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**OPINION, U.S. COURT OF APPEALS
FOR THE FOURTH CIRCUIT
(FEBRUARY 9, 2024)**

UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

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,

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.

No. 22-2190

Appeal from the United States District Court
for the Western District of Virginia,
at Charlottesville. Norman K. Moon,

Senior District Judge.
(3:21-cv-00042-NKM-JCH)

Aruged: January 25, 2024
Decided: February 9, 2024

Before: KING and BENJAMIN, Circuit Judges,
and KEENAN, Senior Circuit Judge.

Affirmed by unpublished per curiam opinion.

PER CURIAM:

This civil action stems from the University of Virginia Health Systems’ COVID-19 vaccination mandate for employees and plaintiff Catherine Antunes’s November 2021 discharge from her position as a nurse for refusing to comply with that mandate. Following her termination, Antunes sued in the Western District of Virginia, asserting a variety of state and federal claims by her operative Third Amended Complaint of March 2022 (the “Complaint”). In pertinent part, the Complaint alleges that the University of Virginia Health Systems and the Rector and Visitors of the University of Virginia (together, the “UVA Health Defendants”) contravened Antunes’s Fourth and Fourteenth Amendment rights in discharging her. The Complaint also alleges that several federal officials—specifically, the U.S. Department of Health and Human Services (the “DHHS”); Xavier Becerra, the Secretary of the DHHS; the Food and Drug Administration (the “FDA”); and Robert Califf, the FDA Commissioner (collectively, the “Federal Defendants”)—violated the Fourteenth Amendment and the Food, Drug, and Cosmetic Act by

failing to prevent the UVA Defendants from firing Antunes.

In September 2022, the district court dismissed all Antunes’s claims against the UVA Health Defendants under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, and all claims against the Federal Defendants under Rule 12(b)(1) for lack of constitutional standing to sue. *See Antunes v. Rector & Visitors of Univ. of Va.*, 627 F. Supp. 3d 553 (W.D. Va. 2022) (the “Memorandum Opinion”). Antunes timely noted this appeal, naming only the University of Virginia Health Systems and Secretary Becerra as appellees and contesting the dismissal of the claims described above.

Having assessed the various submissions of the parties and with the benefit of oral argument, we are satisfied that the district court did not err in dismissing Antunes’s claims. Indeed, we readily adopt the court’s carefully crafted and well-reasoned Memorandum Opinion addressing the relevant issues. We therefore reject each of Antunes’s appellate contentions and affirm.

AFFIRMED

**JUDGMENT, U.S. COURT OF APPEALS
FOR THE FOURTH CIRCUIT
(FEBRUARY 9, 2024)**

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

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,

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.

No. 22-2190
(3:21-cv-00042-NKM-JCH)

Filed: February 9, 2024

JUDGMENT

In accordance with the decision of this court, the judgment of the district court is affirmed.

This judgment shall take effect upon issuance of this court's mandate in accordance with Fed. R. App. P. 41.

/s/ Nwamaka Anowi

Clerk

**MEMORANDUM OPINION, U.S. DISTRICT
COURT FOR THE WESTERN DISTRICT OF
VIRGINIA CHARLOTTESVILLE DIVISION
(SEPTEMBER 12, 2022)**

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CATHERINE ANTUNES,

Plaintiff,

v.

RECTOR & VISITORS
OF THE UNIV. OF VA., ET AL.,

Defendants.

Case No. 3:21-CV-00042

Before: Norman K. MOON,
United States District Judge.

MEMORANDUM OPINION

Plaintiff began working as a nurse at the University of Virginia (“UVA”) in 2020. According to Plaintiff’s Third Amended Complaint, in late 2021, the University required health-care employees to provide proof of vaccination for COVID-19. When Plaintiff failed to provide proof of vaccination and had not submitted a request for a religious or medical exception,

the University suspended her and later terminated her employment. Plaintiff filed suit against the Federal Food and Drug Administration (“FDA”) and the Department of Health and Human Services (“HHS”) and their officials, and UVA, alleging violations of her constitutional rights and wrongful termination of employment.

Plaintiff’s suit will be dismissed in its entirety. Plaintiff’s claims against Federal Defendants will be dismissed for lack of standing. Plaintiff’s claims against the UVA Defendants will be dismissed for failure to state a claim.

I. Background

The following facts are alleged in Plaintiff’s Third Amended Complaint and assumed true for purposes of resolving this motion. *See King v. Rubenstein*, 825 F.3d 206, 212 (4th Cir. 2016) (reiterating the appropriate standard of review). Plaintiff Catherine Antunes, a nurse with thirteen years of experience in healthcare and six years of experience as a nurse, began employment within the UVA healthcare system in January 2020. Dkt. 40 (“Third Amend. Compl.”) ¶¶ 1, 10, 30. At her most recent evaluation (6/30/2021), UVA Health management rated her work as “fully meets expectations,” in addition to describing her as “an exceptional asset to the team” who possesses “astute clinical skills” and “natural leadership ability.” *Id.* ¶ 1.

On March 27, 2020, then-Secretary of the U.S. Department of Health and Human Services (“HHS”) Alex Azar II issued a declaration (*Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3). *Id.* ¶ 24. This

declaration stated that, on February 4, 2020, Secretary Azar determined, in relation to the novel coronavirus, that “[p]ursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad.” *Id.* Pursuant to Secretary Azar’s March 27 declaration, on December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the “BioNTech” vaccine manufactured by pharmaceutical company Pfizer to prevent COVID-19’s spread. *Id.* ¶ 26. The FDA similarly issued an EUA for Moderna’s vaccine on December 18, 2020, *id.* ¶ 27, and Janssen (Johnson and Johnson)’s vaccine on February 27, 2021. *Id.* ¶ 28.

On August 23, 2021, the FDA fully approved Pfizer’s vaccine (“Comirnaty”), additionally noting Comirnaty as “legally distinct” with “certain differences” from Pfizer’s BioNTech vaccine. *Id.* ¶¶ 33-34; *id.* (Ex. G). At the time in which Plaintiff filed her Third Amended Complaint, Spikevax (manufactured by Moderna), was the only other vaccine that received full approval from the FDA, which it received January 31, 2022. *Id.* ¶ 42.

On August 25, 2021, UVA executives, via an organization-wide email, announced: “[W]e . . . will now require all team members without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021,” going on to say, “[a]ny team member not meeting the vaccination requirement deadline will be subject to disciplinary action up to and including termination.” *Id.* ¶ 36; *id.* (Ex. H). In September

2021, UVA expressed a belief that the legality of this mandate was “unclear.” *Id.* ¶ 37, *id.* (Ex. I).

Following Comirnaty’s full approval by the FDA, Plaintiff Antunes, on August 29, 2021, began emailing an account set up by UVA to field COVID-19 vaccine-related questions. *Id.* ¶ 37. In this email exchange, the account administrator “informed Ms. Antunes that UVA was not offering the vaccine that had received full FDA approval, ‘Comirnaty,’ to its employees because it was not available to UVA, and that UVA would make the Comirnaty available to them when they were able to acquire it.” *Id.* ¶ 38; *id.* (Ex. J).

Plaintiff Antunes, at the time in which she filed her Third Amended Complaint, had not received any COVID-19 vaccines and had no plans to receive any vaccines, though she has no categorical objection to vaccines. *Id.* ¶¶ 44-45. On November 1, 2021, UVA informed Plaintiff Antunes that, beginning on November 2, 2021, UVA Health would suspend her for a five-day period, pending verification that she received a COVID-19 vaccine. *Id.* ¶ 47. On November 9, 2021, UVA terminated Plaintiff’s employment. *Id.* ¶ 48. Unlike Plaintiff, many with religious and/or medical exemptions to UVA Health’s vaccine mandate continue to work at UVA Health. *Id.* ¶¶ 49-50.

II. Legal Standard

When a party attacks the subject matter jurisdiction of the Court under Rule 12(b)(1) of the Federal Rules of Civil Procedure, the court generally must first determine that it has jurisdiction as a threshold matter. *Sinochem Int’l Co. Ltd. v. Malaysia Int’l Shipping Corp.*, 549 U.S. 422, 431-32 (2007) (citing *Steel Co. v. Citizens for a Better Environment*, 523 U.S.

83, 89 (1998)). Where, as here, a defendant challenges the sufficiency of a plaintiff's allegations to establish subject matter jurisdiction, the court must accept the truth of the plaintiff's allegations at this stage, but still, it is the plaintiff's burden to establish that the allegations are sufficient to support subject matter jurisdiction. *See, e.g., FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990); *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982).

Second, to survive a Rule 12(b)(6) motion to dismiss, a complaint must "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). The purpose of a Rule 12(b)(6) motion is to "test the sufficiency of a complaint," not to "resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses." *King*, 825 F.3d at 214 (quoting *Edwards v. City of Goldsboro*, 178 F.3d 231, 243-44 (4th Cir. 1999)). "Thus, when considering a motion to dismiss, a court must consider the factual allegations in the complaint as true and draw all reasonable inferences in favor of the plaintiff." *Bing v. Brivo Systems, LLC*, 959 F.3d 605, 616 (4th Cir. 2020). Nevertheless, only facts can render a claim for relief plausible. "[F]ormulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. Nor is it sufficient for a plaintiff to plead facts merely consistent with liability. The plaintiff must plead enough factual content to nudge a claim across the border from mere possibility to plausibility. *Id.* at 570. *See also Francis v. Giacomelli*, 588 F.3d 186, 193 (4th Cir. 2009).

III. Analysis

A. Claims Against Federal Defendants Should Be Dismissed Pursuant to 12(b)(1) Due to Lack of Subject Matter Jurisdiction

i. Lack of Standing

Plaintiff alleges that Federal Defendants¹ violated the Food, Drug, and Cosmetic Act (“FDCA”) and the Equal Protection Clause, Third Amend. Compl. ¶¶ 51-59, 63-65, 67-68, and she seeks a declaration holding Federal Defendants’ challenged conduct unlawful, *id.* p. 16. She asserts that Federal Defendants violated the FDCA by (1) failing to indicate that the COVID-19 pandemic, which HHS declared a public emergency, “involved a biological, chemical, radiological, or nuclear agent or agents or a disease or condition that may be attributable to such agent or agents,” *id.* ¶¶ 51-54, and (2) failing to ensure vaccine distribution according to the FDCA’s “required conditions section,” *id.* ¶¶ 55-59. She asserts that Federal Defendants violated the Equal Protection Clause due to the HHS setting up a discriminatory framework for COVID-19 vaccine distribution, *id.* ¶¶ 63-65, 67-68. Plaintiff lacks standing to bring such claims against Federal Defendants.

Standing is a threshold jurisdictional injury, and to establish standing, a plaintiff must demonstrate that she has “(1) suffered an injury in fact, (2) that is

¹ Federal Defendants include Xavier Becerra, in his official capacity as Secretary of U.S. Department of Health and Human Services; Janet Woodcock, in her official capacity as Acting Commissioner of the Food and Drug Administration; the U.S. Department of Health and Human Services; and the Food and Drug Administration.

fairly traceable to the challenged conduct of the defendant, and (3) that it is likely to be redressed by a favorable decision.” *Spokeo v. Robbins*, 578 U.S. 330, 338 (2016). Further, a plaintiff must establish standing “for each claim” and “each form of relief,” the plaintiff seeks. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006).

Traceability requires “a causal connection between the injury and the conduct complained of—the injury has to be ‘fairly trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)). Various courts have held that an employer’s vaccination policy is not fairly traceable to the federal government’s decision to authorize vaccine marketing. See *Davis v. Biden*, No. ADC-21-2904, 2022 WL 2343966, at *2 (D. Md. June 29, 2022), *appeal filed*, No. 22-1734 (4th Cir.) (“Moreover, even the argument that Towson University was emboldened and encouraged by guidance from the Centers for Disease Control and Prevention is not enough to show an injury traceable to Defendant [University, alleged to have removed Plaintiff for her failure to comply with its vaccination policy].”); *Children’s Health Def. v. FDA*, 573 F. Supp. 3d 1234, 1243 (E.D. Tenn. 2021) (“The [employer’s] vaccine mandates, and the potential consequences for refusing those mandates, are not fairly traceable to the specific actions of the FDA.”); *Null v. FDA*, No. cv 09-1924, 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009) (“[S]tate action [in requiring healthcare workers to be vaccinated] cannot be attributed to the federal government merely because the federal government had some

role in authorizing a decision independently taken by the state.”); *Perez v. Becerra*, No. 1:21-cv-02039, 2022 WL 1102203, at *4 (D.D.C. Apr. 13, 2022) (“Vaccine requirements, mask mandates, and vaccine passports are typically managed at the local and state level. The [Plaintiffs] thus cannot trace these requirements to the Department [of Health and Human Services].”); *see also Disability Rights South Carolina v. McMaster*, 24 F.4th 893, 901-03 (2022) (finding parents of students with disabilities who attend South Carolina public schools and two disability advocacy organizations that challenged a provision in the South Carolina state budget prohibiting school districts from using appropriated funds to impose mask mandates lacked standing to sue, in part due to lack of traceability).

Additionally, a plaintiff bears the burden of establishing that it is “likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision,” *Lujan*, 504 U.S. at 561 (citation and internal quotation marks omitted), and “[t]o determine whether an injury is redressable, a court will consider the relationship between the judicial relief requested and the injury suffered.” *California v. Texas*, 141 S. Ct. 2104, 2115 (2021). Redressability is “‘substantially more difficult’ to establish” when “a plaintiff’s asserted injury arises from the government’s allegedly unlawful regulation (or lack of regulation) of *someone else*.” *Lujan*, 504 U.S. at 662 (quoting *ASARCO Inc. v. Kadish*, 490 U.S. 605, 615 (1989)) (emphasis in original). The District Court for the District of Columbia, for example, has recognized in a vaccine mandate context with plaintiffs seeking similar relief from federal defendants that “the Court could grant the relief the [Plaintiffs] seek and [their home state] could implement its own

requirements for vaccines, masks, and vaccine passports.” *Perez*, 2022 WL 1102204, at *4. The Court concluded that “the relief the [Plaintiffs] seek does not redress their alleged injuries.” *Id.*

Plaintiff Antunes alleges injury based on UVA Health’s suspension and subsequent termination of her employment. Third Amend. Compl. ¶¶ 47-48. She does not offer any allegations that Federal Defendants participated in UVA Health’s decision to suspend or terminate her or that they have authority to direct UVA Health to rehire Plaintiff. Nor does she allege she would seek to regain her position if claims against the Federal Defendants succeed. She alleges that 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) includes the condition that the HHS Secretary

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.

Third. Amend. Compl. ¶ 55. She further alleges of this statutory provision: “[t]he presence of language referring to a choice set alongside the obligation upon the Secretary to ensure that the choice exists would be an absurdity.” *Id.* ¶ 58. Yet, her argument that “[t]he statute binds the Secretary to inform the users of the option to refuse the product, but also to ensure that that option actually exists,” is conclusory. *Id.* ¶ 56. Without non-conclusory factual allegations supporting Federal Defendants’ role in her injury, her suspension and termination are not fairly traceable to the Federal Defendants.

Plaintiff seeks a declaration holding Federal Defendants' challenged conduct unlawful, but such relief would not redress her alleged injury. She has failed to allege any facts that such a declaration would (1) redress her injury by causing UVA Health to re-hire plaintiff or (2) prevent UVA Health from maintaining its vaccination policy in the future. *See, e.g., Scenic Am., Inc. v. United States Dep't of Transp.*, 836 F.3d 42, 52 (D.C. Cir. 2016) (holding that invalidating federal guidance regarding digital billboards would fail to redress any injury such billboards cause, as states would still be free to construct them, and a plaintiff's supposition that states would stop doing so was speculative). Thus, Plaintiff's claims against Federal Defendants fail for lack of standing.

ii. No Waiver of Sovereign Immunity

Plaintiff's claims against Federal Defendants also lack subject matter jurisdiction because there has been no waiver of sovereign immunity.

"[T]he United States, as sovereign, is immune from suit save as it consents to be sued . . . and the terms of its consent to be sued in any court define that court's jurisdiction to entertain the suit." *United States v. Mitchell*, 445 U.S. 535, 538 (1980) (quoting *United States v. Sherwood*, 312 U.S. 584, 586 (1941)). A waiver of sovereign immunity "must be unequivocally expressed." *Id.* (quoting *United States v. King*, 395 U.S. 1, 4 (1969)). Sovereign immunity generally extends to federal officers sued in their official capacity. *Dugan v. Rank*, 372 U.S. 609, 620-22 (1963); *Portsmouth Redevel. & Hous. Auth. v. Pierce*, 706 F.2d 471, 473 (4th

Cir. 1983). And the plaintiff has the burden to demonstrate a waiver of sovereign immunity. *Welch v. United States*, 409 F.3d 646, 651 (4th Cir. 2005).

The Administrative Procedure Act (“APA”) provides a limited waiver of sovereign immunity but exempts “agency action [that] is committed to agency discretion by law,” from judicial review. 5 U.S.C. § 701(a)(2); *see Angelex Ltd. v. United States*, 723 F.3d 500, 506 (4th Cir. 2013) (discussing that the district court lacked subject matter jurisdiction when agency action fell within the 5 U.S.C. § 701(a)(2) exception).

Plain statutory language dictates that the HHS’ vaccine emergency use authorization is “committed to agency discretion.” 21 U.S.C. § 260bbb03(i) (“Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.”). Courts have consequently recognized decisions regarding emergency use authorization for vaccines as expressly reserved by statute to agency discretion. *Ass’n of Am. Physicians & Surgeons v. FDA*, No. 20-1784, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (“[E]mergency-use authorizations are exempt from review under the APA.”); *Wise v. Inslee*, No. 2:21-cv-0288, 2022 WL 1243662, at *2 (E.D. Wash. Apr. 27, 2022), *appeal filed*, No. 22-35426 (9th Cir.); *Doe #1-#14 v. Austin*, 572 F. Supp. 3d 1224, 1237-38 (N.D. Fla. 2021); *see also Conn. Nat’l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) (“[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says there.”) (internal references omitted).

Though Plaintiff also refers to other statutes in her Third Amended Complaint, no statute referenced

waives sovereign immunity. By its own terms, 42 U.S.C. § 1983 “is of only limited scope” and “does not reach . . . actions of the Federal Government.” *District of Columbia v. Carter*, 409 U.S. 418, 424-25 (1973). The general federal question statute, 28 U.S.C. § 1331, “is not a general waiver of sovereign immunity.” *Randall v. United States*, 95 F.3d 339, 345 (4th Cir. 1996). The same holds true for the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, *Circuit City Stores, Inc. v. EEOC*, 75 F. Supp. 2d 491, 504 (E.D. Va. 1999), *aff’d*, 232 F.3d 887 (4th Cir. 2000), and the general jurisdictional provision related to civil rights, 28 U.S.C. § 1343. *Randall*, 95 F.3d at 345 (holding that a jurisdictional statute “merely establishes a subject matter that is within the competence of federal courts to entertain”) (internal reference omitted); *Radin v. United States*, 699 F.2d 681, 685 n.9 (4th Cir. 1983) (presenting a jurisdictional statute as “merely a jurisdictional grant that in no way affects the sovereign immunity of the United States”); *Jachetta v. United States*, 653 F.3d 898, 907-08 (9th Cir. 2011); *Perkins v. Comm’r*, No. 20-cv-3142, 2020 WL 6544834, at *3 (D. Md. Nov. 6, 2020). Further, the statute authorizing vaccine emergency use, 21 U.S.C. § 360bbb-3, lacks any unequivocal expression of a waiver of immunity, thus failing to meet the *Mitchell* standard presented above. *Mitchell*, 445 U.S. at 538. The same reasoning makes Plaintiff’s mention of unspecified “nonstatutory equitable jurisdiction,” Third Amend. Compl. ¶ 5, unavailing in terms of conveying jurisdiction. Thus, as there has been no waiver of Federal Defendants’ sovereign immunity, Plaintiff’s claims against Federal Defendants must be dismissed.

B. Claims Against UVA Should Be Dismissed Pursuant to 12(b)(6) for Failure to State a Claim

i. Plaintiff Fails to Allege Facts Supporting That UVA Violated the Equal Protection Clause

Plaintiff alleges that UVA violated the Equal Protection Clause when the institution decided to require employees to receive a COVID-19 vaccination, asserting that UVA “was able to do so because HHS has set up a discriminatory framework for the administration of the vaccines.” Third Amend. Compl. ¶ 63. She alleges that “[i]n the context of the vaccines in question, HHS has created two similarly situated classes of people, one with more protections against coercion than the other.” *Id.* ¶ 67. Plaintiff bases this on the idea that, under 21 C.F.R. Part 50, “if UVA, while administering a clinical trial on behalf of a pharmaceutical company, ordered its employees to participate or lose their jobs, such a policy would be a clear instance of coercive influence that would constitute a violation of the relevant regulations,” and “[a]lthough the FDA issued its Emergency Use Authorization alongside clinical trials that remain ongoing, it acknowledges no such protections against coercion in its administration of . . . that statute that created the EUA.” *Id.* ¶¶ 66-67.

“[A] classification neither involving fundamental rights nor proceeding along suspect lines . . . cannot run afoul of the Equal Protection Clause if there is a rational relationship between disparity of treatment and some legitimate governmental purpose.” *Cent. State Univ. v. Am. Ass’n of Univ. Professors*, *Cent. State*

Univ. Chapter, 526 U.S. 124, 127-28 (1999) (citations omitted). Courts within the Fourth Circuit have found that policies treating unvaccinated individuals differently than those vaccinated do not target a suspect class. *Bauer v. Summey*, 568 F. Supp. 3d 573, 597 (D.S.C. 2021) (“Although the Policies treat unvaccinated individuals differently than those vaccinated by only subjecting the former to potential termination, such differential treatment does not target a suspect class.”); *McArthur v. Brabrand*, No. 1:21-cv-1435, 2022 WL 2528263, at *7 (E.D. Va. July 27, 2020) (“[H]eightedened review is not justified because the quarantine policy . . . is a vaccination-based classification.”) (citing cases holding that unvaccinated people do not constitute a suspect class).

UVA’s policy bears a rational relationship to some legitimate end, thus meeting the rational basis standard presented above. The vaccination requirement is related to the government interest in preventing COVID-19 from spreading amongst UVA Health personnel and patients. Thus, Plaintiff’s Equal Protection Clause claim against UVA Defendants shall be dismissed.

ii. Plaintiff Fails to Allege Facts Supporting That UVA Violated the Due Process Clause

Plaintiff alleges that UVA’s conduct violates the Fourteenth Amendment by “using economic power to secure ‘consent’ to an unwanted medical treatment.” Third Amend. Compl. ¶ 72. She alleges this based on the U.S. Supreme Court previously recognizing 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.” *Id.* ¶ 70 (quoting *Cruzan v. Director, Missouri Dep’t of Health*, 497 U.S. 261, 278 (1990)). However, other courts have found similar arguments misplaced in a vaccine mandate context. *E.g.*, *Mass. Correction Officers Federated Union v. Baker*, 567 F. Supp. 3d 315, 326 n.5 (D. Mass. 2021) (recognizing the plaintiff’s appeal to *Cruzan* as misplaced, since “*Cruzan*’s holding . . . was limited to an individual’s choice related to the refusal of lifesaving medical care and nutrition, with no impact on the health of others or the public.”); *Bauer*, 568 F. Supp. 3d at 592 n.5 (finding for the same reason that “the caselaw involving the refusal of medical treatment that plaintiffs rely on is inapposite to the instant action.”); *We the Patriots USA, Inc. v. Hochul*, 17 F.4th 266, 293 (2d Cir. 2021) (“In *Cruzan*, a case relied upon by Plaintiffs for the proposition that they have a fundamental constitutional right to refuse medical treatment, the Court expressly recognized its holding in *Jacobson* that ‘an individual’s liberty interest in declining an unwanted smallpox vaccine’ was outweighed by ‘the State’s interest in preventing disease.’”) (internal reference omitted).

Courts apply a deferential standard when considering the constitutionality of vaccination requirements as related to the Due Process Clause. *Jacobson v. Massachusetts*, 197 U.S. 11, 27, 31 (1905) (discussing that the judiciary can review legislation affecting the general welfare, as “if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and

thereby give effect to the Constitution.”); *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring) (presenting the *Jacobson* standard as “essentially . . . rational basis review.”); *Antietam Battlefield KOA v. Hogan*, No. 20-311, 2022 WL 1449180, at *2 (4th Cir. May 9, 2022) (affirming the district court’s determination that *Jacobson* “provided the proper scope for review of Plaintiff’s constitutional claims” regarding the Maryland Governor’s COVID-19 orders). Courts across the country have relied on such a standard when facing COVID-19-related vaccination mandates, including in the context of University policies. *See, e.g., Norris v. Stanley*, No. 1:20-cv-756, 2022 WL 247507, at *3 (W.D. Mich. Jan. 21, 2022) (university employment context); *Klaasen v. Trustees of Ind. Univ.*, 7 F.4th 592, 594 (7th Cir. 2021) (university student context); *Children’s Health Def., Inc. v. Rutgers State Univ. of New Jersey*, No. CV2115333-ZNQTJB, 2021 WL 4398743, at *5-6 (D.N.J. Sept. 27, 2021) (university student context); *Harris v. Univ of Mass., Lowell*, No. 21-cv-11244, 2021 WL 3848012, at *8 (Sept. 27, 2021) (university student context).

To establish a Due Process violation, Plaintiff Antunes must demonstrate that she has “been deprived of a protected interest in ‘property’ or ‘liberty.’” *American Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999). Such a claim requires government action that is “so ‘arbitrary’ and ‘egregious’ that it ‘shocks the conscience,’ usually because a state actor intended harm without justification.” *Waybright v. Frederick Cnty., Md.*, 528 F.3d 199, 205 (4th Cir. 2008) (quoting *County of Sacramento*, 523 U.S. 833, 845-46, 849 (1998)).

Plaintiff has not (1) identified any right triggering heightened protection under substantive due process or

(2) demonstrated any arbitrary, egregious, and conscience-shocking governmental action. Plaintiff argues only that UVA’s vaccine mandate infringes on her right to be free from unwanted medical treatment. Third. Amend. Compl. ¶¶ 70–72. Courts have refused to recognize this as a fundamental right in the vaccine mandate context. *E.g.*, *Lukaszczyk v. Cook Cnty.*, 2022 WL 3714639, at *7-8 (7th Cir. Aug. 29, 2022). Consequently, Plaintiff has not identified a right triggering heightened protection under substantive due process. Further, requiring vaccines for healthcare workers does not demonstrate any arbitrary, conscience-shocking, or oppressive governmental action. Consequently, the *Jacobson* rational basis standard applies. Based on the risk of COVID-19 contagion in a health care setting, a vaccination requirement for healthcare staff is rationally related to the legitimate state interest of preventing the spread of COVID-19. *See, e.g.*, *Norris*, 2022 WL 247507 at *3; *Klaasen*, 7 F.4th at 594; *Children’s Health Def., Inc.*, 2021 WL 4398743, at *5-6; *Harris*, 2021 WL 3848012, at *8.

Thus, Plaintiff has failed to state a claim for violation of the Due Process Clause.

iii. Plaintiff Fails to Allege Facts Supporting That UVA Violated the Fourth Amendment

Plaintiff advances the novel argument that UVA “is using economic coercion to seize and commandeer [Plaintiff’s] immune system for its own purposes and has provided very little explanation or justification for its actions,” therein violating the Fourth Amendment. Third Amend. Compl. ¶ 75. Plaintiff cites no authority accepting such an argument in a similar context.

To have Fourth Amendment standing, a Plaintiff must show that “the disputed search and seizure has infringed an interest of the [Plaintiff’s] which the Fourth Amendment was designed to protect.” *Rakas v. Illinois*, 439 U.S. 128, 140 (1978). Even if UVA Health’s vaccination mandate qualified as a seizure under the Fourth Amendment, Plaintiff never received a vaccination. Thus, there was no intrusion on her privacy in the form of a warrantless seizure, and Plaintiff lacks standing to raise such a Fourth Amendment claim.

Further, UVA Health’s mandate appears not to be a seizure under the Fourth Amendment. A Fourth Amendment seizure of a person can occur via “physical force” or “a show of authority” that “in some way restrain[s] the liberty of” a person. *Terry v. Ohio*, 392 U.S. 1, 19, n.16 (1968). For reasons outlined above, requiring an at-will employee to receive a vaccination is not a restraint on one’s liberty rights under the Fourteenth Amendment. *See also Oklahoma v. Biden*, 577 F. Supp. 3d 1245, 1245 (W.D. Okla. 2021) (“Guard members ‘are not being coerced to give up a fundamental right since there is no fundamental right to refuse vaccination.’ The result is the same with a traditional (and narrower) seizure analysis.”) (quoting *Smith v. Biden*, No. 1:21- cv-19457, 2021 WL 5195688, at *8 (D.N.J. Nov. 8, 2021), *appeal filed*, No. 21-3091 (3d Cir.)).

Even if the mandate were deemed a restraint on Plaintiff’s liberty, the Fourth Amendment protects only against unreasonable searches and seizures, *e.g.*, *Florida v. Jimeno*, 500 U.S. 248, 250 (1991), and Plaintiff has not alleged any facts indicating that the UVA Health policy would fail to pass a Fourth Amendment reasonableness balancing test. Courts uphold searches

and seizures in an array of contexts by “balancing [any] intrusion on the individual’s Fourth Amendment interests against its promotion of legitimate governmental interests.” *Yernonia Sch. Dist. 47J v. Acton*, 515 U.S. 646, 653–54 (1995). COVID-19 vaccination and testing requirements evidence legitimate government interests. *See, e.g., Roman Cath. Diocese of Brooklyn*, 141 S. Ct. at 67 (“Stemming the spread of COVID-19 is unquestionably a compelling interest.”); *Streight v. Pritzker*, No. 3:21-CV-50339, 2021 WL 4306146, at *6 (N.D. Ill. Sept. 22, 2021) (addressing this in a Fourth Amendment context). Plaintiff has alleged no facts, taken as true, that would establish that the vaccination policy intrudes on her Fourth Amendment interests in a manner outweighing UVA Health’s promotion of legitimate governmental interests. Thus, Plaintiff has failed to state a claim under the Fourth Amendment.

iv. Plaintiff Fails to Allege Facts Supporting That UVA’s Vaccination Requirement Amounts to an Unconstitutional Condition

Plaintiff alleges that UVA’s vaccination requirement is an unconstitutional condition on her “constitutional right to refuse unwanted medical treatment in order to be employed at a public university.” Third Amend. Compl. ¶ 3. Under the unconstitutional conditions doctrine, the government “may not deny a benefit to a person on a basis that infringes his constitutionally protected interests.” *Perry v. Sindermann*, 408 U.S. 593, 597 (1972). Again, Plaintiff advances no authority which has accepted such an argument in the context of a COVID-19 requirement.

As outlined above, a state entity acts within its constitutional constraints when directly enacting a vaccination requirement if it has a rational basis to do so.

Further, as Plaintiff Antunes is an at-will employee, no government benefit has been denied. “Where an employee has a property interest in her job, the only protection we have found the Constitution gives her is a right to adequate procedure. And an at-will employee . . . generally has no claim based on the Constitution at all.” *Waters v. Churchill*, 511 U.S. 661, 679 (1994) (plurality opinion) (reasoning incorporated by *Engquist v. Or. Dep’t of Agr.*, 553 U.S. 591, 606 (2008)). When considering a case with facts similar to those in the case currently before the Court, the Western District of Michigan recently arrived at such a conclusion. In *Norris v. Stanley*, plaintiffs, current and former employees of Michigan State University, alleged an unconstitutional condition claim based on the university’s COVID-19 vaccination requirement. *Norris*, 2022 WL 247507. The court reasoned that “the ‘benefit’ at issue here is Plaintiffs’ employment at MSU, to which they are not constitutionally entitled,” and “[b]ecause of the lack of governmental benefit at issue in this matter, the Court finds that Plaintiffs have failed to plead sufficient facts to allege a violation of the unconstitutional conditions doctrine to survive Defendants’ motion to dismiss.” *Id.* at *4. The same reasoning applies to Plaintiff Antunes’ allegation that UVA violated the unconstitutional conditions doctrine, and this claim thus must be dismissed.

v. Plaintiff Fails to Allege Facts Supporting a Wrongful Discharge Claim Under Virginia Law

Plaintiff alleges that “[b]y insisting on the unwanted touching and physical invasions of a vaccination at the price of her job, UVA has engaged in the wrongful termination of [Plaintiff]” under Virginia law. Third Amend. Compl. ¶ 15.

“Virginia adheres to the common-law rule that when a contract calls for the rendition of services, but the period of its intended duration cannot be determined by a fair inference from its provisions, either party is ordinarily at liberty to terminate the contract at will upon giving reasonable notice of intention to terminate.” *Bowman v. State Bank of Keysville*, 331 S.E.2d 797, 798, 800 (Va. 1985) (citations omitted); see also, e.g., *Hice v. Mazzella Lifting Techs., Inc.*, No. 2:21-cv-281, 2022 WL 636640, at *8 (E.D. Va. Mar. 4, 2022). However, the common-law rule governing at-will employment termination “is not absolute.” *Id.* at 801. Employees “discharged in violation of an established public policy” fall within an exception to the common-law rule, and they may raise a *Bowman* claim for wrongful discharge if within the exception. *Id.*

The Supreme Court of Virginia has recognized three situations in which a discharged employee may show her discharge violated public policy. *Wells v. Enter. Leasing Co. of Norfolk/Richmond, LLC*, 500 F. Supp. 3d 478, 487 (E.D. Va. 2020) (internal citations omitted). First, a litigant may rely on “a statute stating explicitly that it expresses a public policy of the Commonwealth.” *Id.* Second, a litigant may rely on a statute “designed to protect the property rights,

personal freedoms, health, safety or welfare of the people in general.” *Id.* (internal citation omitted). For both the first and second situation, the aggrieved employee must also show that she “is a member of the class of individuals the public policy is intended to benefit.” *Id.* (internal citation omitted). Virginia case law makes clear that “[t]he public policy on which a plaintiff must rely to qualify for the first and second *Bowman* exceptions must be expressed in an existing Virginia statute.” *Id.* at 487-88 (parenthetically summarizing supporting case law). A *Bowman* claim cannot rely on a federal statute or constitutional provision. *E.g.*, *McCarthy v. Texas Instruments*, 999 F. Supp. 823, 829 (E.D. Va. 1998) (“This effort is facially unavailing, as Title VII, a federal statute, does not provide an expression of Virginia’s public policy. A *Bowman* claim must find root in a state statute. For this reason, too, a plaintiff’s reliance on the Fourteenth Amendment . . . is misplaced.”) (internal citation omitted). Third, a *Bowman* claim may be established “where the discharge was based on the employee’s refusal to engage in a criminal act.” *Id.* (internal citation omitted).

Here, Plaintiff has failed to allege (1) any Virginia state law that qualifies for the first or second *Bowman* exception, or (2) facts supporting any refusal to engage in a criminal act. To support her wrongful termination claim, Plaintiff cites *Cavuoto v. Buchanan Cnty.*, 605 S.E.2d 287, 289 (Va. Ct. App. 2004) (citing *U.S. v. Charters*, 829 F.2d 479 (4th Cir. 1987)) for the principle that Virginia courts have recognized “[t]he right to be free of unwanted physical invasions . . . as an integral part of the individual’s constitutional freedoms.” Third Amend. Compl. ¶ 78. She further states: “By insisting

on the unwanted touching and physical invasions of a vaccination at the price of her job, UVA has engaged in the wrongful termination of Ms. Antunes.” *Id.* ¶ 79. Thus, Plaintiff alleges only a violation of federal constitutional freedoms in support of her wrongful discharge claim, rather than a Virginia statute expressing state public policy. As such, her claim does not fit within a *Bowman* exception to the common-law at-will employment rule. Her wrongful termination charge shall thus be dismissed.

V. Conclusion

Because Plaintiff lacks standing to sue Federal Defendants, the motion to dismiss as to those Defendants will be granted in an accompanying Order. As Plaintiff’s assertions against UVA do not “contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face,’” the motion to dismiss as to UVA will be granted in an accompanying Order. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570).

* * * *

The Clerk of the Court is hereby directed to send this Memorandum Opinion to all counsel of record.

Entered this 12th day of September, 2022.

/s/ Norman K. Moon
United States District Judge

**ORDER, U.S. DISTRICT COURT FOR THE
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION
(SEPTEMBER 12, 2022)**

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF VIRGINIA
CHARLOTTESVILLE DIVISION

CATHERINE ANTUNES,

Plaintiff,

v.

RECTOR & VISITORS
OF THE UNIV. OF VA., ET AL.,

Defendants.

Case No. 3:21-CV-00042

Before: Norman K. MOON,
Senior United States District Judge.

ORDER

This matter is before the Court on Defendants' Motions to Dismiss, Dkt. 48, Dkt. 50. For the reasons set forth in the Court's Memorandum Opinion, to follow, the Court **GRANTS** the Motions as to each claim and dismisses this case.

It is so **ORDERED**.

App.30a

The Clerk of Court is directed to send a certified copy of this Order to all parties.

Entered this 12th day of September, 2022.

/s/ Norman K. Moon
Senior United States District Judge

**THIRD AMENDED COMPLAINT
(MARCH 25, 2022)**

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

CATHERINE ANTUNES,

Plaintiff,

v.

RECTOR AND VISITORS OF THE UNIVERSITY
OF VIRGINIA; THE U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
THE FOOD AND DRUG ADMINISTRATION;
XAVIER BECERRA, in his official capacity as
Secretary) of the U.S. Department of Health and
Human Services; and ROBERT CALIFF, M.D.,
in his official capacity as Commissioner of
the U.S. Food and Drug Administration,

Defendants.

Civil Action No. 3:21-cv-00042

**THIRD AMENDED COMPLAINT FOR
DECLARATORY JUDGEMENT AND
INJUNCTIVE RELIEF**

INTRODUCTION

1. Catherine Antunes is a nurse with 13 years of experience in the healthcare field, including six as a

nurse. She has been employed within the healthcare system at the University of Virginia (“UVA Health” or “UVA”) since January of 2020, where she worked mandatory overtime during the height of the COVID-19 pandemic and risked exposure to the SARS-COV-2 virus on a daily basis. UVA Health management’s most recent evaluation (6/30/2021) rated her work as “fully meets expectations” and described her as “an exceptional asset to the team,” with “astute clinical skills” and “natural leadership ability.”

2. Despite this dedication and performance, UVA Health fired Catherine, not because she has failed in her ability to provide needed healthcare, and not because UVA found that she presents an actual medical risk to her patients and co-workers. UVA Health fired her because she has declined to accept a vaccine that, at the time of her termination, had yet to receive full FDA approval.

3. In respectfully declining the COVID-19 vaccine, Ms. Antunes is simply asking for the treatment that UVA Health is required to afford to its patients as a matter ethics, policy, and law—the ability to accept or decline medicine within a framework of informed consent, which, by definition, excludes any coercive measures. By forcing Ms. Antunes to choose between a relatively new and not fully approved vaccine and her livelihood, UVA Health is exerting coercive pressure on a private healthcare decision.

4. Operating within a discriminatory framework that the U.S. Department of Health and Human Services has created and enforces, UVA is not only abandoning its professed commitments to the bedrock principles of medical ethics, UVA Health is also violating applicable laws and the U.S. Constitution.

JURISDICTION AND VENUE

5. This Court has jurisdiction over this case pursuant to the Administrative Procedure Act, 5 U.S.C. § 702, 28 U.S.C. §§ 1331, 1343(a)(3)-(4), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. The claims here arise under the Constitution and statutes of the United States and because the Plaintiff seeks prospective redress against state actors in their official capacity to end the deprivation, under state law, of her rights, privileges, and immunities secured by federal law.

6. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391 because a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, where the University of Virginia is principally located.

7. This Court's equitable powers permit it to issue nonstatutory injunctions to protect the Plaintiff against state actors. *See Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) [citing *Ex parte Young*, 209 U.S. 123, 155-156 (1908) (holding that federal courts may enjoin state officials to conform their conduct to federal law)]. Defendants UVA possess the necessary connection to the establishment and enforcement of UVA Health's vaccine mandate. *See, e.g., Bostic v. Schaefer*, 760 F.3d 352, 371 n.3 (4th Cir. 2014) (Virginia's Registrar of Vital Records could be sued under *Ex parte Young* for unconstitutional actions related to marriage rights because he was charged with ensuring compliance with the Commonwealth's marriage laws).

8. This Court may also issue declaratory relief pursuant to 28 U.S.C. § 2201. Additionally, "[f]urther necessary or proper relief based on a declaratory

judgment may [also] be granted . . . ,” including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) (“A declaratory judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202. . . .”).

9. This Court also has concurrent jurisdiction over the state claims pursuant to 28 U.S.C. § 1367 and Virginia Code §§ 8.01-620 and 8.01-328.

PARTIES

10. Plaintiff Catherine Antunes is a Registered Nurse (2015) with a B.S. in Science and Nursing from Shenandoah University (2014). As a staff and temporary travel nurse, she gained experience working within seven different hospital systems, including John Hopkins Bayview Medical Center in Baltimore, Maryland, before she joined UVA Health. Prior to earning her certification as a Registered Nurse, she worked as a Certified Nurse Aide, combining for a total of thirteen (13) years of healthcare experience. She joined UVA Medical Center in Charlottesville in January of 2020. Since the beginning of the COVID-19 pandemic, she has worked two rounds of mandatory overtime during a time when the system added 40 beds but lost over 100 nurses.¹

11. The Rector and Visitors of the University of Virginia is the governing body of the University of Virginia. UVA Health is the medical division of UVA, and is one of the most well-respected health systems in the nation,² including an academic medical center

¹ UVAHealth.com, *Facts & Statistics*, at <https://uvahealth.com/about/facts-stats> (last visited November 5, 2021).

² UVAHealth.com, citing U.S. NEWS AND WORLD REPORT,

and health system featuring a cancer center, a children's hospital, three community hospitals, and a network of clinics throughout the Commonwealth of Virginia. In 2021, UVA Health employed 8,492 Full-Time Equivalents, including 4,257 professional nurses.

12. The U.S. Department of Health and Human Services (HHS) is a department of the executive branch of the U.S. Government. The mission of HHS is to enhance the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. As part of this mission, HHS oversees the drug approval process, including clinical trials, including those of all existing COVID-19 vaccines.

13. Xavier Becerra is the Secretary of Health and Human Services, charged with overseeing the operations of HHS. Plaintiff sues him in his official capacity.

14. The Food and Drug Administration (FDA) is an office of HHS that regulates clinical investigations of products under its jurisdiction, such as drugs, biological products, and medical devices, and promotes and protects public health by ensuring the safety, efficacy, and security of products subject to the Food, Drug, and Cosmetic Act.³ The FDA has direct oversight of the drug approval process, including those of all existing COVID-19 vaccines.

<https://uvahealth.com> (last visited November 5, 2021).

³ See U.S. FOOD & DRUG ADMIN., WHAT WE DO, <https://www.fda.gov/AboutFDA/WhatWeDo/> (last visited Nov. 30, 2021); see also 21 U.S.C. § 393(b).

15. Robert Califf, M.D. is the Commissioner of the Food and Drug Administration (FDA), which is an HHS subsidiary. Plaintiff sues him in his official capacity.

PROCEDURAL BACKGROUND AND NOTE RELEVANT TO AMENDMENT

16. Plaintiff submitted a complaint to the Court on November 9, 2021, but the Plaintiff did not propose, and the Court did not issue, a summons as to defendants.

17. On November 30, 2021, Plaintiff filed an Amended Complaint.

18. On December 29, 2021, the Court issued summonses as to Defendants.

19. On January 12, 2022, Plaintiff's counsel submitted an affidavit that service of summons occurred on January 5, 2022.

20. On January 26, 2022, Plaintiff filed a Second Amended Complaint.

21. Defendants UVA Health filed a Motion to Dismiss the Second Amended Complaint on February 22, 2022.

22. Defendants U.S. Department of Health and Human Services (HHS), U.S. Food and Drug Administration (FDA), HHS Secretary Xavier Becerra, and FDA Commissioner Robert Califf ("Government Defendants") filed a Motion to Dismiss on March 8, 2022.

23. Plaintiff filed a Response to UVA Health's Motion to Dismiss on March 15, 2022.

FACTUAL BACKGROUND

24. In a declaration dated March 27, 2020, the then-Secretary of the U.S. Department of Health and Human Services, Alex Azar II, issued a declaration entitled, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3* (the “Declaration”). In that Declaration, he stated that, on February 4, 2020, he had determined that,

[P]ursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2009-nCoV).

25. Upon information and belief, the Secretary of HHS has never stated or implied, that COVID-19 is “a biological, chemical, radiological, or nuclear agent or agents.” See Exhibit A.

26. On December 11, 2020, pursuant to the Declaration, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the pharmaceutical manufacturer Pfizer’s vaccine (the “BioNTech” vaccine), which it developed for the prevention of coronavirus disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (“COVID-19” or “COVID” herein). See Exhibit B.

27. On December 18, 2020, FDA issued an EUA for Moderna's vaccine for the prevention of COVID-19. See Exhibit C.

28. On February 27, 2021, FDA issued an EUA for Janssen (Johnson and Johnson)'s COVID-19 vaccine. See Exhibit D.

29. On April 23, 2021, the FDA amended its Janssen EUA to warn of a "very rare and serious type of blood clot in people who receive the vaccine." See Exhibit E.

30. UVA Health hired Ms. Antunes in January of 2020.

31. From the beginning of her tenure, in response to the COVID-19 pandemic, UVA Health began implementing measures to mitigate the spread of the disease among staff and to patients. This included mandatory Personal Protective Equipment (PPE), but also daily attestation that the employee was not experiencing any symptoms.

32. On July 7 of this year, UVA Health notified its employees via company-wide email that employees who were not vaccinated for COVID-19 and whose work required them to be physically present at UVA at any time would have to receive weekly testing for COVID beginning August 2 of this year. Cosigners of the email included K. Craig Kent, MD, Chief Executive Officer of UVA Health; Bobby Chhabra, MD, President of University Physicians Group; Pam Cipriano, PhD, Dean of the School of Nursing; Wendy Horton, PharmD, MBA, Chief Executive Officer of the Medical Center; and David Wilkes, MD, Dean of the School of Medicine. See Exhibit F.

33. On August 23, 2021, the Food and Drug Administration (FDA) fully approved Pfizer's COVID vaccine, "Comirnaty."

34. In accompanying literature, FDA noted that "Comirnaty" is "legally distinct" with "certain differences" from Pfizer's BioNTech vaccine that had received an EUA. See Exhibit G.

35. The BioNTech vaccine remains authorized only according the EUA process and has not received full approval from the FDA.

36. On August 25 of this year, the same UVA executives mentioned above, via company-wide email, and citing "the increasing number of new COVID-19 cases in recent weeks" announced that "[W]e . . . will now require all team members without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021." The same email went on to say, "Any team member not meeting the vaccination requirement deadline will be subject to disciplinary action up to and including termination." See Exhibit H.

37. In University-published material on the matter, UVA expressed that it believed the legality of its vaccine mandate to be "unclear." See Exhibit I.

38. Subsequent to Comirnaty's approval, Ms. Antunes began inquiring about the vaccines that UVA would be making available to its employees. On August 29 of 2021, Ms. Antunes began emailing the email account that UVA set up to field questions regarding the COVID vaccine, "covidvax@hscmail.mcc.virginia.edu." In an exchange that went back-and-forth over the course of several days, the administrator of the account (the "Account Administrator," who only identified himself or herself as "EH") informed Ms.

Antunes that UVA was not offering the vaccine that had received full FDA approval, “Comirnaty,” to its employees because it was not available to UVA, and that UVA would make the Comirnaty available to them when they were able to acquire it. See Exhibit J.

39. Upon information and belief, UVA still had not made Comirnaty available to its employees when it terminated Ms. Antunes.

40. Upon information and belief, UVA has not yet offered Comirnaty to its employees.

41. Upon information and belief, at the time of this filing, the vaccine that may properly be labeled “Comirnaty,” is not yet available anywhere in the United States.

42. Only one other vaccine has received full approval from the FDA—Spikevax, as of January 31, 2022.

43. Upon information and belief, at the time of this filing, Spikevax is also unavailable in the United States.

44. UVA is a state University and is the recipient of numerous grants to administer both state and federal health programs, and is otherwise the recipient of a large amount of public funding and benefits, both federal and state.

45. Ms. Antunes has not, to date, received any of the vaccines currently available for the treatment of COVID-19 and currently has no plans to receive any.

46. Ms. Antunes does not have a categorical objection to vaccines and is, for example, in the practice of receiving the influenza vaccine every year.

47. On November 1, UVA informed Ms. Antunes that, beginning on November 2 of this year, UVA Health would suspend her for a period of five days pending verification that she had received a COVID vaccine.

48. On November 9 of this year, UVA terminated Ms. Antunes's employment.

49. UVA Health has granted health and religious exemptions to its vaccine mandate for other employees that, upon information and belief, number in the dozens or hundreds.

50. Many of those with religious and / or medical exemptions continue to work at UVA Health despite not having been vaccinated against COVID-19.

COUNT ONE

Violation of provisions of the Food, Drug, and Cosmetic Act [Against Government Defendants]

A. Emergency Use Authorization is not available where the treatment is not for a biological, chemical, radiological, or nuclear agent or agents

51. 21 U.S.C. § 360bbb-3(b) provides, in relevant part that,

[T]he Secretary [of Health and Human Services] may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of 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

52. As noted above, then-Secretary Alex Azar issued a *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. In that Declaration, he stated that, on February 4, 2020, he had determined that:

[P]ursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV)

53. The Secretary did not, in his Declaration or elsewhere, indicate that the referenced public health emergency involved a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents, according to the statutory requirement.

54. The Secretary, and the Department of Health and Human Services, in acting beyond the confines of the statutory language found in the FD&C Act, acts in a manner that is *ultra vires*, in excess of statutory

authority, and is otherwise not in accordance with the law [5 U.S.C. § 706].

B. Failure to ensure distribution according to “required conditions.”

55. The “required conditions” section of the Food, Drug, & Cosmetic Act under which the three vaccines Ms. Antunes was able to access during her employment at UVA became available, 21 U.S. Code § 360bbb-3(e)(1)(A)(ii)(III), includes the condition that the HHS Secretary “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.”

56. The statute binds the Secretary to inform the users of the option to refuse the product, but also to ensure that that option actually exists.

57. In the absence of such conditions—that is—where a person is experiencing economic or other coercion or force to use such a product, as is the case with Ms. Antunes, it is necessary for the Secretary to deny distribution of the drug, or to take some other measures to ensure compliance with the statute, but has not.

58. The presence of language referring to a choice set alongside the absence of any obligation upon the Secretary to ensure that the choice exists would be an absurdity.

59. This is, in the formulation of the Administrative Procedure Act, without observance of procedure required by law.

COUNT TWO
Violation of the U.S. Constitution
Unconstitutional condition
[Against UVA Health]

60. The Supreme Court has, over the years, struck down laws and policies that impose unconstitutional conditions on the expenditure of federal funds. *See, e.g., Federal Communications Commission v. League of Women Voters of California et al.* 468 U.S. 364 (1984).

61. Here, UVA imposes an unconstitutional condition on employment at a public university: that employees surrender their constitutional right to refuse unwanted medical treatment in order to be employed at a public university. Unlike some other rights and privileges, even some that are express in the Constitution, but similar to others, such as political speech and association, the nature of this surrender is complete and irreversible. Ms. Antunes, in other words, cannot be vaccinated at work and unvaccinated in her private life.

62. For this deprivation under color of federal and state law of the right to benefit as an employee from the expenditure of federal funds without having unconstitutional conditions imposed on her, Defendants have incurred liability under 42 U.S.C. 1983.

COUNT 3
Violation of the U.S. Constitution Equal
Protection [Against all defendants]

63. When UVA decided to require its employees to receive a COVID-19 vaccine as a condition of employment, it was able to do so because HHS has set

up a discriminatory framework for the administration of the vaccines.

21 CFR Part 50 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.

64. The regulation goes on to state that, except in situations where conditions make informed consent impossible (where, for example, there is an immediate danger and a medical condition makes consent impossible):

[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.

65. Key to this regulatory passage are the concepts of “coercion” and “undue influence.” Threatening a person’s job or livelihood to obtain his or her consent to be a part of a clinical trial would be, according to HHS’ own definitions of its terms, a form of coercion that these regulations render impermissible.

66. According to this regulatory framework, if UVA, while administering a clinical trial on behalf of a pharmaceutical company, ordered its employees to participate or lose their jobs, such a policy would be a clear instance of coercive influence that would constitute a violation of the relevant regulations and would be impermissible.

67. Although the FDA issued its Emergency Use Authorization alongside clinical trials that remain ongoing, it acknowledges no such protections against coercion in its administration of 21 U.S.C. § 360bbb-3, the statute that created the EUA, despite subsection (e)(1)(A)(ii)(III), which requires “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.”

68. In the context of the vaccines in question, HHS has created two similarly situated classes of people, one with more protections against coercion than the other. This is, in the formulation of the APA, constitutional right, power, privilege, or immunity.

69. For this deprivation under color of federal and state law of the right to the equal protection of the

laws, Defendant UVA Health has incurred liability under 42 U.S.C. 1983.

COUNT FOUR
Violation of the U.S. Constitution
Fourteenth Amendment liberty interest in
refusing unwanted medical treatment
[Against UVA Health]

70. The Supreme Court in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), recognized 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.” *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, (1990).

71. The Court rooted this principle in the Due Process clause of the Fourteenth Amendment.

72. This principle is what makes UVA’s conduct in this episode unlawful. It is using economic power to secure “consent” to an unwanted medical treatment. This is the same type of “consent” that harassers seek from the harassed in the sex discrimination context.

73. For this deprivation under color of federal and state law of the right to refuse unwanted medical treatment free from coercion and harassment, Defendant UVA Health has incurred liability under 42 U.S.C. 1983.

COUNT FIVE
Violation of the U.S. Constitution
Fourth Amendment prohibition against
unreasonable searches and seizures
[Against UVA Health]

74. The Fourth Amendment, which provides 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 [. . .]”

75. Here, the state, through UVA Health, is using economic coercion to seize and commandeer Ms. Antunes’s immune system for its own purposes, and has provided very little explanation or justification for its actions.

76. For this deprivation under color of federal and state law of the right to be free of unreasonable searches and seizures without experiencing coercion and harassment, Defendant UVA Health incurred liability under 42 U.S.C. 1983.

COUNT SIX
Wrongful termination [against UVA Health]

77. The Virginia Supreme Court has “recognized a common law cause of action in tort for wrongful termination of employment under an exception to the common-law doctrine of employment-at-will. This exception applies to terminations from employment which violate the public policy of this Commonwealth. *See, Shaw v. Titan Corp.*, 498 S.E.2d 696, 699 (1998) (internal citations omitted).

78. Furthermore, Virginia courts have recognized that,

The right to avoid unwanted touching of one's person forms the basis of the doctrine of informed consent. The doctrine of informed consent provides that a patient has a right to be informed of the value and possible consequences of a treatment and to refuse or consent to that treatment.

The right to be free of unwanted physical invasions has been recognized as an integral part of the individual's constitutional freedoms, whether termed a liberty interest protected by the Due Process Clause, or an aspect of the right to privacy contained in the notions of personal freedom which underwrote the Bill of Rights. The right to refuse medical treatment has been specifically recognized as a subject of constitutional protection. *Cavuoto v. Buchanan County*, 605 S.E.2d 287, 289 (Va. App. 2004)[citing, *U.S. v. Charters*, 829 F.2d 479 (4th Cir. 1987)]

79. By insisting on the unwanted touching and physical invasions of a vaccination at the price of her job, UVA has engaged in the wrongful termination of Ms. Antunes.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, respectfully pray for relief as follows:

- A. Hold unlawful and set aside UVA's vaccine mandate
- B. Hold unlawful and set aside Secretary Becerra and Commissioner Califf's unequal treatment

of similarly situated classes of vaccine recipients under the FD&C Act

- C. Issue declaratory relief declaring the Defendants' actions unlawful
- D. Issue permanent injunctive relief enjoining Defendants UVA and their agents from requiring COVID-19 vaccination as a condition of employment and restore Ms. Antunes to her position as though no termination or other punitive measures had occurred between her termination and the issuance of the relief
- E. Award compensatory and punitive damages to Ms. Antunes
- F. Award Plaintiff costs and reasonable attorneys' fees
- G. Award such other and further relief as the Court deems equitable and just under the circumstances.

App.51a

Respectfully Submitted,

/s/ E. Scott Lloyd

Counsel

Law Office of E. Scott Lloyd, PLLC

Bar # 76989

20 E. 8th Street, Suite 3

Front Royal, VA 22630

(540) 631-4081

edwardscottlloyd@protonmail.com

Counsel for the Plaintiff

Dated: March 25, 2022

**HEALTH AND HUMAN SERVICES
DECLARATION OF EUA
(MARCH 27, 2020)**



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

**DECLARATION THAT CIRCUMSTANCES EXIST
JUSTIFYING AUTHORIZATIONS PURSUANT TO
SECTION 564 OF THE FEDERAL FOOD, DRUG, AND
COSMETIC ACT, 21 U.S.C. § 360BBB-3**

On February 4, 2020, I determined pursuant to section 564 of the Federal Food, Drug and Cosmetic (FD&C) Act that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2009-nCoV). The virus is now named SARS-CoV-2, which causes the illness COVID-19.

On the basis of this determination, I hereby declare that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Alex M. Azar II

Date: Mar 27, 2020

**UVA ANNOUNCES VACCINATION
AND TESTING GUIDANCE,
UNIVERSITY OF VIRGINIA
(JULY 7, 2021)**

HEALTH SYSTEM ANNOUNCEMENTS

UPDATE (Revised Dates): Vaccination and Testing
Guidance for Team Members

Dear UVA Health Team Members,

UVA Health considers it our duty—and our honor—to protect the health and safety of our patients, team members and community. To that end, UVA Health expects all team members to be vaccinated for COVID-19. Consistent with Policy OCH-002, which grants the Medical Center Hospital Epidemiologist authority to require team members to undergo any additional screening, vaccinations or tests as may be necessary for infection control and patient safety, UVA Health is instituting the following enhanced requirements:

- **Newly hired team members** – All newly hired UVA Health faculty and team members receiving an offer as of June 25 or later with a start date of July 11 or later are required to receive the COVID-19 vaccine. New team members can either provide proof of vaccination or receive their first dose at their Employee Health visit or any independent or UVA Health vaccination clinic. Those previously infected with COVID-19 are not exempt from this vaccination requirement. New team

members may schedule a vaccination appointment in VaxTrax once they receive their UVA Health user ID.

- **Team members whose work requires them to be physically present in a UVA Health facility at any time** – At this time, unvaccinated team members in this group will be required to undergo weekly prevalence testing beginning August 2.
- **Team members whose work does not require them to be physically present in UVA Health facilities at any time** – No change at this time.

In making these decisions, the executive leadership team thoroughly reviewed data and recommendations from the Centers for Disease Control and Prevention and consulted with our own clinical and Infectious Disease leaders. Evidence continues to show that COVID-19 vaccines are very safe and highly effective—preventing transmission, hospitalizations, and serious illness from the virus.

The following procedures apply to the Medical Center, School of Medicine, School of Nursing, UVA Physicians Group and Claude Moore Health Sciences Library:

1. Vaccinated team members who did not schedule their vaccinations through VaxTrax should provide proof of vaccination to Employee Health by **July 12. Please** send a scanned image or photo of your immunization records, such as a CDC card or official medical record, along with your UVA computing ID to covidvax@hscmail.mcc.virginia.edu. Employee Health

will use this information to validate and update team members' records (VaxTrax data will be available to managers). Any other forms of documentation will be reviewed on a case-by-case basis.

2. Vaccinated team members who have lost their CDC card should contact their vaccination site for a replacement. **Team members who received their COVID vaccination at UVA Health can now download a replacement vaccination card here.**
3. Unvaccinated team members should make arrangements to be fully vaccinated at any vaccination site (this is considered paid time for team members). Those who were previously infected with COVID-19 are encouraged to get vaccinated as soon as they have recovered from clinical illness. Team members may schedule appointments at a UVA Health vaccination site through VaxTrax.
4. Employee Health will monitor the compliance of all unvaccinated team members undergoing weekly prevalence testing.
5. Prevalence testing should not be used for symptomatic tests or post-exposure testing. If there are symptoms or a recent exposure, you should contact Employee Health before testing.
6. Exceptions for the weekly prevalence testing will be granted for team members who:

- are fully vaccinated (two weeks since final shot) with a vaccine listed on WHO's Emergency Use List (EUL)
 - have tested positive for COVID-19 in the last 150 days are fully vaccinated (two weeks since final shot) with a vaccine listed on WHO's Emergency Use List (EUL)
 - are working remotely 100% of the time indefinitely
7. UVA Health team members can view testing location information and self-schedule prevalence tests online using the Time2Test application. Prevalence testing procedures for UVA Health team members outside of the Charlottesville area are being finalized; testing locations and other details will be shared as soon as they are available.
 8. Team members should talk with their manager if they need to schedule vaccination or testing during working hours.

We understand you may have questions about the vaccine. There are many resources available to help answer those questions on our COVID-19 Vaccination Program page.

We are so grateful for your ongoing commitment to delivering exceptional care and service to our patients. Thank you for taking these steps to help protect against COVID-19 here at UVA Health and throughout our community. If you have any questions regarding these new requirements, please contact CovidVax@hscmail.mcc.virginia.edu.

Sincerely,

K. Craig Kent, MD
Executive Vice President for Health
Affairs, University of Virginia
Chief Executive Officer, UVA Health

Bobby Chhabra, MD
President, University Physicians Group

Pam Cipriano, PhD
Dean, School of Nursing

Wendy Horton, PharmD, MBA
Chief Executive Officer, Medical Center

David Wilkes, MD
Dean, School of Medicine

**UVA ANNOUNCES VACCINATION
REQUIREMENT
(AUGUST 25, 2021)**

HEALTH SYSTEM ANNOUNCEMENTS

UVA Health to Require COVID-19 Vaccination for Team Members Effective Nov. 1

Dear Colleagues,

After seeing a steady decline in positive COVID-19 tests and hospitalizations this spring and early summer, the increasing number of new COVID-19 cases in recent weeks (particularly the highly transmissible delta variant) is a reminder that we must remain committed to protecting the health and well-being of our teams, communities and every patient who entrusts us with their care. In the interest of keeping our environment as safe and healthy as possible, the University of Virginia is working hard to ensure strong vaccination rates across faculty and staff as well as mandating vaccination for students. At UVA Health, we take this commitment—and this responsibility—seriously and will now require all team members without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021. Any team member not meeting the vaccination requirement deadline will be subject to disciplinary action up to and including termination.

We firmly believe that a mandatory COVID-19 vaccination program is the most important thing we can do to protect our team members, our patients and our communities. The available vaccines are effective and safe and are proven to prevent against serious

infection, hospitalization and death. For any team member who has been reluctant to receive the vaccine, we want to address any questions or concerns you have. Details about the vaccine requirement and resources for more information are available at our COVID-19 Vaccination Program site, including instructions for applying for a medical or religious exemption.

We do not take this important step lightly. We have some of the world's foremost infectious disease experts and epidemiologists, and their expertise continues to guide UVA Health's strong response to COVID-19 as do the recommendations from major public health and professional organizations—including the American Medical Association, the American Hospital Association, the American Nurses Association, the Virginia Hospital and Healthcare Association and many others—regarding the requirement of healthcare workers to get vaccinated.

Unvaccinated team members should make arrangements to be fully vaccinated at any vaccination site (this is considered paid time for team members). Team members may schedule appointments at a UVA Health vaccination site through VaxTrax. Please note that weekly COVID-19 testing is still required between vaccination doses (Moderna and Pfizer) and for 14 days after the last dose (or the first/only dose with the Johnson & Johnson vaccine). Those who were previously infected with COVID-19 are encouraged to get vaccinated as soon as they have recovered from clinical illness. A detailed timeline about key dates in this process is attached. Please take some time to read through the attached details and Frequently Asked Questions.

Thank you for your steadfast dedication to UVA Health and the care of our patients. Together, we have

an opportunity and responsibility to take this next important step toward protecting our patients, communities and each other.

Sincerely,

K. Craig Kent, MD
Executive Vice President for Health
Affairs, University of Virginia
Chief Executive Officer, UVA Health

Bobby Chhabra, MD
President, University Physicians Group

Pam Cipriano, PhD
Dean, School of Nursing

Wendy Horton, PharmD, MBA
Chief Executive Officer, Medical Center

David Wilkes, MD
Dean, School of Medicine

**EMAIL CORRESPONDENCE
BETWEEN CATHERINE ANTUNES
AND UNIVERSITY OF VIRGINIA ON
WHETHER VACCINE OFFERED BY UVA IS
FDA APPROVED OR EXPERIMENTAL
(AUGUST-SEPTEMBER 2021)**

From: Antunes, Catherine M *HS
Sent: Sunday, August 29, 2021 10:46 PM
To: CovidVax
Subject: EUA or FDA

To whom it may concern,

Is the FDA approved COMIRNATY (COVID-19 Vaccine, mRNA) BNT162b2 available to employees? Or are we required to take one of the Emergency Authorized Use vaccines to retain employment?

If you are not able to answer this question, to whom should I redirect this question?

Thanks,

Catherine Antunes

From: covidvax@hscmail.mcc.virginia.edu
<covidvax@hscmail.mcc.virginia.edu>
Sent: Monday, August 30, 2021 7:57 AM
To: Antunes, Catherine M *HS
Subject: [VaxTrax] Issueid {22017}

Dear Team member, Comirnaty is the same vaccine Pfizer/Biontech vaccine, formulated and manufactured in the same way by the same company. They can't state a brand name until after it is FDA approved. That is the vaccine that will be administered. Currently using

vials labeled as EUA. No specific date on when the vial names will change here. Thank you, EH

From: Antunes, Catherine M *HS
Sent: Monday, August 30, 2021 11:18 AM
To: CovidVax
Subject: Re: [VaxTrax] Issueid {22017}

Just to clarify, you will only be administering vaccines, labelled EUA as you put it, that has a liability shield and will have a liability shield for the manufacturer through November 1st?

From: covidvax@hscmail.mcc.virginia.edu
<covidvax@hscmail.mcc.virginia.edu>
Sent: Monday, August 30, 2021 3:28 PM
To: Antunes, Catherine M *HS
Subject: [VaxTrax] Issueid {22017}

The pharmacy has told me that they will get the vials labelled as Comirnaty whenever they show up and they can not predict when that will be.

From: covidvax@hscmail.mcc.virginia.edu
<covidvax@hscmail.mcc.virginia.edu>
Sent: Wednesday, September 1, 2021 11:25 AM
To: Antunes, Catherine M *HS
Subject: [VaxTrax] Issueid {22018}

Hi Catherine, Team members will be able to choose between Pfizer (which has been granted full FDA approval), Moderna, and J&J. Comirnaty is the trade name for the Pfizer vaccine.

From: Antunes, Catherine M *HS
Sent: Friday, September 3, 2021 12:08 AM
To: CovidVax
Subject: Re: [VaxTrax] Issueid {22018}

It is my understanding that there are two vaccines made by Pfizer: BNT162 mRNA vaccine and COMIRNATY BNT162b2. The BNT162 Emergency Use Authorization has been extended, and BNT162b2 (Comirnaty) has FDA approval.

Is the BNT162b2 being offered for use before the November 1st deadline for employees?

Thank you for your time in clarifying this.

From: Antunes, Catherine M *HS
Sent: Wednesday, September 8, 2021 2:56 PM
To: CovidVax
Subject: Re: [VaxTrax] Issueid {22018}

To whom it may concern,

It is very important for my decision making about the different vaccines that I have this question answered. I sent this question a few days ago, but if you could get back to me ASAP that would be great.

It is my understanding that there are two vaccines made by Pfizer: BNT162 mRNA vaccine and COMIRNATY BNT162b2. The BNT162 Emergency Use Authorization has been extended, and BNT162b2 (Comirnaty) has FDA approval.

Is the BNT162b2 being offered for use before the November 1st deadline for employees?

Thank you for your help,

Catherine Antunes

From: covidvax@hscmail.mcc.virginia.edu
<covidvax@hscmail.mcc.virginia.edu>
Sent: Tuesday, September 14, 2021 3:34 PM
To: Antunes, Catherine M *HS
Subject: [VaxTrax] Issueid {22018}

Hi Catherine, The vaccines you referenced are both the same. There is no chemical difference between the two. Comirnaty is simple the trade name of the Pfizer vaccine, the same as Tylenol is the same thing as Acetaminophen. The Pfizer vaccine (Comirnaty) has full FDA approval.

**UVA PUBLICATION:
MANDATORY COVID-19 VACCINES PROTECT
OURSELVES AND OUR COMMUNITIES
(SEPTEMBER 7, 2021)**



Ebony Hilton, MD, receives the first COVID-19 vaccine administered at UVA Health.

The important step to require all UVA Health team members to be vaccinated is not one we took lightly. We considered several major public health and professional organizations' recommendations, including the American Medical Association, the American Hospital Association, the American Nurses Association, and the Virginia Hospital and Healthcare Association. We also consulted with some of the world's foremost infectious disease experts and epidemiologists we have in-house, who have guided our strong response to the pandemic. Earlier this summer, I wrote a LinkedIn article about the facts UVA Health was considering regarding a

vaccine mandate. We've learned a lot since I wrote this in July.

The Delta variant has become the dominant strain of COVID-19 and is now the primary driver of recent high transmission rates because it spreads more easily than earlier strains of the virus. As a result, the national rate of hospitalizations for unvaccinated COVID-19 patients continues to grow, filling Emergency Departments, occupying inpatient beds, deferring elective surgeries, and putting more strain on an already exceptionally weary workforce. The FDA gave full approval of the Pfizer vaccine, with others expected in the near future. States, including Virginia, have announced vaccine requirements for state workers, and courts have upheld these requirements. (Read this piece by Margaret Foster Riley, UVA Law professor and public health sciences professor in our School of Medicine, about vaccine mandates and the law.) Finally, more recently, many health systems around Virginia have similarly required vaccines for their team members—including Augusta Health, Bon Secours, Centra, Inova, Mary Washington, Valley Health, VCU, Sentara, and more.

This week, I wanted to re-share that LinkedIn piece to give you some insight into how I thought about this important step for UVA Health. What you see below was originally published on July 2, 2021.

#

The question of whether an employer can mandate workforce coronavirus vaccination is reverberating throughout all industries, but it is an especially critical issue in the world of health care. At UVA Health, it is our primary responsibility to safeguard the health and

well-being of our entire UVA family, which includes patients, faculty, team members, administrators, and the entire Charlottesville community. A key part of protecting the public health involves making sure that we have a high level of vaccinated personnel. A vaccinated staff creates the safest possible environment for the clinical care of patients, and it ensures that a vulnerable population is protected from the threat of the deadly virus. To that end, UVA Health will plan to take a stepwise approach to achieving a fully vaccinated staff.

Some hospitals have already begun mandating vaccinations for all employees. Houston Methodist Hospital and Health System and the University of Pennsylvania Health System (UPHS) are among the first health systems to do so. UPHS is one of the nation's largest health systems, and they are asking their workforce to set an example to end the pandemic. Other health institutions are following suit. RWJBarnabas Health in West Orange, NJ, is now requiring supervisors and above to be vaccinated for COVID-19, with plans to extend the mandate to all employees. As we head into the second half of the year, we expect more hospitals and health systems nationwide to require their workforce to get the COVID-19 vaccine.

At the same time, many healthcare systems are still undecided about requiring staff to be vaccinated. The issue is a complex one, as it involves many sensitive and overlapping issues including public health, ethics, law, labor relations, as well as an individual's right to autonomy. The question that must be answered is this: *How do you balance the need for personal freedom against the necessity to provide a safe hospital*

environment, if not everyone who works at the health system is willing to get vaccinated?

Regarding a vaccine mandate for UVA Health, here are the facts we are considering:

Is it Safe?

The science behind vaccines is vigorous and sound, and the science community overwhelmingly believes the current US vaccines to be safe. More than a hundred million Americans have received COVID-19 vaccines under the most intense safety monitoring in U.S. history. The CDC states that the COVID-19 vaccination will help keep you from getting COVID-19, and all U.S. vaccines have been shown to be safe and effective at preventing the coronavirus. Moreover, the vaccine helps prevent patients who do get the virus from becoming seriously ill. Finally and importantly, getting vaccinated not only protects you, but it may also protect people around you, particularly people at increased risk for severe illness.

Is it Legal?

This is unclear, but there is some historical precedent for having a public mandate for vaccines. As early as 1905, the Supreme Court ruled that the Cambridge, Mass., board of health had the authority to require that the city's population be vaccinated against smallpox, as the disease was sparking outbreaks. Much more recently, Johns Hopkins School of Public Health has said that states have the legal and constitutional authority to require that residents be vaccinated. What's more, workplaces like hospitals, health care and long-term care facilities already require their staff be

vaccinated against the flu each year. One thorny legal question remains, however. COVID-19 vaccines are currently approved under the FDA's emergency use authorization, they do not have full FDA approval yet.

Organizations that provide public health guidance like the CDC and the Occupational Safety and Health Administration (OSHA) have not commented on the question of requiring vaccinations. However, the Equal Employment Opportunity Commission (EEOC) said that employers may mandate vaccinations with some limitations, as mandating coronavirus vaccines would not conflict with federal disability law or civil rights statutes on discrimination. Furthermore, the EEOC said an employer could exclude an employee from a workplace if vaccine refusal posed too great a threat, but the worker must be offered the option of telework or a leave, and employers must allow exemptions for medical and religious reasons.

Is it Ethical?

This depends on who you ask. The World Health Organization (WHO) weighed in on the ethics of mandatory vaccines by saying that “they should be considered only if it is necessary for, and proportionate to, the achievement of an important public health goal identified by a legitimate public health authority. If such a public health goal (e.g., herd immunity, protecting the most vulnerable) can be achieved with less coercive COVID-19 or intrusive policy interventions (e.g., public education), a mandate would not be ethically justified.”

In another opinion, Professor Lawrence O. Gostin, a professor at Georgetown University Law Center with expertise in health law recently told the Washington Post: “Vaccination mandates are ethical. Everyone

has a right to make decisions about their own health and welfare, but they don't have a right to expose other people to potentially dangerous or even lethal diseases."

A final consideration that cannot be ignored is that unvaccinated populations risk enabling new virus mutations that cannot be contained by our current vaccinations. William Schaffner, an infectious disease expert at Vanderbilt University Medical Center stated that: "Every time this virus finds a new person, it multiplies. Every time it multiplies, it creates mutations . . . and those mutations can create a variant that is so different that our current vaccine protection might not work or might not work as well."

Throughout the health care world, we have all faced a year of unprecedented and relentless challenges to keep our communities safe and healthy. We have changed policies and amended procedures in rapid succession to limit exposure, treat the sick and provide comfort to hospital staff, patients and families as we fought to contain the virus. Now we have come to a point where the situation is becoming more manageable. We can look forward to a time when life can return to what we used to consider normal, when we have the freedom to go out into the world with fewer restrictions and a lot less fear. At the same time, we still have an obligation to do everything in our power to keep ourselves and others safe. We know that the COVID-19 vaccine is safe, mandating it is ethical, and although the legal question might be still up in the air, getting the vaccination as soon as possible is the right thing to do. It is the right choice to protect ourselves, our families, and our communities from future harm.

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