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' COMBINED OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION (ECF NO. 30) AND DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

In warfare, disease has historically accounted for more service member deaths than battlefield injuries. The current Department of Defense ("DoD") immunization program, which has been in place for decades, requires that all service members obtain nine immunizations, and an additional eight may be required depending on circumstances like deployment. In the midst of a deadly pandemic that has killed over 770,000 Americans, DoD added a vaccine for COVID-19 to the long list of immunizations already required for service members. Plaintiffs—two service members currently exempt or seeking an exemption from the vaccination requirement—seek an order enjoining the COVID-19 vaccination requirements for the entire U.S. military, based on their (incorrect) belief that the DoD mandate requires use of an unlicensed vaccine. They also seek an order that the Military Services grant a medical exemption for anyone claiming to have had a previous infection by COVID-19, despite the military's judgment that such a previous infection is insufficiently protective. The injunction Plaintiffs seek would be extraordinary and unprecedented, particularly as the Supreme Court has consistently cautioned against judicial interference in military affairs.

As set forth further below, Plaintiffs' motion for a preliminary injunction should be denied, and this lawsuit should be dismissed, because none of Plaintiffs' claims are justiciable. One plaintiff has been granted a temporary medical exemption from the vaccination requirement and the other has an exemption request pending. Neither will suffer any adverse employment or disciplinary consequences for non-compliance while they have an exemption or a pending exemption request. In these circumstances, any alleged present or future injury is entirely speculative and insufficient to establish the Court's jurisdiction. Even if exemptions are denied or expire and all administrative appeals have been exhausted, the military is entitled to determine in the first instance what course of action to take before any judicial review proceeds.

Plaintiffs also fail to show any likelihood of success on the merits required to obtain extraordinary preliminary injunctive relief. Plaintiffs' claims under the Administrative Procedure Act ("APA") fail because DoD's actions and requirements for vaccinations are plainly reasonable and consistent with all relevant statutory and regulatory requirements. DoD has properly required administration of a vaccine approved by the Food and Drug Administration ("FDA") and made reasonable judgments about military needs. Moreover, although Plaintiffs name FDA and the Department of Health and Human Services ("HHS") as defendants, they allege no cognizable claim against them and, for that reason alone, those Defendants should be dismissed.

The remaining injunction factors also favor Defendants. Plaintiffs cannot establish irreparable harm because they are not going to be forcibly vaccinated, and none of their other claimed injuries are irreparable. Moreover, immunization requirements have been commonplace in the military for generations and are critical to reducing infectious disease morbidity and mortality in the armed forces where service members must routinely operate in close quarters. An injunction against DoD's requirements for a COVID-19 vaccine would degrade military readiness, undermine the efforts to combat the deadly coronavirus, and harm national security.

This Court previously denied Plaintiffs' motion for a temporary restraining order against the DoD vaccine directive, and three other courts have already denied service members' similar motions for preliminary injunctions. *See Church v. Biden*, 2021 WL 5179215 (D.D.C. Nov. 8, 2021); *Doe v. Austin,* 3:21-cv-1211-AW, slip op. (N.D. Fla. Nov. 12, 2021), ECF No. 47; *Navy Seal 1 v. Biden*, 8:21-cv-02429-SDM-TGW, 2021 U.S. Dist. LEXIS 224656 (M.D. Fla. Nov. 22, 2021). The Court should likewise deny Plaintiffs' motion and grant Defendants' motion to dismiss the case.

BACKGROUND

I. The COVID-19 Pandemic

The virus SARS-CoV-2 causes a disease known as COVID-19 that "spreads when an infected person breathes out droplets and very small particles that contain the virus." Centers for Disease Control and Prevention ("CDC"), *How COVID-19 Spreads*, https://perma.cc/4ZBC-8WYQ.[1] In January 2020, the then-Secretary of HHS declared a public health emergency because of COVID-19. HHS, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), https://perma.cc/VZ5X-CT5R.

In July 2021, the United States began to experience "a rapid and alarming rise in . . . COVID-19 case[s] and hospitalization rates," driven by the Delta variant, an especially contagious strain. *See* CDC, *Delta Variant*, https://perma.cc/4RW6-7SGB. Community transmission rates remain high in 40 states and substantial in ten other states. *See* CDC, *COVID Data Tracker*, https://perma.cc/QQN6-THKC. And daily case rates are once again increasing. *Id.* To date, more than 47,000,000 Americans have been infected, and more than 770,000 Americans have died from COVID-19. *Id.* In DoD alone, "there have been 252,658 cases" of COVID-19 in service members, "of which 2,280 have required hospitalizations and led to 76 deaths." Ex. 12 (Decl. of Scott Stanley) ¶ 3. Of those 76 service members, "none were fully vaccinated." *Id.* Moreover, many "otherwise healthy Service members have developed 'long-haul' COVID-19, potentially impacting their long-term ability to perform their missions." Ex. 11 (Decl. of Tonya Rans, M.D.) ¶ 9.

II. Federal Regulation of and Guidance Concerning the COVID-19 Vaccines

In response to the widening pandemic, the rapid spreading of infections, significant increases in hospitalizations and, in some cases, overloaded facilities, as well as substantial increases in daily and

[1] The Court may take judicial notice of factual information available on government websites. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322–23 (2007).

weekly death tolls, the Government undertook urgent efforts to work with private companies to develop vaccines for COVID-19. *See* Ex. 10 (Decl. of Peter Marks, M.D., Ph.D) ¶ 15. Based on the determination by the Secretary of HHS that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic," EUA Declaration, 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020), FDA issued "emergency use authorizations" ("EUAs") for COVID-19 vaccines developed by Pfizer, Inc. and BioNTech Manufacturing Gmbh (for ease of reference, the joint venture will be referred to as "Pfizer"), and two other manufacturers, *see* Ex. 10 ¶ 7 & Ex. B. An EUA authorizes the marketing of vaccines (and other FDA-regulated products) "intended for use" in responding to an emergency. 21 U.S.C. § 360bbb-3. The EUAs for the COVID-19 vaccines were based on FDA's review of extensive safety and efficacy data, including from a Pfizer clinical trial with approximately 46,000 participants. Ex. 10, Ex. B. Starting in 2020, EUA-approved vaccines were available throughout the nation to begin inoculations, and more than 350 million doses of COVID-19 vaccines were administered under the EUAs between December 2020 and August 2021. *See* CDC, *Trends in Number of COVID-19 Vaccinations in the US*, https://perma.cc/L2VD-UBRJ.

On August 23, 2021, FDA approved Pfizer's Biologics License Application ("BLA") for its vaccine to prevent COVID-19 in individuals 16 years of age and older, meaning that it has received licensure for that use. Ex. 10 ¶ 6 & Ex. A. This means that the vaccine, having successfully completed "the agency's standard process for reviewing the quality, safety and effectiveness of medical products," is no longer available only through an EUA.[2] FDA, *News Release – FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://perma.cc/C4DD-PWE5. Upon approval of Pfizer's BLA, FDA also

[2] "Even after FDA approved Comirnaty, [the trade name for the approved Pfizer vaccine], FDA authorized continued use of the Pfizer-BioNTech Covid-19 vaccine under an EUA for indications that included the approved use." Ex. 10 ¶ 8.

considered the safety and effectiveness of the vaccine for individuals who previously had COVID-19, and FDA identified no safety or efficacy concerns for that population. *See* Ex. 10 ¶¶ 24–25.

III. Department of Defense COVID-19 Vaccine Directive

The U.S. military instituted its first immunization program in 1777 when General Washington directed the inoculation of the Continental Army for smallpox. *See* Stanley Lemon, et al., *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the US Military*, National Academies Press, 2002, *available at* https://perma.cc/E545-TQ9G. Deaths due to infectious diseases outnumbered those due to direct combat injuries until World War II, after vaccines became widespread. *Id.* at 3. More recently, infectious disease accounted for nearly 70% of U.S. Army Hospital admissions during the Persian Gulf War. *Id.* at 10. Military-mandated vaccines have played a key role in reducing infectious disease morbidity and mortality among military personnel. *Id.*, Table 1-1. For decades, the military has implemented a variety of enduring or situational inoculation measures to maintain the readiness of the force. *Id.*; *see also* Ex. 9 (Congressional Research Service, Defense Health Primer: Military Vaccinations).

The Department of Defense's immunization program is governed by DoD Instruction ("DoDI") 6205.02. Nine vaccines are required for all service members, including the annual influenza vaccine, while eight others are required when certain elevated risk factors are present. *See* Ex. 5 (Army Regulation ("AR") 40-562), Table D-1.[3] In general, DoD aligns its immunization requirements and eligibility determinations for service members with recommendations from the CDC and its Advisory Committee on Immunization Practices. Ex. 4 (DoDI 6205.02) at 3. The Military Services have separately issued regulatory guidance for the administration of vaccines to service members including

[3] Army Regulation 40-562 applies to all the Military Services, as well as the U.S. Coast Guard. *See* Ex. 5.

processes to seek medical and religious exemptions. *See* Ex. 5, Chapter 2.6.

On August 9, 2021, the Secretary of Defense, noting the impact COVID-19 rates have on military readiness, announced that he would add the COVID-19 vaccine to the list of vaccines required for all service members by the earlier of mid-September or upon approval by FDA. *See* Ex. 1 (Mem. for all Defense Employees (Aug. 9, 2021)). On August 24, 2021, after FDA announced the approval of the Pfizer COVID-19 vaccine, the Secretary directed the Secretaries of the Military Departments to immediately begin full vaccination of all members of the armed forces under DoD authority who were not already fully vaccinated. *See* Ex. 2 (Mem. For Senior Pentagon Leadership, Commanders of the Combatant Commands, Defense Agency and DoD Field Activity Directors (Aug. 24, 2021)). Only FDA-licensed vaccines are required, in accordance with FDA labeling and guidance. *Id.*

Shortly thereafter, the Military Services issued guidance for implementing the DoD directive. As with other vaccine requirements, Service implementation guidance establishes a process to seek medical and religious exemptions. *See* Ex. 6 (Fragmentary Order ("FRAGO") 5 to Army Executive Order 225-21) ¶ 3.D.8.B.6; Ex. 8 (MARADMIN 462/21) ¶¶ 3j, 3k. Each Service has an appeal process available to service members seeking exemptions if their initial requests are denied. *See, e.g.*, Ex. 13 (Decl. of Michele Soltis) ¶¶ 13, 17, 19, 20 (Army); Ex. 14 (Decl. of Peter Huntley), ¶ 12.b (Marines).

A service member who refuses vaccination without an approved exemption may be subject to discipline or adverse administrative action. *See, e.g.*, Ex. 6 ¶¶ 3.D.8.B.1.A–E. But adverse action will not be taken against a service member with a pending exemption request. Ex. 6 ¶ 3.D.8.B.1.F; Ex. 13 ¶¶ 8, 17, 20, 24; Ex. 14 ¶¶ 9 n.5, 12.7. Only senior military officers may initiate adverse action for refusing vaccination. *See* Ex. 6 ¶ 3.D.8.B.2; Ex. 8 ¶ 3.l.

IV. Procedural History

On August 17, 2021, Plaintiffs Dan Robert, a Staff Sergeant in the U.S. Army,[4] and Hollie Mulvihill, a Staff Sergeant in the U.S. Marine Corps, filed suit against DoD, HHS, and FDA, challenging the DoD directive. *See* Compl., ECF No. 1. On August 30, 2021, Plaintiffs filed a motion for a temporary restraining order, *see* TRO Mot., ECF No. 7, which the Court denied, *see* Order, ECF No. 8. Plaintiffs then filed two motions for a preliminary injunction and an amended complaint on September 23 and 24, all of which have been superseded by later filings.

Plaintiffs filed their second amended complaint ("SAC") on October 6, 2021. Plaintiffs allege that they have previously been infected with COVID-19 and do not want to take any COVID-19 vaccine, and they purport to represent a class of all service members. *See* SAC 1–3, ECF No. 29. Plaintiffs raise five claims: (1) DoD violated the APA by issuing the directive contrary to its own regulations, *id.* ¶¶ 45–48; (2) DoD violated 10 U.S.C. § 1107 and DoDI 6200.02 by requiring service members "to submit to COVID-19 vaccinations with an unlicensed [Investigational New Drug (IND)], or a vaccine 'unapproved for its applied use' status," *id.* ¶ 51; (3) DoD, HHS, and FDA violated 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," *id.* ¶ 55; (4) DoD, HHS, and FDA violated 50 U.S.C. § 1520 by requiring service members to "submit to COVID-19 vaccinations in any FDA status," *id.* ¶ 59; and (5) DoD violated Plaintiffs' Equal Protection rights by treating individuals who have previously been infected differently from those who have been vaccinated, *id.* ¶ 63.

[4] Plaintiff Dan Robert is described as "an infantryman currently on active duty stationed at Fort Bragg, North Carolina." *See* Second Amended Complaint ("SAC") ¶ 1, ECF No. 29. He is in fact a Drill Sergeant stationed at Fort Benning in Georgia. *See* Ex. 15 ¶ 2 (Decl. of Darek Wilcox). In addition, although Plaintiffs' later filings refer to him as "Daniel Robert," the initial complaint and the paperwork he submitted to the Army list his name as "Dan Robert." *See* Compl., ECF No. 1; Ex. 15 attachments.

On November 2, 2021, Plaintiffs filed their operative motion for a preliminary injunction.[5] Plaintiffs request that the Court order DoD to stop compelling service members to get vaccinated, to exempt all service members who have had COVID-19 from the vaccination requirement, and to refrain from taking any adverse administrative or disciplinary action against service members who refuse to comply with the DoD directive.[6] *See* Mot. 23, ECF No. 30.

LEGAL STANDARDS

I. Motion to Dismiss

"The federal courts are courts of limited subject-matter jurisdiction." *Gad v. Kan. State Univ.*, 787 F.3d 1032, 1035 (10th Cir. 2015). Plaintiffs bear the burden of establishing jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). "When the court lacks subject matter jurisdiction over a claim for relief, dismissal is proper under Rule 12(b)(1)." *Brito v. Denver Convention Ctr. Hotel Auth.*, 2021 WL 4149619, at *2 (D. Colo. Sept. 13, 2021).

For a motion under Rule 12(b)(6), the Court assesses "whether the complaint contains enough facts to state a claim to relief that is plausible on its face." *Ridge at Red Hawk, L.L.C. v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007). In evaluating a claim's plausibility, a court "need not accept . . . conclusory allegations." *S. Disposal, Inc., v. Tex. Waste*, 161 F.3d 1259, 1262 (10th Cir. 1998).

II. Preliminary Injunction

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v.*

[5] Plaintiffs represent that they "attempted to confer with counsel for Defendants." Mot. ¶ 10. But Plaintiffs' counsel did not contact undersigned counsel concerning their motion, despite having counsel's contact information.

[6] Plaintiffs argue that without a preliminary injunction Defendants "will continue to violate the federal rights of . . . federal contractors." Mot. ¶ 5. But Plaintiffs did not bring a challenge to any vaccine requirements for federal contractors. *See generally* SAC. Nor could they, as they would not have standing to raise such a challenge.

NRDC, 555 U.S. 7, 24 (2008). To justify such a remedy, "the movant must establish that four equitable factors weigh in its favor: (1) it is substantially likely to succeed on the merits; (2) it will suffer irreparable injury if the injunction is denied; (3) its threatened injury outweighs the injury the opposing party will suffer under the injunction; and (4) the injunction would not be adverse to the public interest." *Beltronics USA, Inc. v. Midwest Inventory Distrib., LLC*, 562 F.3d 1067, 1070 (10th Cir. 2009).[7]

ARGUMENT

I. Plaintiffs Seek a Preliminary Injunction That Is Specifically Disfavored.

As an initial matter, the preliminary injunction that Plaintiffs seek is the type of preliminary injunction that is "specifically disfavored" in this Circuit. *Schrier v. Univ. of Colo.*, 427 F.3d 1253, 1259 (10th Cir. 2005). Plaintiffs request, among other things, that this Court "ensure that individual service members with preexisting COVID-19 exposure for serological immunity are given an exemption under Defendant DoD's regulations." Mot. 23. But such a preliminary injunction would operate as a mandatory injunction by ordering DoD to take action by granting all requests for permanent medical exemptions based on previous COVID-19 infection and would thereby alter the status quo. *See Fish v. Kobach*, 840 F.3d 710, 723–24 (10th Cir. 2016) (describing disfavored injunctions). Because Plaintiffs seek a specifically disfavored injunction, they "must 'make[ ] a strong showing both with regard to the likelihood of success on the merits and with regard to the balance of harms.'" *Id.* at 724 (quoting *Beltronics*, 562 F.3d at 1071). Plaintiffs cannot meet their heightened burden.

[7] Contrary to Plaintiffs' contention, *see* Mot. ¶ 12 and as this Court has recognized, "The Tenth Circuit no longer applies a 'modified test' for determining temporary or preliminary injunctive relief" because it is "inconsistent with" the Supreme Court's decision in *Winter*. *Martin/Martin, Inc. v. Kling Stubbins, Inc.*, 2019 WL 2357303, at *1 (D. Colo. June 4, 2019) (Moore, J.) (citing *Diné Citizens Against Ruining Our Env't v. Jewell*, 839 F.3d 1276, 1282 (10th Cir. 2016)).

II. Plaintiffs Are Unlikely to Succeed on the Merits of Their Claims.

This Court lacks jurisdiction over of Plaintiffs' claims because they are not yet ripe. This lack of jurisdiction forecloses any finding of substantial likelihood of success on the merits. *Wideman v. Colorado*, 2007 WL 757639, at *9 (D. Colo. Mar. 8, 2007). Even if they could establish jurisdiction, Plaintiffs cannot show that they are likely to succeed on any of their five claims. Accordingly, no preliminary injunction is warranted, and Plaintiffs' claims should be dismissed.

A. Plaintiffs' Claims Are Not Yet Ripe for Judicial Review.

Plaintiffs' primary grievance appears to be that they will be required to receive an "unlicensed drug of unknown long-term safety profile" and that they will be "subject to or threatened with disciplinary action under the Uniform Code of Military Justice ("UCMJ"), including adverse administrative action that would characterize [their] voluntary service as 'other than honorable[,]'" if they refuse to comply with the DoD directive. SAC ¶¶ 48, 52, 56, 60, 64. But these claims are not ripe for judicial review because they rest upon "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (1985). Moreover, in the present context where "[c]ivilian courts must, at the very least, hesitate long before entertaining a suit which asks the court to tamper with the established relationship between enlisted military personnel and their superior officers[,]" *Bois v. Marsh*, 801 F.2d 462, 468 (D.C. Cir. 1986), Plaintiffs' claims must be particularly scrutinized for ripeness.

Here, Staff Sergeant Mulvihill has sought and obtained a temporary medical exemption from the COVID-19 vaccination requirement, and that medical exemption is expected to be renewed for

several more months. Ex. 16 (Decl. of Christopher Tilque) ¶ 9.[8] Similarly, Staff Sergeant Robert has sought an exemption from the vaccination requirement. Ex. 15 (Decl. of Darek Wilcox) ¶ 3. That request is pending, and he will not be required to receive the COVID-19 vaccination during the pendency of that request. *Id.* Accordingly, neither Plaintiff is facing a "direct and immediate dilemma" as a result of the challenged DoD directive. *Wyoming v. Zinke*, 871 F. 3d 1133, 1143 (10th Cir. 2017) (quoting *Awad v. Ziriax*, 670 F.3d 1111, 1125 (10th Cir. 2012)). Plaintiffs' only potential "hardship" is uncertainty as to the outcome of the exemption request (or in the case of Staff Sergeant Mulvihill, the renewal of that exemption), and this is not enough to demonstrate ripeness. *See Isenbarger v. Farmer*, 463 F. Supp. 2d 13, 20–21 (D.D.C. 2006) (uncertainty of time required to stay on active duty not sufficient to show ripeness); *see also Nat'l Parks Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 811 (2003) (explaining that if "mere uncertainty" constituted hardship "courts would soon be overwhelmed with requests for what would essentially be advisory opinions").

Even if the exemptions are denied or expire, and if Plaintiffs then refuse to comply with an order to receive the vaccination and face adverse action, the case still would not be ripe. The military has extensive administrative procedures that offer them multiple opportunities to present their arguments to their Service and for their Service to respond. *See* Ex. 13 ¶¶ 21–23 (Army); Ex. 14 ¶¶ 13–21 (Marines). Anyone subject to discipline can challenge the lawfulness of the vaccination requirement in those military proceedings. *See United States v. Kisala*, 64 M.J. 50 (C.A.A.F. 2006). For adverse action less than discharge, each Service has administrative procedures that can provide relief.

[8] At Plaintiffs' counsel's request, the government has redacted portions of Captain Tilque's declaration because it identifies Plaintiff's medical condition. On November 23, 2021, Plaintiffs' counsel indicated that Plaintiffs intend to file a motion under Local Rule 7.2 to restrict access to the unredacted declaration within a week. In the event the Court denies Plaintiffs' forthcoming motion or Plaintiffs do not file the motion within a week, Defendants will file the unredacted Tilque declaration on the public docket.

See Ex. 13 ¶¶ 21–22 (Army); Ex. 14 ¶¶ 13–14 (Marines). And should Plaintiffs be discharged for non-compliance with the DoD directive, they can appeal to the applicable Discharge Review Boards and Boards of Correction of Military Records. *See* Ex. 13 ¶ 23 (Army); Ex. 14 ¶ 22 (Marines). As another Court recently found in a nearly identical context, review of Plaintiffs' claims without first allowing the military's internal administrative process to conclude would "infringe on the military's expertise and interest in handling its own personnel matters." *Church*, 2021 WL 5179215 at *23. Until those processes are complete, Plaintiffs' claims are not ripe. *See Shaw v. Austin*, 2021 WL 1840397, at *10 (D.D.C. May 1, 2021); *Standage v. Braithwaite*, 526 F. Supp. 3d 56, 93–94 (D. Md. 2021); *Diraffael v. Cal. Mil. Dep't*, 2011 WL 13274364, at *3 (C.D. Cal. Mar. 21, 2011); *Vaughan v. Ky. Army Nat'l Guard*, 2013 WL 211075, at *6 (E.D. Ky. Jan. 18, 2013).

B. The DoD Directive Complies with the APA.

Plaintiffs raise several APA claims and contend these are grounds for enjoining the Secretary's decision to add a COVID-19 vaccine licensed by FDA to the list of inoculations required by service members.[9] Each argument is without merit.

1. The Court's APA Review Is Limited to Whether the Military Followed Applicable Law, Regulation, and Procedure.

The Court's review of any agency action under the APA must be "deferential" and "narrow." *Dep't of Commerce v. New York,* 139 S. Ct. 2551, 2569 (2019). Review under the APA does not permit the Court to "substitute its own policy judgment for that of the agency," but "simply ensures that the agency has acted within a zone of reasonableness" and "has reasonably considered the relevant issues

[9] In Counts Two, Three, and Four, Plaintiffs allege violations of 10 U.S.C. § 1107, 10 U.S.C. § 1107a, and 50 U.S.C. § 1520. SAC ¶¶ 49–60. Because none of these three statutes contain a private right of action, *see, e.g.*, *Norman v. Campbell*, 87 F. App'x 582, 584 (7th Cir. 2003), an action seeking review of these allegedly unlawful agency actions may only be brought under the APA, which is the presumptive mechanism for reviewing agency action, *see Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 614–15 (2012).

and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). In the present setting, the Court's review is even more deferential. *See 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.). "This deferential standard is calculated to ensure that the courts do not become a forum for appeals" for every military member, "a result that would destabilize military command and take the judiciary far afield of its area of competence." *Stewart v. Spencer*, 344 F. Supp. 3d 147, 153 (D.D.C. 2018) (applying deferential standard to service member APA claims) (quoting *Cone v. Caldera*, 223 F.3d 789, 793 (D.C. Cir. 2000)).

Moreover, judicial review of military decisions under the APA is limited to whether the military followed proper law, regulation, and procedure. "The merits of a service secretary's decision regarding military affairs are unquestionably beyond the competence of the judiciary to review." *Daniels v. United States*, 947 F. Supp. 2d 11, 19 (D.D.C. 2013) (quoting *Adkins v. United States,* 68 F.3d 1317, 1322 (Fed. Cir. 1995)); *Hill v. Dep't of Air Force*, 844 F.2d 1407, 1408 (10th Cir. 1988) (agreeing "that 1) courts are not permitted to second-guess the merits or wisdom of military or national security decisions [and] 2) the only proper basis for review of a military or national security decision is to determine whether pertinent procedural regulations were followed"). Accordingly, because the Secretary's decision to add the COVID-19 vaccine to the list of nine other vaccines required by all service members is unquestionably a military decision and did not violate any law, regulation, or procedure, the merits of that decision are not subject to judicial review.

2. Notice and Comment Rulemaking Is Not Required.

Plaintiffs claim that the Secretary's directive violates the APA because it allegedly modified DoD and Army regulations without going through notice-and-comment rulemaking procedures. Mot. ¶ 46. But Congress has specifically exempted agency policy involving a "military or foreign affairs

function of the United States" from the APA's rulemaking provisions. 5 U.S.C. § 553(a)(1). DoD and the Military Services frequently issue Directives, Instructions, and Manuals pertaining to the manning, equipping, and training of the armed forces—none of which are subject to notice and comment.[10] As one court has already found, the Secretary's directive requiring service members to receive the approved COVID-19 vaccine (unless otherwise exempt) to maintain the medical readiness of the force is one of many issuances falling within this exemption. *See Doe v. Austin,* slip op. at 8–10; *see also United States v. Mingo*, 964 F.3d 134 (2d Cir. 2020) (DoD designation of military offenses constituting a sex offense falls within military function exemption of 5 U.S.C. § 553(a)(1)); *McDonald v. McLucas*, 371 F. Supp. 837 (S.D.N.Y. 1973); *Am. Fed'n of Gov't Emps. v. McNamara*, 291 F. Supp. 286, 289 (M.D. Pa. 1968).[11]

3. The DoD Directive Is Not Contrary to Army Regulation 40-562.

Plaintiffs next argue that the DoD directive violates the APA because it is contrary to Army Regulation 40-562. Mot. 14–15. But the Secretary of Defense unequivocally has the authority to modify Army regulations. The Constitution confers authority over the military upon the executive and legislative branches of government. *Lindenau v. Alexander*, 663 F.2d 68, 70 (10th Cir. 1981). Under this authority, Congress has long since delegated the responsibility for the manning, equipping, and training of the armed forces to the Military Service Secretaries. *See* 10 U.S.C. §§ 7013, 8013, 9013. This authority specifically includes administering to the "welfare" of service members, *id.*, and it has

[10] DoD Issuances are available online at https://www.esd.whs.mil/DD/DOD-Issuances/ (last accessed Nov. 20, 2021).

[11] In addition to being exempt from normal rulemaking procedures as a military function, the DoD directive is also "a matter relating to agency management or personnel" and is therefore exempt from rulemaking provisions pursuant to 5 U.S.C. § 553(a)(2). *See Harmon v. Thornburgh*, 878 F.2d 484 (D.C. Cir. 1989) (DOJ drug-free workforce plan exempt from rulemaking requirements as a matter related to agency management or personnel under 5 U.S.C. § 553(a)(2)).

been used to institute vaccine mandates for service members during more than two centuries of armed conflict, *see* Ex. 9. In 1947, Congress put these authorities under the direction, authority, and control of the Secretary of Defense. *See* 50 U.S.C. § 3002; 10 U.S.C. § 113(b); *see also* 10 U.S.C. §§ 7013(b)(9), 8013(b)(9),9013 (b)(9). Accordingly, as a superior to the Secretary of the Army, both statutorily and within the military chain of command, the Secretary of Defense may modify an Army regulation.

Moreover, Plaintiffs misread both the DoD directive and AR 40-562. AR 40-562, titled "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases," applies to all the Military Services and provides requirements for the military's vaccination program. *See* Ex. 5. Pursuant to AR 40-562, service members may seek a medical exemption from an immunization requirement. *See id.* ¶ 2-6a. The DoD directive does not eliminate the procedures for service members to obtain a medical exemption; rather, it incorporates them. Ex. 2 (vaccination requirement "subject to any identified contraindications and any administrative or other exemptions established in Military Department policy"); *see also* Ex. 6 (allowing soldiers to pursue exemptions in AR 40-562).

Plaintiffs contend that AR 40-562 "presumptively exempts from vaccination service members whom the military knows have a previously documented infection with the disease for which the vaccination is being ordered." Mot. 14. Not so. Instead, the regulation makes clear that the decision to grant a medical exemption from an immunization requirement is made by a health care provider on a case-by-case basis, taking into consideration an individual's health and the nature of the immunization. Ex. 5 ¶ 2-6a ("Health care providers will determine a medical exemption based on the health of the vaccine candidate and the nature of the immunization under consideration."); *see also* Ex. 13 ¶ 11 ("[E]xemptions are not presumptive in nature but rather are granted after review of an individual's circumstances and the nature of the request on a case-by-case basis."). AR 40-562 provides "[g]eneral examples of medical exemptions," which include, among other things, "[e]vidence

of immunity based on serologic tests, documented infection, or similar circumstances." Ex. 5 ¶ 2-6a(1)(b). The regulation cautions, however, that "serologic or other tests can be used to identify pre-existing immunity from prior infections" only "[f]or *some* vaccine-preventable diseases." *Id.* ¶ 2-1.g (emphasis added). Therefore, service members "with previous infections or positive serology are not automatically exempt from full vaccination requirements." Ex. 13 ¶ 11; *see also* Ex. 14 ¶ 7. There is no automatic exemption based on prior infection because "natural infection for some diseases, in some cases, can result in longstanding immunity (e.g., measles)," whereas other diseases, such as "Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus," "do not mount long-standing immunity." Ex. 11 ¶¶ 22–23; *see also* Ex. 13 ¶ 11. Thus, while a service member who had the measles may be granted an exemption from the requirement to get the measles vaccine based on his prior infection, a service member who previously had the flu may not be granted an exemption from the requirement to get the influenza vaccine on that basis. *See* Ex. 13 ¶ 11. Thus, Plaintiffs' interpretation of AR 40-562 as requiring a presumptive exemption to a vaccine requirement on the basis of prior infection is incorrect, and, as shown in Part II.B.4, DoD's determination that individuals who have had COVID-19 are not presumptively exempt from the vaccine requirement is rational.

4. The DoD Directive Is Not Arbitrary and Capricious.

Even if the Court were permitted to review the merits of the Secretary's directive, it would easily survive such a review. DoD policy—long predating the COVID-19 pandemic—is to make immunization requirement and eligibility determinations for DoD personnel "in accordance with recommendations from the [CDC] and its Advisory Committee on Immunization Practices." Ex. 4 at 3. In accordance with this policy, military regulations require 17 vaccinations upon entry into the service, as part of a routine immunization cycle during service, or upon elevated risk factors. *See* Ex. 5, Table D-1. And currently the "CDC recommends everyone ages 5 and older get a COVID-19

vaccine to help protect against COVID-19." CDC, https://perma.cc/52FF-3FCN.

In his August 9, 2021 memorandum, the Secretary noted the rise in COVID-19 infection rates due to the Delta variant, and after "consult[ing] closely with the Chairman of the Joint Chiefs of Staff, the Secretaries of the Military Departments, the Service Chiefs, and medical professionals," he announced his intention to "seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the [FDA] licensure, whichever comes first." Ex. 1. Then, upon FDA approval of the Pfizer vaccine and "[a]fter careful consultation with medical experts and military leadership, and with the support of the President," the Secretary "determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people." Ex. 2. Accordingly, the Secretary added the FDA-approved COVID-19 vaccine to the list of "[m]andatory vaccinations [] familiar to all of our Service members," *id.*, consistent with DoD policy, Ex. 4 at 3. This is more than enough to substantiate the Secretary's decision. *See Mazares v. Dep't of Navy*, 302 F.3d 1382, 1385 (Fed. Cir. 2002) ("The military has broad authority and discretion in dealing with its personnel, both military and civilian, including the protection of their health.").

With regard to "natural immunity" against COVID-19, DoD, in reliance on CDC guidance, has assessed that because there is insufficient data concerning both the length of time antibodies stay in the body following infection and the level of antibodies necessary to indicate that an individual is protected from infection, "a medical exemption based on the history of COVID-19 disease or serology results does not meet 'evidence of immunity'" and the "presence of antibodies" does not make an individual immune. Ex. 11 ¶¶ 19–24; *see also* Ex. 13 ¶ 11. And the CDC's recommendation that individuals who have previously been infected get vaccinated is based on, among other things, a study that "showed that unvaccinated people who already had COVID-19 are more than 2 times as

likely than fully vaccinated people to get COVID-19 again." CDC, *Frequently Asked Questions about COVID-19 Vaccination* (updated Nov. 5, 2021), https://perma.cc/S3BT-257B. Another study conducted by the CDC made similar findings and concluded that "[a]ll eligible persons should be vaccinated against COVID-19 as soon as possible, including unvaccinated persons previously infected with SARS-CoV-2." Catherine Bozio, et al., *Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021*, Morbidity and Mortality Weekly Report (MMWR) (Oct. 29, 2021), https://perma.cc/R4HU-82YF; *see also* Ex. 11 ¶¶ 20–21. Accordingly, DoD's determination that prior infection does not render a service member automatically exempt from the vaccination requirement is grounded in the CDC's medical guidance and is not contrary to AR 40-562. *See Valdez v. Grisham*, WL 4145746, at *8 (D.N.M. Sept. 13, 2021) (rejecting the plaintiffs' argument that it was irrational for the government to "fail[] to take into account that 'Covid-recovered individuals have equal to or better immunity response than vaccinated individuals'"), *appeal filed*, No. 21-2105 (10th Cir. Sept. 15, 2021).

5. The DoD Directive Does Not Otherwise Violate Federal Law.

Next, Plaintiffs argue that DoD's directive violates 10 U.S.C. § 1107 and § 1107a, 21 U.S.C. § 355, and DoD Instruction 6200.02. SAC ¶¶ 45–56; Mot. 8–15. As an initial matter, Plaintiffs have failed to state a claim against HHS and FDA because the vaccine directive was issued by DoD alone, in reliance on FDA guidance. *See* Ex. 2. Nor have Plaintiffs sought any relief with respect to FDA or HHS or identified an FDA or HHS action that could have violated the cited statutory provisions.

Second, Plaintiffs lack standing to raise this claim because no injury would be ameliorated if they were ordered to take only the licensed vaccine. Plaintiffs do not dispute that the licensed vaccine and the EUA vaccine are medically interchangeable. *See* Mot. 9–12 (arguing only that the BLA and EUA vaccines are "legally distinct"). Moreover, as discussed in more detail below, the licensed vaccine

is available, negating Plaintiffs' standing to challenge use of the unlicensed doses. *Cf. Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (Kavanaugh, J.) (explaining that availability of vaccines other than the ones to which plaintiffs objected eliminated plaintiffs' standing). Two courts recently denied motions for preliminary injunctions on behalf of service members where "no plaintiff claims he or she was specifically denied a BLA-compliant dose or offered only a dose from a non-BLA-compliant vial." *Doe v. Austin*, slip op. at 15–16; *Navy Seal 1 v. Biden*, 2021 U.S. Dist. LEXIS 224656, at *7–9. Similarly, these Plaintiffs have not alleged that they have been denied a dose of the licensed vaccine.

In any event, Plaintiffs misunderstand the cited provisions. As shown above, Congress has given the Secretary of Defense and Military Services wide latitude in establishing a vaccination program for the armed forces. Although Plaintiffs claim that authority has been restricted by 10 U.S.C. § 1107 and § 1107a, which sometimes require the provision of certain notices, those circumstances are not applicable to the facts of this case.

Section 1107 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*, 2019 WL 6312008, at *2 (D.D.C. Nov. 25, 2019); Ex. 10 ¶ 7 n.2. Similarly, DoD Instruction 6200.2 applies to the use of investigational new drugs for force health protection. DoD's COVID-19 vaccine directive does not implicate these provisions, as none of the COVID-19 vaccines provided to service members are investigational new drugs (meaning, provided in the context of clinical trials) or drugs unapproved for their applied use. *See* Ex. 10 ¶¶ 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.").[12]

10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3 concern products authorized for "emergency use," which are separate and distinct from the drugs described in 10 U.S.C. § 1107. DoD's directive does not contravene those statutes either; DoD has not required that service members receive COVID-19 vaccines approved only for emergency use. As the Secretary's memorandum makes clear, "Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure . . . in accordance with FDA-approved labeling and guidance." Ex. 2. Guidance from the Services contains similar provisions. *See* Ex. 6 ¶ 3.D.8.A; Ex. 7 (ALNAV 062/21) ¶ 3; Ex. 8 ¶ 2.

Pfizer's COVID-19 vaccine, under the name Comirnaty, obtained FDA approval for its intended use by people aged 16 years and older. Ex. 10 ¶ 6 & Ex. A. In approving 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." *Id.* ¶ 9 & Ex. B at 10.[13] DoD relied on this determination, as well as FDA guidance that health care providers may "use doses distributed under the EUA to administer

[12] Plaintiffs also cite 21 U.S.C. § 355 for the proposition that Defendants "illegally required members of the class of Plaintiffs to submit to COVID-19 vaccinations in an EUA status." *See* SAC ¶ 55. To the extent Plaintiffs were referring to the regulation of "investigational new drugs" under Section 355(i), *see* SAC ¶ 31, Section 355(i) imposes several requirements on the administration of drugs in clinical trials, including that participants in clinical trials generally must consent to participation, subject to exceptions. As discussed above, COVID-19 vaccines administered to service members under the mandate are not investigational new drugs being administered as part of a clinical trial. To the extent Plaintiffs refer to restrictions on drugs governed by Emergency Use Authorizations, those are governed instead by 21 U.S.C. § 360bbb-3.

[13] Until very recently, the Pfizer EUA vaccine was always the same formulation as the licensed vaccine. Ex. 10 ¶ 10. On October 29, 2021, FDA amended the EUA to include a modified formulation of the Pfizer vaccine for use in children 5 through 11 years old (referred to as the "Tris formulation"). *Id.* The agency additionally authorized a version of the Tris formulation for those 12 years of age and older population. *Id.* FDA determined that the "12 and older" version of the Tris formulation may be used interchangeably with Comirnaty and the original formulation of the EUA vaccine. *Id.* The Tris formulation for those 12 years of age and older, however, is not currently available in the U.S. *Id.*

the series as if the doses were the licensed vaccine," to instruct its health care providers. Ex. 3 (Acting Assistant Secretary of Defense Memorandum).[14]

In addition, according to FDA, vaccines produced at facilities listed in Pfizer's BLA and released in accordance with BLA requirements "are manufactured in compliance with the BLA" and "are not subject to the EUA requirements when used for the approved indication." Ex. 10 ¶ 14 & Ex. C at 27 (identifying BLA lots). These vaccines are manufactured in compliance with the BLA even though they bear the EUA label. *Id.* ("[The] conditions in the Letter of Authorization for the EUA—including the condition requiring vaccination providers to provide recipients with the Fact Sheet for Recipients, which advises recipients that 'under the EUA, it is your choice to receive or not receive the vaccine'—do not apply when these lots or other BLA-compliant lots are used for the approved indication"). "As of November, 2021, the DoD has received hundreds of thousands of BLA-manufactured, EUA-labeled vaccine doses, and is using them." Ex. 11 ¶ 18. Plaintiffs do not plausibly allege any facts to the contrary.

Even though they did not raise this claim in their complaint, *see generally* SAC, Plaintiffs also argue in a single paragraph in their motion that the EUA must be improper because a vaccine cannot be the subject of both an EUA and a biologics license, *see* Mot. 11. To the extent this paragraph implies a challenge to the EUA itself, the EUA statute explicitly states that HHS's "[a]ctions under

[14] FDA included this interchangeability clarification in the authorization letter "to avoid the unnecessary operational complications that may have resulted if pharmacies or other healthcare practitioners had believed that the authorization did not include use in individuals who had received Pfizer-BioNTech for the first dose and Comirnaty for the second dose, or vice versa." Ex. 10 ¶ 10. Plaintiffs confuse this factual finding with the statutory interchangeability determination under a separate subsection of the Public Health Service Act. *See* Mot. 10 (citing 42 U.S.C. § 262(k)(4)). Under Section 262(k)(4), FDA may make a statutory interchangeability determination when reviewing a BLA for a biological product manufactured by one company and comparing it with a product manufactured by another company. But FDA did not make a statutory interchangeability finding under (k)(4). Ex. 10 ¶ 11. FDA made a scientific determination, based on FDA's technical expertise and consistent with its statutory authority. *See also Doe v. Austin*, slip op. at 22–23 (rejecting similar argument).

the authority of this section . . . are committed to agency discretion" and are therefore unreviewable. *See* 21 U.S.C. § 360bbb-3(i); *Ass'n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (holding that EUAs are unreviewable); *Jensen v. Biden*, No. 4:21-CV-5119-TOR, 2021 U.S. Dist. LEXIS 224094, at *13–14 (E.D. Wash. Nov. 19, 2021) (same); *see also* 5 U.S.C. § 701(a)(2). Plaintiffs' contention is also wrong. Even if the Comirnaty vaccine were sufficiently available to meet the needs of the population, which it is not, the statute grants FDA discretion to decide whether or when to revoke existing EUAs. *See* 21 U.S.C. § 360bbb-3(g)(2) (discretionary, permissive standards for revocation). The statute allows for an EUA to continue after an approval of an equivalent product, even if certain other standards are no longer met.[15]

Accordingly, because the DoD directive only requires service members to be vaccinated with licensed vaccines, Plaintiffs have not stated an informed consent claim. *See Doe v. Austin*, slip op. at 15–16 (finding no likelihood of success on service members' informed consent claim); *Navy Seal 1 v. Biden*, 2021 U.S. Dist. LEXIS 224656, at *7–9 (same); *Norris v. Stanley*, 2021 WL 3891615, at *2 (W.D. Mich. Aug. 31, 2021) (no likelihood of success on EUA claim because it "would be moot" if plaintiff were offered the FDA-approved Pfizer vaccine); *Valdez*, 2021 WL 4145746, at *4 (rejecting claim that state vaccine mandate violated the EUA statute because "the FDA has now given its full approval –

[15] Plaintiffs' citation to 21 U.S.C. § 360bbb-3(b) provides no evidence to the contrary. That subsection addresses the issuance and termination of a declaration of a public health emergency, not the revocation of a product-specific EUA, which is addressed in subsection (g). Although subsection (b)(2)(A)(ii) states that a declaration of a public health emergency terminates on a "a change in the approval status of the product such that the circumstances [requiring emergency use authorization] have ceased to exist," *id.*, that is not the case here. Even if the change in approval status coincided with the relevant conditions ceasing to exist (a contention that plaintiffs have not demonstrated), Comirnaty has not been approved for all emergency uses. *See id.* § 360bbb-3(a)(2)(B). Moreover, the declaration of a public health emergency for COVID-19 covers EUAs for hundreds of drugs, biologics, and medical devices. Plaintiffs provide no reason to interpret the statute to revoke the enabling declaration of a public health emergency covering all of these products based on a change in approval status for any one of them.

not just emergency use authorization – to the Pfizer vaccine").

C. Plaintiffs Fail to Show a Likelihood of Success on the Merits for Claims They Did Not Address in their Motion.

Plaintiffs' motion for a preliminary injunction does not even mention their fourth or fifth causes of action—alleged violations of 50 U.S.C. § 1520 and the Fourteenth Amendment—let alone explain why Plaintiffs are likely to succeed on the merits of these claims. *See generally* Mot. Assuming they are seeking a preliminary injunction based in part on these claims, Plaintiffs have failed to meet their burden of showing that they are entitled to injunctive relief. *See RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1208 (10th Cir. 2009). And by failing to make any argument concerning the likelihood of success on the merits on Counts 4 and 5 in their opening brief, they have waived any such argument. *See Bohner v. Colvin*, 2015 WL 1815977, at *11 (D. Colo. Apr. 20, 2015). Even if they had briefed the issues, Plaintiffs are unlikely to succeed on the merits of either claim and dismissal of those claims is warranted.

1. DoD, HHS, and FDA Did Not Violate a Repealed Statute or the Current Version of a Statute Concerning Testing on Human Subjects.

Plaintiffs allege that DoD, HHS, and FDA violated 50 U.S.C. § 1520 by "illegally requir[ing] [service members] to submit to COVID-19 vaccinations in any FDA status." SAC ¶ 59. Here again, Plaintiffs have failed to state a claim against HHS and FDA because those two agencies are not requiring Plaintiffs or any service members to get the COVID-19 vaccine. *See* Ex. 2.

Moreover, 50 U.S.C. § 1520 was repealed in 1998. *See* Omnibus Consolidated and Emergency Supplemental Appropriations Act, Pub. L. No. 105–277, 112 Stat. 2681, 2886 (1998). Plaintiffs cannot obtain relief against any Defendant based on a statute that was repealed more than 20 years ago. *See Martinez v. Grisham*, 2020 WL 6507377, at *1 (D.N.M. Nov. 5, 2020).

Presumably, Plaintiffs intended to bring a claim under 50 U.S.C. § 1520a, which concerns

restrictions on DoD on the use of human subjects for testing of chemical or biological agents.[16] *See Ash v. Minnesota*, 2021 WL 2289738, at *1 n.1 (D. Minn. May 19, 2021) (recognizing that 50 U.S.C. § 1520 "has been repealed and the relevant language is now located at § 1520a"). However, even if Plaintiffs had pled such a claim, they have no likelihood of success on the merits. Plaintiffs have cited nothing to show that mandating that service members take an FDA-licensed vaccine is the equivalent of "testing of a chemical agent or biological agent on human subjects." 50 U.S.C. § 1520a(a)(2); *see United States v. Schwartz*, 61 M.J. 567, 570 (N-M Ct. Crim. App. 2005) (rejecting a similar argument), *aff'd*, 64 M.J. 199 (C.A.A.F. 2006). Likewise, Plaintiffs do not and cannot allege that this FDA-licensed vaccine, found to be safe and effective in preventing disease, including being found to be safe when administered to individuals previously infected with the infectious disease that it aims to prevent, can meet the statutory definition of "biological agent." *See* 50 U.S.C. § 1520a(e) (defining "biological agent" as an agent that causes "death, disease, or other biological malfunction," or environmental or material degradation).

Instead, Plaintiffs invoke experiments by "Nazi doctors" to argue that it is illegal to require service members "to submit to COVID-19 vaccinations in any FDA status." SAC ¶¶ 59, 59 n.8. Courts have consistently found such arguments to be entirely meritless. *See, e.g.*, *Bridges v. Houston Methodist Hosp.*, 2021 WL 2399994, at *2 (S.D. Tex. June 12, 2021) (further finding such argument to be "reprehensible"), *appeal filed*, No. 21-20311 (5th Cir. June 14, 2021); *Doe v. Franklin Square Union Free Sch. Dist.*, 2021 WL 4957893, at *20 n.24 (E.D.N.Y. Oct. 26, 2021), *appeal filed*, No. 21-2759 (2d Cir. Nov. 2, 2021).

[16] The provisions of this statute do not apply to HHS or FDA, so even if Plaintiffs intended to bring a claim under 50 U.S.C. § 1520a, they nevertheless could not state a claim against these two agencies. *See* 50 U.S.C. § 1520a.

2. The DoD Directive Does Not Violate Principles of Equal Protection.

Plaintiffs allege that DoD violated the Fourteenth Amendment's Equal Protection Clause by treating individuals who have had COVID-19 differently from those who have been vaccinated against COVID-19. SAC ¶ 63. But Plaintiffs cannot state a claim against DoD under the Fourteenth Amendment because "actions of the Federal Government and its officers are beyond the purview of the Amendment." *District of Columbia v. Carter*, 409 U.S. 418, 424 (1973).

Presumably, Plaintiffs intended to allege that DoD violated the equal protection component of the Fifth Amendment's Due Process Clause. *See Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 217–18 (1995). "Equal protection is essentially a direction that all persons similarly situated should be treated alike." *Dalton v. Reynolds*, 2 F.4th 1300, 1308 (10th Cir. 2021) (citation omitted). "[T]o assert a viable equal protection claim, plaintiffs must first make a threshold showing that they were treated differently from others who were similarly situated to them." *Barney v. Pulsipher*, 143 F.3d 1299, 1312 (10th Cir. 1998). Plaintiffs "must then demonstrate that the [government's] differential treatment of [them] cannot pass the appropriate standard of scrutiny." *Dalton*, 2 F.4th at 1308.

Plaintiffs identify the two classes that they allege the DoD directive treats disparately as individuals who have vaccine-induced immunity and individuals who have infection-induced immunity. SAC ¶ 63. Because DoD's vaccine mandate does not "categorize[] persons based on suspect classifications, such as race and national origin," or "on 'quasi-suspect' classifications, such as gender and illegitimacy," *Save Palisade FruitLands v. Todd*, 279 F.3d 1204, 1210 (10th Cir. 2002), the Court must apply rational-basis review, asking "whether the government's classification bears a rational relation to some legitimate end," *Dalton*, 2 F.4th at 1308; *see also Kheriaty v. Regents of Univ. of Cal.*, 2021 WL 4714664, at *7 (C.D. Cal. Sept. 29, 2021) (applying rational basis review to a claim that a vaccine policy treated individuals who had been previously infected differently from those who had

been vaccinated).

Rational-basis review "is a paradigm of judicial restraint." *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313–14 (1993). Under this standard, the challenged agency action enjoys "a strong presumption of validity," and the challenger bears "the burden to negative every conceivable basis which might support it" without regard to "whether the conceived reason for the challenged distinction actually motivated the [decision-maker]." *Id.* at 314–15 (quotation omitted). Under rational-basis review, if Plaintiffs fail to negate every conceivable reason for DoD's directive, not limited to the reasons advanced by the Government, their equal protection claim fails. *See Heller v. Doe*, 509 U.S. 312, 320 (1993); *see also ETP Rio Rancho Park, LLC v. Grisham*, 2021 WL 4478383, at *33–35 (D.N.M. Sept. 30, 2021) (applying this standard to uphold state executive orders issued to combat COVID-19).

DoD's directive easily survives rational-basis review, especially given the judiciary's "healthy deference to . . . executive judgments in the area of military affairs." *Rostker*, 453 U.S. at 66 (applying deference principles to an equal protection challenge against the draft); *Weiss v. United States*, 510 U.S. 163, 177 (1994) (applying deference principles to a due process challenge concerning rights of service members). Upon recognizing that "a healthy and ready Force" is imperative "[t]o defend this Nation," the Secretary determined that a COVID-19 vaccine mandate was "necessary to protect the Force and defend the American people." Ex. 2. The Secretary further determined that "vaccination of the Force will save lives," *id.*, will "protect [service members'] unit[s], [their] ship[s], and [their] co-workers," and "will ensure we remain the most lethal and ready force in the world." Ex. 1.

There can be no question that stemming the spread of a highly contagious and deadly disease among service members—whose jobs often keep them in close quarters with their unit and who must be ready to deploy on short notice—is a legitimate government interest. *See Valdez*, 2021 WL 4145746, at *7 (finding that, in the civilian context, "[t]he governmental purpose of stemming the spread of

COVID-19, especially in the wake of the Delta variant, is not only legitimate, but is 'unquestionably a compelling interest'" (quoting *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020)). And the vaccination directive is rationally related to DoD's legitimate purpose of ensuring the readiness of the Force because it is based on guidance from FDA and CDC that the vaccines are safe and effective at reducing the spread of COVID-19, including among those who have previously been infected. *See supra* Part IV.B.4; *see also Bacon v. Woodward*, 2021 WL 5183059, at *5 (E.D. Wash. Nov. 8, 2021) ("The City's vaccination requirement is rationally related to [its] interest [in stopping the spread of COVID-19] because it is based on overwhelming evidence that the vaccines are safe and effective, and increasing vaccination rates among employees who come into regular contact with the public is a rational action to reduce the spread of COVID-19."); *Jensen*, 2021 U.S. Dist. LEXIS 224094, at *24.[17]

Although Plaintiffs and their purported experts "draw a different conclusion based on their perception of current medical science," "merely drawing different conclusions based on consideration of scientific evidence does not render the [v]accine [p]olicy arbitrary and irrational." *Kheriaty*, 2021 WL 4714664, at *8 (finding that a policy that treats previously infected individuals differently from vaccinated individuals passed rational-basis review). Thus, Plaintiffs' Equal Protection Claim fails.

III. Plaintiffs Will Not Suffer Irreparable Harm Absent a Preliminary Injunction.

"To constitute irreparable harm, an injury must be certain, great, actual and not theoretical." *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (quotation omitted). Irreparable harm is more than "merely serious or substantial" harm. *Id.* (citation omitted). And the injury must be "of such imminence that there is a clear and present need for equitable relief to prevent irreparable

[17] Indeed, even for a requirement for deploying soldiers to receive non-FDA-approved medications, the D.C. Circuit concluded that DoD's legitimate governmental interests in the uniform administration of drugs and military success "counterbalance an individual's interest in being free from experimental treatment without giving informed consent." *Doe v. Sullivan*, 938 F.2d 1370, 1383 (D.C. Cir. 1991).

harm." *Id.* (citation omitted). Therefore, Plaintiffs "must establish both that harm will occur, and that, when it does, such harm will be irreparable." *Vega v. Wiley*, 259 F. App'x 104, 106 (10th Cir. 2007). In the context of military personnel decisions, "courts have held that the showing of irreparable harm must be especially strong before an injunction is warranted, given the national security interests weighing against judicial intervention in military affairs." *Church*, 2021 WL 5179215, at *17 (quoting *Shaw*, 2021 WL 1840397, at *9). Plaintiffs have failed to make such a showing.

Plaintiffs argue that they will suffer irreparable harm from "a non-consensual injection of an unlicensed substance." Mot. 16. This argument misses the mark for three reasons. First, Staff Sergeant Mulvihill has been granted a temporary medical exemption and is currently exempt from the vaccine requirement. Ex. 16 ¶¶ 9–10. She plainly cannot show any imminent harm from the DoD directive. *See Church*, 2021 WL 5179215, at *16 (finding no irreparable harm when a service member was temporarily exempted from the DoD vaccine directive).

Staff Sergeant Robert has a pending exemption request. Ex. 15 ¶ 3. He is not required to get the vaccine while his request is pending and likewise suffers no imminent harm. *See id.*; Ex. 13 ¶¶ 8, 20, 24; *see also Church*, 2021 WL 5179215, at *16 (finding no irreparable harm when exemption requests were pending); *Williams v. Brown*, 2021 WL 4894264 *10 (D. Or. Oct. 19, 2021) (same); *Burcham v. City of Los Angeles*, 2021 WL 5049099, at *4 (C.D. Cal. Oct. 27, 2021) (same). If his request is granted, Staff Sergeant Robert will not face any adverse consequences from the vaccine mandate. *See Pelekai v. Hawaii*, 2021 WL 4944804, at *1 (D. Haw. Oct. 22, 2021) (finding no injury when exemption requests were granted).

Second, even if Staff Sergeant Robert's exemption request is denied or Staff Sergeant Mulvihill's temporary exemption expires, the vaccine (and any alleged attendant harm from it) would

not be forced on them.[18] Ex. 6 ¶ 3.D.8.B.4; Ex. 13 ¶¶ 6, 8, 20; Ex. 14 ¶ 4 n.2. Plaintiffs' reliance on *Cruzan ex rel. Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), and *King v. Rubenstein*, 825 F.3d 206 (4th Cir. 2016), is therefore misplaced, as those cases involved individuals being forcibly given medical treatment. As courts have repeatedly recognized, vaccine mandates are "a far cry" from forced medical care. *See, e.g.*, *Klaassen v. Trs. of Ind. Univ.*, 2021 WL 3073926, at *25 (N.D. Ind. July 18, 2021); *Smith v. Biden*, 2021 WL 5195688, at *8 n.2 (D.N.J. Nov. 8, 2021), *appeal filed*, No. 21-3091 (3d Cir. Nov. 10, 2021); *Rydie v. Biden*, 2021 WL 5416545, at *4 (D. Md. Nov. 19, 2021) *Bauer v. Summey*, 2021 WL 4900922, at *9 n.5 (D.S.C. Oct. 21, 2021); *Kheriaty*, 2021 WL 4714664, at *5; *Bridges*, 2021 WL 2399994, at *2.

Third, as shown above, the Pfizer vaccine is not "an unlicensed substance," as FDA has approved Pfizer's BLA. This case is unlike *Doe*, 297 F. Supp. 2d at 135, which concerned a directive that service members take a vaccine that the court found was not licensed for its mandated use.

Moreover, Plaintiffs' argument that the vaccine itself would, if taken, cause irreparable harm is not supported by credible evidence. *See* Mot. 16–19. As this Court previously found, "[t]heir contention that they will be uniquely harmed from vaccines that, according to the CDC, more than 200 million people had received by the time Plaintiffs' Motion was filed, is specious." Order at 5, ECF No. 12. Other courts have reached the same conclusion. *See, e.g.*, *Altschuld v. Raimondo*, No. 21-cv-2779, slip op. at 11 (D.D.C. Nov. 8, 2021), ECF No. 23 ("Regulatory authorities tasked with

[18] Although service members who refuse the vaccine and do not have a pending or granted exemption request may suffer from adverse employment consequences for non-compliance with the DoD directive, Plaintiffs do not appear to argue that any other administrative or disciplinary action taken against service members, including separation from service, is irreparable. Nor could they, as courts have consistently rejected such arguments. *See, e.g.*, *Church*, 2021 WL 5179215, at *17; *Guerra v. Scruggs*, 942 F.2d 270, 274 (4th Cir. 1991); *Hartikka v. United States*, 754 F.2d 1516, 1518 (9th Cir. 1985); *Chilcott v. Orr*, 747 F.2d 29, 34 (1st Cir. 1984).

protecting the public's health and safety have found them proven, effective, and safe, and the vaccines are estimated to have already saved hundreds of thousands of lives."); *Wise v. Inslee*, 2021 WL 4951571, at *3 (E.D. Wash. Oct. 25, 2021) (finding "overwhelming evidence that the vaccines are safe and effective"). And two courts have rejected the opinions by one of Plaintiffs' purported experts, Dr. Peter McCullough, on the safety of the COVID-19 vaccines.[19] *See Harris v. Univ. of Mass., Lowell*, 2021 WL 3848012, at *3 n.5 (D. Mass. Aug. 27, 2021), appeal filed, No. 21-1770 (1st Cir. Sept. 28, 2021); *Klaassen*, 2021 WL 3073926, at *28–32; *see also United KP Freedom All. v. Kaiser Permanente*, No. 3:21-cv-07894, 2021 WL 5370951, at *2 (N.D. Cal. Nov. 18, 2021) (in a case where the plaintiffs submitted a declaration by Dr. McCullough (ECF No. 27-8), finding that "[t]he plaintiffs have submitted

[19] The Court can similarly disregard the affidavit by Plaintiffs' other putative expert, Lieutenant Colonel Theresa Long, as she has no experience or background concerning the safety of vaccines and is thus not qualified to offer opinions on the safety of the COVID-19 vaccines. *See generally* Long Aff., ECF No. 30-2. Moreover, her affidavit is replete with anonymous hearsay, *see, e.g.*, *id.* ¶ 38, and riddled with errors. For example, she incorrectly refers to the COVID-19 vaccines as investigational new drugs, *id.* ¶ 29, and although she states that the Army should have a "screening program" for vaccine side effects, *id.* ¶¶ 17–25, she fails to recognize that the Army already has procedures in place to address any side effects of the vaccines, *see* Ex. 17 (Decl. of Nicole Powell-Dunford) ¶ 8. Lieutenant Colonel Long's attempt to downplay the effect of COVID-19, *see* Long Aff. ¶ 19, ignores that the disease "has had a devastating impact upon the lives and families of the Fort Rucker community," where she is stationed, Ex. 18 (Decl. of Whitney Gardner) ¶ 3. Finally, Lieutenant Colonel Long's purported concerns with the vaccines that have led her to conclude that all flight crews should be grounded, Long Aff. ¶¶ 36–39, is belied by the fact that "since the beginning of the Army COVID immunization program, approximately 602,322 Army flight hours have been flown without a COVID-19 vaccine-related incident," Ex. 17 ¶ 9.

In any event, Plaintiffs' reliance on their putative experts is exactly the type of "expert testimony" the Supreme Court has dismissed in the military context as "quite beside the point," *Goldman v. Weinberger*, 475 U.S. 503, 509 (1986), and has chastised district courts for "palpably exceed[ing] its authority" for "relying on [such] testimony," *Rostker*, 453 U.S. at 81. And even if Lieutenant Colonel Long's affidavit could be considered, Plaintiffs have failed to comply with DoD's and Army's *Touhy* requirements, which specifically prohibit present or former Department of the Army personnel from disclosing official information, 32 C.F.R. § 516.41(a), or from providing expert or opinion testimony in a case in which the United States has an interest for a party whose interests are adverse to the interests of the United States, 32 C.F.R. § 516.52; *see also* 32 C.F.R. § 97.6(e) (DoD's *Touhy* regulations prohibiting DoD personnel from providing "opinion or expert testimony concerning official DoD information, subjects, or activities, except on behalf of the United States or a party represented by the Department of Justice"). The Court should take into account this lack of compliance when deciding how much, if any, weight to give to her affidavit.

declarations contesting the safety and efficacy of COVID-19 vaccines (as well as asserting that the vaccines are not 'vaccines' at all), but it appears unlikely that much of this testimony would stand up under Rule 702 of the Federal Rules of Evidence").

Plaintiffs also point to the number of deaths and "Serious Adverse Events" purportedly resulting from COVID-19 mRNA vaccines that were reported to CDC's Vaccine Adverse Event Reporting System ("VAERS"), *see* Mot. 17–18, but ignore the limitations of this data. Both the CDC and FDA have recognized that "[r]eports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem." CDC, *Selected Adverse Events Reported after COVID-19 Vaccination* (Nov. 16, 2021), https://perma.cc/2ZZ4-JUJ3; Ex. 10 ¶ 23 (stating that VAERS "reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness"). One factor inhibiting inference of causality is that "FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause." CDC, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://perma.cc/2ZZ4-JUJ3. In addition, "[s]ome reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable," "VAERS reports often lack contextual information," and "[m]ost reports to VAERS are voluntary, which means they may be subject to biases." CDC, *Vaccine Adverse Event Reporting System*, https://perma.cc/JM88-6MUR; CDC, *Myths and Facts about COVID-19 Vaccines* (Oct. 4, 2021), https://perma.cc/HY88-SY2C; *see also Streight v. Pritzker*, 2021 WL 4306146, at *7 n.9 (N.D. Ill. Sept. 22, 2021) (noting the same limitations of the VAERS data); *Klaassen*, 2021 WL 3073926, at *11.

Plaintiffs contend that the VAERS reports show that there are "unprecedented numbers of adverse reactions," which "exceed the entirety of all other vaccines." Mot. 17. But FDA has found that there are "particular scientific limitations in comparing VAERS reports for COVID-19 vaccines

with reports for previously approved vaccines for other conditions." Ex. 10 ¶ 23. Specifically, the EUAs for the vaccines require vaccination providers "to report to VAERS serious adverse events following vaccination with the COVID-19 vaccines 'irrespective of attribution to vaccination' and regardless of how long after vaccination the adverse event occurs." *Id.* In addition, the CDC uses a smartphone-based application only for the COVID-19 vaccines to solicit adverse events directly from patients, and "extensive media coverage" of the vaccines and potential side effects make it more likely that individuals will report adverse events to VAERS involving COVID-19 vaccines than for other vaccines. *Id.* Plaintiffs point to the number of deaths reported to VAERS following a COVID-19 vaccination, *see* Mot. 17, but the CDC has not found a causal link between death and mRNA COVID-19 vaccines after reviewing available information, including autopsy and medical records. *See* CDC, *Selected Adverse Events Reported after COVID-19 Vaccination*, https://perma.cc/2ZZ4-JUJ3; *see also Harris*, 2021 WL 3848012, at *3 n.5 (noting same).

Plaintiffs also allege that certain individuals developed myocarditis and pericarditis after taking an mRNA COVID-19 vaccine.[20] *See* Mot. 17–19. But it is entirely speculative that Plaintiffs would suffer from these side effects from the vaccine, as "the risk of myocarditis appears to be exceptionally small." *Klaassen*, 2021 WL 3073926, at *10. Moreover, in licensing the vaccine, FDA specifically considered the risk of myocarditis and pericarditis, finding that the predicted benefits of avoiding impacts associated with COVID-19 clearly outweighed the predicted risks associated with myocarditis and pericarditis. *See* Ex. 10 ¶ 26, Ex. C at 23–24. The CDC has reached the same conclusion. *See* CDC, *Myocarditis and Pericarditis After mRNA COVID-19 Vaccination*, https://perma.cc/SV62-A6LH.

[20] "Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of the outer lining of the heart." CDC, *Myocarditis and Pericarditis After mRNA COVID-19 Vaccination* (Nov. 12, 2021), https://perma.cc/SV62-A6LH. "In both cases, the body's immune system causes inflammation in response to an infection or some other trigger." *Id.*

Finally, Plaintiffs ignore that COVID-19 itself "is a strong and significant risk factor for myocarditis." Tegan Boehmer, et al., *Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021*, Morbidity and Mortality Weekly Report (MMWR) (Sept. 3, 2021), *available at* https://perma.cc/GRL8-3D4B; *see also Klaassen*, 2021 WL 3073926, at *30.

IV. The Equities and the Public Interest Weigh Against Preliminary Injunctive Relief.

A party seeking a preliminary injunction must also "establish . . . that the balance of equities tips in [its] favor, and that [the] injunction is in the public interest." *Winter*, 555 U.S. at 20. These factors merge when a plaintiff seeks an injunction against the Federal Government. *See Nken v. Holder*, 556 U.S. 418, 435 (2009). Even when "irreparable injury may otherwise result to [a] plaintiff," courts have discretion to deny an injunction that would "adversely affect a public interest." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312–13 (1982) (quotation omitted).

An injunction against the DoD directive would adversely impact the public interest and the national security of the United States. The Secretary of Defense "determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people." Ex. 2 (further stating that "[t]o defend this Nation, we need a healthy and ready Force"). The Secretary made this decision after consulting with "medical experts and military leadership," *id.*, including the "Chairman of the Joint Chiefs of Staff, the Secretaries of the Military Departments, [and] the Service Chiefs," Ex. 1. The Service Secretaries likewise found that COVID-19 impacts military readiness and that mandatory vaccination is necessary to prevent the spread of COVID-19 in the Force. *See, e.g.*, Ex. 6 ¶ 3.B.3; Ex. 7 ¶ 2. The Court must "give great deference" to the "professional military judgments" of these leaders when it comes to what is needed to ensure military readiness. *See Winter*, 555 U.S. at 24–25; *see also Church*, 2021 WL 5179215, at *18 (deferring to the judgment of military leaders concerning the importance of vaccination for military readiness).

These professional military judgments are supported by the evidence showing COVID-19's harmful impact on the Force. Since the onset of the COVID-19 pandemic, hundreds of thousands of service members have been infected, thousands have been hospitalized, and dozens have died. Ex. 12 ¶ 3. All the service members who have died were not fully vaccinated. *Id.* Plaintiffs argue that "[t]here is no indication that the last 18 months of the pandemic . . . has in any way reduced rates of military effectiveness, created a significant loss of personnel or readiness, or in any way affected DoD's ability to perform its missions." Mot. 20. But this is a military judgment to which the Court must defer, and that judgment is "supported by a lengthy record replete with data demonstrating the necessity of a general vaccine mandate." *Church*, 2021 WL 5179215, at *18; *see also Rydie*, 2021 WL 5416545, at *6 (in the civilian context, rejecting the argument that the federal government could "simply continu[e] with the measures implemented since March 2020").

COVID-19 has "impacted exercises, deployments, redeployments, and other global force management activities," Ex. 12 ¶ 6 (including rendering one of the U.S. Navy's eleven aircraft carriers non-operational because of an outbreak, *id.* ¶ 8); caused the cancellation of "19 major training events, many of which involved preparedness and readiness training with our foreign partners," *id.* ¶ 9; *see also* Ex. 18 ¶ 6; and "required significant operational oversight" by the most senior military leaders, Ex. 12 ¶ 4. Further, vaccination requirements of other nations restrict the ability of unvaccinated service members to participate in joint training exercises, which are "vital to the preservation of national security and the protection of our foreign interests." Ex. 12 ¶¶ 10–11. In addition, because health care providers have had to care for COVID-19 patients, certain service members have not been able to "address non-emergency conditions and undergo routine medical and health assessments that are required under military directives to maintain medical readiness." *Id.* ¶¶ 13–14.

Vaccinations have promoted readiness by reducing the risk of infections, hospitalizations, and

deaths of service members, reducing the number of service members who are required to quarantine, and permitting the military to return to higher levels of occupancy in DoD facilities and hold in-person trainings. *Id.* ¶¶ 3, 14–19; *see also* Ex. 18 ¶ 8 (describing increased number of flight hours and trainings). As this Court found in denying Plaintiffs' motion for a temporary restraining order, "the public interest in the nation's military readiness may well be served by allowing military officials who are familiar with the unique challenges posed by the COVID-19 pandemic in a military setting to manage those challenges without this Court's intervention." Order 6, ECF No. 12. The same holds true today.

Even an injunction of the DoD directive limited solely to the named Plaintiffs would harm the national defense and the public interest. If they are unvaccinated, Plaintiffs could get infected with COVID-19, become seriously ill, and face hospitalization and death—all of which would affect the readiness of their unit. Ex. 11 ¶¶ 7–9. Unvaccinated service members also could spread the coronavirus to others, which is of particular concern for the military, given that many service members work in close quarters or in operational settings. *Id.* ¶ 9; Ex. 12 ¶ 8; *see Mass. Correction Officers Federated Union v. Baker*, 2021 WL 4822154, at *8 (D. Mass. Oct. 15, 2021) (noting the public interest in preventing the spread of COVID-19 in "congregate facilities"). That concern is particularly acute for these Plaintiffs, as they both work in close quarters instructing others. Ex. 15 ¶ 2; Ex. 16 ¶¶ 3–4. And an outbreak at the Air Traffic Control Facility where Staff Sergeant Mulvihill is stationed would "significantly reduc[e] allotted training times" for 14 squadrons, thus resulting in "a direct and detrimental effect on the resident squadrons' training capacity and military readiness." Ex. 16 ¶ 6.

Plaintiffs also request that the Court enjoin the government from taking any adverse employment action or discipline for non-compliance with the DoD directive. *See* Mot. 23. But the military has discretion to handle matters of good order and discipline without interference from the judiciary. *Chappell v. Wallace*, 462 U.S. 296, 300–01 (1983). The Army and the Marine Corps have

specific processes that must be followed before the implementation of any discipline or adverse employment action, *see* Ex. 13 ¶¶ 21–22; Ex. 14 ¶¶ 13–21, and the Services' "interest in good order and discipline is best served by adjudicating each refusal [to comply with the DoD directive] on a case-by-case basis," Ex. 14 ¶ 23; *see also* Ex. 13 ¶ 21. An injunction prohibiting the military from initiating or completing those processes "would be a disruptive force as to affairs peculiarly within the jurisdiction of the military authorities[,]" *Orloff v. Willoughby*, 345 U.S. 83, 95 (1953), and contrary to the public interest, *see Reinhard v. Johnson*, 209 F. Supp. 3d 207, 221 (D.D.C. 2016) (noting the "public's interest in the proper functioning of the military, which includes its ability to discharge personnel as it deems necessary without unnecessary intrusion"); *see also Guerra*, 942 F.2d at 275; *Shaw*, 2021 WL 1840397, at *10.

More generally, enjoining the DoD directive would harm the public interest in slowing the spread of COVID-19 among millions of service members and the members of the public with whom they interact. In recognition of the government's "compelling interest" in "stemming the spread of COVID-19," *Cuomo*, 141 S. Ct. at 67, numerous courts reviewing "executive action designed to slow the spread of COVID-19" have concluded that "[t]he public interest in protecting human life—particularly in the face of a global and unpredictable pandemic—would not be served by" an injunction. *Tigges v. Northam*, 473 F. Supp. 3d 559, 574 (E.D. Va. 2020); *see also, e.g.*, *Church*, 2021 WL 5179215, at *18–19; *Rydie*, 2021 WL 5416545, at *5–6; *Altschuld v. Raimondo*, slip op. at 11–12; *Am.'s Frontline Drs. v. Wilcox*, 2021 WL 4546923, at *8 (C.D. Cal. July 30, 2021); *Valdez*, 2021 WL 4145746, at *13; *Harris*, 2021 WL 3848012, at *8; *Williams*, 2021 WL 4894264, at *10–11; *Wise*, 2021 WL 4951571, at *6; *Bacon*, 2021 WL 5183059, at *6; *Mass. Correction Officers*, 2021 WL 4822154, at *7–8; *Johnson v. Brown*, 2021 WL 4846060, at *26–27 (D. Or. Oct. 18, 2021). Indeed, in denying Plaintiffs' motion for a temporary restraining order, this Court previously found that "the public interest is

advanced by applying scientific principles to get new cases under control." Order 5–6, ECF No. 12.

Plaintiffs argue that unlike the State of Massachusetts in *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), the federal government has no interest in "assuming the harms of 'their' citizenry."[21] Mot. 19. But, as another court recently found, "the federal government has at least as much, if not broader, power and deference in this instance where it is acting as an employer than the State of Massachusetts had in *Jacobson* in exercising its police power." *Smith*, 2021 WL 5195688, at *7; *see also Rydie*, 2021 WL 5416545, at *3. And this power and deference is even more heightened for the military, as the Secretary has determined that readiness depends on a healthy Force. *See* Ex. 1, Ex. 2.

In sum, the balance of interests weighs heavily against the entry of preliminary injunctive relief, in light of the harms that would result to the national defense, to the health of service members, and more broadly to the public health of the United States.

V. HHS and FDA Should Be Dismissed from the Case.

Apart from whether the Court should dismiss the case in its entirety, the Court should, at a minimum, dismiss Defendants HHS and FDA from the case. Plaintiffs challenge the DoD COVID-19 vaccine directive, which was put in place by DoD, not HHS or FDA. And the two claims they allege against HHS and FDA—violation of 10 U.S.C. § 1107a (Count 3) and 50 U.S.C. § 1520 (Count 4), *see* SAC ¶¶ 53–60—are alleged violations of statutes that plainly do not apply to HHS or FDA. Nor do Plaintiffs seek any relief against HHS or FDA. *See* SAC 20–21. Because the second amended complaint does not challenge any action by HHS or FDA or raise any cognizable claim or seek relief

[21] Plaintiffs also attempt to distinguish *Jacobson* by arguing that "these shots are *not* vaccines." Mot. 19; *see* SAC 2 n.1. Plaintiffs are incorrect. Both FDA and CDC consider the mRNA vaccines to be vaccines. *See* Ex. 10 ¶ 6; CDC, *Myths and Facts about COVID-19 Vaccines* (Oct. 4, 2021), https://perma.cc/HY88-SY2C; *see also Messina v. Coll. of N.J.*, 2021 WL 4786114, at *8 (D.N.J. Oct. 14, 2021) (rejecting a similar argument); *Smith*, 2021 WL 5195688, at *8 n.2 (same).

against them, HHS and FDA should be dismissed from the case.

CONCLUSION

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction should be denied and the case should be dismissed.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 23, 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.

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