No.

In the Supreme Court of the United States

AILA CURTIS, *et al.*,
Petitioners,

v.

JAY ROBERT INSLEE,
GOVERNOR 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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The Ninth Circuit held that Petitioners' substantive due process claims were foreclosed by *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) and *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025).

Because *Carvalho*, pending as No. 25-765,* cites the present case as an example of the detrimental effects of the *Carvalho* ruling, the Court may wish to consider this case in conjunction with *Carvalho*. Additionally, *Sweeney v. University of Colorado Hospital Authority*, No. 25-1055, involves a materially similar factual and legal backdrop and identical procedural errors by both the district and circuit courts as those detailed herein. The Court may wish to consider these petitions in tandem to address the recurring issues of party presentation and premature merits adjudication at the pleading stage.

Question 1:

Does *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) limit a court's review of government-mandated investigational medical treatments to whether the mandate is rationally related to a legitimate government objective, or does *Jacobson* first require the court to determine if the scope and means of the mandate constitute a legitimate exercise of the police power of the state that does not infringe upon the federal domain?

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* This Court issued a call for response on February 5, 2026.

Question 2:

Did the Ninth Circuit violate the principle of party presentation by *sua sponte* deciding a major constitutional question — whether *Jacobson* forecloses any substantive due process right to refuse an investigational drug — based on facts neither raised, briefed, nor argued by any party, to affirm dismissal under Federal Rule of Civil Procedure 12(b)(6)?

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees of PeaceHealth: Aila Curtis, Shannon Lee Adams, Ciera Agee, Nelli Antonov, Alison Archer, Rebecca Barcenas, David Bennett, Kathy Bordeaux, Daniel Brickert, Britney Brown, Christine Amber Bruce, Susan Buchanan, Kirsten Clarke, Diane Clemans, Jeff Coffey, The Estate of Cherie Coiner, Sheila Craig, Rae Lynn Crocker, Lisa Daluz, Christina Dawson, Margarita Demchenko, Monica Dickinson, Hayley Dixon, Jason Dong, Kristin Ellison, Katerina Erokhina, Shanta Gervickas, The Estate of Caleb Gervickas, Eduard Goncharuk, Staci Gray, Amy Haserot, Betheny Hayden, Rhonda Holmes, Mikayla Holsinger, Amy James, Josey Kolbo, Whitney Konrady, Tamara Kopp, Sumiko Kuba, Lindsey Lamb, Nadezhda Litvinenko, Liliya Lopatin, Misty Lyons, Sheila Lyons, Irina Maksimenko, Lyubov Melnychuk, Ashley Mendoza, Monica Miller, Cheryl Mitchell, Damaris Mocan, Kathryn Morgan, Nick Morzhov, Dwain Nash, Lysander Nerida, Yelena Onofrey, Kathryn Ortega, Yvonne Quashie, Leslie Quintana, Emma Ranson, Shannon Ringnalda, Angela Ripp, Violetta Roberts, Mallory Schlang, Igor Shapoval, Melissa Smithdeal, Lori Souders, Amy Tallbut, Brooke Tanner, Amber Taylor, Tracie Thomas, Dena Thorp, Jennifer Torres, Lyubov Tshuprin, Olga Tsytsyna, Linda Veatch, Roxana Volynets, Hannah Wagar, Vera Yadlovskiy, Alla Kutsar Zabolotska, Dina Zabolotska, Nelya Zabolotska, and Kristine Zamudio.

Respondents are Jay Robert Inslee, Governor of the State of Washington, in his individual capacity, and PeaceHealth, a not-for-profit healthcare system headquartered in Clark County, Washington; Liz

Dunne, President and Chief Executive Officer of PeaceHealth, in her official and individual capacities; and Doug Koekkoek, Chief Physician and Clinical Executive of PeaceHealth, in his official and individual capacities.

CORPORATE DISCLOSURE STATEMENT

Petitioners have no information to disclose under Rule 29.6.

LIST OF DIRECTLY RELATED CASES

Curtis, et al. v. Inslee, et al., No. 24-1869, U.S. Court of Appeals for the Ninth Circuit. Judgment entered October 6, 2025.

Curtis, et al. v. Inslee, et al., No. 3:23-cv-05741-RJB, U.S. District Court for the Western District of Washington. Judgments on motions to dismiss entered December 21, 2023 and January 23, 2024; Judgment denying leave to amend entered February 27, 2024.

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF CONTENTS
(continued)

TABLE OF AUTHORITIES

CASES

TABLE OF AUTHORITIES
(continued)

TABLE OF AUTHORITIES
(continued)

TABLE OF AUTHORITIES
(continued)

CONSTITUTIONAL PROVISIONS

FEDERAL STATUTES

TABLE OF AUTHORITIES
(continued)

FEDERAL REGULATIONS

TABLE OF AUTHORITIES
(continued)

FEDERAL RULES

PETITION FOR A WRIT OF CERTIORARI

Petitioners Aila Curtis, *et al.* respectfully seek a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Ninth Circuit, which affirmed orders granting Respondents' Rule 12(b)(6) motions to dismiss and denying Petitioners' motion for leave to amend.

OPINIONS BELOW

The Ninth Circuit's opinion is published at *Curtis v. Inslee*, 154 F.4th 678 (9th Cir. 2025), and reproduced at Appendix A.

The U.S. District Court for the Western District of Washington's decision dismissing Respondent Inslee is published at *Curtis v. Inslee*, 709 F.Supp.3d 1257 (W.D. Wash. 2023), and is reproduced at Appendix D. The District Court's decision dismissing Respondent PeaceHealth is found at *Curtis v. PeaceHealth*, 2024 WL 248719; the District Court's denial of leave to amend is found at *Curtis v. Inslee*, 2024 WL 810503; these decisions are reproduced at Appendix C and B, respectively.

JURISDICTION

The Ninth Circuit issued its opinion on October 6, 2025. Petitioners requested an extension of time in which to file the instant petition for a writ of *certiorari*, and were granted an extension by Justice Kagan until March 5, 2026, No. 25A703. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Constitutional provisions involved are included at Appendix E, App. 96a:

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

The relevant statutory provisions are included at Appendix E, App. 97a–102a:

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

INTRODUCTION

This Petition presents a constitutional crisis of national importance that urgently requires this Court's immediate intervention: whether a state may impose mandatory investigational medical treatment in direct defiance of federal law, or whether federal law remains supreme as the Constitution commands. Under the Supremacy Clause and more than two centuries of this Court's unbroken precedents, the answer is axiomatic — federal law prevails. Yet the Ninth Circuit radically inverted that foundational order. It misconstrued *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), to require courts to examine only the state's asserted public-health objective, while

rendering wholly irrelevant whether the means chosen constitute a legitimate exercise of police power or brazenly intrude upon the field Congress has exclusively occupied for itself under the Supremacy Clause.

The Ninth Circuit's errors are both profound and multifaceted. It *sua sponte* resolved a sweeping constitutional question — whether *Jacobson* categorically forecloses any substantive due process right to refuse an investigational drug — based on facts that no party had raised, briefed, or argued, violating the principle of party presentation. *See United States v. Sineneng-Smith*, 590 U.S. 371 (2020). It also engaged in blatant appellate fact-finding by dismissing mandatory federal statutes, regulations, and binding agreements as mere "suggestions" and by inventing a novel "clinically identical" doctrine that effectively rewrites the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 301 *et seq*., insofar as it permits public and private entities to treat unapproved drugs as if they are approved when they are "clinically identical." Most concerning is that such a precedential ruling serves as a blank check for wrongdoers because the court did not define "clinically identical," leaving it to society to prescribe its own meaning. The Ninth Circuit judicially manufactured a fourth, implied exception to 21 U.S.C. § 355(a) — one Congress has never enacted — thereby authorizing the involuntary use of unapproved investigational drugs in direct contravention of the FDCA and this Court's holding in *United States v. Rutherford*, 442 U.S. 544 (1979), that lower courts may not create exceptions to FDCA that Congress itself has not authorized.

What began as a straightforward claim for monetary damages under 42 U.S.C. § 1983 for the deprivation of Petitioners' Fourteenth Amendment rights was transformed by the Ninth Circuit into a sweeping declaration of state supremacy over federal drug regulation, labeling, and administration. The opinion is not merely erroneous; it is an unprecedented abuse of judicial power. *Certiorari* is essential to restore the constitutional hierarchy, reaffirm the supremacy of federal law in drug regulation, and prevent the Ninth Circuit's ruling from becoming a dangerous nationwide precedent that eviscerates Congress' strict regulation of investigational drugs and covered countermeasures. Compelling healthy citizens to inject investigational drugs into their bodies while simultaneously depriving them of any right to judicial redress if injured — all as a condition of retaining state-conferred privileges such as employment within the healthcare industry — is an abusive and oppressive exercise of governmental power. The Ninth Circuit's novel extension of *Jacobson* to sanction such a result cannot be reconciled with the Due Process Clause of the Fourteenth Amendment.

STATEMENT OF THE CASE

The underlying action challenged mandatory policies promulgated and enforced by Respondents. Governor Inslee issued Proclamation 21-14-1,[1] which prohibited state-licensed healthcare facilities from employing licensed healthcare providers who had not been injected with an investigational COVID-19

[1] ECF No. 8 ¶¶ 25–26

vaccine not licensed for any indication[2] by October 18, 2021. PeaceHealth cited the Proclamation as the basis for implementing its mandatory policy[3] requiring full "vaccination" with available investigational drugs by October 15, 2021.[4] Petitioners alleged that PeaceHealth engaged in a scorched-earth policy,[5] including requiring publicly displayed vaccination badges to disclose Petitioners' private health information and leaving binders in public hallways containing Petitioners' full name, employee ID, and vaccination status. Petitioners also alleged that they were openly harassed, ridiculed, mocked, and intimidated as a result,[6] and that staff managers continually invaded their privacy by asking publicly if and when they would be injected with one of the drugs and why they would not use the product.

Starting on October 15, 2021, and continuing through 2022, on the state's behalf, PeaceHealth, through employment termination, punished Petitioners who refused to accept one of the available COVID-19 investigational drugs.[7] On August 18, 2023, Petitioners filed their Complaint.[8] On August 28, 2023, the court, *sua sponte,* required Petitioners to reduce their page count.[9] On August 31, 2023, Petitioners filed an Amended Complaint.[10] Governor Inslee filed his Rule 12(b)(6) motion to dismiss on

[2] *Id.* ¶¶ 30–32
[3] *Id.* ¶ 123
[4] *Id.* ¶ 137
[5] *Id.* ¶ 156
[6] *Id.* ¶ 162
[7] *Id.* ¶ 27
[8] ECF No. 1
[9] ECF No. 7
[10] ECF No. 8

October 30, 2023,[11] and PeaceHealth filed its motion to dismiss on November 30, 2023.[12]

Governor Inslee's primary defense rested on his assertion that the drugs made available for compliance were not investigational drugs.[13] PeaceHealth alleged that "[b]y the time Plaintiffs were required to receive a COVID vaccine under PeaceHealth's policy, an FDA-approved vaccine was available."[14] Both Respondents alleged that Petitioners cited to no authority that provided a private right of action. Petitioners filed oppositions relying upon the FDA's EUA (Emergency Use Authorization) letters that described the available drugs as "an investigational vaccine not licensed for any indication."[15] Petitioners informed the court that the presence of an EUA means that an approved drug is not available for use and alleged, with supporting judicially noticeable documentation, that "the FDA and Pfizer informed the public that although Comirnaty was licensed for commercial use, the drug was never available in the U.S."[16]

On December 21, 2023, the district court granted Governor Inslee's motion to dismiss,[17] and factually concluded, based on no evidence, that because the FDA approved Comirnaty, it was available for policy compliance. The district court thus found that the mandates were lawful because the available drugs were FDA-approved drugs rather than investiga-

[11] ECF No. 18
[12] ECF No. 30
[13] ECF No. 18 at 19, "i"
[14] ECF No. 30 at 15, 11-12
[15] ECF No. 8, ¶¶ 30-32
[16] ECF No. 29 at 18-19
[17] ECF No. 32

tional.[18] On January 18, 2024, Petitioners filed a Rule 59(e) Motion to Alter or Amend, or in the Alternative, Motion for Leave to File Second Amended Complaint,[19] and attached a proposed Second Amended Complaint with judicially noticeable documents as exhibits.[20] While the Motion to Alter or Amend was pending, on January 23, 2024, the district court granted PeaceHealth's motion to dismiss on the same basis that it granted Gov. Inslee's.[21] On February 27, 2024, the district court denied Petitioners' Motion to Alter or Amend/Motion for Leave to File Second Amended Complaint.[22]

On March 26, 2024, Petitioners filed a timely appeal to the Ninth Circuit.[23] The Ninth Circuit held that any error of the lower court relating to whether the drug was investigational was "harmless." App. 5a. The Court affirmed the district court's dismissals by (a) issuing a novel ruling that *Jacobson* precludes any argument of a constitutional right to refuse investigational drugs, (b) dismissing mandatory federal statutes, regulations, and binding agreements as mere "suggestions," and (c) inventing a novel "clinically identical" doctrine that effectively rewrites the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA), 21 U.S.C. § 301 *et seq*.

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[18] *Id*.
[19] ECF No. 38
[20] ECF Nos. 38-2 through 38-10
[21] ECF No. 41
[22] ECF No. 54
[23] ECF No. 56

REASONS FOR GRANTING THE WRIT

The Court should grant the petition because it presents important and recurring questions of federal procedure, Supremacy Clause preemption, and substantive due process that only this Court can authoritatively resolve. Review is necessary to protect the comprehensive federal framework Congress has carefully constructed over more than eight decades to safeguard public health, drug safety, and the fundamental liberty interests in informed consent and bodily integrity.

This Court may grant *certiorari* when "a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court, or has decided an important federal question in a way that conflicts with relevant decisions of this Court." Sup. Ct. R. 10(c). Both criteria are squarely met. The Ninth Circuit's entire opinion rests on its recasting of *Jacobson,* supported only by improper fact-finding at the pleading stage. Only this Court can correct the lower court's inversion of the Supremacy Clause, restore the proper analysis of *Jacobson*, and safeguard the liberty interest that Congress has strictly enforced through its legislative efforts for the protection of the American people.

Although PeaceHealth is a private entity, Petitioners alleged that it was acting on behalf of official state policy when it deprived them of their Fourteenth Amendment rights — a contention the Ninth Circuit expressly acknowledged. App. 6a. The panel made clear that it was not addressing whether PeaceHealth qualified as a state actor or whether qualified immunity applied to any Respondent. Additionally, the panel referred to Petitioners as "at-

will employees." That characterization has no bearing on this case. PeaceHealth did not invoke the State of Washington's at-will employment doctrine to terminate Petitioners' employment; it relied on Governor Inslee's proclamation — the very official state policy the petitioners are challenging. Finally, the court's repeated use of the term "employees" to refer to Petitioners is misleading. They were citizens who were denied meaningful use of their state-issued healthcare licenses because a state policy barred them from entering healthcare facilities unless they participated in the CDC's COVID-19 Vaccination Program on the terms set forth in the Governor's proclamation.

I. The Ninth Circuit misconstrued *Jacobson* and inverted the Supremacy Clause.

The Ninth Circuit held that "*Jacobson* and *Carvalho* foreclose Employees' substantive due process claim regarding the purported 'right to refuse an investigational drug without penalty or pressure'" because they "have failed to plausibly allege that the state action in this case was an exercise of 'arbitrary power' rather than merely 'that broad discretion required for the protection of the public health.'" App. 19a.

This holding rests on a fundamental mischaracterization of *Jacobson*'s two-prong analysis. *Jacobson* first requires a court to determine whether the challenged policy is a legitimate exercise of the state's police power — including whether its scope and means intrude upon the federal domain occupied by Congress under the Supremacy Clause. Only if the policy survives that threshold inquiry does the court then ask whether the regulation is reasonable

and not arbitrary, oppressive, or beyond what is necessary for the protection of the public health. The Ninth Circuit determined that Petitioners failed to plausibly allege the state action was not arbitrary because it ignored *Jacobson*'s required inquiry of whether the scope and extent of the mandates were a legitimate exercise of the state's police powers. In doing so, the panel erroneously implied that federal law governing investigational drug use is irrelevant to the legitimacy of the state's conduct. This is a clear constitutional error. By reading *Jacobson* to insulate state mandates from federal statutory limits and the Supremacy Clause, the Ninth Circuit inverted the constitutional hierarchy and eviscerated the very limits this Court has long imposed on state police power.

Jacobson is clear that the first inquiry is whether the scope and extent of the statute constitute a legitimate exercise of the state's police powers.

> A local enactment or regulation, even if based on the acknowledged police powers of a State, must always yield in case of conflict with the exercise by the General Government[24] of any power it possesses under the Constitution, or with any right that instrument gives or secures. *Jacobson, supra* at 25.

In *Railroad Company v. Husen,* 95 U.S. 465 (1877), a case where the state's legitimate interest extended to slowing the spread of the Texas or Spanish flu, the Court acknowledged states' rights to enact sanitary laws for the protection of life, liberty, health, or property. Yet, this Court struck down the public health policy because it "went beyond the

[24] In historical and constitutional contexts, particularly in opinions like *Jacobson*, the term "general government" refers to the federal (or national) government of the United States, as distinguished from individual state governments.

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 ("It seems hardly necessary to argue at length that unless the statute can be justified as a legitimate exercise of the police power of the state, it is a usurpation of the power vested exclusively in Congress.") Only after inquiring whether the scope and extent of the statute rests within "the authority of the State to enact th[e] statute," *Jacobson* at 25, did the court move to the second prong of inquiry of whether the means prescribed by the state for the "protection of the public health and the public safety" furthered a legitimate interest of the state that was not arbitrary, oppressive, or an unreasonable exercise of the state's police powers. *Id.* at 31.

The Ninth Circuit now establishes new precedent that "our *only inquiry* is whether Employees' treatment is rationally related to the State's objective."[25] That approach directly contradicts this Court's opinion in *City of Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 441 (1985), that when reviewing an equal protection claim, rational-basis review applies only to "interests the State has the authority to implement."

Because Petitioners alleged that the challenged mandates are preempted by federal law, the Ninth Circuit, as a matter of law, cannot supply any legitimate state interest at the pleading stage. A policy that violates federal law is not a legitimate exercise of police power; it is void under the

[25] App. 23a (internal quotation marks omitted) (emphasis added).

Supremacy Clause. The Ninth Circuit's inverted framework — treating federal preemption as irrelevant once a state invokes "public health" — cannot be reconciled with *Jacobson, Cleburne*, or the Supremacy Clause.

The panel acknowledged Petitioners' allegations that the challenged mandates might plausibly violate federal law, stating: "even if these regulations applied to the conduct at issue here," App. 12a; "[e]ven assuming this language applies to Defendants and their conduct, Congress has limited the enforcement of the FDCA to public actions," App. 9a; and "[e]ven if the FWA created such a duty, and such a duty applied to Defendants," App. 13a. Still, the panel would not defer to the authority of its coequal constitutional partners to even consider whether the state policy infringed upon Congressional authority.

The panel's opinion casts the state as sovereign and the federal government as the stepstool, turning *Jacobson* on its head, effectively ruling that once a state invokes "public health," federal statutes, regulations, and binding agreements governing the administration of investigational drugs become irrelevant, and a court's only inquiry is limited to whether the mandate is rationally related to a legitimate state objective.

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

law." *Arizona v. United States*, 567 U.S. 387, 399, 416 (2012). For more than eighty-five years, since the FDCA's enactment in 1938, Congress has occupied the entire field of unapproved drug regulation, under its power to regulate interstate commerce, leaving no room for state intrusion.

The Ninth Circuit's precedential holding reduces every Fourteenth Amendment challenge of a state public health policy to the single, deferential question: whether the "mandate … has a real or substantial relation to the protection of public health,"[26] while pointedly refusing to inquire whether the policy is a legitimate exercise of the state's police power. App. 19a. The panel thereby places Petitioners in an impossible position: to claim that the right to refuse an investigational drug is a fundamental right they must prove as both "deeply rooted in this Nation's history and tradition" and "implicit in the concept of ordered liberty," such that "neither liberty nor justice would exist if [it] were sacrificed," *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997). Yet the Ninth Circuit voids all such arguments the instant Respondents utter the words "public health."

This ruling directly contradicts the federal government's determination that protecting public health requires preserving the unfettered right to refuse investigational medical treatments without incurring a penalty or losing an otherwise-entitled benefit. The Ninth Circuit's refusal to apply the *Jacobson* framework rests not on law, but on its own policy preferences.

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[26] The Ninth Circuit referenced this Court's opinion in *Biden v. Missouri*, 595 U.S. 87, 93 (2022) to imply that this Court has affirmed the right of states to mandate investigational medical treatments, despite no such facts presented in that case. App. 24a.

II. Respondents' mandates were not a legitimate exercise of state police power.

Petitioners expressly alleged that "[n]o person has the legal authority to require another person to inject an unlicensed investigational drug into their body as a condition to earn, receive, or enjoy a privilege of the State or conduct commerce, including employment."[27] Respondents never disputed this allegation at any stage of the litigation, and the district court never rejected it. Only the Ninth Circuit, acting *sua sponte* and without any prompting from the parties, invented a defense on the Respondents' behalf, effectively ruling that it has been definitively resolved under *Jacobson* that governments can require Americans to accept the administration of investigational drugs under threat of penalty.

The Ninth Circuit engaged in improper fact-finding and premature merits adjudication at the Rule 12(b)(6) stage. The panel dismissed Petitioners' allegations concerning federal statutes, regulations, and binding agreements by recharacterizing them as imposing only "merely precatory obligation[s] on the government" that "do not create enforceable rights." App. 8a. In so doing, the court ignored the expressly mandatory language — "must," "ensure," "shall," "obtain," and "require" — that appears throughout Petitioners' cited authorities. Such language imposes ministerial, nondiscretionary obligations, not mere hortatory suggestions, that can lead to claims of entitlement upon full discovery.

By reframing these expressly mandatory federal mandates as mere precatory suggestions, the Ninth

[27] ECF No. 8 ¶ 28

Circuit committed a separation-of-powers violation by judicially implying that such sources of authority are not binding federal mandates but rather mere suggestions for Respondents to consider. The panel compounded the violation by affirmatively holding — without any discovery or factual development — that those sources of federal authority create no private right of action, despite not having an informed understanding of the matters of first impression that would arise from discovery. At the pleading stage, the court was constitutionally required to accept Petitioners' factual allegations as true and draw all reasonable inferences in their favor. Instead, it resolved contested questions of statutory and contractual interpretation against Petitioners and effectively found facts outside the pleadings — precisely the type of improper appellate fact-finding and premature merits adjudication that violates Rule 12(b)(6) and this Court's precedents under *Bell Atlantic Corp. v. Twombly* (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *See also Wroblewski v. City of Washburn*, 965 F.2d 452 (7th Cir. 1992) ("[t]he rational basis standard … cannot defeat the plaintiff's benefit of the broad Rule 12(b)(6) standard. The latter standard is procedural, and simply allows the plaintiff to progress beyond the pleadings and obtain discovery, while the rational basis standard is the substantive burden that the plaintiff will ultimately have to meet to prevail on [a constitutional] claim.") (quoting *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

A. The Federal Food, Drug and Cosmetic Act preempts mandates of investigational drugs.

The Ninth Circuit's ruling — that Respondents may mandate administration of an investigational drug whenever they subjectively believe it would protect public health — contains no requirement that the drug first be authorized by the Secretary of Health and Human Services (Secretary) under any of the FDCA's three statutory exemptions discussed below. The decision therefore expands to include the investigational drug classification in general, not merely those granted Emergency Use Authorization under 21 U.S.C. § 360bbb-3.

The foundational prohibition of the FDCA states that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug" unless the Secretary has approved a new-drug application. 21 U.S.C. § 355(a). Through this provision and its subsequent amendments, Congress has exercised its Commerce Clause authority to occupy the field of regulating the introduction of unapproved drugs into interstate commerce. States are therefore precluded from creating exceptions to this federal ban or intruding upon the Secretary's exclusive authority to determine the conditions under which such drugs may be used.

Congress has created only three narrow, expressly conditioned exemptions to § 355(a):

(1) The Investigational New Drug pathway, 21 U.S.C. § 355(i), which conditions the exemption on the sponsor "obtain[ing] … consent" from the participant (§ 355(i)(4));
(2) Expanded-access (compassionate-use) provisions, § 360bbb, which condition use upon a

licensed physician's compliance with the informed-consent requirements of § 355(i)(4), see § 360bbb(b)(4) (a "clinical protocol consistent with the provisions of section" § 355(i)(4) must be submitted); and

(3) Emergency Use Authorization (EUA), § 360bbb-3, which authorizes temporary population-wide access only when the Secretary "shall ensure" that potential recipients are informed "of the option to accept or refuse administration of the product" § 360bbb-3(e)(1)(A)(ii)(III).

Congress expressly withheld from the Secretary any power to mandate that an individual participate in the authorized activity of accepting the administration of an EUA drug. *See* § 360bbb-3(l) ("Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity"). The Secretary must, by statute, incorporate the conditions of voluntary participation and the right to refuse — as expressly stated in each EUA letter of authorization — as mandatory terms governing the manufacturer's authorization to introduce the investigational drug into interstate commerce. Respondents possess no authority to override, interfere with, or nullify those binding federal conditions.

First, the phrase "obtains … consent" in § 355(i)(4) is mandatory, not precatory; it is an express condition precedent to lawful use of the drug. Failure to satisfy that condition renders the administration unlawful. The same mandatory informed-consent requirement governs expanded access and EUA products. These are ministerial, nondiscretionary

duties imposed by Congress, not discretionary suggestions.

Second, no federal statute, regulation, or executive agreement authorizes any state official (including Respondents) to mandate involuntary administration of a product exempted from § 355(a), to amend the Secretary's conditions of authorization, or to nullify the statutory right of refusal through penalties or loss of employment. It is firmly established that, since 1938, Congress has exercised comprehensive and exclusive authority over the regulation of drugs in interstate commerce, preempting conflicting state action. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (*en banc*), *cert. denied*, 552 U.S. 1159 (2008) (affirming no constitutional right to unapproved drugs outside the FDCA framework, as "the FDCA's comprehensive scheme" occupies the field).

The Ninth Circuit committed an error of law when it held that the Governor's and PeaceHealth's subjective belief that the investigational drugs "would protect public health" authorized their mandatory administration. App. 18a. By so ruling, the panel judicially created a fourth, implied exception to § 355(a) — one Congress has never enacted — thereby permitting the introduction of unapproved drugs into interstate commerce for involuntary use. This is a classic violation of the separation of powers doctrine. In *Rutherford*, *supra*, this Court expressly rejected the Tenth Circuit's attempt to imply an additional exception for terminal

patients, holding "that the ACT makes explicit provision for carefully regulated use of certain drugs not yet demonstrated safe and effective reinforces our conclusion that no exception for terminal patients may be judicially implied. Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." *Id.* at 559. The Court issued a warning that "federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy." *Id*. at 555.

The same principle applies here. 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." *Arizona v. United States*, *supra*, at 399. Under the FDCA, states cannot enact public health policies that piggyback on 21 U.S.C. § 355(a) exemptions to require what Congress explicitly prohibits — namely, involuntary use of unapproved medical treatments, nor can they condition the option to refuse on whether an individual submits a medical or religious exemption request to exercise such option. They are completely preempted from establishing a legal requirement that conflicts with the FDCA's voluntary requirement of investigational drug use, irrespective of the method of exemption Congress has prescribed.

To circumvent Congress, the Ninth Circuit inserted a necessity defense on Respondents' behalf, stating that "a community has the right to protect itself against an epidemic of disease which threatens the safety of its members, [so] a vaccine mandate that has a real or substantial relation to the protection of public health is not in palpable conflict with the Constitution." App. 18–19a. (quoting

Jacobson, *supra*, at 27, discussing the necessity defense). This Court foreclosed precisely that argument in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001). There, patients seeking access to marijuana for medical purposes contended that "medical necessity" should be read into the Controlled Substances Act because necessity was a common-law defense. The Court rejected the claim outright, explaining that "[u]nder any conception of legal necessity, one principle is clear: The defense cannot succeed when the legislature itself has made a determination of values." *Id*. at 491.

The FDCA embodies exactly such a legislative value judgment. In *Abigail Alliance*, the D.C. Circuit explained the meaning of *Oakland Cannabis*:

> Congress may limit or even eliminate a necessity defense that might otherwise be available. That is precisely what the FDCA has done. Congress has prohibited general access to experimental drugs, *see* 21 U.S.C. § 355(a), and has prescribed in detail how experimental drugs may be studied and used by the scientific and medical communities, *see id.* § 355(i). Given the Supreme Court's conclusion that the common law defense of necessity remains controversial and cannot override a value judgment already determined by the legislature, the common law doctrine of necessity provides little support to the Alliance's proposed right.

Abigail Alliance at 713.

By judicially creating a necessity-based exception to the FDCA's mandatory informed-consent and

voluntary-use requirements, the Ninth Circuit directly contravened this Court's holding in *Oakland Cannabis* and impermissibly elevated its own policy preferences over Congress' explicit value-based judgments.

B. The Public Readiness and Emergency Preparedness Act expressly preempts EUA mandates.

The Public Readiness and Emergency Preparedness (PREP) Act was enacted as Division C of the Defense Appropriations Act for Fiscal Year 2006, Pub. L. No. 109-148, 119 Stat. 2818 (Dec. 30, 2005). It amends the Public Health Service Act by inserting sections 319F-3 and 319F-4, codified at 42 U.S.C. §§ 247d-6d and 247d-6e. The Act erects a product liability shield, designed to immunize covered persons from suits and liability for claims arising from the manufacture, distribution, administration, or use of designated counter-measures during a declared public health emergency. Congress vests exclusive authority in the Secretary to issue declarations specifying the covered countermeasures, qualified persons, geographic areas, effective periods, and other conditions triggering such immunity. *See* 42 U.S.C. § 247d-6d(b).

For purposes of this action, the PREP Act's express preemption clause clarifies the proper application of the *Jacobson* doctrine, under which state police powers must yield to federal supremacy. The clause informs that:

> During the effective period of a declaration under subsection (b) … no State or political

> subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that — (A) is different from, or is in conflict with, any requirement applicable under this section; and (B) relates to the…administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.]

42 U.S.C. § 247d-6d(b)(8).

The Secretary's ministerial duty to ensure that potential participants are informed of their option to refuse administration — and to refrain from mandating use — establishes statutory conditions applicable to a covered countermeasure that is introduced into interstate commerce under the FDCA. Respondents are therefore expressly preempted from imposing a legal requirement that conflicts with the FDCA's option to refuse, which their respective mandates violate. Therefore, the scope and extent of the mandates were not legitimate exercises of police power because they directly conflicted with the Secretary's ministerial obligations. The Ninth Circuit sidestepped this allegation by stating that "[t]he Supremacy Clause itself 'is not a source of any federal rights' enforceable under Section 1983." App. 16a. While that observation is technically accurate, it is materially misleading in this context. The Supremacy Clause establishes that the mandates were invalid from the outset as preempted exercises

of police power. Because those unlawful mandates arbitrarily deprived Petitioners of protected property and liberty interests, the resulting emotional and economic damages are actionable under 42 U.S.C. § 1983. The panel's reasoning conflates the source of the underlying federal prohibition with the separate constitutional violation redressable through § 1983.

C. Federalwide Assurance and legally effective informed consent prohibits involuntary use of investigational drugs.

To safeguard the nation's due process rights and fundamental protections for individuals involved in investigational medical treatments, Congress enacted the National Research Act (NRA) of 1974, Pub. L. No. 93-348, 88 Stat. 342 (codified as amended in scattered sections of 42 U.S.C.). The NRA amended the Public Health Service Act, including 42 U.S.C. § 289, to require the Executive Branch to "protect the rights" of individuals offered an opportunity to use an investigational new drug through the establishment of Institutional Review Boards to provide lawful oversight. The right, as established by the Secretary under Congressional mandate, is known as legally effective informed consent. *See* 45 C.F.R. 46.116(a)(1). Informed consent is legally effective only when it is voluntary and free of coercion, undue influence, or unjustifiable pressure that might compromise the subject's autonomy.

To ensure compliance with its obligations under 42 U.S.C. § 289(a) to protect the rights of the public, the Executive Branch established the Federalwide Assurance (FWA) program requiring any entity desiring to conduct business with the federal

government to provide written assurance[28] to the Health and Human Services agency that they will, at minimum, obtain legally effective informed consent when involving humans with federally funded investigational drugs, including "cooperative" agreements, such as the CDC COVID-19 Vaccination Program. Petitioners alleged that the State of Washington was under FWA00000327[29] and PeaceHealth operated under FWA00003906,[30] binding them to the legally effective informed consent requirement, even when offering individuals an opportunity to use an investigational drug authorized under 21 U.S.C. § 360bbb-3.

The duty to obtain legally effective informed consent is mandatory, not precatory. It is spelled out in exacting detail in 45 C.F.R. § 46.116 and constitutes a condition of performance that expressly conditions the expenditure of federal funds. *See* 45 C.F.R. § 46.122. The FWA program likewise requires strict adherence to the Belmont Report's core principle of voluntariness — a requirement to which the Executive Branch has bound both exempt and non-exempt activities. *See* 45 C.F.R. § 46.101(c) and (i). Thus, the Executive Branch, through the FWA and 45 C.F.R. Part 46, has given the Belmont Report's voluntariness requirement the full force of federal regulation.

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[28] *See* 45 CFR 46.103(a) (entities "shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy.")

[29] ECF No. 8 ¶ 79

[30] ECF No. 8 ¶ 138

D. Public and private entities cannot assign a medical indication to an investigational drug.

The Ninth Circuit erred when it held that "the absence of a legal indication does not negate the obvious inference that the available COVID-19 [investigational] vaccine would be rationally related to the protection of public health." App. 25a. The panel's opinion rests on impermissible appellate fact-finding at the pleading stage.

Under the FDCA, a sponsor (or any person acting on its behalf) "shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." 21 C.F.R. § 312.7(a). Promotion of an unapproved use of a licensed drug likewise constitutes misbranding under 21 U.S.C. §§ 331(a), 352(a) and (f). The federal government has long enforced this prohibition. *See, e.g., Justice Department Announces Largest Health Care Fraud Settlement in Its History* (DOJ Press Release Number: 09-900, Sept. 2, 2009):[31]

> Under the provisions of the Food, Drug, and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to the FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses — *i.e.,* any use not specified in an application and approved by FDA.

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[31] https://www.justice.gov/archives/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history (last visited March 4, 2025)

Secretary Becerra, acting under congressional mandate, required Respondents under each EUA to "conspicuously" state that the products have "not been approved or licensed by the FDA."[32] This resulted from the FDA informing Respondents that the subject drug "is an investigational vaccine not licensed for any indication."[33]

Under the FDCA, states are preempted from promoting a drug, biologic, or device for any use not authorized by its approved labeling. *See* 21 U.S.C. § 352. Recipients of EUA products must be informed of the product's known and potential risks and benefits based solely on the Secretary's determinations resulting from incomplete clinical trials. Such determinations do not provide a state any authority to claim that the drug "will," "would," or "can" prevent disease transmission. Because the FDCA expressly forbids promotion of unapproved uses, a state's subtive belief that an investigational product will protect public health cannot supply a legitimate state interest for rational-basis review, because such promotion infringes upon the FDA's exclusive authority to make such determinations and constitutes the criminal act of misbranding. *See* 21 U.S.C. § 331.

Most troubling is the panel's additional act of improper appellate fact-finding based on phrases with unknown meanings, which created a binding precedent that, because the investigational drugs share the same "medical formulation" (unknown meaning) as an FDA-approved vaccine, "there is no material distinction" between the refusal of a licensed vaccine and Petitioners' refusal of an

[32] ECF No. 8-4, FDA EUA letter to Pfizer, Inc., Dec. 11, 2020.
[33] ECF No.8 ¶¶ 30–32

investigational drug that is "clinically identical" (unknown meaning) to one. App. 18a. The panel's assertion is nonsensical, as the entire litigation is about the material legal differences between investigational and approved drugs. The panel nowhere defines "clinically identical," cites no authority for the assertion, and fails to explain how this extra-record "fact" overrides the FDCA's labeling and status-based regulatory scheme.

Federal rights and obligations under the FDCA are governed exclusively by a product's labeling and regulatory classification — not its molecular composition. The FDA regulates approximately 19,000 approved drugs in the U.S. marketplace, many of which are manufactured, labeled, and administered for investigational purposes under distinct statutory regimes. A biologic is licensed only when it meets the conditions prescribed under 42 U.S.C. § 262. The Ninth Circuit judicially implied an exception from 42 U.S.C. § 262(a)(1) to permit public and private entities to treat unapproved biologics as if they are approved when they are supposedly "clinically identical." Further, a manufacturer is *not required to maintain its approved formulation* under an investigational drug label, since its purpose is experimental. Factually, Pfizer informed the CDC that it never manufactured any vials of its original licensed formulation.[34]

The panel created binding precedent for the Ninth Circuit, that investigational drugs deemed "clinically identical" in formulation to an FDA-approved product are legally identical for all regulatory purposes under the FDCA — and that this

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[34] *See* https://www.cdc.gov/vaccines/programs/iis/downloads/Preview-Posting-of-COVID-19-Vaccine-Codes-and-Crosswalk-20230228.xlsx

equivalence supplies states with a legitimate exercise of police power to mandate their administration, even when such mandates directly contradict the product's approved labeling and federal prohibitions. This unprecedented judicial legislation injects profound uncertainty into the multi-trillion-dollar pharmaceutical industry and operates as a green light for public and private persons to misbrand pharmaceutical products (a federal crime).

III. *Jacobson* does not foreclose an individual's right to refuse an investigational new drug.

A. Individuals possess a fundamental right to bodily integrity.

It was irrational for the Ninth Circuit, confronting matters of first impression, to foreclose Petitioners' claims by relying on *Jacobson* — a decision rendered 120 years earlier that could not possibly have considered the federal statutes, regulations, and binding agreements on which those claims rest, none of which had yet been enacted by Congress.

The Ninth Circuit held that when claiming a right is fundamental, Petitioners "must therefore articulate a 'careful description' of a fundamental right," citing *Stormans, Inc. v. Wiesman*, 794 F.3d 1064, 1085 (9th Cir. 2015). App. 17a. However, the *Wiesman* court dismissed plaintiff's claims because the plaintiffs' asserted right not to take life was too broad. This is not the case here, as the court correctly identified Petitioners' narrow and specific claim that they allege a "substantive due process right 'to refuse unwanted investigational drugs.'" App. 17a. Furthermore, Petitioners supplied a half-century of

federal acts prohibiting the use of investigational drugs, aptly demonstrating at the pleading stage sufficient "probative weight" to survive a Rule 12(b)(6) dismissal.

Space in this petition does not permit a full exposition of how deeply rooted in this Nation's history and tradition — and implicit in the concept of ordered liberty — the right to refuse investigational medical treatments has become since *Jacobson*, such that "neither liberty nor justice would exist if [it] were sacrificed." *Washington v. Glucksberg*, *supra*. Nevertheless, because the federal government exclusively determines the conditions under which investigational drugs may be used prior to FDA approval, and because Congress has expressly mandated the protection of individual rights in such use under 42 U.S.C. § 289 — a mandate the Executive Branch has implemented through 45 C.F.R. Part 46 and made contractually binding via the Federalwide Assurance — the right to refuse stands on exceptionally strong constitutional footing.

It is difficult to conceive how the right could be more deeply rooted to qualify as fundamental under the Due Process Clause. This right should be developed through discovery and full adversarial briefing, not be categorically foreclosed at the pleading stage by a 120-year-old decision that predates the modern federal framework.

This Court has repeatedly recognized that the right to bodily integrity and the right to refuse unwanted medical treatment lie at the core of substantive due process. See *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261, 273 (1990); *Washington v. Glucksberg, supra*; *Albright v. Oliver*, 510 U.S. 266, 272 (1994). It is untenable to hold, on the one hand, that individuals have no constitutional

right to access investigational drugs outside the FDCA framework because it might harm them (*Rutherford, supra*; *Abigail Alliance*, *supra*), while holding, on the other, that healthy individuals may be compelled to receive investigational drugs that might result in irreparable harm — with no right to judicial redress if injured. Such a rule, if allowed to become binding precedent, would eviscerate the FDCA's protective regime and render the right to bodily integrity illusory.

The regulatory framework described hereto, authorizing the use of investigational drugs, all of which require voluntary use, together establish a uniform congressional command that no investigational drug may ever be administered except on a fully informed and voluntary basis. The language is classically rights-creating: it uses mandatory "shall" directives and speaks directly to the benefit conferred on identified individuals ("each individual," "the person," "individuals to whom the product is administered," "any person"), creating a concrete entitlement — the option to refuse — that no governmental actor may override. Congress's command functions as a statutory *Miranda* warning for investigational drugs. Just as *Miranda v. Arizona*, 384 U.S. 436 (1966), requires law enforcement to inform a suspect of the right to remain silent and ensures that any waiver is "the product of a free and deliberate choice rather than intimidation, coercion, or deception," *Berghuis v. Thompkins*, 560 U.S. 370, 382–83 (2010), the FDCA requires the government to inform every potential recipient of the right to refuse an investigational drug and prohibits coercive pressure that would destroy the meaningful exercise of that right.

Under 42 U.S.C. § 289, Congress imposes a

ministerial obligation on the Executive Branch to ensure the public's rights are protected, and the Executive Branch enforces that mandate through its FWA program. The duty to obtain "legally effective informed consent" confers upon the potential recipient the right not to be pressured or punished for refusing, which duty establishes a "legitimate claim of entitlement" to grant or withhold consent — a property interest protected by the Due Process Clause. *See Cruzan* at 270 ("the logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment."); *Board of Regents v. Roth*, 408 U.S. 564, 577 (1972); *Perry v. Sindermann*, 408 U.S. 593, 601 (1972). When Respondents conditioned Petitioners' employment and licensure on surrender of that statutorily guaranteed option, they deprived Petitioners of a right secured by federal law, which 42 U.S.C. § 1983 provides a private right of action to redress. *Health & Hospital Corp. v. Talevski*, 599 U.S. 166, 183–84 (2023).

B. The PREP Act implicates the Due Process Clause.

This Court has long held that "the hallmark [of] property ... is an individual entitlement grounded in state law, which cannot be removed except for cause." *Logan v. Zimmerman Brush Co.,* 455 U.S. 422, 430 (1982). *See also Board of Regents v. Roth* at 577. Specifically, this Court has recognized that a cause of action is a species of property protected by the Fourteenth Amendment's Due Process Clause. *See Logan* at 428. In fact, this Court, as far back as 1882, held that a "vested right of action is properly in the same sense in which tangible things are property,

and is equally protected from arbitrary interference." *Pritchard v. Norton*, 106 U.S. 124, 132 (1882).

Because a cause of action is a species of property protected by the Fourteenth Amendment, any state action that substantially interferes with an individual's claims or precludes his or her opportunity to be heard violates procedural due process. *Mullane v. Central Hanover Bank & Trust Co.,* 339 U.S. 306, 314 (1988); *Barrett v. United States,* 689 F.2d 324, 322 (2d Cir. 1982).

Petitioners expressly alleged a Constitutional right to refuse covered countermeasures under the PREP Act because the Act's grant of immunity from tort liability necessarily forces individuals to prospectively waive their constitutional right to seek judicial remedies for any injury caused by the countermeasure, its administration, or any causally connected activity. The Ninth Circuit sidestepped this allegation entirely by raising and resolving an issue no party had presented: the supposed "limit on the Congressional power to grant immunity." App. 20a.

To mandate the use of a PREP Act-covered countermeasure is, by definition, to compel a prospective waiver of due-process rights. A waiver must be "the product of a free and deliberate choice rather than intimidation, coercion, or deception." *Berghuis v. Thompkins,* at 382–83. The state may not accomplish indirectly what it is constitutionally forbidden to do directly. *See Speiser v. Randall*, 357 U.S. 513 (1958); *Bailey v. Alabama*, 219 U.S. 219 (1911). When a complaint plausibly alleges the infringement of a fundamental right, the court must apply strict scrutiny even at the pleading stage. The mandate at issue is precisely such an infringement: it conditions Petitioners' effective use of a state-

issued medical license and other state-conferred benefits under the CDC Program on the surrender of a fundamental right inherent to the use of PREP Act countermeasures. Because this allegation alone is dispositive, the panel's refusal to address it constitutes reversible error.

IV. The Ninth Circuit violated the principle of party presentation.

"In our adversarial system of adjudication, we follow the principle of party presentation." *United States v. Sineneng-Smith*, 590 U. S. 371, 375 (2020). The parties "'frame the issues for decision,'" while the court serves as "'neutral arbiter of matters the parties present.'" *Ibid.* (quoting *Greenlaw v. United States*, 554 U. S. 237, 243 (2008)). As this Court put it in *Clark v. Sweeney*, 607 U.S. 7, 9 (2025), "courts 'call balls and strikes'; they don't get a turn at bat." (quoting *Lomax v. Ortiz-Marquez*, 590 U. S. 595, 599 (2020)).

Petitioners expressly alleged a constitutional right to work within the state's licensed healthcare industry without that right being conditioned on the administration of investigational drugs or the coerced waiver of due-process protections when confronted with a PREP Act-covered counter-measure. Respondents did not dispute this allegation, nor did the district court dismiss the case on the ground that Petitioners did not hold such a right. On appeal, the Ninth Circuit transformed the case and *sua sponte* invoked *Jacobson* — a decision issued decades before the modern FDCA framework — to declare that no fundamental right to refuse investigational drugs exists and to argue a necessity defense on Respondents' behalf, to which the Court

did not provide Petitioners an opportunity to respond. Neither party had briefed or argued that *Jacobson* categorically forecloses such a right. Respondents had never contested the right, never claimed authority to override it, and never asserted that investigational drug mandates would advance a legitimate state interest sufficient to defeat it. By resolving this sweeping constitutional question on its own initiative, the Ninth Circuit violated the party presentation principle.

Compounding the error, the panel announced a novel, "clinically identical" doctrine that Congress never enacted. The Ninth Circuit's combination of *sua sponte* constitutional innovation and premature merits adjudication under Rule 12(b)(6) is precisely the sort of "drastic[]" departure from proper judicial procedure that this Court has condemned. *Sinenenq-Smith*, *supra*, at 379. By judicially creating a fourth, implied exception to 21 U.S.C. § 355(a) that Congress never enacted, and by rendering the Executive Branch powerless to enforce its congressional mandates under 42 U.S.C. § 289, the panel engaged in legislative, not adjudicative, action. The Ninth Circuit's use of its own *sua sponte* legal theory was a violation of Petitioners' Due Process rights.

The following ten cases, involving hundreds of plaintiffs represented by undersigned counsel, are poised to petition this Court or are working their way through the Ninth Circuit. They all involve nearly identical legal issues as those identified herein, and have or will be impacted by, the Ninth Circuit's ruling in this case:

- *Horsley v.* Kaiser Found. Hosps., Inc., No. 24-5812 (9th Cir. Nov. 17, 2025). *See* No. 25A880.

- *Boysen v. PeaceHealth*, No. 24-5204 (9th Cir. Dec. 3, 2025). *See* No. 25A910.
- *Roberts v. Inslee*, No. 24-1949 (9th Cir, Dec. 10, 2025). *See* No. 25A911.
- *Brock v. City of Bellingham*, No. 25-1070 (9th Cir, pending oral argument).
- *Martinez v. Eastside Fire & Rescue*, No. 25-5982 (9th Cir., briefing in progress).
- *Schroeder v. LAUSD*, No. 2:23-CV-10307 (C.D. Cal., awaiting ruling on motion to dismiss).
- *Abrigo v. Kaiser Foundation Hospitals*, No. 25-2154 (9th Cir, stayed pending instant *Curtis v. Inslee petition*).
- *Wilson v. Kaiser Foundation*, No. 2:24-cv-2142 (W.D. Wash., stayed pending instant *Curtis v. Inslee* petition).
- *McMahon v. City of Los Angeles*, No. 25-6872 (9th Cir, stayed pending instant *Curtis v. Inslee* petition).
- *Edwards v. County of Los Angeles,* No. 2:24-cv-1736 (C.D. Cal., stayed pending instant *Curtis v. Inslee* petition).

V. Dismissal with prejudice was an abuse of discretion.

Federal Rule of Civil Procedure 15(a)(2) directs that "the court should freely give leave [to amend] when justice so requires." This Court has repeatedly emphasized that this mandate reflects the fundamental principle that pleading is not "a game of skill" in which a single misstep should decide the outcome, but rather a means "to facilitate a proper decision on the merits." *Foman v. Davis*, 371 U.S. 178, 181–82 (1962). Accordingly, dismissal with prejudice on the first Rule 12(b)(6) motion — without

granting at least one opportunity to amend[35] — is strongly disfavored and ordinarily constitutes an abuse of discretion unless the complaint is incurably defective and amendment would be futile. *Id*. at 182.

Here, the district court abused its discretion by resolving the central factual dispute — whether FDA-approved COVID-19 drugs were available in the marketplace — at the pleading stage, notwithstanding judicially noticeable documents from the Executive Branch and Pfizer, Inc. confirming that no such approved products existed. The Ninth Circuit compounded this error by affirming the dismissal with prejudice, not on the grounds presented to the district court, but on a novel legal theory the panel itself advanced *sua sponte*. The outright denial of any opportunity to amend, particularly in light of the lower courts' errors, constitutes an abuse of discretion that violates this Court's settled precedents favoring liberal amendment to reach the merits.

CONCLUSION

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

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[35] The first Amended Complaint was filed at the court's direction, not at Petitioners' request.

Respectfully submitted,

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