NO. _____

In the Supreme Court of the United States

CATHERINE ANTUNES,

Petitioner,

v.

XAVIER BECERRA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF HEALTH, ET AL.,

Respondents.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Does the Constitutional right to bodily integrity encompass the right to decline a vaccine?

2. Is *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), applicable to an employer's mandate for a vaccine, and is it still good law?

3. May an employer lawfully achieve through economic coercion what would be battery if it achieved the same thing through physical force (the administration of unwanted medical treatment)?

4. Does the PREP Act impose a duty on the Secretary of the U.S. Department of Health and Human Services to provide the option to decline a drug or device authorized under the emergency provisions of the PREP Act?

5. Is it a violation of the Equal Protection Clause of the Fifth Amendment for the U.S. Secretary of Health and Human Services to extend different protections to two different groups of people in the administration of the same drug?

PARTIES TO THE PROCEEDINGS

Petitioner and Plaintiff-Appellant

- Catherine Antunes

Respondents and Defendants-Appellees

- Xavier Becerra, in his official capacity as Secretary of the U.S. Department of Health and Human Services
- Rector and Visitors of the University of Virginia

Respondents and Defendants below

- University of Virginia Health Systems
- U.S. Department of Health and Human Services
- Food and Drug Administration
- Robert Califf, M.D., in his official capacity as Commissioner of the U.S. Food and Drug Administration

LIST OF PROCEEDINGS

United States Court of Appeals for the Fourth Circuit

No. 22-2190

Catherine Antunes, *Plaintiff-Appellant*, v. Xavier Becerra, in his official capacity as Secretary of U.S. Department of Health and Human Services; Rector and Visitors of the University of Virginia, *Defendants-Appellees* and University of Virginia Health Systems; U.S. Department of Health and Human Services; Food and Drug Administration; Robert Califf, M.D., in his official capacity as Commissioner of the U.S. Food and Drug Administration, *Defendants*

Date of Final Opinion: February 9, 2024

United States District Court, Western District of Virginia, Charlottesville Division

No. 3:21-CV-00042

Catherine Antunes, *Plaintiff*, v. Rector & Visitors of the University of VA., et al., *Defendants*.

Memorandum Opinion and Order: September 12, 2022

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Catherine Antunes requests that this Court issue a writ of certiorari to allow the Petitioner to seek reversal and remand of the decisions below.

OPINIONS BELOW

The United States District Court for the Western District of Virginia Division at Charlottesville on September 12, 2022, granted Respondents' motion to dismiss for failure to state a claim upon which Relief could be granted and for lack of standing. (App.6a). On February 9, 2024, the Fourth Circuit affirmed (App.1a), which is unpublished as *Antunes v. Becerra*, No. 22-2190, 2024 WL 511038 (U.S. App. Ct. 4th Cir. Feb. 9, 2024).

JURISDICTION

The judgment of the Court of Appeals was entered on February 9, 2024. (App.1a). This Court's jurisdiction rests on 28 U.S.C. § 1254(a).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Const., amend. IV

> The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

U.S. Const., amend. V

> In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury of the state and district wherein the crime shall have been committed, which district shall have been previously ascertained by law, and to be informed of the nature and cause of the accusation; to be confronted with the witnesses against him; to have compulsory process for obtaining witnesses in his favor, and to have the assistance of counsel for his defense.

21 U.S.C § 360bbb-3(e)(1)(A)(ii)(III)—The Public Readiness and Emergency Preparedness (PREP) Act

> 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:

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[.]

5 U.S.C. § 702—Administrative Procedures Act

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party.

21 C.F.R. Part 50

Protection of Human Subjects applies to:

[A]ll clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food

> and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.

21 C.F.R. § 50.20 states that, with exceptions not applicable here:

> [N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

STATEMENT OF THE CASE

A. Factual Background

On November 9, 2021, the Rector and Board of Visitors of the University of Virginia ("UVA") fired Ms. Catherine Antunes[1], an experienced Registered Nurse in good standing who had worked in its university health system from January 2020 until then. Ms. Antunes had worked overtime with UVA throughout the COVID-19 pandemic and had displayed "astute clinical skills" and "natural leadership ability."

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[1] Pronounced ANN-toons

UVA fired Ms. Antunes according to its COVID-19 vaccination policy, announced in August of 2021, which required all health personnel to be vaccinated using one of the available COVID-19 vaccinations, all of which the Food and Drug Administration (FDA) / Department of Health and Human Services (HHS) and its principals, the Commissioner of the FDA and the Secretary of HHS (together the "Federal Defendants"), approved according to the Emergency Use provision of the Food, Drug, and Cosmetics Act (FDCA). (App.52a). UVA would fire those who did not comply with the vaccine mandate. UVA opined soon after announcing its mandate that it was "unclear" if the mandatory vaccination policy was legal. As to the question of whether it was ethical, according to UVA, it "depends on who you ask." (*See* App.65a).

The Secretary of the U.S. Department of Health and Human Services, (HHS), meanwhile, was to provide to recipients of drugs approved under the emergency provisions of the PREP Act "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).

At the same time, clinical trials were ongoing for all of the available vaccines, and per HHS regulation, the participants in these trials, who were receiving identical formulations of the vaccine, were the beneficiaries of explicit HHS regulatory protections against coercive pressure to accept them—trial administrators could not: "involve a human being in

research . . . unless the investigator has obtained the legally effective informed consent of the subject[.]" Trial administrators could seek that informed consent "only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence." (21 C.F.R. § 50.20).

B. Procedural History

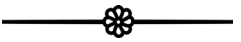
Ms. Antunes originally filed for a Temporary Restraining Order on November 9, 2021, to prevent her termination, which the District Court denied. UVA terminated her on the same day. She amended her complaint to pray for declaratory and injunctive relief that would restore her to her employment at UVA and would provide her compensation for the financial difficulty she had suffered. Both UVA and the Federal Defendants moved to dismiss her complaint according to F. R. Civ. P. 12(b)(1) and 12(b)(6). The District Court held oral arguments on the Motions to Dismiss on August 26, 2022, and issued a Final Order granting the motions to dismiss on September 12, 2022. (App.6a, 29a).

Ms. Antunes filed her Appeal on November 14, 2022. The Fourth Circuit Court of Appeals docketed the case on November 18, 2022, and oral arguments occurred on January 25, 2024. The Fourth Circuit issued an unpublished *per curiam* opinion on February 9, 2024, affirming the decision of the lower court. The Court issued the mandate on April 2, 2024.

The District Court found that Ms. Antunes lacked standing for the claims against the Secretary, because her termination was not fairly traceable to his actions (App.6a), and that it was not likely that

she would receive redress from a favorable decision regarding those claims. The District Court furthermore found that Congress had not waived the federal government's sovereign immunity on this point, as it had made decisions under the PREP Act unreviewable.

The District Court dismissed the rest of the claims under 12(b)(6): that Ms. Antunes failed to allege facts supporting a violation of the Equal Protection Clause or the Due Process Clause by UVA; that she failed to allege facts supporting a violation of the Fourth Amendment or the imposition of an unconstitutional condition on employment. The Fourth Circuit panel concurred in the District Court's opinion.



REASONS FOR GRANTING THE PETITION

I. SUPREME COURT PRECEDENT IS, OR APPEARS TO BE, IN CONFLICT WITH ITSELF ON THE QUESTION OF BODILY INTEGRITY AND THE RIGHT TO REFUSE UNWANTED MEDICAL TREATMENT

Ms. Antunes, an educated woman, is one among the millions of Americans who received from the culture and from her education the understanding that she has a right rooted in the U.S. Constitution to bodily integrity, and that part of the right is the right to refuse unwanted medical treatment. This is certainly in part because of *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), which stated that, "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." It is also a result

of the Fourth Amendment, which states explicitly that "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated[.]"[2]

Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705 (1973) and *Planned Parenthood v. Casey*, 505 U.S. 833, 112 S.Ct. 2791 (1992) dealt with similar concepts, as did the development of Title VII sexual harassment jurisprudence, the #MeToo movement,[3] and advances in informed consent in medical care and human research, which she would be especially attuned to because of her medical training.[4]

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[2] Petitioner acknowledges that courts have uniformly applied the Fourth Amendment in the criminal context, especially because the next clause references warrants and probable cause. There seems to be, however, nothing to prohibit recognition of this language asserting security in one's person as textual authority, partial or indirect as it may be, for the right that *Cruzan* recognized.

[3] Stephanie Zacharek, Eliana Dockterman & Haley Sweetland Edwards, *Time Person of the Year 2017: The Silence Breakers*, TIME (2017), https://time.com/time-person-of-the-year-2017-silence-breakers/. Nadia Khomami, *Women Worldwide Use Hashtag #MeToo Against Sexual Harassment*, THE GUARDIAN, Oct. 20, 2017, https://www.theguardian.com/world/2017/oct/20/women-worldwide-use-hashtag-metoo-against-sexual-harassment.

[4] *See, e.g.,* HHS.gov, *The Belmont Report*, at https://www.hhs.gov/ohrp/regulations-and-policy/belmontreport/index.html:

> Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance . . . Unjustifiable pressures usually occur when persons of authority or commanding influence – especially where possible sanctions

She is also among the millions who were shocked and scandalized to encounter the idea that this understanding of her rights and her legal standing was wrong, and that it was wrong because of a Supreme Court opinion from 1905 involving smallpox.

II. *JACOBSON V. MASSACHUSETTS* NEEDS TO BE OVERTURNED, UPDATED, AND/OR REAFFIRMED IN LIGHT OF THE LEGAL DEVELOPMENTS THAT HAVE OCCURRED SINCE

Jacobson v. Massachusetts, to the extent that it stands for the notion that a state may mandate a vaccine, appears to be in direct conflict with the understanding of the rights to bodily integrity and the right to refuse medical treatment that the culture has received from this Court.

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are involved – urge a course of action for a subject. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

See also, The American Medical Association Code of Medical Ethics Opinion 2.1.1: Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making. (available at: https://www.ama-assn.org/deliveringcare/ethics/informedconsent#:~:text=Code%20of%20Medical%20Ethics%20Opinion%202.1.,-1&text=Patients%20have%20the%20right%20to,and%20supports%20shared%20decision%20making.)(Last visited January 23, 2023).

Whether the popular understanding of these rights corresponds with reality is not a concern for the Court so much as the fact that *Jacobson* is an anachronism. Since 1905, many of the developments in the law have been some of the most important in our nation's history: the overturning of the same 1905 Court's *Lochner v. New York* 198 U.S. 45 (1905); women's suffrage, admission to the bar, and elevation to the bench; *Buck v. Bell* and the eugenics movement,[5] which had *Jacobson* at its core; the end of Jim Crow era; the beginning of the Civil Rights era; the application of Title VII of the Civil Rights Act to sexual harassment; *Roe v. Wade*, *Planned Parenthood v. Casey*, and *Dobbs v. Jackson Women's Health Org*., 597 U.S. 215, 142 S.Ct. 2228 (2022); the Tuskegee experiments; the *Belmont Report*; and modern notions of informed consent among them.

Because of this history and all that has occurred since *Jacobson*, it is impossible for public officials and the judiciary who act or rule in reliance on it to escape the appearance that they are trying to, or actually are, getting away with something. Whether or not this Court intends for *Jacobson* to be the rule for the next 120 years is something that this Court should say definitively, and after analyzing the question with explicit reference to the legal, ethical, and cultural developments that have occurred since the rule.

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[5] *See, e.g.,* Teryn Bouche and Laura Rivard, *America's Hidden History: The Eugenics Movement*, SCITABLE BY NATURE EDUCATION, (September 18, 2014), available at https://www.nature.com/scitable/forums/genetics-generation/america-s-hidden-history-the-eugenics-movement-123919444/.

Although comprehensive numbers are difficult to come by, it seems safe to say that a significant portion of the American workforce encountered some form of a COVID-19 vaccination mandate,[6] with untold numbers losing their livelihoods, if only temporarily. All told, it may be one of the most significant re-orientations within the economy in recent history. The number of people who took the vaccine against their better judgment in order to save their jobs is likely to be even higher.

Furthermore, with mRNA technology taking hold in other applications,[7] the potential for more mandates remains ever-present. For the Court to speak on the rights of individuals to refuse unwanted bodily intrusions in the form of medical interventions without consequence is among the most important issues that the Court could address at this moment in history.

Similarly, it is necessary for the Court to establish a rule that is easier to understand and that is easier to follow. It is not clear from *Jacobson*'s application whether it is a "modest decision," or one that "overshadows the Constitution during a pandemic." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141

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[6] Danielle Ivory et al., *See Where 12 Million U.S. Employees Are Affected by Government Vaccine Mandates*, N.Y. TIMES (Dec. 18, 2021), https://www.nytimes.com/interactive/2021/12/18/us/vaccine-mandate-states.html.

[7] Mark Zipkin, *The Next Next-Gen Vaccines*, NAURE.COM (May 18, 2023) at https://www.nature.com/articles/d43747-023-00035-x("One commonly overlooked distinction between mRNA and more traditional technologies is that mRNA itself is not actually a vaccine—it effectively turns human cells into vaccine factories by inducing them to produce viral antigens.")

S.Ct. 63, 70 (2020) (Gorsuch, J., concurring). It is furthermore not clear if the fact that the law in question in *Jacobson* was a legislative act has the same application where, as in Ms. Antunes's case, there has not been an act of the legislature. It is also not clear whether it is intended to announce a standard of review for such cases. *See*, *Id.* It furthermore remains an open question whether such a standard, if it is indeed a rational basis standard, remains appropriate after the removal of liability for vaccine producers,[8] the increase in the number of diseases for which a vaccine is available,[9] the changes in the relevant legal jurisprudence that have occurred since the announcement of the rule, and changes in vaccine technology. The time for the Court to speak on the continued applicability of *Jacobson* has come. The question of whether a state employer imposes an unconstitutional condition on an employee when imposing a vaccine will flow from this analysis.

III. THE COURT SHOULD SPEAK TO THE ISSUE OF WHETHER COERCION IN PURSUIT OF MEDICAL BATTERY IS UNLAWFUL OR NOT

Virginia has a strong legal tradition recognizing the importance of informed consent in medical treatment. Absent that consent, Virginia courts recognize that a medical professional is guilty of battery or trespass.[10]

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8 42 U.S. Code § 300aa–22

9 Paul A. Offit, *Vaccine History: Developments by Year*, Children's Hosp. of Phila. (Aug. 21, 2023), https://www.chop.edu/centers-programs/vaccine-education-center/vaccine-history/developments-by-year.

10 *Morvillo v. Shenandoah Mem'l Hosp.*, 547 F. Supp. 2d 528,

531 (W.D. Va. 2008) states:

> Under Virginia law [. . .] the tort of battery is "an unwanted touching which is neither consented to, excused, nor justified." *Koffman v. Garnett*, 265 Va.12, 574 S.E.2d 258, 261 (Va. 2003). The Supreme Court of Virginia has recognized that the relationship between a physician and a patient is a consensual one. *Washburn v. Klara*, 263 Va. 586, 561 S.E.2d 682, 685 (Va. 2002). Thus, "unless an emergency or unanticipated problem arises, a physician or surgeon must first obtain the consent of a patient before treating or operating on that patient." *Id.* In the absence of an unanticipated problem or emergency, a medical procedure or operation performed without a patient's consent constitutes a "technical" battery. *Id.* (internal citations and quotations omitted); *see also Pugsley v. Privette*, 220 Va. 892, 263 S.E.2d 69, 74 (Va. 1980) ("A surgical operation on the body of a person is a technical battery or trespass unless he or some authorized person consented to it.") (internal citations, quotations, and alterations omitted). A technical battery also occurs when a medical procedure is performed that exceeds the scope of a patient's consent, or a medical procedure is continued after a patient's consent has been unequivocally withdrawn. *See Washburn*, 561 S.E.2d at 686 (battery claim predicated on the allegation that the defendant exceeded the scope of the plaintiff's consent by performing a diskectomy at the C7-T 1 level of the plaintiff's spine, even though she only consented to a diskectomy at the C6-7 level); *Woodbury v. Courtney*, 239 Va. 651, 391 S.E.2d 293, 294, 6 Va. Law Rep. 2226 (Va. 1990) (battery claim predicated on the assertion that the defendant exceeded the scope of the plaintiff's consent to a breast biopsy by ultimately performing a partial mastectomy); *Pugsley v. Privette*, 263 S.E.2d at 74-76 (battery claim predicated on the assertion that the plaintiff withdrew her consent prior to surgery, and thus, that she was operated on by a surgeon without

If UVA had attempted to achieve Ms. Antunes's vaccination by physical force instead of economic coercion, its actions would have been unlawful and would have exposed UVA to liability.

This raises the question of whether coercion in pursuit of what would be battery if performed physically is also unlawful. This line of analysis tracks the developments that have occurred in the context of sexual harassment, where in 1977 the *Barnes v. Costle* case solidified the legal convention that has stood for over 40 years and has led to the protection of countless women (and men)—that sexual harassment is discrimination on the basis of sex and carries with it legal consequences. 561 F.2d 983 (D.C. Cir. 1977). Before this development, courts treated sexual harassment as "a personal matter having nothing to do with work or a sexual assault that just happened to occur at work." Reva B. Siegel, *A Short History of Sexual Harassment*, in DIRECTIONS IN SEXUAL HARASSMENT LAW 11, (Catherine McKinnon, ed. 2003).

Direction from the Court on this matter will help direct the understanding of an employer's relationship to his employee's body and medical choices.

IV. THE COURT SHOULD STATE WHETHER THE PREP ACT IMPOSES A DUTY TO PROTECT RECIPIENTS OF AN EMERGENCY-AUTHORIZED PRODUCT

In the Administration of drugs and devices authorized under the PREP Act, 21 U.S. Code § 360bbb–3(e)(1)(A)(ii)(III) states that the HHS Secretary must "ensure that individuals to whom the product is

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her consent).

administered are informed…of the option to accept or refuse administration of the product."

There is, of course, no real option where one choice involves the loss of one's livelihood, which was the case with Ms. Antunes. Congress' reference to an "option," however, raises the question of whether Congress intended for the Secretary to identify that option and ensure that exists where it does not.

Ms. Antunes urged the courts below to adopt the position that any other interpretation—*e.g.* informing recipients of an option that does not exist—would reduce this provision to an absurdity. (App.1a, 6a)

She also urged the Courts below to recognize that the Secretary's failure to do so while extending protections to trial recipients of the same vaccine was a violation of the Equal Protection Clause of the Fifth Amendment,[11] as the two different groups were receiving the same formulations of the same drugs but were receiving different protections without a rational basis for doing so.

For the Court to speak on these issues in this case would also give the Court the opportunity to

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[11] 21 C.F.R. § 50.20 states that,

> [N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

address a concerning and potentially dangerous line of analysis. The lower courts here held that the Secretary's failure to provide the protections mandated in the statute was not reviewable under the sovereign immunity exceptions provided under Section 702 of the Administrative Procedure Act. 5 U.S.C. § 702. (*Id.*) If this were to become the rule, Department heads would have discretion not only over how they apply the law but also whether they apply the law at all, including the U.S. Constitution. This cannot be what the APA means. This Court should speak with clarity on this issue to clarify that, while Congress may exempt a Department head's actions from review under the APA, Courts cannot interpret this discretion to include the Secretary's self-exemption from his legal obligations. Doing so as part of this case would also provide the Court the opportunity to indicate whether an employment termination that occurred in the absence of these protections would be fairly traceable to the Secretary for the purpose of a 12(b)(1) analysis, and whether a favorable decision would provide redress to Ms. Antunes.

CONCLUSION

The legal issues implicated in the termination of Ms. Antunes from her position at UVA implicate some of the most consequential issues the nation has faced in a generation, speaking to the relationship of a person's body to her employer and to the providers of medicine, what the employer may achieve through economic coercion, and the duties and limitations of the Executive Branch. Accordingly, this Court should grant Ms. Antunes's petition.

Respectfully submitted,

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