

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

JOHN DOE #1–14 and JANE DOE #1–2,

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; **FRANK KENDALL**, in his official capacity as Secretary of the Air Force; **CARLOS DEL TORO**, in his official capacity as Secretary of the Navy; **JANET WOODCOCK**, in her official capacity as Acting Commissioner of the U.S. Food and Drug Administration; and **CHRISTINE WORMUTH**, in her official capacity as Secretary of the Army,

Defendants.

Case No. 1:21-cv-01211-AW-HTC

**DEFENDANTS' OPPOSITION TO
PLAINTIFFS' MOTIONS FOR A TEMPORARY RESTRAINING ORDER
AND PRELIMINARY INJUNCTION**

Table of Contents

BACKGROUND.....	2
I. The COVID-19 Pandemic.....	2
II. Federal Regulation of and Guidance Concerning COVID-19 Vaccines.....	3
III. Department of Defense COVID-19 Vaccine Directive	6
IV. Procedural History.....	9
LEGAL STANDARDS	11
ARGUMENT	12
I. Plaintiffs Are Unlikely to Succeed on the Merits of Their Claims.	12
A. Plaintiffs’ Claims Are Not Ripe.	12
B. DoD’s Directive Complies with the APA.....	17
C. Plaintiffs Cannot Show a Likelihood of Success on Their Claims Against FDA.	28
D. Plaintiffs’ Constitutional Claims Are Unlikely To Succeed.	48
II. Plaintiffs Do Not Face Irreparable Harm.	54
A. Plaintiffs Who Have Not Taken The Vaccine Will Not Suffer Irreparable Harm.	55
B. John Doe #4 Cannot Establish Irreparable Harm.	60
III. The Equities and the Public Interest Weigh Heavily Against Preliminary Injunctive Relief.	61
A. An Injunction Against DoD and the Military Services Would Adversely Affect Military Readiness.	62
B. An Injunction Against FDA Would Greatly Harm Public Health.	65

TABLE OF EXHIBITS

Exhibit Number	Exhibit Description
1.	Secretary of Defense Message to the Force (Aug. 9, 2021)
2.	Secretary of Defense Memorandum For Senior Pentagon Leadership, Commanders of the Combatant Commands, Defense Agency and DoD Field Activity Directors (Aug. 24, 2021)
3.	Acting Assistant Secretary of Defense for Health Affairs Memorandum for Assistant Secretary of the Army (Manpower and Reserve Affairs), Assistant Secretary of the Navy (Manpower and Reserve Affairs), Assistant Secretary of the Air Force (Manpower and Reserve Affairs), and Director of the Defense Health Agency (Sept. 14, 2021)
4.	Department of Defense Instruction (“DoDI”) 6205.02
5.	Army Regulation (“AR”) 40-562
6.	Fragmentary Order 5 to Headquarters Department of the Army Executive Order 225-21 (“Army FRAGO 5”)
7.	ALNAV 062/21
8.	NAVADMIN 190/21, NAVADMIN 225/21
9.	MARADMIN 462/21, MARADMIN 533/21
10.	Secretary of Air Force Memorandum for Air Force Commanders (Sept. 3, 2021)
11.	Dep’t of the Air Force COVID-19 Vaccine Implementation Guidance (Sept. 3, 2021)
12.	Congressional Research Report Defense Health Primer: Military Vaccinations
13.	Declaration of Peter Marks, M.D., Ph.D.
14.	Declaration of Colonel Tonya Rans, M.D.
15.	Declaration of Major Scott Stanley
16.	Declaration of Colonel Michele Soltis
17.	Declaration of Vice Admiral William Merz
18.	Declaration of Lieutenant General David J. Furness
19.	Declaration of Lieutenant Colonel Nekitha M. Little
20.	Declaration of Colonel Artemio C. Chapa

21.	Declaration of Chaplain, Major Matthew J. Streett
22.	Declaration of Colonel Elizabeth M. Hernandez
23.	Declaration of William J. McWaters
24.	Declaration of Captain Kenneth C. Collins, II
25.	Declaration of Brigadier General Jason L. Morris
26.	Declaration of Lieutenant Colonel Sarah J. Brehm
27.	Declaration of Lieutenant Colonel Joseph D. Langan
28.	Declaration of Lieutenant Colonel Donald H. Schmidt
29.	Table Summarizing Each Plaintiffs' Lack of Standing and Ripeness
30.	CDC COVID Data Tracker Weekly Review (Oct. 15, 2021)

INTRODUCTION

In warfare, disease has traditionally accounted for more service member deaths than battlefield injuries. General Washington instituted the first vaccine mandate for the Continental Army in 1777, and a program to inoculate the troops on either a routine or situational basis has existed in the American military ever since. The current Department of Defense 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.

Despite this historical backdrop, Plaintiffs contend that the Secretary of Defense lacks the authority to add COVID-19 to the list of diseases for which routine immunizations are required for all service members. The preliminary injunction Plaintiffs seek is truly extraordinary. They ask this Court to enjoin an inoculation program that applies to the entire armed forces and to invalidate the Food and Drug Administration (“FDA”) licensure of a vaccine that is one of the primary tools for ending the global pandemic.

Plaintiffs fail to establish any of the requirements for such extraordinary injunctive relief. Their claims are not ripe and are deeply flawed on the merits. Plaintiffs do not establish irreparable harm. And the balance of equities and the public interest weigh against intruding on a decision of the military concerning how to protect the health and welfare of the troops. Even if applied to just the named

Plaintiffs, such an injunction would degrade military readiness and undermine the efforts to combat the deadly coronavirus. For these reasons, set forth further below, Plaintiffs' motions should be denied.

BACKGROUND

I. The COVID-19 Pandemic

On January 31, 2020, the Secretary of Health and Human Services ("HHS") declared a public health emergency because of COVID-19, a respiratory disease caused by the novel coronavirus named SARS-CoV-2. HHS, *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), <https://perma.cc/VZ5X-CT5R>. On March 13, 2020, the President declared the COVID-19 outbreak a national emergency. 85 Fed. Reg. 15,337 (Mar. 13, 2020).

In July 2021, the United States experienced "a rapid and alarming rise in . . . COVID-19 case and hospitalization rates," driven by an especially contagious strain of SARS-CoV-2 known as the Delta variant. *See* Centers for Disease Control and Prevention ("CDC"), *Delta Variant* (updated Aug. 26, 2021), <https://perma.cc/4RW6-7SGB>. Today, community transmission rates of SARS-CoV-2 are substantial or high in all fifty states. *See* COVID Data Tracker, CDC, https://covid.cdc.gov/covid-data-tracker/#cases_community (last accessed Oct. 20,

2021).¹ More than 240,000 service members have been infected, more than 2,000 service members have been hospitalized, and 67 service members have died from COVID-19. Ex. 14 (Decl. of Col. Tonya Rans, M.D.) ¶ 11.

II. Federal Regulation and Guidance Concerning COVID-19 Vaccines

FDA has authority to review and approve “biological products,” including vaccines. *See* 42 U.S.C. § 262(a)(1), (i)(1). In an emergency, FDA may issue an “emergency use authorization” (“EUA”), which authorizes the marketing of vaccines (and other FDA-regulated products) “intended for use” in responding to the emergency. 21 U.S.C. § 360bbb-3.

In March 2020, the Secretary of HHS determined 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). Based on that determination, FDA issued an EUA for a COVID-19 vaccine developed by Pfizer, Inc., as well as EUAs for two other COVID-19 vaccines. *See* Ex. 13 (Decl. of Peter Marks, M.D., Ph.D) Exs. B, C. These EUAs were based on FDA’s review of extensive safety and efficacy data, including from a Pfizer clinical trial with approximately 46,000 participants. *Id.*

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

On August 23, 2021, Pfizer’s COVID-19 vaccine, under the name Comirnaty, obtained FDA approval for intended use by people aged 16 years and older even outside the “emergency” context pertinent to the EUA. *Id.* at Ex. A. This means that the vaccine successfully completed “the agency’s standard process for reviewing the quality, safety and effectiveness of medical products.”² FDA, *News Release – FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), <https://perma.cc/C4DD-PWE5>.

FDA concluded that the Pfizer vaccine was safe based on data evaluating the vaccine in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo, 16 years of age and older. Approximately 12,000 vaccine recipients were followed for safety outcomes for at least six months after receiving their second dose of the vaccine, and FDA also considered safety information from the millions of vaccine doses administered under the EUA. FDA, *Comirnaty Approved Prescribing Information* at 12, <https://perma.cc/P87N-YGX2>. <https://perma.cc/P87N-YGX2>. FDA further determined the vaccine was 91.1% effective in preventing COVID-19 disease and between 95% and 100% effective in preventing severe COVID-19, based on an analysis of effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients. *Id.* at 15–18; *see also*

² “Even after FDA approved Comirnaty, FDA authorized continued use of the Pfizer-BioNTech Covid-19 vaccine under an EUA for indications that included the approved use.” Ex. 13 ¶ 8.

Ex. 13 ¶¶ 16–20.

Also on August 23, 2021, FDA issued responses to three citizen petitions regarding the COVID-19 vaccines. In two of the responses, FDA addressed the petitioners’ expressed safety concerns with vaccinating individuals who have had COVID-19, finding that their assertions had no scientific basis or were unsupported by the cited sources. *See* FDA, *Response to Citizen Petition*, at 13–15 (Docket No. FDA-2021-P-0529) (Aug. 23, 2021); FDA *Response to Citizen Petition*, at 8 n.31 (Docket No. FDA-2021-P-0786) (Aug. 23, 2021). FDA also addressed a petitioner’s expressed concern with the efficacy of the COVID-19 vaccine for individuals who have had COVID-19, stating that while “there is scientific uncertainty about the duration of protection provided by previous natural infection, . . . the scientific community believes that vaccines may provide a longer duration of protection than that provided by natural infection.” FDA *Response to Citizen Petition*, at 8 n.31 (Docket No. FDA-2021-P-0786) (Aug. 23, 2021).

In addition, the CDC has recommended that individuals who have already had COVID-19 get vaccinated. *See* CDC, *Frequently Asked Questions about COVID-19 Vaccination* (updated Oct. 13, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>. The CDC based this recommendation on 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.” *Id.* (citing

Cavanaugh, Alyson, *et al.*, *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021*, *Morbidity & Mortality Weekly Report*, 70(32):1081–83 (Aug. 13, 2021), <http://dx.doi.org/10.15585/mmwr.mm7032e1>).

III. Department of Defense COVID-19 Vaccine Directive

The U.S. military instituted its first vaccination program in 1777 when General Washington directed the inoculation of the Continental Army to protect personnel from smallpox.³ Deaths due to infectious diseases outnumbered those due to direct combat injuries until World War II. *Id.* And more recently, disease accounted for nearly 70% of U.S. Army Hospital admissions during the Persian Gulf War. *Id.*, *see also* Table 1-2 (showing infectious disease threats for various conflicts). Military-mandated vaccines have played a key role in reducing infectious disease morbidity and mortality among military personnel. Accordingly, for decades, the military has implemented a variety of enduring or situational inoculation measures to maintain the readiness of the force. Ex. 12 (Congressional Research Report Defense Health Primer: Military Vaccinations).

³ Lemon S, Thaul S, Fisseha S, O’Maonaigh H, editors, *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the US Military*, National Academies Press, 2002, available at <https://perma.cc/E545-TQ9G> last check Oct. 21, 2021.

The Department of Defense's ("DoD") current immunization program is governed by DoD Instruction ("DoDI") 6205.02. Certain vaccines are required for all service members while others are required when certain elevated risk factors are present. *See* Ex. 5 (Army Regulation ("AR") 40-562), Table D-1. The policy states that DoD will make immunization requirements and eligibility determinations for service members in accordance 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 establishing a process by which service members may seek, and the Services may grant, medical or administrative exemptions to vaccine requirements. *See* Ex. 5, Chapter 2.6.

On August 9, 2021, Secretary of Defense Lloyd Austin, noting the rise in infection rates due to the Delta variant of COVID-19 and the impact these rates might 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 full approval by the FDA. *See* Ex. 1 (Mem. for all Defense Employees (Aug. 9, 2021)). On August 24, 2021, after the FDA announced full approval of the Pfizer COVID-19 vaccine, Secretary Austin 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 fully vaccinated against

COVID-19. *See* Ex. 2 (Mem. For Senior Pentagon Leadership, Commanders of the Combatant Commands, Defense Agency and DoD Field Activity Directors (Aug. 24, 2021)). Only vaccines that have received full licensure from the FDA are required. *Id.* Service members with a previous COVID-19 infection are not considered fully vaccinated. *Id.*

Shortly thereafter, the Military Services began issuing guidance for implementing the Secretary's directive. The implementation guidance for each Service provides for a process for a service member to seek medical, administrative, and religious exemptions. *See* Ex. 6 (Fragmentary Order ("FRAGO") 5 to Headquarters Department of the Army Executive Order 225-21) ¶ 3.D.8.B.1; Ex. 8 (NAVADMIN 190/21) ¶ 3.d; Ex. 9 (MARADMIN 462/21) ¶¶ 3j, 3k; Ex. 11 (Dep't of the Air Force COVID-19 Vaccine Implementation Guidance (Sept. 3, 2021)) ¶ 4.5, 5.1. If a service member refuses vaccination and does not have an approved exemption, that service member may be subject to discipline and adverse administrative action. *See, e.g.,* Ex. 6 ¶¶ 3.D.8.B.1.D, 3.D.8.B.1.E. However, adverse action will not be taken against a service member with a pending exemption request. *Id.* And each Service specifically withholds adverse action against a service member who refuses vaccination from unit commander to higher (and in several instances centralized) authority. *See* Ex. 6 ¶ 3.D.8.B.1; Ex. 8 ¶ 3.e.(5); Ex. 9 ¶ 3.n;

Ex. 10 (Secretary of Air Force Memorandum for Air Force Commanders (Sept. 3, 2021)).

IV. Procedural History

On October 6, 2021, sixteen service members, who have moved to proceed anonymously,⁴ filed suit against DoD, the Military Services, HHS, and FDA. *See* ECF No. 1; Corrected Compl., ECF No. 6.

Plaintiffs raise 11 claims, including that DoD’s COVID-19 vaccine directive and the Military Services’ implementation guidance are arbitrary and capricious and contrary to law under the Administrative Procedure Act (“APA”) (Counts 1 and 5, as well as Count 6 against DoD only), *id.* ¶¶ 108–112, and violate statutes governing investigational new drugs (“INDs”), 10 U.S.C. § 1107, and emergency use products, 10 U.S.C. § 1107a, 21 U.S.C. § 360bbb-3 (Count 2), *id.* ¶¶ 113–117. Plaintiffs further allege that the DoD directive violates their substantive due process and equal protection rights (Count 7 and 9), *id.* ¶¶ 144–153, 159–164, and imposes unconstitutional conditions (Count 8), *id.* ¶¶ 154–158. Plaintiffs allege that the FDA violated the APA by approving a Biologics License Application for Comirnaty (Counts 3 through 6), *id.* ¶¶ 118–143. And Plaintiffs raise claims under 42 U.S.C. § 1983 (Count 10). *Id.* ¶¶ 165–167. Finally, Plaintiffs allege that the DoD directive

⁴ On October 20, 2021, Defendants filed an opposition to that motion.

and FDA's Comirnaty approval violate "separation of powers and federalism" (Count 11). *Id.* ¶¶ 168–171.

Six weeks after Secretary Austin issued the vaccine mandate, on October 6, 2021, Plaintiffs filed their first "emergency" motion for an administrative stay, declaratory judgment, temporary restraining order, and preliminary injunction. *See* Pls.' Mot., ECF No. 3. In support of that motion, Plaintiffs raise only their statutory claims (Counts 1 through 6). *See* Pls.' 1st Br., ECF No. 3-2. Plaintiffs request that the Court "immediately grant an administrative stay of the DOD and FDA proceedings" and "issue a declaratory judgment, and enter a TRO and/or preliminary injunction against the DOD Vaccine Mandate, the Armed Services' implementation thereof to Plaintiffs, and the FDA Comirnaty Approval." *Id.* at 33; *see also* Proposed Order ¶ 2, ECF No. 3-1. Plaintiffs also urge the Court to enjoin DoD and the Military Services from "taking any adverse employment or disciplinary actions against Plaintiffs for non-compliance" with the DoD mandate.⁵ Proposed Order ¶ 2, ECF No. 3-1.

Two days later, on October 8, 2021, Plaintiffs filed a second motion seeking the same relief, but relying on Plaintiffs' constitutional claims (Claims 7 through 11). *See* Pls.' Mot., ECF No. 10.; Pls.' 2nd Br., ECF No. 11.

⁵ The proposed order also appears to request one form of additional relief, but the clause is incomplete. *See* Proposed Order ¶ 2, ECF No. 3-1.

Plaintiffs’ proposed orders seek relief for themselves and “similarly situated Plaintiffs,” Proposed Order ¶ 2, ECF No. 3-1, Proposed Order ¶ 2, ECF No. 10-1—effectively seeking a nationwide injunction—but Plaintiffs’ counsel clarified at a hearing on October 8, 2021, that they are seeking relief only for the sixteen individual Plaintiffs. Tr. 11:14–12:4 (Oct. 8, 2021).

LEGAL STANDARDS

“A preliminary injunction is an extraordinary remedy never awarded as of right.” *Winter v. NRDC, Inc.*, 555 U.S. 7, 24 (2008). To justify this “drastic remedy,” the movants must “clearly establish[] the burden of persuasion” on the following four elements: (1) Plaintiffs have a substantial likelihood of success on the merits; (2) there is a substantial threat that Plaintiffs will suffer irreparable injury absent an injunction; (3) the threatened injury to Plaintiffs outweighs the damage an injunction would cause to Defendants; and (4) the injunction would not be adverse to the public interest. *Davidoff & CIE, S.A. v. PLD Int’l Corp.*, 263 F.3d 1297, 1300 (11th Cir. 2001); *Ga. Advoc. Off. v. Jackson*, 4 F.4th 1200, 1208 (11th Cir. 2021); *Schiavo ex rel. Schindler v. Schiavo*, 403 F.3d 1223, 1225 (11th Cir. 2005) (same standard for TRO); *Scroos LLC v. Att’y Gen. of U.S.*, 2020 WL 5534281, at *2 (M.D. Fla. Aug. 27, 2020) (same standards for a stay under 5 U.S.C. § 705). “Failure to show any of the four factors is fatal[.]” *ACLU of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009).

ARGUMENT

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

This Court lacks jurisdiction over this case, because Plaintiffs' claims are not ripe and they lack standing to challenge the FDA approval and authorization action. The lack of jurisdiction forecloses any finding of substantial likelihood of success on the merits. *See Digital Properties, Inc. v. City of Plantation*, 121 F.3d 586, 591 n.5 (11th Cir. 1997). Even if Plaintiffs could establish jurisdiction, they cannot show they are likely to succeed on the merits of any of their claims. Accordingly, the case should be dismissed in its entirety.

A. Plaintiffs' Claims Are Not Ripe.

Plaintiffs' claims are not ripe because no plaintiff has exhausted available administrative remedies. *See Elend v. Basham*, 471 F.3d 1199, 1205 (11th Cir. 2006) ("ripeness present[s] the threshold jurisdictional question"). The circumstances of Plaintiffs whose identities are known to Defendants confirm they have failed to exhaust their administrative remedies, either because they did not apply for a relevant exemption or because they sued before their requests for exemptions had been finally adjudicated. *See* Ex. 29 (chart explaining why each Plaintiff lacks a ripe claim). Plaintiffs' claims are also not ripe because none have been subject to final disciplinary action, much less exhausted appeals through available administrative processes.

Here, Plaintiffs' claims must be particularly scrutinized for ripeness because the "military occup[ies] a unique position" with "specialized regulations and procedures, including military administrative procedures." *Frame v. United States*, 2010 WL 883804, at *2 (N.D. Fla. Mar. 5, 2010). "Until Plaintiff has received a decision from the military, judicial review of his claim, even if available, has not arisen." *Id.* at *2.

Claims of Plaintiffs who have pending exemption requests are not ripe because they will be exempted from the COVID-19 vaccination requirement if that exemption is granted. They also will not be subject to any adverse employment or disciplinary action while their requests are pending. Ex. 17 (Decl. of William Merz) ¶¶ 9, 12; Ex. 18 (Decl. of David Furness) ¶¶ 9, 12; Ex. 16 (Decl. of Michele Soltis) ¶¶ 8, 14; Ex. 21 (Decl. of Matthew Streett) ¶ 13. Accordingly, any harm from receiving the vaccine or facing adverse discipline action rests "upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003).

Medical exemptions may be available for those with underlying health conditions like "immune competence, pharmacologic or radiation therapy, pregnancy, and/or previous adverse response to immunization." Ex. 5 ¶ 2-6 a.(1)(a). Each Service each has a process for reviewing medical exemption requests, exempts members while that request is pending, and some have a process for a second opinion

or appeals if a request is initially denied. Ex. 16, ¶¶ 10–13 (Army); Ex. 17, ¶ 6–10 (Navy); Ex. 18, ¶ 7–11 (Marines); Ex. 20 (Decl. of Col. Artemio Chapa) ¶ 8 (Air Force). Of the identified Plaintiffs, only John Doe #10 has applied for a medical exemption. *See* Ex. 26 (Decl. of Sarah Brehm) ¶ 6 (John Doe #10 does not appear to have sought a second opinion and subsequently requested a religious accommodation).

Similarly, service members who request religious exemptions are excused from the required immunization while their requests are pending. *See e.g.*, Ex. 5 ¶ 2–6 b.(3). And if an initial request is denied, each branch has an appeal process. Ex. 16, ¶ 14 (Army); Ex. 17, ¶ 11 (Navy); Ex. 18, ¶ 12.b (Marines); Ex. 21, ¶¶ 12–13 (Air Force). None of the identified Plaintiffs’ religious exemption requests have been denied, and no Plaintiff has completed the appeal process for a requested exemption. *See* Ex. 23 (Decl. of William McWaters) ¶ 4.f. (John Doe #1); Ex. 27 (Decl. of Joseph Langan) ¶¶ 13–14 (John Doe #2); Ex. 29 (Decl. of Lt. Col. Richard Turner) ¶¶ 3–5 (John Doe #9); Ex. 26 ¶¶ 7–8 (John Doe #10).

Another Plaintiff, John Doe #7, has challenged the lawfulness of his order to be vaccinated through the military administrative process. His claim cannot be ripe until that process is complete.

Plaintiffs’ only potential “hardship” while waiting is uncertainty as to the outcome of the exemption request, and that kind of uncertainty 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 Hospitality Ass'n*, 538 U.S. at 811 (explaining that if “mere uncertainty” constituted hardship “courts would soon be overwhelmed with requests for what would essentially be advisory opinions”).

Even if the exemption requests are denied, Plaintiffs refuse to comply, and then face adverse action, the military has administrative procedures that offer Plaintiffs multiple opportunities to present their arguments to their Service and for their Service to respond. *See* Decl. of Elizabeth Hernandez, Ex. 22 ¶¶ 3–14 (Air Force); Ex. 16, ¶¶ 16–18 (Army); Ex. 17, ¶ 13–17 (Navy); Ex. 18, ¶¶ 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) (allowing a challenge to the lawfulness of an anthrax vaccination requirement). For adverse action less than discharge, each Service has administrative procedures that can provide relief. *See* Ex. 22 ¶ 6–8 (Air Force); Ex. 16, ¶¶ 16–18 (Army); Ex. 17, ¶¶ 11, 17 (Navy); Ex. 18, ¶ 12–18 (Marines). And should any Plaintiffs be discharged for non-compliance with the DoD mandate, they can appeal to the applicable Discharge Review Boards and Boards of Correction of Military Records. *See* Ex. 22, ¶ 9–14 (Air Force) Ex. 16, ¶¶ 16–18 (Army); Ex. 17, ¶ 18 (Navy); Ex. 18, ¶ 22 (Marines). As many courts have held, 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*, WL 1060342, at *31 (D. Md. Mar. 18, 2021); *Diraffael v. California Mil. Dep't*, 2011 WL 13274364, at *3 (C.D. Cal. Mar. 21, 2011); *Vaughan v. Kentucky Army Nat. Guard*, 2013 WL 211075, at *6 (E.D. Ky. Jan. 18, 2013).

Finally, this Court should not consider any anonymous declarations of persons not disclosed to Defendants. "To carry [their] burden," the movants "must offer proof beyond unverified allegations in the pleadings"; "vague or conclusory affidavits" will not suffice. *Palmer v. Braun*, 155 F. Supp. 2d 1327, 1331 (M.D. Fla. 2001). The parties have agreed to a protective order, which the Court issued. ECF No. 29. Plaintiffs provided the identities of some declarants, but there are many others—including Jane Does 1 and 2, and John Does 3, 6, 7, 8, 12, and 14—who are still unknown. The Court should not consider these anonymous declarations as reliable facts.

Where Plaintiffs' identities are known their declarations often provide incomplete descriptions of ongoing administrative proceedings. For example, John Doe #2 claimed that he was "subjected to an Article 15, disciplinary action for defying a 'lawful order' and for merely requesting to receive a fully licensed and approved vaccine." Decl. John Doe 2 ¶ 6, ECF No. 1-19. But after receiving his name, the Air Force investigated and discovered that Article 15 proceedings were

initiated against him because he failed to receive the vaccine or request a religious exemption by a specific deadline in a written order. Ex. 27 ¶¶ 7–9. After John Doe #2 submitted a religious exemption request, the officer overseeing the Article 15 terminated the proceedings.⁶ *Id.* ¶ 13. Until the exemption request process is complete, John Doe #2 has a temporary exemption and would not face any additional adverse action. Ex. 21 ¶ 12. But Defendants could not have discovered those critical facts without John Doe #2’s identity.

B. DoD’s Directive Complies with the APA.

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

1. The Secretary Has Clear Legal Authority to Issue the Directive.

First, Plaintiffs question the Secretary’s authority to issue a vaccine directive to members of the armed forces and claim that he bypassed Congress and the States with its issuance. Pls.’ 2nd Br. 24. But the “Constitution emphatically confers authority over the military upon the executive and legislative branches of government.” *Aktepe v. United States*, 105 F.3d 1400, 1403 (11th Cir. 1997), and

⁶ The commander instead provided a Letter of Reprimand, which has not been finalized, for not complying with the order to submit the exemption request by the deadline. Ex. 27 ¶ 13.

there has been no requirement for the leaders of the armed forces to consult with the States on matters of military readiness since its enactment. *See* Federalist Papers 29 (“It is, therefore, with the most evident propriety, that the plan of the convention proposes to empower the Union to provide for organizing, arming, and disciplining the militia, and for governing such part of them as may be employed in the service of the United States....”).

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 (Department of Army); 10 U.S.C. § 8013 (Department of Navy); 10 U.S.C. § 9013 (Department of Air Force). This authority specifically includes administering to the “welfare” of service members. *Id.* And it has been used to institute vaccine mandates for service members during more than two centuries of armed conflict. Ex. 12. In the National Security Act of 1947, Congress put these authorities under the direction, authority, and control of the Secretary of Defense. *See* 50 U.S.C. § 3002 (setting forth congressional purpose in enacting the National Security Act of 1947 as placing the Military Services under the direction, authority, and control of the Secretary of Defense); 10 U.S.C. § 113(b); *see also* 10 U.S.C. §§ 7013 (b)(9), 8013 (b)(9), 9013 (b)(9).

Utilizing this authority, delegated directly from Congress, the Secretary of Defense created DoD’s Immunization Program. *See* Ex. 4 at 5. Contrary to

Plaintiffs’ speculation, this is not an unheralded program but one that existed for decades prior to the COVID-19 pandemic. *See id.* at 1. The current immunization program requires service members to obtain multiple immunizations to be considered medically ready for worldwide deployment, including a requirement for service members to receive the annual influenza vaccine. *Id.* at 3. The COVID-19 vaccination is one of many immunizations required of service members pursuant to these authorities.

Next, Plaintiffs argue that DoD’s directive violates 10 U.S.C. § 1107 and § 1107a and 21 U.S.C. § 360bbb-3.⁷ Pls.’ 1st Br. 13–15; Compl. ¶ 114. But Plaintiffs misunderstand those 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. That authority has only been restricted by 10 U.S.C. § 1107 and § 1107a, which require informed consent in certain limited circumstances that 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

⁷ Although Plaintiffs appear to have alleged these statutory violations as a stand-alone claim, Compl. ¶¶ 113–17, because none of these 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).

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. 13 ¶ 7 n.2. DoD’s directive does not implicate this provision, as none of the COVID-19 vaccines provided to service members are provided as investigational new drugs in the context of clinical trials or drugs unapproved for their applied use. *See* Ex. 13 ¶¶ 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.”).

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 any of these statutes because, 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. Implementation guidance from the Services contain similar provisions. *See* Ex. 6 ¶ 3.D.8.A; Ex. 7 (ALNAV 062/21) ¶ 3; Ex. 8 ¶ 2; Ex. 9 ¶ 3.b; Ex. 11 ¶ 3.1.1.

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. 13 ¶ 6. 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. DoD relied on this determination to instruct its health care providers. Ex. 3 (Acting Assistant Secretary of Defense Memorandum).

In addition, FDA considers vaccines produced at facilities listed in Pfizer’s BLA “to be manufactured in compliance with the BLA and they are not subject to the EUA requirements when used for the approved indication.” Ex. 13 ¶ 13. FDA has recognized that some of these vaccines may still bear the EUA label even though they are BLA-compliant. *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 October 16, 2021, the DoD has in its possession hundreds of thousands of BLA-compliant vaccine doses that are EUA-labeled, and is using them.” Ex. 14 ¶ 18. Accordingly, because the DoD directive only requires service members to be vaccinated with licensed vaccines, Plaintiffs do not have a likelihood of success on the merits of their informed consent claim. *See 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 offered the FDA-approved Pfizer vaccine); *Valdez v. Grisham*, WL 4145746, at *4 (D.N.M. Sept. 13, 2021) (rejecting claim that state vaccine mandate violated the EUA statute because “the FDA has now given its full approval – not just emergency use authorization – to the Pfizer vaccine”).

2. Notice and Comment Rulemaking Is Not Required.

Next, Plaintiffs claim that the Secretary’s directive violates the APA because it allegedly modified Army Regulation 40-562 without going through notice and comment rulemaking procedures. Pls.’ 1st Br. 10–12. 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 issue hundreds of Directives, Instructions, and Manuals pertaining to the manning, equipping, and training of the armed forces—none of which are subject to notice and comment.⁸ The Secretary’s directive requiring service members to receive the approved COVID-19 vaccination (unless otherwise exempt) to maintain the medical readiness of the force is one of many issuances falling within this exemption. *See, e.g., United States v. Mingo*, 964 F.3d 134 (2d Cir. 2020) (DoD designation of military offenses constituting a sex offense falls

⁸ DoD Issuances are available online at <https://www.esd.whs.mil/DD/DOD-Issuances/> last checked October 21, 2021.

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 Employees v. McNamara*, 291 F. Supp. 286, 69 (M.D. Pa. 1968).⁹

Further, as previously discussed, Part B.1., the Secretary of Defense unequivocally has the authority to modify an Army regulation. Moreover, the Secretary’s memorandum does not eliminate the procedures for service members to obtain a medical exemption, Pls.’ 1st Br. 11–12; 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).

3. The Secretary’s Action Was Plainly Reasonable.

Plaintiffs also contend that the Secretary’s decision was arbitrary and capricious. Pls.’ 1st Br. 12–13. The Court’s review of any agency action under 5 U.S.C. § 706(2)(A) must be “deferential” and “narrow.” *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019). The Court “may not substitute its own policy judgment for that of the agency,” but “simply ensures that the agency has acted

⁹ 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)).

within a zone of reasonableness” and “has reasonably considered the relevant issues and reasonably explained the decision.” *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The requirement of “reasoned decisionmaking” means that “agency action is lawful only if it rests ‘on a consideration of the relevant factors.’” *Michigan v. EPA*, 576 U.S. 743, 750 (2015).

In the present setting, the Court’s review must be even more deferential. Judicial review of claims involving the “complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force,” *Gilligan v. Morgan*, 413 U.S. 1, 10 (1973), is highly constrained. *Rostker v. Goldberg*, 453 U.S. 57, 66 (1981) (Because of the “healthy deference to legislative and executive judgments in the area of military affairs,” courts employ a relaxed scrutiny in reviewing military policy.); *Aktepe*, 105 F.3d at 1403 (“[T]he political branches of government are accorded a particularly high degree of deference in the area of military affairs.”); *see also Winck v. England*, 327 F.3d 1296, 1302–04 (11th Cir. 2003). “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)); *see also Orloff v. Willoughby*, 345

U.S. 83, 94 (1953). “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)).

Under this highly deferential standard of review, Plaintiffs’ APA claim easily fails. 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 either upon service entry, as part of a routine immunization cycle during service, or upon elevated risk factors. *See* AR 40-562, Table D-1. And currently the “CDC recommends everyone 12 years and older should get a COVID-19 vaccination to help protect against COVID-19.”¹⁰

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-

¹⁰https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html?s_cid=11369:cdc%20children%20covid%20vaccine:sem.ga:p:RG:GM:gen:PTN:FY21 last checked Oct. 21, 2021.

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,” Secretary Austin “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. *Robert v. Austin*, 21-cv-2228 (D. Colo. 2021), Order Denying Temporary Restraining Order, ECF 12 (denying a temporary restraining order of the DoD vaccine mandate where plaintiffs made similar arguments); *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.”).

Plaintiffs offer the testimony of their putative expert, Dr. Jane Ruby, that the COVID-19 vaccination will interfere in “the course of [service member] duties to protect the American people, the American homeland and the U.S. Constitution.” ECF No. 1-18 at 3. But this 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 chastised district courts for “palpably exceed[ing] [their] authority” for “relying on,” *Rostker*, 453 U.S. at 81.

Plaintiffs also seem to take issue with the timing of the Secretary’s directive, noting that it was issued “the very next day” after the FDA approval of Comirnaty. Pls.’ 1st Br. 12. Plaintiffs’ baseless speculation that the timing of the Secretary’s announcement is suspect should be rejected. When put into context with the Secretary’s August 9, 2021 memorandum, noting the rise in COVID-19 infection rates, and his previously announced intention to institute a vaccination requirement “immediately upon the [FDA] licensure[,]” an order issued the day after licensure should not have been a surprise, much less suspect. Ex. 1 (noting that public reporting suggested that the Pfizer-BioNTech vaccine would soon receive full FDA licensure). *See Dodson v. Dep’t of Army*, 988 F.2d 1199, 1204 (Fed. Cir. 1993) (“[M]ilitary administrators are presumed to act lawfully and in good faith like other public officers, and the military is entitled to substantial deference in the governance of its affairs.”).¹¹

¹¹ Judicial review of agency action is limited to “the whole record or those parts of it cited by the party.” 5 U.S.C. § 706; *Fla. Power & Light Co. v. Lorio*, 470 U.S. 729, 743-44 (1985). Plaintiffs seek to present their own extra record material and to obtain extra record material through discovery. Pls.’ 1st Br. 26. However, supplementation of the record is inappropriate absent strong evidence of bad faith. *Marllantas, Inc. v. Rodriguez*, 806 F. App’x 864, 867 (11th Cir. 2020). In any event, Plaintiffs’ request is premature as Defendants have not produced an administrative record and would not be required to do so until after the Court rules on a forthcoming motion to dismiss.

C. Plaintiffs Cannot Show a Likelihood of Success on Their Claims Against FDA.

Plaintiffs cannot establish a likelihood of success on their statutory challenges to the FDA approval of the BLA for the Pfizer COVID-19 vaccine because they lack standing and the agency’s scientific determination that approval was appropriate is reasonable. Plaintiffs’ challenge to the determination that the EUA vaccine and the licensed vaccine are medically interchangeable also fails.

1. Plaintiffs Lack Standing to Challenge the FDA’s BLA Approval.

Plaintiffs cannot challenge the FDA actions here for the same reasons explained above – they are not currently suffering any injury. *See supra* Part I.A. And even if Plaintiffs could challenge the DoD directive, their injury is not traceable to FDA, nor redressable by an order against FDA. *See Null v. FDA*, 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009) (rejecting argument that a New York vaccine mandate was fairly traceable to FDA’s approval of a vaccine); *see also Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 413 (2013). None of the DoD mandate case law cited by Plaintiffs specifically discusses standing to sue FDA. *See* Pls.’ Mot. at 7.¹² Any alleged “injuries” are not caused by FDA’s actions, but by DoD’s

¹² Nor are Plaintiffs’ other citations helpful. In *Stauber v. Shalala*, 895 F. Supp. 1178, 1187-88 (W.D. Wis. 1995), the plaintiffs wanted milk without certain hormones and alleged that FDA’s approval made acquisition of other milk impossible. Here, Plaintiffs do not want a COVID-19 vaccine; any requirement that they get one is traceable solely to DoD. And the denial of a citizen petition filed by someone else does not create an Article III injury. In *Tummino v. Torti*, 603 F. Supp.

independent decision to require vaccination. Here, prior to the approval of Comirnaty, DoD indicated its intention to move forward with a vaccine requirement for the military by mid-September even if the vaccine had not received FDA approval. *See* Ex. 1. Plaintiffs’ insistence that FDA caused their injury is not only speculative; it is contrary to the available evidence.

2. Plaintiffs’ APA Claims Against the FDA Are Meritless.

Plaintiffs challenge FDA’s approval of the Pfizer vaccine on the ground that it was unsupported by “substantial evidence,” that FDA failed to follow proper procedures, that FDA had an “improper purpose”, that the license is improper in light of the EUA, and because the interchangeability finding is invalid. Pls.’ 1st Br. at 15–31. Even if Plaintiffs had standing to bring those claims, each one fails on the merits. As set forth below, FDA’s actions were entirely in accord with its statutory authority, well documented, and reasonable.

(i) Statutory and Regulatory Background.

The Public Health Service Act (“PHSA”) prohibits introducing a biological product—including a vaccine—into interstate commerce without a license. 42 U.S.C. §§ 262(a)(1), (i)(1). FDA “shall” approve a biologics license if (1) “the biological product . . . is safe, pure, and potent,” (2) “the facility in which the

2d 519,541 (E.D.N.Y. 2009), plaintiffs were challenging FDA’s refusal to authorize over-the-counter dispensing of a particular drug that they wanted. Plaintiffs here have not alleged any such loss.

biological product is manufactured, process, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent,” and (3) “the applicant . . . consents to the inspection of the facility.” 42 U.S.C. § 262(a)(2)(C). Once FDA has made these three findings under the statute, it will license the manufacturer to introduce the vaccine into interstate commerce for its intended uses. The FDA has promulgated regulations for biologics, *see* 21 C.F.R. Pt. 600, and procedures for applications for a biologics license, *see* 21 C.F.R. Pt. 601. FDA has issued other guidance and public documents on biologics and on vaccine development. *See generally* Marks Decl. ¶ 5.

There is an exception to the license requirement for products distributed under an EUA. *See* 21 U.S.C. § 360bbb-3(a)(1). The Secretary (acting through the FDA Commissioner) may issue an EUA for an unlicensed vaccine if he declares a public emergency arising from (for example) a virus, *id.* §§ 360bbb-3(a)(1), (a)(2)(b)(1)(C), and finds that certain conditions are met, including “that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating” the virus, *id.* § 360bbb-3(c)(3). If later those conditions “are no longer met,” the Secretary “may revise or revoke an authorization.” *Id.* § 360bbb-3(g)(2) (emphasis added). The Secretary’s decisions under this authority “are committed to agency discretion.” *Id.* § 360bbb-3(i).

(ii) The FDA's Actions Are Reasonable and Supported by the Evidence.

Contrary to Plaintiffs' contention, FDA's approval of the Pfizer vaccine was plainly reasonable. FDA considered the relevant statutory and regulatory criteria in determining that Pfizer's vaccine is "safe, pure and potent" and reasonably explained its decision.

Under the APA, the Court "may not 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 and reasonably explained the decision." *Prometheus Radio Project*, 141 S. Ct. at 1158. The Court's review here is "at its most deferential" because the challenged actions involve "scientific determination[s]" that are "within [HHS's] area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *Nat'l Mining Ass'n v. Sec'y, U.S. Dep't of Labor*, 812 F.3d 843, 866 (11th Cir. 2016) (noting "an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise"). Moreover, "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in grant of application for stay); *Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 262 (D.C. Cir. 2020). In addition, the "focal point for judicial review" under the APA "should be the

administrative record already in existence, not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (*per curiam*); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985); *Pres. Endangered Areas of Cobb’s Hist., Inc. v. U.S. Army Corps of Eng’rs*, 87 F.3d 1242, 1246 (11th Cir. 1996). The Court is therefore “limited to evaluating the agency’s contemporaneous explanation in light of the existing administrative record.” *Dep’t of Commerce*, 139 S. Ct. at 2573.

The Court should also decline to consider any information not presented to FDA for another reason. FDA regulations provide that “[a]n interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new [Citizen Petition] to modify the action.” 21 C.F.R. § 10.45(f). Ordinarily, “a reviewing court will not consider arguments that a party failed to raise in timely fashion before an administrative agency.” *Mahon v. USDA*, 485 F.3d 1247, 1254–55 (11th Cir. 2007); *see also Ass’n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21 (D.D.C. 2008), *aff’d*, 358 F. App’x 179 (D.C. Cir. 2009).

Under these principles, FDA’s actions are lawful. As reflected by the Summary Basis for Regulatory Action (“SBRA”), in approving the Comirnaty BLA, FDA reviewed the vaccine’s composition, its manufacturing processes and facilities, data from nonclinical studies (i.e., animal testing), the results of two ongoing clinical

studies, collectively involving tens of thousands of individuals, as well as several other sources and reviews. *See* Ex. 13 ¶¶ 16–21 & Ex. D. FDA considered six months of safety and efficacy data from these two clinical trials as well as safety information from the millions of vaccine doses administered under the EUA. *Id.*

Plaintiffs argue that the Court should not defer to FDA’s approval decision because Plaintiffs believe that the decision was made too quickly and was “politicized.” *See* Pls.’ 1st Br. 15–16, 25–26.¹³ Plaintiffs do not cite a case for the proposition that acting expeditiously in the face of urgent public need is evidence of “bad faith” or unworthy of deference under APA standards, and the Marks Declaration describes how the Comirnaty application met the statutory standards. Ex. 13 ¶¶ 16–24. Nor have Plaintiffs pointed to any evidence that FDA decisionmaking was “politicized.” “Disagreement with an agency’s analysis is not enough to warrant the consideration of extra-record evidence, which, after all, is ‘the exception, not the rule.’” *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng’rs*, 255 F. Supp. 3d 101, 125 (D.D.C. 2017). In short, Plaintiffs’ disagreement with the agency experts is not a reason to ignore ordinary APA standards.

¹³ Plaintiffs cite an accurate press release that the original EUA was based on a “randomized, controlled, blinded ongoing clinical trial of thousands of individuals.” Pls.’ 1st Br. at 18. Plaintiffs claim this press release was intended to “mislead the public” because of their mistaken conclusion that the clinical trials were insufficiently controlled and were unblinded too soon. As explained in the Marks Declaration, Plaintiffs are wrong. Ex. 13 ¶¶ 16–24. But Plaintiffs’ disagreement – even if it had a basis – would not be a basis for a finding of bad faith.

Plaintiffs also challenge FDA’s action by citing and quoting the wrong statute. The approval of a BLA under the PHSa, 42 U.S.C. § 262(a)(2)(C), is not governed by the standards for a New Drug Application under the FDCA, *see* Pls.’ 1st Br. 16-17 (citing 21 USC § 355(d), (e), (h)). A product approved pursuant to a BLA need not be approved pursuant to a New Drug Application. 42 U.S.C. 262(j); 21 C.F.R. § 310.4. FDA expects similar levels and types of evidence for both types of applications, but the applicable standards for a biologics license are provided by the PHSa.

Plaintiffs’ additional arguments about the clinical data do not undermine FDA’s conclusions:

Unblinding. Consistent with medical ethical standards and the clinical study protocol, participants in clinical trial C4591001 who had been assigned to the placebo group could be “unblinded” and offered the vaccine, either when eligible for vaccination under local recommendations or after conclusion of their six-month post–Dose 2 study visit. Ex. 13 ¶¶ 16–17.¹⁴ FDA reasonably determined that the

¹⁴ Blinding means that one or more parties of the clinical trial are kept unaware of the treatment assignment. Blinding “may be done to prevent skewing of the data by the placebo effect, by risk-seeking behavior, by unconscious bias or by other factors” but blinding “may impose a significant burden on the volunteer trial participants, and medical ethicists generally agree that researchers are sometimes ethically bound to unblind a study and permit placebo recipients to receive an effective treatment at some point” and the “availability of effective treatment also encourages participation

data collected during the clinical trial allowed FDA to evaluate the safety and effectiveness of the vaccine, considering the data collected during the blinded stage and the other information submitted supporting safety and effectiveness. *Id.* That decision was reasonable and explicitly considered all relevant factors.

Plaintiffs rely on the Ruby Declaration for the proposition that “[u]nblinding after the initial two-month period converted a well-controlled, randomized clinical trial into a modified open-label, observational, variable dose trial, and invalidated the results.” *See* Pls.’ 1st Br. 17. Any substantive consideration of the Ruby Declaration is improper because it was not before the agency decisionmaker, nor the subject of a Citizen Petition. But Ruby’s assertion is also wrong because FDA reasonably concluded it had sufficient reliable data to support approval, notwithstanding the “unblinding.” Ex. 13 ¶ 17. Even if this Court were to consider the Ruby Declaration, deference is due to the agency experts, “particularly on issues about which experts disagree.” *See Nat’l Coal. For Marine Conservation v. Evans*, 231 F. Supp. 2d 119, 127 (D.D.C. 2002).

But even if consideration of an extra-record declaration were appropriate, Ruby’s unsupported allegations would not survive a motion to exclude. *See Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579 (1993). First, she lacks “scientific,

in clinical trials.” Ex. 13 ¶ 16 n. 5. The decision regarding when to unblind a clinical trial involves a delicate balance of competing priorities. *Id.*

technical, or other specialized knowledge” that would “help the trier of fact to understand the evidence or to determine a fact in issue” under Federal Rule of Evidence 702. Ruby is not a medical doctor and her Ph.D. is in psychology. She lacks any relevant expertise with respect to vaccines, vaccine study design, virology, or any issue before the Court. Ruby’s public statements on COVID-19 vaccines as a pundit reveal a lack of basic medical research knowledge and have been widely debunked as false.¹⁵ And Ruby’s “opinions” are not based on sufficient data and do not use “reliable principles and methods.” Indeed, the Declaration is rife with error and reflects a lack of basic understanding of the field. *See* Ex. 13 ¶ 25.

Special Populations. Plaintiffs also argue that FDA permitted Pfizer to “exclude important ‘special populations’ from clinical trials, including: (1) individuals with previous COVID-19 infections; (2) pregnant or lactating women; and (3) individuals with other medical conditions identified in the June 2020 Industry Guidance.” Pls.’ 1st Br. 18–19. Plaintiffs do not have standing to raise

¹⁵ *See, e.g.*, No proof for speculation that COVID-19 vaccine deaths will rival COVID-19 deaths, Politifact, (June 11, 2021), <https://www.politifact.com/factchecks/2021/jun/11/instagram-posts/no-proof-speculation-covid-19-vaccine-deaths-will-/>; Video makes false claims on Covid-19 vaccines and ‘magnetofection,’ AFP Factcheck (July 7, 2021), [https://factcheck.afp.com/http%253A%252F%252Fdoc.afp.com%252F9E94UF-1](https://factcheck.afp.com/http%253A%252F%252Fdoc.afp.com%252F9E94UF-1;); Fact Check: Video does not prove COVID-19 vaccines cause blood anomalies, Reuters (Aug. 26, 2021), <https://www.reuters.com/article/factcheck-video-anomalies/fact-check-video-does-not-prove-covid-19-vaccines-cause-blood-anomalies-idUSL1N2PX1T6>.

categories (2) and (3) as none of them purport to fall in those categories and cannot be injured by FDA's failure to consider a specialized risk to someone else. But the argument fails regardless. FDA reasonably considered and rejected a similar argument in the context of a Citizen Petition. *See* Ex. 13 ¶¶ 22–24. Some of the populations identified by those petitioners were included in the clinical trials supporting approval and additional information will be obtained from post-marketing studies. *See id.* ¶¶ 16, 22. In response to the petition, FDA concluded that the petitioners had not provided scientific justification for requiring effectiveness data from clinical trials specific to each population group and specifically designed to evaluate disease endpoints of varying severity, and that their argument was not consistent with “scientifically valid methods of assessing safety and effectiveness,” such as immuno-bridging or extrapolation across population groups. *See id.* ¶ 22 & Ex. G, at 7–8.

With respect to individuals with previous cases of Covid-19, approximately 3% of the clinical trial participants had evidence of prior infection. *See id.* ¶ 22. FDA explained that there was scientific uncertainty about the duration of immunity after infection and that petitioners had not provided sufficient scientific support for the claim that such individuals might be at higher risk of adverse effects from the vaccine. *See id.* ¶¶ 22–23 & Ex. G, at 8–9 (also specifically considering evidence submitted by petitioners). FDA reached similar conclusions with respect to another

citizen petition. *See* FDA, Response to Citizen Petition, at 13–15 (Docket No. FDA-2021-P-0529) (Aug. 23, 2021). For pregnant women, there are studies ongoing. *See id.* ¶ 22. Some participants in both the treatment and placebo arms of the trial became pregnant during the trial, and pregnancy outcomes were similar between the vaccine and the placebo groups. *See id.* FDA reasonably considered all evidence before the decisionmaker, and Plaintiffs’ criticisms of FDA’s substantive scientific judgment are not likely to succeed under the APA.

(iii) FDA Followed Proper Procedures.

Plaintiffs also contend that FDA did not follow proper procedures because (1) Phase 3 clinical trials were not complete, and (2) FDA did not consult the Advisory Committee. Pls.’ 1st Br. 22-23. Neither argument is a basis for invalidating the FDA Approval.

Vaccines typically undergo three phases of clinical trial prior to approval, and they may also be subject to post market study requirements after approval. *See* Ex. 13 ¶ 15. Phase 1 generally involves 20 to 100 healthy volunteers and focuses on safety; Phases 2 and 3 typically enroll more subjects and are designed to gather more safety information on common short-term side effects and risks, examine the relationship between the dose administered and the immune response, and generate critical efficacy data. *Id.* In the case of the COVID-19 vaccines, although those phases overlapped to speed the development process, no phases were skipped. *Id.*

Comirnaty was also designated as “Fast Track,” a program designed to expedite development and review of drugs for serious conditions. *Id.*

Plaintiffs argue that the approval was arbitrary because Phase 3 was not “complete” before approval. The applicant’s continued collection of information is not a logical or scientific basis for denial of the license. Here, FDA reasonably determined the information collected to support the BLA was sufficient to support the vaccine’s safety and effectiveness. *See* Ex. 13 ¶¶ 16–17 & Ex. E, at 15.

Although clinical trials are ongoing and safety will be evaluated for at the duration of the study, FDA determined that there was adequate data to support the BLA.

Most adverse events linked to vaccination occur within two months of vaccination and Comirnaty BLA included safety information for approximately 12,000 recipients who were followed for at least six months. This is in keeping with the general approach for gathering safety data to evaluate other vaccines. *Id.*

Plaintiffs also argue that the approval was arbitrary because FDA did not consult its Advisory Committee about the BLA. But FDA is not required to do so before acting on an application. *See* 21 C.F.R. § 14.171(a). Rather, the “relevant factors” to consider in approving a vaccine BLA are in the PHSA, and Plaintiffs have not established a likelihood of success on any challenge to the findings regarding those factors. Moreover, as set forth in the SBRA, the Advisory Committee had previously met and discussed the Pfizer EUA request and licensure

issues for COVID-19 vaccines in general, including for example, unblinding issues and risk factors. SBRA, at 26–27. FDA considered whether to refer the application to the Advisory Committee for additional consideration and decided not to do so because “the information submitted to this BLA did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.” *Id.* FDA is not required to refer applications to the Advisory Committee and had a rational explanation for not doing so here, where the Advisory Committee had previously commented on key issues. *See* Ex. 13 ¶ 18.

(iv) FDA Did Not Have an “Improper Purpose.”

Plaintiffs argue that the FDA had an “improper purpose” and considered impermissible factors – namely, “a larger federal program to mandat[e] vaccinations for nearly all Americans, rather than any demonstration that Comirnaty satisfied the statutory criteria for approval.” Pls.’ 1st Br. 23–26. Plaintiffs’ conclusion is both wrong and irrelevant.

First, Plaintiffs include no evidence for the proposition that FDA is somehow trying to mandate vaccinations for everyone. FDA does not enact and has not enacted vaccine mandates for the public; it acts to evaluate applications and to approve safe and effective vaccines, a process that is particularly important during a deadly pandemic. Plaintiffs argue that the “timing” of subsequent federal vaccine mandates is “strong[] evidence” that that approval was intended to assist those

mandates. Pls.’ 1st Br. 24. That conclusion does not logically or plausibly follow. DoD had *already* announced its intention to move forward with requiring COVID vaccinations by mid-September even if FDA had not yet fully approved a vaccine. Other agencies or private employers may have considered FDA’s approval to support their own decisions to require vaccinations for their workforce, but those decisions are not attributable to FDA. Plaintiffs’ additional complaints about FDA’s speed are also unavailing. Acting quickly and efficiently during a deadly pandemic that has killed over 700,000 Americans is not evidence of bad faith.

And, as with military officials, FDA officials are presumed to have properly discharged their official duties, unless there is “clear evidence to the contrary.” *Latif v. Obama*, 677 F.3d 1175, 1178 (D.C. Cir. 2012). Plaintiffs have presented no such evidence here. On the contrary, those portions of the record available to the Court at this preliminary stage demonstrate the agency’s careful consideration of all relevant data.

Finally, Plaintiffs’ arguments – even if they had support – would not state a claim. The Supreme Court has explained that “a court may not reject an agency’s stated reasons for acting simply because the agency might also have had other unstated reasons” and that “a court may not set aside an agency’s policymaking decision solely because it might have been influenced by political considerations or prompted by an Administration’s priorities.” *Dep’t of Com.*, 139 S. Ct. at 2573.

Even if Plaintiffs had some evidence for the proposition that FDA was motivated in part by a desire to support vaccine mandates, that would not state a claim under the APA.

(v) The FDA License is Not Mutually Exclusive with the EUA.

Plaintiffs also insist that FDA acted contrary to law by both approving the Pfizer BLA and maintaining the EUA for the Pfizer vaccine, claiming that the actions are “mutually exclusive” as to the same use. *See* Pls.’ 1st Br. 27–29. Although Plaintiffs argue as a statutory matter that the EUA cannot be maintained after the BLA is approved because the approved vaccine is now “approved, adequate and available,” they illogically seek to invalidate *the license* rather than the EUA, presumably because this Court lacks jurisdiction over a challenge to the EUA. The EUA statute provides that HHS’s “[a]ctions under the authority of this section . . . are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i); *Ass’n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (holding that EUAs are unreviewable); *see also* 5 U.S.C. § 701(a)(2) (agency action is unreviewable under the APA when it “is committed to agency discretion by law”). The Emergency Declaration and the Pfizer EUA state that each was issued under the authority of the EUA statute. *See* Ex. 13 ¶¶ 7–9 & Exs. B, C. They are therefore unreviewable under the APA. It does not follow, however, that Plaintiffs can instead seek invalidation of *the license*, which even under their reading of the statute, is

perfectly valid. Under Plaintiffs' reading, the continuation of the EUA would be invalid, not the license.

Plaintiffs are also wrong that the agency has exceeded its statutory authority by not revoking the EUA. First, even though FDA approved Comirnaty, the agency found that there remains "no adequate, approved, and available alternative" to the EUA vaccines (including Pfizer's) because (1) there is not sufficient approved vaccine available for distribution to [the 16-year-old and older] population in its entirety; and (2) there are not products that are approved to prevent COVID-19 in individuals age 12 through 15, for a third dose in certain populations, and for a "booster" dose in certain circumstances. Ex. 13 ¶¶ 7–9 & Exs. B, C. Plaintiffs object to the finding that the Comirnaty vaccine is not sufficiently available for the adult population because, according to Plaintiffs, "[a]vailability is a binary requirement under the statute; an alternative either is or is not available" and "[t]here is no room in the statute for the FDA to add a third option - not available in sufficient quantity." Pls.' 1st Br. 28. This puzzling interpretation reduces "available" to meaning "in existence." The existence of a single dose for sale somewhere in the world does not mean that all use of the vaccine authorized under the EUA must immediately cease everywhere else. FDA reasonably found that vaccine doses labelled "Comirnaty" are not available to fill the current need. Plaintiffs appear to agree. *See* Compl. ¶ 77.

Accordingly, Plaintiff cannot show a likelihood of success on any argument that Cominarty is “available.”

Second, even if the Comirnaty vaccine were an “adequate, approved, and available alternative” to the EUA vaccines, nothing in 21 U.S.C. § 360bbb-3 requires FDA to revoke existing EUAs. Indeed, the provision governing “Review and Revocation of Authorization” says that, if the criteria justifying the original issuance of an EUA “are no longer met,” then FDA “*may* revise or revoke” that EUA. 21 U.S.C. § 360bbb-3(g)(2) (emphasis added). The verb “may” is ordinarily permissive. *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947); *MSPA Claims I, LLC v. Kingsway Amigo Ins. Co.*, 950 F.3d 764, 773–74 (11th Cir. 2020). The statute thus contemplates that an EUA could continue after an approval of an equivalent product. A permissive reading of “may” also accords with the statutory purpose of giving FDA flexibility to “permit rapid distribution of promising new drugs and antidotes in the most urgent circumstances,” *see* 2004 U.S.C.C.A.N. S17, S18 (Statement of President Bush), because it removes the need for manufacturers to limit supply or delay seeking approval to exhaust supplies of authorized product. Thus, even if the EUA were reviewable, and even if Comirnaty were “available,” Plaintiffs’ challenge would fail because there is no requirement to revoke the existing EUA upon approval of the equivalent vaccine. It is therefore not “mutually exclusive” with the License, even as to the same use.

Plaintiffs further argue that the extension of the EUA is somehow inconsistent with FDA’s determination that the Pfizer EUA vaccine is medically interchangeable with Comirnaty, because FDA regulates the Pfizer vaccines under two regimes. First, FDA’s determination that the vaccines are medically interchangeable – a factual finding that Plaintiffs do not dispute – is not inconsistent with the vaccines being legally distinct, for example, with respect to labeling requirements. Ex. 13 ¶¶ 11–12. Second, because *revocation* of an EUA is explicitly discretionary (as well as nonreviewable), Plaintiffs’ notion that FDA cannot simultaneously regulate the vaccine under two distinct legal regimes is wrong as well. Congress intentionally left open the possibility that the same vaccine could be subject to both a license and an EUA.¹⁶

(vi) The Plaintiffs Cannot Establish a Likelihood of Success with Respect to the Interchangeability Determination.

Plaintiffs challenge the Comirnaty license based on an undisputed finding in the EUA – that Comirnaty and the Pfizer EUA vaccine have the same formulation

¹⁶ This situation is thus readily distinguishable from the statutory provisions at issue in a case cited by Plaintiffs, where the court held that “the FDCA’s text unambiguously foreclosed” an interpretation under which FDA would have discretion to regulate the same product as either a drug or a device. *See Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 637 (D.C. Cir. 2021). Among other reasons, the court found that both regimes created mandatory, incongruent regulatory effects, and that the legislative history supported the specific conclusion that the same product should not be subject to both regimes. *Id.* at 639-41. No such considerations apply here because the EUA statute is discretionary and designed to maximize flexibility.

and can be used interchangeably without presenting any safety or effectiveness concerns. Plaintiffs lack standing to challenge this factual finding for several reasons. First, Plaintiffs' stated objection – that the interchangeability determination is invalid – has no relationship to their requested relief against FDA in the Complaint, invalidation of the license, and thus any injury is not traceable to the Approval. Moreover, Plaintiffs have identified no harm from the finding. DoD has a supply of Comirnaty, and Plaintiffs have set forth no reason to think that they would be required to be vaccinated with something else. *See* Ex. 14 ¶ 18; Ex. 13 ¶ 13; *cf. Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275 (D.C. Cir. 2012) (Kavanaugh, J.) (explaining that availability of vaccines other than the ones to which plaintiffs objected eliminated plaintiffs' standing). DoD's decision to rely on FDA's (undisputed) finding that the vaccines are medically interchangeable does not create standing to challenge any action by FDA.

FDA's determination that the EUA-authorized product and the BLA-approved product can be used interchangeably without safety or effectiveness concerns was both lawful and reasonable. As explained in the EUA letter, the "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." FDA acknowledged that the "products are legally distinct with certain differences that do not impact safety or

effectiveness.” *See* Ex. 13 at Ex. C, at 2 n.8. The licensed and EUA vaccines have an identical formulation and are made by the same manufacturer under current good manufacturing practice requirements. “FDA included this clarification in the authorization letter to avoid the unnecessary operational complications that may have resulted if pharmacies or other healthcare practitioners had believed that individuals who had received Pfizer-BioNTech for the first dose were not authorized to receive Comirnaty for the second dose, or vice versa.” Ex. 13 ¶ 9. FDA’s scientific determination was reasonable.

Plaintiffs confuse this factual finding with the statutory interchangeability determination under a separate subsection of the PHSA. *See* Pls.’ 1st Br. 29–31 (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. 13 ¶ 10. FDA made a scientific determination, based on FDA’s technical expertise and consistent with its statutory authority.

For all the foregoing reasons, Plaintiffs have not established a likelihood of success on their challenges to the FDA License.

D. Plaintiffs’ Constitutional Claims Are Unlikely To Succeed.

1. Rational Basis Review Applies To Plaintiffs’ Constitutional Claims.

Plaintiffs’ constitutional claims are unlikely to succeed on the merits. By arguing that strict scrutiny applies to their constitutional claims, Plaintiffs rely on the wrong standard of review and ignore longstanding precedent (consistently reaffirmed) that vaccine requirements are subject to a rational basis standard. Pls.’ 2nd Br. 2.

“Rational basis review is the test [that] *normally* applies to Fourteenth Amendment challenges, so long as they do not involve suspect classifications based on race or some other ground, or a claim of fundamental right.” *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring).¹⁷ Unless the challenged regulation treats persons differently based on a suspect class or deals with a fundamental right, the government “must only show a rational basis” to overcome an Equal Protection or Due Process challenge. *Panama City Med. Diagnostic Ltd. v. Williams*, 13 F.3d 1541, 1545 (11th Cir. 1994).

Plaintiffs fail to identify any group that the DoD mandate treats differently, much less any suspect classification that would trigger strict scrutiny. Plaintiffs

¹⁷ The Equal Protection Clause of the Fourteenth Amendment applies to the Federal Government under the Fifth Amendment’s Due Process Clause. *Bolling v. Sharpe*, 347 U.S. 497, 500 (1954).

seem to argue that the mandate discriminates based on “alienage.” That is false— all service members are required to be vaccinated unless they have an approved exemption. Ex 2.

Rational basis review also applies because the mandate does not burden any “fundamental right ingrained in the American legal tradition”—“vaccination requirements, like other public-health measures, have been common in this nation” throughout history. *Klaassen v. Tr. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021), *emergency application for relief denied*, No. 21A15 (Barrett, J., in chambers) (Aug. 12, 2021); *accord, e.g., Doe v. Zucker*, 520 F. Supp. 3d 217, 249–53 (N.D.N.Y. 2021); *see Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (“a state may require all members of the public to be vaccinated against smallpox,” under penalty of criminal sanctions); *Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944); *Zucht v. King*, 260 U.S. 174, 177 (1922).

Courts have thus “consistent[ly] use[d] . . . rational basis review to assess mandatory vaccination measures.” *Klaassen v. Trs. of Ind. Univ.*, 2021 WL 3073926, at *24 (N.D. Ind. July 18, 2021); *accord, e.g., Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App’x 348, 355–56 (4th Cir. 2011); *Norris v. Stanley*, --- F. Supp. 3d. ---, 2021 WL 4738827, at *2 (W.D. Mich. Oct. 8, 2021); *Harris v. Univ. of Mass., Lowell*, No. 21-11244, 2021 WL 3848012, at *6 (D. Mass. Aug. 27, 2021); *Zucker*, 520 F. Supp. 3d at 249–53; *see also Cuomo*, 141 S. Ct. at 70 (Gorsuch, J.,

concurring) (explaining that *Jacobson* “essentially applied rational basis review” to a state vaccination requirement).

Courts considering recent challenges to COVID-19 vaccination requirements have continued to apply rational basis review to these challenges. *See, e.g., Klaassen*, 2021 WL 3073926, at *24–*25; *Norris*, 2021 WL 4738827, at *2 (not applying strict scrutiny because the “policy does not violate any of Plaintiff’s fundamental rights”); *Harris*, 2021 WL 3848012 at *3, *6.

Plaintiffs’ reliance on *Cruzan ex rel. Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 279 (1990) to argue otherwise misses the mark. *See* Pls.’ 2nd Br. 14. *Cruzan* held only that “the Constitution granted competent persons a ‘constitutionally protected right to refuse lifesaving hydration and nutrition’” should they later become terminally ill and non-responsive. *Cruzan*, 497 U.S. at 279. The DoD mandate at issue here is nothing like forcing someone to undergo intrusive, years-long treatment against their will even if they are in a vegetative state. Instead, vaccinations are a fairly routine occurrence, and of course, Plaintiffs volunteered to join the military where vaccinations have long been a requirement. *See, e.g., Klaassen*, 2021 WL 3073926, at *25 (university’s mandate was “a far cry” from forced medical care); *Bridges v. Houston Methodist Hosp.*, 2021 WL 2399994, at *2 (S.D. Tex. June 12, 2021) (similar).

Plaintiffs next argue that the mandate should be considered “medical experimentation” in violation of a fundamental right to bodily integrity and thus subject to strict scrutiny. Pls.’ 2nd Br. 17. A case relied on by Plaintiffs explains why none of these “medical experimentation” cases applies to vaccine mandates in the military. *See Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 871 (W.D. Mich. 2004) (distinguishing *Heinrich, Stadt*, and *Cincinnati Radiation*—also cited in Plaintiffs’ brief—from an anthrax vaccine mandate). The *Ammend* Court concluded that “[t]o hold that violations of the right to bodily integrity occurred” when the military mandated anthrax vaccines “would require this Court to chart new constitutional ground”—something it was not willing to do given the Supreme Court’s admonishment to “lower courts to exercise restraint when asked to expand the rights protected by constitutional substantive due process.” *Id.* at 872 (citing *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992)).

Plaintiffs next claim that strict scrutiny is required under the Supreme Court’s reasoning in *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S.Ct. 63, 67 (2020). But *Cuomo* applied strict scrutiny to a First Amendment Free Exercise challenge to a regulation of gatherings that were “not ‘neutral’ and of ‘general applicability.’” *Id.* Nothing in *Cuomo* suggests that the Court silently reversed more than a century of precedent holding that vaccine mandates are subject to rational basis review—instead Justice Gorsuch’s concurrence emphasizes that vaccine

mandates should continue to receive rational basis review. *See Cuomo*, 141 S. Ct. at 70 (Gorsuch, J., concurring).¹⁸

2. Plaintiffs Cannot Meet Their Burden Under Rational Basis Review.

Under rational basis review, the Court must uphold the mandate unless plaintiffs overcome “every conceivable basis which might support it.” *Jones v. Governor of Fla.*, 975 F.3d 1016, 1034 (11th Cir. 2020). When “mounting a facial challenge” under rational basis review, a plaintiff’s “burden is heavy: he must demonstrate that no possible application” of the regulation “can be squared with the Fifth Amendment.” *Doe v. Sullivan*, 938 F.2d 1370, 1383 (D.C. Cir. 1991).

The mandate easily satisfies this standard because it is rationally related to the government’s interest in maintaining “a healthy and ready force” of warfighters ready to defend our nation and in preventing the spread of infectious disease. Ex. 2; *see, e.g., Klaassen*, 2021 WL 3073926, at *26.

Plaintiffs cite no case in which a vaccination requirement has been found to lack a rational basis, and Defendants are aware of none. Instead, Plaintiffs claim

¹⁸ Plaintiffs’ other arguments lack support. Pls.’ 2nd Br. 9–13. Other than noting that the mandate is not imposed by a State exercising inherent police power, Plaintiffs fail to develop the argument. Plaintiffs also propose, with no legal support, that judicial scrutiny should depend on disease-specific facts. Plaintiffs claim the definition of “vaccine” on CDC’s website changed, but do not explain how that would inform judicial scrutiny. Plaintiffs also note that the defendant in *Jacobson* faced different consequences than a service member might under the mandate, but again, they fail to explain why that would matter.

that because the COVID-19 vaccine is newly developed there can be no rational reason for a mandate. Pls.’ 2nd Br. 17. This argument ignores that the FDA has approved this vaccine, minimizes the hundreds of thousands of American lives that have been lost to COVID-19, and omits the costs and disruptions COVID-19 caused to military operations. It also fails to grapple with the military’s mandate for an annual, newly developed influenza vaccine. Ex. 5 ¶ 4–7. In any event, Plaintiffs’ claim otherwise fails. When the D.C. Circuit applied the rational basis test to a requirement for deploying soldiers to receive non-FDA-approved medications, the court concluded that DoD’s two legitimate government 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.” *Sullivan*, 938 F.2d at 1383 (R.B. Ginsburg, J.).¹⁹

3. Plaintiffs’ Other Constitutional Claims Lack Merit.

Plaintiffs’ unconstitutional conditions claim fails as well. *See* Pls.’ 2nd Br. 19. “A predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing.” *Koontz v. St. Johns River Water*

¹⁹ Even if strict scrutiny applied, the requirements would still be constitutional because mandatory vaccines are the least restrictive means to further a compelling government interest in preventing infectious disease. *See F.F. on behalf of Y.F. v. State*, 65 Misc. 3d 616, 633, (N.Y. Sup. Ct. 2019); *Brown v. Smith*, 24 Cal. App. 5th 1135, 1145 (2018); *Love v. State Dep’t of Educ.*, 29 Cal. App. 5th 980, 996 (2018).

Mgmt. Dist., 570 U.S. 595, 612 (2013). The order is constitutional for the reasons described herein, so the doctrine does not apply. *See Norris*, 2021 WL 4738827, at *3 (rejecting an unconstitutional conditions challenge). Regardless, this doctrine would not apply because the military is directly ordering Plaintiffs—not indirectly regulating by withholding benefits.

Plaintiffs’ tenth cause of action claims the federal defendants violated 42 U.S.C. § 1983, Compl. ¶¶ 165–167, but “42 U.S.C. § 1983 does not provide a viable cause of action against [Federal] Agents since they are federal officers and therefore were not ‘acting under color of state law,’” *Fuqua v. Turner*, 996 F.3d 1140, 1147 n.3 (11th Cir. 2021).

II. Plaintiffs Do Not Face Irreparable Harm.

“[E]ven if Plaintiffs establish a likelihood of success on the merits, the absence of a substantial likelihood of irreparable injury would, standing alone, make preliminary injunctive relief improper.” *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (citations omitted).

Irreparable harm “must be neither remote nor speculative, but actual and imminent.” *Ne. Fla. Chapter of Ass’n of Gen. Contractors v. City of Jacksonville, Fla.*, 896 F.2d 1283, 1285 (11th Cir. 1990). “Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.” *Id.* (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)). “The

possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation, weighs heavily against a claim of irreparable harm.” *Sampson*, 415 U.S. at 90. “In cases involving claims related to military personnel decisions, moreover, 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.” *Shaw*, 2021 WL 1840397, at *9 (citations omitted). Plaintiffs have failed to make such a showing.

A. Plaintiffs Who Have Not Taken The Vaccine Will Not Suffer Irreparable Harm.

Plaintiffs first argue that they will suffer irreparable harm from the “involuntary administration of the vaccine,” Pls.’ 2nd Br. 24–25, and being forced “to submit to an inoculation without informed consent,” Pls.’ 1st Br. 31. But no one will physically force them or any other service member to get a COVID-19 vaccine. *See, e.g.*, Ex. 6 ¶ 3.D.8.B.4 (“There will be no involuntary (forcible) immunizations.”); Ex. 16 ¶¶ 6, 8, 15; Ex. 17 ¶ 3 n.2; Ex. 18 ¶ 4 n.2. At least three other courts have found that facing a choice among taking a vaccine, obtaining an exemption, and facing adverse employment consequences is not irreparable harm. *See Beckerich v. St. Elizabeth Med. Ctr.*, 2021 WL 4398027, at *7 (E.D. Ky. Sept. 24, 2021); *Am.’s Frontline Drs. v. Wilcox*, 2021 WL 4546923, at *7 (C.D. Cal. July

30, 2021); *Harsman v. Cincinnati Children's Hosp. Med. Ctr.*, 2021 WL 4504245, at *4 (S.D. Ohio Sept. 30, 2021).

Plaintiffs rely on *Doe v. Rumsfeld* to argue that “[r]equiring a person to submit to an inoculation without informed consent” constitutes irreparable harm. Pls.’ 1st Br. 31; Pls.’ 2nd Br. 25. But *Doe* does not apply because that case involved the provision of investigational new drugs under 10 U.S.C. § 1107 to service members. *See Doe*, 297 F. Supp. 2d at 131. No COVID-19 vaccine given to service members is an IND that would trigger the informed consent procedures set out in 10 U.S.C. § 1107. And, as set forth above, DoD’s mandate does not violate any rights of informed consent.

Plaintiffs next argue that the administrative and disciplinary actions that may be taken against them if they do not comply with the DoD mandate would force them to “sacrifice their current and future employment, benefits, reputation, [and] freedom,” thus constituting irreparable harm. Pls.’ 1st Br. 31; Pls.’ 2nd Br. 25. If Plaintiffs refuse to take the vaccine, and they do not have a valid exemption, they will be subject to a “range of administrative and disciplinary actions,” which may include a court martial proceeding. Ex. 7 ¶ 5; *see also* Ex. 6 ¶ 3.D.8.B.1–3.D.8.B.1.D, 3.D.8.B.2, Annex XX; Ex. 18 ¶ 14; Ex. 22 ¶¶ 10–12; UCMJ art. 92, 10 U.S.C. § 892. But courts have consistently found that these types of administrative and disciplinary actions, including separation and a less than honorable discharge,

are not irreparable injuries because the service member could later be reinstated and provided back pay if he or she prevailed on their claim. *See, e.g., McCurdy v. Zuckert*, 359 F.2d 491 (5th Cir. 1966) (finding that “a general discharge” is not “irreparable”); *Hartikka v. United States*, 754 F.2d 1516, 1518 (9th Cir. 1985) (holding that “loss of income, loss of retirement and relocation pay, and damage to his reputation resulting from the stigma attaching to a less than honorable discharge” is “insufficient . . . to justify injunctive relief”); *Chilcott v. Orr*, 747 F.2d 29, 34 (1st Cir. 1984); *Guitard v. Sec’y of Navy*, 967 F.2d 737, 742 (2d Cir. 1992); *Guerra v. Scruggs*, 942 F.2d 270, 274 (4th Cir. 1991); *Shaw*, 2021 WL 1840397, at *10; *Reinhard v. Johnson*, 209 F. Supp. 3d 207, 220 (D.D.C. 2016); *Bors v. Allen*, 607 F. Supp. 2d 204, 211 (D.D.C. 2009); *Wilburn v. Dalton*, 832 F. Supp. 943, 948 (E.D. Pa. 1993).

Even being subject to court martial does not constitute an irreparable injury. For example, the Supreme Court in *Schlesinger v. Councilman* reversed an injunction that prevented the military from proceeding with an impending court martial; finding that the “inconvenience of having to defend against a single criminal prosecution, cannot [] be considered irreparable....” 420 U.S. 738, 755 (1975) (quotation omitted and cleaned up)); *see also, e.g., Hall v. McHugh*, 2010 WL 596499, at *2 n.4 (S.D. Ga. Feb. 17, 2010); *Waters v. Schlesinger*, 366 F. Supp. 460,

462 (N.D. Tex. 1973); *U.S. ex rel. New v. Perry*, 1996 WL 420175, at *1 (D.D.C. Jan. 16, 1996).

Plaintiffs finally argue that the deprivation of their constitutional rights—either by depriving them of their ability to “refuse unwanted, unnecessary, and unproven experimental medical treatments” or by instituting administrative or disciplinary proceedings that could result in loss of “current and future employment, benefits, reputation, freedom and other enumerated constitutional rights”—constitutes irreparable injury. Pls.’ 2nd Br. 24–25; Pls.’ 1st Br. 32. But, DoD is not violating Plaintiffs’ constitutional rights. And, although Plaintiffs rely on *Jessen v. Village of Lyndon Station*, 519 F. Supp. 1183, 1189 (W.D. Wis. 1981), to imply that Plaintiffs will be deprived of property rights if any adverse employment action is taken against them, *see* Pls.’ 2nd Br. 25; Pls.’ 1st Br. 32, it is well established that service members do not have a property right to continued employment in the military, *see Guerra*, 942 F.2d at 277–78; *Spadone v. McHugh*, 842 F. Supp. 2d 295, 304 (D.D.C. 2012).

The deprivation of constitutional rights causes irreparable injuries only in those limited circumstances where the deprivation has an “intangible nature” such that the plaintiffs “could not be compensated . . . by money damages; in other words, plaintiffs could not be made whole.” *Ne. Fla.*, 896 F.2d at 1285. Even if Plaintiffs had established a substantial likelihood of success on any of their constitutional

claims, they nevertheless do not face irreparable harm because they can refuse the vaccine, face any administrative or disciplinary consequences, and later be made whole through, for example, the correction of their military records, back pay, and reinstatement. *See Norris*, 2021 WL 3891615, at *2–3 (rejecting a similar argument).

Plaintiffs also cannot establish irreparable harm for the same reasons they cannot demonstrate ripeness and imminent harm. *See Ne. Fla.*, 896 F.2d at 1285. Eleven have pending religious exemption requests or intend to request a religious exemption. *See* Ex. 29. While an exemption request is pending, service members are not required to be vaccinated and no disciplinary action will be taken. *See* Ex. 6 ¶ 3.D.8.B.1.F; Ex. 8 ¶ 3.e.(4); Ex. 9 ¶¶ 2.c.3, 2.c.4 (Example 3); Ex. 11 at Attachment 1; Ex. 16 ¶¶ 8, 15, 19; Ex. 17 ¶ 9, n.6, 11 n.9; Ex. 18 ¶ 9 n.5, ¶ 12 n.9; Ex. 21 ¶ 13. No administrative or disciplinary action has been taken against any of the service members with pending exemption requests.²⁰ *See* Ex. 23 ¶¶ 6–7; Ex. 24 ¶¶ 7–8; Ex. 25 ¶¶ 7–8; Ex. 26 ¶ 8; Ex. 27 ¶ 13; Ex. 28 ¶ 12. And a service member will not face any adverse consequences from the vaccination mandate if an exemption is granted. *See* Ex. 17 ¶ 12; Ex. 18 ¶ 13. Therefore, because the exemption process has not yet been completed for these Plaintiffs, Plaintiffs Jane Doe #2 and John Does #1, 2, 3,

²⁰ John Doe #2 was issued a letter of reprimand for his actions prior to submission of his religious exemption request. *See* Ex. 27 ¶¶ 7–14.

6, 8, 9, 10, 11, 12, and 14 do not face imminent harm and it is entirely speculative whether they will face any disciplinary or administrative consequences for refusal to take the vaccine. *See Williams v. Brown*, 2021 WL 4894264 *10 (D. Or. Oct. 19, 2021) (finding no irreparable harm when exemption requests were pending).

Even for the Plaintiffs who have not sought exemptions, the result of any future disciplinary actions is speculative.²¹ *See Shaw*, 2021 WL 1840397, at *10 (speculative that sailor would suffer harm where administrative procedures incomplete). For example, if a service member is subject to a discharge board, that board may determine not to discharge the member. *See id.* Likewise, if an individual is court-martialed, the members or the military judge may determine that the service member is not guilty. Moreover, certain disciplinary proceedings can take months and even up to a year to conclude. *See, e.g.*, Ex. 17 ¶ 16; Ex. 22 ¶ 7, 9, 12. Such actions cannot be considered imminent. *See Shaw*, 2021 WL 1840397, at *10.

B. John Doe #4 Cannot Establish Irreparable Harm.

John Doe #4 attests that he took a COVID-19 vaccine. *See* Decl. of John Doe #4, ¶ 7 (Sept. 27, 2021), ECF No. 1-19. Assuming that attestation is accurate, then the military will consider him fully vaccinated and he will have no further

²¹ John Doe #8 and #13 allege that they were given or are facing “Page 13 sanctions” for non-compliance with the DoD directive. John Doe #8 Decl. ¶ 7; John Doe #13 Decl. ¶ 7. But a “Page 13 is not punitive or an adverse administrative action” and is merely “a formal record of counseling.” Ex. 24 ¶ 4; Ex. 17 ¶ 13.

obligations under the DoD mandate. *See* Ex. 2. He cannot establish any imminent harm, and he is not entitled to injunctive relief. *Alabama v. U.S. Army Corps of Eng'rs*, 424 F.3d 1117, 1134 (11th Cir. 2005).

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

Plaintiffs must also “establish . . . that the balance of equities tips in [their] 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). Indeed, the Supreme Court has cautioned that “courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” *Winter*, 555 U.S. at 24 (quotation omitted). Regardless of whether Plaintiffs seek a nationwide injunction or relief just as to the named Plaintiffs, *see* Pls.’ 1st Br. 33, Pls.’ 2nd Br. 27; Proposed Orders ¶ 2; Tr. 11:14–12:4 (Oct. 8, 2021), either injunction would be contrary to the public interest and the harms to the military and FDA would far outweigh any speculative harms to the Plaintiffs.

A. An Injunction Against DoD and the Military Services Would Adversely Affect Military Readiness.

An injunction against the DoD directive and the Military Services' implementation guidance would have an adverse impact on the public interest in national defense. 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; Ex. 10. The Court must "give great deference" to the "professional military judgment" of these military leaders concerning the importance of slowing the spread of COVID-19 to ensure military readiness. *See Winter*, 555 U.S. at 24–25.

These professional military judgments are supported by the evidence showing COVID-19's impact on the Force. Hundreds of thousands of service members have been infected, thousands have been hospitalized, and dozens have died. Ex. 14 ¶ 11. And COVID-19 has "impacted exercises, deployments, redeployments, and other global force management activities," Ex. 15 (Decl. of Major Scott Stanley) ¶ 6

(including rendering an aircraft carrier non-operational because of an outbreak, *id.* ¶ 8), caused the cancellation of “19 major training events, many of which involved preparation and training with our foreign partners,” *id.* ¶ 9, and has “required significant operational oversight” by the most senior military leaders, *id.* ¶ 4. Certain countries have vaccine requirements, such that unvaccinated service members would not be able to participate in training exercises with partner nations, which are “vital to the preservation of national security and the protection of our foreign interests.” *Id.* ¶¶ 10–11. 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, for example, return to higher levels of occupancy in DoD facilities and hold in-person trainings. *Id.* ¶¶ 3, 14–19. Enjoining the DoD mandate would undermine military readiness by preventing DoD from using the most effective means to stop the spread of COVID-19.

Enjoining the DoD mandate solely as to the named Plaintiffs is also not in the public interest. If they are unvaccinated, they could get infected with COVID-19, become seriously ill and face hospitalization and death, which affects the readiness of their particular unit. Ex. 14 ¶¶ 7–9. Unvaccinated service members also could spread the coronavirus to others, which is especially a problem for the military, given that many service members work in close quarters or in operational settings (e.g., on

ships, in deployed austere environments, etc.). *Id.* ¶ 9; Ex. 15 ¶ 8; Ex. 24 ¶ 7; Ex. 25 ¶ 4; Ex. 27 ¶ 3. Accordingly, even as it relates to individual Plaintiffs, enjoining the DoD mandate would impact readiness.

Plaintiffs also request that the Court enjoin DoD and the Military Services from “taking any adverse employment or disciplinary actions against Plaintiffs for non-compliance” with the DoD mandate. Proposed Orders ¶ 2. But the military must have discretion to handle matters of good order and discipline without interference from the judiciary. *Chappell v. Wallace*, 462 U.S. 296, 300-01 (1983); *see also* Ex. 17 ¶ 19; Ex. 18 ¶ 23. Each Service has a specific process that must be followed before the implementation of any discipline or adverse employment action. *See* Ex. 16 ¶¶ 9–15; Ex. 17 ¶¶ 12–17; Ex. 18 ¶¶ 13–21; Ex. 22 ¶¶ 3–12. An injunction prohibiting the military from initiating or completing that process “would be a disruptive force as to affairs peculiarly within the jurisdiction of the military authorities[,]” *Orloff*, 345 U.S. at 95, and contrary to the public interest, *see Guerra*, 942 F.2d at 275; *Shaw*, 2021 WL 1840397, at *10; *McBride v. West*, 940 F. Supp. 893, 897 (E.D.N.C. 1996).

Plaintiffs ignore the body of case law requiring judicial deference to the professional judgment of military leaders and argue only that there is a public interest in “ensuring the rights of informed consent” and ensuring that their constitutional

rights are not violated. Pls.' 2nd Br. 26; Pls. 1st Br. 32–33. But, as shown above, DoD's mandate violates neither.

B. An Injunction Against FDA Would Greatly Harm Public Health.

An injunction of FDA's approval of Pfizer's vaccine would have an adverse impact on public health. "The virus's effects on individual and community health is well documented." *Castillo v. Whitmer*, 823 F. App'x 413, 417 (6th Cir. 2020). COVID-19 has already infected over 44 million Americans, hospitalized over 3.1 million, and killed over 700,000. Ex. 30 (CDC Weekly Review). So far, over 217 million Americans have received at least one dose of a COVID-19 vaccine. *Id.*

Despite these efforts, the virus that causes COVID-19 is still spreading throughout the United States.²² The vaccines have been shown to be effective at protecting people from COVID-19, especially severe illness and death, and "have been estimated to have already saved hundreds of thousands of lives." Ex. 13 ¶ 26. "One of the most significant barriers to widespread vaccination is vaccine hesitancy and vaccine misinformation." *Id.* Because "[a]n injunction here would call into question the data supporting FDA's determination that Comirnaty is safe and effective," and would cause "considerable public and administrative confusion as to the effect of the injunction because the identical formulation has been authorized

²² See COVID Data Tracker, CDC, https://covid.cdc.gov/covid-data-tracker/#cases_community (last accessed Oct. 20, 2021).

pursuant to an EUA” such an injunction could “seriously undermine the government’s efforts to encourage vaccination in all eligible populations by exacerbating vaccine hesitancy.” *Id.* “Even a more limited injunction, somehow limited to these plaintiffs, would generate extraordinary doubt and confusion.” *Id.* Any injunction that would cause individuals to hesitate in getting a life-saving vaccine in the middle of a pandemic that has killed over 700,000 Americans is unquestionably against the public interest.

* * *

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*, 2020 WL 4197610, at *10 (E.D. Va. July 21, 2020); *see also, e.g., Brown v. Azar*, 497 F. Supp. 3d 1270, 1298 (N.D. Ga. 2020), *aff’d*, 4 F.4th 1220 (11th Cir. 2021); *Does 1-6 v. Mills*, 2021 WL 4783626, at *17 (D. Me. Oct. 13, 2021); *Am.’s Frontline Drs.*, 2021 WL 4546923, at *8; *Valdez*, 2021 WL 4145746, at *13; *Harris*, 2021 WL 3848012, at *8. The Court should likewise find that the public interest weighs heavily against the requested injunction.

CONCLUSION

For the foregoing reasons, Plaintiffs' motions for a preliminary injunction should be denied.

Dated: October 21, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

ALEXANDER K. HAAS
Director, Federal Programs Branch

ANTHONY J. COPPOLINO
Deputy Director

/s/ Andrew E. Carmichael

ANDREW E. CARMICHAEL

AMY E. POWELL

Senior Trial Counsel

ZACHARY A. AVALLONE

COURTNEY D. ENLOW

Trial Attorneys

United States Department of Justice

Civil Division, Federal Programs Branch

1100 L Street, N.W.

Washington, DC 20005

Tel: (202) 514-3346

Fax: (202) 616-8470

Email: Andrew.e.carmichael@usdoj.gov

Counsel for Defendants

CERTIFICATE OF COMPLIANCE

I hereby certify that this submission contains 15,935 words, not including the case style, signature block, and certificate of service, according to Microsoft Word's word count function and thus is in compliance with Local Rule 7.1(F).

/s/ Andrew E. Carmichael

United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 514-3346
Fax: (202) 616-8470
Email: Andrew.e.carmichael@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on October 21, 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/ Andrew E. Carmichael

United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, DC 20005
Tel: (202) 514-3346
Fax: (202) 616-8470
Email: Andrew.e.carmichael@usdoj.gov