No. _____

In the Supreme Court of the United States

KEITH M. WILKNS,
Petitioner,

v.

STEVE HERRON, CHAD LOWE, STEVEN COOK, PAUL DEAN, BEND-LAPINE ADMINISTRATIVE SD 1,
Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

When Congress amended the Food, Drug, and Cosmetic Act ("FDCA") in 2004 to permit emergency use authorization of certain experimental drugs in a declared emergency, they did not forget to include the right of informed consent. However, since 1938, the FDCA has required that all actions under the FDCA shall be in the name of the United States. The Ninth Circuit in this case, and all other courts to have considered the issue, reject private enforcement of an individual right to informed consent for EUA authorized experimental drugs.

QUESTION:
May an individual bring a lawsuit via 42 U.S.C. § 1983 for violation of his right to informed consent to the administration of an EUA experimental drug or device?

LIST OF PARTIES TO THE PROCEEDING

The caption contains the names of all interested parties.

CORPORATE DISCLOSURE STATEMENT

Petitioner is an individual.

LIST OF DIRECTLY RELATED CASES

Wilkins v. Herron, et al., No. 24-80, U.S. Court of Appeals for the Ninth Circuit. Judgment entered December 23, 2024; rehearing denied January 30, 2025.

Wilkins v. Herron, et al., D.C. No. 6:23-cv-00169-AA, U.S. District Court for the District of Oregon, Eugene Division. Judgment entered November 30, 2023.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Keith Wilkins respectfully petitions for a writ of *certiorari* to review a judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The Ninth Circuit's unpublished opinion is available at 2024 U.S. App. LEXIS 32644 (9th Cir. Dec. 23, 2024), and is reproduced at Appendix B. The Ninth Circuit's denial of petitions for panel rehearing and rehearing en banc is reproduced at Appendix A. The District of Oregon's opinion is available at 2023 U.S. Dist. LEXIS 213628 (D. Or. Nov. 30, 2023), and is reproduced at Appendix C.

JURISDICTION

The Ninth Circuit issued its opinion on December 23, 2024, and denied petitions for rehearing on January 30, 2025. Petitioner's application for an extension of time until June 27, 2025 to file the instant petition for a writ of *certiorari* was granted by Justice Kagan, No. 24A1021. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

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.

10 U.S.C. § 1107a. Emergency use products

(a) Waiver by the President.

(1) In the case of the administration of a product authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3] to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) of such Act [21 USCS § 360bbb-3(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.

(2) The waiver authority provided in paragraph (1) shall not be construed to apply to any case other than a case in which an individual is required to be informed of an option to accept or refuse administration of a particular product by reason of a determination by the Secretary of Health and Human Services that emergency use of such product is authorized under section 564 of the Federal Food, Drug, and Cosmetic Act.

(b) Provision of information.

If the President, under subsection (a), waives the condition described in section 564(e)(1)(A)(ii)(III) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3(e)(1)(A)(ii)(III)], and if the Secretary of Defense, in consultation with the Secretary of Health and Human Services, makes a determination that it is not feasible based on time limitations for the information described in section 564(e)(1)(A)(ii)(I) or (II) of such Act [21 USCS § 360bbb-3(e)(1)(A)(ii)(I) or

(II)] and required under paragraph (1)(A) or (2)(A) of such section 564(e), to be provided to a member of the armed forces prior to the administration of the product, such information shall be provided to such member of the armed forces (or next-of-kin in the case of the death of a member) to whom the product was administered as soon as possible, but not later than 30 days, after such administration. The authority provided for in this subsection may not be delegated. Information concerning the administration of the product shall be recorded in the medical record of the member.

(c) Applicability of other provisions.

In the case of an authorization by the Secretary of Health and Human Services under section 564(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 360bbb-3(a)(1)] based on a determination by the Secretary of Defense under section 564(b)(1)(B) of such Act [21 USCS § 360bbb-3(b)(1)(B)], subsections (a) through (f) of section 1107 [10 USCS § 1107] shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective.

STATEMENT OF THE CASE

Keith Wilkins has been an employed staff member since 2007 at Oregon's Bend-LaPine Administrative SD 1 ("Bend-LaPine Schools" or "District"). Over his tenure, Wilkins worked at two different schools, serving in various capacities including as a teacher, football coach, and Dean of Students.

During the COVID-19 crisis, Petitioner Wilkins refused to comply with the District's mandates that he wear a mask or get injected with a COVID-19 vaccine. The COVID-19 vaccines and face masks were not approved by the FDA—they were only authorized under Emergency Use Authorization ("EUA") under the Food, Drug, and Cosmetic Act ("FDCA") § 564. Due to Wilkins' refusal to comply with the District's vaccine and mask mandates, the District placed Wilkins on unpaid leave in February 2021, a status that persists to date.

At no time did the District provide Wilkins informed consent for the medical interventions that they required. Like many others in the United States Wilkins suffered the loss of his job and career due to COVID countermeasures.

Petitioner Wilkins sued the state actors who violated his right to informed consent and placed him on unpaid leave. The U.S. District Court for the District of Oregon granted Respondents' motion to dismiss, and the Ninth Circuit affirmed. These ruling asserted that Respondents may defeat a § 1983 action because the FDCA contains no provision for a private right of action to enforce its provisions.

Prior to 2004, private rights of action to enforce provisions of the FDCA were repeatedly rejected by courts including this Court: "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions. ..." *Buckman Co. v. Plfs' Legal Comm.*, 531 U.S. 341, 349 n. 4 (2001). *Buckman* concerned alleged fraudulent representations made to the FDA by a medical device manufacturer to obtain approval for an orthopedic bone screw. *Id.* at 343.

But in 2004, Congress amended the FDCA through the Project Bioshield Act of 2004, 118 Stat. 835, P.L. 108-276 to authorize the emergency use of experimental drugs in emergencies. Newly included in § 564 of the amended FDCA was an individual right to informed consent, a provision which, unlike those considered in *Buckman*, did not concern any representations by a manufacturer to the federal government or the public concerning its products. Instead, the individual right to informed consent was a provision related *exclusively* to a new congressional grant of power to the executive branch — a power to authorize *un*approved, *un*licensed (*i.e.,* still in the experimental stage) medical devices or drugs for emergency use only.

Following the multiple violations of informed consent by the States and state actors against inviduals during the COVID-19 emergency, every court who has considered this issue, including the Ninth Circuit in this case, has ruled that individuals may not enforce their § 564 right to informed consent under 42 U.S.C. § 1983, citing 21 U.S.C. § 337, which was enacted long before the individual right to informed consent to emergency use only drugs. These rulings effectively deny individuals any remedy for the injuries inflicted by state actors, and ensure that they have *no* right to informed consent for experimental drugs under the EUA statute because their right to informed consent will never be enforced by the United States.

REASONS FOR GRANTING THE WRIT

Section 564 of the Food, Drug, and Cosmetic Act was enacted 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, including 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).

Informed consent to medical interventions is a basic human right. When Congress passed § 564 of the FDCA, codified at 21 USC § 360bbb-3, providing for Emergency Use Authorization of unapproved drugs and devices, it did not forget to provide for informed consent. 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." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii).

The right of informed consent in § 564 is presumptively enforceable under 42 U.S.C. § 1983. *See Health & Hosp. Corp. v. Talevski*, 599 U.S. 166, 172 (2023). Yet, the Ninth Circuit in this case, and every other court to consider it, have rejected private enforcement of this right of informed consent, a grave injustice that this Court needs to correct.

This case presents sort of an inverse problem from what this Court considered in *Talevski*. The FDCA is primarily directed toward regulating the approval of medical products. As such, since its initial enactment in 1938, the FDCA has included an express statement that all actions for violations of the FDCA must be in the name of the United States. 21 U.S.C. § 337(a). Such a rule is entirely appropriate for the FDA approval processes for medical devices. This Court found that obvious in 2001. *See Buckman*, 531 U.S. at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the ***medical device provisions***. ...") (emphasis added).

But the provision at issue here is not a medical device provision—it is an informed consent provision added to the FDCA three years after *Buckman* and 66 years after the express preclusion provision of 21 U.S.C. § 337(a). And the right of informed consent for medical experimentation on humans is not a run-of-the-mill right. It is a basic human right, obscenely violated during the horrors of the Holocaust, which led to its articulation in the Nuremberg Code. Informed consent has been "firmly embedded" in United States law for the past 60 years. *See Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 182 (2nd Cir. 2009). Indeed, the prohibition against medical experimentation on humans is a fundamental and universal norm recognized as *jus cogens*. *Siderman de Blake v. Argentina*, 965 F.2d 699, 715 (9th Cir. 1992). "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." *Abdullahi*, 562 F.3d at 182.

The statutory enactment shows that Congress was so concerned in protecting the right to informed consent that they created only a very narrow exception that could only be invoked by the President, only on the grounds of national security, and then only as to military personnel.

The FDCA's vintage 1938 remedial scheme (requiring actions be in the name of the United States), despite its purported exclusivity, cannot be the exclusive avenue through which an individual may assert a claim for violation of a newly-added individual right of informed consent. "By its terms, § 1983 is available to enforce every right that Congress validly and unambiguously creates." *Talevski*, 599 U.S. at 192. To deny Petitioner the right to enforce his right to informed consent is to deny him civil liberty. *See Marbury v. Madison*, 1 Cranch 137, 163 (1803) ("The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury.")

I. Section 564 unambiguously creates a right to informed consent.

A. EUA medical products require informed consent.

Section 564 permits the FDA to "authorize" a drug or a device for emergency use prior to licensure by the FDA. 21 USC § 360bbb-3(a)(1) ("the Secretary may authorize ... a drug, device, or biological product intended for use in an actual or potential emergency"). The term "authorized" is a term of art in the FDA with a very different meaning from "approved." "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(a); 21 U.S.C. § 355(b)(1)(A)(i); *see also*, FDA, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19*, (Oct. 2020).[1] Approved drugs are also referred to as marketed drugs. *PLIVA v. Mensing*, 564 U.S. 604, 612 (2011). During the COVID crisis, both the COVID-19 vaccines and face masks were only authorized under § 564—they were not approved.

An unapproved medication is an experimental drug and use of such products is by definition an experiment. *See* 21 C.F.R. § 312.3 ("an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.").[2]

Prior to COVID, only one court had addressed the use of an experimental vaccine—for inhaled anthrax. In the case of the experimental anthrax vaccine, the district court in *Doe #1 v. Rumsfeld* issued an injunction forbidding its forced administration to military service members without their informed consent. *Doe #1 v. Rumsfeld,* 297 F. Supp. 2d 119, 134–35 (D.D.C. 2003). The *Doe #1* court stated powerfully:

> The women and men of our armed forces put their lives on the line every day to preserve and safeguard the freedoms that all

[1] https://www.fda.gov/media/138490/download

[2] *See also*, FDA, *Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19* (Oct. 2020) ("An investigational drug can also be called an experimental drug."); NIH, *Experimental coronavirus vaccine highly effective*, https://www.nih.gov/news-events/nih-research-matters/experimental-coronavirus-vaccine-highly-effective (Jan. 12, 2021) (describing Moderna COVID-19 vaccine as "experimental.")

> Americans cherish and enjoy. ***Absent an informed consent*** or presidential waiver, the United States cannot demand that members of the armed forces also serve as ***guinea pigs*** for ***experimental drugs***.

Id. at 135 (emphasis added).

The long-standing world-wide norm requiring informed consent by individuals who receive an unlicensed medical product is codified in the law of at least 84 countries and is an accepted principle of international common law. As explained by the Second Circuit:

> We have little trouble concluding that a norm forbidding nonconsensual human medical experimentation every bit as concrete—indeed even more so—than the norm prohibiting piracy ... The Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm.

Abdullahi v. Pfizer, 562 F.3d at 184.

Section 564 includes this same principle in its text. Section 564 provides that a ***condition*** of EUA authorization is that "individuals to whom the product is administered are informed ... of ***the***

option to accept or refuse administration of the product ....” 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) (emphasis added).

The text of § 564, its statutory framework, the history surrounding its passage and its consistent interpretation by the FDA, Centers for Disease Control and Prevention (“CDC”), the Department of Defense (“DOD”), and other federal agencies show that “the option to accept or refuse,” provides a right of informed consent

B. Congress intended to provide an individual right to informed consent.

Section 564 was enacted after the United States experienced September 11, 2001, and subsequent acts of terror, including envelopes with anthrax being sent through the United States Postal Service. S. L. Nightingale, *et al.*, “Emergency Use Authorization (EUA) to Enable Use of Needed Products in Civilian and Military Emergencies, United States,” *Emerging Infectious Diseases*. 2007; 13(7):1046 (detailing “the need for and genesis of the EUA, its requirements, its broad application to civilian and military populations, and its features of particular importance to physicians and public health officials.”).[3] Along with § 564, Congress enacted a very narrow exception to the right of informed consent. Congress passed 10 U.S.C. 1107a (“Section 1107a”), permitting the President to waive “the option to accept or refuse” requirement of § 564 for members of the military under limited circumstances of national

[3] https://doi.org/10.3201/eid1307.061188 (viewed June 23, 2025).

security.

1. *Use of EUA products must be completely voluntary.*

Every indication is that Congress intended to follow the long-standing and entrenched state, federal, and international principle that administration of unlicensed medical products generally cannot be anything but completely voluntary. That this principle was carried forward when Congress included the words "the right to accept or refuse" in § 564 is reinforced by the legislative discussions surrounding the passing of the section. On July 16, 2003, in deliberating § 564, 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 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 (daily ed. July 16, 2003) (statement of Rep. Hays) (emphasis added).[4]

The statute, as evinced by the commentary concerning it, provides for the basic human right to

[4] https://www.congress.gov/congressional-record/2003/7/16/house-section/article/h6908-1 (viewed June 23, 2025).

informed consent.

2. *The exception that proves the rule.*

That Congress intended "the option to accept or refuse" as a prohibition on mandating an unlicensed medical product comes into sharp focus by the fact 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 product is ***only*** superseded when the President of the United States issues a finding of national security. As provided in § 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***.

10 U.S.C. § 1107a(a)(1) (emphasis added).

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.

If informed consent were not an individual right under § 564, 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 override informed consent. The exception proves the rule that informed consent is required for administration of an EUA product.

3. *Federal agencies understand that § 564 provides an individual right of informed consent.*

Consistent with its language. the FDA viewed § 564 as providing a substantive right to refuse:

> [A]s a general rule, persons must be made aware of their right to refuse the product (or to refuse it for their children or others without the capacity to consent) and of the potential consequences, if any, of this choice. An exception to this rule is that the president, as commander in chief, can waive military personnel's right to refuse this product. If the right is not specifically waived by the president for a particular product given under EUA, ***military personnel have the same right to refuse as civilians***.

Nightingale, *supra*, at 1049 (emphasis added).

Similarly, the CDC's Advisory Committee on Immunization Practices has interpreted § 564 as a consent provision and not merely a requirement to inform. When responding to an inquiry regarding

whether the COVID-19 vaccines can be required, the Executive Secretary of ACIP responded that informed consent was required for EUA products:

> Dr. Cohn reminded everyone that under an EUA, vaccines are not allowed to be mandatory. Therefore, early in the vaccination phase individuals will have to be consented and cannot be mandated to be vaccinated.

Advisory Committee on Immunization Practices, Summary Report, 56 (Aug. 26, 2020).[5]

4. *The definition of "option."*

A critical word in § 564 is "option." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) ("Appropriate conditions designed to ensure that individuals to whom the product is administered are informed of the ***option*** to accept or refuse administration of the product ... .") (emphasis added) "Option" means "the power or right to choose: freedom of choice."[6]

It is illogical that Congress would require that individuals be informed of a "freedom of choice" if that choice is illusory. It is illogical that Congress would invoke "freedom of choice" reflecting the long-standing principle that unlicensed medical products generally cannot be anything but completely voluntary, yet also permit Respondents to inflict the punishment of the loss of one's job on Petitioner Wilkins.

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[5] https://stacks.cdc.gov/view/cdc/157579 (viewed June 23, 2025).

[6] Merriam-Webster.com, https://www.merriam-webster.com/dictionary/option (viewed June 23, 2025).

If the "option to accept or refuse" were not a substantive right to make a completely voluntary choice with no consequences, there would be no need for the President to make a national security finding to require the military to receive an EUA product. The military exception was also unnecessary if Congress intended to permit any entity to impose its own mandate with "consequences" for refusing an EUA product.

C. Section 564 unambiguously confers an individual right making the right presumptively enforceable.

The test for whether a statute confers an individual right was established in *Gonzaga Univ. v. Doe*, 536 U.S. 273 (2002). *Talevski*, 599 U.S. at 183. "[T]he *Gonzaga* test is satisfied where the provision in question is 'phrased in terms of the persons benefited' and contains 'rights-creating,'individual-centric language with an 'unmistakable focus on the benefited class." *Id*. When this test is satisfied the individual right is "deemed 'presumptively enforceable' under § 1983." *Id*. at 184.

Section 564 is phrased in the terms of the persons benefitted because it requires that "individuals" be informed of their "option to accept or refuse." *See* 21 U.S.C. § 360bbb-3(e)(1)(A)(ii). Petitioner is the "individual" of whom the statute speaks and the "option to accept or refuse" is Wilkins' substantive right to make a completely voluntary choice with no consequences, also known as informed consent. The provision providing that an individual has an "option to accept or refuse" is a "condition" of authorization of the medical product. 21 U.S.C. § 360bbb-3(e).

Section 564 thus provides an individual right to informed consent to recipients of any EUA product, a right that is presumptively enforceable under § 1983.

II. The presumption of enforceability is not rebutted.

The presumption of enforceability can be rebutted by "demonstrating that Congress did not intend that § 1983 be available to enforce those rights." *Talevski*, 599 U.S. at 186. "[T]he *sine qua non* of a finding that Congress implicitly intended to preclude a private right of action under §1983 is incompatibility between enforcement under §1983 and the enforcement scheme that Congress has enacted." *Id.* at 187. "In all events, the question is whether the design of the enforcement scheme in the rights-conferring statute is inconsistent with enforcement under §1983, such that a court must infer that Congress did not intend to make available the §1983 remedy for these newly created rights." *Id.* (cleaned up).

"Put another way, the inquiry boils down to what Congress intended, as divined from text and context. The application of the traditional tools of statutory construction to a statute's remedial scheme may reveal no incompatibility between the enforcement scheme that Congress crafted in the rights-conferring statute and enforcement under §1983, or it may uncover sufficient incompatibility to make manifest Congress's intent to preclude §1983 actions." *Id.*

This Court has in three cases found that statutory enactments precluded claims under § 1983. *Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246,

252, (2009) (referring to *Middlesex Cnty. Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1 (1981), *Smith v. Robinson*, 468 U.S. 992 (1984), and *City of Rancho Palos Verdes v. Abrams*, 544 U.S. 113 (2005)).

"In all three cases, the statutes at issue required plaintiffs to comply with particular procedures and/or to exhaust particular administrative remedies prior to filing suit." *Fitzgerald,* at 254. In each of these cases, allowing enforcement via § 1983 would have been "inconsistent with Congress' carefully tailored scheme." *Id*. at 254–55.

A. An ancient statutory provision is not indicative of Congress' intent in 2004.

This case is unique because the FDCA includes an ancient statutory provision that expressly requires all actions under the FDCA shall be in the name of the United States. 21 U.S.C. § 337(a). This provision was enacted with virtually identical language in 1938. Fed. Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040, 1046 (1938); *see also Zyla Life Scis, v. Wells Pharma of Hous.*, 134 F.4th 326, 330 (5th Cir. 2025).

To defeat the presumption of enforceability under § 1983, a defendant must demonstrate that Congress did not intend that § 1983 be available to enforce those rights. *Talevski*, 599 U.S. at 186.

In this case, 21 U.S.C. § 337(a) was enacted by Congress in 1938, a time when § 1983 "lay virtually dormant." Harry A. Blackmun, "Section 1983 and Federal Protection of Individual Rights—Will the Statute Remain Alive or Fade Away?" 60 *N.Y.U. L. Rev.* 1, 12 (1985). Section 1983 did not emerge from

this dormant phase until *Monroe v. Pape*, 365 U.S. 167 (1961). *Id.* at 17. Congress could not have been thinking about private enforcement of rights under § 1983 when 21 U.S.C. § 337(a) was first enacted in 1938.

The enactment of 21 U.S.C. § 337(a) predated Section 564 by 66 years. In 1938, Congress could not have had in mind the right of informed consent inserted into the FDCA in 2004. The enactment of 21 U.S.C. § 337(a) also predated explicit provisions establishing the right to informed consent by a dozen years because the evolution of principles of informed consent began with the Nuremberg war crimes trials after World War II. *See Abdullahi*, 562 F.3d at 177.

A statute could expressly forbid § 1983's use. *Talevski*, 599 U.S at 186. But under the circumstances of the gaps in time between the FDCA's enactment in 1938, the evolution of the right of informed consent beginning in 1949, the resurrection of § 1983 in civil rights actions in 1961, and the amendment of the FDCA to include a right to informed consent, the language of 21 U.S.C. § 337(a) does not evidence that Congress intended to foreclose use of § 1983 to enforce the right to informed consent in Section 564.

B. The FDCA has no remedial scheme to protect the right to informed consent.

Alternatively, a defendant can show that § 1983 is implicitly prohibited by showing that Congress created a "comprehensive enforcement scheme that is incompatible with individual enforcement under § 1983." *Talevski*, 599 U.S. at 186.

The FDCA has absolutely no scheme for

enforcing the right to informed consent. The prohibited acts under the FDCA are identified in 21 U.S.C. § 331, which is far from comprehensive. The acts prohibited under 21 U.S.C. § 331 rarely mention § 564, and then 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) (emphasis added), 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) (emphases added). These prohibited acts do not include a remedy for violations of informed consent under § 564(e)(1)(A)(ii)(III).

Nor are the provisions of the FDCA inconsistent with § 1983 enforcement of the right to informed consent. The entire enforcement scheme of 21 U.S.C. § 337 envisions the United States *enforcing requirements on manufacturers and suppliers*, and does not envision, consider or mention informed consent of individuals to the use of any medical devices, much less conflict with individual enforcement of informed consent. This Court has recognized that there is no doubt that the enforcement scheme for the medical device provisions of the FDCA was limited to the United States. *Buckman*, 531 U.S. at 349 n. 4 ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"). Notably, *Buckman* limited the scope of its comment to "medical device provisions." The observation in *Buckman* does not exclude the private enforcement of other provisions under § 1983, provisions that were not at issue in *Buckman*.

Three years after *Buckman*, § 564 was enacted with an individual right to informed consent. Although the Ninth Circuit cited *Buckman* as support for its conclusion, *Buckman* predated and did not consider the provision of an individual right to informed consent.

C. 21 USC § 337 is appropriately read as compatible with § 564's right to informed consent.

"In all events, the question is whether the design of the enforcement scheme in the rights-conferring statute is inconsistent with enforcement under §1983, such that a court must infer that Congress did not intend to make available the §1983 remedy for these newly created rights." *Talevski,* 599 U.S. at 187. As *Buckman* indicated, 21 USC § 337 certainly applies to the "medical device provisions" of the FDCA. The design of the enforcement scheme in the FDCA for "medical device provisions" is not inconsistent with enforcement under § 1983 for the informed consent provision.

The design of the enforcement scheme in the FDCA simply ignores the right to informed consent It would be completely impractical to apply the enforcement scheme in the FDCA to an individual right to informed consent.

Clearly, the federal government is not going to run around the country suing on behalf of every individual who refused a COVID-19 vaccine or who refuses to wear a mask to protect their right to informed consent. Indeed, the United States itself was arguably the biggest violator of individual informed consent in the COVID era. See, *e.g.*, *Health*

Freedom Def. Fund v. Biden, 572 F. Supp. 3d 1257, 1261 (M.D. Fla. 2021) (challenge to federal requirement to wear mask on airplanes and other public transportation); *Biden v. Missouri*, 595 U.S. 87, 89 (2022) (challenge to federal requirement for COVID-19 vaccination).

The absurdity of the United States enforcing informed consent for every citizen affected is further exposed by the very narrow exception to informed consent. The one narrow exception to § 564's informed consent provision requires a Presidential writing that national security is at stake. 10 U.S.C. § 1107a(a)(1). Could it be that Congress intended for the United States to sue the United States to enforce compliance with this exception? Such absurdities could not have been intended by Congress.

The express enforcement scheme of the FDCA is completely consistent with enforcement under § 1983.

D. The right at issue is a super right—a *jus cogens* right.

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, the Supreme Court has 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." *Id.* (quoting *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." *Id.* "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 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. 21 C.F.R. § 50.20. The FDA has very specific rules on the necessary elements of informed consent. 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).

Further, any use of an experimental drug is an experiment. 21 C.F.R. 312.3 ("an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice."). When a drug or device is authorized under § 564 it necessarily involves unapproved medical products which are experimental. Authorizing such unapproved medical products to be used by the public is by definition an experiment. 21 C.F.R. 312.3.

The evolution of explicit prohibitions on coerced medical experimentation on human beings began with the Nuremberg war crimes trials. *Abdullahi*, 562 F.3d at 177. The prohibition on nonconsensual medical experimentation on human beings is

accepted by nations around the world without significant exception. *Id.* "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." *Id*. at 182.

The norm expressed in the Nuremberg Code is a *jus cogens*, also called a "peremptory norm," of international law. It "is a norm that 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 714.

The right of informed consent in § 564 is not a run-of-the-mill right—it is a *jus cogens* right binding on all nations, and that does not depend on the consent of a nation for their binding force. *Siderman*, 965 F.2d at 715–16.

Seventy five years after Nuremberg, the FDCA cannot be read to block enforcement of a *jus cogens* right by not providing an individual right to enforce.

E. In our system of government, individuals who are harmed are entitled to claim protection of the laws.

A law without a means of enforcement is just a piece of paper. "The very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury." *Marbury v. Madison*, 1 Cranch at 163.

"By its terms, § 1983 is available to enforce every right that Congress validly and unambiguously creates." *Talevski*, 599 U.S. at 192. The informed consent provision of § 564 is an unambiguously created right—Petitioner Wilkins should be allowed to enforce it via § 1983.

CONCLUSION

Petitioner respectfully urges this Court to grant a writ of *certiorari* to consider whether individuals may enforce their right to informed consent under FDCA § 564 via § 1983.

Respectfully submitted,

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