

No. 25-1327

In the Supreme Court of the United States

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

v.

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

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

—◆—
REPLY BRIEF OF PETITIONERS

—◆—
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ARGUMENT

The American people have been deprived of their statutory right, under the Federal Food, Drug, and Cosmetic Act (FDCA) and other federal authorities, to refuse administration of an investigational drug introduced into commerce under a statutory exemption from 21 U.S.C. § 355(a) when a State actor merely claims said drug is “clinically identical” to a licensed drug. App. 68a. Worse, Americans in the Ninth Circuit are now required to either give up their protected property interest to work in a state-licensed industry or waive their right to sue in a court of law if injured when complying with a state’s public health policy—unconstitutional conditions this Court has never permitted to exist.

This is the third court in which Governor Inslee¹ and Shriners have had the opportunity to identify the source of their authority to require—under threat of penalty—that a person accept an investigational drug introduced into commerce under a statutory exemption from 21 U.S.C. § 355(a), or a covered countermeasure designated by the Secretary under the PREP Act. Respondents have failed to do so each time.

It is the question of authority to issue such a requirement, and to enforce it under current federal law, that Respondents refuse to directly address. If establishing and implementing Respondents’ mandates were an unconstitutional exercise of power

¹ Jay Inslee has been sued in his individual capacity only. Because the State of Washington (not sued) is arguing on Inslee’s behalf and Petitioners *never sued* Bob Ferguson in *any* capacity, citations to “Ferguson’s” response will be referenced as the “State,” with the understanding that this means Respondent Inslee only.

over Petitioners, the resulting injuries are actionable under 42 U.S.C. § 1983—even if none of the cited statutes themselves confer a private right as Respondents claim. Those injuries include denial of equal protection under the Fourteenth Amendment; deprivation of Petitioners’ protected property interest in working in a state-licensed industry; deprivation of protected interests in the CDC COVID-19 Vaccination Program; and punishment for refusing to waive their fundamental right and privilege of citizenship to sue in a court of law if injured by a PREP Act-covered countermeasure.

The petition for a writ of certiorari should be granted, and the judgment of the Ninth Circuit reversed. “It is the duty of courts to be watchful for the constitutional rights of the citizen, and against any stealthy encroachments thereon.” *Boyd v. United States*, 116 U.S. 616, 635 (1886). And “[a]s usual when a lower court has invalidated a federal statute, we granted certiorari.” *Iancu v. Brunetti*, 588 U.S. 388, 391 (2019).

I. The court should grant *certiorari* to protect the interests of the United States government and the rights of the American people.

As the State notes, the panel below devoted only “two sentences” of “analysis [to] the Employees’ federal claims,” affirming that *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025), controlled the case below. State’s BIO 15. Therefore, a review of *Curtis* is necessary to this case.

A. Congress has not authorized the Ninth Circuit’s “clinically identical” exception to informed consent.

Shriners quotes the Ninth Circuit’s statement that “there is no material distinction between the refusal of a vaccine and ... refusal of administration of an investigational drug that is clinically identical to a vaccine.” Shriners’ BIO 9. Since 1938, the FDCA has established a single, unqualified rule: unapproved drugs may not enter interstate commerce except on terms Congress prescribes. Those terms are clear. First, 21 U.S.C. §§ 355(i), 360bbb, and 360bbb-3 vest in the Secretary alone the duty to set the conditions governing investigational use of a drug exempted from § 355(a); they name no other actor. Second, each statutory exemption from § 355(a) requires that administration of the drug be the product of voluntary, informed consent. Third, none of the three exemption provisions confers authority *to anyone* to compel acceptance. As to products authorized for emergency use (EUA), Congress expressly denied the Secretary “any authority to require any person to carry out any activity that becomes lawful pursuant to” the authorization. *See* Pet. 2–3.

Congress recognizes no “clinically identical” exception to the FDCA’s informed-consent requirement. In *United States v. Rutherford*, 442 U.S. 544, 599 (1979), this Court affirmed that exceptions to FDCA requirements “is a question for legislative judgment, not judicial inference.” *See* Pet. 21. Respondents cite federal letters asserting that Pfizer’s two products—the “mandated,” *unlicensed* investigational EUA drug vs. the *licensed* COMIRNATY® (never distributed or available in the

U.S.)—shared a formulation, or had the “same medical formulation.” State’s BIO 14; Shriners’ BIO 1. This disputed medical fact has no bearing on the *legal* distinction between these two drugs, which is foundational to an individual’s option to refuse under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

Most instructive is the State’s citation of Dr. Peter Marks’ declaration that “while there are ‘legal distinctions’ between the labels applied to these products, the FDA ‘exercise[d] its enforcement discretion’ not to enforce them.” State’s BIO 7. This falsely implies that FDA refused to enforce any requirement applicable to Pfizer’s EUA-labeled products. But Dr. Marks was referring to specific test run lots from Pfizer’s newly licensed facility. For only those lots, the agency did not enforce the EUA requirement that a recipient receive the fact sheet stating that “it is your choice to receive or not receive the vaccine.” CA9 SER-009 ¶13. For every other lot of Pfizer-BioNTech COVID-19 Vaccine produced before or after COMIRNATY®, the agency required that fact sheet so potential recipients would be told of their federal right to withhold consent.

Thus, the Executive Branch does not recognize the Ninth Circuit’s clinically identical exception to informed consent. And a “shared” or “same” medical formulation has no legal bearing on whether an individual may keep working in a state-licensed industry after exercising the federal right to refuse. The Ninth Circuit has imposed competing legal requirements that interfere with the President’s duty to take care that the laws be faithfully executed—despite Shriners’ claim that “nothing in the court of appeals’ decision imposes any limit on the federal government’s authority to enforce federal law.” Shriners’ BIO 17. A judicially implied exception to a

statute is a *limit* on the government’s lawful enforcement of it.

Respondents do not contest that they were bound by the FWA² and the CDC Program to obtain informed consent, or that Shriners agreed to act for the Secretary under state monitoring. They fail to show that the Secretary relieved them of the ministerial duty to obtain consent for Pfizer’s EUA product. They cannot. The federal government never ceased regulating the Pfizer-BioNTech COVID-19 Vaccine under the laws governing investigational medical products. Respondents nevertheless presented Pfizer’s EUA product as if it were licensed and not subject to the informed-consent requirement of 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), or to the Secretary’s authorization conditions, which required a fact sheet informing Petitioners of their federal right to refuse without consequence.

Finally, the State argues that because COVID-19 EUA products could not be used in a “clinical investigation,” “EUA drugs are distinct from and subject to separate regulatory requirements than ‘investigational’ drugs.” Notably, no such requirements were cited. State’s BIO 4. To the contrary, under each EUA, the Secretary required Pfizer to submit research data from the product’s investigational use to Investigational New Drug Application No. 19736. That research activity is subject to 42 U.S.C. § 289, which 45 C.F.R. Part 46 implements and the FWA enforces. It requires the individual’s legally effective informed consent—a duty separate from the EUA statute’s own consent condition. The statute imposes those duties on the Executive Branch and anyone acting on its behalf, such as

² Federalwide Assurance agreement, *see* Pet. 3-4.

Respondents under the CDC Program. Further, the Secretary informed the nation that Pfizer’s EUA drug “is an investigational vaccine not licensed for any indication.” CA9 ER-0532, ¶199.

B. Respondents are preempted under the Supremacy Clause from punishing the option to refuse.

This Court has consistently held that state law must yield when it intrudes upon a field Congress has reserved to exclusive federal control or when it stands as an obstacle to accomplishing federal objectives. See *Gade v. National Solid Wastes Management Ass’n*, 505 U.S. 88 (1992); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013); *Crosby v. National Foreign Trade Council*, 530 U.S. 363 (2000); *Arizona v. Inter Tribal Council of Arizona, Inc.*, 570 U.S. 1, 14 (2013).

Respondents do not dispute that “A State cannot, consistent with the Supremacy Clause, compel individuals to participate in the statute’s framework and then impose conditions that deprive them of the federally secured option to refuse that Congress attached to that framework.” See Pet. 13. 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, 410 (2012). Therefore, the governor of Washington may not condition working in a state-licensed industry upon accepting a drug authorized under 21 U.S.C. § 360bbb-3. Such drug’s exemption from § 355(a) is predicated on administration being the product of voluntary,

informed consent. Any State mandate invades the field of federal regulation and the Secretary’s exclusive authority to execute the statute—that is, to govern the administration of EUA products under strictly voluntary conditions. Respondents, acting under the Secretary’s authority via the CDC Program and having promised to carry out his authorization conditions, cannot achieve a result the Secretary himself is forbidden to command: involuntary acceptance of the product. 21 U.S.C. § 360bbb-3(l); *see* Pet. 8.

Shriners’ first question suggesting that Petitioners claim the Supremacy Clause “support[s]” a § 1983 cause of action is grossly misleading. Shriners’ BIO i, 2. Petitioners have never alleged that the Clause itself supplies a cause of action. Respondents dodge the point actually made by Petitioners: “a State cannot, consistent with the Supremacy Clause, insert itself into this federal scheme and compel individuals to accept an investigational product that Congress has conditioned on the individual’s informed consent.” *See* Pet. 12.

C. The “mandates” are an unconstitutional exercise of police powers under *Jacobson*.

Jacobson v. Massachusetts, 197 U.S. 11 (1905) requires a threshold inquiry: whether the State policy invades a field reserved to the United States. If it does, the policy is a usurpation of the power vested exclusively in Congress, and rational-basis review never attaches. *See* Pet. 18–19. This is why Petitioners raise “a host of ... statutory and regulatory violations.” Shriners’ BIO 2. Where enforcement depriving Petitioners of their property

interest in working in a state-licensed industry are unconstitutional exercises of police power, that deprivation is redressable under 42 U.S.C. § 1983, because property interests are protected under the Fourteenth Amendment’s Due Process Clause. A policy that itself violates federal law cannot supply a rational basis for ending the careers of licensed professionals. The government “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).

This Court has held that a waiver of a constitutional right cannot be the product of coercion. *See* Pet. 37. Access to the courts when injured is such a right. The State may not condition a license to work in a state-regulated profession on surrender of that right, directly or indirectly. *Id.* This Court has long recognized that a conditioned choice is no choice at all. Respondents gave Petitioners “no choice except a choice between the rock and the whirlpool — an option to forego a privilege which may be vital to [their] livelihood or submit to a requirement which ... constitute[s] an intolerable burden.” *Frost Trucking Co. v. R.R. Comm.*, 271 U.S. 583, 593 (1926).

Acceptance of a PREP Act-covered counter-measure, under threat of exclusion from a state-licensed livelihood, is not a voluntary waiver of the right to sue—it is unconstitutional coercion. Respondents offer no argument to the contrary.

II. The decision below is wrong.

Respondents’ mandate required Petitioners to surrender their fundamental right to sue for injury caused by the drugs as a condition of continuing to use their state-issued licenses, but the Ninth Circuit

held that *Curtis* forecloses this claim, with no explanation. App. 3a. *Curtis*, sans analysis, simply stated that the “substantive due process claim regarding the PREP Act’s grant of immunity also fails.” App. 69a–70a. The Ninth Circuit now relies on the unsupported *Curtis* opinion to reject Petitioners’ claim that, because the PREP Act extinguishes fundamental rights upon administration of a covered countermeasure, a State may not compel such administration by mandate and force an indirect forfeiture of the right to sue for injury.

Respondents fail to provide any authority to the contrary; instead, the State claims Petitioners failed to argue in district court that the PREP Act “strips nearly all state-law remedies” for related injuries. State’s BIO 23. But Petitioners have always claimed that use of countermeasures under the PREP Act results in the “forfeiture of civil litigation rights resulting from injuries.” CA9 ER-0547.

On one hand, the PREP Act extinguishes all state-law tort claims arising from the administration of a covered countermeasure, except the narrow tort of willful misconduct. Simultaneously, it bars any person from pursuing even that limited claim in state court. *See* Pet. 34–35.

This Court has held that “a cause of action is a species of property protected by the Fourteenth Amendment’s Due Process Clause.” *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). By conditioning access to a state-licensed industry on acceptance of a PREP Act-covered countermeasure, Respondents required Petitioners to prospectively surrender—by operation of law upon administration—their protected property interest in the state-law causes of action the Act extinguishes. Petitioners were forced to choose to surrender their

livelihoods or their right to litigate in State court if injured by the mandated drug. “The government may not deny a benefit to a person because he exercises a constitutional right.” *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (citation omitted). This principle is at work here—the “unconstitutional conditions doctrine” prohibits the type of “coercive pressure” that results when government “deni[es] ... a governmental benefit” because “someone refuses to cede a constitutional right.” *Id.* at 607–08.

Respondents, citing *Curtis*, treat a mandate to use a covered countermeasure as subject only to “rational basis” review. State’s BIO 14; Shriners’ BIO 10. Yet this Court has held that access to the courts is a fundamental right. *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002). State action burdening that liberty interest is subject to strict scrutiny.

In *Curtis*, the Ninth Circuit went further. It foreclosed even the argument that the right to refuse an investigational drug is fundamental under *Washington v. Glucksberg*, 521 U.S. 702 (1997), on the theory that *Jacobson* had already shut that door. Respondents cannot square that holding with *Glucksberg*.

To decide whether a right is fundamental, *Glucksberg* requires an examination of “our Nation’s history, legal traditions, and practices.” *Id.*, at 710. That inquiry is not frozen at 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.). The Ninth Circuit ignored 120 years of that development—most of it after *Jacobson*, and much of it after Congress first used the term “investigational” in the Kefauver-Harris Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962)—and denied that Americans even have a substantive right of refusal under *Glucksberg*.

**III. The questions presented are important,
and this case is an ideal vehicle to resolve
them.**

Respondents do not argue that the State or its agents had authority to engage in the challenged conduct. They do not even dispute that the FDCA preempts them from conflicting with the consent requirement. Neither Respondent could utter the word “consent,” or discuss their duties under the CDC Program, the FWA, and the laws that protect the right to withhold consent.

The State falsely claims (1) that Petitioners failed to raise in the district court the Secretary’s lack of authority to mandate EUA products. State’s BIO 22; but *see* CA9 ER-0574, ¶375; (2) that Petitioners did not plead that the PREP Act forfeits due-process rights to access courts. State’s BIO 22–23; but *see* CA9 ER-0575, ¶163, ¶379; and (3) that arguments about whether PREP Act immunity unconstitutionally extinguishes property rights are “a purely hypothetical question that has nothing [to] do with the *Curtis* decision.” State’s BIO 19. These claims are not supported by the Ninth Circuit’s decision.

Shriners contends it is not a State actor. This is a fact for discovery, not for a Rule 12(b)(6) dismissal. If

the State owed a duty to obtain Petitioners’ consent to use a federal product through a federal program, and Shriners voluntarily contracted to perform that duty, Shriners is a State actor under *West v. Atkins*, 487 U.S. 42 (1988).

Both Respondents claim qualified immunity. As the Ninth Circuit itself has held, “[m]inisterial acts are unshielded by qualified immunity, which protects ‘only actions taken pursuant to discretionary functions.’” *Groten v. California*, 251 F.3d 844, 851 (9th Cir. 2001). Honoring Petitioners’ choice to refuse was a ministerial act. Respondents had no discretion to override it.

It is urgent that this Court protect American professionals on the front lines of healthcare who exercised their protected property interests and declined to waive their constitutional rights. The Court should consolidate this case with *Boysen* (25-1280), *Boyd* (26-220), and *Brock* (26-268) because they all address public employment, private actors performing governmental duties, and the right to work in a state-licensed industry relating to the questions presented here.

CONCLUSION

For all the reasons above, this Court should grant *certiorari*.

Respectfully submitted,

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