

No. 25-1280

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

—◆—
REPLY BRIEF OF PETITIONERS
—◆—

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

Counsel for Petitioners

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ARGUMENT

The question presented is not whether an employer may fire someone. It is whether the Due Process Clause permits State officials—and a private party acting for the State—to strip a person of benefits already held: the right to work in a licensed profession without submitting to an investigational drug and without waiving the fundamental right to sue if compliance with the mandate causes injury; and the right to keep one’s job after exercising the state-conferred option, offered to the public under the CDC COVID-19 Vaccination Program, to be informed of the risks, benefits, and alternatives and to accept or refuse without external pressure, cost, penalty, or loss of benefits.

The question sits at the center of *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). *Jacobson* held that a local health measure “must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution.” *Id.* at 25. This Court cited its earlier decision in *Railroad Co. v. Husen*, 95 U.S. 465 (1877), where it vacated a public health policy aimed at keeping “Spanish or Texas fever” out of the State because the law invaded a domain the Constitution reserved to the National Government. *Id.* at 470–73.

Respondents’ “mandate” was not a legitimate exercise of police power. It violated the FWA and CDC Program agreements requiring that the products be offered to the public voluntarily. It conflicted with Congress’s command that the Secretary ensure administration of EUA products is the product of voluntary, informed consent. It required Petitioners to waive their liberty interest in

suing if injured. It was conduct expressly preempted by the PREP Act.

Respondents, in opposition, never answer whether the federal statute at issue, the Executive Branch agreements, and the Supremacy Clause forbid a mandate of this kind. Petitioners argue that they do—that these emergency use only, investigational COVID-19 drugs could not lawfully be made a condition of work in the State’s licensed healthcare industry. Petitioners supported the complaint’s allegations concerning Respondents’ legal obligations with judicially noticeable documents—the CDC COVID-19 Vaccination Program Provider Agreement, EUA letters issued by the HHS Secretary, and the terms of the Federalwide Assurance program, including Respondents’ federal contract numbers—showing that Respondents agreed to terms that preclude them from coercing involuntary use of COVID-19 investigational drugs.

Further, receiving the administration of an investigational drug under the PREP Act extinguishes the recipients’ right to a civil remedy for any injury caused by the drug. Under federal law, refusal was supposed to carry no penalty; the State and its agents made refusal the end of a licensed livelihood. That is not consent. It is a coerced condition that the Due Process Clause and this Court under *Berghuis v. Thompkins*, 560 U.S. 370 (2010) do not allow. *See* Pet. 27–28.

The State¹ points this Court to an unpublished decision, *Brock v. City of Bellingham*, No. 25-1070 (9th Cir. May 26, 2026) (petition for cert. pending,

¹ The “State” refers to the Respondent *State officials* sued below.

No. 26-268, distributed for conference September 28, 2026). State BIO 14. The *Brock* court accepted as true that the mandated investigational product “posed a significant risk of serious adverse effects and did not prevent transmission of or infection with COVID-19—it only lessened the severity of symptoms.” *Brock*, slip op. at 3–4. It then extended *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) to cover that product anyway—licensed or investigational. *Id.* at 4. It further held that a substantive-due-process claim grounded in the PREP Act—that a person may refuse a covered countermeasure because acceptance forfeits the right to a judicial remedy—is “foreclosed by *Curtis*.” *Id.*, citing *Curtis v. Inslee*, 154 F.4th 678, 692 (9th Cir. 2025). That is the pattern the opposition briefs invite this Court to treat as settled law. PH BIO 1.

Brock is not a reason to deny the petition. It is a reason to grant it.

I. The decision below departs from this Court’s well-established precedents.

PeaceHealth incorrectly asserts that “Petitioners identify no decision of this Court or any court of appeals that conflicts with the decision below.” PH BIO 1.²

A. The Ninth Circuit decision conflicts with *Jacobson v. Massachusetts*.

The State agreed to offer the CDC Program and its investigational drugs to the public under conditions of voluntary informed consent without

² PeaceHealth is referenced herein as “PH.”

coercion or punishment. It then recruited Peace-Health to help discharge that governmental duty. Respondents have never contested these allegations.

Curtis held that *Jacobson* forecloses any claims based on the right to refuse an investigational drug because a State actor “could rationally have decided” that a COVID-19 mandate “would further the legitimate state interest of stemming the spread of COVID-19.” App. 58a.

Jacobson recognizes a constitutional limit: State police power “must always yield” when it conflicts with federal power or with a right the Constitution secures. *Id.*, at 25. *Jacobson* does not permit a State to regulate conduct “in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.” *Arizona v. United States*, 567 U.S. 387, 399 (2012).

This Court has long held that States are preempted from imposing requirements that conflict with the FDCA’s regulation of persons subject to that Act. *See* Pet. 23 (consolidated cases). The Secretary must ensure that the administration of an EUA product is the product of voluntary, informed consent, and the Supremacy Clause preempts State actors from conflicting with that requirement. Further, Respondents, acting under active FWA contracts, promised the federal government not to apply external pressure on any individual to accept investigational drugs such as the Pfizer-BioNTech COVID-19 Vaccine. If Respondents contracted to perform the ministerial function of honoring a potential participant’s choice whether to take part in the CDC Program’s investigational products, they cannot claim a legitimate interest in denying Petitioners’ right to continue working in the State’s

licensed healthcare industry when Petitioners opt to refuse. They have no authority “to implement” punishments based on the chosen option. *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 441 (1985).

Curtis departs from *Jacobson*’s affirmance that the State must “yield” to valid federal authority. It holds that, even when State actors are under a federal obligation never to pressure anyone to accept an unlicensed, unapproved, investigational drug, such actors may do so anyway .

Congress has occupied the field of unapproved drug regulation for more than eighty-five years and left no room for State intrusion. It has determined that protecting the public health requires preserving the unfettered right to refuse investigational medical treatments without penalty or loss of an otherwise-entitled benefit. *See* Pet. 22. Wherever Congress exempts an unapproved drug from 21 U.S.C. § 355(a), administration of that drug must be the product of voluntary, informed consent. *See* Pet. 11–15.

Under *Arizona*, the Supremacy Clause preempts States from interfering with the informed-consent requirements that attach to drugs exempt from § 355(a). The products Respondents mandated were authorized only for emergency use under 21 U.S.C. § 360bbb-3. That statute required Respondents, as federally authorized providers, to inform potential recipients of their federal right to refuse. Congress secured that voluntariness by withholding from the Secretary any power to mandate involuntary use. Pet. 24. If the Secretary may not issue such a mandate, persons acting under his authority pursuant to each EUA may not assume that

authority for themselves.

Further, 42 U.S.C. § 247d-6d(b)(8) expressly barred the State from issuing or enforcing any legal requirement that would deprive Petitioners of their right to refuse without penalty. *See* Pet .8. During a PREP Act declaration, “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” is “different from, or is in conflict with, any requirement applicable under this section” and that relates to the product’s use or administration, or to any matter covered by this section, this chapter, or the FDCA. *Id.* § 247d-6d(b)(8). The FDCA’s informed consent requirements for drugs operating under exemption from 21 U.S.C. § 355(a) are applicable to the PREP Act’s covered countermeasure. The Ninth Circuit did not confine its analysis of whether States can mandate an EUA drug; it held that it can mandate any investigational drug, irrespective of how it is introduced into commerce.

Respondents do not deny the obligations they assumed. They do not dispute that they stood under an FWA not to coerce use of the mandated drugs. They do not dispute that the CDC Program bound them to offer those drugs to the public only on voluntary terms. They do not dispute that the FDCA bars them from mandating such products. They do not dispute that the PREP Act expressly preempts a mandate of this kind. Instead, Respondents imply that, in a public-health emergency, they cannot be bound by federal agreements, statutes, regulations, or the Constitution. This is not so; the products and the federal and state programs that offered them

were created for that emergency.

Respondents treat those federal constraints as irrelevant, relying on the *Curtis* decision to claim a rational-basis interest in “stemming the spread.” That is not an answer. It is an admission that the police-power argument begins only after the federal prohibitions are ignored. *Curtis* departs from *Jacobson*. It treats federal restraints as irrelevant to a constitutional challenge to a public-health policy. *Jacobson* treats lawful federal restraints as the first question; measures that conflict with federal law are not legitimate.

**B. The Ninth Circuit decision conflicts with
Board of Regents of State Colleges v. Roth.**

Curtis held that the FWA and the CDC Program do not give rise to a claim under 42 U.S.C. § 1983. App. 47a–48a. Neither the *Curtis* court nor the court below allowed discovery, examined Respondents’ FWA agreements, required a full account of the CDC Program’s terms, or identified the “existing rules or understandings” that define the interest. *Board of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972). Property is not created by judicial guesswork. It is created by the rules that secure the benefit.

Petitioners cited a federally conferred option: accept or refuse without penalty. They held a property interest in exercising that option, and in being informed of the products’ benefits, risks, and alternatives without “incurring cost or penalty upon refusal.” See Pet. 30. Respondents agreed to protect this federally conferred option on the federal government’s behalf for Petitioners’ benefit and it was adopted into official State policy. The duty to

obtain consent and to inform Petitioners of their option “support[s] claims of entitlement to those benefits.” *Roth*, at 577.

Roth is clear. A § 1983 claim proceeds when the State has “deprived” a person “of liberty or property protected by the Fourteenth Amendment.” 408 U.S. at 569, 579. Petitioners, as licensed workers in Oregon’s healthcare industry, have a property interest in continuing to work in that industry while exercising the federally conferred benefit of refusing investigational drugs after being informed of their risks. Those benefits and property interests are protected under *Roth*, which requires “some kind of hearing” before those benefits are taken. *Id.* at 570.

The Ninth Circuit has already settled this point. In *Groten v. California*, 251 F.3d 844, 851 (9th Cir. 2001), it recognized a “Fourteenth Amendment right to due process in the application procedure” for a State license. “State statutes providing for particular procedures may create entitlements protected by due process.” *Id.* at 850. The rules at issue here did the same. Oregon’s official policy, under its FWA and CDC Program obligations, was to offer the programs without external pressure or cost. Petitioners were entitled to be told of that option and to accept or refuse it without penalty. The ministerial duty was to honor the choice. *Groten* does not permit State officials to erase the procedure after the benefit has been conferred and then call the loss a mere employment decision.

The panel below conflicts with *Roth* and *Groten*. Those cases treat an officially conferred benefit—and the procedures that define it—as property protected by the Fourteenth Amendment and enforceable under § 1983. The Ninth Circuit departs from *Roth*

by failing to recognize benefits a State offers to the public under a federal program are protected property interests subject to the Due Process Clause.

C. The Ninth Circuit decision conflicts with *Berghuis v. Thompson*.

The PREP Act grants immunity from “all claims for loss caused by, arising out of, relating to, or resulting from” administration or use of an EUA product. 42 U.S.C. § 247d-6d(a)(1). The only remaining action is for willful misconduct, *id.* § 247d-6d(d)(1), and only in the District of Columbia, *id.* § 247d-6d(e)(1). State courts are closed. The right to sue is the “right conservative of all other rights,” *Chambers v. Baltimore & Ohio R. Co.*, 207 U.S. 142, 148 (1907), and a protected liberty interest under the Fourteenth Amendment. *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002). A waiver of that right cannot be the product of “coercion.” *Berghuis v. Thompson*, 560 U.S. 370, 382 (2010). Making the waiver of this right the price of a licensed job is coercion. *Curtis* departs from this Court’s precedence in holding that such coercion is permissible under a State’s public health policy. It also disregards this Court’s decisions in *Garrity v. New Jersey*, 385 U.S. 493, 497 (1967) (“The option to lose their means of livelihood or to pay the penalty of self-incrimination is the antithesis of free choice.”); *Lefkowitz v. Turley*, 414 U.S. 70, 83 (1973) (“A waiver secured under threat of substantial economic sanction cannot be termed voluntary.”).

Respondents raise no argument demonstrating their “right” or authority to coerce a waiver of Petitioners’ right to sue under a public health policy

pursuant to the precedents of this Court.

II. Respondents rely on the impermissible fact-finding of the Third and Ninth Circuits.

The State says the Ninth Circuit “did not rule on ‘whether the Due Process Clause prohibits a State from requiring that individuals be injected with an investigational drug.’” State BIO 1. This is not so. *Curtis* said “our analysis holds even if the drug in question was deemed ‘investigational.’” *Curtis*, at 686; App. 39a. *Curtis* foreclosed any and all substantive and procedural due process arguments relating to the administration of investigational drugs.

The State further says, “plaintiffs had alleged facts demonstrating the COVID-19 vaccine was authorized for use as a vaccine.” State BIO 7. This conflates two different legal acts. A biologic is licensed as a vaccine when its labeling meets the required conditions under 42 U.S.C. § 262(a). Such drugs cannot be issued an EUA. 21 U.S.C. § 360bbb-3(a)(2)(A). The products here were authorized for emergency use under 21 U.S.C. § 360bbb-3. Authorization is not licensure. The record described the products as “an investigational vaccine not licensed for any indication.” CA9 ER-297. The State uses “authorization” as if EUA means approved under 21 U.S.C. § 355(a); it does not.

If the emergency authorized drugs were subject to the CDC and FWA Programs, and if the mandates were preempted by the FDCA and the PREP Act, then the arguments must answer those sources of law. Neither Respondents nor the Ninth Circuit may invent exceptions to federal statutes. Courts should

enforce, not ignore, statutory requirements. The *Curtis* court manufactured the phrase “clinically identical,” never defined it, and thereby implied an exception to informed consent. *See* Pet. 31–32.

Finally, the State now points to the Third Circuit, which manufactured another undefined phrase—“functional equivalent”—and treated it as a judicial exception to the FDCA’s informed consent rule. State BIO 14; *see Boyd v. Shriners Hosps. for Children*, No. 25-1183, slip op. at 2 & n.1 (3d Cir. Apr. 14, 2026), petition for cert. filed, No. 26-220 (U.S. Aug. 12, 2026). Congress wrote neither phrase. No federal statute recognizes them. A court may not add an exception the law does not contain. *See United States v. Rutherford*, 442 U.S. 544, 555 (1979).

III. The question presented is important, and this case is an ideal vehicle to resolve it.

PeaceHealth contends that this Court should not review this case because it is “an unpublished, nonprecedential opinion that applies settled law to undisputed facts.” PH BIO 1. The Ninth Circuit expeditiously repeats its errors; it now dismisses any claims relating to the right to refuse investigational drugs or PREP Act countermeasures in an unpublished opinion by citing *Curtis*—which was also dismissed under Rule 12(b)(6). Until this Court halts such judicial activism, it will keep recurring. Future litigants will be met with immediate dismissal by the Ninth, claiming *Curtis* controls their case. *See, e.g., Brock*, dismissed under an unpublished opinion. *See* Pet. 33.

PeaceHealth incorrectly asserts that this Court must answer state-actor and qualified-immunity questions before it can answer the questions presented. PH BIO 11. The Ninth Circuit did not consider these questions and they are not before this Court. However, the Ninth Circuit holds that “[m]inisterial acts are unshielded by qualified immunity, which protects ‘only actions taken pursuant to discretionary functions.’” *Groten at* 851. Respondents were under a duty to obtain Petitioners’ legally effective informed consent, thus Respondents are not entitled to qualified immunity.

The question presented is narrow, and of national importance. May a State require licensed professionals to be injected with federally regulated investigational drugs and, as the price of keeping their livelihoods, to waive the right to sue if that product causes injury? If the answer is yes, *Berghuis* does not control and *Frost Trucking Co. v. R.R. Comm*, 271 U.S. 583 (1926), is no longer the law. This Court has held that a State “may not impose conditions which require the relinquishment of constitutional rights.” *Id.*, at 594. “If 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.” *Id.* The decision below permits exactly that unconstitutional condition.

CONCLUSION

The petition should be granted.

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