

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA**

NAVY SEAL # 1, et al.,

Plaintiffs,

v.

JOSEPH R. BIDEN, JR., in his official
capacity as President of the United States, *et al.,*

Defendants.

Case No. 8:21-cv-02429-SDM-TGW

**DEFENDANTS' MOTION TO DISMISS,
OR, IN THE ALTERNATIVE, MOTION TO SEVER**

Plaintiffs, thirty-one service members across all the Military Services, raise religious objections to the Department of Defense's ("DoD") COVID-19 vaccination directive and also claim that vaccination violates the Federal Food, Drug, and Cosmetics Act ("FDCA") and 10 U.S.C. §§ 1107 and 1107a. Dismissal—either in whole or in part—is warranted for several reasons.

This case should be dismissed in its entirety on ripeness and exhaustion grounds. Some Plaintiffs have not received final adjudications of their religious exemption requests, and no Plaintiff has completed separation proceedings. If the case is not dismissed in its entirety on jurisdictional grounds, the Court should dismiss Plaintiffs' challenge under the FDCA, 10 U.S.C. §§ 1107 and 1107a because those statutes do not contain a private right of action. Moreover, only vaccines that have received full licensure by the Food and Drug Administration ("FDA"), in accordance with FDA-approved labeling and guidance, are required under the relevant policies,

and no Plaintiff alleges that he or she has requested or has been denied a dose of a licensed vaccine.

If the Court does not dismiss the case in its entirety, the Court should sever the claims of the 31 Plaintiffs. All Plaintiffs allege violations of the Religious Freedom Restoration Act (“RFRA”) and the First Amendment in connection to their individual religious exemption requests. Only four of the 31 Plaintiffs allege any connection to Florida. There is no reason to continue litigating these individualized claims—often on emergency motions for a temporary restraining order or preliminary injunctive relief—in this district. They should instead be severed and litigated in districts where venue is proper.

PROCEDURAL BACKGROUND

Defendants have previously set forth the background on the COVID-19 pandemic, the Food and Drug Administration’s regulation of and guidance concerning COVID-19 vaccines, and the Department of Defense COVID-19 vaccination directive, as well as the Military Services’ implementing guidance, in their opposition to Plaintiffs’ motion for a preliminary injunction and incorporate that background by reference. *See* ECF No. 23.

On February 18, 2022, thirty-two service members filed their second amended complaint challenging the DoD directive governing members of the Armed Forces and the adjudication of their individual religious exemption requests.¹ *See* Second Am.

¹ On March 18, 2022, Plaintiffs filed a notice of voluntary dismissal to dismiss Plaintiff United States Marine Corps Major from the case. ECF No. 137.

Compl., ECF No. 105. Plaintiffs purport to bring a class action of “military servicemembers who have been denied religious exemption from the Federal COVID-19 Vaccine Mandate.” *Id.* ¶ 203. Plaintiffs allege that the “Federal COVID-19 vaccine mandate” violates: (1) the FDCA, 21 U.S.C. § 360bbb-3, *id.* ¶¶ 212–39; (2) the First Amendment, *id.* ¶¶ 240–57; and (3) RFRA, 42 U.S.C. § 2000bb-1, *id.* ¶¶ 258–80. Plaintiffs seek a declaratory judgment and nationwide injunction against the military that would prevent implementation of the DoD COVID-19 vaccination directive, require the government to grant all religious exemption requests, and prevent the military from taking any adverse action or discipline against service members. *Id.* Prayer for Relief at 127–31.

LEGAL STANDARDS

I. Dismissal

“‘Federal courts are courts of limited jurisdiction’ and ‘possess only that power authorized by Constitution and statute.’” *Bishop v. Reno*, 210 F.3d 1295, 1298 (11th Cir. 2000) (citation omitted). Where plaintiffs fail to demonstrate a court’s subject-matter jurisdiction, dismissal is appropriate pursuant to Federal Rule of Civil Procedure 12(b)(1). *Langston v. Tex. Cap. Bank, NA*, No. 8:20-CV-2954-VMC-AAS, 2021 WL 698171, at *2 (M.D. Fla. Feb. 23, 2021).

To withstand a motion to dismiss pursuant to Rule 12(b)(6), a complaint must contain “sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation omitted).

Mere “labels and conclusions” and “naked assertion[s] devoid of further factual enhancement” are insufficient. *Id.* Rather, a court must disregard “pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth,” and determine whether the remaining “well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief.” *Id.* at 679.

II. Joinder and Severance

Individuals may join in a single action if “(A) they assert any right to relief jointly, severally, or in the alternative with respect to or arising out of the same transaction, occurrence, or series of transactions or occurrences; and (B) any question of law or fact common to all plaintiffs will arise in the action.” Fed. R. Civ. P. 20(a)(1). “Even if the requirements of Rule 20 are satisfied, a court enjoys considerable discretion to sever claims in the interests of judicial economy.” *Walters v. BMW of N. Am.*, No. 8:18-CV-02875, 2019 WL 6251366, at *2 (M.D. Fla. Nov. 22, 2019). Courts consider the following factors when considering whether Plaintiffs’ claims should be joined or severed: “(1) the interest of avoiding prejudice and delay; (2) ensuring judicial economy; (3) safeguarding principles of fundamental fairness; and (4) whether different witnesses and documentary proof would be required for plaintiffs’ claims.” *Id.* (quoting *Torres v. Bank of Am.*, No. 8:17-CV-1534-T-26TBM, 2017 WL 10398671, at *2 (M.D. Fla. Oct. 6, 2017)). Although “[m]isjoinder of parties is not a ground for dismissing an action,” “the court may at any time, on just terms, add or drop a party,” or “sever any claim against a party.” Fed. R. Civ. P. 21.

III. Deference Principles

Judicial review of claims involving the “complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force,” *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973), is highly constrained. *Rostker v. Goldberg*, 453 U.S. 57, 66 (1981) (Because of the “healthy deference to legislative and executive judgments in the area of military affairs,” courts employ a relaxed scrutiny in reviewing military policy.); *Aktepe v. United States*, 105 F.3d 1400, 1403 (11th Cir. 1997) (“[T]he political branches of government are accorded a particularly high degree of deference in the area of military affairs.”); *see also Winck v. England*, 327 F.3d 1296, 1302–04 (11th Cir. 2003), *abrogated on different grounds as recognized in Santiago-Lugo v. Warden*, 785 F.3d 467, 475 n.5 (11th Cir. 2015)). Such deference extends to constitutional claims and military decisions about the health and welfare of the troops. *E.g.*, *Solorio v. United States*, 483 U.S. 435, 448 (1987); *Mazares v. Dep’t of Navy*, 302 F.3d 1382, 1385 (Fed. Cir. 2002). And such deference explicitly applies when it involves religious liberty claims. *See Goldman v. Weinberger*, 475 U.S. 503, 507 (1986) (“But within the military community there is simply not the same [individual] autonomy as there is in the larger civilian community. . . . [W]hen evaluating whether military needs justify a particular restriction on religiously motivated conduct, courts must give great deference to the professional judgment of military authorities concerning the relative importance of a particular military interest.” (first bracket in original; internal quotation marks omitted)).

ARGUMENT

The Court lacks jurisdiction over this case because Plaintiffs' claims are not ripe and they have failed to exhaust administrative remedies. Several Plaintiffs have not completed the process for requesting exemptions, and, for those Plaintiffs who have had their exemption requests finally adjudicated, no Plaintiff has exhausted their administrative remedies through subsequent proceedings. Even if Plaintiffs could establish jurisdiction, they have failed to state a claim that the military violated the FDCA, 10 U.S.C. §§ 1107 or 1107a. Finally, the individualized nature of the 31 Plaintiffs' claims warrant severance.

I. Plaintiffs' Claims Are Not Ripe and They Have Failed to Exhaust Administrative Remedies.

Plaintiffs filed suit before many received final decisions on their requests for a religious exemption to DoD's COVID-19 vaccination directive and before any completed adverse administrative or discipline processes that follow a final denial of an exemption request. *See* Second Am. Compl. ¶¶ 32–64, 128–59. Currently, 15 Plaintiffs have not received final decisions on their requests for religious exemptions,² and no Plaintiff who has had their exemption request finally adjudicated has completed subsequent administrative or discipline processes. *See* Ex. 1 (Decl. of Major

² In addition, one Plaintiff has not submitted a request for a religious exemption. Plaintiff Technical Sergeant, U.S. Air Force, has been on maternity leave and personal leave since December 9, 2021. Ex. 2 (Parks Decl.) ¶ 4. On September 21, 2021, she requested, and was granted, a temporary medical exemption. *Id.* That exemption expired on January 15, 2022. *Id.* She has not been present for duty since her temporary medical exemption expired. *Id.* Although she has not requested a religious exemption to the COVID-19 vaccination requirement, if she submits such a request when she returns from leave, "it would be processed in accordance with applicable [Air Force] and Department of Defense regulations." *Id.*

Alyssa S. Tetrault) ¶ 6; Ex. 2 (Decl. of Colonel Michael B. Parks) ¶ 4; Ex. 3 (Decl. of Colonel Kevin J. Mahoney) ¶¶ 4–6; Ex. 4 (Decl. of Second Lieutenant Eugene Bryl McCarthy IV) ¶¶ 2–3 & Ex. A; Ex. 5 (Decl. of Captain Mery-Angela Sanabria Katson) ¶¶ 2–3 & Ex. A; Ex. 6 (Decl. of Commander Kelly C. Blackburn) ¶ 3.

Plaintiffs with pending exemption requests do not have ripe claims because any harm from receiving the vaccine or facing adverse action rests “upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1988) (citation omitted). If the military grants the requests, the service members will be exempted from the COVID-19 vaccination requirement, and while they wait for a determination, they are not subject to any adverse employment or disciplinary action. ECF No. 23-18 ¶¶ 9 n.6, 14 n.12; ECF No. 23-19 ¶¶ 9 n.5, 12 n.8; ECF No. 23-17 ¶¶ 8, 17, 24; ECF No. 23-22 ¶ 13; ECF No. 23-25 ¶¶ 10–11. “Until Plaintiff[s] ha[ve] received a decision from the military, judicial review of [their] claim[s], even if available, has not arisen.” *Frame v. United States*, No. 4:09-CV-458-RH/WCS, 2010 WL 883804, at *3 (N.D. Fla. Mar. 5, 2010) (concluding that “because Plaintiff’s application to have his discharge changed to an honorable discharge is still pending, this case is not ripe”); *see also Digital Props., Inc. v. City of Plantation*, 121 F.3d 586, 590 (11th Cir. 1997) (finding that because the plaintiff filed suit before “a binding conclusive administrative decision” was issued, “no tangible controversy exists and, thus, [the court] ha[s] no authority to act”). And because a final decision has not yet been reached on some Plaintiffs’ requests for religious exemptions, the military has not yet articulated with finality its views as to the least

restrictive means of furthering its compelling government interest.

Even if their exemption requests are denied, but Plaintiffs still do not get vaccinated and face adverse action, the military has administrative appeal procedures that offer many opportunities for them to present their arguments and for their Service to respond. *See* ECF No. 23-23 ¶¶ 3–14 (Air Force); ECF No. 23-17 ¶¶ 21–23 (Army); ECF No. 23-18 ¶¶ 15–22 (Navy); ECF No. 23-19 ¶¶ 14–21 (Marines); ECF No. 23-25 ¶ 10 (Coast Guard). Until those military procedures are exhausted, Plaintiffs cannot seek relief in this Court. *Winck*, 327 F.3d at 1302 (“[O]ur respect for coordinate judicial systems and their autonomy, has led us, time and again, to require exhaustion in military cases.”) (cleaned up); *Von Hoffburg v. Alexander*, 615 F.2d 633, 637 (5th Cir. 1980) (“[T]his court has consistently held that a plaintiff challenging an administrative military discharge will find the doors of the federal courthouse closed pending exhaustion of available administrative remedies.”) (collecting cases); *Hodges v. Callaway*, 499 F.2d 417, 420 (5th Cir. 1974) (“[T]his Court has firmly adhered to the rule that a plaintiff challenging an administrative military discharge will find the doors of the federal courthouse closed pending exhaustion of available administrative remedies.”); *Leicht v. McHugh*, No. 13-60015-CIV, 2013 WL 11971266, at *2 (S.D. Fla. May 24, 2013) (“The exhaustion doctrine should be strictly applied.”); *Doe v. Ball*, 725 F. Supp. 1210, 1211 (M.D. Fla. 1989), *aff’d sub nom. Doe v. Garrett*, 903 F.2d 1455 (11th Cir. 1990) (requiring exhaustion of administrative remedies before bringing facial challenge to Navy’s HIV regulations).

The nature of Plaintiffs’ claims does not excuse their failure to exhaust. Even

when a plaintiff “allege[s] the deprivation of a constitutional right” or “alleg[es] that the military has acted in violation of applicable statutes,” he still must “exhaust[] available intraservice corrective measures” before bringing suit in federal district court. *Mindes v. Seaman*, 453 F.2d 197, 201 (5th Cir. 1971).

The exhaustion requirement is especially important in the military context because it serves the important purpose of allowing the military to apply its “specialized expertise” in the first instance. *Lawrence v. McCarthy*, 344 F.3d 467, 470 (5th Cir. 2003). If Plaintiffs are dissatisfied with the military’s decision, they may seek judicial review only after exhausting military appeals, allowing the military to make its decision and fully articulate its interests. *See Winck*, 327 F.3d at 1302–04.

As other courts have recently found in similar contexts, judicial review of service members’ claims without first allowing the military’s internal processes to conclude “would undermine the purpose of exhaustion and infringe on the military’s expertise and interest in handling its own personnel matters.” *Church v. Biden*, --- F. Supp. 3d ---, 21-cv-2815, 2021 WL 5179215, at *11 (D.D.C. Nov. 8, 2021) (citing, *inter alia*, *Orloff v. Willoughby*, 345 U.S. 83, 94 (1953)). In *Short v. Berger*, the court concluded that a Marine Corps officer whose appeal had been denied failed to exhaust administrative remedies because “he still must undergo separation proceedings before any permanent adverse consequences are imposed.” Order, *Short v. Berger*, No. 2:22-cv-1151 (C.D. Cal. Mar. 3, 2022), ECF No. 25 at 5.³ Moreover, the officer would

³ The *Short* Order is filed on the docket at ECF No. 132-5.

have the opportunity to submit a “written rebuttal” during separation proceedings, and four different individuals would consider his separation, “any one of which could decide to close the process upon review of Plaintiff’s written submissions.” *Id.* (citing *Diraffael v. Cal. Mil. Dep’t*, No. 10-cv-07240, 2011 WL 13274364, at *3 (C.D. Cal. Mar. 21, 2011)). The court rejected the plaintiff’s argument that the administrative remedies would be futile, finding that there is “no evidence, other than argumentative conjecture, that separation proceedings are always decided against the appealing servicemember.” *Id.* at 5–6. The court also rejected the plaintiff’s argument that exhaustion was required because he otherwise would suffer irreparable harm, finding that separation was not a foregone conclusion and that even if he were separated, that harm could be redressed with back pay and reinstatement into the military. *Id.* at 13–14. The same is true here—separation proceedings are not futile so as to excuse the exhaustion requirement and Plaintiffs suffer no irreparable injury from going through separation proceedings. *See Leicht*, 2013 WL 11971266, at *3 (finding no irreparable harm in requiring the service member to pursue administrative remedies at the Board for Correction of Military Records before filing suit).

Accordingly, because Plaintiffs’ claims are not ripe and they failed to exhaust administrative remedies, this case should be dismissed for lack of jurisdiction. *Von Hoffburg*, 615 F.2d at 641 n.15 (“[W]here the exhaustion requirement does apply, the district court has no further jurisdiction over the case until the requirement is satisfied.”).

II. Any Claims that Require Review of the Military's Assignment Decisions Are Non-justiciable.

To the extent that Plaintiffs' claims extend to the review of military assignment decisions (including temporary reassignments), their claims are non-justiciable. The "Constitution vests '[t]he complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force' exclusively in the legislative and executive branches." *Kreis v. Sec'y of the Air Force*, 866 F.2d 1508, 1511 (D.C. Cir. 1989) (quoting *Gilligan*, 413 U.S. at 10). Courts have consistently held that decisions as to who is placed in command of our troops or assigned to a particular billet are beyond the judiciary's competence and are constitutionally entrusted to the military and political branches. *See, e.g., Orloff*, 345 U.S. at 93–94; *accord Speigner v. Alexander*, 248 F.3d 1292, 1298 (11th Cir. 2001); *see also Antonellis v. United States*, 723 F.3d 1328, 1336 (Fed. Cir. 2013) ("Courts are in no position to determine the 'best qualified Officer' or the 'best match' for a particular billet."); *Bryant v. Gates*, 532 F.3d 888, 899 (D.C. Cir. 2008) (Kavanaugh, J., concurring) ("[T]he Supreme Court has indicated" that "military decisions and assessments of morale, discipline, and unit cohesion . . . are well beyond the competence of judges."); *Cargill v. Marsh*, 902 F.2d 1006, 1007 (1990). Consistent with this precedent, courts routinely find challenges to military assignment decisions to be non-justiciable. *See, e.g., Harkness v. Sec'y of the Navy*, 858 F.3d 437, 443–45 (6th Cir. 2017) (collecting cases). Accordingly, to the extent Plaintiff's claims extend to a challenge to any military assignment decision, those claims are not justiciable.

III. Plaintiffs Fail to State a Claim with Respect to 21 U.S.C. § 360bbb-3 and 10 U.S.C. §§ 1107 and 1107a.

Plaintiffs allege that DoD's directive violates 21 U.S.C. § 360bbb-3, "as applied by 10 U.S.C. §§ 1107 and 1107a," which concerns notice requirements for drugs authorized pursuant to an Emergency Use Authorization ("EUA"). Second Am. Compl. ¶¶ 212–34. This claim fails for three distinct reasons. First, no Plaintiff alleges that he or she has sought (much less been denied) a COVID-19 vaccine that complies with an approved Biologics License Application ("BLA"). Second, Plaintiffs' statutory challenge to the COVID-19 vaccination requirement fails to identify a cause of action. And third, this claim is premised on the mistaken belief that DoD is requiring service members to receive vaccines that have not been approved by FDA as safe and effective for their intended use against COVID-19. Moreover, to the extent Plaintiffs challenge the issuance of the EUA for the Pfizer COVID-19 vaccine or the Emergency Declaration, the Court lacks jurisdiction over that claim. For any of these reasons, Count I of Plaintiffs' Second Amended Complaint must be dismissed.

A. Plaintiffs Have Not Alleged That They Were Denied a COVID-19 Vaccine That Complied With an Approved Biologics License Application.

No Plaintiff claims that he or she would take *any* COVID-19 vaccine, regardless of whether it was produced under an EUA or an approved BLA. Indeed, they all allege that their religious beliefs "preclude them from complying with the [DoD vaccine directive] because of the connections between the various COVID-19 vaccines and the cell lines of aborted fetuses, whether in the vaccines' origination, production,

development, testing, or other inputs.” *Id.* ¶ 85; *see also id.* ¶ 96 (“Plaintiffs’ sincerely held religious beliefs preclude them from accepting any one of the three currently available COVID-19 vaccines”); *id.* ¶¶ 105, 113, 114, 115. And, as this Court has already found, no Plaintiff claims that he or she “requested or was denied a Pfizer vaccine complying with the FDA license.” *Navy SEAL 1 v. Biden*, No. 8:21-CV-2429-SDM-TGW, 2021 WL 5448970, at *3 (M.D. Fla. Nov. 22, 2021); *see also Doe #1–#14 v. Austin*, No. 3:21-CV-1211-AW-HTC, 2021 WL 5816632, at *6 (N.D. Fla. Nov. 12, 2021) (finding that plaintiffs failed to show a likelihood of success on the merits of their claim under 10 U.S.C. § 1107a because “no plaintiff claims he or she was specifically denied a BLA-compliant dose or offered only a dose from a non-BLA-compliant vial”); *Crosby v. Austin*, No. 8:21-CV-2730-TPB-CPT, 2022 WL 603784, at *2 (M.D. Fla. Mar. 1, 2022) (same); *Norris v. Stanley*, No. 1:21-cv-756, 2021 WL 3891615, at *2 (W.D. Mich. Aug. 31, 2021) (no likelihood of success on EUA claim because it “would be moot” if offered the FDA-approved vaccine). Because no Plaintiff has alleged that the military will require them to “receive an emergency vaccine not complying with the FDA license,” they have failed to state a claim under the FDCA, 10 U.S.C. §§ 1107 or 1107a. *Navy SEAL 1*, 2021 WL 5448970, at *3.

B. Plaintiffs Have Not Identified a Cause of Action.

“[P]rivate rights of action to enforce federal law must be created by Congress.” *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001), and “[t]here must be clear evidence of Congress’s intent to create a cause of action,” *Love v. Delta Air Lines*, 310 F.3d 1347, 1353 (11th Cir. 2002) (citation omitted). Where the necessary intent is absent, “a cause

of action does not exist and courts may not create one.” *Sandoval*, 532 U.S. at 286–87.

As this Court has already found, 21 U.S.C. § 360bbb-3 does not provide a waiver of sovereign immunity or a cause of action for these Plaintiffs. *Navy SEAL 1*, 2021 WL 5448970, at *3 (citing *Doe v. Franklin Square Union Free Sch. Dist.*, --- F. Supp. 3d ---, 2021 WL 4957893, at *20 (E.D.N.Y. Oct. 26, 2021), *appeal filed*, No. 21-2759 (2d Cir. Nov. 2, 2021); *Bridges v. Hous. Methodist Hosp.*, 543 F. Supp. 3d 525, 527 (S.D. Tex. June 12, 2021), *appeal filed*, No. 21-20311 (5th Cir. June 14, 2021)); *see also Garfield v. Middle Tenn. State Univ.*, No. 3:21-CV-00613, 2021 WL 5770877, at *3 (M.D. Tenn. Dec. 6, 2021) (citing *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995); *Loreto v. Proctor & Gamble Co.*, 515 Fed. App’x 576, 578–79 (6th Cir. 2013)); *Donohue v. Hochul*, No. 21-CV-8463 (JPO), 2022 WL 673636, at *7 (S.D.N.Y. Mar. 7, 2022) (citing *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997)). To the contrary, the FDCA reserves exclusive enforcement authority to the United States, with one limited exception for state enforcement. 21 U.S.C. § 337(a); *see Guilfoyle v. Beutner*, No. 2:21-cv-05009-VAP, 2021 WL 4594780, at *26–27 (C.D. Cal. Sept. 14, 2021). Nor does 10 U.S.C. §§ 1107 or 1107a provide a waiver of sovereign immunity or a cause of action. *See Norman v. Campbell*, 87 F. App’x 582, 584 (7th Cir. 2003) (finding that it was “doubtful” that a “statute directed at the Secretary of Defense” allows a private cause of action). Because Plaintiffs have failed to identify a cause of action, the Court should dismiss this claim.

C. DoD Has Not Violated Statutory Requirements.

Plaintiffs’ statutory claim would otherwise fail because Congress has given the

Secretary of Defense and the Services wide latitude to establish a vaccination program for the welfare of the troops. *See* 10 U.S.C. §§ 113(b), 7013 (b)(9), 8013 (b)(9), 9013 (b)(9). 10 U.S.C. § 1107a⁴ and 21 U.S.C. § 360bbb-3 impose certain notice requirements (and, in the case of § 1107a, the possibility of a waiver of those notice requirements), for products authorized for “emergency use.” DoD’s directive does not contravene those statutes because DoD has not required that service members receive COVID-19 vaccines only authorized for emergency use. As the Secretary’s memorandum makes clear, “[m]andatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure . . . in accordance with FDA-approved labeling and guidance.” ECF No. 1-4. Guidance from the Services contains similar provisions. *See, e.g.*, ECF No. 23-7 at ¶ 3.D.8.A

FDA approved the Pfizer-BioNTech COVID-19 vaccine under the name Comirnaty. In its contemporaneous reissuance of Pfizer’s EUA, FDA determined that “[t]he licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns.” ECF No. 23-14 at Ex. C at 2 n.8.

⁴ Plaintiffs erroneously cite 10 U.S.C. § 1107, which concerns “investigational new drug[s]” and “drug[s] unapproved for [their] applied use”; service members may not be required to take those drugs unless certain procedures are followed. 10 U.S.C. § 1107(a), (g); *see also* 21 U.S.C. § 355(i) (defining investigational new drugs as those used in clinical trials); *Gallagher v. FDA*, No. 18-cv-2154, 2019 WL 6312008, at *2 (D.D.C. Nov. 25, 2019). DoD’s directive does not implicate this provision, as none of the COVID-19 vaccines provided to service members are provided as investigational new drugs in the context of clinical trials or drugs unapproved for their applied use. *See* ECF No. 23-14 ¶¶ 7, 7 n.2; *see also Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 132 (D.D.C. 2003) (“Title 10 U.S.C. § 1107 and the attendant DoD regulation apply only if the FDA determines that [the vaccine] is an investigational drug or a drug unapproved for its present purpose.”).

DoD relied on this determination, as well as FDA guidance that health care providers may “use doses distributed under the EUA to administer the vaccination series as if the doses were the licensed vaccine.” ECF No. 1-7. This is consistent with the text and purpose of § 1107a; *see also Navy SEAL 1*, 2021 WL 5448970, at *3 (finding that Plaintiffs failed to identify any factual or legal distinction “between Pfizer's vaccine bearing the emergency label but produced in compliance with the FDA license and Pfizer’s ‘interchangeable’ vaccine bearing the Comirnaty label”).

Accordingly, because the DoD directive can be satisfied by use of a vaccine that FDA has licensed as safe and effective for its intended use, Plaintiffs’ claim fails. *See Valdez v. Grisham*, --- F. Supp. 3d ---, 2021 WL 4145746, at *4 (D.N.M. Sept. 13, 2021) (rejecting claim that state vaccine mandate violated the EUA statute because “the FDA has now given its full approval – not just emergency use authorization – to the Pfizer vaccine”), *appeal filed* No. 21-2105 (10th Cir. Sept. 15, 2021).

D. The Court Lacks Jurisdiction Over a Challenge to the Emergency Declaration or EUA.

Finally, to the extent that Plaintiffs seek to challenge FDA’s EUA itself, that challenge is fundamentally misconceived. *See* Second Am. Compl. ¶¶ 212–39. As an initial matter, Plaintiffs have not sued the FDA, and so there is no proper defendant in this action for such a claim. And even if Plaintiffs had sued FDA, they could not challenge the EUA or the underlying emergency declaration because the EUA statute explicitly states that FDA’s “[a]ctions under the authority of this section . . . are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i); *Ass’n of Am. Physicians &*

Surgeons v. FDA, No. 20-1784, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (holding that EUAs are unreviewable); *see also* 5 U.S.C. § 701(a)(2) (agency action is unreviewable under the APA when it “is committed to agency discretion by law”). Accordingly, even if the issuance of the EUAs were relevant to Plaintiffs’ claims, the Court would lack jurisdiction to review any such claim.⁵

IV. Severance of Claims Is Warranted.

If the Court does not dismiss the case, severance of claims is warranted because Plaintiffs’ Second Amended Complaint joins claims that should be addressed separately. Federal Rule of Civil Procedure 20 permits joinder of claims arising out of “the same transaction [or] occurrence, or series of transactions or occurrences” and if “any question of law or fact common to all plaintiffs will arise in the action.” Fed. R. Civ. P. 20(a). Here, “[w]hile Plaintiffs’ claims may raise similar legal issues, they are not logically related because they do not arise from common operative facts.” *Barber v. Am.’s Wholesale Lender*, 289 F.R.D. 364, 367 (M.D. Fla. 2013); *Golden Scorpio Corp. v. Steel Horse Bar & Grill*, 596 F.Supp.2d 1282, 1285 (D. Ariz. 2009) (“[a] finding of a common question of law or fact does not necessarily mean that the claims against the

⁵ In any event, both the Emergency Declaration and the EUAs are clearly proper under the statutory standards. The February and March 2020 public health emergency determinations satisfy the standards for an emergency declaration under 21 U.S. Code § 360bbb-3(b)(1)(C) because they find a “public health emergency” that affects “national security or the health and security of United States citizens living abroad” that involves a “biological” agent—the novel coronavirus—and a disease caused by the coronavirus—COVID-19. *See* Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020); Emergency Use Authorization Declaration, 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020). FDA has authorized three COVID-19 vaccines pursuant to EUAs, based on FDA’s review of extensive safety and efficacy data. *See, e.g.*, ECF No. 23-14 at Exs. B, C; *see also* FDA, COVID-19 Vaccines, <https://perma.cc/5FWS-RJ5L>.

various defendants arise from a common transaction or occurrence”); *see also Wigand v. W. City Partners, Inc.*, No. 07-61492-CIV, 2008 WL 384394, at *1 (S.D. Fla. Feb. 11, 2008) (finding severance was warranted even when 43 plaintiffs all alleged that the form contract they all signed “fail[ed] to comply with the Federal Interstate Land Sales Full Disclosure Act” because the contracts were for “different units, on different dates, and for different prices”); *Walters*, 2019 WL 6251366, at *2 (finding severance was warranted due to “substantial factual differences among the Plaintiffs’ claims”). In their Free Exercise Clause and RFRA claims, Plaintiffs challenge the COVID-19 vaccination directive “as applied” to Plaintiffs. Second Am. Compl. ¶¶ 244–53, 256, 268–74, 276, 279. Each of the 31 Plaintiffs must independently demonstrate a substantial burden on “a belief, not a preference, that is sincerely held and religious in nature, not merely secular.” *GeorgiaCarry.org, Inc. v. Georgia*, 687 F.3d 1244, 1256 (11th Cir. 2012). For each Plaintiff who makes these showings, under RFRA, the burden shifts to the Government to “demonstrat[e] that the application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling government interest.” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006) (quoting 42 U.S.C. § 2000bb-1(b)). Each of these issues must be separately analyzed with respect to each Plaintiff.

Because each Plaintiff performs a different function in the military, the military considers their particular circumstances in determining whether the government’s compelling interest requires that each Plaintiff be vaccinated against COVID-19. For

example, the Navy assesses the need for a commander of 300 sailors onboard a destroyer to be vaccinated in light of the requirements of that particular job, while the Army, Marine Corps, Air Force, and Coast Guard do the same for different occupations (such as an Army Ranger, supervisor for new Marine recruits, an Air Force training instructor, or a Coast Guard pilot). Each Service has been conducting individualized assessments regarding whether vaccination is the least restrictive means to accomplishing its mission.

The Court would therefore review an individualized assessment of each Plaintiff's RFRA claim based on the record compiled by the relevant Military Department at the time of its eventual decision for each applicant. Assuming each Plaintiff's religious accommodation request is finally denied (which may not occur), adjudicating these claims together in one case would require judicial review of a separate administrative record for each finally denied religious accommodation request, in addition to the administrative record for the challenged DoD directive itself. That could be as many as 31 administrative records. In these circumstances, courts have found that severance is appropriate. *See, e.g., Coal. for a Sustainable Delta v. U.S. Fish & Wildlife Serv.*, No. 1:09-CV-480, 2009 WL 3857417, at *8 (E.D. Cal. Nov. 19, 2009) ("Each separate agency action will have a separate administrative record. Although there may be some overlap if similar information . . . was before each agency at the time of its decision . . . , each record will include extensive, unique, unrelated information about the different agency action in question."). Accordingly, because each religious exemption request is considered on an individualized basis, any final

denials are separate “transactions or occurrences” under Rule 20 such that joinder of Plaintiffs’ claims is improper. *See Barber*, 289 F.R.D. at 367 (noting that because “Plaintiffs’ claims involve conduct by different Defendants, different loan documents, different dates, and different operative factual scenarios,” the “individualized nature of Plaintiffs’ claims” rendered joinder improper).

“Even if joinder was technically appropriate under Rule 20(a), considerations of judicial economy, case management, prejudice to parties, and fundamental fairness dictate that Plaintiffs’ claims be severed under Rule 21.” *Id.* at 368 (citing *Coleman v. Quaker Oats Co.*, 232 F.3d 1271, 1296 (9th Cir. 2000); *In re Amergi ex rel. Amergi v. Palestinian Auth.*, 611 F.3d 1350, 1367 (11th Cir. 2010); *Anderson v. Moorer*, 372 F.2d 747, 750 n.4 (5th Cir. 1967); *Acevedo v. Allsup’s Convenience Stores, Inc.*, 600 F.3d 516, 521–22 (5th Cir. 2010)); *Torres*, 2017 WL 10398671, at *1–2. As described above, “[t]he fact-specific nature of the claims and defenses that have been, or will be, raised by the parties, precludes any conclusion that judicial economy would be served by joinder.” *Barber*, 289 F.R.D. at 368–69.

In addition, considerations of case management, prejudice to parties, and fundamental fairness warrant severance. “[A]llowing this case to proceed as filed would violate the principles of judicial resource allocation embodied in the separate docketing and random assignment protocols which are employed by federal courts to ensure equitable distribution of judicial workloads and efficient, timely, and impartial resolution of cases.” *Ahmed v. Miller*, 452 F. Supp. 3d 721, 727 (E.D. Mich. 2020). Here, only four of the 31 Plaintiffs allege that they have any connection to Florida

(much less the Middle District of Florida). *See* Second Am. Compl. ¶¶ 33, 37, 39, 64. Three Plaintiffs and one service member seeking to intervene in the case—none of whom have any connection with this venue in Florida—have filed emergency motions for temporary restraining orders (and the non-party even filed two such motions). *See* ECF Nos. 60, 94, 121, 130; *see also Barber*, 289 F.R.D. at 369 n.8 (finding that the number of docket entries at an early stage in the case illustrated the “procedural and case management difficulties associated with the joinder of so many plaintiffs”). Although separation proceedings are lengthy and do not warrant emergency motions, past behavior indicates that Plaintiffs will continue to file motions for temporary restraining orders once the military initiates separation proceedings. Aside from the burdens this would impose on the Court, the resolution of 31 motions for temporary restraining orders and preliminary injunctions, and judicial review of 31 different individualized administrative records concerning religious accommodation requests by service members throughout the country with no connection to this forum, is unnecessary. Rather, judicial review should be divided among courts in forums that have a closer relationship to the parties. Severing Plaintiffs’ claims and requiring them to proceed in a district where venue is proper will not prejudice those Plaintiffs because each will be able to pursue his/her claims in a proper venue.

Severance would be consistent with proceedings in another case in this district. In *Crosby v. Austin*, fifteen service members from five different military services challenged the DoD COVID-19 vaccination directive. Order, *Crosby v. Austin*, No.

8:21-cv-02730 (M.D. Fla. Feb. 22, 2022), ECF No. 44 at 1.⁶ All but one of the plaintiffs asserted objections to the vaccine requirement based on religion. *Id.* at 1–2. As in this case, the *Crosby* plaintiffs brought both facial and as-applied First Amendment and RFRA challenges to the DoD COVID-19 vaccination directive and a claim that the DoD directive violates the FDCA and 10 U.S.C. § 1107a. Compl., *Crosby v. Austin*, 8:21-cv-02730 (M.D. Fla. Nov. 19, 2011), ECF No. 1 ¶¶ 111–17, 159–73, Prayer For Relief ¶¶ C, D, F. And, similar to this case, “[o]nly one of the Plaintiffs ha[d] anything to do with the Middle District of Florida.” Order, *Crosby*, No. 8:21-cv-02730, ECF No. 44 at 2. The *Crosby* court found that “even if the fifteen Plaintiffs here satisfy the two-prong test for joinder, the differences between their claims are too numerous to promote judicial economy.” *Id.* at 3. The court further found that “it is clear that resolution of many of these claims – such as the religious claims – would require a separate analysis and involve different proof and different witnesses, located in various places across the country.” *Id.* The court concluded that severance “is necessary to promote judicial economy” and severed and dismissed without prejudice the claims of all plaintiffs except for the only plaintiff with any connection to the Middle District of Florida. *Id.* The Court should follow a similar path here.

⁶ The *Crosby* Order is attached as Exhibit 7 to this filing.

CONCLUSION

For these reasons, the Court should dismiss Plaintiffs' Second Amended Complaint. If the Court does not dismiss the case in its entirety, it should dismiss the FDCA, 10 U.S.C. §§ 1107 and 1107a claim and sever the remaining claims.

LOCAL RULE 3.01(g) CERTIFICATION

On March 18, 2022, undersigned counsel conferred via email with Plaintiffs' counsel, who represented that they oppose the relief sought in this motion.

Dated: March 18, 2022

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney
General

ALEXANDER K. HAAS
Director, Federal Programs Branch

ANTHONY J. COPPOLINO
Deputy Director

Respectfully submitted,

/s/ Courtney D. Enlow
ANDREW E. CARMICHAEL
AMY E. POWELL
Senior Trial Counsel
ZACHARY A. AVALLONE
COURTNEY D. ENLOW
CATHERINE YANG
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 616-8467
Email: courtney.d.enlow@usdoj.gov
Counsel for Defendants