

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JOSHUA WILSON, *et al*

Plaintiffs,

v.

LLOYD AUSTIN, III, *et al.*,

Defendants.

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Case No. 4:22-cv-438-ALM

PLAINTIFFS’ MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure (“FRCP”), Plaintiffs Joshua Wilson, et al., by and through counsel, move this court for a Preliminary Injunction *in limine* in accordance with this Court’s July 1, 2022 Order. The *Feres* doctrine – and the Supreme Court’s reaffirmation of it in *United States v. Stanley*, 483 U.S. 669 (1987) – prohibits military members from suing for monetary damages under the Federal Tort Claims Act (“FTCA”). A preliminary injunction is necessary “to preserve the court’s ability to later order meaningful relief.” *Drew v. Liberty Mut. Ins.*, 480 F.2d 69, 72, 74 (5th Cir. 1973). The injunctive relief sought is consistent with the Supreme Court’s directive in *Austin v. U.S. Navy SEALs 1-26*, 142 S.Ct. 1301 (2022), because it does not seek to preclude consideration of Plaintiffs’ “vaccination status in making deployment, assignment, and other operational decisions.” Therefore, unless the Court issues a preliminary injunction, Plaintiffs will suffer harms that cannot be otherwise remedied. A proposed order accompanies this Motion as Exhibit 1.

PROCEDURAL HISTORY AND BACKGROUND

1. On May 23, 2022, plaintiffs filed a class action complaint that included 14 named plaintiffs and the Members of the Armed Forces for Liberty (“MAFL”), an unincorporated

association with over 500 service member plaintiffs. See ECF 1. The facts and allegations stated in Plaintiffs' Complaint are hereby incorporated into and made a part of this motion for preliminary injunction, as if fully set forth herein.

2. Defendants' actions are the latest iteration in a long institutional history of policies, procedures, and practices using service members for medical experimentation without their knowledge or informed consent. Congress has held many hearings condemning such practices and programs because of the obvious criminality of such actions.¹ From Atomic Veterans and so-called "Man-Break" tests using mustard and lewisite gases in World War 2, to MKULTRA (using LSD on unwitting military members) during the Cold War (1952-1964), to the use of the defoliant "Agent Orange" during the Vietnam War, all the way to Gulf War illness resulting from the use of unlicensed and experimental drugs and vaccines as prophylaxes against *possible* enemy chem-bio weapons, Defendant DOD's illegal and unethical experiments have harmed millions of American service members.² Congress (eventually) stepped in and explicitly prohibited Defendant DOD from doing this anymore by statute, in part because taxpayers ultimately have to foot the bill for the service-related disabilities that have resulted from Defendants' prior instances of unlawful medical experimentation.

¹ See, e.g., "Human Experimentation, An Overview on Cold War Era Programs," U.S. General Accounting Office (GAO), Sep. 28, 1994, GAO/T-NSIAD-94-266; *Is Military Research Hazardous to Veterans' Health? Lessons from World War II, the Persian Gulf War, and Today*, Senate Committee on Veterans' Affairs, 103rd Cong. May 6, 1994; see also *Veterans at Risk: The Health Effects of Mustard Gas and Lewisite*, Pechura, C.M. & Rall, D.P. (Eds.) Institute of Medicine, National Academy Press (Washington, DC, 1993) at 3-4, 6-8, 50-52, 224-226.

² See Compl., ¶¶ 45-52; Ex. 2, Efthimios Parasidis, *Justice and Beneficence in Military Medicine and Research*, 73 Ohio St. L.J. 723, 732-39 & 759-60 (2012); see also U.S. Senate, *Human Drug Testing by the CIA, 1977: Hearings Before the Subcommittee on Health and Scientific Research, Committee on Human Resources* at 169 (Sept. 20-21, 1977).

3. Abuses in illegally testing vaccines first during the Gulf War, and then with the anthrax vaccine in the runup to the second Gulf War, led Congress to pass 10 U.S.C. §1107 in 1997 in order to prohibit the Defendant DOD from compelling members of the All-Volunteer Force (AVF) to use unlicensed (“investigational”) products. Despite this, Defendant DOD began the anthrax vaccine immunization program (AVIP) right in the shadow of Congress’ actions, so Congress strengthened 10 U.S.C. §1107 repeatedly through 2000, and in 2004 Congress added 10 U.S.C. § 1107a, prohibiting the mandate of Emergency Use Authorization (“EUA”) drugs or vaccines after the passage of the 2004 Project BioShield Safety Act (21 U.S.C. §360bbb-3).

4. While Congress is now (justifiably) celebrating passage of the Promise to Address Comprehensive Toxics (“PACT”) Act of 2022—providing \$280 billion to cover health costs for veterans exposed to Agent Orange, burn pits and other toxins after DOD and DOJ (and even the Veterans Administration) fought against it in court for decades, DOD is creating the next veterans’ health disaster that we will all be paying for in decades to come, with Plaintiffs paying the heaviest price with their health and lives.

5. Defendants’ unlawful actions must also be considered in light of the Biden Administration’s other illegal vaccine mandates and DOD’s systematic violations of service members’ rights in executing the DOD Mandate. In September 2021, President Biden announced the issuance of a series of executive orders and other vaccine mandates that would require all or nearly all U.S. citizens and lawful residents to be vaccinated as a condition for employment, education, or participation in the Nation’s social or economic life. With the exception of the DOD

Mandate, the five other federal mandates were quickly enjoined by the Courts.³ Several courts have found that the DOD’s implementation of the Mandate to be unlawful insofar as DOD and the other Armed Services have refused to grant any religious accommodation requests (“RARs”) without regard to merit or sincerity of religious objections (“No Accommodation Policy”).⁴

6. Plaintiffs have pursued all available military remedies, including requests for religious accommodations⁵ and medical exemptions (“ME”), which have been denied or ignored.⁶

All Plaintiffs face adverse employment or disciplinary actions, up to and including separation.

³ See *Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661 (2022) (“*OSHA*”) (enjoining OSHA mandate, which was subsequently withdrawn); *Feds for Medical Freedom v. Biden*, --- F.Supp.3d ---, 2022 WL 188329 (S.D. Tex. Jan. 21, 2022) (nation-wide stay of federal employee mandate), *vacated and remanded* 30 F.4th 503 (5th Cir. Apr. 7, 2022), *reh'g en banc granted and vacated* --- F.4th ---, 2022 WL 2301458 (5th Cir. June 27, 2022) (reinstating nationwide stay); *Georgia v. Biden*, --- F.Supp.3d ---, 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021) (nation-wide stay of federal contractor mandate); *Texas v. Becerra*, --- F.Supp.3d ---, 2021 WL 6198109 (N.D. Tex. Dec. 31, 2021) & *Louisiana v. Becerra*, --- F.Supp.3d ---, 2022 WL 16571 (W.D. La. Jan. 1, 2022) (staying Head Start Mandate in 25 states). The Healthcare Mandate was stayed nationwide in *Louisiana v. Becerra*, --- F. Supp. 3d ---, 2021 WL 5609846 (W.D. La. Nov. 30, 2021), but that injunction was dissolved and the case remanded by the Supreme Court in *Biden v. Missouri*, 142 S. Ct. 647, 654–55 (2022). The healthcare worker mandate is now back before the district court to consider constitutional challenges not addressed in the Supreme Court’s decision.

⁴ See generally *U.S. Navy SEALs 1-26 v. Biden*, --- F.Supp.3d ---, 2022 WL 34443 (N.D. Tex. Jan. 3, 2022) (“*Navy SEALs 1-26*”), *stay denied*, 27 F.4th 346 (5th Cir. Feb. 28, 2022) (“*Navy SEALs 1-26 Stay Order*”). See also cases cited Plaintiffs’ Complaint, ECF 1, FN 64.

⁵ The Complaint does not include any claims that Plaintiffs have under the Religious Freedom Restoration Act (“RFRA”) or other violations of their religious liberties, although more than 450 of the named Plaintiffs and MAFL members have submitted religious accommodation requests (“RAR”) that have been uniformly denied.

⁶ See, e.g., ECF 3-4, Brown Decl., ¶11 (denied ME for lack of vaccine supply); ECF 3-5, Wilson Decl., ¶ 8 (ME despite documented allergy to vaccine, recommendation from two doctors and previous documented infections); ECF 3-6 Groothousen Decl., ¶¶ 9-12 (permanent ME denied despite history cancer, Bell’s palsy, migraines and high blood pressure and temporary ME for participating in clinical trial withdrawn); ECF 4-6, Gibson Decl., ¶ 7-8 (1 ME request ignored, a second denied, despite doctor’s concurrence with ME).

discharge for “misconduct,” court martial, loss of postseparation veterans’ benefits, and permanent damage to their reputation and employment prospects resulting from less than an “honorable” discharge, which all Plaintiffs have unquestionably earned by their service thus far, many in combat.⁷ In the meantime, they are non-deployable and prohibited from travel, training, permanent change of station (“PCS”), promotion, and new assignments.⁸ They have faced these adverse actions even while their RAR or MEs were pending and/or FDA-licensed vaccines were unavailable, in flagrant violation of service regulations claiming to prohibit adverse actions during the pendency of such requests.⁹

LEGAL STANDARD

To obtain a preliminary injunction, Plaintiffs must establish:

(1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest.

Ladd v. Livingston, 777 F.3d 286, 288 (5th Cir. 2015). Courts may employ “a sliding scale” to “balance the hardships ... with the degree of likelihood of success on the merits.”¹⁰

⁷ See ECF 3-4, Brown Decl., ¶ 9 (will be involuntarily separated by July 1, 2022 with less “Honorable” discharge); ECF 3-9, Puckett Decl., ¶¶ 12-16 (faces loss of benefits & recoupment of benefits that may render her homeless after separation); ECF 4-2, Fields Decl., ¶¶ 17-18 (selected for Colonel (O-6) but will be forced to retire as Lt Col and faces “misconduct” discharge or placement into Inactive Ready Reserve (“IRR”)); ECF 4-5, Gross Decl., ¶ 12 (denied ME and opportunity to see doctor while on deployment).

⁸ See, e.g., ECF 4-6, Gibson Decl., ¶¶ 8-9; ECF 4-5, Gross Decl., ¶ 11.

⁹ See ECF 3-4, Brown Decl., ¶ 8; ECF 3-5, Wilson Decl., ¶¶ 7-8.

¹⁰ *Fla. Med. Ass’n, Inc. v. U. S. Dep’t of Health, Ed. & Welfare*, 601 F.2d 199, 203 n.2 (5th Cir. 1979)(citation and quotation marks omitted). See also *Knights of Ku Klux Klan, Realm of La. v. E. Baton Rouge Par. Sch. Bd.*, 578 F.2d 1122, 1125 (5th Cir. 1978) (“Where one or more of the

I. THIS COURT HAS SUBJECT MATTER JURISDICTION.

A. Plaintiffs' Claims Are Justiciable.

Although civilian courts have traditionally been reluctant to intervene in the conduct of military affairs, Courts will hear servicemembers claims that meet the two-part justiciability test set forth in *Mindes v. Seaman*, 453 F.2d 197, 201 (5th Cir. 1971) (“*Mindes*”). Plaintiffs’ claims satisfy the *Mindes* tests for largely the same reasons as those in *Navy SEALs 1-26* and other cases enjoining enforcement of the DoD Mandate.¹¹ *Mindes* allows judicial review if there is (1) an allegation that the military has violated service members’ statutory or constitutional rights, or that it “has acted in violation of applicable statutes or its own regulations,” and (2) “exhaustion of available intra service corrective measures.” *Id.* at 201. Plaintiffs meet those tests because they allege constitutional, statutory, and regulatory violations, and because they have exhausted, or are exempt from exhaustion of, military remedies to the extent remedies are actually available at all.

For plaintiffs who meet the threshold criteria, the Court must then weigh four factors to determine if their claims are justiciable:

(1) the nature and strength of the plaintiffs’ challenge; (2) the potential injury to the plaintiffs if review is refused; (3) the type and degree of anticipated interference with the military function; and (4) the extent to which military expertise or discretion is involved.

Navy SEALs 1-26, at *4 (citing *Mindes*, at 201-202).

Plaintiffs satisfy these criteria as well.

factors is very strongly established, this will ordinarily be seen as compensating for a weaker showing as to another or others.”).

¹¹ See *supra* note 4.

1. Plaintiffs Have Exhausted Military Remedies, and In Any Case Qualify for One or More Exemptions from Exhaustion.

To the extent that military remedies are available—and generally speaking they are not— Plaintiffs have exhausted those remedies. Certain Plaintiffs have unsuccessfully challenged the lawfulness of the DoD Mandate and/or sought medical exemptions that have been categorically eliminated (*i.e.*, for previous documented infections, vaccine injuries, or medical conditions placing them at heightened risk of adverse reaction).

To the extent that any Plaintiffs or other class members are deemed not to have exhausted military remedies, they each qualify for one or more exemptions from exhaustion based on: (1) futility; (2) inadequacy; (3) irreparable harm; or (4) substantial constitutional questions. *See Navy SEALs 1-26*, at *6 (*discussing Von Hoffburg v. Alexander*, 615 F.2d 633, 638-40 (5th Cir. 1980)).¹² In the context of RFRA and First Amendment claims, several courts have found that the military’s No Accommodation Policy is unlawful and amounts to little more than “theater.” *Navy SEALs 1-26*, 2022 WL 34443, at *1; *Air Force Officer*, 2022 WL 468799, at *1. Their outcome (denial) is “pre-determined.” *Navy SEALs 1-26*, at *6 (citation omitted).

This applies *a fortiori* to the military remedies for challenging the unlawful orders at issue here. The only military “remedy” potentially available to Plaintiffs was to seek a medical exemption. Secretary Austin unilaterally eliminated all pre-existing categories of medical exemptions in his August 24, 2021 memo, except for those participating in clinical trials. *See* ECF

¹² With respect to Plaintiffs’ APA-based claims for violations of the Informed Consent Laws and APA, there is no exhaustion requirement. APA review requires exhaustion of remedies only where “the statute or rule clearly mandates” exhaustion. *Darby v. Cisneros*, 509 U.S. 137, 113 S.Ct. 2539 (1993). Neither the APA nor 10 U.S.C. §1107a mandate exhaustion.

4-12 at 1. As Plaintiffs such as LCDR Groothousen demonstrate, even that exemption is subject to revocation at the whim of Defendants' agents who are pressured to obtain 100% vaccination rates, regardless of what exemptions are available, necessary, or medically prudent. Being required to pursue a medical exemption that has been categorically eliminated is the definition of a futile and inadequate remedy. Plaintiffs also qualify for exemptions based on the threat of irreparable harm absent review, *see infra* Section III, and because their claims raise substantial constitutional questions (*i.e.*, satisfy the first *Mindes* factor). *See infra* Section I.A.2.

In other proceedings, the DoD has claimed that service members must exhaust remedies up to and through the Boards of Correction of Military Records ("BCMR"). This defense is based on a fundamental mischaracterization of the role and authority of BCMRs.

A BCMR is a clemency-oriented body with authority to "correct an error or remove an injustice, 10 U.S.C. § 1552(a), not to declare the law. ... [It] has no authority to declare the challenged regulations invalid."¹³

BCMRs may make recommendations, but "the Service Secretary always has the final say over [BCMR] decisions[.]" *Hodges v. Callaway*, 499 F.2d 417, 423 (5th Cir. 1974).

2. Plaintiffs Satisfy the Four *Mindes* Factors.

First, review is favored where, as here, Plaintiffs raise constitutional claims "founded on infringement of specific constitutional rights," like Defendants' violations of the Fifth Amendment rights to procedural due process, substantive due process, and equal protection. *See Navy SEALs I-26*, at *7 (citation omitted). Plaintiffs' statutory claims are also strong, as they are identical to

¹³ *Glines v. Wade*, 586 F.2d 675, 678 (9th Cir. 1978), *rev'd on other grounds sub nom. Brown v. Glines*, 444 U.S. 348 (1980); *see also Adair v. England*, 183 F.Supp.2d 31, 55 (D.D.C. 2002) ("resolving a claim founded solely upon a constitutional right is singularly suited to a judicial forum and clearly inappropriate to an administrative board." (citation omitted)).

the those addressed in the *Doe v. Rumsfeld* series of cases,¹⁴ where the D.C. District court enjoined the same violation of the same statutes (*i.e.*, the APA and the Informed Consent Laws) by the same Defendants (DoD, FDA, and HHS) for the same class of plaintiffs as present here. Indeed, it is Plaintiffs' contention that the Defendants' DOD and FDA are estopped by the doctrine of collateral estoppel/issue preclusion from even arguing that they can mandate an EUA vaccine to servicemembers for the reasons set forth *infra*, II.E.

Second, Plaintiffs face irreparable harm from the infringement of their rights under the Fifth Amendment and the Informed Consent Laws. *See infra* Section III. They also face harm from discharge; loss of veterans' benefits; medical coverage; retirement eligibility; obstacles to civilian employment; and severe family disruptions, including being involuntary transferred away from their current jobs, homes, and families, or by being indebted for previously transferred Post-9/11 GI Bill benefits. *See, e.g.*, Compl. ¶¶ 124-127 & *supra* ¶ 6.

A Marine who has not been fully vaccinated is not considered worldwide deployable and shall be assigned or reassigned, locally, to billets which account for health risks to the unvaccinated Marine and those working in proximity to the Marine...

Marines separated for vaccination refusal... will be subject to recoupment of any unearned special or incentive pays and advance educational assistance. Marines who do not complete their service obligation for Transfer of Education Benefits will lose their eligibility to retain transferred Post-9/11 GI Bill benefits and may be subject to recoupment if the Veterans Affairs has already processed a payment for transferred benefits.¹⁵

¹⁴ *John Doe No. 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003) ("*Rumsfeld I*"), modified *sub nom. John Doe No. 1 v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) ("*Rumsfeld II*"), modified *sub nom. John Doe No. 1 v. Rumsfeld*, 2005 WL 774857 (D.D.C. Feb. 6, 2005) ("*Rumsfeld III*").

¹⁵ MARADMIN 612/21, ¶¶3c, 3h. Available here: <http://tinyurl.com/42sbmcfb>

Third, judicial review would not interfere with military functions. Nearly 98% of active-duty service members are “vaccinated.”¹⁶ Permitting a small number of servicemembers to remain unvaccinated would not interfere with military functions because it makes no difference with regard to the central justification for mandating a vaccine: prohibiting transmission of the virus.

Fourth, the constitutional issues in this case do not implicate “[t]he complex[,] subtle, and professional decisions” that “are essentially professional military judgments.” *Air Force Officer*, *8 (citations omitted). While “judges don’t make good generals,” *id.* (citing *Orloff v. Willoughby*, 345 U.S. 83, 93, 73 S.Ct. 534 (1953)), “Generals don’t make good judges—especially when it comes to nuanced constitutional issues.” *Id.* Whether the DOD Mandate can withstand judicial scrutiny “doesn’t require ‘military judgment. . . . Such an issue is purely a legal matter” appropriate for judicial review. *Air Force Officer*, at * 8 (quoting *Mindes*, 453 F.2d at 201).

B. Plaintiffs Have Standing.

1. Plaintiffs Have Article III Standing.

A plaintiff establishes standing by demonstrating (1) a “concrete and particularized” injury that is “actual or imminent”; (2) “fairly traceable to the challenged conduct”; and (3) “likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robbins*, 578 U.S. 856, 136 S. Ct. 1540, 1547 (2016).

Each of these requirements are easily met. Plaintiffs will suffer an “actual and imminent”

¹⁶ See, e.g., Dept. Air Force, *DAF COVID-19 Statistics – June 2022*, available at: <https://tinyurl.com/mrx7kvnd> (last visited June 20, 2022) (98.5% vaccination rate); Dept. Navy, NAVADMIN 225/21 (Oct. 13, 2021) (over 98% of active-duty sailors vaccinated as of October 13, 2021), available at: <http://tinyurl.com/4c236sre> (last visited June 20, 2022); Peter Aitken, *Army Nears 100% Vaccination, Claims Only 1% Refusal Among Troops*, Fox News (May 22, 2022), available at: <http://tinyurl.com/46un8w4w> (last visited June 20, 2022).

“concrete and particularized” injury” due to the unlawful and unconstitutional DOD Mandate and related challenged final, agency actions. Several named Plaintiffs have already faced adverse personnel or disciplinary actions, *see supra* ¶ 6, and a full catalog of the harms suffered by the entire group of Plaintiffs would require this Motion to be submitted in separate volumes. Courts have routinely granted standing to service members challenging a new vaccine mandate applicable to them. *See generally Rumsfeld I* and *Rumsfeld II*. Plaintiffs also satisfy the Article III “injury-in-fact” standing requirement due to the “increased risk of future harm” they face if they take the vaccine.¹⁷ Because they face a “severe” threat, *i.e.*, death or permanent injury,¹⁸ they need only show a “relatively modest increment of risk.” *Beaty*, 853 F.Supp.2d at 36 (citation and quotation marks omitted).

The latter two elements, traceability and redressability, normally “overlap as two sides of the causation coin.” *Dynalantic Corp. v. DoD*, 115 F.3d 1012, 1017 (D.C. Cir. 1997). Where, as here, the plaintiff “is the object of the challenged agency action, there is usually little doubt of causation.”¹⁹ Plaintiffs’ injury is directly traceable to the actions of the DOD in adopting the DOD Mandate and would be redressed by the relief sought in this Motion.

¹⁷ *Beaty v. FDA*, 853 F.Supp.2d 30, 36 (D.D.C. 2012) (“*Beaty*”), *aff’d in part, vacated in part sub. nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (“*Cook*”).

¹⁸ *See* Compl., ¶¶ 116-118 (12,000 deaths, including 119 service members, 13,000 permanently disabled, including 300 service members). By Defendant HHS’ own legally required pharmacovigilance data (VAERS), 119 “military” died from the current mRNA shots as of Feb. 11, 2022. *See* ECF 5-13, Long Decl., at 13. The DOD’s expert has averred in written testimony that “[i]n total, 31 active-duty service members have died from COVID-19 as of the end of February 2022.” ECF 3-1, Rans Decl., at 11 & Table. The government’s data demonstrates that the “vaccines” killed four times as many service members in 6 months as the Covid-19 virus itself killed in (at least) 23 months of prevalence (using March 2020 as a starting point).

¹⁹ *Teva Pharmaceuticals USA, Inc. v. FDA*, 514 F.Supp.3d 66, 91 (D.D.C. 2020) (“*Teva*”) (*citing Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62, 112 S. Ct. 1230 (1992) (“*Lujan*”).

Plaintiffs also have standing for their claims against the FDA and HHS because the DOD Mandate and elimination of medical exemptions are traceable to FDA and HHS actions. Courts have permitted service members to challenge FDA approval of a vaccine where the FDA's approval provided the legal basis for a DOD mandate.²⁰ Just as in *Rumsfeld I* and *II*, this case alleges the interconnected actions of multiple agencies, not merely a single decision by the DoD on its own. Plaintiffs seek both declaratory judgment and injunctive relief because *each* the DoD, FDA, and HHS acted in concert by failing to adhere to statutes and regulations governing the exact same activity as was enjoined in *Doe*—illegally mandating an EUA vaccine in violation of 10 U.S.C. §1107a—and their coordinated actions are the cause of Plaintiffs' injuries, which would be redressed by an order from this Court.

2. Plaintiffs Have Prudential Standing for Statutory Claims.

Under the APA, “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.” *Lujan*, 497 U.S. 871 at 882 (quoting 5 U.S.C. § 702). The “zone of interests” tests for standing “is not meant to be especially demanding and is applied in keeping with Congress’s evident intent when enacting the APA to make agency action presumptively reviewable.”²¹ Plaintiffs easily meet the APA standing requirements. *See Rumsfeld I* and *II*.

Plaintiffs have standing under the Informed Consent Laws because they are the subject

²⁰ *See Doe #1-#14 v. Austin*, 2021 WL 5816632, at *7 (N.D. Fla. Nov. 12, 2021) (“*Austin*”) (finding that “plaintiffs have shown enough as to standing” for FDA claims because DoD Mandate traceable to FDA); *Rempfer v. Eschenbach*, 535 F.Supp.2d 99, 101 (D.D.C. 2008) (“*Rempfer*”), *aff’d sub. nom. Rempfer v. Sharfstein*, 583 F.3d 860 (D.C. Cir. 2009).

²¹ *Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak*, 567 U.S. 209, 224, 132 S.Ct. 2199 (cleaned up).

of the challenged agency action. *See Teva*, 514 F.Supp.3d at 91. They meet the other requirements for standing for the same reasons as set forth above and in *Austin*, *Rumsfeld I*, *Rumsfeld II*, and *Rempfer*. While the “zone of interests” does not require Congress to have enacted a statutory provision “specifically intend[ing] to benefit the plaintiff,” *Nat’l Credit Union Admin. v. First Nat’l Bank & Trust Co.*, 522 U.S. 479, 118 S.Ct. 927, 935 (1998), 10 U.S.C. § 1107a was specifically intended to benefit service members like Plaintiffs by codifying their right to refuse an EUA drug mandated by the military under Title 10.

Plaintiffs also have standing under the PHSA, as they are in the class of (involuntary) consumers that these statutes are intended to protect. The requirements violated by the FDA include the specific approval requirements for biologics (which were misapplied to mRNA gene therapy products), the “interchangeability” requirements adopted to protect consumers, and the PHSA’s mandatory, non-waivable labeling requirements.²²

C. Plaintiffs’ Claims Are Ripe.

“When determining ripeness, we must balance the fitness of the issues for judicial decision with the hardship to the parties of withholding court consideration.” *Pearson v. Holder*, 624 F.3d 682, 684 (5th Cir. 2010). Plaintiffs’ claims do not “rest[] upon contingent future events that may not occur as anticipated, or may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300, 118 S.Ct. 1257 (1998) (internal quotations omitted). Nor is there any risk of “premature adjudication”

²² *See, e.g., Washington Legal Found. v. Kessler*, 880 F.Supp. 26 (D.D.C. 1995) (“WLF”) (public interest group had standing to challenge FDA misbranding policy that restricted information available to consumers and doctors similar to EUA Fact Sheets at issue here); *Stauber v. Shalala*, 895 F.Supp. 1178, 1187-88 (W.D. Wis. 1995) (finding that consumers had standing under the FDCA to sue FDA because “plaintiffs’ injury is their exposure to a potentially dangerous drug whose safety has not been demonstrated in accordance with the act.”).

or “entangling” the court in “abstract disagreements over administrative policies” that “have not been formalized and its effects felt in a concrete way by the challenging parties.” *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49, 87 S. Ct. 1507 (1967).

Instead, Plaintiffs challenge discrete, final agency actions that set forth Defendants’ consistent and unchanging policy since the DOD Mandate was issued August 24, 2021. There are no contingencies or uncertainties. All Plaintiffs are required to be “vaccinated” because the Secretary has placed these novel mRNA shots on the “Required Vaccines” list for service in the military; Plaintiffs will not be exempted. Defendant DOD’s service components have issued a wide range of orders and regulations that make anyone not getting these shots “non-deployable” and subject to a wide array of adverse actions including being ineligible for command, transfer, continuing education in their specialty, etc. (See, e.g., MARADMIN 612/21, ¶¶3c-3h, *supra*, p. 8). Plaintiffs have suffered a wide range of adverse actions, many with career-ending consequences. See Compl., ¶¶ 124-127. There is no question as to the likelihood that Plaintiffs will suffer injury or hardship; they have and they will. Accordingly, there is no “benefit from any further factual development,” and “the court would be in no better position to adjudicate these [legal] issues in the future than it is now.” *Pearson*, 624 F.3d at 684 (citation and quotation omitted).

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON MERITS.

A. Substantive Due Process Claim.

1. **Pfizer/BioNTech and Moderna mRNA Products Are Gene Therapy Treatments, Not Vaccines.**

The DoD regulation governing vaccinations is DoD Instruction 6205.02, “DoD Immunization Program” (July 23, 2019). It defines “vaccination” and “vaccine” as follows:

vaccination. The administration of a vaccine to an individual for inducing immunity.

Vaccine. A preparation that [1] contains one or more components of a *biological agent* or toxin *and* [2] induces a protective immune response *against that agent* when administered to an individual.

Ex. 3, DoDI 6205.02, G.2 (emphasis added).

The mRNA shots being forced on the Plaintiffs do not meet the DoD’s own requirements to be “vaccines.” The first and second clause establish an identity relationship between the “biological agent” administered (*i.e.*, mRNA) and “that agent” against which the vaccine “induces a protective immune response.”²³ The identity relationship presents a binary choice—either the agent in [1] the same as “that agent” in [2], or is it not—with no space in between for ambiguity. The mRNA shots do not “contain” a single molecule of the COVID-19 virus; they are not the same as COVID-19 and therefore the mRNA shots are not vaccines.

The mRNA treatments also fail to satisfy the FDA and CDC definitions. In recognition of this fact, the CDC had to radically change the definition of “vaccine” to eliminate the word “immunity” to encompass these treatments just 8 days after the DoD issued its mandate on August 24, 2021, without any legal or scientific basis or any public notice or comment. *See* Compl., ¶¶ 84-86. Prior to approval, Defendant FDA considered mRNA products as gene therapies. Other jurisdictions still treat mRNA products as gene therapies, as acknowledged by BioNTech and Moderna SEC filings. *See id.*, ¶¶90-91. These gene therapy products are not “vaccines” because they do not provide immunity, nor do they prevent infection or transmission, as the FDA and other

²³ That is to say, vaccination involves the administration of weakened, killed or fragmented disease-causing biological agents or toxins, to “induc[e] immunity” against that same disease-causing biological agent or toxin. The mRNA shots do not induce immunity against mRNA; instead, they seek to induce a response against COVID-19—instructing the recipient’s immune system to produce a similar spike protein—that is an entirely distinct biological agent from the mRNA administered. *See* Compl., ¶¶ 87-88.

public health agencies acknowledge. *See id.*, ¶89. The limited protection they do provide wanes rapidly over time, *see id.*, ¶¶107-109, and Pfizer’s CEO has acknowledged that the mandated two-dose regimen offers “very limited protection, if any, against the Omicron variant.” *Id.*, ¶108 (citation omitted).

The premise for the unique constitutional treatment of vaccines—and vaccine mandates—is that they actually *stop* the spread of the disease and can even (potentially) eradicate the disease, as has been the case with smallpox or polio vaccine. There is no dispute that these gene therapy products do not prevent infection or transmission, and thus fail this test. Instead, the mRNA shots provide only “protection from the worst effects” of COVID-19. In other words, they are a treatment that mitigates the severity of an infection but cannot prevent it.

2. Defendants’ Interpretations of Terms Defining Scope of Constitutional Rights Are Not Due Deference.

This Court does not owe Defendants any deference on matters of constitutional interpretation. Courts must always “make an independent assessment of a citizen’s claim of constitutional right when reviewing agency decision-making.” *Porter v. Califano*, 592 F.2d 770, 780 (5th Cir. 1979).²⁴ Agencies cannot eliminate constitutional rights simply by redefining the words that stake out the boundaries of those rights, yet that is what Defendants have done by redefining “vaccines” to encompass products that are excluded by their own pre-Mandate regulations and the centuries-old understanding of that term by doctors, legislators, regulators, the courts, and the public upon which the *Jacobson* decision was based. *See infra* note 33. Deference

²⁴ Courts cannot defer to agency interpretations of their own regulations, like DoDI 6205.02, “unless the regulation is genuinely ambiguous. . . . If uncertainty does not exist, there is no plausible reason for deference.” *Kisor v. Wilkie*, 139 S.Ct. 2400, 2415 (2019).

to agency decisions abridging constitutional rights is all the more impermissible here given the pattern of illegality and lawless agency behavior surrounding COVID-19 mandates and the DoD Mandate, *see supra* ¶¶ 2-5, which eliminates any “presumption of regularity” they might otherwise be due. *See infra* Section II.1.

3. DOD Mandate Violates Plaintiffs’ Right to Bodily Integrity and Informed Consent.

One of the most fundamental principles of Anglo-American law is the right to bodily autonomy and informed consent. It is arguably the oldest and most cherished right that there is—the inviolability of the individual—and predates the Constitution itself.

At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that [n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law. ***This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment.*** ... Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages. ***The informed consent doctrine has become firmly entrenched in American tort law.***

Cruzan v. Director, Mo. Dept. of Health, 497 U.S. 261, 269 (1990) (“*Cruzan*”)(citations and quotation marks omitted) (emphasis added). This interest also includes the concomitant right to *refuse* a particular treatment or drug: “[t]he logical corollary of the doctrine of informed consent is that the patient generally possesses the right *not* to consent, that is, to refuse treatment.” *Cruzan*, 497 U.S. at 270 (emphasis added). The *Cruzan* decision concludes 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.”²⁵ The Court subsequently confirmed that the right to “bodily integrity” is a “fundamental right,” and assumed that “the traditional right to refuse unwanted ... medical treatment” is as well. *Washington v. Glucksberg*, 521 U.S. 702, 720, 117 S.Ct. 2258 (1997) (citations omitted).

4. DoD Mandate Fails Heightened Scrutiny.

Because the injections are treatments, and not vaccines, heightened or strict scrutiny applies. In reviewing violations of this fundamental right, the Supreme Court applies a standard that is functionally the same as strict scrutiny, even if it has labeled it as such.²⁶ Thus, where the government burdens a person’s liberty interest in bodily integrity, the government must: (1) “adequately demonstrate a compelling need for the intrusion,” (2) “a lack of reasonable alternatives,” and (3) appropriate “procedural and medical safeguards.”²⁷ The DoD Mandate does not satisfy any of these three requirements.

Plaintiffs do not dispute that preventing, or eradicating, COVID-19 is a compelling interest. But the DoD Mandate cannot and does not *further* that compelling interest. It is undisputed that the Pfizer/BioNTech and Moderna mRNA treatments cannot prevent infection or transmission,

²⁵ *Id.* at 279. *See also id.* at 278-79 (discussing *Washington v. Harper*, 494 U.S. 210, 223, 110 S. Ct. 1028 (1990) (“[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.”) and *Vitek v. Jones*, 445 U. S. 480, 445 U. S. 494 (1980) (recognition of general liberty interest in refusing medical treatment)).

²⁶ Lower courts have applied strict scrutiny analysis to violations of the fundamental rights protected by the Substantive Due Process Clause. *See, e.g., Democracy North Carolina v. North Carolina State Bd. of Elections*, 476 F.Supp.3d 158, 220 (M.D.N.C. 2020); *U.S. v. Juvenile Male*, 670 F.3d 999, 1012 (9th Cir. 2012).

²⁷ *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490, 506 (6th Cir. 2012) (discussing *Riggins v. Nevada*, 504 U.S. 127, 135-36, 112 S.Ct. 1810 (1992)).

and they have been rendered “obsolete” by the Delta and Omicron variants, *see* ECF 3-3, McCullough Decl., ¶ 10.

The DoD has never considered any alternatives to requiring 100% vaccination, as revealed by the administrative record materials produced in a related case, *see infra* Section II.3, and their uniform denials of Plaintiffs exemption requests. Treating all servicemembers the same, regardless of their individual medical status, risk factors, and natural immunity is not “narrowly tailored.” The blanket mandate ignores individual factors increasing or decreasing the risks that the plaintiffs pose to themselves or to others.²⁸ Several courts have found the DoD’s failure to consider any alternatives, or to perform any individualized assessment for service members, failed to satisfy the similar less restrictive means analysis under RFRA and the First Amendment. *See supra* note 4.

Finally, the Defendants have eliminated medical or procedural safeguards. DoD has categorically eliminated pre-existing medical exemptions and eliminated procedural safeguards to ensure that no exemptions will be granted (in particular, by removing the discretion of treating physicians to grant exemptions, which now must be granted by a flag officer). *See, e.g.*, Compl. ¶19. Defendant FDA licensed the mRNA treatments without any exceptions (or contraindications) for key populations (e.g., those with previous infections, pregnant/nursing women, or those with other medical conditions that may face higher risks of adverse effects), despite the fact that these key populations were not included or specifically studied in the ongoing clinical trials for these shots.

²⁸ For example, many of the Plaintiffs are fighter pilots or crew in aircraft that use individual oxygen, such that some of these plaintiffs do not even share the same air with anyone else while performing their duties. Nor did DoD give any consideration to the fact that Plaintiffs have successfully performed their missions and duties over the last two years while unvaccinated.

5. *Jacobson* Does Not Justify A Federal Administrative COVID-19 Vaccine Mandate.

First, the *Jacobson* court grounded its decision in the State police power to regulate the health of those within its borders through the legislature.²⁹ Defendant DoD is not a state legislature, but a federal agency run by a political appointee, who is acting directly contrary to the governing statute and the DoD's own regulations. Second, the Court specifically noted that its justification was in large part predicated on the lethality of smallpox³⁰ that is orders of magnitude more deadly than Covid-19. The mortality rate for smallpox is about 30%.³¹ By contrast, the mortality rate for COVID-19 is less than 1%, and approximately 0.02% (*i.e.*, one out of 5,000) for fit citizens who are culled from among the general populace and required to maintain high levels of fitness and body composition for military service.³² Third, and perhaps most fatal to Defendants mandate, is that relying on *Jacobson* means being bound by that Court's understanding of what constituted a "vaccination." Defendants cannot simultaneously claim *Jacobson* for the sweeping language

²⁹ *Jacobson*, 197 U.S. at 38 ("The safety and the health of the people of Massachusetts are, in the first instance, for that Commonwealth to guard and protect. They are matters that do not ordinarily concern the National Government.")

³⁰ *See, e.g., Jacobson*, 197 U.S. at 37-38 ("We are not prepared to hold that a minority, residing or remaining in any city or town where smallpox is prevalent... may thus defy the will of its constituted authorities, acting in good faith for all, under the legislative sanction of the State... [if the Court did allow such opt-outs] the spectacle would be presented of the welfare and safety of an entire population being subordinated to individual concerns.").

³¹ *See* Ellner, P.D. *Smallpox: Gone but not forgotten*, *Infection* 26, 263–269 (1998) (same), available at: <https://doi.org/10.1007/BF02962244> (last visited June 20, 2022). *Accord. Klaassen v. Trustees of Ind. Univ.*, 549 F.Supp.3d 836, 2021 WL 3073926, at *17 (N.D. Ind. July 18, 2021); *see also id.* (smallpox has killed at least 300 million people in the 20th Century alone).

³² According to the DOD, as of June 10, 2022 there have been 415,956 "Military" cases, with a total of 95 deaths. *See, e.g., DoD, Coronavirus: DOD Response*, DOD COVID-19 Cumulative Totals, available at: <https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/>.

regarding government authority to mandate a vaccine, but then try to simultaneous hide from the fact that mRNA gene therapy products are not “vaccines” as that term was understood by the Jacobson court and for centuries by legislators, regulators, and the general public up until September 2021.³³ Finally, the *Jacobson* Court explicitly exempted, even from state legislative mandates, those who faced serious risk of injury or death from vaccination. *See Jacobson*, 197 U.S. at 39. There are a number of Plaintiffs in the case such as LCDR Groothousen that clearly would fit in this rubric under any reasonable consideration of their cases, but Defendant DOD has eliminated these medical safeguards and exemptions. *See* Compl., ¶¶ 119-122 & ECF 5-13, Long Decl., at 6.

B. Procedural Due Process Claim

Defendants have violated Plaintiffs’ Procedural Due Process Rights insofar as their actions have deprived, or threaten to deprive, Plaintiffs of protected life, liberty and property interests. There is no question that the DoD Mandate “substantially burden[s]” the constitutionally protected “liberty interests” of Plaintiffs “put to a choice between their job(s) and their jab(s).” *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021) (“*OSHA*”).³⁴

³³ The *Jacobson* opinion quotes the trial judge’s jury instruction “that for nearly a century, most of the members of the medical profession have regarded vaccination... as a preventive of smallpox; that... the risk of such an injury too small to be seriously weighed as against the benefits coming from the discreet and proper use of the preventive[.]” *Jacobson* at 23-24.

³⁴ Plaintiffs face not only face the loss of the current employment, but also will be barred from employment by the federal government or federal contractors—the largest employers of former services members—and will also face significantly difficulties with private employers and local and state government due to their vaccination and discharge status and loss of security clearances for “misconduct.” They also face significant risk of death and permanent disability from these treatments—at least four times greater than from the disease itself, *see supra* note 18, while the Vaccine Injury Plaintiffs have already suffered injuries—and loss of protected property interests

Plaintiffs, along with all other class members and U.S. citizens, were deprived of their procedural due process rights through Defendants’ actions, both unilateral and in concert, to expand their pre-Mandate definitions of “vaccines” and “vaccination” to include the Pfizer/BioNTech and Moderna mRNA treatments that would have been expressly excluded by those definitions (and current definitions in the case DoDI 6205.02). *See supra* Section Pfizer/BioNTech and Moderna mRNA Products Are Gene Therapy Treatments, Not Vaccines.I.A.1. That they did so contemporaneously with the FDA approval of Comirnaty and the issuance of the DoD Mandate eliminates any doubt as to the purpose: to enable vaccine mandates and to circumvent constitutional and statutory prohibitions on mandating treatments and to deprive them of their constitutional rights defined by the *Cruzan* line of cases and 10 U.S.C. § 1107a. Plaintiffs, like all other Americans, had no notice or hearing before Defendants unilaterally changed the pre-Mandate definitions through unaccountable and, in their view, unreviewable administrative fiat.

C. Fifth Amendment Equal Protection Claim

1. The Challenged Actions Define a New Class Based on Irrational Animus, Prejudice and Political Demonization.

The Equal Protection Clause is violated where a government regulation treats similarly situated persons differently based on their membership in a suspect class frequently accompanied by the deprivation of a fundamental right. This includes members of “politically unpopular” groups where the adverse impact, and the class itself, is based on membership in a disfavored group

from loss of government benefits, in particular those with over 18 years of service who should be protected by sanctuary rules and permitted to reach 20 years for full retirement benefits.

defined by irrational animus, prejudice, or demonization by politicians.³⁵ In these cases, courts apply “heightened rational basis review,” a more searching inquiry into motives and evidence than traditional rational basis review.³⁶

While vaccination status has not historically been a “suspect class” or the unvaccinated a demonized minority, the COVID-19 pandemic and the hysteria has been cynically manipulated by politicians to create one and to use this classification to deny the unvaccinated fundamental rights and to purge them from the Armed Services and other public institutions. Further, there is 90-100% overlap between the members of this new class the government seeks to disenfranchise through vaccine mandates and the class of those whose objections are protected by the First Amendment’s prohibition on suppression of free exercise of religious or viewpoint discrimination. The RFRA cases prove that hostility to religion is one of the primary motives driving the mandate. *See supra* note 4. Such animus, whether by the military or civilian authorities is due no deference.

If this does not seem plausible at first glance, consider the following:

- In September 2021, President Biden announced a sweeping series of vaccine mandates that would require nearly all U.S. citizens or lawful residents to be vaccinated as a condition for employment, public service, education, or participation in the Nation’s cultural, social or economic life, based on false claims that we faced a “pandemic of the unvaccinated,” and his “anger” and “frustration” with the unvaccinated. *see* Ex. 4, Biden Statement, at 2 & 6;

³⁵ *See, e.g., Plyler v. Doe*, 457 U.S. 202, 102 S.Ct. 2382 (1982) (non-citizen children); *Romer v. Evans*, 517 U.S. 620, 116 S.Ct. 1620 (1996) (sexual orientation); *Lawrence v. Texas*, 539 U.S. 558, 123 S.Ct. 2472 (2003) (same); *United States v. Windsor*, 570 U.S. 744, 133 S. Ct. 2675 (2013) (gay marriage); *Jimenez v. Weinberger*, 417 U.S. 628, 94 S.Ct. 2496 (1974) (illegitimate children); *USDA v. Moreno*, 413 U.S. 528, 93 S.Ct. 2821 (1973) (low-income housing).

³⁶ *See, e.g., Bishop v. Smith*, 760 F.3d 1070, 1099 (10th Cir. 2014) (Holmes, J., concurring)(surveying cases employing heightened rational basis review). *See also Swanson v. City of Plano, Texas*, 2020 WL 7060817, at *3 n.2 (E.D. Tex. Dec. 3, 2020) (discussing “ordinary rational basis” scrutiny and “heightened rational basis review,” noting that the Fifth Circuit has not addressed the issue, but concluding that any regulation “impelled by animus is a poisoned and poisonous one.”) (citation omitted).

- Five of the six federal vaccine mandates were found to likely violated federal law and enjoined, *see supra* ¶ 5;
- The coordinated effort by federal agencies to suppress and censor “disinformation” regarding vaccination spread by U.S. citizens slandered as “extremists” or even terrorists;³⁷
- The coordinated effort between federal agencies and social media companies like Twitter to suppress and censor any alternative views regarding COVID-19 vaccine, *id.* at 18 (describing efforts to coordinate with Twitter to counter vaccine “disinformation”);
- An unprecedented purge of the Armed Services that, based on the current number of RARs (at least 25,000, not including the Army) and the approval rate (0.0%), will result in the expulsion of tens of thousands of service members for refusal to take a drug, *see Compl.*, ¶¶ 102-105 & Table 1, at the same time as we face the prospect of a multi-front war with Russia, China, and their proxies in Iran and North Korea;
- Recruiting and retention are in “crisis”³⁸ based in part on the unfortunately accurate perception that the military is hostile to people of faith and to those who have traditionally served;

The foregoing facts demonstrate that Defendants, acting in coordination with other agencies and private media companies, have taken actions to define the demonized group of vaccine “refusers” or “deniers” and sought to deprive this group of employment, education and their fundamental rights. This class has a 90% or greater overlap with a group those who object to vaccine mandates based on protected First Amendment rights. This should trigger strict scrutiny or at least the heightened rational basis scrutiny applicable to classifications defined by irrational animus, prejudice, or political demonization. *See supra* note 35. Where such heightened review is triggered, the Court must engage in a more searching inquiry as to whether the regulation is

³⁷ *See* Ex. 5, Sen. Grassley Letter to DHS Secretary Mayorkas (June 7, 2022) & DHS Memorandum, *DHS Efforts to Counter Disinformation* (Sept. 13, 2021) (DHS efforts to counter “disinformation” related to “effects of COVID-19 vaccines” used by “domestic violent extremists”).

³⁸ *See, e.g.*, Thomas Novelly, et al., *Military Throwing Cash at Recruiting Crisis as Troops Head for Exits*, *Military News* (May 13, 2022), available at: <http://tinyurl.com/2bjmmnhs> (last visited June 22, 2022).

motivated by an impermissible purpose and the factual evidence presented by the parties. *See, e.g., Plyler*, 457 U.S. at 228-30. The purpose and effect of the federal vaccine mandates is the same as that in *Plyler*, namely, to create[e] and perpetuat[e] ... a subclass” that will be barred from military service, employment and education, based on their religious views and/or medical conditions.

2. The DoD Mandate Cannot Withstand Heightened Review.

A cursory comparison of the DoD Mandate’s supposed purpose—“national security” and “military readiness”—with its actual effects conclusively demonstrates that the stated purposes are a mere pretext. Over the last two years, there have been a total of 95 military deaths from COVID-19, *see supra* note 32, and 30-something among active-duty service members. *See* ECF 3-1, Rans Decl., ¶ 11 & Table. Yet the DoD and the Armed Service will discharge at least 25,000 for religious objections alone, *see* Compl., Table 1, and likely a multiple of that because those numbers include only a small number from the Army or those who have not sought religious accommodations.³⁹ Each of these unvaccinated service members will be discharged for a 100% permanent loss (i.e., as opposed to spending a few days in quarantine or even hospital). This Court should treat a claim by the military that a policy that will intentionally result in the permanent loss of hundreds for each one “saved” the same as one by a doctor testifying that a medical procedure that kills hundreds of his patients for each life saved is justified: with extreme skepticism of that doctor’s judgement and expertise, accompanied by demands extraordinary proof and an inquiry into the real motive for such a disastrous policy.

³⁹ *See, e.g.,* Lolita C. Baldor, *Army Guard Troops Risk Dismissal as Vaccine Deadline Looms*, *Army Times* (June 26, 2022) (“40,000 Army National Guard soldiers” are unvaccinated, and “at least 14,000 ... could be forced out” now that June 30 deadline has passed), available at: <http://tinyurl.com/yc5v7drh> (last visited June 30, 2022).

While the hysteria among the general public appears to be fading, it is not among politicians and federal agencies, who must be the subject of any inquiry into government animus toward “disfavored groups.” The United States has already been through multiple cycles of war or pandemic hysteria used to demonize politically unpopular groups⁴⁰ and many more cycles of abusing service members in illegal experiments. *See supra* ¶ 2. This Court can put this cycle on hold until we regain their senses and stop trying to scapegoat conscientious objectors.

3. Defendants’ Elimination of Natural Immunity and Medical Exemptions Fails Heightened Rational Basis Review.

The Natural Immunity Plaintiffs’ Equal Protection rights under the Fourteenth Amendment are violated by the Defendants’ arbitrary, unscientific, unsupportable distinctions between Natural Immunity Plaintiffs and other similarly situated military members who have only artificially induced immunity through mRNA treatments. The scientific evidence shows that vaccines (a) do not stop reinfection among the vaccinated, and (b) do not stop spread of the virus by the vaccinated. *See Compl.*, ¶¶ 120-124. Thus, there is no impact on good order and discipline or the health of the Total Force by Plaintiffs who have already had COVID-19 remaining unvaccinated. Accordingly, the policy cannot satisfy either rational basis review, much less the strict or intermediate scrutiny that should be applied here. Moreover, the fact that Defendants target those with natural immunity and disregard their medical exemptions proves Defendants’ policy is driven by improper animus against the small minority (1-2% for active-duty personnel) of servicemembers who are unvaccinated nearly all of whom also have sought religious accommodations.

⁴⁰ *See, e.g., Dr. A v. Hochul*, 142 S.Ct. 552, 558-59 (2021) (Gorsuch, J., dissenting) (discussing the Supreme Courts cycles of allowing persecution against disfavored groups and subsequent course corrections in wars and pandemics).

D. Defendants' Violations of Informed Consent Laws and PHSA

In addition to their constitutional violations, Defendants have systematically violated express statutory provisions the Informed Consent Laws and the Public Health Safety Act and/or taken *ultra vires* actions in excess of their statutory authority thereunder.⁴¹

As an initial matter, Defendants are not due deference on statutory interpretation, where the statutory language is clear and unambiguous. *See, e.g., Gulf Fishermens Assoc. v. NMFS*, 968 F.3d 454, 460 (5th Cir. 2020). Nor will courts “defer to an agency interpretation that is inconsistent with the design and structure of the statute as a whole.” *Id.* (citations internal quotation marks omitted). Further, a statute’s silence as to the asserted authority—whether to regulate or to exempt from statutory requirements—does not create ambiguity or “gaps” for the agency to fill. “This ... argument presumes power given if not excluded,” *id.* at 462, which would grant agencies “virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well.” *Id.* at 461 (*quoting Texas*, 809 F.3d at 186). Nor are they due any “presumption of regularity,” in light of the long-standing pattern and practice of Defendants colluding to violate or circumvent servicemembers Informed Consent rights, collusion and coordination among Defendants for same, the proven lawlessness of federal COVID-19 vaccine mandates generally, and the implementation of the DoD Mandate in particular. *See supra* ¶ 2.

⁴¹ These statutes do not include an express private right of action. Plaintiffs, who have been harmed by Defendant agency actions for which there is no other adequate remedy, bring these actions under 5 U.S.C. § 704 for violations of 5 U.S.C. § 706(2)(C). *See, e.g., Austin*, at *2 & *7 n.12 (informed consent violations are “APA claims”). It is well-settled that, where a statute does not expressly provide a cause of action, plaintiffs may enforce agency violations of the statute’s substantive requirements through the judicial review provisions of the APA. *See, e.g., Dunn-McCampbell Royalty Int., Inc. v. Nat’l Park Serv.*, 112 F.3d 1283, 1286 (5th Cir. 1997).

The Supreme Court has recently and repeatedly struck down agency rules, and denied agencies deference, where they acted *ultra vires* in excess of their statutory authority or acted outside the specific area of expertise in seeking to enact “public health” measures using emergency authorities.⁴² The Court is particularly skeptical of agency actions with vast significance affecting millions of people where “the agency has no comparative expertise.” *EPA*, slip op. at 25 (citation and quotation marks omitted). The DoD Mandate, and the other challenged agency actions, must be considered as just one part of the Biden Administration’s efforts to impose universal vaccine mandates on all U.S. citizens and lawful residents immediately after FDA approval of Comirnaty on August 23, 2021, through illegal agency actions and executive orders.⁴³ See *supra* ¶ 5. The DoD Mandate is thus part of a “broad public health regulation” beyond its comparative expertise, rather than a specific measure to promote military readiness. The DoD did the same in going beyond the FDA and treating EUA and licensed products as legally, rather than medically, interchangeable. Deference also is not due where Congress has repeatedly debated the matter in question yet declined to take action the matter. See *EPA*, slip op. at 27-28. Congress has spent trillions of dollars and passed several pieces of major legislation to address COVID-19, but it has expressly declined to impose *any* federal vaccine mandates. Further, Congress has spoken directly to the issue of

⁴² The Supreme Court summarized these cases and the criteria it applies in *West Virginia v. EPA*, No. 20-1530 (June 30, 2022) (“*EPA*”). See *id.* slip op. at 17-18 (discussing *OSHA*, 142 S.Ct. 661 (staying *OSHA* Mandate because it was a “broad public health regulation”); *Alabama Assn. of Realtors v. HHS*, 141 S.Ct. 2485 (2021) (striking down CDC rent moratorium)

⁴³ Chief Justice Roberts in the *OSHA* oral argument suggested that the “government is trying to work across the waterfront and it’s just going agency by agency. ... [T]his has been referred to ... as a workaround, and I’m wondering what it is you’re trying to work around.” Ex. 6, *NFIB v. OSHA* Oral Argument Transcript, at 79:21-25

military vaccine mandates: 10 U.S.C. § 1107a prohibits for EUA products without a Presidential waiver of informed consent.

1. Informed Consent Violations

It is undisputed that the FDA-licensed COVID-19 vaccines (Comirnaty and Spikevax) were not available when the DOD Mandate was issued and that the DOD has systematically mandated unlicensed EUA vaccines that prominently bear EUA labels. *See, e.g., Austin*, 2021 WL 5816632, at *7. The Informed Consent Laws prohibit the mandatory administration of an EUA product. See 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3. Defendants seek to circumvent this express statutory prohibition on mandating an EUA product through guidance documents asserting that *any EUA vaccine* “should” be used interchangeably with, or “as if” it were an FDA-licensed vaccine.⁴⁴ While Congress and the President have delegated the Secretary of Defense broad authority, they have expressly withheld the authority to mandate an EUA vaccine without Presidential waiver, which Secretary Austin has neither received nor requested. Apart from Presidential approval, there are no exceptions, or even any criteria for discretionary grants of exceptions. Nor is there any ambiguity in the statutory text, or any “gap” to fill. Just silence. “This nothing-equals-something argument is barred by [Fifth Circuit] precedent.” *NMFS*, 968 F.3d at

⁴⁴ *See, e.g.,* ECF 4-7, Aug. 23, 2021 EUA Re-Issuance Letter, at 2 n.8 ; Compl., ECF 5-2, September 14, 2021 Adirim Memo, at 1; ECF 5-9, Sept. 3, 2021 Air Force Mandate, § 3.1.1; *see also* Ex. 8, ¶ 10 (June 2, 2022 Response in *Coker v. Austin*). Defendant FDA compounds this violation exercising its “enforcement discretion” to not require the inclusion of the EUA Fact Sheet. *See* ECF 5-3, Marks Decl., ¶13. This factsheet is a required part of the required “labeling” that informs recipients of their statutory “option to accept or refuse,” 10 U.S.C. § 1107a(a)(1) and 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III) & 360bbb-3(e)(2)(A). This violation of statutory labeling requirements is discussed in the following section.

460; *see also EPA*, slip op. at 27-28. Accordingly, this Court owes no deference to agency Defendants' interpretations of the statutes that permit what the statutory text expressly prohibits.

The FDA documents relied on by Defendants expressly state that the EUA and the licensed product are “legally distinct” and acknowledge that there are “certain differences” between these products. These legal distinctions include the fact that the EUA BioNTech Vaccine is subject to the laws governing EUA products, including the statutory right of informed consent (*i.e.*, the “option to accept or refuse”), to be labeled as an unlicensed, EUA product, and the requirement to inform recipients that the product is not licensed and that he or she has an “option to accept or refuse.” *See* Compl., ¶¶ 81-82.⁴⁵ Plaintiffs do not advance solely a legal argument on this point, either.

The New England Journal of Medicine published a study on this exact issue of nearly identical mRNA shots and Defendants are undoubtedly aware of it – because the study is a part of the ongoing experiment for the licensure of BNT162b2. The NEJM made an explicit comparison of BioNTech BNT-162b1 and BNT162b2 and found that despite their similarity, that they are NOT identical. The comparison makes clear that even these “chemically similar” products are different and produce different effects when injected into the human body.⁴⁶

The reason for the lower reactogenicity of BNT162b2 than of BNT162b1 *is not certain*, given that the two vaccine candidates share the same modRNA platform,

⁴⁵ While the FDA initially asserted that EUA products and the FDA-licensed products are interchangeable because they have the “same formulation,” while admitting that there are “certain differences” between them, the FDA subsequently expanded the scope of interchangeable products to encompass products with different formulations that are chemically distinct but “analytically comparable.” *Cf.* Compl., ECF 4-7, Aug. 23, 2021 Pfizer/BioNTech EUA Re-Issuance Letter & ECF 5-4, March 29, 2022 Pfizer/BioNTech EUA Re-Issuance Letter.

⁴⁶ *See* “Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates,” *N. Engl. J. Med.* 2020; 383:2439-50. <https://www.nejm.org/doi/full/10.1056/NEJMoa2027906>

RNA production and purification processes, and formulation of lipid nanoparticles. They differ in the nucleotide sequences that encode the vaccine antigens and in the overall size of the RNA constructs, which results in a number of RNA molecules in 30 µg of BNT162b1 that is approximately 5 times as high as that in 30 µg of BNT162b2. The nucleotide composition of RNA has been reported to affect its immune stimulatory activity and reactogenicity profile, and this is a possible explanation for the differences in these vaccine candidates.⁴⁷

It is, therefore, an extraordinary – and illicit – claim by both Defendants to base the mandate of an unlicensed product in place of a licensed one on the use of an entirely novel adjective – “medically interchangeable” – while simultaneously ignoring the actual statutory requirements for “interchangeable” products mandated by Congress under the PHSA. See sub-para. 2 below.

The final aspect of the informed consent violations by Defendants concerns the precedent established by the first EUA vaccine that Defendant FDA ever granted: the anthrax vaccine in 2005. In that prior case, both the Defendants DoD and FDA took the *opposite* legal position from that which they are taking right now. As the Fifth Circuit recently noted in issuing a Preliminary Injunction against the OSHA vaccine mandate:

Because it is generally “arbitrary or capricious” to “depart from a prior policy *sub silentio*,” agencies must typically provide a “detailed explanation” for contradicting a prior policy, particularly when the “prior policy has engendered serious reliance interests.” OSHA’s reversal here strains credulity, as does its pretextual basis. Such shortcomings are all hallmarks of unlawful agency actions.⁴⁸

After the D.C. District Court initially enjoined the Defendant DoD’s anthrax vaccine program,⁴⁹ the Defendants DoD and FDA both took various actions to continue Secretary Cohen’s 1998 anthrax mandate. See Doe v. Rumsfeld, 341 F.Supp.2d 1 (D.D.C. 2004). After being enjoined

⁴⁷ Id., at 2449 (emphasis added).

⁴⁸ BST Holdings, LLC v. OSHA, No. 21-60845, p. 12 (5th Cir. 2021)(citations omitted)(emphasis added).

⁴⁹ 297 F. Supp. 2d 119 (D.D.C. 2003)

again, and facing a permanent injunction, the Defendant DoD filed an emergency motion to Modify the Injunction because Defendant FDA had reclassified the anthrax vaccine as an EUA product – the first time any vaccine had ever been granted that status.

Defendants have now filed an Emergency Motion to Modify the Injunction, seeking clarification that there exists a third option - an alternative to informed consent or a Presidential waiver - by which defendants can administer AVA to service members even in the absence of FDA approval of the drug: that is, pursuant to an Emergency Use Authorization (“EUA”) under the Project BioShield Act of 2004, 21 U.S.C.A. § 360bbb-3.”⁵⁰

The FDA placed several conditions on the EUA grant to DOD, but only one is important to this litigation. Noting that 21 USC 360bbb-3(e)(1)(A)(ii)(III) contains not only an informed consent requirement, but also a requirement that individuals to whom the product is administered be informed of the option to accept or refuse administration of the product, the FDA determined that an option to refuse vaccination meant that DOD’s AVIP could **not** be mandatory, and that there could be no disciplinary or other punitive measures taken against service members, civilian employees, or civilian contractors who refused the shot.

With respect to condition (3), above, relating to the option to accept or refuse administration of AVA, the AVIP will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. *There may be no penalty or loss of entitlement for refusing anthrax vaccination.*

70 ed Reg. 5452, 5455 (Feb.2, 2005)(emphasis added).

⁵⁰ The *Doe v. Rumsfeld* order is attached as Ex. 7.

Doe v. Rumsfeld may not be binding precedent on this Court, but it is a binding determination on these same Defendants on the same issue and, therefore, these Defendants are estopped from re-litigating the issue against the Plaintiffs. These two Defendants have already had a full and fair opportunity to litigate the same exact issue in the first instance when the statute was just passed and the doctrines of judicial estoppel and issue preclusion both prohibit these Defendants from now claiming the exact opposite in fundamentally the same litigation against an identical class of plaintiffs.⁵¹

The *Doe v. Rumsfeld* series of decisions is, therefore, directly relevant on multiple levels: (1) it has obvious factual relevance because it involved injunctive relief by servicemembers against a mandatory vaccination program; (2) it was the first vaccine ever granted EUA status by the FDA; (3) both the Defendants FDA and DoD took public, official positions exact contrary on the same legal issue in the instant case – whether or not servicemembers could refuse an EUA product without penalty – and is therefore relevant to whether or not the agency has abused its discretion record; (4) both Supreme Court and 5th Circuit precedent direct the courts to consider the “reliance interests” that attended a prior policy; and (5) both Defendants were part of a consent order and took record positions 17 years ago to NOT do what they are now doing – violating the informed consent rights of military servicemembers – in keeping with their long history of abrogating the rights of members of the Armed Forces and using them as human guinea pigs.

⁵¹ See, generally, *New Hampshire v. Maine*, 532 U.S. 742 (2001).

2. FDA Violations of PHSA and Informed Consent Laws.

The PHSA expressly prohibits the sale of any biologic product in interstate commerce unless the package is “plainly marked with” “the proper name of the biological product,” (*i.e.*, Comirnaty or Spikevax) and “the name, address and applicable license number of the manufacturer.” 42 U.S.C. § 262(a)(1)(B)(i)-(ii). These requirements are mandatory, not discretionary.⁵² The FDA has stated that it has exercised its “enforcement discretion”⁵³ not to enforce labeling requirements—or the requirement to provide the EUA factsheet that includes the “option to accept or refuse” the EUA vaccine—so that unlicensed, EUA vaccines may be treated “as if” they were licensed vaccines and eliminating the statutory right to informed consent. The FDA’s action disregards the express, non-waivable statutory requirements. The FDA has illegally abandoned enforcement of a huge swath of the Act it has been chartered by Congress to enforce, 42 U.S.C. §262 and 21 U.S.C. § 360bbb-3, as well as the marketing and labeling requirements in its own regulations, and the criminal laws against mislabeling and misbranding of regulated products.

⁵² See 21 C.F.R. § 610.60(a)(1)(2) (directing that the “proper name” and “license number” “shall appear on the label” of biological product); *see also* 21 C.F.R. § 207.37(a)(2) (a product is “deemed ... misbranded” if labeling codes used to “denote or imply FDA approval of [an unapproved] drug.

⁵³ See ECF 5-3, Marks Decl., ¶13 (“FDA is exercising its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label,” and not requiring providers to provide “the Fact Sheet for Recipients, which advises recipients that ‘under the EUA, it is your choice to receive or not receive the vaccine’”). While in the Marks Declaration, the FDA purports to limit this exercise of “enforcement discretion” only to “BLA-compliant” lots, there is no record evidence supporting this limitation, and all other public available record materials indicate that the FDA treated all EUA-labeled products “as if” they were FDA-licensed products.

In doing so, the FDA went far beyond permissible agency enforcement discretion, which pertains to enforcement priorities. Instead, in Defendants’ view, the FDA’s non-enforcement action confers a legal benefit and a heightened legal status—FDA licensure of an unlicensed EUA product—and deprives servicemembers and other Americans the right to refuse the EUA treatment (*i.e.*, the right to informed consent). As such, the FDA’s decision is equivalent to an affirmative, and unlawful agency action—granting a license to an unlicensed EUA product—that expressly violates statutes it enforces.⁵⁴ It is not within the FDA’s discretion to confer a legal benefit for a product (*i.e.*, licensure), or to exempt an unlicensed products from labeling and other requirements applicable to them, when Congress has already established an “intricate process,” *Texas*, 809 F.3d at 179, governing licensure and the benefits thereof in the PHS Act. Moreover, this is not an isolated instance, as the FDA has applied the same policy to Pfizer/BioNTech and Moderna.

The FDA’s mix of actions and inactions are similar to the FDA “enforcement discretion” policy that the D.C. Circuit found to have violated mandatory provisions of the Food, Drug and Cosmetics Act (“FDCA”), as well as the APA, in *Beatty* and *Cook*. There, the court emphasized that the FDCA provision in question, like 42 U.S.C. § 262(a) here (“no person shall ...”), used mandatory language “shall,” which “generally indicates a command that admits of *no* discretion.” *Beatty*, 853 F.Supp.2d at 37 (citation omitted). As with 42 U.S.C. § 262(a), the FDCA provision did not provide for exceptions or other language suggesting FDA enforcement discretion. Also as

⁵⁴ See, e.g., *Texas v. U.S.*, 809 F.3d 134, 166-69 (5th Cir. 2015) (“*Texas*”), *aff’d* 136 S.Ct. 2271 (2016) (agency action was not immune from review as exercise of enforcement discretion where it adopted general policy conferring legal status and benefits); see also *id.* at 166-67 (agency action “need not directly confer ... benefits” to be “more than nonenforcement; instead “removing a categorical bar on receipt of [governmental] benefits and thereby making a class ... newly eligible” for such benefits).

here, the FDA’s purported nonenforcement decision amounted to “affirmative acts of approval”—
 treating unlicensed, misbranded products as if they were licensed and labeled in accordance with
 FDA regulations—“rather than refusal to take enforcement action.” *Cook*, 733 F.3d at 7. The same
 analysis applies to the FDA’s decision not to require the statutorily mandated EUA Fact Sheet
 advising recipients of their right to refuse the EUA product.⁵⁵

The FDA’s interchangeability determination is illegal, or else it is of no legal consequence.
The FDA acknowledges that it has never made a “statutory interchangeability determination”
 because the PHSA’s requirements have not been satisfied, and instead describes its actions as
 finding that the two are “medically interchangeable.” Compl., ¶ 81 & ECF 5-3, Marks Decl., ¶ 11.
 The PHSA grants the FDA the authority only to make “statutory” interchangeability
 determinations,⁵⁶ which is governed by an “intricate process,” *Texas*, 809 F.3d at 179, set forth by
 Congress in the PHSA. The PHSA does not authorize the FDA to create new, alternative categories
 or criteria for “interchangeable” products. As such, the FDA’s action must be held unlawful as
 ultra vires. Because FDA has not made a “statutory” determination, then the two products are not
 “legally interchangeable” and cannot be the basis for the DOD’s position that an unlicensed, EUA

⁵⁵ The FDA’s actions here also have the same additional defects relied on in *Beatty*, *see id.*, at 41-43, namely: (1) the FDA’s actions violated the FDA’s own regulations, *see* Compl., ¶ 55 (discussing FDA violations of 21 C.F.R. § 610.60(a)(1)(2) and § 207.37(a)(2)); (2) departed from long-standing policy prohibiting mandate of EUA products, *see, e.g., Rumsfeld III* (conditioning EUA grant on requirement that anthrax vaccine would only be voluntarily administered); and (3) it undermines the purpose of the PHSA to protect consumers and ensure that no mislabeled products are permitted to be distributed in interstate commerce.

⁵⁶ Notably, the FDA has never made a statutory interchangeability determination, whether for Comirnaty or any other product. The FDA “Purple Book” lists biological products licensed under the PHSA, and the on-line database includes a blank column for “interchangeable” products. *See* FDA, *Purple Book Database of Licensed Biological Products*, available at: <https://purplebooksearch.fda.gov/>.

“vaccine” can be substituted – much less *mandated* – in the place of a licensed, unavailable vaccine. Either the FDA and DOD have both violated the PHSA, or only the DOD has; either way, Plaintiffs have been unlawfully mandated EUA products and face discipline and discharge for challenging the lawfulness of the order. See supra ¶ 6.

E. Defendants’ APA Violations.

1. Defendants Are Not Due Deference.

Where an agency’s decisions are driven by improper purposes or extra-statutory criteria, then the courts do not owe the agency deference to which it would otherwise be due. Nor are courts required to bury their head in the sand and “defer” to the agency’s pretextual explanations for its actions and decisionmaking. *See, e.g., Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2574-76 (2019) (“Our review is deferential, but we are ‘not required to exhibit naivete from which ordinary citizens are free.’”) (citation omitted). Where, as here, there is significant evidence of improper purposes, political interference, and significant departures from normal decisionmaking processes, this constitutes evidence of the agency’s “bad faith that renders its decision arbitrary and capricious.” *Tummino*, 603 F.Supp.2d at 544.

2. No Legal or Evidentiary Basis for DoD Mandate.

The entirety of the DOD Mandate is a two-page memorandum from the Secretary of Defense that cites no statute, regulation, executive order or other legal authority, and indeed in many places appears to patently exceed his authority, insofar as it seeks to regulate State Guardsman. Secretary Austin’s sole statement justification is a conclusory statement that the Secretary has “determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people.” ECF 4-12, SECDEF Memo at 1. Given that the DOD Mandate was issued on the very next day after FDA Comirnaty Approval, it is apparent the DoD

either blindly relied on the FDA approval and out-of-context FDA statements regarding interchangeability or was fully involved in a scheme to commit fraud upon members of the Armed Forces by denying them their Constitutional and statutory rights and obviate the Congressional requirements of 10 U.S.C §1107a.⁵⁷

The DOD Mandate is also arbitrary and capricious because it constitutes an unannounced and unexplained departure from a prior policy. See supra, II “[A]gencies must typically provide a detailed explanation for contradicting a prior policy that has engendered serious reliance interests.” *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 614 (5th Cir. 2021). Such “reversal[s]” on a “pretextual basis” as have occurred here “are all hallmarks of unlawful agency actions.” *Id.*

3. DoD Failed Altogether to Consider Any Alternatives.

The DoD and Army administrative records provide further confirmation that Defendants acted arbitrarily and capriciously in enacting the mandate because Defendants failed altogether to consider any alternatives to 100% vaccination, including measures that had been effectively employed over the previous two years prior to the mandate (e.g., masking, social distancing, testing, quarantine, etc.). Nor did Defendants provide any explanation in the record as to why these alternatives were inadequate or consider the relative costs and benefits of alternative measures. This is confirmed by the findings of the five U.S. district courts in the RFRA context that the DOD and other Armed Services failed to consider any alternative less restrictive measures. *See, e.g.,*

⁵⁷ Defendants also purport to rely on the CDC’s recommendations in adopting the two-dose regimen, but have ignored the CDC’s unanimous recommendation that all eligible adults should receive a third booster shot. *See CDC, CDC Expands Eligibility for COVID-19 Booster Shots to All Adults*, CDC Media Statement (Nov. 19, 2021), available at: <https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html>. Such selective picking and choosing of which recommendations to follow, without any explanation, is the essence of arbitrary and capricious decision-making.

Navy SEAL I, at *18; *Air Force Officer*, *10. Where an agency like DOD “provide[d] little or no explanation for the [its] choices,” “omit[s] explanation for rejecting alternatives,” and did “not address alternative (or supplementary) requirements,” its order is arbitrary and capricious and must be vacated. *Health Freedom Def. Fund v. Biden*, 2022 WL 1134138, at *18-19 (M.D. Fla. Apr. 18, 2022) (vacating CDC transportation mask mandate).

4. Elimination of Medical Exemptions.

Finally, the DOD Mandate and Armed Services Guidance are arbitrary and capricious, and unsupported by substantial evidence, insofar as they categorically eliminated existing exemptions for previous documented infections under AR 40-562, or to consider natural immunity in its religious exemption decisions. *See, e.g., Navy SEAL I*, at *16 & n.10; *Navy SEALs I-26*, at *10; *Air Force Officer*, at *10. In doing so, Defendants have “entirely failed to consider an important aspect of the problem.” *State Farm*, 463 U.S. at 43.

III. PLAINTIFFS HAVE SUFFERED IRREPARABLE HARM.

The deprivation of certain constitutional rights, however, “for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976). This applies to violations of the right to privacy, which includes the right to bodily integrity, because “once an infringement has occurred it cannot be undone by monetary relief.” *Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. 1981) (citation omitted). Violations of constitutional rights to due process and equal protection of the laws also presumptively cause irreparable harm. *See, e.g., DeLeon v. Perry*, 975 F.Supp.2d 632, 663 (W.D. Tex. 2014).

The denial of a stay or an injunction—and permitting the involuntary administration of the vaccine—is an injury that cannot be undone and will permanently prevent Plaintiffs from

exercising their right to refuse unwanted experimental medical treatment. “[R]equiring a person to submit to an inoculation without informed consent or the presidential waiver is an irreparable harm for which there is no monetary relief.” *Rumsfeld I*, 297 F.Supp.2d at 135.

IV. BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR GRANTING PRELIMINARY INJUNCTION.

A preliminary injunction is proper when “the balance of equities tips in [its] favor, and that an injunction is in the public interest.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20, 129 S.Ct. 365 (2008). “These factors merge when the Government is the opposing party.” *Nken v. Holder*, 556 U.S. 418, 435, 129 S.Ct. 1749 (2009). “[I]t is always in the public interest to prevent the violation of a party's constitutional rights.” *Campaign for S. Equal. v. Mississippi Dep't of Hum. Servs.*, 175 F. Supp. 3d 691, 711 (S.D. Miss. 2016) (citation and quotation marks omitted). That is true even though COVID-19 is involved. *Cf. Cuomo*, 141 S. Ct. at 68 (“[E]ven in a pandemic, the Constitution cannot be put away and forgotten.”).

There is also a strong public interest in ensuring the rights of informed consent, and that citizens are not subject to unwanted, unnecessary and unproven experimental medical treatment. Informed consent fosters trust and support in the doctor-patient relationship. It is also in the public interest for those seeking vaccines to receive accurate, truthful, complete information, and that they give informed consent—or refusal—to experimental treatments. Conversely, the DOD has no legitimate interest whatsoever in forcing Plaintiffs to receive an experimental shot that doesn't provide immunity from the virus, doesn't stop transmission of the virus, and in ¼ the time has likely killed four times the number of members of this particular population cohort. these plaintiffs deserve an opportunity to have the merits of their claims adjudicated in this Court.

V. CONCLUSION

This Court should grant the preliminary injunction and adopt the Proposed Order.

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Respectfully submitted,

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