

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
GALVESTON DIVISION**

MICHAEL BAZZREA, et al

Plaintiffs,

v.

LLOYD AUSTIN, III, et al.,

Defendants.

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Case No. 3:22-cv-00265

PLAINTIFFS’ MOTION FOR PRELIMINARY INJUNCTION

Pursuant to Rule 65 of the Federal Rules of Civil Procedure (“FRCP”), Plaintiffs U.S. Coast Guard (“USCG”) members Michael Bazzrea, Sabrina Wilder, Courtney Cheatum, Timothy Jordan, and Caleb Wadsworth, along with 125 USCG members who moved to intervene on August 12, 2022, *see* ECF 13, move the Court for a Preliminary Injunction to enjoin Defendants’ constitutional and statutory violations as set forth in the Plaintiffs’ July 25, 2022 complaint (“*Compl.*”). ECF 1.

FACTUAL BACKGROUND

1. On July 21, 2021, in a CNN Town Hall, President Biden informed the American people that “You’re not going to get COVID if you have these vaccinations.”¹ On August 23, 2021, Defendant Food and Drug Administration

¹ See Jason Lemon, *Video of Biden Saying Vaccinations Prevent COVID Resurface After Infection*, Newsweek (July 21, 2022), available at: <https://www.newsweek.com/joe-biden-2021-video-saying-vaccinations-prevent-covid-resurfaces-1726900> (last visited Aug. 8, 2022).

("FDA") approved Pfizer/BioNTech's Comirnaty, and the very next day, on August 24, 2021, Secretary Austin announced the DoD Mandate, *see* ECF 1-6, issued pursuant to and in accordance with DoD Instruction 6205.02, "DoD Immunization Program" (July 23, 2019) ("DoDI 6205.02"). *See* Ex. 1. Roughly two weeks later, on September 9, 2021, President Biden announced the issuance of a series of executive orders and other vaccine mandates that would cover 100 million Americans. *See* Ex. 2, September 9, 2021 Biden Mandates.

2. On July 21, 2022, exactly one year later, the White House announced that a fully vaccinated and double boosted President Biden had contracted COVID. Contrary to previous statements, his spokesperson informed the American public that the President and his doctors "knew this was going to happen" and that "at some point, everyone is going to get COVID." Ex. 3, July 21, 2022 White House Press Briefing, at 16.

3. It has long been known that the mandated mRNA vaccines cannot prevent infection or transmission, and at most, can reduce the severity of infections, like other COVID treatments. *See* Compl., ¶ 78; ECF 1-20, McCullough Decl., ¶¶ 8-10; Ex. 4, Bhattacharya Decl., ¶¶ 28-32. On August 11, 2022, the Centers for Disease Control and Prevention ("CDC") issued updated guidance that, consistent with current scientific understanding, no longer distinguishes between vaccinated and unvaccinated. *See* Ex. 5, Aug. 11, 2021 CDC Summary of Guidance.

4. The Defendants knew at the time not only that the mRNA treatments

would not prevent infection or transmission, but that there were not “vaccines” at all under the DoD’s own immunization regulation, DoDI 6205.02, the only authority cited by Secretary Austin in the DoD Mandate. The Defendants also eliminated, without any scientific or legal basis, pre-existing categories of medical exemptions, including those for previous documented infections (or natural immunity) (“Categorical ME Ban”). *See* Compl., ¶ 50 & ECF 1-10, AR 40-562.

5. While there is much debate as to the efficacy of the mRNA treatments for the Omicron variant and natural immunity, the following facts are not disputed. First, no active-duty service member, whether vaccinated or not, has died since November 2021 when the Omicron variant became prevalent. *See* Ex. 6, Rans. Decl., at 12-13 & Table. Second, the FDA’s own data shows that the treatment for the virus has killed more service members (119), *see* Ex. 7, Dr. Teresa Long Decl. at 13 than the virus itself (96), and in a much shorter time period. *See* Ex. 6, Rans Decl., ¶ 12. Third, Pfizer’s CEO, the *New England Journal of Medicine*, and apparently Defendants acknowledge that the mandated two-dose regimen “offer[s] little, if any protection against [Omicron] infection.”² Fourth, the military will lose

² *See* Heba N. Altarawneh, *et. al.*, *Effects of Previous Infection and Vaccination on Symptomatic Omicron Infections*. NEW ENGLAND J. MED. (June 15, 2022), available at: <https://www.nejm.org/doi/full/10.1056/nejmoa2203965> (last visited Aug. 15, 2022); *New COVID-19 Vaccine That Covers Omicron ‘Will Be Ready in March,’ Pfizer CEO Says* Yahoo!Finance (Jan. 10, 2022) (transcript of video interview with Pfizer CEO Albert Bourla) (same), available at: <https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html> (last visited Aug. 8, 2022).

hundreds or even thousands from discharges for each life lost to COVID, but has not provided any estimate of lives saved by vaccination. Fifth, the mRNA vaccines have killed over 12,000 Americans, permanently disabled over 13,000, and resulted in hundreds of thousands of vaccine injuries. *See* Compl., ¶ 79; ECF 1-19, McCullough Decl., ¶ 27; ECF 1-20, McCullough Decl., ¶ 17.

6. Defendants' actions are just 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 held many hearings condemning such practices and programs because of the obvious criminality of such actions.³ 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 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* chem-bio weapons, Defendant DoD's illegal and unethical experiments have harmed millions of American service members. Abuses in testing unlicensed products, including vaccines, during the Gulf War likely caused

³ *See generally* Ex. 8, 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).

or exacerbated Gulf War Syndrome/Illness and, after multiple hearings and reports, Congress passed 10 U.S.C. §1107 in 1997 in order to prohibit the Defendant DoD from compelling members of the all-volunteer force to use unlicensed (“investigational”) products. In 2004 Congress added the statute at issue here, 10 U.S.C. § 1107a, prohibiting the mandate of Emergency Use Authorization (“EUA”) drugs or vaccines.

7. President Biden’s federal administrative mandates have not fared well in the courts, where all of the non-DoD mandates were quickly enjoined.⁴ Several courts have enjoined the DoD Mandate and the Categorical RA Ban and failure to provide the statutorily required individualized evaluation of RARs,⁵ including two

⁴ See *Nat’l Fed’n of Indep. Bus. v. OSHA*, 142 S. Ct. 661 (2022) (“OSHA”) (staying OSHA mandate, which was subsequently withdrawn); *Feds for Medical Freedom v. Biden*, 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*, 2022 WL 2301458 (5th Cir. June 27, 2022) (reinstating nationwide stay); *Georgia, v. Biden*, 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021) (nation-wide stay of federal contractor mandate); *Texas v. Becerra*, 2021 WL 6198109 (N.D. Tex. Dec. 31, 2021) & *Louisiana v. Becerra*, 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*, 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.

⁵ See generally *U.S. Navy SEALs 1-26 v. Biden*, 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*”); *Navy SEAL 1 v. Austin*, 2022 WL 534459 (M.D. Fla. Feb. 18, 2022) (“*Navy SEAL 1*”), *stay denied pending appeal* No. 22-10645 (11th Cir. Mar. 30, 2022); *Air Force Officer v. Austin*, 2022 WL 468799 (M.D. Ga. Feb. 15, 2022) (“*Air Force Officer*”); *Poffenbarger v. Kendall*, 2022 WL 594810

that have issued service-wide injunctions for all members of the Air Force and Navy who have submitted RARs.⁶

8. Secretary Austin’s Mandate and the other challenged agency actions have already resulted in the separation or discharge of over 7,000 service members, and they may result in the loss of up to 300,000 service members.⁷ They are also directly responsible for massive recruiting shortfalls, with the Coast Guard expecting a 25% shortfall for FY22,⁸ not to mention “crippling shortages” in key positions like pilots. *See* ECF 1-5, Wadsworth Decl., ¶ 19. The losses of current personnel and future recruits due to these illegal, arbitrary and irrational policies

(S.D. Oh. Feb. 28, 2022) (“*Poffenbarger*”); *Doster v. Kendall*, 2022 WL 982299 (S.D. Ohio Mar. 31, 2022) (“*Doster*”).

⁶ *See Navy SEALs 1–26 v. Austin*, No. 4:21-cv-1236, 2022 WL 1025144 (N.D. Tex. Mar. 28, 2022) (Navy class-wide preliminary injunction), *appeal filed* No. 22-10534 (5th Cir. May 27, 2022); *Doster v. Kendall*, 2022 WL 2974733 (S.D. Ohio July 14, 2022) (Air Force class-wide PI).

⁷ This includes at least 25,000 who have submitted religious accommodation requests, *see* Compl., ¶¶ 109 & Table 1, and nearly 270,000 service members who are partially-, but not fully-, vaccinated as of July 13, 2022. *See* DoD. *Coronavirus: DoD Response*, Table: DoD Vaccination Data, available at: <https://www.defense.gov/Spotlights/Coronavirus-DoD-Response/> (last visited July 19, 2022). These numbers do not include the over 60,000 unvaccinated Army reserve and National Guard were barred from service or being paid effective July 1, 2022. *See* Allie Griffin, *Army Bars More Than 60K National Guards, Reservists from Service, Cutting Off Pay*, NY POST (July 8, 2022), available at: <https://nypost.com/2022/07/08/army-cuts-pay-from-over-60k-unvaccinated-national-guard-reserves/> (last visited Aug. 8, 2022).

⁸ *See* Kyle Mitchell, *Coast Guard Expects 25% Recruitment Shortfall This Year*, HOLLAND SENTINEL (Aug. 6, 2022), available at: <https://www.hollandsentinel.com/story/news/2022/08/06/coast-guard-expects-25-recruitment-shortfall-year/10233756002/> (last visited Aug. 12, 2022).

are so great that they “put national security at risk,”⁹ and pose a “long-term threat to the all-volunteer force.”¹⁰

Defendants’ Religious Liberty Violations & Plaintiffs’ Injuries

9. Defendants have established a policy of refusal to grant any religious accommodation requests (“RAR”) for the DoD Mandate (the “No Accommodation Policy” or “Categorical RA Ban”). For example, the Navy adopted a process that does not even permit the possibility of approval. *See Ex. 9, Navy SEALs 1-26 Whistleblower Decl.*, at 2-4 (describing process) & *Navy SEALs 1-26, 2022 WL 34443*, at *5-6 (granting injunction based on whistleblower declaration).

10. On August 30, 2021, just one week after the issuance of the DoD Mandate, the USCG adopted a new RAR process. *See Compl.*, ¶ 56 & ECF 1-11, COMDTINST 1000.15. COMDTINST establishes distinct, centralized procedures for immunization-related RARs, which must be approved by the Commandant, rather than the commanding officers as for other requests. *See COMDTINST, Encl. 1*. The new rules also require RARs and RAR appeals to be processed within

⁹ *See* Maj. Gen. James Eifert, *The Vaccine Mandate Puts National Security at Risk*, Wall Street J. (Aug. 4, 2022) (op-ed by commanding general of Florida National Guard), available at: <https://www.wsj.com/articles/vaccine-mandate-puts-national-security-at-risk-involuntary-termination-armed-forces-military-covid-pandemic-lockdowns-11659645396> (last visited Aug. 12, 2022).

¹⁰ Tom Jurkowsky, *The Military Has a Serious Recruiting Problem – Congress Must Fix it*, The Hill (June 21, 2022) (*quoting* Sen. Thom Tillis (R-N.C.)), available at: <https://thehill.com/opinion/national-security/3527921-the-military-has-a-serious-recruiting-problem-congress-must-fix-it/> (last visited July 17, 2022).

30 days, but the USCG has uniformly failed to meet these deadlines. *See* Compl, ¶¶ 59-60. As a result of these new policies, the USCG has not granted any RARs based on the latest publicly available data. *See id.*, ¶ 61 & Table 1.

Defendants’ Violations of Plaintiffs’ Religious Liberties

11. Plaintiffs have pursued available military remedies, including requests for religious accommodations and medical exemptions (“ME”) that have been denied. Each Plaintiff has had both their initial RAR denied and their RAR appeal denied (although Plaintiff Jordan was informed by email and never received a denial letter). *See* Compl., ¶¶ 87-88. Each denial letter is essentially identical to those received by other Plaintiffs and similarly situated class members. *See id.*, ¶¶ 89-90.¹¹ The only variations are names, dates, and descriptions of service members position and responsibilities, which are frequently incorrect. *See, e.g.*, ECF 1-2, Wilder Decl., ¶ 9 (incorrect description of duties for herself and unit).

12. All Plaintiffs face adverse employment or disciplinary actions, up to and including separation, discharge for “misconduct,” court martial, loss of postseparation veterans’ benefits, and permanent damage to their reputation and employment prospects resulting from less than a full “honorable” discharge. In the meantime, they are non-deployable; have been removed from leadership

¹¹ Moreover, they have been informed that even if an RAR were granted, the service member will still be discharged. *See* ECF 1-2, Wilder Decl., ¶ 7 (Wilder’s Director email stating that: “Please do not think you will be allowed to continue to serve if exempted. either way if they don’t get the vaccine, they will be discharged.”).

positions; received one or more letters of reprimand; and prohibited from travel, training, permanent change of station (“PCS”), promotion, and new assignments. *See* Compl., ¶¶ 96-100. Plaintiffs’ discharge status will result in denial of VA benefits and the loss of medical care for dependents ongoing lifesaving medical treatment.¹² Despite the unconstitutional and unconscionable treatment by Defendants, Plaintiffs have perform their duties with the highest degree of professionalism, frequently standing in for the vaccinated colleagues out sick with COVID, and ask only that they be permitted to serve their country.¹³

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.

¹² On May 16, 2022, Plaintiff Jordan was informed of his RAR denial within 90 days of End of Enlistment date in August 2022, and he was not permitted to PCS to his new assignment or to reenlist. He faces extreme family hardship because he will be ineligible for VA benefits, will not have time to submit a VA disability claim, and he will not be able to obtain medical insurance to cover the costly and extraordinary treatments his wife requires. *See* ECF 1-4, Jordan Decl., ¶ 19.

¹³ On September 13, 2021, Plaintiff Jordan was told he was non-deployable due to his vaccination status, yet the very next day he was told to deploy on a presidential security mission. He subsequently performed 15 temporary duty assignments (*i.e.*, deployments) for a total of 189 days away from his unit and his family, successfully completing all assignments and training. *See* ECF 1-4, Jordan Decl., ¶ 20. Plaintiff Wadsworth’s unit is facing a “crippling pilot shortage,” “routinely resulting in 80+ hour work weeks.” ECF 1-5, Wadsworth Decl., ¶ 19.

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.” *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). In a case involving the First Amendment, however, there is a presumption of irreparable injury, such that satisfaction of the first element is dispositive for other factors. *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct 63, 67, 208 L.Ed.2d 206 (2020) (“*Cuomo*”). This applies equally to violations to RFRA because it enforces First Amendment freedoms. *See, e.g., Opulent Life Church v. City of Holly Springs*, 697 F.3d 279, 295 (5th Cir. 2012).

I. THIS COURT HAS SUBJECT MATTER JURISDICTION.

A. The Challenged Actions Are “Major Policy Decisions.”

Plaintiffs challenge a series of discrete, final, coordinated and unlawful agency actions by Defendants¹⁴ to enable the illegal, *ultra vires* mandates and to discipline and discharge Plaintiffs and hundreds of thousands of other service

¹⁴ The Complaint challenges, *inter alia*, the following agency actions: (1) the DoD Mandate, *see* ECF 1-6; (2) the No Accommodation Policy or Categorical RA Ban; (3) Categorical ME Ban, *see* ECF 1-6; (4) FDA determinations that unlicensed “vaccines” subject to an EUA are “interchangeable” with FDA-licensed vaccines (the “FDA Interchangeability Determination”), *see* ECF 1-15 at 2 n.8 & 1-17, Marks Decl., ¶¶ 9-10; (5) FDA waiver of mandatory labeling and informed consent requirements (“FDA Waiver”), *see* ECF 1-17 & Marks Decl., ¶ 13; (6) DoD determinations that EUA vaccines are legally interchangeable with, and may be mandated “as if,” they were FDA-licensed vaccines (“DoD Interchangeability Determinations”). *See* ECF 1-7 & 1-8.

members. Each challenged action is at a minimum a “major policy decision,” rather than a routine, “day-to-day” exercise of agency discretion, enforcement decisions, or “personnel management decisions.” *Nat’l Treasury Employees Union v. Horner*, 854 F.2d 490, 496 (D.C. Cir. 1988).¹⁵

The DoD Mandate, the Categorical RA and ME Bans, and the DoD Interchangeability Determination apply without exception or individualized assessment to over two million service members, and over 50,000 USCG members. These policies substantially modify the terms of eligibility for enlistment, retention, deployment, promotion, completing an existing term of service, and disciplinary rules. Several thousand service members have already been discharged, and they will result in the discharge tens or hundreds of thousands more, causing the services fall short Congressionally mandated strength levels by tens of thousands. *See supra* ¶ 6. The FDA Waiver is also a reviewable major policy decision because it goes well beyond enforcement discretion, violating mandatory

¹⁵ Each of these actions also violates the “Major Questions” doctrine insofar as they directly impose, or intentionally enable, a federal vaccine mandate, not only in the absence of express statutory authorization, but in violation of federal statutes and/or the agency’s own regulations. Federal vaccine mandates are unquestionably “major questions” because they impact the lives and livelihoods of millions and impose billions of dollars in costs. *See OSHA*, 142 S.Ct. at 668 (Gorsuch, J., concurring) (OSHA mandate); *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 617 (5th Cir. 2021) (“*BST*”) (same); *Kentucky v. Biden*, 23 F.4th 585, 607-608 (6th Cir. 2022) (federal contractor mandate).

statutory labeling provisions of federal statutes it implements and creating an exemption not permitted or even contemplated by Congress.¹⁶

Similarly, the FDA Interchangeability Determination ignored entirely the Public Health Safety Act’s (“PHSA”) requirements for a statutory interchangeability determination and instead made the determination in a letter order footnote. *See* ECF 1-15 at 2 n.8. These actions affirmatively conferred a legal benefit and a heightened legal status—in Defendants’ view converting an unlicensed EUA vaccine into FDA-licensed vaccine—that was relied on by DoD and other federal agencies to impose vaccine mandates on over 100 million Americans. Each of Defendants’ action easily meets the requirement for a justiciable and reviewable “major policy decision,” which need only affect “scores” or hundreds.¹⁷

¹⁶ *See Alliance for Bio-Integrity v. FDA*, 116 F.Supp.2d 166 (D.D.C. 2000) (“*Alliance for Bio-Integrity*”) (FDA policy not to enforce requirements against a whole category of products or “not to regulate an entire class of conduct” was a “major policy decision” that exceeded enforcement discretion and was subject to review and therefore was not immune from review for actions “committed to agency discretion”); *Beatty v. FDA*, 853 F.Supp.2d 30, 36 (D.D.C. 2012), *aff’d in part, vacated in part sub. nom. Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (FDA non-enforcement amounted to “affirmative acts of approval” granting license to unlicensed products).

¹⁷ *See, e.g., Harrison v. Austin*, 2022 WL 1183767, at *11 (E.D. Va. Apr. 6, 2022) (“*Harrison*”) (rejecting justiciability, reviewability, and military deference arguments and finding that DoD deployment policy for HIV-positive service members based on “major policy decisions” doctrine). Courts have enjoined and treated as “major policy decisions” categorical bans affecting HIV positive service members who accounted for only 0.027% of active-duty service members and “scores” of transgender service members. *See Roe v. Shanahan*, 359 F.Supp.3d 382, 421 (E.D. Va. 2019) (“*Roe I*”) (HIV-positive ban), *aff’d sub nom., Roe v. Dept. of Defense*, 947 F.3d 207 (4th Cir. 2020) (“*Roe II*”); *Doe 1 v. Trump*, 275 F.Supp.3d

The Supreme Court has recently and repeatedly struck down agency rules, and denied agencies deference, where they acted in seeking to enact “public health” measures using emergency authorities,¹⁸ where “the agency has no comparative expertise.” *EPA*, 142 S.Ct. at 2613 (quoting *Kisor v. Wilkie*, 139 S.Ct. 2400, 2417 (2019)). The DoD Mandate, and the other challenged agency actions, are just one part of the Biden Administration’s efforts to impose near-universal federal vaccine mandates, *see supra* ¶ 7, and as such is a “broad public health regulation” beyond its comparative expertise.

1. Challenged Actions Exceed Agency Authority and Violate the Federal Statutes and/or Agency Regulations.

Congress has “plenary authority” “To raise and support Armies’; ‘To provide and maintain a Navy’; “and ‘To make Rules for the Government and Regulation of the land and naval Forces.’” *Chappell v. Wallace*, 462 U.S. 296, 301, 103 S.Ct. 2362

167, 206 (D.D.C. 2017) (“*Doe 1*”), *stay denied pending appeal* 2017 WL 6553389 (D.C. Cir. Dec. 22, 2017) (transgender ban).

¹⁸ The Supreme Court summarized these cases and the criteria it applies in *W. Va. v. EPA*, 142 S.Ct. 2587, 2608 (2022) (“*EPA*”) (*discussing OSHA*, 142 S.Ct. 661 (staying OSHA Mandate because it was a “broad public health regulation”) & *Ala. Assn. of Realtors v. HHS*, 141 S.Ct. 2485 (2021) (striking down CDC rent moratorium)). Deference also is not due where Congress has repeatedly debated the matter in question yet declined to take action the matter. *See EPA*, 142 S.Ct. 2614. 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 military vaccine mandates: 10 U.S.C. § 1107a expressly prohibits military mandates for EUA products without Presidential authorization.

(1982) (*quoting* U.S. Const. Art. I, § 8, cls. 12-14). This includes the authority to regulate who may, or must, serve, and to set the conditions of eligibility for service, accession, and retention. *See, e.g., Rostker v. Goldberg*, 453 U.S. 57, 101 S.Ct. 2646 (1981). While the “primary business” of the Armed Forces is “to fight or be ready to fight wars,” “the responsibility for determining how best [they] shall attend to that business rests with Congress,” and the President for its execution. *Schlesinger v. Ballard*, 419 U.S. 498, 510 (1975) (citations and quotations marks omitted).

Thus, “major policy decisions” affecting strength levels and the ability of the military to fight wars are to be made by Congress and the President acting together, and no deference is due to an agency—even the DoD—where it “attempt[s] to usurp major policy decisions properly made by Congress.” *NLRB v. South Cent. Bell Telephone Co.*, 688 F.2d 345, 351 (5th Cir. 1982) (quotation marks omitted). While Congress has undoubtedly granted Secretary Austin and Secretary Mayorkas the authority to enact measures regarding the health and welfare of military personnel, it has not precluded judicial review of those measures, nor has it authorized them to violate the Constitution, federal statutes, or their own regulations in doing so. Nor has it delegated the authority to major new policies to purge tens or hundreds of thousands with religious objections. *See supra* ¶ 8.

2. Defendants’ Actions Are Not Due Deference.

Deference to military judgment or discretion, or to agency expertise more generally, is due only where the agency has actually applied its discretion and went

through a deliberative process in adopting the policy or rule. Here, as in the case of the Military HIV+ and Transgender Bans, these decisions were made “without any of the formality or deliberative processes that generally accompany the development and pronouncement of major policy changes that will gravely affect the lives of many Americans.” *Doe 1*, 275 F.Supp.3d at 213. The “level of deference,” if any, due to the military in such cases is based on the extent to which the decisions and policies are “support[ed]” by the record, *Stone II*, 400 F.Supp.3d at 351, and an underlying deliberative process. There is no record evidence of that here.

Nor are Defendants due deference regarding their violations of RFRA, the Informed Consent Laws, or the PHSA, where the statutory language is clear and unambiguous, while the “agency interpretation ... is inconsistent with the design and structure of the statute as a whole.” *See, e.g., Gulf Fishermens Assoc. v. NMFS*, 968 F.3d 454, 460 (5th Cir. 2020) (citations internal quotation marks omitted). RFRA requires individualized determinations and does not permit categorical bans; 10 U.S.C. § 1107a permits EUA products to be mandated only with express, written Presidential authorization, which is absent here; while the PHSA, 42 U.S.C. § 262(a) does not permit the FDA to make any exception or waive mandatory labeling requirements. 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, and the proven lawlessness of federal COVID-19 vaccine mandates generally, and DoD Mandate in particular. *See supra* ¶¶ 6-7.

B. Plaintiffs’ Claims Are Justiciable and Satisfy the Requirement of *Mindes v. Seamen*.

The Supreme Court has repeatedly and emphatically rejected claims that services members’ claims against the military are necessarily nonjusticiable.

[I]t is the function of the courts to make sure ... that the men and women constituting our Armed Forces are treated as honored members of society whose rights do not turn on the charity of a military commander. ... A member of the Armed Forces is entitled to equal justice under law not as conceived by the generosity of a commander but as written in the Constitution and engrossed by Congress in our Public Laws.

Winters v. United States, 89 S. Ct. 57, 59–60 (1968). Congress has rejected this argument as well. RFRA expressly grants a “person whose religious exercise has been burdened in violation of” RFRA the right to “assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against the government.” 42 U.S.C. § 2000bb-1(c).¹⁹

To date, at least five U.S. District Courts have found that RFRA and Free Exercise Claims nearly identical to Plaintiffs’ satisfy the requirements for

¹⁹ 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. Further, there is “no military exception to *Darby*.” *Standage v. Braithwaite*, 526 F.Supp.3d 56, 84 (D. Md. 2021) (“*Standage*”).

justiciability and exhaustion (or exemption therefrom) set forth in *Mindes v. Seaman*, 453 F.2d 197, 201 (5th Cir. 1971) (“*Mindes*”). *See supra* notes 5-6. Plaintiffs satisfy *Mindes*’ threshold test—because they allege constitutional, statutory, and regulatory violations, and have exhausted or are exempt from exhaustion of military remedies to the extent they are available at all—and the *Mindes*’ four-factor test for the reasons discussed below.

1. Plaintiffs Have Exhausted Military Remedies and Qualify for Exemption from Exhaustion.

Each Plaintiff’s initial RAR and RAR appeals has been denied. *See supra* ¶ 11. Plaintiffs have also sought medical exemptions, but the pre-existing exemption for previous documented infections has been categorically eliminated.

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)). Courts have found that the military’s Categorical RA Ban is unlawful and amounts to little more than “theater,” *Navy SEALs 1-26*, 2022 WL 34443, at *1, because the outcome (denial) is “pre-determined.” *Id.*, at *6 (citation omitted). This is supported by the available data, which establishes that no RARs have been granted by the USCG. *See Compl.*, ¶ 62 & Table 1. To remove any doubt about the futility and inadequacy of USCG remedies, commanders have informed USCG members that they will not “be

allowed to continue to serve if exempted. either way if they don't get the vaccine, [you] will be discharged.” ECF 1-2, Wilder Decl., ¶ 7.

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 is incorrect. “A BCMR is a clemency-oriented body with authority to ‘correct an error or remove an injustice,’ 10 U.S.C. § 1552(a), ... [It] has no authority to declare the challenged regulations invalid.²⁰ Further, a BCMR 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). For the Coast Guard, the review and appeal authority is the Commandant, who reports directly to Secretaries Austin and Mayorkas; there is no reason to believe that the Commandant will find her own decisions to be an “error” or an “injustice.”

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 Plaintiffs’ First Amendment and Fifth Amendment rights. *See Navy*

²⁰ *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). Further, the concerns underlying this judicially-created exhaustion doctrine “are diminished to a vanishing point in this case,” *Roe I*, 359 F.Supp.3d at 402, because Plaintiffs’ RARs were addressed through a “complex, tiered administrative review process,” “culminating in an extensive administrative record and final written decisions” reviewed and approved by senior USCG leadership (effectively the USCG Commandant) acting as the final appeal authority. *See supra* ¶ 10.

SEALs 1-26, at *7 (citation omitted).²¹ Several courts have found similar RFRA and Free Exercise claims to have a substantial likelihood of success and to satisfy *Mindes* for that reason. *See supra* notes 5-6. Plaintiffs demonstrate that they have a substantial likelihood of success on each of their other religious liberty claims, *see infra* Section **Error! Reference source not found.**, though they only need to make this showing for one to satisfy *Mindes*' first factor. *See, e.g., Air Force Officer*, 2022 WL 468799, at *7.²²

Second, Plaintiffs face irreparable harm from the infringement of their First and Fifth Amendment rights, as well as their rights under RFRA and the Informed Consent Laws. *See infra* Section **Error! Reference source not found.** In addition to the presumptively irreparable harms from the loss of First Amendment rights, they face harm from loss of careers; veterans benefits; medical coverage; for some retirement eligibility; severe trouble in finding civilian employment

²¹ Plaintiffs' statutory claims are also strong, as they are nearly identical to the those addressed in the *Doe v. Rumsfeld* litigation, 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 and FDA) for a class that included USCG members. *See 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*").

²² Review is also favored where Plaintiffs raise "far-reaching" challenges to generally applicable regulations that threaten to categorically exclude similarly situated class members "who wish to serve their country," but are "being irrationally and arbitrarily swept from the ranks." *Roe I*, 359 F.Supp.3d at 406.

consistent with their calling and training; and severe family disruptions. *See supra* ¶ 12.

Third, judicial review would not interfere with military functions. Plaintiffs' claims largely seek to require DoD to follow its own regulations and "stated policies and make nonarbitrary, individualized determinations about each service members fitness for service." *Roe II*, 947 F.3d at 218. "Requiring the military to follow its own policies does not interfere with its functions." *Id.* Moreover, it is "illogical to think, let alone argue, that Plaintiff[s'] religious based refusal to take a COVID-19 vaccine would 'seriously impede' military function," when Defendants have permitted thousands of "other service members still on duty who are just as unvaccinated as" Plaintiffs.²³

Fourth, the constitutional issues in this case do not implicate military expertise or discretion. Whether the DoD Mandate or Categorical RA and ME Bans 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). Further, by adopting the Categorical RA and ME Bans, the DoD "declin[ed] to make individualized determinations regarding

²³ *Air Force Officer*, at *7 (*quoting Mindes*, 453 F.2d at 201). *Accord Navy SEALs 1-26 Stay Order*, F.4th at 349. *See also* Section II.A.1 & Table (nearly 20,000 medical and administrative exemptions).

servicemembers' fitness for service," and thereby "failed to apply its expertise to the evidence before it." *Roe II*, 947 F.3d at 218.

C. Defendants' Actions Are Reviewable.

Exceptions to judicial review are "very narrow" and "reserved for those rare instances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Weyerhauser Co. v. U.S. Fish and Wildlife Servs.*, 139 S. Ct. 361, 370 (2018) (citation and quotation marks omitted). The DoD and Coast Guard actions are reviewable because, in addition to being illegal, they are "high-level policy decisions made far from the field of battle." *Harrison*, 2022 WL 1183767, at *12 (citation and quotation marks omitted). In fact, the DoD actions are not uniquely military in nature at all and instead were a relatively small part of the Biden Administration's illegal federal vaccine mandates. *See supra* ¶ 7. Plaintiffs allege that Defendants violated RFRA, the Informed Consent Laws, and their own regulations, *see supra* note 14, each of which "provide[s] a standard by which to review [their] conduct." *Deese v. Esper*, 483 F.Supp.3d 290, 309 (D. Md. 2020) ("*Deese*"). The FDA Waiver is reviewable because it violates express mandatory and non-waivable statutory labeling requirements to grant a legal benefit and status—licensing unlicensed EUA products—relied on by DoD to eliminate service members' informed consent rights. *See infra* Section II.D.2.

D. 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” “concrete and particularized” injury” due to the unlawful and unconstitutional DoD Mandate and related agency actions. Courts have found service members had standing to challenge a new vaccine mandate applicable to them. *See generally Rumsfeld I & II*. Plaintiffs have already faced adverse personnel or disciplinary actions, *see supra* ¶ 12, and irreparable harm, which is more than sufficient for Article III standing purposes.

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.” *Teva Pharmaceuticals USA, Inc. v. FDA*, 514 F.Supp.3d 66, 91 (D.D.C. 2020) (“*Teva*”). 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.

Plaintiffs also have standing for their claims against the FDA because their injuries due to the DoD Mandate and the DoD Interchangeability Determination are directly traceable to the FDA Interchangeability Determination and FDA Waiver. Just as in *Rumsfeld I* and *II*, this case alleges interconnected actions of the DoD and the FDA.²⁴ Plaintiffs allege that the DoD and the FDA 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 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. 5 U.S.C. § 702. Plaintiffs have standing under the Informed Consent Laws because they are the subject of the challenged agency action. *See Teva*, 514 F.Supp.3d at 91. 10 U.S.C. § 1107a was enacted to protect service members like Plaintiffs by codifying their right to refuse an EUA drug mandated by the military. Plaintiffs also have standing under

²⁴ *See also 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); *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).

the PHSA because they are within the zone of interests—potential recipients (albeit involuntary)—that the PHSA’s mandatory, non-waivable labeling and interchangeability requirements seek to protect.²⁵

E. 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 are fit for review because they 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), and Plaintiffs challenge discrete, final agency actions that set forth Defendants’ consistent and unchanging policy since the DoD Mandate was issued.

Each Plaintiffs is required to be vaccinated; has had their RARs and appeal denied; has suffered injuries through the enforcement of the policy; and faces imminent discharge. *See supra* ¶¶ 11-12. 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

²⁵ *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”).

684 (citation and quotation omitted). Indeed, on July 25, 2022, the same day this complaint was filed, the USCG Commandant issued ALCOAST 270/22, instructing all subordinate commands to begin separating “all” “non-compliant” Coast Guardsmen. *See* Ex. 10, ALCOAST 270/22 (July 25, 2022).

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON MERITS.

A. RFRA and Free Exercise Claims.

1. Defendants’ Have Substantially Burdened Plaintiffs’ Free Exercise Rights, Triggering Strict Scrutiny.

RFRA restricts governmental action that “substantially burden[s] a person’s exercise of religion[,] even if the burden results from a rule of general applicability.” 42 U.S.C. § 2000bb-1.²⁶ Defendants have substantially burdened Plaintiffs’ free exercise rights because the DoD Mandate and Categorical RA Ban forces them to “decide whether to lose their livelihoods or violate sincerely held religious beliefs.” *Navy SEALs 1-26*, at *9.

Further, Defendants overtly discriminate against religion and treat comparable secular activity—medical and administrative exemptions—more favorably than religious exemptions. Recent statistics published by the other

²⁶ Because RFRA “provides greater protection ... than is available under the First Amendment,” if a Plaintiff’s “RFRA claim fails, the service member’s First Amendment claim necessarily fails.” *Navy SEAL 1*, at *12. Accordingly, Plaintiffs here follow the approach in *Navy SEAL 1* and other recent cases in focusing their analysis on the RFRA claim, because if Plaintiffs can establish a likelihood of success for RFRA claims, then for “the same reasons” they are “likely to prevail on [their] First Amendment claim[s].” *Air Force Officer*, at *11.

Armed Services show that the religious discrimination has only gotten worse since February 2022 (*i.e.*, the data reflected in Table 1 of the Complaint). *See* Ex. 11-14 (statistics for each service available as of July 18, 2022). Even making the counterfactual assumption that the small number of RARs granted are religious accommodations rather than disguised administrative exemptions, *see* Compl., ¶ 62, the Armed Services have granted ***more than 100 times more*** secular exemptions than RARs.

Table: Religious Accommodations vs. Secular Exemptions

Service	RARs Submitted	RARs Approved	% RAR Approved	Med/Admin Approved	Secular vs. RAR
Air Force	9,139	109	1.2%	1,608	14.8:1
Army	7,701	19	0.25%	17,338	913:1
USCG	1,308	0	0.0%	6	N/A
USMC	3,733	7	0.19%	602	86:1
Navy	4,235	43	1.0%	273	6.3:1
Total	26,116	178	0.7%	19,827	111:1

Plaintiffs have thus presented *prima facie* evidence, based on Defendants’ own data, that Defendants have substantially burdened Plaintiffs’ exercise of religion and have discriminated against religious exercise. This evidence triggers strict scrutiny and shifts the burden of proof to the government to demonstrate that its policy serves a compelling governmental interest using the least restrictive means. *O Centro Espirita Beneficiente Uniao do Vegetal*, 546 U.S. 418, 429 (2006) (“*O Centro*”). RFRA strict scrutiny applies to both “the asserted harm of granting specific exemption to particular religious claimants,” and of “the marginal interest

in enforcing the challenged government action in that particular context.” *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 726-27 (2014) (“*Hobby Lobby*”).

2. Defendants’ Categorical Ban Does Not Further a Compelling Governmental Interest.

While “[s]temming the spread of COVID-19 is unquestionably a compelling interest,” *Cuomo*, 141 S. Ct. at 67, “its limits are finite.” *Navy SEALs 1-26*, at *10. To satisfy strict scrutiny under RFRA, there must be a compelling interest “supporting the specific denial of a specific plaintiff’s exemption and the absence of an alternative for that plaintiff.” *Navy SEAL 1*, at *10. Military Defendants’ “broadly formulated interest in national security,” *id.*, or simply invoking “magic words” like “military readiness and health of the force” will not suffice. *Id.* at *17 (citation omitted). But “[w]ithout individualized assessment” of service members fitness for service, the Defendants “cannot demonstrate a compelling interest in vaccinating these particular Plaintiffs.” *Navy SEALs 1-26*, at *10.

Defendants’ assertion of a compelling governmental interest in 100% vaccination with no exception is contradicted by their actions and their acknowledgment that the mRNA treatments cannot prevent infection or transmission of COVID. First, the Armed Services have granted tens of thousands of exemptions for secular reasons, while categorically banning religious accommodations. Such “underinclusiveness ... is often regarded as a telltale sign that the government’s interest in enacting a liberty-restraining pronouncement is not in fact compelling.” *Navy SEALs 1-26 Stay Order*, 27 F.4th at 352 (*quoting*

BST, 17 F.4th at 616). Second, Defendants claim that any unvaccinated USCG member is a threat to the force and cannot be deployed, yet USCG has not hesitated to require unvaccinated members to deploy when needed. *See, e.g., Navy SEALs 1-26 Stay Order*, 27 F.4th at 352; ECF 1-4, Jordan Decl., ¶ 20 (directed to deploy September 14, 2021, the day after he was told he was non-deployable, and has deployed for at least 189, or more than 50% of the time since that date). Third, Defendants, along with other federal public health agencies, and the White House have acknowledged that mandated treatments cannot prevent infection or transmission of COVID, and thus cannot further any compelling government interest in stopping the spread of disease or military readiness. *See supra* ¶ 2-5. Finally, On Aug. 11, 2022, the CDC issued updated guidance:

CDC's COVID-19 prevention recommendations ***no longer differentiate based on a person's vaccination status*** because breakthrough infections occur, though they are generally mild, and persons who have had COVID-19 but are not vaccinated have some degree of protection against severe illness from their previous infection.

Ex. 5, Aug. 11, 2022 CDC Guidance, at 3 (emphasis added). Defendants' continued insistence on differential treatment by vaccination status now runs directly against the CDC's most recent guidance and the current scientific consensus.

3. Defendants' Policy Is Not the Least Restrictive Means for Achieving Government's Interests.

Defendants have failed to demonstrate that their policies of uniformly denying Plaintiffs' religious exemption requests are the least restrictive means of

furthering their purportedly compelling interests, or for that matter, that any less restrictive alternatives to vaccination were ever seriously considered. In these denial letters, Defendants failed to demonstrate, as they must, that the less restrictive measures “were tried and failed, or that the alternatives were closely and examined and ruled out for good reason.” *Bruni v. City of Pittsburgh*, 824 F.3d 353, 370 (3d Cir. 2016). Instead, these letters indicate that Plaintiffs’ proposed alternatives were denied because the government’s “chosen route [of 100% vaccination] was easier,” rather than a determination that “imposing lesser burdens on religious liberty would fail to achieve the government’s interests.” *Agudath Israel of Am. v. Cuomo*, 983 F.3d 620, 633 (2d Cir. 2020) (citation and quotation marks omitted).

Defendants also dismissed, or failed altogether to consider, natural immunity (possessed by four of the five Plaintiffs) and the cumulative impact of natural and herd immunity with Plaintiffs’ proposed less restrictive measures. Defendants’ conclusory assertions fail to show that “COVID-19 vaccine[s] ... provide more sufficient protection” than Plaintiffs’ “natural immunity coupled with other preventive measures.” *Air Force Officer*, at *10 (citation omitted).

B. Substantive Due Process Claim.

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 permanently eradicate the disease as has been the case with smallpox or polio

vaccine. The mandated Pfizer/BioNTech and Moderna mRNA products are not vaccines, because they do not prevent infection or transmission. After President Biden claimed that vaccinated people would not get COVID on July 21, 2021 (suggesting 100% effectiveness), exactly one year later on July 21, 2022, the quadruple-vaxxed President’s spokesperson acknowledged that they “knew” that “at some point, everyone will get COVID” (suggesting 0% effectiveness). *Supra* ¶¶ 1-2. As medical treatments, they must be analyzed under heightened scrutiny governing bodily integrity and informed consent, rather than rational basis review under *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (“*Jacobson*”).

1. The Pfizer and Moderna Products Are Not Vaccines.

DoDI 6205.02 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.

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.” 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, and therefore the mRNA shots are not vaccines. The only legal authority cited in the DoD Mandate is DoDI

6205.02, and the failure to satisfy the definition strips this directive of any legal authority to treat these products as *vaccines* that may be mandated.

2. DoD Mandate Violates Plaintiffs’ Right to Bodily Integrity and Fails Heightened Scrutiny.

The Supreme Court has recognized that there is a “fundamental right” to “bodily integrity.” *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (“*Glucksberg*”) (citations omitted). “This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment.” *Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261, 269 (1990) (“*Cruzan*”). “The 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; *accord Glucksberg*, 521 U.S. at 720.

Because the injections are medical treatments to be analyzed under *Cruzan* and *Glucksberg*, 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, where the government must: (1) “adequately demonstrate a compelling need for the intrusion,” (2) show “a lack of reasonable alternatives,” and (3) that appropriate “procedural and medical safeguards” are in place. *Planned Parenthood Southwest Ohio Region v. DeWine*, 696 F.3d 490, 506 (6th Cir. 2012) (citation omitted). 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 further that compelling interest because these products cannot prevent infection or transmission. *See supra* ¶ 2. The DoD has never considered any alternatives to requiring 100% vaccination, as revealed by the administrative record materials produced in a related case, *see* Compl., ¶ 181, and their form letter denials of Plaintiffs' RARs. Treating all servicemembers the same, regardless of their individual medical status, risk factors, and natural immunity status is not narrowly tailored. Nor is it consistent with CDC guidance reflecting the current scientific consensus. *See* Ex. 5, Aug. 11, 2022 CDC Guidance. The blanket mandate ignores individual factors increasing or decreasing the risks that the plaintiffs pose to themselves or to others. 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* Section II.A.3, and the APA. *See infra* Section I.A.1. The Defendants have also eliminated any procedural safeguards through the Categorical RA and ME Bans.

3. *Jacobson* Is Easily Distinguished and Does Not Justify Federal Administrative COVID-19 Vaccine Mandate.

First, the *Jacobson* court grounded its decision in a *State's* police power to regulate the health of those within its geographic borders through the legislature. *Jacobson*, 197 U.S. at 38. Defendant DoD is not a state legislature, but a federal agency run by a political appointee that controls no "territory," but instead controls

volunteer servicemembers deployed across the United States and globally, where local conditions of infection and transmission are vastly different. DoD is acting directly contrary to the governing statute and the DoD's own regulations; it is instituting a public health mandate, rather than justifying its mandate through its military expertise as applied to particular battlefield conditions that would justify allowing such an authority over servicemembers bound for a combat zone filled with such threats. Five other federal vaccine mandates have been stayed for agency actions in excess of their authority. *See supra* ¶ 4. Second, the Court specifically noted that its justification was in large part predicated on the lethality of smallpox, *Jacobson*, 197 U.S. at 37-38, which is approximately 30%²⁷ and thus orders of magnitude more deadly than Covid-19 and is approximately 0.02% (*i.e.*, one out of 5,000) for military service members like Plaintiffs.²⁸ Third, and perhaps most fatal to Defendants mandate, is that relying on *Jacobson* means that they are bound by the definition of “vaccine,” as that term was understood by the *Jacobson* court, and for centuries by legislators, regulators, courts and the general public up until September 2021. Fourth, the *Jacobson* Court explicitly noted that its sweeping

²⁷ *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).

²⁸ 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/>.

language would not apply where those challenging a mandate could show they faced serious risk of injury or death from vaccination. *See Jacobson*, 197 U.S. at 39. None of the premises supporting *Jacobson* are present in the current case.

C. 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 job(s)." *BST*, 17 F.4th at 618. 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 are expressly excluded by DoDI 6205.02. That they did so contemporaneously with the FDA approval of Comirnaty and the issuance of the DoD Mandate eliminates any doubt as to the improper purpose: to enable vaccine mandates by circumventing constitutional and statutory prohibitions on mandating treatments and to deprive them of their rights to informed consent under the *Cruzan* line of cases and 10 U.S.C. § 1107a.

D. Defendants' Statutory Violations

1. DoD Mandate and DoD Interchangeability Determinations Violate the Informed Consent Laws.

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.²⁹ 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.³⁰ 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.

²⁹ *See, e.g., Austin*, 2021 WL 5816632, at *7. Plaintiffs repeatedly confirmed that no FDA-licensed vaccines were available as of their vaccination deadlines. *See, e.g.,* ECF 1-5, Wadsworth Decl. ¶¶ 10-13. Despite the impossibility of compliance, Plaintiffs were punished and now face imminent discharge.

³⁰ *See* ECF 1-7 & 1-8 (DoD Interchangeability Determinations for Pfizer/BioNTech and Moderna treatments). *See also* Ex. 15, ¶ 10 (June 2, 2022 Response in *Coker v. Austin*, NDFL No. 3:21-cv-1211) (confirming that all EUA vaccines are treated as if they are FDA-licensed and may be mandated). Plaintiffs’ note that, in other legal challenges to the DoD Mandate, Defendants have asserted the affirmative defense that the DoD Mandate is limited to EUA-labeled, (but) “BLA-compliant” vaccines (*i.e.*, vaccines manufactured in accordance with the Comirnaty BLA). *See* Compl., ¶¶ 167-68. Plaintiffs will address that defense if raised in Defendants’ response.

Apart from Presidential approval, there are no exceptions, or even any criteria for discretionary waiver. 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 460. Accordingly, this Court owes no deference to agency Defendants’ interpretations of the statutes that permit what the statutory text expressly prohibits. *See supra* Section I.A.2.

The FDA documents that the DoD relied on in making the DoD Interchangeability Determinations, *see* ECF 1-7 & 1-8, 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 products are subject to the Informed Consent Laws granting recipients the “option to accept or refuse”; the non-waivable statutory requirement to be labeled as an unlicensed, EUA product; and the requirement to include in product labeling an EUA factsheet informing recipients that the product is not licensed and that he or she has an “option to accept or refuse.” *See* Compl., ¶ 65.³¹

³¹ 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.* ECF 1-15, Aug. 23, 2021 Pfizer/BioNTech EUA Re-Issuance Letter, at 2 n.8 & Ex. 16, July 8, 2022 Pfizer/BioNTech EUA Re-Issuance Letter, at 17 & n.28.

The *Doe v. Rumsfeld* cases addressed the same violations of the Informed Consent Laws and the APA and granted similar relief to that requested by Plaintiffs. Indeed, the *Doe v. Rumsfeld* series of cases is not only *persuasive* legal precedent because it dealt with the exact same issue in a different circuit, but they arguably estop Defendants DoD and FDA from taking a contrary position before this Court.³² The DoD consistently maintained the position adopted at the time the EUA statute was enacted in 2004, which was included in the voluntary *Rumsfeld III* consent decree, through at least July 2021. *See* Compl., ¶ 180 & Ex. 17, July 6, 2021 Office of Legal Counsel Memorandum at 17-18. These “established practice[s]” are not only due greater deference than sudden, unexplained reversals, *see BST*, 17 F.4th 604, but the long-standing and consistent refusal to exercise a claimed power (*i.e.*, to mandate an EUA product) is “significant in determining whether such a power was actually conferred.” *EPA*, 142 S. Ct. at 2610 (citation and quotation marks omitted).

³² *Doe v. Rumsfeld* involved: (a) the same Defendants (DoD and FDA); (b) the same statute, issues, and product, an unlicensed EUA product sought to be mandated; (c) these issues were fully litigated, resulting in a 2004 permanent injunction in *Rumsfeld II* against the same Defendants that was voluntarily modified pursuant to an emergency request by DoD and FDA, resulting in the 2005 *Rumsfeld III* consent decree, prohibiting mandate of EUA products or any disciplinary action against service member for refusal; (d) some of the same Plaintiffs, namely, those who were subject to anthrax mandate and covered by DoD-wide injunction and consent decree; and (e) engendered significant reliance interests for those plaintiffs. *See* Compl., ¶¶ 176-179.

2. FDA Waiver and FDA Interchangeability Determinations Violate the 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. To justify the FDA Waiver, the FDA has stated that it has exercised its “enforcement discretion”³³ 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 refuse the unwanted treatment.

In doing so, the FDA went far beyond permissible agency enforcement discretion, which pertains to enforcement priorities and agency inaction. Instead, the FDA’s decision is an affirmative and unlawful agency action—granting a license to an unlicensed EUA product—that violates the express terms of the statute it enforces.³⁴ It is not within the FDA’s discretion to confer a legal benefit for a

³³ See ECF 1-17, 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’”).

³⁴ 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

product (*i.e.*, licensure), or to exempt an unlicensed products from labeling and 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 PHSA.

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 *Beaty* and *Cook*. *See supra* Section I.A. 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.” *Beaty*, 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. 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.

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 is sufficient).

The same conclusion applies to the FDA's waiver of the requirement to include the EUA Factsheet advising recipients of their right to refuse the EUA product.³⁵

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." ECF 1-17, Marks Decl., ¶ 11. The PHSA grants the FDA the authority only to make "statutory" interchangeability determinations, 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 the FDA has not made a "statutory" determination, then the two products are not "legally interchangeable" and the FDA's footnote cannot be the basis for the DoD and USCG position that the EUA and licensed vaccines are "legally" interchangeable.

³⁵ The FDA's actions here also have the same additional defects relied on in *Beaty*, *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.

E. Defendants' APA Violations.

1. Categorical RA and ME Bans Violate APA.

RFRA, DoDI 1300.17, and COMDTINST 1000.15 each require individualized assessments of RARs, while AR 40-562 requires individualized assessment of medical exemptions. An agency violates the APA where it adopts a categorical ban, like the Categorical RA Ban or Categorical ME Ban, when the statute in question or DoD “regulations require individualized determinations based on objective evidence to determine a servicemembers fitness for duty or separation.” *Roe II*, 947 F.3d at 222. Under the APA and the DoD’s own regulations, a “categorical predictive assessment,” “based on speculation” rather than evidence or individualized assessments, cannot be a “a satisfactory explanation for discharging each servicemember.” *Id.* Nor can such categorical bans be upheld where they are based on “obsolete understandings,” *Deese*, 483 F.Supp.3d at 314; *see also Roe II*, 947 F.3d at 228 (same), namely, that an already obsolete vaccine can prevent infection or transmission from Omicron or future variants. Nor can they be justified based on deference to military judgment or discretion because the categorical ban precludes the exercise of such discretion. *See, e.g., Roe I*, 359 F.Supp.3d at 406; *Roe II*, 947 F.3d at 218.

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, except for DoDI 6205.02, which cannot provide a legal basis because the

mandated treatments are not “vaccines” as defined in the regulation. Secretary Austin’s sole 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 1-6 at 1. Given that the DoD Mandate was issued on the very next day after FDA Comirnaty Approval, it is apparent the DoD blindly relied on the FDA (rather than its military expertise) and selectively applied CDC recommendations. *See Compl.*, ¶ 174 (DoD relied on CDC recommendation for two doses, but ignored recommendation for boosters).

The DoD Mandate is also arbitrary and capricious because it constitutes an unannounced and unexplained departure from the prior policy adopted at the time of enactment in 2004 through July 2021. *See supra* Section II.D.1. “[A]gencies must typically provide a detailed explanation for contradicting a prior policy that has engendered serious reliance interests.” *BST*, 17 F.4th at 614. Such “reversal[s]” on a “pretextual basis” “are all hallmarks of unlawful agency actions.” *Id.*

3. DoD Failed Altogether to Consider Any Alternatives.

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., Navy SEAL 1*, 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).

III. PLAINTIFFS HAVE SUFFERED IRREPARABLE HARM.

Plaintiffs have shown above they are currently being deprived of their religious liberties protected by the First Amendment and enforced through RFRA’s statutory protections. There can be “no question” that these types of restrictions on religious exercise “will cause irreparable harm.” *Cuomo*, 141 S.Ct. at 67; *see also Elrod*, 427 U.S. at 373 (plurality opinion) (“[t]he loss of First Amendment freedoms, even for minimal periods of time, unquestionably constitutes irreparable injury.”). Violations of constitutional rights to due process also presumptively cause irreparable harm. *See, e.g., DeLeon v. Perry*, 975 F.Supp.2d 632, 663 (W.D. Tex. 2014).

Plaintiffs also face irreparable harm from imminent discharge because the “circumstances surrounding [their] discharge, together with the resultant effect on the employee ... so far depart from the normal situation that irreparable injury may

be found.” *Sampson v. Murray*, 415 U.S. 61, 90, 94 S.Ct. 937 (1974). Plaintiffs meet this high standard “because these injuries are inextricably intertwined with Plaintiffs’ loss of constitutional rights,” and because “[t]he crisis of conscience imposed by the mandate is itself an irreparable harm.” *Navy SEALs 1-26*, at *13 (citation omitted). In addition to the intertwined constitutional violations, Plaintiffs meet the *Sampson* standing because they will be “discharge[d] without an individualized assessment of their fitness for continued service and for reasons unrelated to their ability to service,” coupled with a discharge with a misconduct characterization and stigmatic injuries that cannot be “address[ed] ... through post-discharge intra-service procedures.” *Roe*, 947 F.3d at 218.

Plaintiffs and class members risk loss of retirement eligibility with more than 15 years of service, or being dropped into the IRR, resulting in irreparable harm from the loss of military medical insurance for themselves and family members. *See, e.g.*, ECF 1-4, Jordan Decl., ¶ 19. It is well-settled that the loss of medical coverage, particularly for dependents with special needs or undergoing lifesaving medical treatment in itself constitutes irreparable harm. *See, e.g., Camacho v. Texas Workforce Comm’n*, 326 F.Supp.2d 794, 802 (W.D. Tex. 2004). Conversely, forcing Plaintiffs to accept unwanted medical treatment and, “requiring 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).

The Defendants cannot claim to suffer any harm that “results only from [their] own failure to comply with RFRA.” *Navy SEAL 1*, at *20. The threat from COVID is fast receding: there have been no COVID deaths for active-duty personnel since November 2021, and the CDC, based on current scientific understanding, has recommended ending discriminatory and punitive treatment of the unvaccinated. Now, it is Defendants’ systematic violations of constitutional rights that threaten national security by purging tens or hundreds of thousands of service members. *See supra* ¶ 8. “Plaintiffs’ loss of religious liberties outweighs any forthcoming harm to” the Coast Guard. *Navy SEALs 1-26*, at *13.

V. CONCLUSION

This Court should grant the Motion and adopt the Proposed Order.

Dated: August 16, 2022

Respectfully submitted,

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CERTIFICATE OF CONFERENCE

This is to certify that counsel for Plaintiffs and Defendants conferred regarding the foregoing Motion by telephone on August 9, 2022, and by email on August 9-11, 2022. Defendants oppose this Motion.

Dated: August 16, 2022

Respectfully Submitted,

/s/ Dale Saran
Dale Saran

CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Motion using the CM/ECF system.

Dated: August 16, 2022

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson