No. _____

In the Supreme Court of the United States

MELANIE CRITES-BACHERT,
Petitioner,

v.

PROVIDENCE HEALTH & SERVICES – OREGON,
Respondent.

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

The NDAA for FY 2004, as amended by the Project BioShield Act of 2004, allows the government to authorize experimental drugs for emergency use, but only with the informed consent of patients. This right to informed consent has been recognized for members of the armed forces but not for civilians.

QUESTION:

Does a civilian have the same private right of action to enforce his right to informed consent to an emergency use authorized drug as members of the armed forces?

LIST OF PARTIES TO THE PROCEEDING

Petitioner is Dr. Melanie Crites-Bachert, a doctor of Osteopathic Medicine and a surgeon.

Respondent is Providence Health & Services – Oregon.

CORPORATE DISCLOSURE STATEMENT

Petitioner has no information to disclose under Rule 29.6. Respondent Providence Health & Services – Oregon is a not-for-profit network of hospitals with no stock ticker, and no publicly held company owns 10% or more of its stock.

LIST OF DIRECTLY RELATED CASES

Crites-Bachert v. Providence Health & Services–Oregon, No. 24-6664, U.S. Court of Appeals for the Ninth Circuit. Judgment was entered on November 10, 2025; petitions for rehearing and rehearing *en banc* were denied on December 19, 2025.

Crites-Bachert v. Providence Health & Services–Oregon, No. 3:23-cv-1510-YY, United States District Court for the District of Oregon. Findings and Recommendations were issued on September 9, 2024, and judgment was entered on September 17, 2024.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Dr. Melanie Crites-Bachert respectfully seeks a writ of *certiorari* to review the judgment of the United States Court of Appeals for the Ninth Circuit, which affirmed an order granting Respondent's Rule 12(b)(6) motion to dismiss.

OPINIONS BELOW

The Ninth Circuit's opinion is unpublished and is available at *Crites-Bachert v. Providence Health & Services – Oregon,* No. 24-6664, 2025 WL 3141932 (9th Cir. Nov. 10, 2025); it is reproduced at Appendix B. The Ninth Circuit's denial of Petitioner's petitions for rehearing on December 19, 2025 are unpublished and reproduced at Appendix A.

The U.S. District Court for the District of Oregon's Findings & Recommendation is unpublished and is available at *Crites-Bachert v. Providence Health & Services – Oregon*, No. 3:23-cv-1510-YY, 2024 WL 4335334 (D. Or. Sept. 9, 2024), and is reproduced at Appendix D. The order adopting the Findings & Recommendation is available at 2024 WL 4333379 (D. Or. Sept. 27, 2024), and reproduced at Appendix C.

JURISDICTION

The Ninth Circuit issued its opinion on November 10, 2025 and denied rehearing on December 19, 2025. Petitioners requested an extension of time in which to file the instant petition

for a writ of certiorari, and were granted an extension by Justice Kagan until May 18, 2026, No. 25A1016. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are included at Appendix F, App. 27a–49a:

10 U.S. C. § 1107a
21 U.S.C. § 331
21 U.S. C. § 337
21 U.S.C. § 360bbb-3
21 C.F.R. § 50.20
21 C.F.R. § 50.25

STATEMENT OF THE CASE

This case involves an important issue concerning an individual right of informed consent for medical products that are authorized for emergency use. Congress passed the NDAA for FY 2004 and the Project BioShield Act of 2004 (together, the "BioShield Act") which allows the government to authorize experimental drugs for emergency use. Such an authorization is called emergency use authorization ("EUA").

When Congress enacted the BioShield Act, it did not forget to protect an individual's right to informed consent for experimental products. It provided that individuals be informed of "the option to accept or refuse administration of the product." This informed

consent provision was so highly valued by Congress that only a threat to national security could trump that right, and even then, only with regard to military personnel. Congress provided that only the President of the United States could overrule the informed consent requirement in the BioShield Act—only if presented with a national security emergency—and only as to military personnel.

The only courts to give effect to the informed consent provision of the BioShield Act have been those that have considered it in the context of military personnel. With respect to civilians, the Ninth Circuit, and every other court that has considered the issue, has refused to give effect to the informed consent provision of the BioShield Act.

The question is critically important because informed consent to medical interventions with experimental products is a *jus cogens* right. The discrepancy between how the right of informed consent for EUA products has been applied to civilians, as compared to military personnel, is untenable. It is far from what Congress intended. This Court should grant *certiorari*.

Background of this case

Dr. Crites-Bachert is a doctor of Osteopathic Medicine and a surgeon who had operating privileges at Providence — not as an employee, but rather as a Professional Staff Member with privileges to use hospital facilities to perform operations. Providence mandated that all Professional Staff Members receive a COVID-19 vaccine to continue their contract with Providence. The only available COVID-19 vaccines were authorized under an EUA, making them experimental. When Petitioner exercised her

right to informed consent, and refused to take a COVID-19 vaccine, she was suspended and denied access to Providence's facilities.

Dr. Crites-Bachert had a thriving urology practice with hundreds of surgeries performed and with many hundreds more prospective surgeries to be performed in future years through her career. Dr. Crites-Bachert was the most sought-after and prolific surgeon in Oregon in her specialty.

Due to Providence's violation of Dr. Crites-Bachert's rights, she had to quit her business and move out of the State of Oregon to practice medicine. She now practices in Ohio and Arizona, traveling across the country every week in order to make a living.

Dr. Crites-Bachert sued Providence in October 2023. Providence's motion to dismiss was granted in September 2024. The Ninth Circuit affirmed the dismissal in November 2025 and denied her petition for rehearing in December 2025.

In dismissing Petitioner's case, the Ninth Circuit failed to acknowledge that 21 U.S.C. § 360bbb-3 and 10 U.S.C. § 1107a both involved the same right to informed consent with respect to emergency use authorization (EUA) of medical products, and rejected Petitioner's informed consent claim on the grounds that 21 U.S.C. § 337(a), requiring enforcement of violations of prohibited acts be "by and in the name of the United States," precludes Petitioner's right to sue Respondent for injuring her when she exercised her "right to refuse" under § 360bbb-3.

No U.S. law requires the federal government to sue on behalf of a citizen whose federal rights are violated by a third party, and the FDCA is no exception. The Ninth Circuit nevertheless cited

Buckman Co v. Plaintiffs' Legal Comm., 531 U.S. 341, 352 (2001) to claim that Congress intended the FDCA be enforced exclusively by the federal government, and that it "explicitly disavow[s] private remedies." App. 5a. This latter statement fully contradicts the law and the evidence that Congress intended to maintain an already-recognized right.

The Ninth Circuit did not seriously analyze whether Dr. Crites-Bachert had an implied right of action under the BioShield Act. The notion that Congress intended *the government* to vindicate individuals' rights to informed consent for EUA products is contrary to well-established precedent, which places the right to claim protection of the laws squarely upon the citizen who is injured.

REASONS FOR GRANTING THE WRIT

Courts have split on the interpretation of identical language of separate but related provisions in 21 U.S.C. § 360bbb-3 ("Section 360bbb-3") and 10 U.S.C. 1107a ("Section 1107a"). Sections 360bbb-3 and 1107a both originated in the parallel legislation, H.R. 1588, H.R. 2122, and S. 15 of the 108th Congress.[1]

Section 360bbb-3 permits the Secretary of Health and Human Services to authorize the introduction into interstate commerce of a drug or device for

[1] Sections 360bbb-3 and 1107a arose from the same congressional act, the National Defense Authorization Act for FY 2004, Pub. L. 108-136. Section 360bbb-3 and 1107a were also included in parallel legislation, Project Bioshield Act of 2003, H.R. 2122, 108th Cong. (2003) which was passed by the House but did not become law. The Project Bioshield Act of 2004, Pub. L. No. 108-276, slightly amended 360bbb-3.

"emergency use" when specific criteria are met. Such emergency use authorizations ("EUA") were issued during the COVID-19 era for, among other things, COVID-19 vaccines. One condition for issuance of an EUA was that the Secretary shall establish:

> 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, 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)(III) (emphasis added) (the "Option"). Petitioner contends that this provision provides her with a right to informed consent to administration of a COVID-19 vaccine, and a right to sue for its violation, which she was denied.

In 10 U.S.C. § 1107, Congress stated how the Option of Section 360bbb-3 is to be applied to members the armed forces:

> (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 U.S.C. § 360bbb-3] 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-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.

10 U.S.C. 1107a(a)(1) (emphasis added) (the "Presidential Waiver").

The Presidential Waiver of Section 1107a specifically relies on the Option specified in Section 360bbb-3, by referring to "condition described in section 564(e)(1)(A)(ii)(III)."[2] *Id.* The text of the Waiver Provision in Section 1107a demonstrates how seriously Congress viewed an individual's right to informed consent. Specifically, for the armed forces, option to accept or refuse can be waived "by the President ***only if the President determines***, in writing, ***that complying with such requirement is not in the interests of national security***."

The Waiver Provision of 10 U.S.C. § 1107a(a)(1) is genuinely extraordinary by several independent measures. It employs a rare use of the word "only" twice in a single sentence. The waiver may be exercised *only* by the President personally and the waiver may issue *only* if the President makes a national security finding. Further, it requires the national security finding to be in writing. The combination of these features in a single waiver provision is rare and deliberately demanding. Congress' construction of 10 U.S.C. § 1107a(a)(1) reveals the extraordinary significance Congress

[2] Section 564 of the FDCA was added by NDAA for FY 2004, Pub. L. 108-136, and amended by the Project Bioshield Act of 2004, Pub. L. 108-276, and is codified at 21 U.S.C. § 360bbb-3.

placed in the right to informed consent. Based on the extent Congress went to protect it, there can be no doubt that Congress viewed informed consent as an extraordinarily important right.

Section 360bbb-3 is devoid of any provision that permits waiver of the Option. There is no part of Section 360bbb-3 that allows the Option to be waived, meaning that it cannot be waived. *See Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 439–40 (2002) (same).

The Option is an informed consent provision. The word "option" is defined as "the power or right to choose: freedom of choice."[3] 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 those who choose not to take a COVID injection. It is illogical that Congress would require that individuals be informed of a "freedom of choice" if the individual could not seek redress in a court to enforce that right.

If the "option to accept or refuse" were not a substantive right to make a completely voluntary

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[3] *Option*, Merriam-Webster.com Dictionary, https://www.merriam-webster .com/dictionary/option (viewed May 12, 2026).

choice with no consequences, there would be no need for the President to make a national security finding to waive the Option. The military Waiver Provision would also be unnecessary if Congress intended to permit any entity to impose its own mandate with "consequences" for refusing an EUA product.

The BioShield Act requires that individuals have an actual choice without any element of coercion. Congress did not forget to protect the *jus cogens* informed consent rights of individuals when it passed the BioShield Act. It provided for informed consent for individuals, which to have any meaning, logically includes the right of such individuals to seek remedy for its violation.

The Option is a singular individual right that has been applied completely differently by federal courts. On the one hand, courts that were confronted with the Option in the context of Section 1107a, have treated it with all the respect that it deserves given the extraordinary waiver provision. On the other hand, *every* court confronted with the Option in the context of civilian plaintiffs has denied relief. In this case, the Ninth Circuit held that Petitioner did not have a private right of action to enforce her right to informed consent. App. 5a.

This Court should resolve this split in authority concerning the right to informed consent created by the BioShield Act because: (1) there is a split in authority that has caused civilians to be treated differently than armed forces personnel; and (2) the extraordinary importance of an individual's right to informed consent.

A. Courts addressing the Option in the context of Section 1107a find that the Option is an enforceable informed consent provision.

Section 1107a has risen in court decisions only a couple of times. In *Harkins v. United States*, 174 Fed. Cl. 592, 594 (Fed. Cl. 2025), six United States Coast Guard active-duty personal, representing a putative class, challenged their separation from military service for refusing to receive COVID-19 vaccination. Judge Bonilla explained that Sections 360bbb-3 and 1107a came from the same legislation, and understood the Option as a requirement for informed consent. *Id*. at 601–02. Judge Bonilla noted that the President did not issue an informed consent waiver under Section 1107a. *Id*. at 603. He explained the "backdrop of human experimentation" historically that has been perversely employed by the United States on its service members. *Id*. at 605–06.

Judge Bonilla therefore concluded that "these Coast Guardsmen retained their rights to refuse the EUA vaccine and challenge the administration of the product in the absence of a presidential waiver under § 1107a and the implementing military regulations." *Id*. at 604.

In *Bassen v. United States*, 171 Fed. Cl. 273, 283-84 (Fed. Cl. 2024), the Court of Federal Claims found that the plaintiffs had standing to assert a violation of Section 1107a in their claim for back pay under the Military Pay Act. Similarly, in *Botello v. United States*, 173 Fed. Cl. 26, 41-42 (Fed. Cl. 2024), the Court of Federal Claims found that plaintiffs had standing to assert a violation of Section 1107a in their claim for back pay. In *Doe #1–#14*, 572 F. Supp. 3d 1224, 1235 (N.D. Fla. 2021), the government admitted that the Option (the informed consent

provision of Section 360bbb-3) would prevent the DOD from mandating an EUA drug absent a Presidential waiver.

B. The Ninth Circuit gave short shrift to Petitioner's informed consent claim.

Unlike the courts that considered the Option in the context of Section 1107a, the Ninth Circuit's Memorandum does not acknowledge that the Option of Section 360bbb-3 is an informed consent provision. It characterizes Petitioners claim to a right to informed consent as merely an allegation: "Equally meritless is Crites-Bachert's fifth claim for an ***alleged violation*** of her ***alleged right to "informed consent"*** under the Food, Drug and Cosmetic Act ("FDCA")." (emphasis added). App. 5a.

The Ninth Circuit summarily rejected Petitioner's informed consent claim on the basis that the FDCA requires that enforcement under the FDCA shall be by the United States. App. 5a. (citing 21 U.S.C. § 337(a)). It also cited this Court's opinion in *Buckman Co v. Plaintiffs' Legal Comm*., at 352, for the proposition that 21 U.S.C. § 337(a) "offers 'clear evidence that Congress intended' for the FDCA to 'be enforced exclusively by the Federal Government." App. 5a. The Ninth Circuit did not analyze any further, simply saying that if "Congress wished to empower private citizens to enforce the EUA, when nestling that provision into a broad statute that explicitly disavowed private remedies, it was incumbent upon Congress to announce its departure." App. 5a. The Ninth Circuit ruled that Petitioner had no private remedy to vindicate her informed consent right under the Option. App. 5a.

The Ninth Circuit did not seriously analyze

whether Dr. Crites-Bachert had an implied right of action under the BioShield Act. The notion that Congress intended *the government* to vindicate individuals' rights to informed consent for EUA products is contrary to law.

> "The very essence of civil liberty," wrote Mr. Chief Justice Marshall in *Marbury v. Madison*, 1 Cranch 137, 163 (1803), "certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury. One of the first duties of government is to afford that protection."

Davis v. Passman, 442 U.S. 228, 242 (1979)). Our laws are not designed create a paternalistic government that is watching out for a particular citizen's best interest. "It is not the function of our Government to keep the citizen from falling into error; it is the function of the citizen to keep the Government from falling into error." *American Communications Ass'n v. Douds*, 339 U.S. 382, 442-43 (1950) (J. Jackson, concurring in part).

Contrary to the decision of the Ninth Circuit, the history of the Option, and its importance to Congress, are evidence that Congress intended to imply a private right of action.

C. The BioShield Act private right of action.

Courts have recognized the power to imply private rights of action from federal statutes for more than a century, tracing to *Texas & Pacific Railway Co. v. Rigsby*, 241 U.S. 33, 39 (1916). In *Cort v. Ash,* 422 U.S. 66 (1975), this Court articulated a four-

factor test for determining whether a private remedy is implicit in a statute that does not expressly provide one: (1) whether the plaintiff is a member of the class for whose especial benefit the statute was enacted—that is, whether the statute creates a federal right in favor of the plaintiff; (2) whether there is any indication of legislative intent, either explicit or implicit, to create or deny a private remedy; (3) whether implying a remedy is consistent with the underlying purposes of the legislative scheme; and (4) whether the cause of action is one traditionally relegated to state law, in an area basically the concern of the states, so that inferring a cause of action based solely on federal law would be inappropriate. *Id.*, at 78. This Court later explained that congressional intent is "the central inquiry." *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575 (1979).

The modern inquiry is whether Congress intended to create both a private right of action and a private remedy. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *Gonzaga University v. Doe*, 536 U.S. 273, 284 (2002). It is rare for any statute to confer an enforceable right, particularly spending-power statutes. *Medina v. Planned Parenthood South Atlantic*, 606 U.S. 357, 369 (2025). The congressional act in this case threads the needle. Congress intended to create a private right of action to enforce informed consent when it included a right to refuse an EUA product in the BioShield Act. The U.S. Court of Federal Claims has determined that this right is enforceable through private action.

In the 108th Congress there were three bills that were advanced for the Bush administration's biodefense agenda after the 2001 anthrax attacks. Project BioShield Act of 2004, S. 15, 108th Cong.

(introduced Mar. 2003) (enacted); Project BioShield Act of 2003, H.R. 2122, 108th Cong. (introduced May 2003) (passed by the House); National Defense Authorization Act for Fiscal Year 2004, H.R. 1588, 108th Cong. (Apr. 2003) (enacted). These resulted in two public laws.

H.R. 2122 included both the Option and the Presidential Waiver.[4] The Option appears on page 45 and the Presidential Waiver, several paragraphs later, on page 50. S. 15 also included both the Option and the Presidential Waiver.[5] The Option appears on page 52 and the Presidential Waiver, several paragraphs later, on pages 57-58. Thus, the Option and the Presidential waiver were coupled from the start. During debate of H.R. 2122 in the House, 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). (emphasis added).[6] Representative Hays also explained why the bill included such a stringent limit

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[4] *See* https://www.congress.gov/108/bills/hr2122/BILLS-108hr2122ih.pdf.

[5] *See* https://www.congress.gov/108/bills/s15/BILLS-108s15is.pdf

[6] https://www.congress.gov/108/crec/2003/07/16/CREC-2003-07-16-pt1-PgH6908.pdf (viewed May 13, 2026).

on waiver of informed consent:

> In the 1991 Persian Gulf War, soldiers, sailors, aircrews and Marines were ordered to take experimental drugs and vaccines. Despite Pentagon promises to provide critical medical information and keep accurate medical records, very little information was provided and very few records survived the trip home. That cannot happen again. In the course of 14 hearings on the subsequent health problems of Gulf War veterans, the Government Reform subcommittee I chair reached this stark conclusion: "Unless providing medical information to service members is mandatory, it's just too easy for the military, in the heat of battle, to decide it's just not feasible."
>
> In the war against terrorism, we are all on the front lines. The citizen-soldiers of our all-voluntary Armed Forces fight and die to protect our rights and freedoms. ***They should not be asked to surrender those fundamental rights under different, less rigorous, circumstances than those they left behind***.

Id. (emphasis added).

These statements show that Congress was very aware of the right to informed consent and the harm that can come from experimental drugs. They viewed informed consent as a fundamental, basic human right. They wanted service members to have the same informed consent right as civilians not on the battlefield. The only exception required an

extraordinary written Presidential finding.

In the Senate, during debate of S. 15, Senator Ted Kennedy stated:

> The authorization for the emergency use of unapproved products also includes ***strong provisions on informed consent for patients*** and limits the scope of products that can qualify for emergency authorization.

150 Cong. Rec. S5744 at S5765 (daily ed. May 19, 2004) (emphasis added).[7]

Confirming that the Option is an informed consent provision providing an individual the right to refuse administration, the House Conference Report for H.R. 1588[8] explained the provisions of Section 1107a:

> The amendment would authorize the President to waive ***the right of service members to refuse administration of a product*** if the President determines, in writing, that affording service members the right to refuse the product is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

H.R. Rep. No. 108-354 at 782 (2003) (emphasis added).

As conceived by Congress, the informed consent

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[7] https://www.congress.gov/108/crec/2004/05/19/CREC-2004-05-19-pt1-PgS5744.pdf (viewed May 13, 2026).

[8] The National Defense Authorization Act for FY 2004, H.R. 1588, 108th Cong. (2003), contained the same Option and Presidential Waiver provisions.

to administration of a EUA product was a fundamental human right possessed by every individual to refuse an experimental drug. This is not surprising, because every member of Congress is aware of the Nuremberg Code and the prohibitions on coerced medical experimentation on humans.

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." *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(a)(8). 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." *Id.*

In 1979, the Department of Health, Education and Welfare issued *The Belmont Report* (April 18, 1979).[9] The Belmont Report was developed in response to the revelation of the infamous Tuskegee Syphilis Study in which African Americans with syphilis were lied to and denied treatment for more than 40 years. *Id.*

The Belmont Report summarized some of the history of the exploitation of human subjects for experimentation:

> For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940's, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population.

Id. The evolution of explicit prohibitions on coerced

[9] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U.S. Department of Health, Education, and Welfare, April 18, 1979. https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf (Apr. 18, 1979) (viewed May 13, 2026).

medical experimentation on human beings began with the Nuremberg war crimes trials. *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163, 177 (2nd Cir. 2009). The prohibition on nonconsensual medical experimenttation 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 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.

The Nuremberg Code (1949) (emphases added). App. 25a. The Nuremberg Code is accepted in the United States and worldwide as a *jus cogens* norm, which "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 v. Republic of Argentina*, 965 F.2d

699, 715 (9th Cir. 1992). In short, human beings have an inherent and fundamental right not to be coerced into taking experimental medication.

The extraordinary importance that Congress placed on the Option is substantiated by the Nuremberg Code and the well-documented history of government abuses. The Presidential Waiver is so narrow and strict due to abuses of human rights by our own government.

The right to informed consent in Section 360bbb-3 is an implied private right of action. No person other than the individual "to whom the product is administered," 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), has the authority to decide for that person whether to consent. Nuremberg Code (the person involved is to exercise his free power of choice without any element of coercion and with sufficient knowledge so he can make an understanding and enlightened decision). Informed consent is inherently a decision exercised by an individual. No one is allowed to make an informed consent decision for another competent person. The ability of an individual to make an informed consent is a basic human right. 108 Cong. Rec. H6908 at H6935, *supra*; 150 Cong. Rec. S5744 at S5765, *supra.* The DOD recognized the implied right of a service member to "***refuse*** administration of the product." DOD Instruction 6200.02 § E3.4 (Feb. 27, 2008).[10] The Option of Section 360bbb-3 of the BioShield Act implies a private right of action.

The BioShield Act also implies a private remedy. Congress did not contemplate that the government would protect an individual's right to informed consent. Quite the opposite—Congress viewed the

[10] https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620002p.pdf (viewed May 13, 2026).

government as the nefarious entity that individuals needed to be protected from. An individual has a personal right to refuse. *See* DOD Instruction 6200.02, *supra*. When that right is infringed, the person injured may sue for a remedy: "[t]he 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*, at 163. An individual whose right to informed consent is violated has a private and implied private right to sue for damages. *See Harkins*, 174 Fed. Cl. at 604. ("these Coast Guardsmen ***retained their rights to*** refuse the EUA vaccine and ***challenge the administration of the product*** in the absence of a presidential waiver under § 1107a and the implementing military regulations" (emphases added)).

D. The Ninth's Circuit analysis denies a right to civilians which military personnel enjoy.

The intent of Congress is best understood by looking at the bill itself—the BioShield Act. The Option and the Presidential Waiver were combined in the same bill and closely tied in subject matter. An understanding of Congress' intent requires reading them together in the context of the BioShield Act.

When codified, the Option landed in the Food, Drug, and Cosmetic Act, Title 21, at 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III). And the Presidential Waiver landed in Title 10 at 10 U.S.C. § 1107a(a)(1).

The Food, Drug, and Cosmetic Act contains a provision requiring that all enforcement proceedings "shall be by and in the name of the United States." 21 U.S.C. § 337. This Court also stated that "[t]he 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. Plaintiffs' Legal Comm.*, at 349 n.4. The Ninth Circuit relied on this authority to reject Petitioner's appeal and refused to look further.

Section 337 does not negate Petitioner's implied cause of action for two reasons: (1) Section 337 is not comprehensive; and (2) there is nothing inconsistent between § 337 and a private right of action. The Ninth Circuit did not do the necessary analysis. It failed to analyze the FDCA to determine if it has a comprehensive enforcement scheme that would protect Petitioner so as to preclude a private right of action. *See Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103, 106 (1989). (Congress can show a remedy is foreclosed "by providing a comprehensive enforcement mechanism for protection of [the] federal right.")

The FDCA is primarily directed to licensing issues related to the approval of products for interstate commerce. The prohibited acts referred to in 21 U.S.C. § 337, enforceable "by and in the name of the United States," are exhaustively identified and laid out in comprehensive detail in 21 U.S.C. § 331.

The acts prohibited under 21 U.S.C. § 331 rarely mention Section 564 [21 U.S.C. § 360bbb-3], 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) (emphasis added).

By contrast, nothing in the FDCA authorizes violations of Petitioner's right to informed consent to be enforced "by and in the name of the United States," and such enforcement would have no precedence in U.S. law. The prohibited acts in § 331 do *not* include a violation of Dr. Crites-Bachert' right to informed consent under Section 564(e)(1)(A)(ii)(III) [21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III)]. There is no provision in the FDCA that explicitly provides, or limits or restrains, how Petitioner's right to informed consent — and her right to refuse — may be brought to the courts.

There is nothing inconsistent between § 337 and recognition of an implied private cause of action to enforce Petitioner's right to informed consent under Section 360bbb-3. Section 337 is devoid of mechanisms for protecting the right of informed consent. The statute provides no mechanism for enforcement of the right to informed consent that would conflict with a private right of action. The entire enforcement scheme of Section 337 envisions the United States enforcing requirements on manufacturers and suppliers relating to the approval of medical products. *See* 21 U.S.C. § 331. Thus, the FDCA enforcement scheme does not conflict with a private right of action to enforce a right to informed consent. A non-comprehensive statutory framework that does not conflict with an implied right of action does not preclude private enforcement. Recognizing an implied private right of action in this context is entirely consistent with express enforcement of specific provisions of the FDCA.

E. The decision below creates a split of authority which only this Court can resolve.

The Ninth Circuit's rejection of Petitioner's implied right of action is plainly wrong.

1. Congress understood that informed consent to experimental medical products was a basic human right. 108 Cong. Rec. H6908 at H6935, *supra*. Congress wrote what it thought were strong provisions on informed consent to patients. 150 Congressional Record S5744 at S5765, *supra*. Congress understood that the right to informed consent for experimental products was extraordinarily important.

The importance that Congress placed in informed consent to EUA products is reflected by the extraordinary high bar for waiving informed consent, requiring a written Presidential national security finding, and then only as to the armed forces. 10 U.S.C. § 1107a(a)(1). Congress wrote this extraordinarily rigorous waiver provision due to learned experience and broken promises demonstrating that the government cannot be trusted to protect informed consent. 108 Cong. Rec. H6908 at H6935, *supra*. Service members had to receive the same protection as civilians "they left behind" except under the most extraordinary circumstances. *Id*.

In sum, under the BioShield Act, the protection of informed consent for civilians and the military are the same, except that service members' rights could be waived with a written finding by the President.

2. A conflict exists in the treatment of informed consent between civilians and military personnel under the BioShield Act. The few courts that have considered service members' informed consent rights

have honored those rights and permitted them to sue. In contrast, the Ninth Circuit, and every other court which has considered the civilian right to informed consent has blocked it on a superficial analysis of the FDCA.

3. Petitioner has a private right of action under the FDCA. The BioShield Act was written with the knowledge, experience, and expectation that it would be the government that would abuse the informed consent rights of individuals. 108 Cong. Rec. H6908 at H6935, *supra.*

The FDCA is completely silent on how informed consent rights of individuals are to be protected. The FDCA's enforcement mechanisms do not comprehend such rights. A private right of action does not conflict with the existing FDCA enforcement mechanisms. The FDCA does *not* eviscerate the right to informed consent, nor does it explicitly exclude the rights of individuals to remedy in the courts for violations of recognized federal rights.

4. The right at issue, informed consent for experimental products, is no ordinary right or interest. The right to informed consent for human experimentation is recognized worldwide as a *jus cogens* right from which no derogation is allowed. *Siderman*, at 715. The wholesale rejection of civilians who have tried to assert their God-given right to dominion over their own bodies has been tragic for this Country.

CONCLUSION

The petition for writ of *certiorari* should be granted.

Respectfully submitted,

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