No.

In the Supreme Court of the United States

JESSICA SWEENEY, *et al.*,
Petitioners,

v.

UNIVERSITY OF COLORADO HOSPITAL AUTHORITY, *et al.,*
Respondents.

.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Tenth Circuit erred in affirming dismissal under Federal Rule of Civil Procedure 12(b)(6) on rational-basis review where the complaint plausibly alleged that federal law and binding agreements precluded the State and its political subdivision from punishing public employees who refused to accept administration of investigational drugs or to waive rights protected by the Fourteenth Amendment.

LIST OF PARTIES TO THE PROCEEDING

Petitioners are former employees of the University of Colorado Hospital Authority (UCHA): Jessica Sweeney, Roxie Blue, Erika Bode, Amber Cano, Julie Deters-Frank, Karen Donelson, Jennifer Eddins, Polly Goodwin, Gabriel Hergenreter, Mary Lou Howard, Gwenn Hren, John Lansford, Jaime Montgomery, Erin Phipps, Kinga Shelton, Stephanie Silvers, Patricia Spoerl, Loni Thalheimer, and Alisha Torbeck.

Respondents are the University of Colorado Hospital Authority (UCHA); Elizabeth Concordia, Margaret Reidy, and Michael Randle in their official capacities as executives or board members of UCHA; Jill Hunsaker Ryan, the Executive Director of the Colorado Department of Public Health & Environment (CDPHE), in her official and individual capacities; D. Randy Kuykendall, the Director of Health Facilities and Emergency Medical Services Division of CDPHE, in his official and individual capacities; CDPHE Board Members Patricia Hammon, Raymond Estacio, Daniel Pastula, Shawn Turk, Tom Butts, Evelinn Borrayo, and Kendall Alexander, in their official and individual capacities ("Board Members")

CORPORATE DISCLOSURE STATEMENT

Petitioners are all individuals.

LIST OF DIRECTLY RELATED CASES

Jessica Sweeney, et al. v. University of Colorado Hospital Authority, et al., No. 25-1005, U.S. Court of Appeals for the Tenth Circuit. Judgment entered October 21, 2025 and published under *Timken v. S. Denver Cardiology Assocs., P.C.,* 155 F.4th 1227 (10th Cir. 2025).

Jessica Sweeney, et al. v. University of Colorado Hospital Authority, et al., No. 1:23-cv-02451-NYW-MDB, U.S. District Court for the District of Colorado. Judgment entered July 12, 2024.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Jessica Sweeney, *et al.* respectfully petition for a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Tenth Circuit, which affirmed an order granting Respondents' Rule 12(b)(6) motion to dismiss.

OPINIONS BELOW

The Tenth Circuit's opinion is published as *Timken v. S. Denver Cardiology Assocs., P.C.,* 155 F.4th 1227 (10th Cir. 2025), and appears at Appendix A. The District of Colorado's opinion is reproduced at Appendix B and can be found at *Sweeney v. Univ. of Colo. Hosp. Auth.,* 2024 U.S. Dist. LEXIS 142362 and 2024 WL 3713835.

JURISDICTION

The Tenth Circuit issued its opinion on October 21, 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 Gorsuch until February 18, 2026, No. 25A751. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Constitution, Art. VI, Cl. 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all

Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

Fourteenth Amendment, § 1

No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state 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.

42 U.S.C. § 1983

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable. For the purposes of this section, any Act of Congress applicable exclusively to the District of Columbia shall be considered to be a statute of the District of Columbia.

21 U.S.C. § 360bbb-3 (relevant excerpts)

(a) In general.

(1) Emergency uses. Notwithstanding any provision of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product. An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), 512, or 515 of this Act [21 USCS § 355, 360(k), 360b, or 360e] or section 351 of the Public Health Service Act [42 USCS § 262] or conditionally approved under section 571 of this Act [21 USCS § 360ccc] (referred to in this section as an "unapproved product"); ...

(4) Definitions. For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act.

(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).

(C) The term "product" means a drug, device, or biological product.

(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A). ...

(b) Declaration of emergency or threat justifying emergency authorized use.

(1) In general. The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of— ...

> (C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents;
>
> ...

(e) Conditions of authorization.

(1) Unapproved product.

> (A) Required conditions. With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:
>
> (i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—
>
> > (I) that the Secretary has authorized the emergency use of the product;
> >
> > (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such

benefits and risks are unknown; and

(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—

(I) that the Secretary has authorized the emergency use of the product;

(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and

(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

INTRODUCTION

This petition presents a profound question of federal law and constitutional import that warrants this Court's review: whether a state or political subdivision may condition public employment on the coerced relinquishment of the fundamental right to refuse unlicensed investigational drugs—implicating bodily integrity under the Fourteenth Amendment—and the waiver of due process rights to seek judicial remedies for resulting injuries, particularly when such mandates violate federal statutes, regulations, and binding agreements requiring voluntariness and informed consent. As one recent petition to this Court asked, "are there any meaningful limits on a government's ability to impose medical mandates in

the name of public health?" (*Health Freedom Defense Fund, Inc. v. Carvalho*, No. 25-765, petition for *certiorari* filed Dec. 23, 2025.[1])

In presenting their case to the district court, Petitioners set forth factual allegations sufficient to allow a reasonable inference that Respondents were "liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The claims were straightforward: Respondents mandated that Petitioners accept the administration of an investigational drug, disclose private health information to medical researchers, and waive their due process rights to seek judicial remedies for resulting injuries—all enforced under the PREP Act, 42 U.S.C. § 247d-6d, as a condition of continued public employment. Petitioners refused and were terminated by Respondents. Petitioners' Complaint averred that conditioning their public employment on the forfeiture of the Fourteenth Amendment right to refuse unlicensed investigational drugs under the required legal conditions, violated the Unconstitutional Conditions Doctrine, and Respondents' federal obligations.

Respondents did not contest the allegation that mandating unlicensed investigational drugs to public employees violated federal law or the Fourteenth Amendment. Instead, Respondents' motions to dismiss asserted conflicting factual allegations that other fully approved drugs were available for compliance with the mandate and that the statutes, regulations, and agreements cited by Petitioners did not create a private right of action. The Tenth Circuit, bypassing Petitioners' factual allegations, focused solely on the absence of a private right (*i.e.,*

[1] Call for response issued Feb 5, 2026.

legal theories) of action under the cited sources of authority, granting dismissal and implicitly endorsing the constitutionality of the mandates without addressing Petitioners' claims of federal prohibitions. The panel affirmed the Rule 12(b)(6) dismissal, failing to confront the allegations of unlawfulness, and erroneously claiming that Petitioners' substantive due process claims were raised for the first time on appeal—an assertion contradicted by the record.

By evading questions of lawfulness and deeming the conduct to satisfy rational basis review—despite the alleged infringements of fundamental rights to bodily integrity and due process, as well as the limits of state authority under the Supremacy Clause, U.S. Const. art. VI, cl. 2—the Tenth Circuit granted Respondents a "get out of jail free" card. Respondents were never required to justify their authority to impose such coercion in light of the Constitution and federal obligations, nor to articulate a compelling state interest for mandating unlicensed investigational drugs as a condition of public employment. The Tenth Circuit evaded meaningful review by averring that Petitioners merely "argue that an employer cannot obstruct these rights by imposing a vaccine requirement"[2] without confronting the gravamen of the case: whether Respondents could lawfully and constitutionally obstruct those rights under any circumstances, particularly through coercive mandates involving investigational drugs.

The Tenth Circuit did not merely dismiss Petitioners' Complaint under Rule 12(b)(6); it issued a substantive precedential ruling that states and

[2] App. 12a.

political subdivisions can mandate public-sector employees' use of unlicensed investigational drugs and waive due process rights to seek judicial remedies for resulting injuries, without affording discovery into Respondents' federal obligations or verifying the factual basis for Petitioners' claims. In effect, the Tenth Circuit created a new exception to the Federal Food, Drug, and Cosmetic Act's (FDCA)[3] informed consent requirements when unlicensed drugs are introduced into interstate commerce. This mirrors the judicial overreach rebuked in *United States v. Rutherford,* 442 U.S. 544 (1979), where the Tenth Circuit directed the FDA to promulgate regulations "as if" an unapproved drug had been found safe and effective for terminally ill patients. This Court unequivocally rejected such activism: "Under our constitutional framework, 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. Here, without a scintilla of discovery and absent any assertion by Respondents of authority to engage in the challenged conduct, the Tenth Circuit judicially amended the FDCA, sanctioning coercion that contravenes constitutional rights and federal mandates for voluntariness and informed consent.

Punishing public-sector employees for refusing unlicensed investigational drugs—under threat of losing their livelihoods—while stripping them of due process rights to seek judicial remedies for harms inflicted strikes at the heart of our constitutional freedoms, betraying the sacred promise of bodily autonomy and justice that every American deserves.

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[3] The Federal Food, Drug, and Cosmetic Act (FD&C Act) was enacted as Pub. L. 75-717, ch. 675, 52 Stat. 1040 (June 25, 1938), and is codified at 21 U.S.C. ch. 9, §§ 301–399i.

This is not mere policy; it is a profound assault on the dignity and security of our nation's healthcare heroes, eroding the bedrock of fairness that defines our Republic. For over 50 years, Congress has enacted safeguards to prohibit external pressure on Americans to accept investigational medical products or participate in related research activities. The allegations here are grave: Permitting the unfettered imposition of unconstitutional medical mandates risks widespread deprivations of life, liberty, and property. This Court should grant certiorari to safeguard the fundamental rights, safety, and health of the American people.

STATEMENT OF THE CASE

The underlying action challenged mandatory policies promulgated and enforced by the Respondents, CDPHE and UCHA. The Complaint alleged that the policies directly deprived Petitioners' constitutional rights, resulting in severe financial and emotional distress. Petitioners made clear that they were not challenging whether it was lawful to issue a mandate relying on FDA-licensed drugs; only whether such mandates could rely exclusively on the use of unlicensed investigational drugs that were immunized from liability under the Public Readiness and Emergency Preparedness (PREP) Act.

The Complaint alleged that Respondents' policies mandated that Petitioners be administered unlicensed investigational drugs authorized solely for emergency use under 21 U.S.C. § 360bbb-3 (the EUA statute), designated as covered countermeasures pursuant to the PREP Act, distributed exclusively through the federally funded

CDC COVID-19 Vaccination Program (CDC Program), and owned by the federal government until the point of administration. Petitioners further alleged that the CDC Program required research activities that impacted Petitioners' rights, including the disclosure of private health information to unknown persons for unspecified reasons and durations. Petitioners further averred that the State of Colorado voluntarily agreed to distribute the investigational drugs via its existing immunization program under "strictly voluntary conditions," with Respondent UCHA voluntarily participating in the CDC Program.

Respondent CDPHE filed a motion to dismiss, establishing its defense by disputing Petitioners' allegations that only unlicensed investigational drugs were available for compliance with the challenged policies. CDPHE presented their own factual allegation that "Plaintiffs had available a fully approved, and therefore not 'investigational,' vaccine available before they faced disciplinary action." Petitioners filed an opposition, informing the court that CDPHE was under a duty to comply with "any EUA." Under each EUA, Petitioners alleged, Respondents were under a ministerial obligation to "conspicuously [] state that: This product has not been approved or licensed by FDA." CDPHE further offered differing facts stating that "Plaintiffs were not subjected to medical research; they were not participants in a human trial." Petitioners' opposition corrected this mischaracterization, informing the court that research is not limited to human trials but also encompasses activities such as monitoring and reporting adverse events. CDPHE supported its Rule 12(b)(6) motion by presenting its own factual allegation that a fully approved drug

existed, rendering Petitioners' theories inapplicable to the challenged conduct. Notably, CDPHE neither asserted authority to mandate the use of unlicensed investigational drugs nor disputed Petitioners' allegations that it is unconstitutional to condition public employment on the compelled use of unlicensed investigational drugs. They simply contested Petitioners' factual allegations regarding the availability of licensed drugs.

Similarly, Respondent UCHA filed a Rule 12(b)(6) motion to dismiss, disputing Petitioners' factual allegation that only unlicensed investigational drugs were available for policy compliance, and asserting that "Plaintiffs' argument rests on the premise that UCHA's Vaccine Policy required them to take an investigational drug. Wrong. Plaintiffs could have complied with the Vaccine Policy by accepting the Pfizer-BioNTech vaccine, fully FDA-approved months before the Vaccine Policy's deadline."

Petitioners filed an opposition, informing the district court that the Pfizer-BioNTech COVID-19 Vaccine was legally distinct from the FDA-approved COMIRNATY® and that UCHA was under a ministerial obligation to conspicuously state that the Pfizer-BioNTech COVID-19 Vaccine was not approved by the FDA. UCHA also disputed Petitioners' factual allegation that the CDC Program involved medical research activities, stating that "UCHA's Vaccine Policy isn't experimental research." Petitioners' opposition corrected those mischaracterizations, stating, "Medical experimentation is entirely different from research activities" and that Petitioners never claimed that "UCHA's Vaccine Policy was 'experimental research.'" UCHA supported its Rule 12(b)(6) motion by presenting its

own factual allegation that a fully approved drug existed, rendering those theories inapplicable to the challenged conduct. UCHA neither asserted authority to mandate the use of unlicensed investigational drugs nor disputed Petitioners' allegations that it is unconstitutional to condition public employment on the compelled use of unlicensed investigational drugs.

Rather than accepting Petitioners' factual allegations as true, the district court erred by accepting Respondents' allegations and granting the Rule 12(b)(6) motions to dismiss. The court held that:

> Plaintiffs contend that this case implicates the fundamental rights of bodily autonomy and bodily integrity, and that "[r]equiring Plaintiffs to have their bodies injected with an EUA/PREP Act drug violates" these fundamental rights. [Doc. 49 at 22]. They attempt to distinguish a requirement to take "an FDA-licensed vaccine," which they concede "may require a rational basis standard," from a requirement to be "injected with an unlicensed EUA/PREP Act drug," which they insist requires a higher level of scrutiny. [*Id.*]. Plaintiffs cite no cases in support of their argument. *See* [*id.*]. The Court is not persuaded that a fundamental right is implicated in this case.[4]

Petitioners filed a timely motion under Federal Rule of Civil Procedure 59(e) to alter or amend the judgment, or alternatively, for leave to amend the complaint. The motion sought to rectify the district

[4] App. 63a.

court's failure to address Petitioners' allegations that states are lawfully prohibited from mandating the use of unlicensed drugs and PREP Act covered countermeasures, which omission resulted in a manifest error of law by effectively ruling that states may condition public employment on the relinquishment of fundamental bodily autonomy rights and judicial remedies for resulting injuries. In the alternative, a proposed amended complaint was attached. The district court denied the motion and held:

> … to the extent Plaintiffs are suggesting that the Court failed to take their allegations that the COVID-19 vaccine was investigational as true, the Court respectfully disagrees. The Court expressly considered these allegations and decided that these allegations did not change the Court's analysis.

Petitioners filed a timely appeal to the Tenth Circuit Court of Appeals, and it was was consolidated with *Timken, et al v. South Denver Cardiology Associates, et al*, No. 24-1378. The Tenth Circuit affirmed the district court's order on October 21, 2025.

REASONS FOR GRANTING THE WRIT

The petition raises unresolved issues concerning the interplay between federal statutory protections and executive agreements for investigational new drugs and medical countermeasures requiring a waiver of due process rights, and state authority to impose vaccination mandates exclusively relying on

such medical products, implicating core principles of federal authority, due process, and federal informed consent requirements. Under Supreme Court Rule 10(c), certiorari is warranted when "a state court or a United States court of appeals has decided…an important federal question in a way that conflicts with relevant decisions of this Court." The Circuit's ruling conflicts with numerous decisions of this Court.

I. Court misapplied Rule 12(b)(6).

A. To survive a Rule 12(b)(6) motion, a complaint need only provide factual content allowing a reasonable inference of the defendant's liability for the alleged misconduct—putting the defendant on notice of a Fourteenth Amendment violation—without pinning the claim to a precise legal theory.

The Tenth Circuit affirmed the district court's ruling based on two flawed premises: (1) it dismissed Petitioners' Fourteenth Amendment claims by implicitly carving out an exception to the FDCA's informed consent requirements, in which Petitioners have a property interest, thereby empowering states to violate constitutional and federal obligations, undermining the Supremacy Clause (U.S. Const. art. VI, cl. 2), and (2) it rejected the legal theories (e.g., federal statutes, regulations, and agreements) underpinning Petitioners' claims without addressing whether factual allegations that the federal government prohibits states and political subdivisions from mandating investigational drugs

are plausible. This faulty approach renders Fourteenth Amendment violations nearly impossible to prove because it presumes that the challenged conduct falls within a state's authority depriving Petitioners of their property interest in federal statutes and program and precluding any inquiry into federal constraints on states' powers or into the infringement of fundamental rights.

At the pleading stage, dismissal for failure to properly plead a *legal theory* is improper. *See Bell Atlantic v. Twombly*, 550 U.S. 544 (2007). (Rule 12(b)(6) requires only a "reasonable expectation that discovery will reveal evidence" of the claim, not a premature merits resolution) and *Iqbal*, *supra.* (courts must accept factual allegations as true and draw inferences in the plaintiff's favor, evaluating only facial plausibility.) *See also Skinner v. Switzer*, 562 U.S. 521, 530 (2011) ("Skinner's complaint is not a model of the careful drafter's art, but under the Federal Rules of Civil Procedure, a complaint need not pin plaintiff's claim for relief to a precise legal theory ... See 5 C. Wright & A. Miller, Federal Practice & Procedure §1219, pp. 277–278 (3d ed. 2004 and Supp. 2010)." In *Johnson v. City of Shelby*, 574 U.S. 10, 11 (2014) (per curiam), this Court held, "Federal pleading rules call for 'a short and plain statement of the claim showing that the pleader is entitled to relief,' Fed. Rule Civ. Proc. 8(a)(2); they do not countenance dismissal of a complaint for imperfect statement of the legal theory supporting the claim asserted." *See also McBeth v. Himes*, 598 F.3d 708, 716 (10th Cir. 2010) ("Generally, failure to set forth in the complaint a theory upon which the plaintiff could recover does not bar a plaintiff from pursuing a claim." (quoting *Elliott Indus. Ltd. P'ship v. BP Am. Prod. Co.*, 407 F.3d 1091, 1121 (10th Cir.

2005)).

Moreover, as succinctly stated by the Seventh Circuit court of appeals in *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."

Therefore, the Tenth Circuit misapplied the Rule 12(b)(6) standard when it affirmed the district court's ruling on the basis of Petitioners' imperfect legal theories.

B. The Tenth Circuit erred by issuing a ruling on an argument not advanced by the public employees and not disputed by Respondents.

Reviewing the Tenth Circuit's opinion, a hidden but substantive ruling emerges. Although ambiguous in its approach, the decision reveals unspoken truths: First, the Circuit affirmed that Petitioners' allegations implicated the right "to refuse unwanted investigational drug treatments."[5] (emphasis added). It further upheld the district court's application of rational basis review to the Respondents' conduct. From these holdings, two critical inferences arise: first, the panel implicitly concluded that coercing individuals to accept investigational drugs and covered countermeasures falls within the power of a

[5] App. 20a.

state or political subdivision (as rational basis review presupposes actions within the bounds of state power, *see* Supremacy Clause, U.S. Const. art. VI, cl. 2); and second, public-sector employees do not have a fundamental right to bodily autonomy in refusing investigational drugs (as rational basis does not apply when fundamental rights are implicated, triggering strict scrutiny instead. *See Washington v. Glucksberg,* 521 U.S. 702 (1997) (bodily integrity as a core liberty interest demanding narrow tailoring to a compelling interest)).

The Public Employees' challenge did not contest Respondents' authority to mandate vaccination with a fully licensed drug. Instead, they argued solely that Respondents lacked the authority to require them to accept the administration of an investigational EUA/PREP Act drug. The Tenth Circuit, therefore, should have limited its analysis to the specific issue of investigational status, rather than addressing vaccination mandates in general. This Court reaffirms that Petitioners, as "masters of their complaint," determine the legal theories and factual claims that define their case. *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). Respondents pointed to no part of the record disputing Petitioners' assertions that it is unlawful and unconstitutional for a state or its political subdivision to coerce individuals into accepting federally funded EUA/PREP Act drugs through external pressure or punishment for refusal. Nor did Respondents identify any argument that such conditions serve a legitimate governmental interest. Respondents' defense against the Fourteenth Amendment claims rested entirely on the premise that the drugs at issue were approved under 21 U.S.C. § 355 *et seq*., and not unlicensed products lacking any approved "legal indication to

treat, cure, or prevent any disease" per their labeling.[6] The Tenth Circuit overlooked these contentions. While acknowledging the drugs' investigational nature, it failed to address cited federal statutes and agreements plausibly proving that public employers cannot list such product under a legal requirement subject to penalty.

The Tenth Circuit justified its decision, stating: "Sweeney cite[s] [to] no authority and make[s] no argument that the vaccination policies are not rationally related to any legitimate government interest."[7] This statement is demonstrably disputed by the record. Petitioners cited numerous authorities establishing that vaccination policies cannot include unlicensed investigational drugs, PREP Act countermeasures, or drugs granted exceptions under 21 U.S.C. § 355(a).[8] Therefore, the Tenth Circuit abused its discretion by affirming the district court's *sua sponte* application of rational basis review to the challenged conduct, as it prematurely resolved merits issues without accepting as true Petitioners' well-pleaded allegations of deprivation of fundamental rights and violation of federal statutes—contravening the Rule 12(b)(6) standard that demands evaluation of facial plausibility alone, not substantive validity. See *Iqbal*, *supra* (courts must "assume the veracity" of factual allegations and avoid merits adjudication at dismissal stage).

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[6] ECF No. 1 ¶ 62.
[7] App. 22a.
[8] ECF No. 1 – see generally.

C. Implicated fundamental rights preclude application of rational basis review as grounds for dismissal under Rule 12(b)(6).

To state a cause of action under Section 1983 for violation of the Due Process Clause, Petitioners' complaint must implicate a recognized liberty or property interest within the purview of the Fourteenth Amendment. *See Ingraham v. Wright,* 430 U.S. 651, 672 (1977). This Court has expanded the definition of "liberty" beyond the core textual meaning of that term to include not only the privileges expressly enumerated by the Bill of Rights but also the fundamental rights implicit in the concept of ordered liberty, deeply rooted in this nation's history and tradition under the Due Process Clause. *See, Glucksberg, supra*; *Hewitt v. Helms,* 459 U.S. 460, 466 (1982); *Moore v. City of East Cleveland,* 431 U.S. 494, 503 (1977).

The Fourteenth Amendment's Due Process Clause provides that no state shall "deprive a person of life, liberty, or property without due process of law." The Supreme Court has noted that the substantive component of the Due Process Clause "protects individual liberty against certain government actions regardless of the fairness of the procedures used to implement them." *Collins v. City of Harker Heights,* 503 U.S. 115, 125 (1992) (citing *Daniels v. Williams,* 474 U.S. 327, 331 (1986)).

1. Bodily integrity

"The protections of substantive due process have, for the most part, been accorded to matters relating to marriage, family, procreation, and the right to

bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994).

Contrary to Petitioners' allegations, the district court held: "the right implicated here is not the right to bodily autonomy or bodily integrity, but the right to continued employment at UCHA without receiving the COVID-19 vaccine."[9] Yet, Petitioners' allegations were unambiguous:

> Plaintiffs adamantly assert that an individual has the absolute Constitutional and federally secured right to refuse the administration of an Emergency Use Authorization (EUA) drug (e.g., Pfizer BioNTech COVID-19 Vaccine), biologic, or device (e.g., EUA testing articles and masks) or a 'covered countermeasure' under PREP Act immunity without incurring a penalty or losing a benefit to which they are otherwise entitled and that such a right is not dependent upon a person seeking a religious or medical exemption.[10]

Petitioners further alleged that "the State of Colorado, and UCHA, a political subdivision of the State, unassailably imposed conditions requiring Plaintiffs to relinquish their constitutional rights as a condition to continue employment in their chosen profession."[11] Finally, Petitioners alleged, "Plaintiffs were not allowed to continue employment unless they voluntarily surrendered their Constitutional protections."[12] Despite these allegations, the district

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[9] App. 63a.
[10] ECF No. 1 ¶ 21.
[11] ECF No. 1 ¶ 286.
[12] ECF 1, ¶ 372.

court reframed Petitioners' allegations as being based on a right of continued employment. The Tenth Circuit followed suit, quoting the district court: "Since 'neither the expectation of employment, nor continued employment, is a fundamental right,' the district courts applied rational basis review."[13]

Count Five of the Complaint, entitled "Unconstitutional Conditions Doctrine," relied upon *Frost Trucking Co. v. R.R. Com*, 271 U.S. 583 (1926). In *Frost*, this Court held that the state "may not impose conditions which require the relinquishment of constitutional rights" as a condition of enjoying a privilege granted by the state. Thus, Petitioners were clear from the beginning of the case that public employment was the privilege granted by the state, not the "right implicated here." The right implicated is that of bodily autonomy and integrity, and due process to seek judicial remedies for resulting injuries as guaranteed by the Fourteenth Amendment, such that Petitioners cannot be required to relinquish that right in order to continue enjoying their privilege of state employment.

This Court "has regularly observed that the [Fourteenth Amendment] specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition. *See, e.g., Moore* v. *East Cleveland, supra*, at 503 (plurality opinion); *Glucksberg*, *supra*. Petitioners explained to the Tenth Circuit that "legally effective informed consent" is a property interest in bodily autonomy and medical decision-making rights, deeply rooted in the nation's history. Because the courts below recast Petitioners' allegations from a fundamental right to bodily

[13] App. 21a.

integrity to a claim of public employment, they failed to analyze the Unconstitutional Conditions Doctrine and how Respondents violated it.

It is well-established by this Court that bodily integrity is a fundamental right protected by the Due Process Clause.[14] Accordingly, complaints plausibly alleging such infringements must survive Rule 12(b)(6) dismissal, as the pleading stage evaluates only whether the facts, accepted as true, state a claim that the infringement fails this exacting standard, permitting discovery for merits resolution. *See Iqbal, supra.* Investigational drugs are not approved for any legal indication, safety, nor assigned known medical contraindications. As explained in Petitioners' Complaint, the potential harm to an individual is incalculable.

Therefore, States and political subdivisions are in no position to assess whether an investigational drug—lacking full FDA approval and labeling for contraindications—will or will not deprive individuals of their life, liberty, or property. "Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk." *Rutherford*, *supra.* Petitioners alleged that Respondents' mandate and its enforcement violated their Fourteenth Amendment rights, including their fundamental right to bodily integrity. The Tenth Circuit erred in dismissing the claim under Rule 12(b)(6) by holding that such a mandate was rationally related to a legitimate state interest, without requiring substantiation of these assertions through discovery or evidentiary development.

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[14] *Cruzan v. Director, Missouri Dep't of Health*, 497 U.S. 261 (1990); *Glucksberg, supra; Albright v. Oliver, supra.*

2. Privacy

As previously discussed, Petitioners alleged that the drugs were only offered through the CDC COVID-19 Vaccination Program. This program required Petitioners to submit "private health information to be collected, studied, and shared with unknown persons for unknown reasons for an unknown length of time." To condition public employment on the relinquishment of private health information under such medical research conditions as a condition of public employment would constitute an invasion of Petitioners' fundamental rights to privacy. *See Griswold v. Connecticut,* 381 U.S. 479, (1965). Such actions permit the state to do indirectly what it may not do directly. *See Bailey v. Alabama*, 219 U.S. 219 (1911). The factual allegations implicate a privacy interest in refusing to participate in the CDC Program.

3. Due Process

The Due Process Clause of the Fourteenth Amendment guarantees that no State shall "deprive any person of life, liberty, or property without due process of law." U.S. CONST. amend. XIV, §1, cl. 3. Petitioners alleged that "Defendants' pronouncement that Plaintiffs must participate in covered countermeasures prospectively denies Plaintiffs their due process rights should they incur injury because the PREP Act denies them access to judicial relief for those injuries."[15] The Tenth Circuit affirmed as much, holding "The statute asserts that the 'sole exception' to its immunity grant is an 'exclusive

[15] ECF 15, p. 54.

Federal cause of action … for death or serious physical injury proximately caused by willful misconduct.'"[16] However, the panel did not address the Act's preemption of Petitioners' due process rights. Rather, it sidestepped the issue by focusing on the Act's express preemption clause and whether it conferred a private right of action, and its prohibition of bringing most tort claims for related injuries without discussing how those facts implicate Petitioners' due process rights. Petitioners alleged that the PREP Act does not deprive a person of their property interest it requires only voluntary participation (42 U.S.C. §247d-6e(c)), but that Respondents, acting under color of law and requiring Petitioners to use a covered countermeasure under threat of penalty, required Petitioners "to nonconsensually surrender their due process rights under the Act."

A state cannot use a vaccination requirement to produce a result that it could not command directly. *Speiser v. Randall*, 357 U.S. 513 (1958). States cannot punish nonconsenting public-sector employees, thereby depriving them of their Fourteenth Amendment right to due process.[17] This Court has held that "[b]y agreeing to pay, nonmembers are waiving their First Amendment rights, and such a waiver cannot be presumed." *Janus v. AFSCME*, 585 U.S. 878 (2018). In this case, participating in the CDC Program requires a waiver

[16] App. 16a.

[17] "A waiver must be "voluntary in the sense that it was the product of a free and deliberate choice rather than intimidation, coercion, or deception," and "made with a full awareness of both the nature of the right being abandoned and the consequences of the decision to abandon it." *Berguis v. Thompkins*, 560 U.S. 370, 382–83 (2010).

of due process rights relating to the countermeasure, and it violates Petitioners' Fourteenth Amendment rights when terminated from public employment for failing to waive that right.

Although the Tenth Circuit acknowledged the effective legal result of receiving the administration of the PREP Act's countermeasures, it failed to address the dispositive issue that Respondents' mandates indirectly compelled Petitioners to prospectively waive their substantive due process rights to access the courts for judicial relief in the event of injury arising from such participation—a clear abuse of discretion.

4. Procedural Due Process

Under *Lane v. Franks*, 573 U.S. 228, 236 (2014), this Court held that it "has cautioned time and again that public employers may not condition employment on the relinquishment of constitutional rights." It also held, "For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, 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 (1972). When, as alleged in the Complaint,[18] states agreed to participate in the CDC COVID-19 Vaccination Program, the states agreed that potential recipients of the Program's investigational drugs had the option to accept or refuse without pressure or penalty. The option to

[18] ECF No. 1 ¶¶ 220, 282, 271, 218

accept or refuse is a constitutionally protected property interest for the potential recipient in the federal program. As such, for any potential recipients who are public employees, they cannot be required to relinquish that property interest as a condition of continuing public employment.

The Tenth Circuit held that "[t]he district court found that Sweeney abandoned her procedural due process claim by failing to respond to the defendants' arguments challenging the claim in their motions to dismiss…Thus, Sweeney's procedural due process claim is waived, and we will not consider it."[19] Respondents' defenses, including those targeting the procedural due process claims, rested entirely on the premise that the drugs at issue were approved (*i.e.,* licensed). Petitioners were not required to respond to inapplicable arguments that did not address their core claims concerning the challenged conduct. Thus, it is impossible to waive a claim through non-response when Respondents failed to challenge the actual allegations presented. Petitioners plausibly alleged a protected property interest in continued public employment and effective use of their state-issued health license, which creates an entitlement to pre-deprivation notice and a meaningful opportunity to be heard under the Fourteenth Amendment. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985) (public employees with a property interest "must be given oral or written notice of the charges against [them], an explanation of the employer's evidence, and an opportunity to present [their] side of the story" before termination). Here, the mandates coerced waivers of judicial remedies for injuries from investigational drugs

[19] App. 20a.

under the PREP Act, and loss of informed consent property interests without any kind of hearing. The Tenth Circuit abused its discretion by deeming Petitioners' claims waived on the basis that they failed to respond to Respondents' arguments in opposition to dismissal—arguments that were inapplicable to the core allegations concerning investigational drugs, as they presupposed the products were fully licensed and thus did not engage the dispositive issues of federal preemption, voluntariness, and fundamental rights.

II. The Tenth Circuit failed to address the scope of Respondents' authority.

The Tenth Circuit's ruling sidestepped the critical question of Respondents' authority to establish requirements that conflict with the duties imposed by Congress on the Executive Branch. "[A] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal, supra* at 678. By implying that states and political subdivisions can require public employees to use immunized investigational drugs as a condition of employment, and by disregarding Petitioners' allegations that such coercive measures contravene federal requirements to the contrary, the court foreclosed Petitioners' opportunity to prove misconduct through discovery. Denying the opportunity to develop evidence undermines the pursuit of justice, as discovery will delineate the scope of Respondents' discretionary and non-discretionary duties—matters central to resolving the case. "Ministerial acts are unshielded by qualified immunity, which protects

'only actions taken pursuant to discretionary functions.'" *Groten v. California*, 251 F.3d 844 (9th Cir. 2001). Moreover, discovery will provide greater clarity on the nature and extent of federally funded benefits to which Respondents may be entitled, further supporting claims of protected property interests.

A. Federal Food, Drug and Cosmetic Act.

"No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug." 21 U.S.C. § 355(a).

Congress provides three exceptions to this prohibition:

(1) 21 U.S.C. § 355(i) authorizes research use, subject to informed consent;

(2) 21 U.S.C. § 360bbb *et. seq*. authorizes single-patient or small-group medical emergency use only when performed by state-licensed healthcare physicians, subject to informed consent protocols outlined under 21 U.S.C. 355(i).

(3) 21 U.S.C. § 360bbb-3 authorizes broad population access during chemical, biological, radiological, nuclear, or pandemic events, subject to the Secretary ensuring that potential participants are informed of their option to refuse.[20] Congress expressly restricts the Secretary's authority to mandate any person's participation in authorized activities,[21] including the use of such products. These

[20] Project BioShield Act of 2004 is codified as Public Law No. 108-276, 118 Stat. 835.

[21] "Nothing in this section provides the Secretary any authority

conditions comply with the legally effective informed consent standard.

This Court has held:

> [T]he [FDCA] 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.

Rutherford, *supra*. Since that ruling, Congress has established conditional exemptions under 21 U.S.C. § 360bbb(a) (expanded access to unapproved therapies) and § 360bbb-3(a) (emergency use authorizations). Under § 360bbb(b)(4), Congress requires the Secretary to ensure that "the sponsor, or clinical investigator, of the investigational drug...submits to the Secretary a clinical protocol consistent with the provisions of section 355(i)." No person may access such drugs, even during a medical emergency, until "after complying with the provisions of this subsection." *Id*. § 360bbb(b).

Under 21 U.S.C. § 360bbb-3, Congress imposed "required conditions" (§ 360bbb-3(e)(1)(A)) upon the Secretary as ministerial obligations to fulfill prior to introducing EUA products into interstate commerce. Among these, the Secretary must establish:

> (1) "[a]ppropriate conditions designed to ensure that individuals to whom the product

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to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section." 21 U.S.C. § 360bbb-3(l).

> is administered are informed" (*Id.* § 360bbb-3(e)(1)(A)(ii));
> (2) "that the Secretary has authorized the emergency use of the product" (*Id.* § 360bbb-3(e)(1)(A)(ii)(I));
> (3) "of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown" (*Id.* § 360bbb-3(e)(1)(A)(ii)(II)); and
> (4) "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks" (*Id.* § 360bbb-3(e)(1)(A)(ii)(III)).

During a declared emergency, the Secretary has exclusive and discretionary authority to establish the required conditions for the introduction into interstate commerce of drugs, biologics, and devices not approved by the FDA for their intended emergency use. Those established conditions are outlined in an authorization letter to the manufacturer, which details who can participate in which activity and under what conditions. The manufacturer and persons acting under the letter's authority are bound by the terms of the letter. The letter represents the Executive Branch's determination of how the product should be introduced into interstate commerce and under what conditions. However, the Executive Branch has no authority "to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section." (§ 360bbb-3(*l*)). It

cannot require any person to manufacture, ship, or accept the administration of the product. (§360bbb-3(e)(1)(A)(ii)(III)). Therefore, the Court's analysis in *Rutherford*, *supra*, is revealing in this case. Just as Congress provided no exception to terminally ill persons at that time, Congress has provided no exception to the administration of an unapproved product to a person without informed consent, and states and political subdivisions cannot establish a legal requirement eliminating the option to refuse. That option must be part of the condition permitting the product's introduction into commerce. Once the option is given, it cannot be removed through a civil penalty. As previously discussed, "A waiver must be 'voluntary in the sense that it was the product of a free and deliberate choice rather than intimidation, coercion, or deception,' and 'made with a full awareness of both the nature of the right being abandoned and the consequences of the decision to abandon it.'" *Berguis v. Thompkins*, *supra*. "In order for a waiver to be meaningful, notice of the right must also be combined with a meaningful opportunity to exercise that right."[22]

The Tenth Circuit did not describe the legal basis for permitting the State of Colorado and its political subdivisions to establish legal requirements conflicting with the FDCA's informed consent mandates for unapproved drugs, nor did it address those issues raised in Petitioners' appeal brief. This Court has routinely struck down state laws conflicting with the FDCA under the Supremacy Clause. *See Buckman Co. v. Plaintiffs' Legal Comm.*,

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[22] Brief for Pacific Legal Foundation as *Amicus Curiae* Supporting Petitioners, *Bennett v. AFSCME Council 31*, Nos. 20-1603 & 20-1786 (U.S. Aug. 25, 2021) citing to *Miranda v. Arizona*, 384 U.S. 436, 479 (1966).

531 U.S. 341, 348 (2001) (preempting state fraud-on-the-FDA claims as conflicting with federal enforcement authority); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (preempting state tort claims imposing requirements "different from, or in addition to" federal device regulations); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (preempting state failure-to-warn claims for generic drugs due to impossibility of compliance with both state and federal law). The Tenth Circuit's ruling that Respondents' investigational drug mandate served a legitimate state interest constitutes reversible error, as it creates an unconstitutional exception to 21 U.S.C. § 355(a) (prohibiting introduction of unapproved new drugs into interstate commerce absent the option to refuse). *See Rutherford, supra.* (rejecting judicially implied exceptions to FDCA approval requirements, as such policy decisions are for Congress); *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 713 (D.C. Cir. 2007) (*en banc*) (affirming no constitutional right to unapproved drugs outside FDCA framework, as "the FDCA's comprehensive scheme" occupies the field), *cert. denied*, 552 U.S. 1159 (2008).

B. Federalwide Assurance Program.

The Tenth Circuit held that "[s]ince the FWA argument is new and was not made before the district court, we deem it waived as well."[23] This assertion is demonstrably false. The Federalwide Assurance (FWA) program is referenced on 19 pages of Petitioners' complaint, including a detailed

[23] App. 27a.

description of the program as a matter of first impression,[24] CDPHE's specific contract number with supporting allegations,[25] and UCHA's contract number with corresponding allegations.[26] Petitioners alleged that Respondents assured the federal government that they would not place individuals under "sanctions," "coercion," "undue influence," or "unjustifiable pressures" to participate in the use of an investigational new drug, biologic, or device when federal funding or authority is involved. Petitioners quoted the CDC's statement that the federal government purchased all the drugs and retained ownership until the point of human administration.[27] These allegations plausibly establish a set of facts demonstrating Respondents' liability for Petitioners' economic and emotional damages, as Respondents acted in violation of their FWA agreement when applying external pressure and punishing Petitioners for refusing to accept the administration of an investigational drug and or to participate in federally funded research activities. The Tenth Circuit committed an abuse of discretion when failing to address Petitioners' FWA claims.

C. CDC COVID-19 Vaccination Program.

Petitioners unambiguously alleged in their complaint that, under the CDC COVID-19 Vaccination Program, Respondents "agreed to execute the Secretary's conditions of authorization, including informing individuals of their right to exercise the option to accept or refuse the Program's

[24] ECF No. 1 at 41-44.
[25] ECF No. 1 ¶ 271.
[26] ECF No. 1 ¶ 218.
[27] ECF No. 1 ¶ 172.

products." They further averred that the enforcement of Respondents' mandates violated Plaintiffs' statutory right to refuse EUA/PREP Act drugs, their programmatic rights to refuse CDC Program drugs without incurring a fee, penalty, or losing a benefit to which they are otherwise entitled, and their Fourteenth Amendment rights to substantive and procedural due process and to be treated equally before the law. The Tenth Circuit held that "Sweeney did not adequately raise this issue in her brief, so she waived this claim."[28]

The court did not address Petitioners' allegation that "Defendants are completely preempted from establishing legal requirements that conflict with the federal goals under the CDC Program and applicable laws," which is a dispositive issue. Petitioners alleged that Respondents issued a policy that was an "'overt threat of harm' to the financial and emotional well-being [of Petitioners] for the express purpose of coercing them to participate in the CDC COVID-19 Vaccination Program outside of their free will and voluntary consent."[29] Petitioners further averred that using one of the Program's drugs required them to waive "civil litigation rights resulting from injuries," permit medical researchers to use "their private identifiable information to be collected and used for a variety of purposes by unknown persons," "allow[] their involvement with the EUA product to be cataloged by various persons for unknown purposes," "allow[] the data collected about their adverse events to be utilized by researchers for unknown purposes and eternity," and assume "greater risks to their safety, health, and legal rights."[30] Discovery will

[28] App. 29a.
[29] ECF No. 1 ¶ 392.
[30] ECF No. 1 ¶ 163.

define the parameters of Petitioners' property interest in the federal program and Respondents' duties to abstain from terminating Petitioners' public employment for exercising federally funded benefits to receive medical counseling and declining to participate. By deeming the claim waived despite its clear pleading, the Tenth Circuit improperly elevated form over substance, denying Petitioners their due process right to have their plausible allegations fairly adjudicated.

D. PREP Act's Express Preemption Clause.

The Tenth Circuit failed to address Petitioners' allegation that the PREP Act's express preemption clause prohibits states and political subdivisions from mandating the use of products authorized under 21 U.S.C. § 360bbb-3 when designated as covered countermeasures.

> 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…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." ("FDCA").

42 U.S.C. § 247d-6d(b)(8)).

The Secretary's ministerial obligation to ensure potential participants are informed of their option to refuse constitutes a "requirement applicable to the countermeasure" under the FDCA. *Id.*; see also 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) (mandating disclosure of "the option to accept or refuse administration"). Therefore, if the challenged conduct was prohibited as a matter of law, Respondents acted outside their lawful authority in terminating Petitioners' employment for choosing an option to refuse that the Secretary established for their benefit under federal authority. Furthermore, Congress places the Secretary under a ministerial duty to educate potential recipients about "the voluntary nature of the program," 42 U.S.C. § 247d-6e(c). States are precluded from interfering with that ministerial duty by establishing legal requirements that punish individuals who refuse to participate voluntarily. The PREP Act's purpose—to facilitate rapid deployment without liability—does not extend to forcing participation

Forcing individuals to accept the administration of an investigational drug while compelling them to waive their due process rights to seek judicial remedies for resulting injuries would evoke the hallmarks of an oppressive regime, fundamentally incompatible with American constitutional values. Such coerced waivers are impermissible under the Fourteenth Amendment's Due Process Clause, as they undermine the right to bodily integrity and meaningful access to the courts. *See Glucksberg, supra.* The Tenth Circuit abused its discretion by failing to address the PREP Act's express preemption clause in relation to Petitioners' allegation that the challenged mandates are unlawful and

unconstitutional as a matter of law.

* * * *

Pursuant to the standard governing motions to dismiss under Federal Rule of Civil Procedure 12(b)(6), a complaint survives if "relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984). The substantive due process rational basis test, applicable to certain Fourteenth Amendment claims, does not abrogate the procedural protections inherent in this capacious Rule 12(b)(6) paradigm. As the Seventh Circuit has elucidated, "[t]he Rule 12(b)(6) inquiry 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." *Wroblewski, supra* (quoting *Hishon*, 467 U.S. at 73). As previously discussed, Petitioners advanced numerous factual averments that plausibly evince Respondents' incapacity to proffer any conceivable rational basis for the mandate in harmony with the Fourteenth Amendment's Due Process Clause and the Supremacy Clause, U.S. Const. art. VI, cl. 2. These assertions include Respondents' prohibition from promulgating such legal requirements that violate Petitioners' fundamental right to bodily autonomy and that violate Respondents' Federalwide Assurance commitments (See "assurance" under 42 U.S.C. § 289 and 45 C.F.R. § 46.103), the covenants embedded within the CDC COVID-19 Vaccination Program Provider Agreements, and the explicit preemption proviso of the PREP Act, which expressly

preempts state laws or requirements that conflict with federal stipulations regarding covered countermeasures, including their administration and informed consent protocols under the FDCA. Moreover, the mandates usurp the nondiscretionary obligations incumbent upon the Secretary of Health and Human Services, as ordained by Congress, to safeguard informed and voluntary consent for investigational drugs not approved for interstate commerce pursuant to 21 U.S.C. § 355(a), as augmented by the emergency use authorization framework under 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), which mandates disclosure of the option to refuse the administration of the drugs.

The district court, in declining to base its ruling on these well-pleaded facts, rendered a *sua sponte* determination that was manifestly erroneous at the pleading stage, effectively sanctioning conduct that violates Petitioners' fundamental rights under the Fourteenth Amendment and federal statutory and regulatory schemes. The Tenth Circuit, in affirming this disposition while similarly disregarding factual allegations sufficient to withstand Rule 12(b)(6) scrutiny, erroneously endorsed the district court's unprompted invocation of rational basis—a defense not advanced by any Respondent. It is axiomatic that a state's police power, though broad, remains subordinate to constitutional constraints, including federal supremacy. See *Arizona v. United States*, 567 U.S. 387, 394, 416 (2012) ("There is no doubt that Congress may withdraw specified powers from the States by enacting a statute containing an express preemption provision"; "[t]he State may not pursue policies that undermine federal law"; "[s]tates are precluded from regulating conduct in a field that Congress, acting within its proper authority, has

determined must be regulated by its exclusive governance."). There can be little argument that since Congress enacted the FDCA, the federal government has exercised broad, undisputed power over drug regulation. This Court should remand for further discovery of facts to ensure Petitioners' fundamental rights and the interests of the United States Government are protected.

CONCLUSION

This Court should grant *certiorari*.

Respectfully submitted,

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