No.

In the Supreme Court of the United States

MICHAEL BROCK, *et al.*,
Petitioners,

v.

CITY OF BELLINGHAM; SETH FLEETWOOD,
Mayor, City of Bellingham, Washington;
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), Congress established a single, unqualified rule: administration of any drug introduced into interstate commerce under an exemption from 21 U.S.C. § 355(a) must be the product of voluntary, informed consent. This Court has likewise held that a waiver of constitutional rights must never be the product of coercion or presumption. *Berghuis v. Thompkins*, 560 U.S. 370 (2010); *Janus v. AFSCME*, 585 U.S. 878 (2018). The Public Readiness and Emergency Preparedness Act ("PREP Act") extinguishes access to all state courts. Access to the courts for a judicial remedy is a fundamental right protected by the Fourteenth Amendment. *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002). The questions presented are:

1. Whether the Fourteenth Amendment prohibits a local government from mandating that a public employee accept the administration of a drug exempt from approval under 21 U.S.C. § 355(a) — on pain of losing benefits — where the FDCA and the National Research Act, 42 U.S.C. § 289(a), together with their implementing regulations, expressly require such administration be the product of voluntary, informed consent.

2. Whether the Fourteenth Amendment prohibits a local government from mandating that a public employee accept the administration of a covered countermeasure — on pain of losing benefits — where the PREP Act's immunity clause, 42 U.S.C. § 247d-6d(a)(1), extinguishes the employee's right to seek judicial redress for any injury the countermeasure causes.

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees and contractors of the City of Bellingham, Washington: Michael Brock, Matthew Leroy Allbaugh, Craig Brewer, Kelly Gambini, Robert Vincent Glorioso, Jason Hagin, Daniel Larsen, Brian Long, Shawn Curtis Manthey, Paul Pluschakov, Caleb Rodriguez, Hannah Snavely, Angela Terry, Dion Terry, Tawsha Kathleen Thompson, William Travis Trueman, Timothy Van Dyke, Tim VanderMey, Elisabeth Oakes, Galina D'Amelio, Joel Douglas, Brennan Jacoby, Jeremiah Leland, David Little, Neal Lunde, Rebekah Royev.

Respondents are the City of Bellingham, a municipal corporation organized under the laws of the State of Washington, and Seth Fleetwood, an individual holding the position of Mayor of the City of Bellingham.

CORPORATE DISCLOSURE STATEMENT

Petitioners are individuals who have no information to disclose under Rule 29.6.

Respondents are a city and its mayor.

LIST OF DIRECTLY RELATED CASES

Brock v. City of Bellingham, No. 25-1070, U.S. Court of Appeals for the Ninth Circuit. Judgment was entered May 26, 2026.

Brock v. City of Bellingham, No. 2:24-cv-00850-BJR, United States District Court for the Western District of Washington. Judgment on motion to dismiss was entered on January 21, 2025.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Michael Brock, *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 an order granting Respondents' Rule 12(b)(6) motion to dismiss.

OPINIONS BELOW

The Ninth Circuit's opinion is unpublished and is available at *Brock v. City of Bellingham*, 2026 U.S. App. LEXIS 14875 and 2026 WL 1470574; it is reproduced at Appendix A.

The U.S. District Court for the Western District of Washington's opinion dismissing Respondents City of Bellingham and Mayor Seth Fleetwood is unpublished and is available at *Brock v. City of Bellingham*, 2025 U.S. Dist. LEXIS 10482 and 2025 WL 254725; it is reproduced at Appendix B.

JURISDICTION

The Ninth Circuit issued its opinion on May 26, 2026. 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. 80a:

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

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

42 U.S.C. § 1983
21 U.S.C. § 355
21 U.S.C. § 360bbb
21 U.S.C. § 360bbb-3
42 U.S.C. § 247d-6d(a)(1)
42 U.S.C. § 247d-6d(b)(8)
42 U.S.C. § 247d-6e(c)
42 U.S.C. § 289.

INTRODUCTION

In the decision below, the Ninth Circuit held that governments may subject public employees to injection of an investigational drug—on pain of termination—even after accepting as true that the product "posed a significant risk of serious adverse effects," "did not prevent transmission of or infection" with the targeted disease, and only "lessened the severity of symptoms." App. 4a. The Circuit failed to acknowledge that the FDCA, the PREP Act, 42 U.S.C. § 289, and their implementing regulations and Federalwide Assurance agreements expressly require that administration of investigational[1]drugs under exemption from 21 U.S.C. § 355(a) must never be the product of "coercion," "undue influence," or "unjustifiable pressures."

[1]"In FDA parlance, experimental drugs that have not yet been approved for public use are deemed 'investigational drug[s].'" *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713, n.1. (D.C. Cir. 2007)

The Circuit further held that a substantive-due-process claim asserting the right to refuse an unwanted PREP Act covered countermeasure—because acceptance inherently waives the right to a judicial remedy if injured—is foreclosed by *Curtis v. Inslee,* 154 F.4th 678 (9th Cir. 2025) (cert. denied). App. 4a. The PREP Act's purpose is to deny injured persons a judicial remedy for harm resulting from activities causally connected to a covered countermeasure. 42 U.S.C. § 247d-6d(a)(1).

This Court held more than a century ago that "the right to sue and defend in the courts is the alternative of force. It is the right conservative of all other rights, and lies at the foundation of orderly government. It is one of the highest and most essential privileges of citizenship." *Chambers v. Baltimore & Ohio R.R. Co.*, 207 U.S. 142, 148 (1907). *Curtis* extinguished that right with a single sentence: "Employees' substantive due process claim regarding the PREP Act's grant of immunity … fails." App. 69a–70a. A right that has stood since King John affixed his seal to Magna Carta in 1215 declaring that "[t]o no one will we sell, to no one will we deny or delay, right or justice," has been extinguished by the Ninth Circuit affixing its seal to governments' coercing a waiver of such rights.

Two petitions are pending before this Court arising from Rule 12(b)(6) dismissals by the Ninth Circuit that present closely related questions: *Boysen v. PeaceHealth*, No. 25-1280 (call for response issued June 17, 2026; response due September 8, 2026), and *Roberts v. Ferguson*, No. 25-1327 (call for response issued July 12, 2026; response due August 24, 2026). This case provides additional and independent support for review of similar legal issues because it involves only state actors who owe

Petitioners obligations under the Fourteenth Amendment. This Court should grant *certiorari* to "clarify the law" and reverse the Ninth Circuit. *See City & County of San Francisco* v. *Sheehan*, 575 U.S. 600, 610 (2015).

STATEMENT OF THE CASE

Petitioners' claims against Respondents are narrowly framed. They assert the right to refuse an unwanted investigational medical product, participation in federally funded research, disclosure of private health information, and a PREP Act-covered countermeasure whose administration, by operation of law, extinguishes their Fourteenth Amendment right to access the courts for any resulting injury—each without penalty or loss of any benefit to which they are otherwise entitled.

A. Factual Background.

Petitioners are former public employees of the City of Bellingham, Washington. They served in positions including EMS Captain, Fleet Manager, Senior Inspector, EMT, Police Officer, Level 3 Mechanic, and Wastewater Collection Supervisor. Respondent Seth Fleetwood was the Mayor of the City of Bellingham at all times material. The City of Bellingham is a municipal corporation and political subdivision of the State of Washington.

1. Respondents' Policy.

On September 21, 2021, Mayor Fleetwood and the City of Bellingham issued Executive Order 2021-

02, "COVID-19 Vaccinations for City of Bellingham Employees, Volunteers, and On-Site Indoor Contractors" (the "Policy"). The Policy required all City employees, volunteers, and contractors to receive injections of a COVID-19 drug no later than December 3, 2021, as a condition of continued employment, or to submit a request for religious or medical accommodation by October 15, 2021. Compliance required employees to obtain the investigational drug from an authorized provider under the CDC COVID-19 Vaccination Program.

2. The CDC COVID-19 Vaccination Program.

In 2020, the Executive Branch established the CDC COVID-19 Vaccination Program ("CDC Program") to administer investigational drugs to the public. In October 2020, the CDC issued operational guidance to states requiring participating states to (1) help the public understand the differences between FDA emergency-use authorization and FDA approval (licensure); (2) recruit public and private entities to assist in administering the products; and (3) monitor local activities to ensure implementation in accordance with federal guidance and requirements. Each recruited vaccination provider was required to execute a Provider Agreement committing to compliance with FDA requirements, including those set forth in any applicable Emergency Use Authorization ("EUA"), and with all applicable state and territorial vaccine laws. Under the Program, the State's health agency served as the "Emergency Response Stakeholder" for each EUA, responsible for identifying and recruiting entities to administer investigational products in compliance with federal and state law governing EUAs.

Manufacturers were required to conduct medical research activities, including monitoring and reporting serious adverse events and cases of multi-system inflammatory syndrome, and to perform post-authorization studies in accordance with agreed-upon study designs. Recruited providers were likewise required to conduct research activities and report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

All products offered under the Program were designated covered countermeasures and introduced into interstate commerce under an exemption from 21 U.S.C. § 355(a) pursuant to 21 U.S.C. § 360bbb-3. Under an EUA, the Secretary required Pfizer to submit research data collected during administration of the product to Investigational New Drug Application No. 19736. On August 23, 2021, after the FDA approved COMIRNATY—a legally distinct product—the agency continued to require providers to conspicuously state that the Pfizer-BioNTech COVID-19 Vaccine "has not been approved or licensed by FDA." COMIRNATY was never available for public distribution; the Secretary continued to issue EUAs for the Pfizer-BioNTech COVID-19 Vaccine on the determination that COMIRNATY was unavailable.

The CDC Program required providers to inform potential recipients of the product's risks, benefits, and alternatives; of their option to accept or refuse; of the availability of free medical counseling; and, for those who elected to receive the product, to provide administrative visit time and ancillary supplies at no cost. Participants who accepted the drugs were required to assume greater physical risk from the investigational product; to become human subjects in ongoing medical research, including perpetual

monitoring for adverse events; to disclose identifiable private information to medical researchers; and to forfeit their right of access to the courts for any injury caused by the product, its administration, or any activity causally connected to it.

B. Legal Background.

1. The FDCA Requires Voluntary, Informed Consent for Drugs Exempt from § 355(a).

Since 1938, the Federal Food, Drug, and Cosmetic Act has prohibited the introduction of a new drug into interstate commerce without FDA approval. 21 U.S.C. § 355(a). Congress created no exceptions to that prohibition until the 1962 Kefauver-Harris Amendments, which provided an exemption for clinical investigations, conditioned on the sponsor certifying to the manufacturer that the sponsor would inform each human subject that the drug was being used for investigational purposes and would obtain that subject's consent. Pub. L. No. 87-781, § 102(d), 76 Stat. 780, 781 (1962).

That informed-consent condition has governed the investigational-use exemption continuously since 1962. The Food and Drug Administration Modernization Act of 1997 restructured and renumbered the provision—the consent condition now appears at 21 U.S.C. § 355(i)(4)—but did not alter its substance. Pub. L. No. 105-115, 111 Stat. 2296 (1997). Congress later created 21 U.S.C. § 360bbb to permit individual-patient access to investigational drugs for serious disease or emergency situations, conditioned on a licensed physician's determination that the patient has no comparable or satisfactory alternative therapy and that the probable risk from the drug is

not greater than the probable risk from the disease, and on the submission of a clinical protocol consistent with the informed-consent requirements of § 355(i). 21 U.S.C. § 360bbb(b)(1)-(4).

In 2004, Congress enacted the Project BioShield Act of 2004, Pub. L. No. 108-276, 118 Stat. 835, authorizing the Secretary to introduce into interstate commerce drugs, biological products, or devices not licensed by the FDA for their intended emergency use in response to chemical, biological, radiological, or nuclear events. That authority, codified at 21 U.S.C. § 360bbb-3, is expressly conditioned on the Secretary's imposition of requirements ensuring that potential recipients are informed of their option to accept or refuse administration of the authorized product after being advised of its known and potential benefits and risks and of any available alternatives. 21 U.S.C. § 360bbb-3(e)(1)(A). Congress further provided that nothing in the section authorizes the Secretary to require any person to carry out any activity that becomes lawful pursuant to an authorization under the section, including the activity of accepting the product's administration. 21 U.S.C. § 360bbb-3(l). The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113-5, 127 Stat. 161, expanded the Secretary's emergency-use authority under § 360bbb-3(b)(1) to encompass threats from emerging infectious diseases, including pandemic influenza.

These provisions are clear: (1) each provision—§ 355(i), § 360bbb, and § 360bbb-3—vests in the Secretary alone the duty to establish the conditions governing the investigational use of a drug exempted from § 355(a) and identifies no other actor as authorized to do so; (2) each provision conditions that exemption on the individual's voluntary, informed

consent, which necessarily includes the right to withhold consent; and (3) none of the three provisions confers authority on the Secretary or anyone else to compel acceptance—and, as to the statutes authorizing EUAs, Congress expressly denied the Secretary "any authority to require any person to carry out any activity that becomes lawful pursuant to" the authorization. 21 U.S.C. § 360bbb-3(l).

2. The National Research Act and its Implementing Regulations Require Consent Free from Coercion, Undue Influence, and Unjustifiable Pressure.

Following the public disclosure of the Tuskegee study, Congress enacted the National Research Act (NRA), Pub. L. No. 93-348, 88 Stat. 342 (1974). The Act required a commission to study "the nature and definition of informed consent in various research settings."*Id*. § 202(a)(1)(B)(iv). The Commission's Belmont Report concluded that consent to participate in research is legally effective only if given voluntarily and that voluntariness "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"; unjustifiable pressure occurs "when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject."

The NRA also required the establishment of institutional review boards to protect human subjects. 42 U.S.C. § 289(a). The Secretary promulgated implementing regulations at 45 C.F.R.

Part 46 (the "Common Rule"). Those regulations provide that federal funds may not be expended for research involving human subjects unless the requirements of the policy have been satisfied. *Id.* § 46.122. Research is any activity designed to add to the generalizable knowledge of the product, process, program, etc. *id.* § 46.102(l). Potential participants must be informed that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." *Id.* § 46.116(b)(8). Consent free from coercion is known as "legally effective informed consent."*Id.* § 46.116(a)(1). Compliance with 42 U.S.C. § 289 is secured through the Federalwide Assurance program, under which entities conducting covered research must commit to the Common Rule and to the ethical principles of the Belmont Report, including the requirement of legally effective informed consent.

Statutory exemptions from 21 U.S.C. § 355(a) are conditioned on research requirements. Section 355(i) is expressly titled "Exemptions of drugs for research." Section 360bbb(b)(4) requires the sponsor or clinical investigator to submit a clinical protocol "consistent with the provisions of section 355(i)." Section 360bbb-3(e)(1)(A)(iii) requires the Secretary to establish "appropriate conditions for the monitoring and reporting of adverse events" associated with the product's use. The Common Rule provides that activities meeting the definition of research constitute research for purposes of 45 C.F.R. Part 46 "whether or not they are conducted or supported under a program that is considered research for other purposes." *Id.* § 46.102(l).

Administration of an investigational drug is therefore, by the terms of its exemption, a research activity subject to the informed-consent protections of the Common Rule.

3. The CDC COVID-19 Vaccination Program Constituted Research Requiring Legally Effective Informed Consent

The CDC Program required the manufacturer, vaccination providers, and Washington State — as the emergency response stakeholder under each EUA — to monitor the drug's administration for adverse events. That monitoring constituted research for purposes of 45 C.F.R. Part 46: it required obtaining information through the individual's interaction with the drug, *id.* § 46.102(e)(1)(i), and collecting the individual's identifiable private information, *id.* § 46.102(e)(5), to "contribute to generalizable knowledge" about the product and the federal program, *id.* § 46.102(l). That made Petitioners "human subjects" of a federally funded research activity — a status that, under 45 C.F.R. § 46.116, required the program to obtain their "legally effective informed consent."The CDC Program was delegated from the Executive Branch to the State of Washington, which in turn delegated it to public and private entities it recruited to act on its behalf.

4. The PREP Act Expressly Preempts Conflicting State Requirements and Extinguishes the Right of Access to the Courts

Congress enacted the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148,

div. C, 119 Stat. 2818 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d to 247d-6e) (the "PREP Act"), to shield manufacturers and administering entities from liability for covered countermeasures. The PREP Act expressly preempts any state or local legal requirement that is "different from, or in conflict with," any FDCA requirement applicable to a covered countermeasure. 42 U.S.C. § 247d-6d(b)(8). Therefore, when the Secretary designates an investigational product as a covered countermeasure, any state or local legal requirements that differ from or conflict with the FDCA's informed-consent requirements are preempted.

In addition, the PREP Act provides near-absolute immunity to covered persons with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure. *Id.* § 247d-6d(a)(1). A judicial remedy is available only for the tort of willful misconduct, *id.* § 247d-6d(d)(1), and even that narrow exception must be pursued exclusively in the United States District Court for the District of Columbia, *id.* § 247d-6d(e)(1), thereby closing access to all state courts for judicial remedy.

C. Procedural History.

After the Policy's compliance deadline passed, Respondents terminated Petitioners' public employment solely because Petitioners refused to accept the administration of one of the CDC Program's investigational products.

On June 13, 2024, Petitioners filed this action in the United States District Court for the Western District of Washington, alleging nine causes of action under 42 U.S.C. § 1983—deprivation of the option to

refuse EUA and PREP Act countermeasures; violation of equal protection; substantive due process (framed separately as to the investigational product, the EUA product, the PREP Act countermeasure, and the unconstitutional-conditions doctrine); procedural due process; deprivation of informational privacy; and municipal liability against the City under *Monell v. Department of Social Services*, 436 U.S. 658 (1978)—together with two causes of action under Washington law for wrongful termination and intentional infliction of emotional distress. Petitioners amended the Complaint twice solely to add plaintiffs without altering the claims or factual allegations originally pleaded. Respondents moved to dismiss under Rule 12(b)(6) on August 19, 2024.

On January 21, 2025, the district court granted the motion to dismiss in full, with prejudice and without leave to amend. App. 7a. The court held that the Pfizer-BioNTech COVID-19 Vaccine, which remains under Investigational New Drug Application No. 19736, "was not investigational." App. 15a. The court also held that the PREP Act does not articulate a fundamental liberty interest to support a substantive due process claim. App. 29a. It also erroneously determined that the "informed consent requirements of the EUA statute do not apply to the Pfizer vaccine." App. 16a.

Petitioners timely appealed on February 18, 2025. On May 26, 2026, the Ninth Circuit affirmed. App. 1a. The Ninth Circuit held that Petitioners' constitutional and state law claims were effectively foreclosed under *Health Freedom Defense Fund v. Carvalho*, 148 F.4th 1020, 1025, 1029–33 (9th Cir. 2025), and *Curtis*, *supra*. The court assumed, without deciding, that Petitioners had alleged a deprivation of a constitutionally protected interest. App. 4a.

The Ninth Circuit also erroneously held that Petitioners had "abandoned" their informational-privacy claim, their *Monell* claim, and their state-law claims for allegedly failing to argue them in the opening brief. App. 5a. Finally, the Ninth Circuit held that the district court did not abuse its discretion in denying leave to amend because Respondents' motion to dismiss placed Petitioners on notice of potential deficiencies. App. 6a.

REASONS FOR GRANTING THE WRIT

I. The Court Should Resolve the Question the Lower Courts Have Failed to Address: Whether the Fourteenth Amendment, in Accordance with Federal Law, Precludes States and their Political Subdivisions from Mandating, on Pain of Penalty, the Administration of Drugs Exempt from 21 U.S.C. § 355(a).

Citing *Curtis* and *Health Freedom*, the Ninth Circuit held that the investigational "status" of the mandated products "does not affect our analysis," App. 5a, concluding that a mandate of this kind survives rational-basis review regardless of whether the product is investigational. App. 4a. That holding cannot withstand scrutiny for two independent reasons.

First, *Health Freedom* does not address whether a product is exempt from 21 U.S.C. § 355(a), nor does it examine the Federalwide Assurance, the requirements for legally effective informed consent, the CDC Program, the PREP Act, or the Common Rule; it supplies only the general rational-basis

framework, not any analysis of the comprehensive federal statutory scheme at issue here. Second, *Curtis* never answered the question that is dispositive of this case: whether federal statutes, their implementing regulations, and the executive agreements issued under them preclude a state actor from coercing, unduly influencing, or applying unjustifiable pressure to public employees to accept the administration of an investigational product—irrespective of the reasons offered for the mandate. This is a question of authority. An entity either possesses the power to act or it does not, regardless of what interest its exercise happens to burden. This Court has recognized the constitutional significance of that threshold inquiry, holding that legitimate state interests are only those "interests the State has the authority to implement." *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 441 (1985).

If federal law prohibits Respondents from imposing mandatory vaccination that relies exclusively on a product exempt from § 355(a), that prohibition resolves the majority of questions presented. The Policy was not a legitimate exercise of local police power; it was a usurpation of authority vested exclusively in Congress.

A. Federal Law Preempts Government Mandates of Drugs Operating Under an Exemption from 21 U.S.C. § 355(a).

The Supremacy Clause provides that the "Laws of the United States which shall be made in Pursuance" of the Constitution "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. States are therefore "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).

The Ninth Circuit relied exclusively on *Jacobson v. Massachusetts,* 197 U.S. 11 (1905) and *Health Freedom* to conclude that state actors may mandate investigational drugs whenever they believe doing so will protect public health. App. 4a, citing to *Curtis*; App. 69a. None of those decisions considered a public-health mandate that relied exclusively on investigational drugs administered through a federal program requiring the recipient's voluntary, informed consent. *Jacobson* did not authorize States, much less local governments, to override federal law in the name of public health. It held the opposite: "a local enactment or regulation, even if based on the acknowledged police powers of a State, must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution." *Jacobson*, *supra*, citing *Railroad Co. v. Husen*, 95 U.S. 465 (1877), a case in which the State's legitimate interest extended to slowing the spread of Texas cattle fever. The *Jacobson* Court acknowledged States' authority to enact sanitary laws toprotect life, liberty, health, or property. Yet *Husen* struck down the public-health measure because it "went beyond the necessity of the case and under the guise of exerting a police power invaded the domain of Federal authority, and violated rights secured by the Constitution."*Jacobson*, 197 U.S. at 25 (citing *Husen*, 95 U.S. at 471–73); see also *Husen*, 95 U.S. at 469 ("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"). *Curtis* extended *Jacobson*, *Zucht v. King,* 260 U.S. 174 (1922), and *Health Freedom* into a categorical rule those cases never established: that a State may mandate any medical product under any legal condition, subject only to rational-basis review, without considering whether the mandate is preempted by federal law.

For more than eighty years, Congress has comprehensively regulated the field of drugs, biologics, and medical devices. It has determined that, to protect public health, individuals must retain the sovereign authority to accept or refuse administration of investigational drugs introduced into commerce under an exemption from 21 U.S.C. § 355(a), after being informed of the product's risks, benefits, and alternatives. Sections 355(i)(4), 360bbb(b)(4), and 360bbb-3(e)(1)(A) vest exclusive authority in the Secretary to implement that voluntary, informed consent requirement. Under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), potential recipients of an EUA product must be informed of their option to accept or refuse administration. Congress further denied the Secretary any authority to require any person to participate in activities made lawful by an EUA. 21 U.S.C. § 360bbb-3(l). Respondents' Policy—requiring City employees to receive an investiga-tional drug authorized for emergency use on pain of penalty—directly conflicts with the federal require-ment that such administration be the product of voluntary, informed consent. Under the principles of *Arizona* and *Jacobson*, the Policy is impliedly preempted because it invades a field Congress has occupied and undermines the federal scheme.

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 the accomplishment of 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).

Under 42 U.S.C. § 289, Congress imposed on the Executive Branch a ministerial duty to protect the rights of individuals involved in federally funded research activities, including the administration of any product exempt from 21 U.S.C. § 355(a). The Executive Branch implemented that duty through 45 C.F.R. Part 46 and the Federalwide Assurance program. The singular right established for that protection is "legally effective informed consent." 45 C.F.R. § 46.116; see also *id.* §§ 46.101(c), (i), 46.122. Consent is legally effective only when the individual is free from external pressure to participate. The State of Washington executed FWA No. FWA00000326, thereby assuring the federal government that it would comply with these requirements when participating in federally funded activities such as the CDC COVID-19 Vaccination Program. Respondents, as a political subdivision of Washington State, are bound by that assurance. Under the Supremacy Clause, Respondents are therefore impliedly preempted from imposing any legal requirement that subjects individuals to external pressure to accept the administration of investigational products or to participate in the federally funded research activities of the CDC Program—the only program through which Petitioners could obtain the products required for Policy compliance.

Moreover, Washington's political subdivisions are subject to and controlled by the State's general laws. The Washington Constitution provides that "[c]ities or towns heretofore or hereafter organized, and all charters thereof framed or adopted by authority of this Constitution shall be subject to and controlled by general laws." Wash. Const. art. XI, § 10. It further provides that any city "may make and enforce within its limits all such local police, sanitary and other regulations as are not in conflict with general laws." *Id.* Art. XI, § 11. The City of Bellingham, as a municipal corporation and political subdivision of the State, possesses only those powers delegated by the Constitution and by general state law, and remains bound by the State's commitments, including the Federalwide Assurance and the CDC Program the State executed as a condition of participating in federally funded research and receiving federal funding.

The informed-consent requirement is an express statutory condition of every exemption from 21 U.S.C. § 355(a). See 21 U.S.C. §§ 355(i), 360bbb(b)(4), 360bbb-3(e)(1)(A). Judicially implying an exception to the informed-consent requirement, as in the case below, is forbidden. *See United States v. Rutherford,* 442 U.S. 544, 555 (1979). Governments are impliedly preempted from interfering with the voluntary, informed consent requirement of drugs under such exemption.

B. *Board of Regents v. Roth* Answers the Protected Property Interest Question the Ninth Circuit Declined to Address.

No State shall ... deprive any person of life, liberty, or property, without due process of law; nor

deny to any person within its jurisdiction the equal protection of the laws." U.S. Const. Amend. XIV, § 1. The Ninth Circuit held, "We assume without deciding that Plaintiffs-Appellants alleged deprivation of a constitutionally protected interest." App. 4a. For over a century, this Court has applied the fundamental, constitutional principle that "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—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.

Petitioners' federally secured rights arise from three independent sources: (1) the CDC COVID-19 Vaccination Program; (2) the guarantee that they be informed of and permitted to exercise "the option to accept or refuse administration of the product," 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), a guarantee Congress reinforced by denying the Secretary himself "any authority to require any person to carry out any activity" an EUA makes lawful, *id.* § 360bbb-3(l); and (3) Washington's Federalwide Assurance, under which the State bound itself to obtain participants' voluntary, uncoerced consent. The Common Rule, which these sources implement, explicitly provides that this protection includes freedom from penalty: refusal to participate "will involve no penalty or loss of benefits to which the subject is otherwise entitled." 45 C.F.R. § 46.116(b)(8). These sources independently secure to Petitioners the right to learn of the investigational product's risks, benefits, and alternatives; to obtain medical counseling without

cost; to accept or refuse administration free of coercion; and to exercise that choice without incurring a penalty or losing a benefit to which they are otherwise entitled.

Congress cannot impose a duty on one party to obtain consent without correspondingly vesting the party whose consent is sought with the right to grant or withhold it. A mandatory obligation running specifically to the potential recipient is precisely the source of law that creates "a legitimate claim of entitlement" under *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972). Consent is therefore a protected property interest under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), the CDC Program, and, as a third-party beneficiary, the FWA, and is thus protected by the Fourteenth Amendment's Due Process Clause. Respondents could not condition public employment — a benefit they otherwise had complete discretion to grant or withhold — on the surrender of those rights, regardless of whether the underlying interest independently qualifies as a property right: "even though a person has no 'right' to a valuable governmental benefit...there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972).

By terminating Petitioners solely for refusing to relinquish the rights federal law secured to them, Respondents did exactly what *Perry* forbids: they imposed an unconstitutional condition by using their control over continued public employment to extort, through the threat of its loss, a surrender of rights they had no independent authority to compel.

Curtis held that "Congress has limited the enforcement of the FDCA to public actions," citing 21

U.S.C. § 337(a). App. 59a. This Court's decision in *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103 (1989), explains why that limitation does not reach the claim here. There, the Court held: "Although the National Labor Relations Board has exclusive jurisdiction to prevent and remedy unfair labor practices by employers and unions, it has no authority to address conduct protected by the NLRA against governmental interference." *Id.* at 109. Section 337's enforcement-exclusivity provision, by its own terms, applies only to the prohibited acts listed in 21 U.S.C. § 331 — a list that does not include a local government issuing a legal requirement that deprives Petitioners of their protected property interest in the statutory option to refuse. Just as the NLRB's exclusive jurisdiction over unfair labor practices left no mechanism to address a city's interference with rights the NLRA secured against government itself, § 337(a)'s exclusive-enforcement scheme for FDCA violations by regulated manufacturers and distributors provides no mechanism to address a municipality's interference with the accept-or-refuse right the statute secures.

C. The Ninth Circuit's Own Findings Describe Medical Treatment Governed by *Cruzan*, Not a Communicable-Disease Measure Governed by *Jacobson*.

The Policy violated Petitioners' substantive due process right to refuse unwanted medical treatment. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) (Cardozo, J.); *see Cruzan v.*

Director, Mo. Dep't of Health, 497 U.S. 261, 278 (1990) (grounding that right in the Due Process Clause). Under *Washington v. Glucksberg*'s careful-description requirement, 521 U.S. 702, 720–21 (1997), the right here is precise: the right to decline a product that posed "a significant risk of serious adverse effects," did not prevent transmission of or infection with COVID-19, and only lessened the severity of symptoms for the recipient. App. 4a.

Jacobson's deference rests on protecting the community from contagion — "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members." 197 U.S. at 27. A product that risks the recipient's health and does not prevent transmission protects no one but that recipient, at a cost borne only by that recipient. What the panel's findings describe is not a communicable-disease measure such as *Jacobson* addressed, but ordinary medical treatment carrying its own acknowledged risk. *Jacobson* does not extend to compelling treatment that, by the government's own account, protects only the person compelled to bear its risk. *Cruzan's* liberty interest governs instead, and the Policy violated it.

II. A Government May Not Condition a Benefit on the Surrender of the Right of Access to the Courts.

The Ninth Circuit held that *Curtis* forecloses Petitioners' claim that the PREP Act requires a person to forfeit the right to a judicial remedy if injured by a covered countermeasure, and that a government therefore cannot mandate use of such a countermeasure because the mandate simultaneously requires the prospective forfeiture of the due-

process right of access to the courts. App. 4a. *Curtis* only held that such a claim "fails." App. 70a. The Ninth Circuit no longer recognizes access to courts as a fundamental right. Thus, any government mandate resulting in a waiver of that right is subject to rational basis review under the Circuit's precedent.

A. The Right of Access to the Courts is Grounded in the Deepest Historical Tradition of Anglo-American Liberty.

In 1215, at Runnymede, King John affixed his seal to Magna Carta. Clause 40 bound the Crown by three distinct promises: "To no one will we sell, to no one will we deny or delay, right or justice." The right to a judicial remedy was not a privilege granted at the sovereign's pleasure; it was a guarantee owed by the sovereign and binding upon him. Sir Edward Coke read Clause 40 as the foundation of the subject's right to the King's courts. *The Second Part of the Institutes of the Laws of England* *45, *55–56 (1642) (commenting on Magna Carta ch. 29 (1225)). The colonists carried that inheritance across the Atlantic, invoked it against the Crown before independence, and ratified the idea of such a right at the Founding. On June 27, 1788, the Virginia Ratifying Convention, proposing amendments to the federal Constitution, declared:

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

> regulations contravening these rights are oppressive and unjust."

J. Elliot, *The Debates in the Several State Conventions on the Adoption of the Federal Constitution*, Vol. 3, p. 327 (2d ed. 1836).

Without sale, without denial, without delay—Magna Carta's exact triad, carried forward five and a half centuries and transplanted into the American constitutional order at its founding moment. The Constitution did not create this right; it presupposed it.

This Court affirmed that right: "The right to sue and defend in the courts is the alternative of force. In an organized society it is the right conservative of all other rights, and lies at the foundation of orderly government. It is one of the highest and most essential privileges of citizenship." *Chambers v. Baltimore & Ohio R.R. Co.*, at 148.

The right to speak is no right at all if no court will hear the claim when a state actor silences it. In *Corfield v. Coryell*, 6 F. Cas. 546, 551–52 (C.C.E.D. Pa. 1823) (No. 3,230) (Washington, Circuit Justice), the court expressly included access to the courts among the fundamental privileges of citizenship—the understanding Justice Thomas traced in explaining what the Privileges or Immunities Clause was ratified to protect. *McDonald v. City of Chicago*, 561 U.S. 742, 819–50 (2010) (Thomas, J., concurring in part and concurring in the judgment).

In *Christopher v. Harbury*, 536 U.S. 403, 415 n.12 (2002), this Court cataloged the textual sources: Article XIV's Privileges and Immunities Clause, the First Amendment's Petition Clause, and the Due Process Clauses of the Fifth and Fourteenth Amendments. The right is not the creature of any

single provision; it is anchored at multiple points because it is foundational to all of them. The Ninth Circuit itself has recognized that "the right of access to the courts is a fundamental right protected by the Constitution." *Delew v. Wagner*, 143 F.3d 1219, 1222 (9th Cir. 1998).

Although space does not permit full development here, a substantial argument exists that the right of access to the courts is independently secured by the Privileges or Immunities Clause of the Fourteenth Amendment and not merely a fundamental right that this Court could in the future foreclose.

B. This Court Settled Long Ago that Such a Right May Not Be Exacted as the Price of a Public Benefit.

The question this case presents is not new—whether a constitutional right can be conditioned on a pubic benefit. In *Insurance Co. v. Morse*, 87 U.S. 445 (1874), Wisconsin conditioned a foreign insurance company's privilege to do business in the State on its agreement never to remove a case to federal court. The State could have excluded the company altogether. What it could not do was exact, as the price of admission, the surrender of access to a federal forum. This Court's rule was categorical: "a man may not barter away his life or his freedom, or his substantial rights." *Id.*, at 451.

The method recurs, and this Court has rejected it every time. *Frost Trucking Co. v. Railroad Commission*, 271 U.S. 583, 593, 594 (1926) ("A State cannot" impose conditions which require the relinquishment of constitutional rights. 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'"); *Bailey v. Alabama*, 219 U.S. 219, 244 (1911) ("What the state may not do directly it may not do indirectly."); *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."); *Perry v. Sindermann*, 408 U.S. 593, 597 (1972) (government "may not deny a benefit to a person on a basis that infringes his constitutionally protected interests").

The standards governing the waiver of fundamental rights are among the most demanding this Court imposes. A waiver must be "voluntary, knowing, and intelligently made," *D.H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 185–86 (1972); "an intentional relinquishment or abandonment of a known right," *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938); and "the product of a free and deliberate choice rather than intimidation, coercion, or deception," *Berghuis v. Thompkins*, 560 U.S. 370, 382–83 (2010). Courts "do not presume acquiescence in the loss of fundamental rights." *Zerbst*, 304 U.S. at 464. Most recently, *Janus v. AFSCME*, 585 U.S. 878, 930 (2018), held that continued participation in an employment arrangement supplies no consent at all: waiver "cannot be presumed" and must be "shown by 'clear and compelling' evidence."

C. Mandating a PREP Act Countermeasure Extorts Precisely that Forbidden Surrender.

The PREP Act provides that a covered person "shall be immune from suit and liability under

Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(1). The sole exception is an exclusive federal cause of action for death or serious physical injury proximately caused by willful misconduct. Id. § 247d-6d(d)(1). The Act further provides that civil actions "shall be filed and maintained only in the United States District Court for the District of Columbia." *Id.* § 247d-6d(e)(1).

There are two sides to this coin. On the 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. On the other hand, the Act bars any person from pursuing even that limited claim in state court. 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 continued public employment 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 between a rock and a whirlpool: either surrender their livelihoods or their future right to litigate in state court under state tort causes of action if injured by the mandated drug. This is precisely the form of coercion this Court prohibits under *Koontz. Id.* at 607–08.

Insurance Co. v. Morse supplies the controlling analogy. Just as Wisconsin could not condition the privilege of doing business on an advance waiver of

access to federal courts, Respondents cannot condition the privilege of public employment on acceptance of a covered countermeasure whose administration automatically extinguishes the right of access to any state court. Respondents could never have told Petitioners: "Sign this waiver of your right to sue anyone for any injury this drug causes, or you are terminated." That would have been *Morse*'s forbidden bargain. They achieved the identical result by mandating the conduct to which Congress attached the same legal consequence. *Bailey v. Alabama* answers that maneuver directly: "What the state may not do directly it may not do indirectly." 219 U.S. at 244. The power to condition public employment is not a means of evading constitutional restrictions.

This Court has long recognized that a conditioned choice may be no choice at all. In *Frost*, a party facing such a condition "is given no choice, except a choice between the rock and the whirlpool—an option to forego a privilege which may be vital to his livelihood or submit to a requirement which may constitute an intolerable burden." 271 U.S. at 593. Applying the same principle to public employment, this Court held that "[p]olicemen, like teachers and lawyers, are not relegated to a watered-down version of constitutional rights. There are rights of constitutional stature whose exercise a State may not condition by the exaction of a price." *Garrity*, 385 U.S. at 500. Termination from public employment for refusing to make that surrender violates the Fourteenth Amendment's Due Process Clause and is actionable under 42 U.S.C. § 1983.

III. The Decision Below is Wrong.

A. The Ninth Circuit Misapplied Rational Basis Review to Respondents' Actions.

Rational-basis review presupposes that the government has authority to act and asks only whether its exercise was reasonable. That premise fails on the facts alleged here in two independent ways, and either one removes the case from rational-basis review before any balancing begins.

First, preemption is a threshold inquiry, not a factor to balance. *Jacobson* itself makes this the antecedent question: a local enactment, "even if based on the acknowledged police powers of a State, must always yield in case of conflict with the exercise by the General Government of any power it possesses under the Constitution." *Id.* at 25. A policy preempted by federal law is not entitled to deference for being rationally related to a legitimate interest—it is not a lawful exercise of state authority at all, and rational-basis review has nothing to weigh once that authority is absent. And a "legitimate interest" sufficient to satisfy any level of review is, by this Court's own terms, limited to "interests the State has the authority to implement." *City of Cleburne,* at 441-442.

No degree of rationality in Respondents' stated purpose supplies them with power Congress withheld. Congress anticipated the very emergency Respondents invoke and did not carve out an exception for it: even where an authorization responds to a pandemic event. Under § 360bbb-3(b)(1)(C), the choice whether to accept the product belongs solely to the potential recipient. The recipient is the one Congress required to be informed

of the product's risks and benefits and of the option to refuse. No political subdivision may override that congressional judgment to punish either choice.

Second, rational-basis review does not apply when a fundamental right is implicated—and two independent fundamental rights are implicated here, neither of which the panel addressed under *Glucksberg*. *Cruzan* grounds the first right (the right to refuse unwanted medical treatment) directly in the Due Process Clause, 497 U.S. 261, 278 (1990). The panel accepted as true that the mandated product "posed a significant risk of serious adverse effects" and "did not prevent transmission ... it only lessened the severity of symptoms," App. 4a. This confirms that this is *Cruzan*'s territory, since *Jacobson* rests on protecting the community from contagion, a rationale a non-transmission-blocking product cannot supply, 197 U.S. at 27.

The second right (access to the courts) is not subjective, and its pedigree is longer than *Jacobson*'s, tracing to Magna Carta, ch. 40 (1215). The Ninth Circuit has already held as much itself: "the right of access to the courts is a fundamental right protected by the Constitution." *Delew v. Wagner*, *supra*. Neither *Curtis* nor the panel below performed the analysis *Glucksberg* requires before the fundamental right designation can be displaced—no "careful description" of the right, no explanation of why a right the same circuit called fundamental in 1998 no longer merits that treatment. 521 U.S. 702, 720–21 (1997). That omission matters because the PREP Act is primarily an immunity statute—its central function is extinguishing the right of access to courts and causes of action for injuries caused by a covered countermeasure. The right of access to the courts for judicial remedy when injured by another member of

society is a fundamental right that requires strict scrutiny, not rational basis review.

B. The Ninth Circuit Misapplied *Carvalho* and *Curtis*.

The panel further held that Petitioners failed "to state a claim for violations of equal protection or substantive due process under the Fourteenth Amendment" and that both claims are subject only to rational-basis review, citing *Carvalho*. App. 3a. That reliance is misplaced. *Carvalho* addressed whether a State could impose a vaccination requirement at all; it did not address whether a State may mandate exclusive reliance on an investigational product for which no licensed alternative exists—the facts alleged here. If Respondents lacked lawful authority to issue the Policy in the first place, no balancing test is required.

The panel stated: "We have already concluded that substantially similar mandates, which were imposed for substantially similar reasons, survive rational basis review." App. 4a. That may be true of the mandate *Curtis* and *Carvalho* addressed, but it is not the governing standard where a plaintiff alleges both a fundamental right and the complete absence of governmental authority to act—precisely what Petitioners alleged in the case below.

Further, the panel rejected Petitioners' procedural due process claim on the ground that "the mandate provided for individualized religious and medical exemptions," citing *Curtis*. App. 4a. Respondents possess no authority to add to, or subtract from, the conditions Congress established for the emergency use of a drug exempt under 21 U.S.C. § 355(a), *id.* § 360bbb-3, or the conditions

under which the CDC Program made that drug available to the public. Those conditions require voluntary, informed consent and secure the individual's right to refuse without penalty. By making a religious or medical exemption the sole means of exercising that statutory option, Respondents imposed a condition that neither the statute providing for EUAs, nor the federal program, authorizes. Once again, the panel adopted *Curtis*' conclusion without independently testing it against the statutory text—the same error running through every holding challenged in this section. The panel's failure to give effect to federal supremacy over the emergency use of an unlicensed product effectively conferred on Respondents an authority Congress itself has withheld.

C. Petitioners Abandoned None of Their Claims.

The panel disposed of Petitioners' *Monell*, privacy, and state-law claims on the ground that Petitioners "abandoned" them by failing "to cite or discuss any relevant authority, or make any argument concerning the application of relevant law to these claims." App. 5a. The district court had already explained why no separate argument was possible: "Because the Court has dismissed all of Plaintiffs' federal constitutional and statutory causes of action on their merits, Plaintiffs are unable to state a claim for liability against the City under *Monell* as well." App. 46a. Petitioners addressed each of those underlying constitutional and statutory claims at length in their opening brief to the Ninth Circuit, as evidenced by the Circuit addressing those claims in its opinion. App. 1a. That they did not

restate the identical argument under a separate heading does not constitute abandonment.

The City's presence in this case was never contingent on Petitioners' Ninth Cause of Action (42 U.S.C. § 1983-*Monell* Liability) surviving in the first place. The Second Amended Complaint names the City directly in the predicate causes of action, brought "against (1) Seth Fleetwood ... and (2) the City of Bellingham ... for its unconstitutional policies, customs, and/or practices under *Monell* ... and its progeny." *Id.* ¶ 4. *Monell*'s policy element is satisfied on the face of those claims by the undisputed fact that Mayor Fleetwood issued the Executive Order as "the final policymaker of the Executive Order." *Id.* ¶ 94. If this Court declines to resolve that question, even a favorable remand on the merits of the constitutional questions would leave unresolved whether the City remains a defendant. Petitioners request that any favorable disposition clarify that they addressed the District Court's basis for dismissing the *Monell* claim under the Ninth Cause of Action, and/or that the *Monell* claim remains attached to all other causes of action.

Petitioners' privacy claim stands on independent footing: Petitioners briefed it under its own heading. As to the state-law wrongful-termination claim, the district court held that Petitioners had "failed to demonstrate that they were exercising a 'legal right or privilege,' under either state or federal constitutional or statutory law." App. 47a. Petitioners' opening brief challenged the district court's refusal to accept their allegations as true, and Petitioners' statement that they "stand by their claims of wrongful termination" was the only practical means of preserving the claim within the word limits imposed by the court's own rules, without

repeating arguments already fully developed under the preceding headings.

IV. This Case Serves as an Ideal Vehicle to Resolve these Important Questions.

The questions presented are critically important, and the stakes are high because injecting investigational drugs can cause irreparable harm. The Ninth Circuit's precedent dismantles the federal framework governing the administration of investigational drugs at every level. It strips the Secretary of exclusive authority to determine the conditions under which such products enter interstate commerce. It renders the FDCA's informed-consent requirements unenforceable against any State that invokes its police power. It nullifies the Federalwide Assurance program, under which every State contractually promised the federal government that it would never subject individuals to investigational products under coercive conditions. It eliminates the role of Institutional Review Boards, whose purpose is to ensure that no administering entity pressures individuals into accepting investigational treatments. And it renders 42 U.S.C. § 289—Congress's post-Tuskegee command that the Executive Branch protect the rights of every person involved in federally funded research—inoperative whenever a State or local actor determines that an investigational product will serve the public health. No provision of the federal scheme survives.

The Ninth Circuit has used this Court's opinion in *Jacobson* to invalidate the entire federal framework designed to protect the American people from unwanted investigational treatments developed after *Jacobson* was decided. Further, the right to

access courts of law for judicial remedy is now a bargaining chip governments can use as a weapon against the American people.

This case is an excellent vehicle for resolving the questions presented. The status of Respondents as state actors is undisputed. Moreover, consolidating this case with *Roberts* and *Boysen* will afford the Court a fuller understanding of the common questions of law presented by similar policies.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for a writ of *certiorari*.

Respectfully submitted,

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