No. _____

In the Supreme Court of the United States

MALCOLM JOHNSON, *et al.*,
Petitioners,

v.

TINA KOTEK, in Her Official Capacity as Governor of Oregon, SEJAL HAITI, in Her Official Capacity as Director of the Oregon Health Authority, *et al.*,
Respondents.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

The well-established law is that medical experimentation on humans cannot be performed without informed consent, or with any degree of duress or coercion. COVID-19, however, turned the world upside down and government officials began to order injections of experimental vaccines on penalty of losing one's job. Oregon's executive officials mandated all executive branch employees, healthcare workers, and school employees be vaccinated for COVID-19. These mandates were deliberately calculated acts with knowledge that the only vaccines available to satisfy the mandate were experimental. This abrogation of the right of informed consent was not only unconstitutional, but a violation of the federal statute authorizing emergency use of experimental vaccines.

QUESTION 1: What is the proper standard of review for a Fourteenth Amendment Due Process challenge to a State official's order that individuals be injected with experimental drugs?

QUESTION 2: Is petitioners' right to informed consent protected by the Privileges or Immunities Clause of the Fourteenth Amendment?

QUESTION 3: Can qualified immunity apply to a premeditated "mandate" made with knowledge that it violated constitutional and statutory rights as well as fundamental human rights?

QUESTION 4: Does a private right of action exist for violation of rights under 21 U.S.C. § 360bbb-3 via 42 U.S.C. § 1983?

PARTIES TO THE PROCEEDING

Petitioners are Malcom Johnson, Stephanie Kaiser, Jessie Clark, Christina Carmichael, Tara Johnson, Kathleen Sanders, Dr. F, Travis Brenneman, Ms. D, Linda Riser, Chad Dillard, Heidi Hopkins, Glenn Hopkins, Leann Wagerle, Teresa Lynn Karn, Boaz Miller, Candy Barnett, Laine Ewry, Margaret Henson, Melissa Swancutt, Ms. B, Wendy Sumner, Adrian Park, Dr. C, Kimberly Swegar, Kelly Hickman, Ms. E, Gail Giltner, Ms. G, Jennifer Brier, Melanie Crites-Bachert, D.O., Marti Lamb, Mary Gabriele, M.D., Elisabeth Coates, Kori DiStefano, Terese Lampa, Jazmin Graff, M.D., Terri Kam, Stephanie Nyhus, Dr. A, David West, Nate Lyons, Susan Burdick, Alyssa Lake, Debra Burdette, Ms. H, Daniel Paul Penna, Ms. J, Janira Brannigan, Amanda Gayken, Karen Carreira, Ms. K, Dr. Shane Baker, Mitchell Moore, Andriele Stodden, Kristin Dill, Carrie Howe, Stacy Fletcher, Lucero Terrazas, Elaine Atkinson, Serena Bordes, Dean Johnson, Dr. Greg Nigh, Tailer Hart, Ms. L, Ms. M, Ms. N, Christina Tressel, Carolyn Brown, Amethyst White, Cassandra Dyke, Tamara Miletich, Free Oregon, Children's Health Defense, Oregon, and Jane/John Does 1 – 1000.

Respondents are Tina Kotek, in her official capacity as Governor of the State of Oregon; Sejal Hathi, in her official capacity as Director of the Oregon Health Authority; Kate Brown, former Governor of the State of Oregon, in her personal capacity; Patrick Allen, former Director of the Oregon Health Authority, in his personal capacity.

CORPORATE DISCLOSURE STATEMENT

Pursuant to this Court's Rule 29.6, petitioners state:

Petitioner Free Oregon has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock. Petitioner Children's Health Defense, Oregon has no parent corporation, and no publicly held corporation owns 10 percent or more of its stock. All other petitioners are individuals.

LIST OF DIRECTLY RELATED CASES

Johnson et al. v. Brown et al., No. 3:21-cv-1494, U.S. District Court for the District of Oregon. Judgment entered July 5, 2022.

Johnson et al. v. Kotek et al., No. 22-35624, U.S. Court of Appeals for the Ninth Circuit. Judgment entered February 23, 2024.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Malcolm Johnson, *et al.* respectfully petition for a writ of certiorari to review a judgment of the Ninth Circuit Court of Appeals.

OPINIONS BELOW

The Ninth Circuit's opinion is available at 2024 U.S. App. LEXIS 4196 (9th Cir. Feb. 23, 2024), and is reproduced at Appendix B. The Ninth Circuit's denial of petitions for panel rehearing and rehearing en banc is available at 2024 U.S. App. LEXIS 7974 (9th Cir. Apr. 3, 2024), and is reproduced at Appendix A. The District of Oregon's opinion is available at *Johnson v. Brown*, 614 F. Supp. 3d 776 (D. Or. 2022), and is reproduced at Appendix C.

JURISDICTION

The Ninth Circuit denied the petitions for rehearing on April 3, 2024. On June 18, 2024, Justice Kagan granted an extension of time to file this petition for writ of certiorari to August 13, 2024, No. 23A1120. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. CONSTITUTION, Amendment XIV, § 1
All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. 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.

Provisions in Appendix D:

Provisions in Appendix E:

STATEMENT OF THE CASE

Petitioners were subjected, under color of state law, to Oregon COVID-19 vaccine "mandates" — executive branch orders from Oregon's governor and health authority — compelling three separate groups (school employees, health workers, and state employees) to take COVID-19 "vaccines" and provide proof of compliance by October 18, 2021. The penalty for failure to comply was the loss of one's job.

At all times, the only *available* COVID-19 vaccines in the United States were *unapproved* pursuant to federal law, and only allowed to be distributed under the emergency use exception of FDCA § 546, meaning that, by definition, they were and are experimental drugs.

Each of the individual petitioners was subject to the vaccine mandates and each was damaged. Many lost their jobs (irrespective of whether they claimed a religious exemption), several submitted to the mandates and subsequently sustained vaccine injuries, some continued to work but were discriminated against because they were unvaccinated.

On October 13, 2021, petitioners brought suit under 42 U.S.C. § 1983 against the Governor of Oregon and the Director of the Oregon Health Authority in their official and individual capacities. Petitioners sought injunctive relief and damages for violations of the 14th Amendment's Due Process and Privileges or Immunities Clauses, violation of their

right to informed consent under the federal EUA statute, and an Oregon state law violation.

In the meantime, Oregon's COVID-19 mandates were lifted, rendering injunctive relief moot.[1] Petitioners still seek to prosecute their damages claims against respondents in their individual capacities.

The district court denied petitioners' motion for a temporary restraining order and later granted respondents' motion to dismiss, rejecting petitioners' contention that the COVID-19 vaccines were experimental, ruling that petitioners failed to allege that the State action was not rationally related to any legitimate state interest. App. 24a-25a.

The Ninth Circuit affirmed the dismissal of petitioners' claim for damages on the grounds that Respondents are entitled to qualified immunity and did not reach the question of the standard of review that applies to a government mandates to take an experimental drug. App. 10a–12a.

REASONS FOR GRANTING THE WRIT

Seventy-five years after the Nuremberg trials established medical experimentation on human beings as a crime against humanity, the COVID-19 panic turned the world upside down. Suddenly, it became a widely accepted practice to "mandate" by executive decree that humans be injected with experimental drugs. The panic so clouded rational discourse that the increasing pleas of the *victims* of

[1] The Ninth circuit reversed and remanded the dismissal of injunctive relief with prejudice with instructions to dismiss without prejudice. This petition does not concern injunctive relief originally sought by petitioners.

the COVID-19 vaccine mandates have fallen on deaf ears.

Governmental authority to mandate experimental drugs must be on a different basis than that for tested and approved drugs. As a matter of first impression here, petitioners ask: In a substantive due process challenge of a State "mandate" to take ***experimental*** drugs, what is the standard of review for balancing an individual's liberty interest in refusing medical treatment with any State interest? This Court has never been asked to review this question before for good reason. Until the COVID-19 panic, it was inconceivable that experimental drugs could be mandated on the public.

It is imperative for this Court to deal with the question because executive orders mandating experimental drugs caused so much devastation of peoples' lives during the COVID-19 panic, and this question will arise again with new experimental vaccines. For example, the United States is funding Moderna to develop a bird flu vaccine[2] and Germany is creating the capacity to manufacture 200 million doses of mRNA vaccines per year.[3]

The lower courts have universally dismissed Fourteenth Amendment Due Process challenges to COVID-19 mandates, applying a rational basis standard of review, and concluding that *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), is controlling.

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[2] AP, *The US will pay Moderna $176 million to develop an mRNA pandemic flu vaccine*. (July 2, 2024) apnews.com/article/bird-flu-moderna-vaccine-mrna-pandemic-7f15d8d274a24d89fa 86e2f57e13cbff (visited Aug. 12, 2024).

[3]Robert Kogon, *Germany Creating Capacity to Produce Over One Billion mRNA Vaccine Doses Per Year*. (July 4, 2024) pandauncut.substack.com/p/germany-creating-capacity-to-produce (viewed Aug. 12, 2024).

Unlike the smallpox vaccine in *Jacobson*, the emergency use authorized COVID-19 vaccines are—by definition—experimental. Thus, *Jacobson* has been repeatedly misapplied—it did not grapple with the modern ethics of informed consent law, nor experimentation on humans. In the context of experimental drugs, a completely different standard of review must apply under a Fourteenth Amendment Due Process challenge; petitioners assert that the proper standard is "no derogation" of rights.

Government mandates of experimental drugs on the public constitutes an entirely new form of abuse of individual liberty. In this case, Oregon mandated that petitioners (and many thousands of others) be injected with an experimental vaccine. Over the entire United States, millions more were subjected to like experimentation.

Indeed, a majority of the world's population has been injected with the COVID-19 experimental drugs, and the results of this live experiment have been devastating. Serious people who have studied data released by Pfizer conclude that Pfizer knew its vaccine was not effective and highly dangerous before it was released.[4] By testing the experimental vaccines on the public, what Pfizer already knew is confirmed—they are not effective.[5] More than a year

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[4] Patrick Delaney, LifeSite News, *'The greatest crime against humanity' in history: Naomi Wolf's 11 revelations from Pfizer vaccine documents*. (Apr. 24, 2023). www.lifesitenews.com/news/the-greatest-crime-against-humanity-in-history-naomi-wolfs-11-revelations-from-pfizer-vaccine-documents/ (viewed Aug. 12, 2024).

[5] Kirsch, Steve, *et. al., A Novel Practical Approach for Directly Assessing COVID-19 Vaccine Efficacy against Hospitalization*. (Aug. 5, 2024). *Preprints* **2024**, www.preprints.org

ago, Edward Dowd published his book analyzing insurance data and documenting the undeniable epidemic of sudden deaths and disability that began in 2021.[6] For example, in the second half of 2021 the millennial generation experienced 61,000 excess deaths—a Vietnam War scale event—in just six months. This rise in excess mortality coincided with the rollout of the COVID vaccines. A stunning statistic reveals the cause: for every unvaccinated person who dies suddenly, 1,000 COVID-19 vaccinated people die suddenly.[7]

The Ninth Circuit avoided petitioners' due process question, finding instead that respondents have qualified immunity. Qualified immunity should not apply to deliberate calculated choices, devoid of split-second decision making. There is a vast difference between "split-second decisions" of police officers and premeditated plans to impose experimental vaccines. Respondents knew that they could not mandate experimental drugs, yet they did it anyway. A circuit split exists concerning whether a lack of split-second decisions is a factor in granting qualified immunity, and this split should be resolved by this Court.

The lower courts have also universally rejected that individuals have a cause of action to vindicate their right to informed consent in the statute that authorized emergency use of experimental drugs. Congress did not abandon the right to informed

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/manuscript/ 202408.0338/v1viewed Aug. 12, 2024).

[6] Dowd, Edward, *Cause Unknown: The Epidemic of Sudden Deaths in 2021 and 2022* (2022).

[7] Kirsch, Steve, *The "died suddenly" vax vs. unvaxxed statistics tell you everything you need to know*. (Oct. 19, 2023). kirschsubstack.com/p/the-died-suddenly-vax-vs-unvaxxed (viewed Aug. 12, 2024).

consent when it wrote the EUA statute, but emphatically recognized that recipients of EUA drugs have a right of informed consent. This right was so significant to Congress that it provided only one narrow exception—a Presidential order finding said drug necessary to be administered to military members in the interests of national security. Yet, the lower courts have universally ignored this Court's precedent in *Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103 (1989). The lower courts have concluded that only the executive branch can vindicate an individual's right to informed consent, when it is that branch that is trying to mandate the experimental vaccines at every turn.

Three quarters of a century after Nuremberg, no organ of state or federal government has stepped in to stop the madness of human experimentation via untested, unknown, unapproved vaccines. And all efforts by the public to vindicate their due process right to refuse experimental medical products have been blocked by the lower courts. This Court should step in now and right the ship before another panic arises.

I. The standard of review for government "mandates" of experimental drugs has never been determined.

Among the many abuses of power that occurred during the COVID-19 panic, one of the most extreme was widespread State (and federal) executive orders ("mandates") for injection of experimental drugs—the COVID-19 vaccines.

The lower courts have dismissed due process challenges by relying on *Jacobson, supra*. *Jacobson*

predated the modern tiers of scrutiny, but has been understood to have applied what today is called a rational basis standard of review. *See, e.g., Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring); *Norris v. Stanley*, 73 F.4th 431, 435 (6th Cir. 2023). *Jacobson* dealt with a legislative decree to take the smallpox vaccine which had been available and used for approximately 100 years. *Jacobson*, 197 U.S. at 32, n.1. Accordingly, the smallpox vaccine in Jacobson's time carried a status equivalent to what is referred to today as "approved" or "licensed" by the FDA.

Unlike the smallpox vaccine in *Jacobson*, the EUA COVID-19 vaccines are "unapproved" which, by definition, means that they are "experimental," as further explained *infra*. In the context of experimental drugs, a completely different standard of review must apply under a Fourteenth Amendment Due Process challenge.

Thus, the question presented by this case: what is the proper standard of review for a Fourteenth Amendment Due Process challenge to a government mandate that individuals be injected with an *experimental* drug? It cannot be the same as for approved and tested drugs, and the rational basis standard applied by the District Court in petitioner's case cannot be correct.

This is an extraordinarily important question because many millions of Americans, like petitioners, have been subjected to mandates of the experimental COVID-19 vaccines with devastating consequences for non-compliance. Not only is this a form and degree of tyranny never experienced before in America, many more experimental vaccines are in the pipeline. The push for a pandemic treaty by the World Health Organization illustrates how the

world's governments are preparing to declare many more "pandemics," and once again, untested, unproven, experimental vaccines will be foisted on the public, without any precedence by this Court to forestall executive tyranny over individuals.

A. The FDA's terminology for approved and unapproved drugs.

The terms "approved" and "authorized" are terms of art in the U.S. Food & Drug Administration (FDA) with very different meanings. "Approval" refers to the FDA's determination that a drug is safe and effective, and that its benefits outweigh its risks. 21 U.S.C. § 355; FDA, *About FDA Approval* (Dec. 29, 2017).[8] Approved drugs are also referred to as "licensed" drugs. 21 U.S.C. § 355(b)(1)(A)(i) (an application for licensure requires "full reports of investigations which ... show that such drug is safe for use and ... is effective in use").

Drugs that are unapproved may still be made available to the public in emergencies. In a relatively new regulatory development 20 years ago, the FDA was given statutory authority to "authorize" an unapproved drug through the Emergency Use Authorization (EUA) mechanism. 21 U.S.C. § 360bbb-3 (FDCA § 564).[9] Until approved by the FDA, an unapproved medical product remains investigational, even after issuance of an EUA. As the National Institutes of Health (NIH) explains: "The issuance of an EUA is different than an FDA

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[8] www.fda.gov/news-events/approvals-fda-regulated-products/about-fda-product-approval (viewed Aug. 6, 2024).

[9] The provisions of FDCA § 564 are codified at 21 U.S.C. § 360bbb-3, and these sections are referred to interchangeably throughout.

approval (licensure) of a vaccine. A vaccine available under emergency use authorization is still considered investigational."[10]

Critically, "investigational" means "experimental." The FDA explains that "[a]n investigational drug can also be called an experimental drug." FDA, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Oct. 2020).[11] In another publication, the NIH described the EUA-authorized Moderna COVID-19 vaccine as "experimental." NIH, *Experimental coronavirus vaccine highly effective* (Jane 12, 2021).[12]

Prior to COVID-19, the FDA had authorized emergency use of only one prior investigational vaccine—for inhaled anthrax. In the case of the anthrax investigational vaccine, the District Court for the District of Columbia issued an injunction forbidding its forced administration to service members without their informed consent. *Doe #1 v. Rumsfeld*, 297 F. Supp. 2d 119, 134-35 (D.D.C. 2003). Judge Emmet G. Sullivan equated the term "investigational" with "experimental," stating:

> This Court is persuaded that AVA is an *investigational* drug and a drug being used for an unapproved purpose. ...
>
> The women and men of our armed forces put their lives on the line every day to preserve and safeguard the freedoms that all Americans cherish and enjoy. Absent an informed consent or presidential waiver, the

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[10] Excerpts of Record in No. 22-35624 (CA9) 2-ER-291.

[11] www.fda.gov/media/138490/download (viewed Aug. 6, 2024).

[12] www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective (viewed Aug. 6, 2024).

> United States cannot demand that members of the armed forces also serve as *guinea pigs for experimental drugs.*

Id. at 135 (emphasis added).

B. The only available COVID-19 vaccines were experimental.

The FDA authorized emergency use of three experimental injectable drugs for COVID-19. The EUA for the Pfizer experimental drug, named Pfizer-BioNTech, was issued December 11, 2020 ("BioNTech").[13] The FDA issued an EUA for the Moderna experimental drug on December 18, 2020.[14] The FDA issued an EUA for the Janssen experimental drug on February 27, 2021.[15]

On August 23, 2021, the FDA approved a Pfizer drug for COVID-19 called Comirnaty.[16] In the approval letter, the FDA admitted (in a footnote buried on page five) that Comirnaty would not be available to the population.[17] Indeed, Comirnaty was

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[13] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Pfizer-BioNTech COVID-19 Vaccine*). www.fda.gov/media/144416/download (viewed Aug. 6, 2024).

[14] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Moderna COVID-19 Vaccine).* www.fda.gov/media/144673/download (viewed Aug. 6, 2024).

[15] FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum (Janssen COVID-19 Vaccine)*, www.fda.gov/media/146338/download (viewed Aug. 6, 2024).

[16] Excerpts of Record in No. 22-35624 (CA9) 2-ER-143-155.

[17] Excerpts of Record in No. 22-35624 (CA9) 2-ER-147 at n. 9 ("there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA."); *see also* Excerpts of Record in No. 22-35624 (CA9) 2-ER-96 ¶ 99 ("In fact, Comirnaty is not available

never available to the public, and the same FDA letter *reauthorized* BioNTech under EUA.[18] Consequently, the only available COVID-19 vaccines that could be used to comply with Oregon's vaccine mandate were experimental drugs.

C. The COVID-19 vaccines were experimental in practice.

Not only were the COVID-19 vaccines classified as experimental drugs, their actual administration was *de facto* experimental as illustrated by the shocking cases of particularly vulnerable individuals—pregnant women and children.

Pregnant women are always excluded from vaccine trials and protected from receiving new drugs. Administration of new drugs to pregnant women has been forbidden since the Thalidomide tragedy 60 years ago. In the late 1950s and early 1960s, Thalidomide was used for the treatment of nausea in pregnant women. It was marketed in 46 countries as a 'wonder drug' between 1957 and 1962. Although it was never tested on pregnant animals, it was advertised that it could be "given with complete safety to pregnant woman and nursing mothers without any adverse effect on mother and child."[19]

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at all in the United States.")

[18] Excerpts of Record in No. 22-35624 (CA9) 2-ER-144 (On August 21, 2021 ... FDA is reissuing the August 12, 2021 letter of authorization ... to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine.")

[19] James H Kim, *et al.*, *Thalidomide: the tragedy of birth defects and the effective treatment of disease*, Toxicol. Sci. (July, 2011) https://pubmed.ncbi.nlm.nih.gov/21507989 (viewed Aug. 8, 2024).

The experimental COVID-19 vaccines were never tested on pregnant women during any vaccine trial.[20] The first use of the experimental COVID-19 vaccines was on unsuspecting pregnant women in the public. Oregon executives ordered that pregnant women get injected with a COVID-19 vaccine to keep their job. Each of the three mandates forbad employment for unvaccinated workers. For example, the order for school employees stated: "After October 18, 2021: (a) Teachers, school staff and volunteers may not teach, work ... unless they fully vaccinated." OAR 333-019-1030(3).[21] Three petitioners were pregnant when Oregon issued its mandate—two of them lost their jobs because they refused to be injected with an experimental drug.

Even more shocking is that the Oregon executives ignored evidence of the danger of the COVID-19 vaccines to pregnant women that was published by the CDC four months prior to Oregon's mandate. In June 2021, the CDC published a study reporting data from hundreds of pregnant women who had already received a COVID-19 vaccine. *See* Tom T. Shimabukuro, M.D., *et al., Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons*, 384 N Engl J Med 2273-82 (June 17, 2021).[22] A total of 827 women were in the study; 700 women received their first COVID-19 vaccine in their third trimester, meaning that 127 women received their first dose during the first two trimesters. Of the 127 women who received a

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[20] Laurel Wamsley, *Pregnant People Haven't Been Part of Vaccine Trials*, www.npr.org/2020/12/11/945196602/pregnant-people-havent-been-part-of-vaccine-trials-should-they-get-the-vaccine (Dec. 11, 2020) (viewed Aug. 8, 2024).

[21] App. 62a.

[22] www.nejm.org/doi/full/10.1056/NEJMoa2104983 (visited Aug. 6, 2024).

COVID-19 vaccine in the first two trimesters, 104 of them suffered spontaneous abortions. *Id.*

The CDC's data thus showed that an alarming 82 percent of the women who received a COVID-19 vaccine during the first and second trimester lost their babies.[23]

Also shocking, the FDA admits that too few children were tested to detect a risk of myocarditis. *FDA, Vaccines and Related Biological Products Advisory Committee October 26, 2021 Meeting Document*, p. 11. ("The number of participants in the current clinical development program is too small to detect any potential risks of myocarditis associated with vaccination.")[24] FDA panel member Dr. Eric Rubin, Editor in Chief of the New England Journal of Medicine explained: "We are never gonna learn about how safe the vaccine is until we start giving it."[25] Translation: we need to treat children like lab rats to figure out if the COVID-19 vaccines are safe.

Injecting children with the COVID-19 vaccines has caused the incidence of myocarditis to go off the charts. Vaccinated kids are suffering myocarditis at a rate that is 100 times normal. Myocarditis is not an insignificant disease—children diagnosed with it are predicted to have a 50 percent chance of dying within five years.[26] Despite these horrific results, nothing

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[23] Rodef Shalom 613, *82% Miscarriage Rate, Yet CDC Team's Creative Word Manipulation and Statistical Sleight-of-Hand Makes Covid-19 Vaccines Seem Safe for Pregnant Women*, www.rodefshalom613.org/2021/07/cdc-teams-creative-word-manipulation-and-statistical-sleight-of-hand-makes-covid-19-vaccines-seem-safe-for-pregnant-women/ (viewed Aug. 6, 2024).

[24] www.fda.gov/media/153409/download (Oct. 26, 2021) (viewed Aug. 10, 2024).

[25] *See, e.g.,* globalresearch.ca/fda-dr-rubin-admits-unknown-safety-experimental-jabs/5768019 (viewed Aug. 10, 2024).

[26] The Expose, *Doctor Claims 50% of Children Who Suffer*

has been done to take these products off the market and stop the carnage.

D. Humans cannot be coerced into taking experimental medications.

Coercing human beings into treatment with experimental medication is forbidden. This right grows out of the common law. "At common law, even touching of one person by another without consent and without legal justification was a battery." *Cruzan v. Director, Missouri Dept of Health*, 497 U.S. 261, 269 (1990). In the 19th Century, this Court observed:

> No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.

Union Pacific R. Co. v. Botsford, 141 U.S. 250, 251 (1891).

"This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." *Cruzan*, 497 U.S. at 269. "Justice Cardozo, while on the Court of Appeals of New York, aptly described this doctrine: 'Every human being of adult years and sound mind has a right to determine what shall be done with his

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Myocarditis Due to COVID Vaccination Will be Dead Within 5 Years, globalresearch.ca/doctor-claims-50-children-who-suffer-myocarditis-due-covid-vaccination-will-dead-within-5-years/5795279 (Oct. 1, 2022) 2022) (viewed Aug. 10, 2024).

own body.'"*Id.,* quoting *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129–130 (1914).

All FDA research into experimental drugs requires informed consent from the human subject. *See* 21 C.F.R. § 50.20. The FDA has very specific rules on the necessary elements of informed consent. *See* 21 C.F.R. § 50.25. These elements include the requirement that "participation is voluntary" and that "refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled." 21 C.F.R. § 50.25(a)(8).

The evolution of explicit written prohibitions on coerced medical experimentation on human beings began with the Nuremberg war crimes trials. *Abdullahi v. Pfizer*, 562 F.3d 163, 177 (2d Cir. 2009). The Nuremberg Code was promulgated as part of the final judgments against German doctors who conducted medical experiments, including immunization experiments, without the subjects' consent during World War II. *Id*. at 178. "Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera." *Id*. The Nuremberg Code's requirement for informed consent states:

> *The voluntary consent of the human subject is absolutely essential.* This means that the person involved should have legal capacity to give consent; should be so situated as to be able to *exercise free power of choice, without* the intervention of *any element of force, fraud, deceit, duress,* over-reaching, or other ulterior form of constraint or *coercion*; and should have sufficient knowledge and comprehension of the elements of the subject

> matter involved, as to enable him to make an understanding and enlightened decision.

2 Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10, 181 (U.S. Government Printing Office 1949) (emphases added) ("Nuremberg Code").[27] This prohibition on nonconsensual medical experimentation on human beings is accepted by nations around the world without significant exception. *Pfizer*, 562 F.3d at 177.

E. The Nuremberg Code and constitutional analysis

In *Cruzan*, this Court recognized that a "competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." 497 U.S. at 278. *Cruzan* cited *Washington v. Harper*, 494 U.S. 210, 222–23 (1990), where this Court recognized that prisoners possess "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment." This Court also stated that "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." *Id.* at 229.

Cruzan was followed by *Washington v. Glucksberg*, 521 U.S. 702 (1997), where the issue before this Court was whether the substantive due process right to refuse medical treatment included

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[27] Available at www.loc.gov/item/2011525364_NT_war-criminals_Vol-II/ (viewed Aug. 7, 2024); *see also* history.nih.gov/display/history/Nuremberg%2BCode (viewed Aug. 7, 2024).

the right to assisted suicide. Significantly, this Court found that the Fourteenth Amendment's Due Process Clause "provides heightened protection against government interference with certain fundamental rights and liberty interests." *Id.* at 720. "We have assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment." *Id.* Hence, petitioners have a due process liberty interest to refuse medical treatment.

What then, in the context of experimental drugs, are the boundaries of this Fourteenth Amendment liberty interest possessed by petitioners? Such questions are answered by consulting our nation's history, legal traditions, and practices. *Id.* at 710. The Nuremberg Code recognizes universal and fundamental rights of human beings. *Siderman de Blake v. Republic of Argentina*, 965 F.2d 699, 715 (9th Cir. 1992). Due to the force of its authority, the Nuremberg Code was one of the primary sources the United States used to write laws relating to medical experimentation:

> Tellingly, the sources on which our government relied in outlawing non-consensual human medical experimentation were the Nuremberg Code and the Declaration of Helsinki, which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation. Today, FDA regulations require informed consent to U.S. investigators' research, whether conducted domestically or in a foreign country, used to support applications for the approval of new drugs.

Pfizer, 562 F.3d. at 182. Further:

> The Department of Health and Human Services has compiled the laws, regulations, and guidelines governing human subjects research in eighty-four countries. It is uncontested that all of the countries identified in this compilation require informed consent to medical experimentation.

Id. at 181 n.12 (internal citations omitted).

> The importance that the United States government attributes to this norm is demonstrated by its willingness to use domestic law to coerce compliance with the norm throughout the world. ... The principles of the Nuremberg Code have been embedded in United States law for 45 years and its validity has never been questioned by any court.

Id. at 182.

The Nuremberg Code itself was first promulgated by the Nuremberg tribunal at the Nuremberg Trials after the crimes were committed. *Id*. at 178. The Nazi defendants contended that they were illegally being prosecuted *ex post facto* for crimes not previously specified as crimes. *Ex parte Hicks*, 153 So. 3d 53, 69 (Ala. 2014) (Moore, J. concurring). The *ex post facto* defense was rejected by the tribunal because a human's right to informed consent is fundamental to humanity, and founded in a higher law—the law of nature and nature's God. *Id*.

Our Nation's history, legal traditions, and practices evince strict adherence to informed consent

without any element of duress or coercion, as commanded by the Nuremberg Code.

F. The applicable standard of review is no derogation.

The rights stated in the Nuremberg Code are accepted in the United States and worldwide as a *jus cogens* norm. *Pfizer*, 562 F.3d at 179. Importantly, the definition of a *jus cogens* norm incorporates a standard of review: no derogation. A *jus cogens* norm "is a norm accepted and recognized by the international community of states as a whole as a norm from which ***no derogation*** is permitted and which can be modified only by a subsequent norm of general international law having the same character." *Siderman de Blake*, 965 F.2d at 715 (emphasis added).

"No derogation" means no compromise of the right. See *Black's Law Dictionary*, 10th ed. ("derogation" is the destruction of a right). No derogation is a higher standard of review than strict scrutiny. Unlike strict scrutiny, no derogation means that there is no balancing of interests between the individual and the state. Unless the government relies on another superseding *jus cogens* norm, no interest of government can possibly overcome an individual's absolute right to refuse without negative consequences. The no derogation standard fits perfectly with the history of the Nuremberg Trials—for what governmental grounds could possibly have rationalized the heinous acts carried out by the Nazi doctors? Similarly, the no derogation standard of review is appropriate for the "mandates" that destroy citizens unless they are injected with experimental drugs.

Under the Fourteenth Amendment Due Process Clause, the standard of review for government mandates of an experimental drug must be different from the standard of review for government mandates of an approved, tested drug.

Petitioners maintain that the proper standard of review for government mandates of experimental drugs is "no derogation." This Court has never considered a standard of review for a government mandate of an experimental drug. The Ninth Circuit avoided answering this question; no other circuit court has addressed this question. This is an extraordinarily important question of federal law that needs to be settled by this Court.

II. This case may be an appropriate vehicle to restore meaning to the Privileges or Immunities Clause.

Petitioners pled violation of the Fourteenth Amendment's Privileges or Immunities Clause as well as the Due Process Clause. Space constraints do not allow exposition in this petition, but the extent of a citizen's right to resist coercion to be injected with an experimental drug, a case of first impression in this Court, may be an opportunity for this Court to begin restoring the meaning of the Privileges or Immunities Clause to protect the rights of the people "with greater clarity and predictability than the substantive due process framework has so far managed." *McDonald v. City of Chicago*, 561 U.S. 742, 812 (2010) (Thomas, J., concurring in part and concurring in the judgment).

III. Respondents are not entitled to qualified immunity.

The Ninth Circuit ruled in conclusory fashion that respondents are entitled to qualified immunity. The panel asserted that a number of decisions have already rejected petitioners' position, citing two circuit court cases, *Lukaszczyk v. Cook County*, 47 F.4th 587, 603 (7th Cir. 2022), and *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 293-94 (2d Cir. 2021). Contrary to the Ninth Circuit's opinion, neither *Lukaszczyk* nor *We the Patriots* address petitioners' argument. Neither case acknowledges that the COVID-19 vaccines are EUA authorized, unapproved, or experimental. Neither case address the standard of review that should apply to mandates to be injected with experimental drugs. Both cases are, however, examples of the short shrift given by the courts—in perhaps hundreds of cases—to the people's resistance to exeutive orders to be injected with experimental drugs or lose their jobs or schooling. No circuit court has addressed the legal analysis presented by petitioners, except the Ninth Circuit here, which gave it short shrift.

Qualified immunity does not apply in this case because: (1) qualified immunity ought not apply to calculated executive decisions; (2) respondents knew that they could not mandate individuals to be injected with experimental drugs, but they did it anyway; and (3) the right asserted by petitioners is a *jus cogens* norm which trumps any right to qualified immunity.

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A. Qualified immunity should never apply to deliberate and calculated executive choices

There is a big difference between "split-second

decisions" by police officers and premeditated plans to impose a vaccine mandate. Police officers often need to make rapid decisions in high-pressure situations. Courts recognize that police officers must frequently make split-second judgments in circumstances that are tense, uncertain, and rapidly evolving. *See, e.g., Mattos v. Agarano*, 661 F.3d 433, 442 (9th Cir. 2011).

1. *There is a circuit split on whether the lack of split-second decisions is a factor in granting qualified immunity.*

In this case, Oregon's executives' decisions to impose COVID-19 vaccine mandates were deliberate, calculated, and devoid of any split-second decision-making. The Ninth Circuit did not take this into account when it decided Oregon's officials were entitled to qualified immunity.

Two circuits have *denied* qualified immunity on the rationale that decisions made were calculated and lacked split-second decision making. *Intervarsity Christian Fellowship/USA v. Univ. of Iowa*, 5 F.4th 855, 867 (8th Cir. 2021) (not extending qualified immunity to university officers who had time to make calculated choices); *Reedy v. Evanson*, 615 F.3d 197, 224 n. 37 (3d Cir. 2010) (no split-second decision to issue warrant months after attack).

Other circuit courts routinely grant qualified immunity for calculated executive acts when no split-second decisions were made. For example, the Fifth Circuit grants such qualified immunity for official acts. *Villarreal v. City of Laredo*, 94 F.4th 374, 406–407 (5th Cir. 2024) (Willett, J. dissenting). A petition for writ of certiorari is now pending in this Court re *Villarreal*. Similarly, the Ninth Circuit applies qualified immunity when no split-second decisions

were made, as in this case, and in, *e.g, Tibbetts v. Kulongoski*, 567 F.3d 529, 539 (9th Cir. 2009) (governor entitled to qualified immunity for issuing press releases concerning employee terminations and failing to provide terminated employees with "name-clearing hearings"); *Price v. State of Hawaii*, 921 F.2d 950, 958–59 (9th Cir. 1990) (former governor entitled to qualified immunity for decisions allocating funds and real estate); *Shinault v. Hawks*, 782 F.3d 1053, 1061 (9th Cir. 2015) (qualified immunity for decision freezing inmates' assets); *Sorrels v. McKee*, 290 F.3d 965, 970–72 (9th Cir. 2002) (qualified immunity for decisions re publications received in prison).

Here, the COVID-19 vaccine mandates were legal documents written by lawyers in the form of executive orders or, for health workers and school employees, in the form of administrative rules. OAR 333-019-1010 and OAR 333-019-1030, Appendix F. There is no justification for immunizing government conduct that carefully weighed the legality of the action taken. This court should grant this petition to resolve the split in the circuits and establish how qualified immunity applies to deliberately calculated decisions of executive officials.

2. Premeditated acts are not entitled to qualified immunity.

The common justification given for qualified immunity is that police officers need breathing room to make split-second judgments in fast-moving, high-pressure, life-and-death situations, a common fact pattern in abuse of force cases. *See, e.g., Plumhoff v. Rickard*, 572 U.S. 765, 775 (2014).

But this rationale fails to justify why deliberate calculated decisions by executives are entitled to the same level of protection as split-second decisions by

police officers. *Hoggard v. Rhodes*, 141 S. Ct. 2421, 2422–23 (2021) (Thomas, J., statement respecting the denial of certiorari) ("But why should university officers, who have time to make calculated choices about enacting or enforcing unconstitutional policies, receive the same protection as a police officer who makes a split-second decision to use force in a dangerous setting? We have never offered a satisfactory explanation to this question.")

Moreover, only 23 percent of qualified immunity appeals involve split-second decision making. See Jason Tiezzi *et al.*, *Unaccountable: How Qualified Immunity Shields A Wide Range of Government Abuses, Arbitrarily Thwarts Civil Rights, and Fails to Fulfill Its Promises*, Institute for Justice (Feb 2024, p. 4). The *majority* of qualified immunity cases involve premeditation of the decision and lack a valid *policy* justification for why the officals received any immunity at all.

This case is an example. Oregon's vaccine mandates were premeditated, with plenty of time to evaluate the lack of legal authority for the action. The fact that Oregon officials deliberated for some time over the mandates is demonstrated by careful wording conditioning the mandate's effective date on when the FDA approved a COVID-19 vaccine. In the case of government workers, Executive Order 21-29 required presenting papers proving vaccination "[o]n or before October 18, 2021, or six weeks after the date that the United States Food and Drug Administration approves a vaccination against COVID-19, whichever is later." App. 54a. This was a legal document written by government attorneys.

Premeditated government acts should not be entitled to any sort of immunity when they violate the civil rights of the public, but this becomes even more apparent when the right violated is as

fundamental and universally understood as the right not to be experimented upon without consent. Oregon's officials had plenty of time to determine the legality of their actions, and such blatant disregard of human rights demands accountability, else this nation is no better than those on trial at Nuremberg.

B. Respondents knew that they could not mandate experimental drugs.

Oregon's vaccine mandate was explicitly conditioned on a vaccine being approved by the FDA. App. 55a. Oregon knew that there was difference between approved and unapproved vaccines and that experimental vaccines could not be mandated. Indeed, this was widely known by government officials.

As explained by a federal government official, "I just wanted to add that, just wanted to remind everybody, that under Emergency Use Authorization, and EUA, vaccines are not allowed to be mandatory. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated."[28]

Why did this government official say that EUA "vaccines are not allowed to be mandatory" and that "they won't be able to be mandated"? It is because of the human rights standard expressed in the Nuremberg Code that has been embedded in United States law for 60 years.

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[28] Dr. Amanda Cohn, Executive Secretary, CDC Meeting of the Advisory Committee on Immunization Practices, 1:14:37 (Aug. 26, 2020) (online presentation), youtu.be/p0zCEiGohJs?si=m3T2Opct6Sqx5dJr&t=4477 (viewed Aug. 13, 2024). *See also* Excerpts of Record in No. 22-35624 (CA9) 2-ER-95-96.

Nonetheless, Oregon only paid lip service to the requirement that the mandated vaccines be approved. Oregon's vaccine mandates were published in early August 2021. Just two weeks later, on August 23, 2021, the FDA issued a letter approving Comirnaty, which the FDA knew was never going to be available in the United States and which was never available in the United States. The only COVID-19 vaccines that were available to satisfy the mandate were unapproved experimental vaccines. However, the approval of a ghost product—never intended to be sold and was never sold in the United States—was enough of a fig leaf for Oregon to proceed with their vaccine mandate which started on October 18, 2024. Respondents knew that the only vaccines that could be used to satisfy the mandate were experimental vaccines, but they implemented the mandate anyway.

What the events in August 2021 look like is a calculated and elaborate government fraud to fool the public into believing they were getting an FDA approved drug, when no approved COVID-19 vaccine existed. None of this behavior should be immunized.

That Respondents specifically conditioned their mandate on the existence of an approved COVID-19 vaccine means they knew that they could not mandate experimental vaccines. Consequently, Respondents' mandate shows that they do not meet the requirement for qualified immunity because they had actual knowledge of "clearly established statutory or constitutional rights." *Mullenix v. Luna*, 577 U. S. 7, 11 (2015). Because of repondents' actual knowledge of the prohibition against mandating experimental drugs, they are not entitled to qualified immunity.

C. A *jus cogens* right trumps the qualified immunity defense.

There can be no immunity for a *jus cogens* right. This is illustrated by an analogous argument made at the Nuremberg trials. The Nazi doctors argued at trial that they could not be convicted *ex post facto* on crimes not written down at the time they were committed. *Ex parte Hicks*, 153 S. 3d at 69 (Moore, J., concurring specifically). "In his opening statement, however, lead prosecutor Robert Jackson (then an Associate Justice on the United States Supreme Court) argued that 'even rulers are, as Lord Chief Justice Coke said to King James, under God and the law.'" *Id.* (cleaned up). "The Nuremberg Court rejected the arguments of the German defendants, noting that 'so far from it being unjust to punish them, it would be unjust if their wrongs were allowed to go unpunished.'" *Id.* (cleaned up).

The same rationale applies here. The defense of qualified immunity is appreciably inferior to the right to be free from *ex post facto* application of criminal law. If a *jus cogens* right trumps the *ex post facto* defense, it must certainly trump qualified immunity.

IV. Informed consent under the EUA statute.

FDCA § 564 was amended in 2004 to permit the FDA to issue an emergency use authorization for a medical product prior to licensure. Now codified at 21 U.S.C. § 360bbb-3, § 564 was enacted after the September 11, 2001 attacks, and the envelopes with anthrax being sent through the United States Postal Service. The legislation created a way to distribute unlicensed and therefore, experimental, medical products in the event of bioterrorism or similar

emergencies, and to create a narrow exception to allow mandates of such a product to members of the military. *See* FDCA § 564 (permitting an EUA) and 10 U.S.C. § 1107a (permitting the President to waive "the option to accept or refuse" requirement in § 564 for service members under limited circumstances of national security).

Congress did not omit the right of informed consent when it permitted emergency use of experimental drugs; § 564 references an individual's right to informed consent regarding EUA products. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). The statute requires that "individuals to whom the product is administered are informed 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."[29]

There is no indication that Congress, in passing § 564 and § 1107a, *supra,* intended to deviate from the long-standing principle and entrenched state, federal, and international principle that any administration of experimental drugs on the public must be completely voluntary. That this principle was carried forward when Congress included the words "the option to accept or refuse" in § 564 is reinforced by the legislative discussions surrounding its passage. On July 16, 2003, in deliberating this section, Representative Hays said, without any objection, that:

> [A]ny authority to actually use experimental drugs or medical devices in emergency situations has to be defined and wielded with nothing less than surgical precision. Prior

[29] App. 49a.

> *informed consent in connection with the administration of experimental therapy is a basic human right*, a right no one should be asked to surrender except under the most extraordinary of circumstances.

108 Cong. Rec. H6908 at H6935 (July 16, 2003). (emphasis added) [30]

That Congress intended "the option to accept or refuse" as a substantive right prohibiting any mandate of an experimental medical product comes into sharp focus considering that Congress specifically carved out only one exception that supersedes an individual's "option to accept or refuse administration of the product." The right to informed consent for an unapproved medical production is only superseded when the President of the United States issues a finding of national security. As provided in 10 U.S.C. 1107a:

> In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act [21 U.S.C. § 360bbb-33(e)(1)(A)(ii)(III)] and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, *may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security*. (emphasis added)

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[30] www.congress.gov/congressional-record/2003/7/16/house-section/article/h6908-1) (viewed Aug. 9, 2024).

Congress so highly valued the right to individual choice that it allowed only a threat to national security to trump that right, and even then, only with regard to military personnel. This limited exception demonstrates that the State of Oregon has no power to mandate an EUA product to the public. If the State of Oregon had the authority and power to mandate an unapproved medical product, there would have been no need to create a separate statute and require a written presidential national security finding to give the President of the United States the authority and power to mandate an unapproved medical product. The exception proves the rule that the State of Oregon is prohibited from mandating an EUA product because that mandate conflicts with federal law.

The Ninth Circuit ruled that there was no private right of action to vindicate this right of informed consent because FDCA § 310, codified at 21 U.S.C. § 337, is an express provision foreclosing a remedy under 42 U.S.C. § 1983.[31] The Ninth Circuit failed to apply this Court's direction of how to determine when an act of Congress specifically forecloses a § 1983 remedy, however.

Section 1983 provides a federal private remedy for "the deprivation of any rights, privileges, or immunities secured by the Constitution and laws" which must be broadly construed. *Golden State Transit Corp. v. Los Angeles*, 493 U.S. 103, 105 (1989). For a § 1983 action to be precluded, Congress must have "specifically foreclosed a remedy under § 1983 by providing a comprehensive enforcement mechanism for protection of a federal right." *Id.* at 106 (cleaned up). Moreover, "the statutory framework must be such that allowing plaintiff to bring a

[31] App. 9a.

§ 1983 action would be inconsistent with Congress' carefully tailored scheme." *Id*. at 106-07 (cleaned up). A court does not lightly conclude that Congress intended to foreclose a plaintiff's reliance on § 1983 as a remedy for violation of a federally secured right. *Id*. at 107.

The Ninth Circuit found that petitioners' § 1983 remedy is precluded by 21 U.S.C. § 337(a) which states that "all such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States." This does *not* preclude petitioners' cause of action under § 1983 for violation of § 564 because: (1) 21 U.S.C. § 337 is not specific to the § 564 right to informed consent; (2) the statute contains no comprehensive mechanism for protection of the stated right to informed consent; (3) there is no carefully tailored scheme to vindicate the right to informed consent; and (4) allowing a § 1983 action would not be inconsistent with 21 U.S.C. § 337. The Ninth Circuit ignored all these factors of *Golden State*.

Further, 21 U.S.C. § 337 was last amended in 1992. Inherently, § 337 says nothing, and could say nothing, *specifically* about the future provisions of § 564 (codified at 21 U.S.C. § 360bbb-3), which was amended in 2004 to permit emergency authorizations of experimental drugs. Thus, no part of 21 U.S.C. § 337 specifically forecloses a private remedy for § 564.

On the other hand, 21 U.S.C. § 331, last amended in 2022, does identify specific prohibited acts relating to § 564, but only as to: (1) "The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564," 21 U.S.C. § 331(d); and (2) "The refusal to permit access to or copying of any record as required by section ... 564 ... ; or the failure to establish or maintain any record, or make any

report, required under section ... 564 ... ," 21 U.S.C. § 331(e). These prohibited acts do not reach petitioners' right to informed consent under § 564, codified at 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), and therefore the statutory framework is *not* comprehensive.

Nowhere in the FDCA is there a carefully tailored scheme to protect an individual's right to informed consent. To the contrary, the FDCA provides absolutely no scheme to protect an individual's right to informed consent. Indeed, the notion that United States' officials will protect petitioners' right to informed consent is absurd, considering that these agents themselves tried to mandate the experimental COVID-19 vaccines at every opportunity.

The enforcement provisions of the FDCA are not inconsistent with an individual right to action under § 1983. Indeed, the entire enforcement scheme of 21 U.S.C. §§ 331 and 337 envision the United States enforcing requirements on manufacturers and suppliers, which does not conflict with the nature of petitioners' claim under § 1983 to protect their rights of informed consent.

The lower courts are stuck in a cycle of group think, so far failing to protect the people from the worst abuse of the COVID-19 panic—government orders to be injected with experimental drugs.

It is manifest that, 75 years after Nuremberg, its lessons need to be reinstituted. In view of three years of failure by the lower courts to make necessary corrections, this Court should take this opportunity to reinforce the United States' commitment to fundamental human rights.

CONCLUSION

Petitioners respectfully urge this Court to grant a writ of certiorari to vindicate their—and millions of other Americans'—right to refuse orders that they be injected with experimental drugs.

Respectfully submitted,

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