (the constitutional right to refuse unwanted medical treatment); *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) (enjoining Department of Defense mandate of an experimental drug to civilian and military personnel: "The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate.").

The *Cruzan* case is particularly instructive here. This Court in *Cruzan* held that the liberty to refuse medical treatment emanates from the long-standing common law principle that "even the touching of one person by another without consent and without legal justification was a battery." *Id.,* at 269. Hence, the *Cruzan* Court concluded that "[t]he informed consent doctrine has become firmly entrenched in American tort law." *Id.* "Before the turn of the century, [the Supreme Court] observed that no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Id., citing Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). As articulated in *Cruzan*, in the more than a

century since *Jacobson* was decided, "[t]his notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Id.* In *Cruzan*, the Court further held that "[t]he logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." *Id.,* at 270. Most importantly the *Cruzan* Court recognized that a person's liberty interest under the Due Process Clause in avoiding unwanted medical treatment "must be determined by balancing his liberty interests against the relevant state interests." *Id.,* at 278-79 (internal citation and quotation marks omitted). In short, the rational basis test—which presumes constitutionality and defers to state interests—is an inappropriate standard to determine if deeply rooted fundamental rights can be abrogated.

Courts have consistently held that neither the American people nor public officials possess a fundamental right—under the Due Process Clause or otherwise—to demand access to unapproved or investigational medical treatments. See *United States v. Rutherford*, 442 U.S. 544 (1979) (terminally ill patients have no constitutional right to obtain investigational drugs outside the FDCA framework); *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) (no fundamental right to access investigational drugs outside FDA-authorized pathways); *L.W. v. Skrmetti*, 83 F.4th 460 (6th Cir. 2023) (rejecting a claimed right to experimental medical treatments). It is constitutionally untenable to hold, on the one hand, that even terminally ill individuals have no right to access investigational

drugs because of the potential harm they might suffer, while simultaneously holding, on the other, that healthy individuals may be compelled to accept investigational drugs—under threat of penalty or loss of public benefits—with no judicial redress if they are injured. Such a contradictory rule would eviscerate the protective regime Congress established in the FDCA and render the fundamental right to bodily integrity meaningless.

Thus, since this Court decided *Jacobson* in 1905, the combined actions of this Court, Congress, the Executive Branch, and every State have uniformly created a comprehensive and deeply rooted national framework that recognizes the right to refuse unwanted medical treatments—including investigational drugs and liability-immunized countermeasures—as a fundamental liberty interest protected by the Due Process Clause of the Fourteenth Amendment. This Court should grant the petition and hold that the right to refuse investigational medical products is a fundamental right under its precedents in *Glucksberg* and *Cruzan*, or, in the alternative, remand the case to the Ninth Circuit for further proceedings on the basis that *Jacobson* did not foreclose the substantive due process argument of the right to refuse investigational drugs.

II. Federal preemption of conditions under which investigational drugs are introduced into interstate commerce.

A. The FDCA preempts states from mandating investigational drugs.

This Court has long recognized that when a state law "regulates conduct that is actually protected by federal law," preemption follows "as a matter of substantive right." *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 109 (1989) (quoting *Brown v. Hotel & Restaurant Employees*, 468 U.S. 491, 503 (1984)). As was the case in *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 691, 701 (2019), preemption in the instant action is a pure question of law for the court, not a factual issue for a jury. The Ninth Circuit's decision below cannot be reconciled with this principle. The panel held that "the penalties imposed on Plaintiffs here were amply justified by public health concerns," yet it never addressed whether the underlying state mandate itself was in conflict with federal law. If investigational-drug mandates are preempted—as Petitioners maintain—then the penalty of denying Petitioners continued employment in state-licensed healthcare facilities was itself an unconstitutional deprivation of liberty protected by the Due Process Clause. The panel's attempt to sidestep this issue by noting that "the Supremacy Clause 'is not a source of any federal rights' enforceable under § 1983," (quoting *Golden State*, 493 U.S. at 107), is materially misleading. While the Supremacy Clause does not itself create a private right of action, it renders the state mandate invalid *ab initio*. Imposing a penalty to enforce a mandate that is preempted and therefore unlawful is itself unconstitutional and actionable under 42 U.S.C. § 1983.

The doctrine of federal preemption is rooted in the Supremacy Clause, which declares federal

statutes "the supreme Law of the Land." U.S. Const. Art. VI, cl. 2. "Under this principle, Congress has the power to preempt state law." *Arizona v. United States,* 567 U.S. 387, 399 (2012). The "purpose of Congress is the ultimate touchstone," and congressional intent is discerned first and foremost from "the explicit statutory language and the structure and purpose of the statute." *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 96 (1992) (internal quotation marks and citation omitted); *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485–86 (1996). The FDCA unequivocally occupies the field of regulating the introduction of new drugs into interstate commerce. It provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" unless the Secretary has approved a new-drug application or biologics license application. 21 U.S.C. § 355(a).

Congress has created only three narrow statutory exemptions to this prohibition, each of which is expressly conditioned on voluntary informed consent:

1. Investigational New Drug (IND) clinical research — The sponsor must assure the Secretary that it will identify participants, limit distribution solely to the authorized investigation, and obtain informed consent. 21 U.S.C. § 355(i)(1)(B), (i)(4).

2. Expanded access (compassionate use) — Use is permitted only when a licensed physician submits a clinical protocol consistent with the informed-consent requirements of § 355(i)(4). 21 U.S.C. § 360bbb(b)(4).

3. Emergency Use Authorization (EUA) — The Secretary may authorize emergency use of unapproved products only if individuals are informed of "the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). The statute expressly prohibits the Secretary from requiring any individual to be vaccinated or to use the product against his or her will. § 360bbb-3(l).

Because each exemption is predicated on voluntary acceptance, a state policy that mandates the use of an investigational drug or covered countermeasure directly conflicts with the conditions Congress itself imposed. *See Arizona, supra.* ("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."). It is indisputable that under each exemption to 21 U.S.C. § 355(a), Congress only empowers the Secretary to determine the market conditions of the investigational drug, which must be subject to strict voluntary uses by the American people.

The Ninth Circuit's ruling—that the penalties were "amply justified by public health concerns"—effectively implies a fourth, judicially-created exception to § 355(a) that Congress never authorized. It permits investigational drugs to be introduced into interstate commerce under compulsory conditions set by state officials rather than the Secretary. This result directly contravenes this Court's holding in *United States v. Rutherford*, 442 U.S. 544, 559 (1979), that "the Act makes explicit provision for carefully regulated use of certain drugs not yet

demonstrated safe and effective" and that "no exception … may be judicially implied." 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.

Unless Congress has authorized the Secretary to introduce an investigational drug into interstate commerce under one of the three narrow exceptions to 21 U.S.C. § 355(a), and unless the Secretary has actually issued an Emergency Use Authorization for the specific product, that drug is not lawfully available for distribution or use. Respondents, therefore, could not lawfully mandate its administration under threat of penalty, because the product would not have been available for compliance with their policies.

Respondents relied on the Secretary's Emergency Use Authorization to make the investigational drugs available but then mandated their use, which directly conflicted with the voluntary-use conditions Congress placed on the Secretary's authorization. States possess no independent authority to introduce investigational drugs into interstate commerce, nor may they impose legal requirements that conflict with the informed-consent conditions Congress expressly mandated in 21 U.S.C. §§ 355(i)(4), 360bbb(b)(4), and 360bbb-3(e)(1)(A)(ii)(III) as established by the Secretary under his expanded access protocols.

B. The PREP Act expressly preempts state mandates of investigational countermeasures.

"There is no doubt that Congress may withdraw specified powers from the States by enacting a

statute containing an express preemption provision." *Arizona, supra*. The preemption provision in question is 42 U.S.C. § 247d-6d(b)(8), which states, 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*.].

Respondents' mandated drugs that are covered countermeasures under the PREP Act, which expressly preempts states from establishing legal requirements "different from" or "in conflict with" any "requirement" applicable to the countermeasure under the FDCA. One "requirement" is the "voluntary nature of the program" (42 U.S.C. § 247d-6e(c)), and thus states cannot establish or enforce legal requirements mandating the use of those countermeasures.

Jacobson v. Massachusetts affirms this result by discussing *Railroad Company*[4] *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

[4] *Hannibal & St. J. R. Co.*

Spanish fever. In *Husen,* the Court acknowledged that while a state's police powers included passing "sanitary laws, and laws for the protection of life, liberty, health, or property," the police power of a State "cannot be exercised over a subject confided exclusively to Congress under the Federal Constitution." *Id*., at 471. The *Jacobson* Court noted that the laws at issue in *Husen* "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.")

Respondent Tomás J. Aragon, Director and State Public Health Officer for the California Department of Public Health, issued a policy requiring Petitioners to be injected with one of the COVID-19 investigational drugs—designated by the Secretary as a covered countermeasure under the PREP Act—as a condition of continuing to work in a state-licensed healthcare facility. This mandate is expressly preempted by the PREP Act because the involuntary administration of covered countermeasures "conflicts" with "the voluntary nature of the program."

Unless reversed, the Ninth Circuit's decision would empower every mayor, police chief, hospital administrator, school superintendent, and public health officer to determine the conditions under which investigational drugs may be introduced into interstate commerce and compelled upon the American people. That sweeping result cannot be

reconciled with the Supremacy Clause, the FDCA's comprehensive federal regulatory scheme, or the Fourteenth Amendment.

Under the Ninth Circuit's approach, the FDCA's informed consent protections would be eradicated on demand by state actors. Thousands of state and local officials could impose their own conditions of use and corresponding penalties for refusing an EUA product.

This inversion of constitutional authority undermines the very protections Congress designed for the American people and is spreading to other Circuits. The Tenth Circuit has already embraced a parallel approach in *Timken v. South Denver Cardiology Associates, P.C.,* 155 F.4th 1227 (10th Cir. 2025). The Sixth and Third Circuits are also following this inverted path. *See Norris v. Stanley*, 73 F.4th 431 (6th Cir. 2023), *cert. denied*, 144 S. Ct. 1353 (2024); *Children's Health Def., Inc. v. Rutgers, the State Univ. of N.J.*, 93 F.4th 66 (3d Cir. 2024), *cert. denied*, 144 S. Ct. 2688 (2024) (both Circuits granting state actors power to penalize individuals for exercising the statutory right to refuse an EUA drug—an authority expressly withheld from the Secretary). Most recently, the Third Circuit followed the Ninth Circuit's erroneous reasoning in *Curtis* to affirm the dismissal of *Boyd v. Shriners Hospitals*, No. 25-1183 (April 14, 2026).

Although this case reaches the Court following a procedural dismissal under Rule 12(b)(6), neither the Ninth Circuit nor any district court within that Circuit has addressed the decisive question of federal preemption. This Court should therefore grant certiorari and resolve whether the FDCA and PREP Act preempt States from imposing legal requirements that directly conflict with the FDCA's express informed consent conditions for

investigational drugs in general and the voluntary nature of PREP Act programs that make covered countermeasures available in interstate commerce.

III. The Ninth Circuit reframed or avoided issues raised by Petitioners.

A. State action does not involve the state's at-will employment doctrine.

The Ninth Circuit dismissed Petitioners' procedural due process claims, holding that "Plaintiffs' procedural due process claim also fails because Plaintiffs' at-will employment with KFH is not a constitutionally protected property interest under the Fourteenth Amendment." App 4a. In so ruling, the panel disregarded Petitioners' well-pleaded factual allegations that Kaiser Permanente was acting as an agent of the State when it terminated Petitioners' employment solely for exercising their federally protected right to be informed of the risks of the investigational COVID-19 vaccines and then refusing their administration. The panel also failed to address Petitioners' asserted property interests arising under federal law, federal programs, and the right to continued employment in the state's licensed healthcare industry—interests that are not forfeited by the exercise of federally guaranteed rights. Significantly, the panel acknowledged that Petitioners "were terminated for refusing to take the COVID-19 vaccine and failing to provide an exemption in violation of KFH's vaccination policy and the State of California's health order." App. 2a. By recognizing the State's health order as a direct basis for the termination, the panel effectively conceded the presence of state

action. Never*t*heless, it found that Kaiser Foundation Hospitals, in implementing that state action, was not a state actor. This constitutes improper fact-finding and violates the Rule 12(b)(6) requirement that courts accept all well-pleaded factual allegations as true and draw all reasonable inferences in the plaintiff's favor.

Moreover, by refusing to inquire into whether the policies violated federal law at the pleading stage, the Ninth Circuit contradicts this Court's decision in *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 441 (1985), that when reviewing an equal protection claim, rational-basis review applies only to "interests the State has the authority to implement." Therefore, the question of federal preemption must first be answered before resolving the procedural due process question. Additionally, the panel held that "the process the state created for granting religious and medical exemptions fulfilled the purpose of the requisite pretermination hearing." App. 4a. This reasoning misses the core of Petitioners' claim. Petitioners did not seek a state-granted religious or medical exemption. Instead, they asserted a constitutional and federal statutory right to refuse the investigational vaccines outright without seeking or obtaining any state-authorized exemption. The punishment imposed was not limited to termination from employment with Kaiser; it was a complete and permanent bar to working in any capacity within California's licensed healthcare industry solely for exercising this federally guaranteed right. By treating Petitioners' constitutional and federal statutory right to refuse as equivalent to a state discretionary exemption, the panel both mischaracterized the claim and failed to address

whether depriving Petitioners of their livelihood across an entire regulated industry satisfied procedural due process.

B. The Ninth Circuit misconstrued the rational basis review standard.

The panel dismissed Petitioners' equal protection claim with the conclusory statement that "the state action, enforcing a vaccine mandate, easily survives rational-basis review." App. 4a. In reaching this holding, the panel never addressed whether the mandate infringed upon the federal domain or upon Petitioners' protected liberty interest in exercising federally funded benefits that both the state and its agent, Kaiser Foundation Hospitals, were contractually obligated to protect. The Ninth Circuit is indisputably establishing novel precedent that the rational basis review standard does not require a threshold inquiry into whether a state policy infringes upon the federal domain, even at the pleading stage. Respondents themselves never asserted that mandating investigational drugs was a legitimate state interest, nor did they invoke rational-basis review. By *sua sponte* supplying and applying that defense on Respondents' behalf, the panel violated Petitioners' fundamental due process right "to present [their] case and have its merits fairly judged." *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 429 (1982).

C. 21 U.S.C. § 377 does not foreclose a 42 U.S.C. § 1983 remedy for violations of informed consent.

The panel held that the FDCA precludes § 1983

enforcement. App. 5a. First, enforcement under the FDCA extend only to "prohibited acts" listed under 21 U.S.C. § 331, and it wholly inapplicable to Petitioners' right to refuse investigational drugs. The duty of persons acting under the FDCA to obtain consent constitutes a property interest of the individual to grant or withhold such consent. That property interest is subject to the Due Process clause. This Court holds that:

> [t]o have a property interest in a benefit, a person clearly must have more than an abstract need or desire for it. He must have more than a unilateral expectation of it. He must, instead, have a legitimate claim of entitlement to it." And "[p]roperty interests, of course, are not created by the Constitution. Rather, they are created, and their dimensions are defined, by existing rules or understandings that stem from an independent source such as state law — rules or understandings that secure certain benefits and that support claims of entitlement to those benefits.

Board of Regents of State Colleges v. Roth, 408 U.S. 564, 577 (1972).

If the right to grant or withhold informed consent is not enforceable under the Due Process Clause through a § 1983 action against state actors, then individuals possess no constitutional right to refuse investigational drugs—an absurd conclusion that directly defeats Congress's express purpose in requiring informed consent as a condition of every statutory exemption to 21 U.S.C. § 355(a). The FDCA contains no private enforcement mechanism to

vindicate the individual's liberty interest in withholding consent to the administration of investigational drugs. Under this Court's controlling decision in *Health & Hospital Corp. of Marion County v. Talevski*, 599 U.S. 166 (2023), the absence of a private enforcement scheme is decisive. In *Talevski*, the Court held that the Federal Nursing Home Reform Act's provisions creating a "right to be free from … any physical or chemical restraints" and a right to advance notice of discharge were "rights-creating" language that unambiguously conferred individual rights enforceable under § 1983. *Id*., at 183–84. The same reasoning applies here. The FDCA's repeated, individual-focused informed-consent mandates create precisely the type of personal, rights-creating language that *Talevski* holds is presumptively enforceable through § 1983.

The duty to obtain consent under § 21 U.S.C. §§ 355(i)(4) and the duty to ensure consent under 21 U.S.C. § 360bbb(b)(4) correlate to a right to give consent. It is impossible to obtain consent if the individual is not empowered to give it. Under §360bbb-3(e)(1)(A)(ii)(III), the duty to inform the individual of the option to accept or refuse denotes the authority of the individual to exercise it. The State cannot punish an individual for choosing to accept the product any more than it can punish an individual for choosing to refuse it. Under the FDCA, the option to accept or refuse belongs exclusively to the individual—not to the State or the federal government. When a State penalizes the exercise of that statutorily protected choice, the individual may enforce the right through 42 U.S.C. § 1983. Although 21 U.S.C. § 337(a) generally limits direct private enforcement of the FDCA to the United States, § 1983 serves as the proper vehicle to vindicate the

individual's constitutional right to exercise the option that Congress expressly conferred.

D. The Ninth Circuit failed to address waiver of due process.

The Ninth Circuit entirely evaded review of whether the state may compel Petitioners to disclose private health information to medical researchers and prospectively waive their due process right to seek judicial redress if injured—all as a condition of continued employment in the state's licensed healthcare industry. These demands implicate fundamental liberty interests protected by the Due Process Clause and are therefore not subject to rational-basis review. This Court has long held that any waiver of constitutional 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). It is equally well settled that a State may not accomplish indirectly what it cannot command directly. *Speiser v. Randall*, 357 U.S. 513 (1958); *Bailey v. Alabama*, 219 U.S. 219 (1911). By conditioning employment in the state's licensed healthcare facilities on acceptance of PREP Act-covered countermeasures, the state forced Petitioners into an unconstitutional choice: surrender core constitutional protections or forfeit their livelihood. "A man may not barter away his life or his freedom, or his substantial rights." *Insurance Co. v. Morse*, 87 U.S. 445, 451 (1874). By evading review of the dispositive constitutional claim, the panel allowed an unconstitutional condition to remain in effect.

CONCLUSION

Petitioners respectfully request that the Court grant the petition for a writ of *certiorari*.

Respectfully submitted,

DAVID J. SCHEXNAYDRE
SCHEXNAYDRE LAW FIRM, LLC
2895 Hwy 190, Ste. 212
Mandeville, LA 70471
(985) 292-2020
david@schexnaydre.com

Counsel for Petitioners