

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO
Judge Raymond P. Moore

DAN ROBERT and **HOLLIE MULVIHILL**

Plaintiffs,

v.

LLOYD AUSTIN, in his official capacity as Secretary of Defense; **XAVIER BECERRA**, in his official capacity as Secretary of Health and Human Services; and **JANET WOODCOCK**, in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration,

Defendants.

Case No. 1:21-cv-02228-RM-STV

**DEFENDANTS' REPLY IN SUPPORT OF THEIR
MOTION TO DISMISS UNDER RULES 12(b)(1) AND 12(b)(6)**

Table of Contents

INTRODUCTION.....1

ARGUMENT.....2

 I. Plaintiffs’ Brief Is Riddled with Procedural Defects and Misstatements.....2

 A. Plaintiffs Filed an Untimely Response.....2

 B. Plaintiffs Cannot Rely on Claims by Non-Parties to Establish Jurisdiction.....2

 C. Plaintiffs Focus on a U.S. Navy Policy that Does Not Apply to Them.....4

 D. Plaintiffs Concede that Claims 2, 4, and 5 Should Be Dismissed.....5

 E. Plaintiffs Concede that Defendants Department of Health and Human Services
 and the Food and Drug Administration Should Be Dismissed from the Case.....5

 F. Plaintiffs Improperly Request that the Court Enter New Relief in Their Favor....6

 G. Plaintiffs Direct Baseless Allegations at Defendants.....6

 II. The Case Must Be Dismissed for Lack of Jurisdiction.....8

 III. Plaintiffs Fail to State a Claim Against the Department of Defense.....10

CONCLUSION.....14

INTRODUCTION

Plaintiffs' opposition to Defendants' motion to dismiss demonstrates that they have a fundamental misunderstanding of the posture of this case, jurisdiction, the military's policies and how they apply to Plaintiffs, the status of related litigation, and both the Federal Rules of Civil Procedure and this Court's Local Rules. Their brief effectively ignores the only two Plaintiffs in this case—U.S. Army Staff Sergeant (“SSG”) Dan Robert and U.S. Marine Corps Staff Sergeant (“SSgt”) Hollie Mulvihill—and instead focuses on purported claims by service members who are not parties to this case. In doing so, Plaintiffs fail to recognize that they cannot overcome their burden to establish jurisdiction by relying on non-parties' allegations. Similarly, Plaintiffs repeatedly refer to members of their two purported “classes,” without recognizing that they have not even filed a motion for class certification, much less that the Court has certified any class. And Plaintiffs focus on a new U.S. Navy policy that does not apply to members of the Army or the Marine Corps and thus does not affect either Plaintiff in this case.

In addition to these numerous errors, Plaintiffs baselessly accuse Defendants of making misrepresentations and ignoring court rulings. But Defendants have not made any misrepresentation to this or any other court. And although Plaintiffs imply that another court enjoined the Department of Defense's COVID-19 vaccine directive, no court has done so. In fact, since Defendants filed the motion to dismiss, two more courts have denied requests to enjoin DoD's COVID-19 vaccine directive. See *Oklahoma v. Biden*, No. 5:21-cv-01136-F, 2021 WL 6126230 (W.D. Okla. Dec. 28, 2021); *Guetlein v. U.S. Merchant Marine Academy*, 2021 WL 6015192 (E.D.N.Y. Dec. 20, 2021).

In sum, Plaintiffs' brief—filed two days late—makes baseless and irrelevant allegations and fails to address the majority of arguments raised in Defendants' motion to dismiss and instead, in contravention to this Court's Local Rules, seeks to add plaintiffs to the case and requests that the

Court enter forms of injunctive relief that Plaintiffs did not even seek in their Second Amended Complaint or motion for a preliminary injunction. The Court should deny these improper requests and dismiss the case.

ARGUMENT

I. Plaintiffs' Brief Is Riddled with Procedural Defects and Misstatements.

A. Plaintiffs Filed an Untimely Response.

Defendants filed their motion to dismiss on Tuesday, November 23. Plaintiffs' response was due three weeks later, on Tuesday, December 14. *See* D. Colo. R. 7.1(d)¹ (“The responding party shall have 21 days after the date of service of a motion, or such lesser or greater time as the court may allow, in which to file a response.”). But Plaintiffs, without seeking leave of the Court, filed their brief two days late, on Thursday, December 16. *See* D. Colo. R. 6.1(b) (setting requirements for seeking an extension of time). Because Plaintiffs failed to seek leave of the Court, the Court may disregard their late filing and dismiss the case for the reasons set forth in Defendants' Motion to Dismiss. *See Charles v. McConnell*, No. 20-CV-01596-RM-KMT, 2021 WL 2311477, at *2 (D. Colo. June 7, 2021) (denying leave to file an untimely response when the plaintiff “fails to offer any explanation as to why the request is so late, or any reason why the court should allow him to file a response to the motion to dismiss at this point in time”).

B. Plaintiffs Cannot Rely on Claims By Non-Parties to Establish Jurisdiction.

Plaintiffs spend a great deal of pages discussing purported claims by two individuals who are not parties to this case—Staff Sergeant (“SSgt”) Cami Long and Staff Sergeant (“SSG”) Steven Brown. *See* Pls.' Resp. 2–8, ECF No. 46. But Plaintiffs cannot rely on purported claims from service members

¹ The District Court modified its Local Rules effective December 1, 2021. The provisions cited in this brief were not amended.

who are not parties to this case to establish jurisdiction. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975) (stating that a “plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties”); *Thomas v. Metro. Life Ins. Co.*, 631 F.3d 1153, 1159 (10th Cir. 2011) (“[T]he named plaintiffs’ failure to maintain a live case or controversy is fatal to the case as a whole—that unnamed plaintiffs might have a case or controversy is irrelevant.” (citing *Clark v. State Farm Mut. Auto. Ins. Co.*, 590 F.3d 1134, 1138 (10th Cir. 2009)); *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 364 (3d Cir. 2015) (“Named plaintiffs are the individuals who seek to invoke the court’s jurisdiction and they are held accountable for satisfying jurisdiction.”).

Plaintiffs claim that two service members, SSgt Cami Long and SSG Steven Brown, “requested to be added as named plaintiffs.” Pls.’ Resp. 2. But Plaintiffs made such a request in a footnote to their reply in support of their motion for a preliminary injunction. *See* Pls.’ Reply 5 n.7, ECF No. 43. As an initial matter, because “[a]rguments raised in a perfunctory manner, such as in a footnote, are waived,” *United States v. Hardman*, 297 F.3d 1116, 1131 (10th Cir. 2002), “the Court need not address this argument,” *Swan Glob. Invs., LLC v. Young*, No. 18-CV-03124-CMA-NRN, 2019 WL 5095729, at *11 (D. Colo. Aug. 20, 2019), *report and recommendation adopted*, 2020 WL 897654 (D. Colo. Feb. 25, 2020). In any event, Plaintiffs have already amended their complaint twice and must seek leave from the Court to file another amended complaint. *See* Fed. R. Civ. P. 15(a)(2). Such a request must be made by a separate motion for leave to file a third amended complaint, not through a footnote in a reply brief. *See* D. Colo. R. 7.1(d) (“A motion shall not be included in a response or reply to the original motion. A motion shall be filed as a separate document.”). Because Plaintiffs failed to follow the local rules, the Court should disregard their request to amend their complaint. *See Ley v. Charles Schwab & Co., Inc.*, No. 18-CV-02207-MSK-STV, 2019 WL 2357064, at *1 (D. Colo. June 4, 2019) (“summarily denying” a motion that was filed as an attachment to the complaint instead of as a

separate document, as required by the Local Rules); *Scarborough v. United States*, No. 15-CV-00242-KLM, 2017 WL 1243014, at *8 (D. Colo. Mar. 17, 2017) (stating that because plaintiff did not file a motion as a separate document, “[p]laintiff’s request may be denied on this basis alone”).

Plaintiffs also claim that SSgt Long and SSG Brown are “eligible members of the plaintiff class.” Pls.’ Resp. 2. But there is no “class” in this case. Plaintiffs have not filed a motion for class certification, and the Court has not certified a class. *See Pasadena City Bd. of Ed. v. Spangler*, 427 U.S. 424, 430 (1976) (refusing to consider the matter as a class action because the district court never certified a class under Federal Rule of Civil Procedure 23); *Oldershaw v. DaVita Healthcare Partners, Inc.*, 255 F. Supp. 3d 1110, 1119 (D. Colo. 2017) (“[U]nless and until a class is certified, there is no class for the plaintiff to represent and thus, no class-based relief to be obtained.”).

Finally, even if the Court had certified a class, Plaintiffs nevertheless could not rely on allegations by members of the class to establish jurisdiction. “The usual rule in class actions is that to establish subject matter jurisdiction one looks only to the named plaintiffs and their claims.” *Pruell v. Caritas Christi*, 645 F.3d 81, 83 (1st Cir. 2011) (citing 5 W. Moore et al., Moore’s Federal Practice § 23.63[1] [b] (3d ed. 2011)); *Thomas*, 631 F.3d at 1159; *Denberg v. U.S. R.R. Ret. Bd.*, 696 F.2d 1193, 1197 (7th Cir. 1983) (en banc) (Where the “district court never had jurisdiction over the claim of the class representative . . . it had no jurisdiction over the class action either even if the claims of some of the members of the class were within its jurisdiction.”), *cert. denied*, 466 U.S. 926 (1984). Accordingly, Plaintiffs’ allegations related to SSgt Long and SSG Brown are entirely irrelevant to this case and must be disregarded.

C. Plaintiffs Focus on a U.S. Navy Policy That Does Not Apply to Them.

In addition to discussing the purported claims of non-parties, Plaintiffs spend several pages of their brief discussing a recently issued U.S. Navy policy that does not affect either Plaintiff. *See* Pls.’

Resp. 5–7 (discussing NAVADMIN 283/21). NAVADMIN 283/21 applies only to members of the U.S. Navy. *See* U.S. Navy, *ALNAV and NAVADMIN Messages*, <https://www.mynavyhr.navy.mil/References/Messages/> (last accessed Dec. 24, 2021) (stating that “ALNAVs [are] [m]essages directed to all Navy units and Marine Corps,” whereas “NAVADMINs [are] Navy specific administrative messages”). Because SSG Robert is in the Army and SSgt Mulvihill is in the Marine Corps, NAVADMIN 283/21 does not apply to them.

D. Plaintiffs Concede that Claims 2, 4, and 5 Should Be Dismissed.

Defendants moved to dismiss all five of Plaintiffs’ claims for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). *See* Defs.’ Mot. 12–27, ECF No. 36. However, Plaintiffs failed to address Defendants’ arguments concerning alleged violations of 10 U.S.C. § 1107 (Claim 2), 50 U.S.C. § 1520 (Claim 4), or the Equal Protection Clause (Claim 5). *See generally* Pls.’ Resp. Because Plaintiffs did not address these arguments, Plaintiffs have conceded that Claims 2, 4, and 5 should be dismissed. *See Trentman v. Salazar*, No. 2:08CV864 TC, 2010 WL 964426, at *1 (D. Utah Mar. 15, 2010); *Miles v. Ramsey*, 31 F. Supp. 2d 869, 875 (D. Colo. 1998). Thus, for the reasons set forth in Defendants’ motion, the Court should dismiss those claims.

E. Plaintiffs Concede that Defendants Department of Health and Human Services and the Food and Drug Administration Should Be Dismissed from the Case.

In their Second Amended Complaint, Plaintiffs brought two claims against the Department of Health and Human Services (“HHS”) and the Food and Drug Administration (“FDA”): an alleged violation of 10 U.S.C. § 1107a, 21 U.S.C. § 355, and DoDI 6200.02 by requiring service members “to submit to COVID-19 vaccinations in an EUA status” (Count 3), Second Am. Compl. ¶ 55, ECF No. 29, and an alleged violation of 50 U.S.C. § 1520 by requiring service members to “submit to COVID-19 vaccinations in any FDA status” (Count 4), *id.* ¶ 59. In their Response, Plaintiffs do not address

Defendants' arguments that neither HHS nor FDA have required service members to take any vaccine. *See generally* Pls.' Resp. Nor do Plaintiffs address Defendants' arguments that 10 U.S.C. § 1107a, 50 U.S.C. § 1520, and DoDI 6200.02 do not govern HHS or FDA, or that the COVID-19 vaccines administered to service members do not implicate 21 U.S.C. § 355, as none of the COVID-19 vaccines are being administered under the DoD directive to service members as part of an ongoing clinical trial. *See generally id.* The Court should treat all of these arguments as conceded, *Trentman*, 2010 WL 964426, at *1; *Miles*, 31 F. Supp. 2d at 875, and, for the reasons set forth in Defendants' motion, dismiss HHS and FDA from the case.

F. Plaintiffs Improperly Request that the Court Enter New Relief in Their Favor.

In contravention of Local Rule 7.1(d), Plaintiffs titled their brief as their "Response to Defendant's [*sic*] Motion to Dismiss and Request for Immediate Relief," Pls.' Resp. 1, and request that the Court issue an order to stop any discharges of service members, require Defendants to provide "a sworn statement regarding the reasons for beginning the mass discharge of members of the plaintiff class, including SSgt Long," and prohibit retaliation against Plaintiffs, *id.* at 10–11. But as explained above, Plaintiffs cannot seek new relief in opposition to Defendants' motion to dismiss. *See* D. Colo. R. 7.1(d). Such requests can be summarily denied for failure to follow the Local Rules. *Ley*, 2019 WL 2357064, at *1; *Scarborough*, 2017 WL 1243014, at *8.

G. Plaintiffs Direct Baseless Allegations at Defendants.

Throughout their brief, Plaintiffs accuse Defendants of "ignoring court rulings and continuing to persecute members of the Armed Forces." Pls.' Resp. 2. Plaintiffs apparently believe that the court in the related *Doe v. Austin* case has enjoined the military's COVID-19 vaccine directive or ordered the Department of Defense or the Military Services not to discharge service members for non-compliance with the directive. *See* Pls.' Resp. 7. But no court, including the *Doe* court, has enjoined the

Department of Defense’s COVID-19 directive or ordered the military to stop any discharge proceedings.² See *Doe v. Austin*, 2021 WL 5816632 (N.D. Fla. Nov. 12, 2021); *Church v. Biden*, 2021 WL 5179215 (D.D.C. Nov. 8, 2021); *Navy SEAL 1 v. Biden*, 2021 WL 5448970 (M.D. Fla. Nov. 22, 2021); *Guettlein v. U.S. Merchant Marine Academy*, 2021 WL 6015192 (E.D.N.Y. Dec. 20, 2021).

Plaintiffs also accuse Defendants of “willfully manipulating this Court’s jurisdiction by discharging named plaintiffs and other members of the plaintiff class.” Pls.’ Resp. 2; see also *id.* at 5. But neither SSgt Mulvihill nor SSG Robert have been discharged. To the contrary, they both have either a granted temporary exemption or a pending exemption request and neither would be discharged while they have an exemption or while their exemption request is pending. See Defs.’ Mot., Ex. 15 (Decl. of Darek Wilcox) ¶ 3, Ex. 16 (Decl. of Christopher Tilque) ¶ 9, ECF Nos. 36-16, 36-17. And, as explained above, the Court has not certified a class, so any claims regarding SSgt Long, SSG Brown, or any other non-party is inapposite. In short, there are no court orders preventing any discharge, and neither of the actual plaintiffs in this case has been discharged.

² Plaintiffs’ confusion concerning the effect of court rulings has extended to this case, as Plaintiffs’ counsel has supplied letters to service members to give to their commanders and has sent letters to commanders implying both that the Court has granted class certification and that the Court has preliminarily enjoined enforcement of the DoD COVID-19 vaccine directive:

I have advised all plaintiff members of both classes not to receive the shots while the litigation is pending because it would jeopardize their standing as members of the plaintiff classes. . . . [Service member] should be legally exempted from the shot until the court has ruled on the merits of the litigation. Attempts to interfere with a person’s rights and status in ongoing federal litigation will be referred to the judge for his consideration and action.

Ex. 1 (Letter from Dale F. Saran) (Oct. 5, 2021); see also Ex. 2 (Letter from Todd S. Callender to U.S. Air Force Lieutenant Colonel Jason A. Soto) (Dec. 20, 2021) (containing similar language).

II. The Case Must Be Dismissed for Lack of Jurisdiction.

As set forth in Defendant’s Motion to Dismiss, Plaintiffs’ claims are not ripe for judicial review because neither Plaintiff is currently required to take a COVID-19 vaccine as SSgt Mulvihill has a temporary medical exemption and SSG Robert’s exemption request remains pending. *See* Defs.’ Mot. 10–11. Defendants further explained that even if SSgt Mulvihill’s exemption expires or SSG Robert’s exemption is denied, and they refuse to comply with an order to take a COVID-19 vaccine, Plaintiffs’ claims still would not be ripe until the military’s administrative procedures have concluded. *Id.* at 11–12.

Plaintiffs do not dispute these facts. Instead, Plaintiffs rely on *Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004), and *Witt v. Department of the Air Force*, 527 F.3d 806 (9th Cir. 2008), to argue that there is “precedent for pleading by military plaintiffs in lieu of being punished and then asking for post-punishment relief.” Pls.’ Resp. 9. This argument misses the mark. As set forth in Defendants’ motion, neither SSgt Mulvihill nor SSG Robert are required to take the vaccine or face any adverse employment or disciplinary consequences for not taking the vaccine while they have an exemption or a pending exemption request. Defs.’ Mot., Ex. 6 (Fragmentary Order (“FRAGO”) 5 to Army Execute Order 225-21) ¶ 3.D.8.B.1.F, Ex. 13 (Decl. of Michele Soltis) ¶¶ 8, 17, 20, 24; Ex. 16 (Tilque Decl.) ¶¶ 10, 11, ECF Nos. 36-7, 36-14, 36-17. *Rumsfeld* is thus inapposite, as the court in that case found the plaintiffs had standing to challenge DoD’s anthrax vaccination requirement because they had all been “ordered to appear for the inoculation.” *See Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 131 (D.D.C. 2003). And Plaintiffs’ circumstances are much different from those in *Witt*, where the Ninth Circuit found that the plaintiff’s constitutional claims were ripe “on account of her long-term suspension.” 527 F.3d at 812; *see also id.* at 812–13 (finding that plaintiff’s procedural due process claim was “not ripe for adjudication” because “the record does not reflect what will appear on her discharge certificate”).

Because Plaintiffs’ theory of harm is “speculative and contingent upon [expiration of the exemption or denial of the exemption request]—an outcome that may never come to pass,” Plaintiffs have not met their burden of establishing that their claims are ripe. *See Church v. Biden*, No. CV 21-2815 (CKK), 2021 WL 5179215, at *10 (D.D.C. Nov. 8, 2021) (in a similar challenge to the DoD COVID-19 vaccine directive, finding that plaintiffs “failed to demonstrate a likelihood of success that their claims are ripe” while their exemption appeals were pending).

In addition, even if Plaintiffs’ exemption requests are eventually denied or expire, and they are ordered to get vaccinated or face adverse administrative or disciplinary consequences, numerous other courts have concluded that cases brought by service members to prevent adverse administrative or disciplinary actions by the military were not ripe. *See, e.g., Smith v. Harvey*, 541 F. Supp. 2d 8, 13 (D.D.C. 2008) (“No final decision on Smith’s separation has yet been made, and the separation board could well decide to retain her in the [U.S. Army Reserves], negating any need for judicial review.”); *Standage v. Braithwaite*, 526 F. Supp. 3d 56, 93–94 (D. Md. 2021); *Frame v. United States*, No. 409CV458-RH/WCS, 2010 WL 883804, at *3 (N.D. Fla. Mar. 5, 2010).

Plaintiffs also assert, without any explanation, that the declarations submitted by two individuals who are not plaintiffs in this case, SSgt Long and SSG Brown, establishes the Court’s jurisdiction over the case. *See* Pls.’ Resp. 2–8. But these declarations do not show that Plaintiff Mulvihill’s or Plaintiff Robert’s claims are ripe. *See generally* Long Decl., ECF No. 43-2; Brown Decl., ECF No. 43-3. And, although Plaintiffs argue that “SSgt Cami Long, USMC, resides in Colorado [and is] clearly within the ambit of this court’s jurisdiction,”³ Pls.’ Resp. 2, as explained above, the Court does not have jurisdiction over claims by other service members who are not parties to this case, and

³ Plaintiffs appear to conflate personal jurisdiction with subject matter jurisdiction. Whether an individual “resides in Colorado,” Pls.’ Resp. 2, is irrelevant to a ripeness analysis.

the alleged circumstances of those non-parties are immaterial to the Court's jurisdiction over the claims presented by the actual plaintiffs here, *see Thomas*, 631 F.3d at 1159.

Plaintiffs also contend that SSG Robert's exemption request is still pending because Defendants "control the entire exemption or religious accommodation process" in an attempt to "control the federal court's jurisdiction." Pls.' Resp. 3. The Court should give no credit to Plaintiffs' baseless allegation. "Government officials are presumed to act in good faith[.]" *Utah Env't Cong. v. MacWhorter*, No. 2:08-CV-118-SA, 2011 WL 4901317, at *7 (D. Utah Oct. 14, 2011). And absent a decision by the Army on SSG Robert's pending exemption request, there is no Article III case or controversy for the Court to review: SSG Robert is not presently injured and may not be injured.

Accordingly, because Plaintiffs fail to meet their burden of establishing jurisdiction, the Court should dismiss the case. *See Daniel v. Duetch Bank Nat. Tr. Co.*, No. 07-CV-01400MS, 2008 WL 536739, at *1 (D. Colo. Feb. 27, 2008) ("The party asserting the existence of subject matter jurisdiction—in this case, the Plaintiff—bears the burden of proving such jurisdiction exists.").

III. Plaintiffs Fail to State a Claim Against the Department of Defense.

As set forth in Defendants' motion, judicial review of the DoD COVID-19 vaccine directive under the Administrative Procedure Act ("APA") is highly deferential, particularly in a military setting; notice and comment rulemaking is not required; the directive is not contrary to Army Regulation ("AR") 40-562 (though the Secretary of Defense has the authority to modify such regulations); and the directive is not arbitrary and capricious or contrary to law, including the informed consent requirements set forth in 10 U.S.C. § 1107a. *See* Defs.' Mot. 12–23.

Plaintiffs appear to make only two arguments with respect to their claims against the Department of Defense, neither of which have merit. First, Plaintiffs argue that individuals who have been infected and recovered from COVID-19 are "presumptively excused from receiving a vaccine"

under AR 40-562. Pls.’ Resp. 8. But Plaintiffs ignore both the plain meaning of the regulation and the Government’s declarations. “[S]erologic or other tests can be used to identify pre-existing immunity from prior infections” only “[f]or *some* vaccine-preventable diseases,” Defs.’ Mot., Ex. 5 (AR 40-562) ¶ 2-1.g (emphasis added), ECF No. 36-6, and under AR 40-562, service members “with previous infections or positive serology are not automatically exempt from full vaccination requirements,” Defs.’ Mot., Ex. 13 (Soltis Decl.) ¶ 11, Ex. 14 (Decl. of Peter D. Huntley) ¶ 7, ECF Nos. 36-14, 36-15. Although Plaintiffs claim that prior infection “matters for every other respiratory or other virus or other inoculation,”⁴ Pls.’ Resp. 8–9, that is not the case. As the Government’s declarations make clear, many diseases such as “Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus,” “do not mount long-standing immunity,” Defs.’ Mot., Ex. 11 (Decl. of Tonya Rans) ¶¶ 22–23, ECF No. 36-12, such that prior infection does not necessarily mean that a service member will be exempt from a vaccination on that basis, Defs.’ Mot., Ex. 13 (Soltis Decl.) ¶ 11, ECF No. 36-14.

Plaintiffs rely on an out-of-circuit district court case, *Louisiana v. Becerra*, for the proposition that the “rejection of natural immunity as an alternative is puzzling.” Pls.’ Resp. 9 (quoting *Louisiana v. Becerra*, No. 3:21-CV-03970, 2021 WL 5609846, at *13 (W.D. La. Nov. 30, 2021)). As an initial

⁴ To the extent Plaintiffs argue that testing individuals for current COVID-19 infection is inconsistent with DoD’s determination that service members with previous COVID-19 infection are not considered fully vaccinated, *see* Pls.’ Resp. 8–9, that argument misses the mark. Tests to determine whether an individual currently has COVID-19 are meant to inform the individual about their current condition, and whether, for example, an individual needs to isolate to prevent spreading the virus. *See* Centers for Disease Control and Prevention (“CDC”), *COVID-19 Testing: What You Need to Know* (Dec. 6, 2021), <https://perma.cc/VB69-LCK7>. Those tests serve a different purpose from serology tests, which “can detect antibodies to SARS-CoV-2 in [the] blood.” *Id.* According to the CDC, such testing is “not currently recommended to determine . . . [w]hether you need to get vaccinated if you are not fully vaccinated.” *Id.*; *see also* Defs.’ Mot., Ex. 11 (Rans Decl.) ¶ 19 (describing the differences between the types of tests and noting that FDA guidance states that “results from a serology test should not be used to find out if you have immunity from the virus”).

matter, the Eleventh Circuit Court of Appeals considered and rejected the same “natural immunity” argument presented by the State of Florida in a challenge to the same vaccine directive, finding that “Florida essentially seeks to substitute its views on epidemiology for the Secretary’s judgment about the best way to protect the public from infection.” *Florida v. Dep’t of Health & Hum. Servs.*, 19 F.4th 1271 (11th Cir. 2021). The Eleventh Circuit further found that courts are “not authorized to substitute our judgment for the agency’s as long as its conclusions are rational” and determined that the Centers for Medicare and Medicaid Services’ (“CMS”) rejection of “natural immunity” as a reason to be exempt from the vaccine requirement was not arbitrary and capricious. *Id.* (quotation omitted).

In any event, the *Louisiana* court criticized the CMS vaccine directive because it did not explain what evidence the agency was relying upon to conclude that “‘natural immunity’ is not equivalent to receiving the COVID-19 vaccine.” 2021 WL 5609846, at *13 (quoting 86 Fed. Reg. 61555, 61559 (Nov. 5, 2021)). In contrast, DoD’s immunization policies make clear that they are developed in accordance with recommendations from the CDC. *See* Defs.’ Mot., Ex. 2 (Secretary of Defense Memorandum (Aug. 24, 2021)), Ex. 4 (DoD Instruction 6205.02) ¶ 1.2(a), Ex. 11 (Rans Decl.) ¶ 19, ECF Nos. 36-3, 36-5, 36-12. As explained in Defendants’ motion, the CDC recommends that individuals who have previously been infected get vaccinated based on studies showing that individuals who had previously been infected were more likely to get COVID-19 again than those who had been fully vaccinated. *See* Defs.’ Mot. 17–18. And courts have upheld vaccine requirements even where (unlike here) the plaintiffs presented “the existence of some scientific debate surrounding . . . whether ‘natural immunity’ from prior COVID-19 infection provides comparable . . . protection from the virus.” *Troogstad v. City of Chicago*, No. 21 C 5600, 2021 WL 6049975, at *5 (N.D. Ill. Dec. 21, 2021); *see also Bauer v. Summey*, No. 2:21-CV-02952-DCN, 2021 WL 4900922, at *12 (D.S.C. Oct. 21, 2021); *Am.’s Frontline Drs. v. Wilcox*, No. EDCV 21-1243 JGB (KKx), 2021 WL 4546923, at *5 (C.D. Cal. July

30, 2021). DoD’s determination, based on the CDC’s recommendations, that prior infection does not render a service member automatically exempt from the vaccination requirement is not arbitrary, capricious, or contrary to law.

Second, Plaintiffs argue that DoD is mandating an unlicensed product in violation of 10 U.S.C. § 1107a because “Comirnaty isn’t available and it can’t be available as a matter of law.”⁵ Pls.’ Resp. 10. But, again as Defendants previously explained, the FDA has stated that vaccines produced at facilities listed in Pfizer’s Biologics License Application (“BLA”) and released in accordance with BLA requirements “are manufactured in compliance with the BLA” and “are not subject to the [Emergency Use Authorization (“EUA”)] requirements when used for the approved indication.” Defs.’ Mot., Ex. 10 (Decl. of Peter Marks) ¶ 14 & Ex. C at 27 (identifying BLA lots), ECF No. 36-11.

Plaintiffs accuse defense counsel of “misle[a]d[ing]” the *Doe* court “during oral argument” concerning the availability of Comirnaty. Pls.’ Resp. 9–10. But, as the *Doe* opinion shows, during oral argument, defense counsel *corrected* an inadvertent error in the briefing and made clear that DoD “was mandating vaccines from EUA-labeled vials.” 2021 WL 5816632, at *5. Defendants asserted in *Doe*, consistent with Defendants’ position in this case, that DoD possesses “hundreds of thousands of BLA-compliant vaccine doses that are EUA-labeled, and is using them.” *Id.* at *6; *see also* Defs.’ Mot. 21 (quoting Defs.’ Mot. Ex. 11 (Rans Decl.) ¶ 18, ECF No. 36-12). The *Doe* court found that “[i]f the DOD is, in fact, administering Comirnaty (albeit EUA-labeled Comirnaty), the plaintiffs’ § 1107a issue disappears.” 2021 WL 5816632, at *6. The *Doe* court then concluded that because “no plaintiff claims

⁵ Plaintiffs do not explain why Comirnaty “can’t be available as a matter of law.” *See* Pls.’ Resp. 10. To the extent Plaintiffs are arguing that a vaccine cannot be produced under both an EUA and an approved BLA, Plaintiffs are incorrect for the reasons set forth in Defendants’ motion. *See* Defs.’ Mot. 21–22. And, in any event, Plaintiffs did not challenge the FDA’s grant of the EUA or approval of the BLA, *see* Second Am. Compl., so any such argument is inapposite.

he or she was specifically denied a BLA-compliant dose or offered only a dose from a non-BLA-compliant vial,” “plaintiffs have not shown a likelihood of success.” *Id.* The same reasoning holds true here: neither SSG Robert nor SSgt Mulvihill claim that they were specifically denied a BLA-compliant dose or offered only a dose from a non-BLA-compliant vial. *See generally* Second Am. Compl. Accordingly, Plaintiffs’ claim under 10 U.S.C. § 1107a should be dismissed.

CONCLUSION

For the foregoing reasons and for those set forth in Defendants’ Motion to Dismiss, the case should be dismissed.

Dated: December 30, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

ALEXANDER K. HAAS
Director, Federal Programs Branch

ANTHONY J. COPPOLINO
Deputy Director

/s/ Courtney D. Enlow
ANDREW E. CARMICHAEL
AMY E. POWELL

Senior Trial Counsel

STUART J. ROBINSON

Senior Counsel

ZACHARY A. AVALLONE

COURTNEY D. ENLOW

LIAM HOLLAND

Trial Attorneys

Department of Justice, Federal Programs Branch

1100 L Street, N.W., Washington, DC 20005

Tel: (202) 616-8467

Email: courtney.d.enlow@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2021, I electronically filed the foregoing paper with the Clerk of Court using this Court's CM/ECF system, which will notify all counsel of record of such filing.

/s/ Courtney D. Enlow
COURTNEY D. ENLOW
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 616-8467
Fax: (202) 616-8470
Email: courtney.d.enlow@usdoj.gov

Table of Exhibits

Reply Exhibit Number	Exhibit Description
1.	Letter from Dale F. Saran (Oct. 5, 2021)
2.	Letter from Todd S. Callender (Dec. 20, 2021)

Reply Exhibit 1

Dale Saran
Attorney at Law

19744 W. 116th Ter.
Olathe, KS 66061

Phone: 800.670.2577
email: dalesaran@gmail.com

05 October 2021

Dear Sir/Ma'am,

I am one of the attorneys of record who filed the civil action *Robert, Mulvihill, et al. v. Department of Defense (DoD), Food and Drug Administration (FDA), et al.*, in Colorado federal district court, #1:21-cv-2228. That case challenges the mandatory vaccine program launched by Secretary of Defense Lloyd J. Austin's Aug. 24, 2021, Memorandum on behalf of two classes of plaintiffs:

- (1) all members of the armed forces who have been ordered to receive vaccination with anything other than a product "fully licensed" by the FDA because that explicitly violates federal law (21 U.S.C. §360bbb-3);
- (2) all members of the armed forces who have already had COVID-19 and therefore have already-acquired, natural immunity.

The second class of plaintiffs are presumptively exempt from being vaccinated against a virus that they have already had, in accordance with longstanding and well-established principles of immunology and virology, which are contained in DoD Instruction AR 40-562¹ - regardless of the licensure status of any vaccine against COVID-19. AR 40-562, ¶2-6, expressly exempts service members from vaccination who have previously had an infection from the same virus.

I have advised all plaintiff members of both classes not to receive the shots while the litigation is pending because it would jeopardize their standing as members of the plaintiff classes. Kristie A. Stefinsky is a member of the class of plaintiffs. Kristie A. Stefinsky should be legally exempted from the shot until the court has ruled on the merits of the litigation. Attempts to interfere with a person's rights and status in ongoing federal litigation will be referred to the judge for his consideration and action.

Sincerely,


DALE F. SARAN
Attorney at Law
MA Bar #654781

Copy to: file

¹ The all-service publication also goes by different service specific names, including AFI 48-110, BUMEDINST 6230.15B, and CG COMDTINST M6230.4G.

Reply Exhibit 2



DISABLED RIGHTS ADVOCATES, PLLC

CHAMPIONS FOR INDIVIDUAL LIBERTIES

BY REGULAR MAIL AND EMAIL:

December 20, 2021

Jason A. Soto, Lt Col, USAF
Commander, 350th Recruiting Squadron
2902 Mcguire blvd, Mcguire AFB, NJ, 08641

RE: Robert et al v. Austin et al in reference to SSgt. Casey Belieu

Dear Lt Col. Soto:

I am one of the attorneys of record who filed the civil action Robert, Mulvihill, et al. v. Department of Defence (DOD), Food and Drug Administration (FDA), et al., in Colorado federal district court, #1:21-cv-2228. That case challenges the mandatory vaccine program launched by Secretary of Defence Lloyd J. Austin's Aug. 24, 2021, Memorandum on behalf of two classes of plaintiffs:

- (1) all members of the armed forces who have been ordered to receive vaccination with anything other than a product "fully licensed" by the FDA because that explicitly violates federal law (21 U.S.C. §360bbb-3);
- (2) all members of the armed forces who have already had COVID-19 and therefore have already-acquired, natural immunity.

The second class of plaintiffs are presumptively exempt from being vaccinated against a virus that they have already had, in accordance with longstanding and well-established principles of immunology and virology, which are contained in DoD Instruction AR40-5621-regardless of the licensure status of any vaccine against COVID-19. AR 40-562, ¶2-6, expressly exempts service members from vaccination who have previously had an infection from the same virus.

I have advised all plaintiff members of both classes to reject the shots while the litigation is pending because it would jeopardize their standing as members of the plaintiff classes. SSgt. Casey Belieu is a member of the class of plaintiffs and as such, should be exempted from the shot/s until the Court has ruled on the merits of the litigation. Attempts to interfere with a person's rights and status in ongoing federal litigation will be referred to the judge for his consideration and action.



**DISABLED RIGHTS
ADVOCATES, PLLC**

CHAMPIONS FOR INDIVIDUAL LIBERTIES

Thanks in advance for your understanding and cooperation in this matter.

Sincerely,

Todd S. Callender, Esq.
Attorney for the Plaintiffs