UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA

JOHN DOE #1-#14 and JANE DOE #1-#2,	)	
Plaintiffs,	)	
vs.	)	
	)	
LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, U.S. Department of Defense	)	
	)	
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,	)	
	)	
FRANK KENDALL, in his official capacity as Secretary of the Air Force, Department of the Air Force,	)	**CIVIL ACTION NO. 3:21-cv-01211-TKW-HTC**
	)	**(ORAL ARGUMENT REQUESTED)**
CARLOS DEL TORO, in his official capacity as Secretary of the Navy, Department of the Navy, and	)	
	)	
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, Department of the Army,	)	
	)	
Defendants.	)	

PLAINTIFFS' BRIEF IN SUPPORT OF EMERGENCY MOTION FOR ADMINISTRATIVE STAY, DECLARATORY JUDGMENT, TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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INTRODUCTION

Pursuant to Rule 65(a) of the Federal Rules of Civil Procedure, Plaintiffs John Doe #1 to #14 and Jane Doe #1 and #2,[1] file this action against Defendants seeking an Administrative Stay of, and Temporary Restraining Order ("TRO") and Preliminary Injunction enjoining: (1) the DOD's August 24, 2021 COVID-19 vaccine mandate ("DOD Mandate"), *see* ECF No. 1-2; (2) the implementation thereof by each of the Armed Services, *see* ECF No. 1-6 to 1-9 ("Armed Services Guidance"); and (3) the FDA's August 23, 2021 Comirnaty approval ("FDA Comirnaty Approval"). *See* ECF No. 1-3. Defendants are sued in their official capacities for injunctive and declaratory relief.

The DOD Mandate, issued just one day after the FDA's Comirnaty approval, requires all Service members to receive a COVID-19 vaccine. Contrary to the applicable DOD regulation, *see* Army Regulation 40-562, "Immunizations and

[1] Plaintiffs are a group of active-duty service members from each branch of the military, *i.e.*, United States Air Force, Army, Marine Corps, and Navy (collectively, "Armed Services"). Plaintiffs include members of key "special populations" that were not studied in the Comirnaty clinical trials, including: (1) individuals with acquired (or "natural") immunity from COVID-19 due to documented prior infection ("Natural Immunity Plaintiffs"); (2) female service members who are pregnant, nursing or are attempting to become pregnant, which the FDA refers to as "Woman of Childbearing Potential" ("WOCBP Plaintiffs"); and (3) other medical conditions or medical history that may put them at additional risk of side effects or adverse reactions to vaccines. Certain Plaintiffs have requested religious exemptions, which are still pending and are not addressed herein.

Chemoprophylaxis for the Prevention of Infectious Diseases" ("AR 40-562"), the DOD Mandate categorically excludes a medical exemption for service members like Plaintiffs who have natural immunity. The DOD Mandate and Armed Services Guidance violate the Administrative Procedures Act ("APA") insofar they modify or repeal AR 40-562 without instituting an APA rulemaking.

The DOD Mandate relies on the FDA's rushed and fatally flawed Comirnaty approval, which is so riddled with substantive and procedural deficiencies that the only explanation for its decision, and the timing thereof, was to enable upcoming vaccine mandates, rather than ensure the vaccine's safety and efficacy. Vaccine development and FDA approval typically takes 10 years or more, yet the FDA approved Comirnaty in a matter of months on an unprecedented timeline by skipping essential procedural requirements, completion of "well controlled" clinical trials, or examination of "special populations" that include Plaintiffs.

The FDA has violated the Food, Drug & Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and Plaintiff service members' informed consent rights, insofar as it has determined that the Pfizer/BioNTech vaccine may be simultaneously subject to two mutually exclusive and distinct regulatory regimes (*i.e.*, both an EUA vaccine and a licensed vaccine for the same indication) and that the EUA BioNTech and the licensed Comirnaty Vaccine can be used interchangeably. The Armed Service commit the same statutory violations insofar

as they direct providers to administer EUA-labeled or manufactured vaccines "as if" they were the licensed vaccine pursuant to the mandate.

Defendants' "bait and switch" of administering an experimental vaccine that cannot be mandated, in place of the unavailable licensed vaccine, appears intended to deceive and/or coerce service members into taking an experimental vaccine that they have every right to refuse. Notwithstanding the FDA's rubber stamping of the application, Comirnaty remains an experimental vaccine, whose long-term safety and efficacy is unknown. The FDA acknowledged the vaccine's experimental and unproven status in re-issuing the EUA on the same day for the same indication as it licensed Comirnaty.

Plaintiffs therefore urge this court to: (1) find that the DOD Mandate and underlying FDA Comirnaty Approval are unlawful, and stay the effective date of these final agency actions; (2) to grant emergency injunctive relief enjoining the implementation and enforcement of the DOD Mandate, including any disciplinary or administrative proceedings against Plaintiffs for non-compliance; (3) vacate and remand the FDA Comirnaty approval to the FDA; (4) find that the FDA erred insofar as it authorized the same product to be both an EUA and a licensed vaccine; (5) find that the FDA and Armed Services "bait and switch," in directing that the EUA and licensed product can be used "interchangeably," is unlawful; and (6) grant any other declaratory or injunctive relief deemed necessary or appropriate by this Court.

I. STATEMENT OF FACTS

The relevant facts are fully set forth in the Complaint. *See* ECF No. 1 ("Statement of Facts"), Sections I-VIII. Given the complexity of the argument and this Court's page limits, the relevant facts shall be referenced as necessary in Section II of this Memorandum.

II. ARGUMENT

A. Jurisdiction and Justiciability

This Court has jurisdiction because this case arises under federal law, namely: the FDCA, 21 U.S.C. § 301 et seq.; the PHSA, 42 U.S.C. § 247d et seq.; 10 U.S.C. §§ 1107 and 1107a; the APA, 5 U.S.C. § 551 et seq.; and AR 40-562. Accordingly, this court has federal question jurisdiction. *See* 28 U.S.C. §§ 1331, 1343(a)(3)-(4). This court also has jurisdiction to provide the declaratory and equitable relief requested herein. *See* 28 U.S.C. §§ 2201-2202.

Plaintiffs' claims against Defendants' SECDEF and the DOD are justiciable. In the Eleventh Circuit, claims by service members against the armed services are normally non-justiciable, except for "facial challenges to military regulations." *Speigner v. Alexander*, 248 F.3d 1292, 1296 (11th Cir. 2001). In light of the near universal federal vaccine mandates issued or announced recently, that would apply to nearly all public or private sector, *see* ECF No. 1, Compl., Section II, this Court should treat the DOD Mandate as a generally applicable employment regulation.

B. Plaintiffs' Standing

1. Constitutional Standing

A plaintiff establishes standing by demonstrating (1) a "concrete and particularized" injury that is "actual or imminent"; (2) "fairly traceable to the challenged conduct"; and (3) "likely to be redressed by a favorable judicial decision." *Banks v. HHS.*, --- Fed.Appx. ---, 2021 WL 3138562 (11th Cir. July 26, 2021) (*quoting Spokeo, Inc. v. Robbins*, 578 U.S. 856, 136 S. Ct. 1540, 1547, 194 L.Ed.2d 635 (2016)).

Each of these requirements are easily met. Plaintiffs will suffer a "concrete and particularized" injury that is "actual and imminent" due to the unlawful and unconstitutional DOD Mandate, and the resulting disciplinary actions for non-compliance. Moreover, the vaccine administered will most likely be an EUA vaccine that cannot lawfully be mandated or administered without Plaintiffs' informed consent.

The latter two elements, traceability and redressability, normally "overlap as two sides of the causation coin." *Dynalantic Corp. v. Dep't of Def.*, 115 F.3d 1012, 1017 (D.C. Cir. 1997). Where, as here, the plaintiff or "petitioner is the object of the challenged agency action, there is usually little doubt of causation." *Teva Pharmaceuticals USA, Inc. v. FDA*, 514 F.Supp.3d 66, 91 (D.D.C. 2020) ("*Teva*") (*citing Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-62, 112 S. Ct. 1230, 119

L.Ed.2d 351 (1992) ("*Lujan*")).

2. Statutory Standing

a) Plaintiffs' Claims Against the DOD and Armed Services

As explained above, Plaintiffs' claims are facial challenges to military regulations based on allegations that the DOD and Armed Services Defendants "acted arbitrarily and capriciously by failing to adhere to statutes and regulations." *John Doe No. 1 v. Rumsfeld*, 297 F.Supp.2d 119, 128 (D.D.C. 2003) ("*Rumsfeld I*"). Under the APA, "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." *Lujan,* 497 U.S. 871 at 882 (*quoting* 5 U.S.C. § 702). Plaintiffs also have standing as the subject of the challenged agency action. *Teva*, 514 Supp.3d at 91.

Courts have routinely granted standing to service members challenging a new vaccine mandate applicable to them. *See generally Rumsfeld I* and *John Doe No. 1 v Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) ("*Rumsfeld II*"). Plaintiffs' injury is directly traceable to the actions of the DOD in adopting the DOD Mandate, and to the Armed Services Guidance. Their injury can be redressed by this Court's grant of the stay and the declaratory and injunctive relief requested in this Motion.

b) Plaintiffs' Claims Against FDA and HHS

Courts have permitted service members to challenge FDA approval of a vaccine where the FDA's approval provided the legal basis for a DOD mandate. *See Rempfer v. Eschenbach*, 535 F.Supp.2d 99, 101 (D.D.C. 2008), *aff'd sub. nom, Rempfer v. Sharfstein*, 583 F.3d 860 (D.C. Cir. 2009); *see also Rumsfeld I* and *Rumsfeld II* (defendants were SECDEF, DOD, FDA and HHS).

Plaintiffs also have standing under the FDCA and the PHSA, as they are in the class of (involuntary) consumers that these statutes are intended to protect by requiring the FDA to ensure the safety and effectiveness of drug products, and the safety, purity, and potency of biologics like the Comirnaty Vaccine. Plaintiffs' alleged injury is that the FDA has approved Comirnaty, despite that fact that Comirnaty does not meet the safety, efficacy and other requirements for approval.[2]

An additional ground for standing is the FDA's denial of the Citizen Petition, which raises many of the same claims and objections to FDA approval as those raised in the Complaint and this Motion. It is not necessary for Plaintiffs to have

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[2] *See, e.g., Stauber v. Shalala*, 895 F.Supp. 1178, 1187-88 (W.D. Wis. 1995) ("*Stauber*") (finding that consumers had standing under the FDCA to sue FDA because "plaintiffs' injury is their exposure to a potentially dangerous drug whose safety has not been demonstrated in accordance with the act."). *See also Tummino v. Torti*, 603 F.Supp.2d 519, 541 (E.D.N.Y. 2009) ("*Tummino*"), *amended sub. nom. Tummino v. Hamburg*, 2013 WL 865851 (E.D.N.Y. Mar. 6, 2013) (adolescent girls had standing to challenge FDA decision because they were "among the class of individuals whom the statute was intended to protect").

filed their own separate petition to have standing to challenge the denial of the Citizen Petition. *See, e.g., Stauber*, 895 F.Supp. at 1188-89. Instead, it is sufficient that the Citizen Petition addressed the potential injuries faced by Plaintiff's due to the FDA's actions, and that Plaintiff's share the concerns raised in the Citizen Petition due to the FDA's alleged improper or unlawful actions. *See, e.g., Tummino*, 603 F.Supp.2d at 540.

Plaintiffs' injuries are also traceable to Defendants FDA and HHS due to the FDA's approval of Comirnaty. The DOD and Armed Services expressly relied on the FDA's licensing of the Comirnaty Vaccine as the grounds for mandating administration of the Comirnaty Vaccine and treating the EUA vaccine and licensed vaccine as "interchangeabl[e]," ECF No. 1-5, BioNTech EUA Expansion Letter at 2 n.8, that can be administered "as if" it were Comirnaty. ECF No. 1-6, Air Force Guidance, § 3.1.1. Accordingly, Plaintiffs' injury is directly traceable to the FDA's erroneous finding. For the same reasons, Plaintiffs' injuries are likely to be redressed by a decision of this Court granting Plaintiffs' requested relief.

C. Legal Standard

1. Preliminary Injunction and Temporary Restraining Order

A district court may grant a preliminary injunction, or a temporary restraining order, if the moving party shows that:

> (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the

> threatened injury to movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be averse to the public interest.

FF Cosmetics FL, Inc. v. City of Miami Beach, 866 F.3d 1290, 1298 (11th Cir. 2017) (*quoting Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000)).

2. Administrative Stay

The Administrative Procedures Act allows a court to:

> [I]ssue all necessary and appropriate ***process*** to postpone the effective date of agency action or to preserve status or rights pending conclusion of the review proceedings.

5 U.S.C. § 705 (emphasis added). The standards for administrative stays are the same as the above for injunctive relief, with the important distinction that preliminary injunctions act on the person, while stays act on the proceeding. *See, e.g., Nken v. Holder*, 556 U.S. 418, 432-33 129 S. Ct. 1749, 173 L.Ed.2d 550 (2009) ("*Nken*"). Here, the proceedings at issue that Plaintiffs seek to stay are the DOD Mandate proceeding, the Armed Services' implementation thereof, and the FDA Comirnaty proceeding.

3. Administrative Procedures Act

Plaintiffs request that this Court "hold unlawful and set aside" Defendants' "actions, findings, and conclusions" on the grounds that they are:

> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right, power, privilege, or immunity;

> (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
>
> (D) without observance of procedure required by law;
>
> (E) unsupported by substantial evidence … on the record …

5 U.S.C. §706(2)(A)-(E). An agency action is arbitrary or capricious if:

> [1] the agency has relied on factors which Congress has not intended it to consider, [2] entirely failed to consider an important aspect of the problem, [3] offered an explanation for its decision that runs counter to the evidence before the agency, or [4] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) ("*State Farm*").

FDA findings are subject to the traditional "substantial evidence" standard of review, whether under the FDCA or the PHSA, *see* 21 U.S.C. § 355(h), or the Administrative Procedures Act. 5 U.S.C. § 706(E).

D. Plaintiffs Have a Substantial Likelihood of Success on the Merits.

1. The DOD and Armed Services Violated Federal Regulations and the Administrative Procedures Act.

a) The DOD & Armed Services Failed to Institute a Notice-and-Comment Rulemaking to Modify or Revoke AR 40-562.

The DOD Mandate, and its proposed implementation through the Armed Services Guidance, violates federal regulations, in particular, AR 40-562, which expressly provides a presumptive medical exemption for service members with natural immunity gained through previous infections, as well as for pregnant women

in certain circumstances. *See* AR 40-562, para. 2-6(a)(1)(a)-(b). The DOD and Armed Services have also violated the APA insofar as they have effectively modified, repealed or nullified AR 40-562, a legislative rule,[3] without instituting the required notice-and-comment rulemaking proceeding to modify or repeal the regulation. Further, by failing to institute a rulemaking, the DOD's action violated the APA because its actions were made "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

"A rule that," like the DOD Mandate, "effectively amends a prior legislative rule [i.e., AR 40-562], is a legislative" rule. *Nat'l Min. Ass'n v. Jackson,* 768 F.Supp.2d 34, 48 (D.C. Cir. 2011) (citation omitted). Where, as here, an agency amends a legislative rule, "effect[ing] a substantive change in the regulation," the agency must institute a new "notice and comment" rulemaking under 5 U.S.C. § 553. *Id.* (*citing U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34-35 (D.C. Cir. 2005)).

AR 40-562 is a legislative rule because it sets forth service members' obligation to receive vaccinations for certain diseases, as well as their rights to

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[3] A legislative rule is a rule promulgated by an agency that "has the force and effect of law," "affecting individual rights and obligations." *Adams v. Crestwood Medical Ctr.*, 504 F.Supp.3d 1263, 1265 n.24 (N.D. Ala. 2020) (citations omitted). *See also Batterton v. Marshall,* 648 F.2d 694, 701–02 (D.C.Cir.1980) (explaining that a legislative rule "grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests;" "narrowly constrict [s] the discretion of agency officials by largely determining the issue addressed"; and "[has] substantive legal effect.").

medical exemptions due to natural immunity, pregnancy, or other medical conditions. The DOD Mandate modifies or partially repeals AR 40-562 insofar as it: (1) imposes an entirely new vaccine requirement not found in the regulation; and (2) eliminates existing medical exemption for which service members could otherwise qualify.

b) The DOD Mandate Is Arbitrary and Capricious.

The DOD and the Armed Services have imposed a sweeping vaccine mandate without identifying the legal basis for their decision and without providing any explanation or justification for their action, or any findings of facts or analysis supporting their determination. The DOD Mandate includes only a conclusory statement that the SECDEF has "determined that mandatory vaccination against [COVID-19] is necessary to protect the Force and defend the American people." ECF No. 1-2, DOD Mandate at 1.

The lack of any legal or factual basis for the SECDEF's diktat is not surprising given that it was ***the very next day*** (*i.e.*, August 24, 2021) after the FDA's approval. There could not have been any meaningful consideration or analysis of the Comirnaty data, the FDA's analysis, the legal consequences or alternatives to compliance with AR 40-562, or the careful and reasoned decision making for such an important decision as required under the APA.

The DOD Mandate is arbitrary and capricious insofar as the DOD and the Armed Services failed to "consider[] relevant data" or "articulate[] an explanation establishing a rational connection between the facts found and the choice made." *Bayer Healthcare, LLC v. FDA*, 942 F.Supp.2d 17 at 24 (D.D.C. 2013). Further, the DOD and Armed Services actions are unsupported by substantial evidence, as there is no indication in the record that the DOD considered any evidence at all in deciding to immediately impose the mandate for all service members on the day following FDA approval, without exemption of service members with natural immunity or pregnancy as required by the DOD's own regulations.

The DOD Mandate is also arbitrary and capricious insofar as it relied on facially unlawful FDA actions. The DOD and the Armed Services failed to consider whether they had the legal authority to issue a mandate for an experimental vaccine subject to a still effective EUA for the same indication as the licensed vaccine. Nor did they consider the illegality of the FDA's actions in seeking to treat the same product as subject to two mutually exclusive statutory regimes, or treating two such legally distinct products as interchangeable.

c) The DOD Mandate and Armed Services Guidance Violates Plaintiffs' Rights to Informed Consent by Mandating the EUA Vaccine.

The DOD Mandate and the Armed Services Guidance violate numerous federal laws, as well as rules and regulations governing informed consent insofar as

they mandate or permit the administration of the EUA BioNTech Vaccine pursuant to the mandate.[4] The DOD may override service members' informed consent rights, provided that it complies with the requirements of 10 U.S.C. § 1107 (investigational new drugs) or § 1107a (EUA products).[5]

The procedures to override service members' informed consent rights have not been followed or implemented by the DOD because, in its view, Plaintiff service members do not have any rights to informed consent or to refuse vaccination now that Comirnaty has been licensed. Notwithstanding the FDA's licensure of Comirnaty, the Pfizer-BioNTech Vaccine remains an experimental EUA product that the Armed Services intend to coerce service members to take "as if" it were the licensed product, or else lose their freedom and livelihoods.

The norm of informed consent has been "firmly embedded" in U.S. law and FDA regulations for nearly 60 years. *Adullahi v. Pfizer, Inc.*, 562 F.3d 163, 182

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[4] While the DOD Mandate itself states that only FDA-licensed vaccines may be mandated, *see* ECF No. 1-2, DOD Mandate at 1, the Armed Services Guidance expressly states that the EUA BioNTech Vaccine may be administered "as if" it were the licensed Comirnaty Vaccine pursuant to the DOD Mandate. *See, e.g.,* ECF No. 1-6, Air Force Guidance, § 3.1.1.

[5] *See* Exec. Order No. 13,139, 64 Fed. Reg. 192, "Improving Health Protection of Military Personnel Participating in Particular Military Operations" (Oct. 5, 1999) (informed consent override procedures under 10 U.S.C. § 1107); DOD Instruction 6200.02, "Application of Food and Drug Administration Rules to Department of Defense Force Health Protection Programs" (Feb. 27, 2008) (override procedures under 10 U.S.C. § 1107a).

(2nd Cir. 2009). Congress first enacted this requirement in 1962 drawing on the Nuremberg Code and the Helsinki Declaration, "which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation." *Adullahi*, 562 F.3d at 182 (citation omitted). Service member's right to informed consent, and their rights to refuse experimental treatments, are codified in 10 U.S.C. § 1107, 10 U.S.C. § 1107a, and 21 U.S.C. § 360bbb-3. *See also* ECF No. 1, Compl., Section IV.D ("Informed Consent Requirements for EUA Products").

The DOD "cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs." *Rumsfeld I*, 297 F. Supp. 2d at 135.[6] This Court must enjoin the DOD and the Armed Services from doing so here, as well as any disciplinary proceedings for Plaintiffs' refusal of this unlawful demand.

2. FDA's Unlawful Approval of the Comirnaty Vaccine in Violates FDA Regulations and the APA.

The FDA's approval of the Comirnaty Vaccine is unlawful, and therefore invalid, because the FDA ignored the science, the evidence, the law, and its own

[6] *See also Rumsfeld II*, 341 F. Supp. 2d at 19 (D.D.C. 2004) (granting injunction against DOD anthrax vaccine mandate for EUA vaccine). Courts have further held that the DOD medical experimentation without informed consent violates statutory and constitutional rights. *See, e.g., Heinrich v. Sweet,* 62 F.Supp.2d. 282 (D.Mass.1999); *Stadt v. Univ. of Rochester,* 921 F.Supp. 1023 (W.D.N.Y.1996); *In re Cincinnati Radiation Litig.,* 874 F.Supp. 796 (S.D. Ohio 1995); *United States v. Stanley,* 483 U.S. 669, 107 S.Ct. 3054, 97 L.Ed.2d 550 (1987).

rules, procedures and policies to meet an "unprecedented timeline,"[7] to license Comirnaty in time to justify the imposition of unconstitutional federal vaccine mandates on nearly all U.S. citizens and lawful residents. In light of the FDA's patently improper motivation, and its numerous violations of the FDCA, PHSA, the APA, the FDA's rules, procedures and policies, this Court cannot defer to the FDA's decision, as it was based more on politicized science, than medical science. Nor is the FDA "entitled to a presumption of regularity" that it would otherwise be due. *Citizens to Pres. Overton Park, Inc. v. Volpe,* 401 U.S. 402, 415, 91 S. Ct. 814, 28 L.Ed.2d 136 (1971) ("*Volpe*"), *abrogated on other grounds by Califano v. Sanders,* 430 U.S. 99, 97 S.Ct. 980, 51 L.Ed.2d 192 (1977).

a) FDA Comirnaty Approval Was Not Supported By Substantial Evidence from "Well Controlled" Clinical Trials.

FDA has failed to satisfy statutory requirements to ensure that Comirnaty is safe and effective, or that it is "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I). The FDA's determinations are also unsupported by substantial evidence. 21 U.S.C. § 355(h). Nor is its decision supported by the more detailed "substantial evidence" standard pursuant to which the FDA can refuse or withdraw

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[7] Justine Coleman, *FDA Grants Full Approval to Pfizer's COVID-19 Vaccine*, THE HILL (Aug. 23, 2021) (quoting Defendant FDA Commissioner Woodcock), available at: https://thehill.com/policy/healthcare/568980-fda-grants-full-approval-to-pfizers-covid-19-vaccine (last visited Sept. 22, 2021).

approval of a new drug application ("NDA") or BLA, which, among other things, requires the sponsor to use "well controlled investigations, including clinical investigations." 21 U.S.C. §§ 355(d) and (e).[8] This the FDA and Pfizer-BioNTech manifestly failed to do.

The Pfizer-BioNTech application included interim six-month safety and efficacy data for its clinical trials, which reveal that Pfizer-BioNTech gave study participants the option to be "unblinded" (*i.e.*, to learn whether they had taken the experimental BioNTech Vaccine or the placebo), and if they had taken the placebo, to take the BioNTech Vaccine. As a result, only approximately seven percent (7%) of study participants remained blinded after six months. *See* ECF No. 1, Compl., Section V.D.2. Unblinding 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* ECF 1-17, Ruby Aff., ¶12.

As a result, the Comirnaty application failed to meet the requirement to provide clinical data from "well controlled" studies. Such an uncontrolled or partially controlled study is "not acceptable as the sole basis for the approval of

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[8] *See also* 21 C.F.R. § 314.126(e) (defining "well-controlled studies" and stating "[u]ncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness."

claims of effectiveness," 21 C.F.R. § 314.126(e), and therefore invalidates the FDA's approval of Comirnaty.

The FDA reliance on uncontrolled or partially controlled studies also renders incorrect and misleading the FDA's statement that Comirnaty approval was based on "randomized, controlled, blinded ongoing clinical trial of thousands of individuals."[9] The general public, employers, health care providers, and other government agencies act in reliance on the FDA's superior expertise and its adherence to law and its own regulations. Where, as here, an agency not only fails to follow its own procedures, but misleads the public about it, then a court should not grant the agency the "presumption of regularity," *Volpe*, 401 U.S. at 415, or the deference to which it would normally be due.

b) FDA Comirnaty Approval Is Unsupported by Substantial Evidence and Fails Altogether to Address Important Part of the Problem.

The FDA's approval of Comirnaty is also arbitrary and capricious, and unsupported by substantial evidence, insofar as the FDA permitted Pfizer/BioNTech 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

[9] FDA, *FDA Approves First COVID-19 Vaccine*, (Aug. 23, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine (last visited Sept. 24, 2021).

Industry Guidance. *See* ECF No. 1, Compl., Section V.D.1. Despite the fact that the FDA expressly directed vaccine developers to include these groups in the June 2020 Industry Guidance, *see* ECF No. 1-10 at 11, the FDA not only approved the Comirnaty application without safety or efficacy data for these groups, but refused to provide any contraindication or limitations on administering the vaccines to these groups.

The FDA CP Response does not dispute that these special populations were in fact excluded, contrary to its June 2020 Industry Guidance, and instead argues that this exclusion and its extrapolations were permissible. *See* ECF No. 1-12, FDA CP Response at 6-8. This is not a minor issue. According to the CDC, there have been over ***confirmed*** 40 million COVID-19 infections as of September 10, 2021,[10] and thus excluded from the FDA's analysis. The number of WOBCP impacted is even larger.

The FDA acknowledged that the "history of infection prior to vaccination is not usually known in [VAERS] reports." ECF No. 1-12, FDA CP Response at 9 n.31. The FDA, in a footnote, responds to the Citizens Petition's well-supported concern that "individuals with previous infection 'may be at heightened risk for

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[10] CDC, COVID Data Tracker Weekly Review (Sept. 10, 2021), available at: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (last visited Sept. 16, 2021).

adverse effects.'" *Id.* at 8 n.31 (*quoting* ECF No. 1-11, Citizen Petition at 5). The FDA CP Response concludes that certain cited studies either did not identify specific concerns with the Comirnaty Vaccine or describes purported methodological limitations. *Id.* The FDA does not dispute that it has no specific safety data whatsoever for individuals with previous infections. While it asserts that this data is unnecessary, this is not sufficient to satisfy its statutory obligations to support its decisions with substantial evidence. The safety of at least 40 million Americans is worth more than passing references in a footnote.

With respect to the well-established virological principle that prior infection typically confers natural immunity, the FDA simply states "that there is scientific uncertainty about the duration of protection provided by previous natural infection, but that the scientific community believes vaccines may provide a long duration of protection than that provided by natural infection." *Id.* at 8 n.31. As support for excluding groups that include more than 100 million Americans (*i.e.*, those with

natural immunity or WOCBP), the FDA cites to a CDC FAQ and a single study in the *Lancet*,[11] neither of which specifically examine the Pfizer-BioNTech vaccines.[12]

The FDA licensed Comirnaty without any specific efficacy data collected in trials for persons with previous infections or for WOCBP. The FDA's response was limited to a cursory discussion of studies supporting its preferred position (Comirnaty approval), while ignoring the numerous studies cited in this Motion and the Complaint that demonstrate superior protection of natural immunity. *See* ECF No. 1, Compl., Section VI.D. To the extent that the FDA goes beyond the record or the sponsor's application, then it must do so in an even-handed manner, rather than cherry picking only the studies that supports their preferred position and outcome.

The FDA's determinations with respect individuals with natural immunity or pregnant or nursing women are not supported by ***any*** evidence from clinical trials,

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[11] FDA CP Response at 8 n.31 (citing CDC, COVID-19 Frequently Asked Questions, last updated August 2021, available at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html ("CDC FAQ") and Boyton, R. and D Altmann, 2021, *Risk of SARS-CoV-2 Reinfection after Natural Infection*, Lancet, 397(10280):1161-1163, available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00662-0/fulltext) ("Lancet Article")). The Lancet Study does not identify which vaccines were used in these studies.

[12] *See* CDC FAQ (*citing* Alyson M. Cavanaugh, DPT, PhD, et al., *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination – Kentucky, May-June 2021*, CDC Morbidity and Mortality Weekly Report (Aug. 13, 2021) 2021;70(32):1081-83 ("Kentucky Study")). The Kentucky Study included participants who had taken one of the EUA vaccines, but it did not break out results or seek to address the efficacy of particular EUA vaccines.

much less the "substantial evidence" required by statute. 21 U.S.C. § 355(h). Further, in failing to collect, or require, any evidence for these key populations, the FDA failed "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. The FDA also declined to provide any contraindication for these populations, despite its acknowledgement that the Cominarty clinical trials did not provide any information regarding these populations. As such, this Court cannot find that FDA engaged in reasoned decisionmaking as the APA requires. *Bowen*, 476 U.S. at 626.

c) FDA Licensed Comirnaty "Without Procedure Required by Law."

As in *Rumsfeld II* regarding mandatory anthrax vaccinations, "[t]his Court has an obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety." *Rumsfeld II*, 341 F.Supp.2d at 19. "The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their bodies have been tested by the greatest scrutiny of all—public scrutiny." *Id.* Unfortunately, the FDA's review and approval of the Comirnaty Vaccine fell woefully short of the substantive and procedural requirement sets forth in the FDCA, PHSA, the APA, and the FDA's own rules, regulations and policies.

The FDA approved the BLA without completion of the required Phase 3 Clinical Trials. Instead, its decision was based on minimal data collected over as

little as two months, and at most six months, from a study that was not "well controlled" using a statistically invalid sample where 93% of participants were unblinded. Nor did the FDA require Pfizer/BioNTech to follow the methodology set forth in the Pfizer/BioNTech application, or convene an Advisory Committee meeting to consider the data or air opposing views.

While the FDA is not required to seek input from the Advisory Committee, this is a standard procedure that provides an opportunity for public comment and input, which is surely needed for a decision of such great import affecting up to 100 million American workers, and a similar number of the previously infected and other special populations. The FDA thereby bypassed a standard procedure for receiving additional comment and input from independent experts and the public that could have presented additional evidence or alternate views. This would have perhaps slowed down the inevitable and politically motivated approval, and was therefore avoided. The FDA's "actions evidencing bias speak louder than words" denying it. *Latecoere Int'l, Inc. v. U.S. Dep't of Navy*, 19 F.3d 1342, 1365 (11th Cir. 1994).

d) FDA Exceeded Statutory Authority by Basing its Decision on Improper and Extra-Statutory Factors.

The FDA's approval of the Comirnaty Vaccine also violated the substantive provisions of the FDCA, PHSA, and the APA, 5 U.S.C. § 706(2)(C), insofar as it based its decision on impermissible criteria. The FDA approved Comirnaty to enable vaccine mandates as part of a larger federal program to mandating

vaccinations for nearly all Americans, rather than any demonstration that Comirnaty satisfied the statutory criteria for approval. Perhaps the strongest evidence that FDA's approval was intended to facilitate vaccine mandates is the timing. The FDA's Comirnaty approval was announced just over two weeks before the September 9, 2019 issuance and announcement of federal mandates applicable to nearly all public and private sector employees. *See* ECF No. 1, Compl., Section II ("Federal Vaccine Mandates"). This conclusion is reinforced by SECDEF's decision to issue the DOD Mandate the very next day.

Further evidence of the FDA's improper purpose is its unprecedented timeline for approval, combined with skipping required procedures and truncating clinical trials needed to demonstrate safety and efficacy studies, despite widespread evidence of rapidly decreasing effectiveness over time. *See generally id.*, Section V.D ("Procedural and Substantive Deficiencies in FDA Comirnaty Review and Approval Process"). The combination of rushing approval and the subsequent federal vaccine announcements demonstrates that enabling and justifying vaccine mandates was the primary motivation driving the FDA's decision, rather than public health.

e) FDA Is Not Owed Deference or Presumption of Regularity due to Improper Purposes.

Where an agency's decisions are driven by improper purposes or extra-statutory criteria, rather than its scientific expertise, then the courts do not owe the agency deference to which it would otherwise be due. Nor are courts required to

bury their head in the sand and "defer" to the agency's pretextual explanations for its actions and decisionmaking. *See, e.g., Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2574-76 204 L.Ed.2d 978 (2019) ("Our review is deferential, but we are 'not required to exhibit naivete from which ordinary citizens are free.'") (*quoting U.S. v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977)). Where, as here, there is significant evidence of improper purposes, political interference, and significant departures from normal decisionmaking processes, this constitutes evidence of "the FDA's bad faith that renders its decision arbitrary and capricious." *Tummino*, 603 F.Supp.2d at 544.

The DOD Mandate must be viewed as part of a larger effort to impose federal vaccine mandates on nearly all U.S. citizens and lawful residents. *See* ECF No. 1, Compl., Section II. This court should not give the FDA or DOD deference to their scientific or military expertise where there is such clear evidence of political pressure, FDA and DOD violations of statutory, regulatory, prudential, evidentiary, and/or procedural requirements, and reliance on impermissible extra-statutory criteria

f) The Court Must Permit Introduction and Discovery of Evidence Beyond the Administrative Record.

Despite the "record rule," a reviewing court may consider extra-record materials in certain circumstances. *See Nat'l Audubon Soc'y v. Hoffman,* 132 F.3d 7, 14 (2d Cir. 1997). Indeed, "a strong showing of bad faith or improper behavior" may

justify supplementing the record. *Volpe,* 401 U.S. at 420. When the agency action cannot be adequately explained in the record it compiled, the court's consideration of evidence outside the agency's administrative record is not only warranted, but necessary to a meaningful judicial review of the agency's action. *See Asarco, Inc. v. EPA,* 616 F.2d 1153, 1160 (9th Cir.1980).

The instant case is most similar to *Tummino*, where there was abundant evidence of improper political interference and improper action by FDA officials. There, the court permitted the consideration of such evidence where there was evidence: (1) of unusual involvement of FDA upper management in the review process; (2) that FDA officials were motivated by improper or extra-statutory purposes; (3) evidence that FDA or other officials had made the decision before FDA staff had completed their review; (4) the resignation of senior officials involved in the review process; and (5) indications of improper communications between the White House and the FDA. *See Tummino*, 603 F.Supp.2d at 543-545. *See also New York*, 139 S. Ct. at 2574-76 (affirming district court's order for extra-record discovery where there was "a significant mismatch between the decision the Secretary made and the rationale he provided"). This Court should therefore permit Plaintiffs to present evidence to supplement the administrative record and to conduct discovery to obtain extra-record evidence substantiating these claims.

3. The FDA and DOD Violations of the FDCA and PHSA

a) Pfizer-BioNTech Vaccine Cannot Simultaneously Subject to Mutually Exclusive Regulation as EUA and Licensed Product for Same Indication or Use.

The FDCA authorizes the FDA to issue an EUA for a medical drug, device or biologic, where certain conditions have been met. As relevant here, first, the HHS Secretary must declare a public health emergency justifying use of an EUA, 21 U.S.C. § 360bbb-3(b)(1), and second, the FDA must find that "there is no [1] adequate, [2] approved, and [3] available alternative to the product for diagnosing, preventing, or treating" the disease. 21 U.S.C. § 360bbb-3(c)(3).

The public health emergency declaration that justifies the use of an EUA for a product "shall terminate upon the earlier of … a change in the approval status" of the EUA product. 21 U.S.C. § 360bbb-3(b)(2)(A)(ii). The FDA's approval of an EUA product for a given indication automatically terminates the EUA for that product; the FDA's approval of Comirnaty for individuals 16 years or older should have automatically terminated the EUA for that use.

The requirements for licensing and EUA are mutually exclusive. The same product—or same vial of vaccine—cannot be concurrently subject to an EUA and licensed for the same indication or use. Yet that is precisely what the FDA has done by: (1) simultaneously licensing Comirnaty Vaccine and re-issuing the EUA for the BioNTech Vaccine for the same indication (individuals 16 years or older); (2) re-

issuing and expanding the existing BioNTech Vaccine EUA for children of 12-15 years of age and permitting the licensed Comirnaty Vaccine to be used for this group; and (3) finding that the EUA BioNTech Vaccine and licensed Comirnaty Vaccine can be used "interchangeably" and may be substituted for each other.

As explained above, to grant an EUA, the FDA must find that there is no alternative that is (1) adequate, (2) approved, and (3) available. 21 U.S.C. § 360bbb-3(c)(3). All three requirements must be met. Comirnaty is approved and presumably adequate, so the FDA's EUA determination is based on that fact that it is not available in sufficient quantities for vaccination requirements. Availability is a binary requirement under the statute; an alternative either is or is not available. There is no room in the statute for the FDA to add a third option – not available in sufficient quantity – for the purpose of enabling vaccine mandates.

The FDA licensed a product that is not available, and then informed the general public that the EUA-labeled and manufactured product can be used "interchangeably" with, or substituted for, for the licensed product.[13] The FDA provides no justification for ignoring and nullifying these express statutory

[13] The FDA BioNTech EUA Expansion letter appears to authorize injection from an EUA-labeled and manufactured vial for the same indications as the licensed product, namely, to individuals 16 years or older pursuant to a mandate; conversely, it would authorize off-label use of Comirnaty Vaccine manufactured and labeled in compliance with the BLA to be administered to a 12 year-old, an indication for which Comirnaty is not licensed.

requirements, which also has the (presumably intended) effect of nullifying Plaintiffs' rights to informed consent and to refuse the administration of an experimental vaccine.

Courts have held that the FDA exceeds its statutory authority, and abuses its discretion, when it applies two distinct regulatory regimes to the same product. *See, e.g., Genus Med. Techs. LLC v. FDA*, 994 F.3d 631 (D.C. Cir. 2020) (holding that the FDA's determination that it could choose to regulate a product as either a drug or a device, or both, as arbitrary and capricious and exceeded authority). This Court must do the same here: stay, vacate and enjoin the FDA Comirnaty Approval, and remand the matter back to the FDA for reconsideration consistent with applicable laws and regulations, and any further guidance or instructions this Court may provide. *See, e.g., A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1492 (D.C. Cir. 1995) (remanding to the FDA to explain what "bioequivalency" means).

b) The FDA's "Interchangeability" Determination Is Contrary to Law and Exceeds Its Statutory Authority.

The FDA erred and acted contrary to law and the FDA's own rules and policies where it found that the licensed Comirnaty Vaccine can be used interchangeably with the EUA BioNTech Vaccine. "Interchangeable" and "interchangeability" are specifically defined terms in Section 351 of the PHS Act,

42 U.S.C. § 262,[14] in relation to a "reference product,"[15] which is a biological product licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a).

This is the precise statutory provision, 42 U.S.C. § 262(a), under which the FDA reviewed BioNTech's application and licensed the Comirnaty Vaccine. The FDA must be presumed to have used the term "interchangeable" as it is defined in this statute and its own guidance. For the purposes of determining "interchangeability," the "reference product" must be an FDA-licensed product. In this case, the FDA-licensed Comirnaty Vaccine. But the "interchangeable" product, the EUA BioNTech Vaccine, must be the subject of a later filed "abbreviated" application under 42 U.S.C. § 262(k), and there is no indication that any such application was filed by BioNTech, or reviewed or approved by the FDA.

The FDA's determination would reverse the temporal order of the licensed product and the interchangeable product. The reference product under 42 U.S.C. § 262(a) is the first licensed product, and therefore the basis for determining the

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[14] "Interchangeable" and "interchangeability" are defined as a "biological product" that "may be substituted for the reference product" by health care providers. 42 U.S.C. § 351(i)(3). To meet the standards in 42 U.S.C. § 262(k)(4) ("Safety standards for determining interchangeability"), the "interchangeable" or substitute biological product (i) must be biosimilar to the reference product and (ii) and "can be expected to produce the same clinical result as the reference product in any given patient." 42 U.S.C. § 262(k)(4).

[15] "Reference product" is defined as "the single biological product licensed" under 42 U.S.C. § 262(a) "against which a biological product is submitted" under 42 U.S.C. § 262(k). 42 U.S.C. § 351(i)(4).

interchangeability of the later product. Here, however, the EUA BioNTech Vaccine is the earlier product that was not manufactured in a BLA-compliant manner, nor has an abbreviated application been filed. The "interchangeability" determination appears to be a transparent attempt to retroactively license the EUA BioNTech Vaccine, solely for the purpose of enabling the mandate.

The FDA simply has not explained what "interchangeable" means in this context, nor could it because its use of these terms is incompatible with the PHSA's statutory framework. Accordingly, this Court must remand the matter to the FDA to explain its decisions. *See, e.g., A.L. Pharma*, 62 F.3d at 1492 (remanding to the FDA to explain what "bioequivalency" means in the animal drug context and how the evidence relied on by the FDA satisfied the standard).

E. Plaintiff Will Suffer Irreparable Harm Absent a Preliminary Injunction and/or Temporary Restraining Order

To satisfy the irreparable harm requirement, Plaintiffs must demonstrate that absent a preliminary injunction, they are "likely to suffer irreparable harm before a decision on the merits can be rendered." *Winter v. NRDC*, 555 U.S. 7, 22 (2008) (citation omitted). "[R]requiring a person to submit to an inoculation without informed consent" is indisputably "an irreparable harm for which there is no monetary relief." *Rumsfeld I*, 297 F.Supp.2d at 135. Once the vaccine has been involuntarily administered, and Plaintiffs' statutory rights violated, there is no way for this Court to restore the *status quo ante* or provide compensation to undo this

irreversible act.

Further, Plaintiffs are faced with a choice between two irreparable harms: (1) accept unwanted, unnecessary, and unproven experimental medical treatment (i.e., vaccination), pursuant to an unlawful mandate, that may irreparably and irreversibly harm their health or (2) refuse to do so and likely sacrifice their current and future employment, benefits, reputation, freedom and other enumerated constitutional rights. Both options constitute violations of Plaintiffs' constitutional rights. *See, e.g., Jessen v. Village of Lyndon Station*, 519 F. Supp, 1183, 1189 (W.D. Wis. 1981).

F. The Balance of Equities (Including the Public Interest) Weighs Heavily in Plaintiff's Favor.

A preliminary injunction is proper when "the balance of equities tips in [its] favor, and thatan injunction is in the public interest." *Winter*, 555 U.S. at 20. "These factors merge when the Government is the opposing party." *Nken*, 556 U.S. at 435.

There is a strong public interest in ensuring the rights of informed consent. Informed consent fosters trust and support in the doctor-patient relationship. It is also in the public interest for those seeking vaccines to receive accurate, truthful, complete information, and that they give informed consent—or refusal—to experimental vaccines. Conversely, the DOD and the Armed Services have no interest in forcing Plaintiffs to get vaccinated before this Court can act on the expedited briefing schedule proposed by Plaintiffs. By granting a stay or injunction

for the DOD Mandate and the FDA Comirnaty Approval, this Court will put a stop to the FDA and DOD "bait and switch" seeking to trick service members into forfeiting their rights to informed consent and to refuse experimental medical treatments.

III. CONCLUSION

For the reasons set out above, the Court should immediately grant an administrative stay of the DOD and FDA proceedings. This Court should also issue a declaratory judgment, and enter a TRO and/or a preliminary injunction against the DOD Vaccine Mandate, the Armed Services' implementation thereof to Plaintiffs, and the FDA Comirnaty Approval. A form of order is attached as an exhibit to the Motion.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this submission contains 7,844 words according to Microsoft Word's word count function, and as such is in compliance with L.R. 7.1(F).

CERTIFICATE OF SERVICE

This is to certify that I have on this 6th day of October, 2021 e-filed the foregoing Plaintiffs' Motion for Declaratory Judgment, Stay, Temporary Restraining Order and Permanent Injunctive Relief and Memorandum in Support Thereof using the CM/ECF system, and that I have delivered the filing to the Defendants by email and FedEx at the following addresses:

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/s/ Ibrahim Reyes

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

JOHN DOE #1-#14 and JANE DOE #1-#2,	)	
	)	
Plaintiffs,	)	
vs.	)	
	)	
LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, U.S. Department of Defense	)	
	)	
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,	)	
	)	**CIVIL ACTION NO.**
FRANK KENDALL, in his official capacity as Secretary of the Air Force, Department of the Air Force,	)	**(ORAL ARGUMENT REQUESTED)**
	)	
CARLOS DEL TORO, in his official capacity as Secretary of the Navy, Department of the Navy, and	)	
	)	
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, Department of the Army,	)	
	)	
Defendants.	)	

ORDER GRANTING STAY AND TEMPORARY RESTRAINING ORDER

1. On September 24, 2021, the plaintiffs filed a complaint and a motion for declaratory judgment, administrative stay, temporary restraining order, and preliminary injunction to stay the effective date of and enjoin Defendant Department of Defense ("DOD"), and the component armed services (Air Force, Army, Marine Corps, and Navy, collectively the "Armed Services") from implementing its August 24, 2021 mandate requiring Plaintiff service members to receive an injection of a COVID-19 vaccine ("DOD Mandate"), and to stay the effective date of, vacate, and remand to the Defendant Food and Drug Administration ("FDA") its August 23, 2021 approval of the Comirnaty vaccine ("FDA Comirnaty Approval").

2. Having examined the complaint, and the enclosures thereto, and the motion, and enclosures thereto, it is hereby:

ORDERED, that: (1) the effective date of the DOD Mandate, and any implementation thereof by the Armed Services, and the FDA Comirnaty Approval; (2) Defendant DOD and Armed Services are temporarily enjoined from enforcing the DOD Mandate with respect to, or administering any COVID-19 vaccine, the Plaintiffs or similarly situated individuals; and (3) Defendant DOD and Armed Services are temporarily enjoined from taking any adverse employment or disciplinary actions against Plaintiffs for non-

compliance with the DOD Mandate or related orders or implementation by the Armed Services or unit commanders.

Dated: October ____, 2021

_____
T. Kent Wetherell II
United States District Court Judge