UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BENJAMIN COKER, *et al.*, **Plaintiffs,** **v.** **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,** **Defendants.**	**Case No. 3:21-cv-01211-AW-HTC**

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

AGENCY ORDERS & GUIDANCE

CASES

RULES & REGULATIONS

STATUTES

OTHER AUTHORITIES

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

BENJAMIN COKER, *et al.*, **Plaintiffs,** **v.** **LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*,** **Defendants.**	**Case No. 3:21-cv-01211-AW-HTC**

INTRODUCTION

Comirnaty was approved by the Food and Drug Administration ("FDA") on August 23, 2021. Yet after nearly six months and hundreds of millions of Pfizer-BioNTech produced, Comirnaty remains unavailable to the Department of Defense ("DOD") or anyone else in the United States. In the absence of Comirnaty, the DOD and Armed Services Defendants are "mandating vaccines from EUA-labeled vials." *Doe #1-#14 v. Austin*, 2021 WL 5816632, at *5 (N.D. Fla. Nov. 12, 2021) ("*Austin*") (citation omitted). This action on its face violates Plaintiffs' rights under 10 U.S.C. § 1107a and 21 U.S.C. § 360bbb-3 (the "Informed Consent Laws"), and their statutory "right to accept or refuse" expressly stated in the product's labeling.

Defendants assert that the DOD Mandate is limited to a subset of Pfizer-

BioNTech "BLA-compliant," EUA-labeled vials. Yet the publicly available record materials before the Court include no such limitation, and instead state that any EUA vaccines may be used interchangeably with Comirnaty for mandatory injection. The DOD and Armed Services records do not even use the term, while the only FDA records that use the term do not address it interchangeability or suggest that BLA-compliant doses are exempt from mandatory FDA labeling requirements.

Instead, the "BLA-compliant" limitation was asserted in the first instance by Defendants' counsel in the response to Plaintiffs' October 6, 2021 TRO Motion. ECF 3.[1] Courts cannot review or give deference to agency actions without the complete administrative record. Nor may they "rely on counsel's statements as to what was in the record," *Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1574 (10th Cir. 1994) ("*Olenhouse*"), or accept "post hoc rationalization by counsel as prime authority for agency decision," *Harrison v. Ocean Bank*, 2011 WL 2607086, at *4 (S.D. Fla. June 30, 2011). This Court must therefore disregard any claims regarding "BLA-compliant" vaccines unless Defendants can produce record materials substantiating the existence of this limitation and the policies and

[1] Defendants' counsel have not cited any agency rule, decision, or practice supporting Defendants' unprecedented Interchangeability determinations. Comirnaty appears to the first instance. *See* ECF 33, Pls. Reply Brief, at 17-18. Nor is there any court precedent. A search of the term "BLA-compliant" in Westlaw's database of all federal cases returns one result: this Court's decision in *Austin*.

procedures adopted to implement this policy.[2]

The other key issue in dispute is the nature of the Interchangeability determinations. While Defendants characterize the FDA's determination as merely a "factual" determination, ECF 65-2 at 42, this determination unquestionably "determine[s] Plaintiffs' right or obligations." *Id.* (citations and quotation omitted).[3] The DOD and Armed Services treat EUA vaccines "as if" they were legally interchangeable with licensed Comirnaty, and they cite this determination as the legal basis for mandating that Plaintiffs accept a vaccine they have a statutory right to refuse and for punishing them for non-compliance.

Since the announcement of the DOD Mandate on August 24, 2021, federal agencies or the Executive Branch have issued five federal vaccine mandates. All have been stayed or enjoined—three nation-wide, two in a large number of States—based on claims nearly identical to Plaintiffs' that the mandates were *ultra vires* or procedurally improper. The DOD Mandate has now been enjoined by two district

---

[2] While "there is apparently no DOD policy in place to ensure that service members receive BLA-compliant vaccines." *Austin*, 2021 WL 5816632, *6, Plaintiffs have nevertheless tried to illustrate the extra layers of administrative, legal, and logistic complexity entailed by Defendants' proposed "BLA" process, compared to a process involving only licensed vaccines. *See* Ex. 2.

[3] The FDA has subsequently moved the goalposts, expanding the scope of interchangeability from products that purportedly have the "same formulation" to those that are "analytically comparable." *See infra* Argument, Section I.D.5.

courts for systematically and categorically denying exemptions. These decisions lend credence to Plaintiffs' foundational claim that the DOD Mandate, rather than being a measure to promote service members health and welfare, is instead part of a larger and illegal federal government campaign to impose nearly universal vaccine mandates, and that the FDA's Comirnaty approval was driven by this larger goal and political timeline, rather than proof of Comirnaty's safety and effectiveness.

BACKGROUND

I. FEDERAL VACCINE MANDATES

Apart from the DOD Mandate, federal agencies and the Executive Branch have issued five federal vaccine mandates: (1) the Occupational Safety & Health Administration ("OSHA") mandate (stayed nation-wide then withdrawn);[4] (2) the Federal Employee Mandate (stayed nation-wide);[5] (3) the Federal Contractor Mandate (stayed nation-wide);[6] (4) the Head Start Mandate (stayed in 25 states);[7]

[4] *See Nat'l Fed'n of Indep. Bus. v. OSHA*, 142 S. Ct. 661 (2022); *see also BST Holdings, LLC v. OSHA*, 17 F.4th 604 (5th Cir. 2021) ("*BST*").

[5] *See Feds for Medical Freedom v. Biden*, 2022 WL 188329 (S.D. Tex. Jan. 21, 2022) ("*Feds for Medical Freedom*").

[6] *See Georgia, v. Biden*, 2021 WL 5779939 (S.D. Ga. Dec. 7, 2021) ("*Georgia*"); *see also State v. Nelson*, 2021 WL 6108948 (Dec. 22, 2021); *Kentucky v. Biden*, 2021 WL 5587446 (E.D. Ky. Nov. 30, 2021), *aff'd* 2022 WL 43178 (6th Cir. Jan. 5, 2021).

[7] *See Texas v. Becerra*, 2021 WL 6198109 (N.D. Tex. Dec. 31, 2021) ("*Texas*"); *Louisiana v. Becerra*, 2022 WL 16571 (W.D. La. Jan. 1, 2022).

and (5) the Centers for Medicare and Medicaid Services Mandate (stayed in 14 states).[8] Four of these mandates were stayed on the same grounds as Plaintiffs assert here, namely, that, the federal agencies or officials acted *ultra vires*, exceeding the authority delegated to them by the President and/or Congress.[9] Many of these courts further found that the proposed justification for the rule in question was a pretext for the real purpose, which was to cobble together unrelated agency authorities[10] to impose a nearly universal federal vaccine mandate and to maximize vaccination rates, which in turn supported the finding that the federal mandate was *ultra vires.*[11]

In addition, two district courts in the Fifth and Eleventh Circuits have enjoined

---

[8] *See Louisiana v. Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021), *modified* 20 F.4th 260 (5th Cir. Dec. 15, 2021) (limiting stay to the 14 plaintiff states). Although the Supreme Court stayed the Fifth Circuit's injunction pending appeal in *Missouri v. Biden*, 142 S. Ct. 647 (Jan. 13, 2022), the district court denied the motion to lift the stay for the 14 plaintiff states. *See Louisiana v. Becerra*, No. 3:21-cv-03970 (W.D. La. Jan. 18, 2022).

[9] *See, e.g., NFIB*, 142 S. Ct. at 665; *Feds for Medical Freedom*, 2022 WL 188329, at *5-6; *Georgia*, 2021 WL 5779939, at *9-10; *Texas*, 2021 WL 6198109, at *7-8.

[10] Chief Justice Roberts in the *NFIB* oral argument echoed Plaintiffs' theory that the "government is trying to work across the waterfront and it's just going agency by agency. … [T]his has been referred to … as a workaround, and I'm wondering what it is you're trying to work around." Ex. 5, *NFIB v. OSHA* Oral Argument Transcript, at 79:21-25.

[11] *See, e.g., NFIB*, 142 S. Ct. at 666; *BST*, 17 F.4th at 616 (inferring that the OSHA Mandate is "to ramp up vaccine intake by any means necessary."); *Georgia*, 2021 WL 5779939, at *9.

the DOD Mandate with respect to certain service member plaintiffs.[12] Each of these courts relied on data submitted by the Armed Services indicating that the services were violating their own rules, as well as federal law, by uniformly denying exemption requests. *See infra* Argument, Section I.A (summarizing data).

II. UNAVAILABILITY OF LICENSED COMIRNATY VACCINES

From the end of 2020 through the end of 2021, Pfizer produced at least three billion doses of its COVID-19 vaccine,[13] at a rate of hundreds of millions per month. Yet nearly six months after the August 23, 2021 approval, Comirnaty remains unavailable.[14] Why? Pfizer should have every incentive to market the FDA-approved and licensed product, rather than an unapproved product labeled as experimental. The market for licensed products—adults 16 and over—is much larger than the market for unapproved products. Pfizer also has strong incentives to strictly

---

[12] *See generally Navy SEALs 1-26 v. Biden*, 2022 WL 34443 (N.D. Tex. Jan. 3, 2022) ("*Navy SEALs 1-26*"); *Navy SEAL 1 v. Biden*, No. 8:21-cv-02429 (M.D. Fla. Feb. 2, 2022) ("*Navy SEAL 1* TRO Order").

[13] Stephanie Baker & Vernon Silver, *Pfizer Fights to Control Secret of $36 Billion Covid Vaccine Recipe*, BLOOMBERG (Nov. 14, 2021), available at: https://www.bloomberg.com/graphics/2021-pfizer-secret-to-whats-in-the-covid-vaccine/ (last visited Feb. 2, 2022).

[14] *See* Ex. 6, NIH-Pfizer Announcement of Comirnaty Unavailability (Sept. 13, 2021) ("Pfizer "does not plan to produce any product with these new [Comirnaty] NDCs and labels over the next few months"); Ex. 7, FDA, Summary Basis of Regulatory Action – Comirnaty at 5 (Nov. 8, 2021) (confirming unavailability of Comirnaty); Ex. 4, FDA, Pfizer EUA Letter at 10 n.19 (Jan. 3, 2022) (same).

comply with the FDA's labeling requirements, having paid over $4,000,000 in fines for FDA rules and related False Claims Act violations. *See* Ex. 8 (DOJ or Attorney General press releases announcing fines summarized in Table 1).

TABLE 1: Pfizer & Affiliates Violations 2001-2016

Company	Primary Offense(s)	Year	Agency	Amount	Source
Pfizer	FDA Labeling False Claims Act	2009	FDA DOJ	$2,300,000,000	DOJ 2009
Pfizer	False Claims Act	2016	DOJ	$784,600,000	DOJ 2016
Pfizer (Wyeth)	FDA Labeling	2013	FDA	$490,900,000	DOJ 2013
Pfizer (Warner-Lambert)	FDA Labeling	2004	FDA	$430,000,000	DOJ 2004
Pfizer	FDA Labeling	2008	Multi-AG	$60,000,000	IL AG 2008
Pfizer	FDA Labeling	2014	Multi-AG	$35,000,000	NY AG 2012

Plaintiffs are not suggesting that Pfizer has engaged in any illegal activity here. In fact, just the opposite, namely, that Pfizer is strictly complying with the law and the FDA's labeling requirements. The most plausible explanation for the lack of FDA-approved and labeled Comirnaty is that the EUA-labeled vaccines that are available are different products and/or do not meet the FDA's requirements to be sold as an FDA-approved product. Defendants' alternative explanation is not only implausible, but also massively multiplies the administrative, legal and logistical complexity to implement the mandate, as Plaintiffs have attempted to illustrate in Exhibit 2, which the "normal" process to Defendants' hypothetical BLA process requiring segregation of BLA-compliant from EUA lots. The lots themselves are

significant. According to Dr. Robert Malone: "There is a reasonable chance that one would see significant lot-to-lot variation in the final product, and that would include the composition of matter."[15]

III. HISTORY OF MILITARY MEDICAL EXPERIMENTATION

The plausibility of Plaintiffs' claims must be considered in light of the long history of the DOD and Armed Services illegal use of service members as unwilling or unwitting subjects of medical research, and covering up such abuses for decades.[16]

Prior to the first Gulf War, the DOD sought to pretreat service members with two investigational new drugs ("IND")—pyridostigmine bromine ("PD") and botulinum toxoid ("BT") vaccine—which could not be administered without informed consent. The DOD successfully petitioned the FDA to establish a new rule waiving informed consent. *See* Parasidis, *supra* note 16, at 742. The administration of these experimental drugs has been correlated with "Gulf War illnesses" that "have debilitated over 174,000 service members." *Id.* at 724 (citations omitted).

---

[15] Dr. Malone statement at 1:06:41, available at: https://youtu.be/prGAsGgByA4.

[16] *See generally* Ex. 9, Efthimios Parasidis, *Justice and Beneficience in Military Medicine and Research*, 73 Ohio St. L.J. 723, 732-39 & 759-60 (2012) (discussing clandestine military research projects using tens or hundreds of thousands of service members, including testing of chemical weapons; deliberate unprotected radiation exposure from nuclear weapons; Tuskegee Syphilis Study; and administration of psychotropic drugs). Plaintiffs' pleadings discussed and cited cases addressing these military abuses. *See* ECF 11, TRO Brief, at 16-18; ECF 33, Reply Brief, at 22-23.

This continued with the campaigns in Iraq and Afghanistan. The DOD sought to override service members informed consent requirements with the experimental Anthrax vaccine, but was enjoined from doing so in 2003.[17] Eight days later, the FDA fully approved the Anthrax vaccine. *See* Parasidis, *supra* note 16, at 745. That FDA decision was vacated by the Court in *Rumsfeld II*, and the injunction was expanded to cover the vaccine after being granted EUA status in *Rumsfeld III*.

LEGAL STANDARD

I. RULE 12(B)(1) SUBJECT MATTER JURISDICTION

To defeat a Rule 12(b)(1) standing challenge, "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss [the Court] presume[s] that general allegations embrace those specific facts that are necessary to support the claim." *Miccosukee Tribe of Indians of Florida v. Southern Everglades Restoration Alliance,* 304 F.3d 1076, 1080–81 (11th Cir.2002).

In assessing a motion to dismiss under Rule 12(b)(1), a district court "may hear conflicting evidence and decide for itself the factual issues that determine jurisdiction." *Colonial Pipeline Co. v. Collins*, 921 F.2d 1237, 1243 (11th Cir.1991).

---

[17] *See generally John Doe No. 1 v. Rumsfeld*, 297 F.Supp.2d 119, 128 (D.D.C.2003) ("*Rumsfeld I*"), *modified sub nom. John Doe No. 1 v Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C.2004) ("*Rumsfeld II*"), *modified sub nom. John Doe No. 1 v. Rumsfeld*, 2005 WL 774857 (D.D.C. Feb. 6, 2005) ("*Rumsfeld III*").

In such cases, "a plaintiff must have ample opportunity to present evidence bearing on the existence of jurisdiction." *Colonial Pipeline*, 921 F.2d at 1243. And "when the jurisdictional basis of a claim is intertwined with the merits of the claim, the district court should apply a Rule 56 summary judgment standard when ruling on a motion to dismiss which asserts a factual attack on subject matter jurisdiction." *Odyssey Marine Expl., Inc. v. Unidentified Shipwrecked Vessel*, 657 F.3d 1159, 1169 (11th Cir.2011) (citations omitted).

II. RULE 12(B)(6) FAILURE TO STATE A CLAIM

"A dismissal under Rule 12(b)(6) 'is viewed with disfavor and rarely granted.'" *Gyasi v. M/V "ANDRE"*, 2008 WL 162644, at *2 (S.D. Fla. Jan. 16, 2008) (*quoting Brooks v. Blue Cross and Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1369 (11th Cir.1997) ("*Brooks*")). *Accord McWilliams v. McNesby*, 2006 WL 156858, at *2 (N.D. Fla. Jan. 20, 2006).

A. The Facial Plausibility Standard

In *Bell Atl. Corp. v. Twombly,* 550 U.S. 544 (2007) ("*Twombly*") and *Ashcroft v. Iqbal,* 556 U.S. 662 (2009) ("*Iqbal*"), the Supreme Court set forth the "plausibility" standard that Plaintiffs must meet to survive a Rule 12(b)(6) motion to dismiss ("*Twombly/Iqbal* Standard"). A complaint "does not need detailed factual allegations," but must merely "be enough to raise a right to relief above the speculative level." *Twombly*, U.S. at 555. In *Iqbal*, the Supreme Court clarified that

"[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S.Ct. at 1949. For an Administrative Procedure Act ("APA") claim, this simply requires the plaintiff "to allege the specific nature of the … obligation [the agency] failed to satisfy." *Speaker v. HHS*, 623 F.3d 1371, 1381 (11th Cir.2010) ("*Speaker*").

B. Standard for Factual Allegations and Legal Theories.

"In ruling on a 12(b)(6) motion," the Court must "accept[] the factual allegations in the complaint as true," and it must "construe[] them in the light most favorable to the plaintiff." *Speaker*, 623 F.3d at 1379 (citation omitted). Further, the Court "must presume that the general allegations in the complaint encompass the specific facts necessary to support those allegations." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 104 (1998).

Legal claims are also to be liberally construed, and an "imperfect statement of the legal theory supporting the claim asserted" is not grounds for dismissal. *Johnson v. City of Shelby, Miss.*, 574 U.S. 10, 11 (2014). Rule 12(b)(6) dismissal "is appropriate only where the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory." *Mendiondo v. Centinela Hosp. Med. Ctr.,* 521 F.3d 1097, 1104 (9th Cir.2008).

In evaluating the sufficiency of Plaintiffs' factual allegations and legal claims,

the Court can consider any matters that are properly the subject of judicial notice, as well as any items in the record, including: the complaint, exhibits, any documents incorporated by reference thereto or that are expressly relied upon, as well as any facts, documents or legal arguments presented in motions, briefs or arguments of counsel, including the Plaintiffs' opposition to the motion to dismiss. *See generally* Tracy Bateman, *et al.*, 27A Fed.Proc., L.Ed. § 62:460 (collecting cases).

C. Standard For Stating APA Claims

A plaintiff asserting an APA claim "is not required to 'demonstrate' anything in order to survive a Rule 12(b)(6) motion to dismiss," and needs only "to *allege* 'sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Pinnacle Armor, Inc. v. United States*, 648 F.3d 708, 721 (9th Cir.2011) (*quoting Iqbal,* 129 S.Ct. at 1949).

For a claim that agency action is arbitrary and capricious, a plaintiff must allege facts sufficient to show one of the types of conduct found to violate the APA. *See, e.g., J.E.C.M. v. Lloyd*, 352 F.Supp.3d 559, 583 (E.D. Va. 2018) ("*J.E.C.M.*") (plaintiff had stated APA claims because agency "was motivated by 'factors which Congress has not intended it to consider'") (*quoting Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983) ("*State Farm*")); *Morrison v. Sec'y of Defense*, 760 F.Supp.2d 15, 20 (D.D.C.2011) (plaintiff presented evidence that agency failed to consider evidence required by regulation).

To state a claim that the agency action is *ultra vires* or in excess of statutory authority, or that it acted without observance of procedures required by law, the plaintiff must identify the law, regulation, rule or procedure violated and provide sufficient factual content to plausibly allege defendants' violation of its obligation(s) thereunder. *See, e.g., J.E.C.M.*, 352 F.Supp.3d at 584; *Int'l Brominated Solvents Ass'n v. Am. Conf. of Governmental Indus. Hygienists, Inc.,* 393 F.Supp.2d 1362, 1383 (M.D. Ga. 2005) ("*Int'l Brominated Solvents*"); *Ohio Coal Assoc. v. Murray Energy Corp.*, 192 F.Supp.3d 882, 905-06 (S.D. Oh. 2016) ("*Ohio Coal*") (agency used extra-statutory criteria as the basis for enacting and enforcing rule).

D. APA Claim Cannot Be Dismissed without Administrative Record.

Judicial review of agency actions under the APA "must proceed on the complete administrative record." *Gupta v. U.S. Attorney General*, 2014 WL 12868884, at *1 (M.D. Fla. Nov. 21, 2014) (citation omitted). *See also Vargus v. McHugh*, 87 F.Supp.3d 298, 302 (D.D.C. 2015) (the court "cannot fully evaluate" the government's arguments for dismissal regardless of "[w]hether ... th[o]se points [were] dispositive of Plaintiff's claims").

A court cannot rule on a motion to dismiss an APA claim of arbitrary and capricious agency action because the court is reviewing not only the legality of the agency's action, but also "the path by which it reached its decision." *Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 339 (D.C. Cir.1989). *See also Farrell v.*

Tillerson, 315 F.Supp.3d 47, 69 (D.D.C.2018) ("*Farrell*") (denying motion to dismiss because agency had not produced complete record). In the absence of the record, a court cannot defer to agency decision-making because Rule 12 requires the court to "accept the Plaintiffs' well-plead factual allegations as true and resolve all reasonable inferences in the Plaintiffs' favor." *Pitman v. USCIS*, 2017 WL 5991738, at *3 (D. Utah Dec. 1, 2017) ("*Pitman*") (citations omitted).

E. Standard for Non-Statutory *Ultra Vires* Claim.

Where an agency has acted in violation of a statute or otherwise in excess of its delegated authority, but the plaintiff "is unable to ground his action on either a specific or general statutory review provision," plaintiffs may still assert a claim for specific relief, or a "non-statutory" *ultra vires* claim. *Rhode Island Dep't of Env't Mgmt. v. United States*, 304 F.3d 31, 41–42 (1st Cir.2002) ("*Rhode Island*") (citation and quotation omitted).[18] A non-statutory *ultra vires* review is available where "the agency's nonfinal action … wholly deprive[s] the [party] of a meaningful and adequate means of vindicating its ... rights." *Id.* at 42 (citation and quotation omitted).

[18] "Such actions are based on the grant of general federal question jurisdiction under 28 U.S.C. § 1331 and the inherent equity powers of the federal courts," and "usually take the form of a suit seeking an injunction, often accompanied by a request for relief under the Declaratory Judgment Act, 28 U.S.C. § 2201." *Rhode Island*, 304 F.3d at 41-42. The SAC cites these statutes as the basis for this Court's subject matter jurisdiction and as the basis for relief, respectively. *See* ECF 56, SAC ¶¶ 11, 39.

To plead a non-statutory *ultra vires* claim, a plaintiff must: (1) "allege facts sufficient to establish that the officer … was not exercising the powers delegated to him by the United States;" and (2) "specify in the complaint the statutory limitation on the powers of the agent relied upon." *Alabama Rural Fire Ins. Co. v. Naylor*, 530 F.2d 1221 (5th Cir.1976) ("*Naylor*"). *See also Davis v. Rucker*, 2002 WL 31235735, at *4 (M.D. Fla. Aug. 23, 2002) ("*Davis*") (applying *Naylor*).

ARGUMENT

I. THIS COURT HAS SUBJECT MATTER JURISDICTION

A. Plaintiffs' Challenges to Military Regulations Are Justiciable.

In *Navy Seal 1 v. Biden*, 2021 WL 5448970, at *11 (M.D. Fla. Nov. 22, 2021) ("*Navy Seal 1*"), the Middle District rejected Defendants' argument that facial challenges to military regulations largely identical to Plaintiffs' were non-justiciable "as-applied challenges to military policies." ECF 65-1 at 13 (*citing Speigner v. Alexander*, 248 F.3d 1292, 1296-98 (11th Cir.2001) ("*Speigner*")). Plaintiffs' claims are facial challenges to a generally applicable military regulation that violates express statutory rights and deprives them of existing medical exemptions.[19]

[19] 10 U.S.C. § 1107a was enacted in 2004 by Congress in response to the DOD Anthrax vaccine mandate and expressly prohibits the DOD from mandating EUA drugs. *See* Ex. 9, Parasidis, *supra* note 16, at 762-63. To the extent *Speigner* could be read as depriving this Court of jurisdiction to enforce 10 U.S.C. § 1107a, then *Speigner* should be deemed to have been overruled by the later enacted statute.

Defendants' claim that this Court lacks jurisdiction because Plaintiffs have failed to exhaust their military remedies, ECF 65-1 at 14, is similarly without merit. As an initial matter, nearly all Plaintiffs have pursued available military remedies including: religious accommodation requests ("RAR") and/or appeals,[20] medical exemptions,[21] administrative exemptions,[22] Article 138 complaints,[23] and Inspector General ("IG") complaints.[24] And some, like Plaintiff DIXON, have tried all of the above exemptions, and been denied across the board. *See* Dixon Decl., ¶6 (temporary pregnancy exemption expired), ¶19 (medical exemption for lack of supply denied) & ¶17 (administrative exemption denied); SAC ¶18 (medical exemption for nursing denied).

Plaintiffs satisfy the Eleventh Circuit's test for exemption from the exhaustion requirement set forth in *Mindes v. Seaman*, 453 F.2d 197 (5th Cir.1971) ("*Mindes*").

---

[20] *See* Harwood Decl., ¶2 (RAR and appeal denied); Snow Decl., ¶2 (RAR denied & appeal pending); Connell Decl., ¶2 (RAR pending); Craymer Decl. ¶2 (same); Kupper Decl., ¶ 7 (same); Lund Decl., ¶3 (same); Morgan Decl., ¶2 (same); Stermer Decl., ¶2 (same).

[21] *See* Karr Decl., ¶4 (denied); Kupper Decl., ¶¶9,12 (sought medical exemptions for previous documented infection, which was denied, and lack of supply (Code MS), which is pending); Morgan Decl., ¶3 (informed exemption for previous documented infection would not be granted); Roberts Decl., ¶7 (temporary medical exemption granted then revoked within less than one week).

[22] *See* Dixon Decl., ¶22.

[23] *See* Roberts Decl., ¶10; SAC ¶29 (Stermer Article 138 complaint denied).

[24] *See* Kupper Decl., ¶ 8; SAC ¶17 (Craymer IG complaint).

Mindes identified "exceptions to military exhaustion," which include "futility" and "inadequacy of administrative remedies." *Navy SEALs 1-26*, 2022 WL 34443, at *5 (citation omitted).[25] Where "the record all but compels the conclusion that the military process will deny relief, exhaustion is inapposite and unnecessary." *Id.* *5 (citation and quotation omitted). This is confirmed by Defendants' January 21, 2022 submission in that proceeding showing that zero RARs approved out of over 20,000 submitted.

Table 1: Religious Accommodation Requests & Appeals[26]

Armed Service	Initial RA Requests			RA Appeals		
	Filed	Denied	Approved	Appeals	Denied	Approved
Air Force	11,713	2,740	0	1,292	1,292	0
Army	2,599	204	0	38	0	0
USCG	1,304	335	0	125	0	0
USMC	3,405	3,324	0	1,091	97	3
Navy	3,930	3,573	0	1,161	0	0
Total	**22,951**	**10,176**	**0**	**3,707**	**1,389**	**3**

This data also confirms that military remedies are inadequate because the

[25] While Plaintiffs have not asserted claims related to their RARs, Defendants assert that this Court lacks jurisdiction for Plaintiffs with pending RARs whose claims are not ripe. *See* ECF 65-1 at 14-15. Plaintiffs highlight the Armed Services' categorical denial of RARs to demonstrate that the military remedies are futile and the pattern of eliminating pre-existing categories of exemptions.

[26] Information from this table is taken from Ex. 10, *Navy SEAL 1 v. Biden*, "Second Notice of Compliance" (Jan. 21, 2022) ("January 21 Report").

Armed Services have "predetermined the denial of the religious accommodations." *Navy SEALs 1-26*, at *6. The same conclusion follows for those seeking AR 40-562 medical exemptions, as there is no military remedy for them to pursue.

B. Plaintiffs' Claims Are Ripe.

Defendants have repeatedly asserted throughout this proceeding that "adverse action will not be taken against a service member with a pending exemption request." ECF 65-2 at 9. This is not true. Plaintiffs with pending exemption requests have suffered a wide range of adverse actions, in some cases, because they have submitted exemption requests. These include: training, travel and duty restrictions;[27] denial or restriction of promotions;[28] non-deployable status;[29] negative counseling letters or reprimands;[30] ineligibility for change of station or new assignments;[31] denied voluntary separation or early retirement;[32] and/or removal from command.[33]

---

[27] *See* Connell Decl., ¶3; Cossette Decl., ¶5; Craymer Decl., ¶3; Karr Decl., ¶7; Kupper Decl., ¶8; Morgan Decl., ¶5; Roberts Decl., ¶ 6; Snow Decl., ¶4.

[28] *See* Connell Decl., ¶3; Cossette Decl., ¶5.

[29] *See* Connell Decl., ¶3; Harwood Decl., ¶7; Thompson Decl., ¶6.

[30] *See* Sigoloff Decl., ¶15 (received a General Officer Memorandum of Reprimand "GOMOR"); Thompson Decl., ¶6. *See also* SAC ¶17 (Craymer Letter of Reprimand).

[31] *See* Cossette Decl., ¶5; Craymer Decl., ¶3; Dixon Decl., ¶21.

[32] *See* Dixon Decl., ¶23; Harwood Decl., ¶7.

[33] *See* Harwood Decl., ¶4 (removed from position as battalion Executive Officer); Sigoloff Decl., ¶16 (removed from position as Medical Director).

Many of these have career ending consequences, even if they do receive an exemption. In addition, Plaintiff SIGOLOFF, a doctor, has been removed from his position as Medical Director, received multiple counseling and reprimands, had his treating privileges suspended and faces loss of his medical license. *See* Sigoloff Decl., ¶¶ 10, 14-18.

Defendants also assert that Plaintiffs' claims are not ripe because they are based on "contingent future events that may not occur as anticipated," and that if the exemption requests are granted they "will be exempted from the COVID-19 vaccination requirement." ECF 65-2 at 14. These are not "contingent" events. Plaintiffs have already suffered the adverse events described above, which are ongoing; the AR 40-562 medical exemptions have already been eliminated, and several plaintiffs have either had their requests denied. As for RARs, denial is a near certainty because the process is a sham. *See Navy SEALs 1-26* & *Navy SEAL 1* TRO Order. Accordingly, their claims are ripe.

C. Plaintiffs Have Standing to Challenge FDA Actions.

1. Comirnaty Approval

This Court previously found that "plaintiffs have shown enough as to standing," *Austin*, 2021 WL 5816632, at *7, based in part on defense counsel's "acknowledge[ment] that if the FDA's licensure were set aside, that would (at least for now) redress plaintiffs' injuries because the DOD could not mandate an

unapproved drug absent presidential approval." *Id.* Defendants seek to overturn this finding based on *Children's Health Defense Fund v. FDA*, 2021 WL 5756085 (E.D. Tenn. Nov. 30, 2021) ("*CHD*"). *See* ECF No. 65-1 at 16.

CHD is inapposite. The sole defendant in *CHD* was the FDA. The *CHD* court concluded that the Plaintiff's injury from the DOD Mandate "results from the independent action of some third party not before the court." *Id.*, at *6 (citation and quotation omitted). That is not the case here where all the agencies necessary to grant the relief sought are parties to this proceeding.

In addition, the *CHD* plaintiffs had "not alleged that the FDA's actions were a 'motivating factor' in the military's decision to impose the vaccine mandates." *Id.*, at *6. Here, Plaintiffs have alleged that the FDA's August 23 Comirnaty Approval and Interchangeability determination were both the proximate and "but for" cause of the August 24 Mandate. *See, e.g.,* ECF 3-2 at 7-8; ECF 33 at 6-8. The SECDEF Memo permits only FDA-licensed vaccines to be mandated; without FDA licensure, there could be no mandate.

Defendants also assert that Plaintiffs lack standing because they did not file a Citizens' Petition. *See* ECF 65-2 at 34-35 (*citing Mahon v. USDA*, 485 F.3d 1247, 1255 (11th Cir.2007) ("*Mahon*")). Plaintiffs addressed the exhaustion argument in their TRO Motion, *see* ECF 3-2 at 7-8, discussing a number of cases where courts had rejected such arguments where Plaintiffs were "among the class of individuals

whom the was intended to protect." *Tummino v. Torti,* 603 F.Supp.2d 519, 541 (E.D.N.Y.2009). In addition, Plaintiffs assert non-statutory *ultra vires* claims against the FDA, which does not require plaintiffs to show that they are in the "zone of interests" for standing. *See, e.g., Ctr. for Biological Diversity v. Trump,* 453 F.Supp.3d 11, 48-49 (D.D.C.2020).[34]

Finally, Defendants erroneously assert that Plaintiffs do not have standing to raise challenges to the FDA's failure to include in clinical trials women who are pregnant or nursing or that have other medical conditions that may subject them to differing or heightened risks. ECF 65-2 at 37. Plaintiff DIXON is nursing and Plaintiff CONNELL has a history of cancer; both sought and were denied medical exemptions. *See supra* note 21.

2. Interchangeability Determination(s)

Plaintiffs have been harmed by the FDA's Interchangeability determinations. The DOD "relied on" these determinations, ECF 65-1 at 28, in treating unlicensed EUA products "as if" the FDA had "grant[ed] formal licensure to the EUA vaccines," *Austin*, at *8. DOD and Armed Services Defendants have stated that: (1)

[34] Defendants also appear to raise an "issue exhaustion" argument, the desirability of a for a court to impose requirement "depends on the degree to which the analogy to normal adversarial litigation applies in a particular administrative proceeding." *Mahon*, 485 F.3d at 1255 (citation and quotation omitted). Such a requirement is not appropriate where, as in the case of the FDA licensing proceeding, the "administrative proceeding [was] not adversarial." *Id*. (citations omitted).

only FDA-approved vaccines are mandated, *see* ECF 65-1 at 27; (2) EUA vaccines "should" be treated "as if" they are licensed, ECF 65-13, Surgeons General Memo; and (3) mandating an EUA-labeled vaccine "is consistent with" 10 U.S.C. § 1107a. ECF 65-2 at 29. The FDA's August 23 Interchangeability determination is both the "but for" and proximate cause of Plaintiffs' injury resulting from the August 24 DOD Mandate.

Further, the guidance issued by the Armed Services appears to have been interpreted by health care providers ("HCPs"), military treatment facilities ("MTFs"), and commanding officers to mean that the EUA-labeled vaccines "are" licensed or "are" Comirnaty, *see* Cossette Decl., ¶7, or that "interchangeability" included "legal interchangeability." Dixon Decl., ¶14. Plaintiffs have also seen the vaccination cards of fellow service members' vaccination cards or medical records that state that they have received Comirnaty (*i.e.*, rather than a BLA-compliant dose). *See* Cossette Decl., ¶8 & Thompson Decl. ¶7. Other Plaintiffs declared that HCPs or MTFs had no idea what a "BLA-compliant" vaccine is or the legal significance of that designation. *See* Harwood Decl., ¶8.

Vacature or reversal of this determination would remove the basis for the DOD and Armed Services' directive that Plaintiffs' must take an EUA product. Accordingly, Plaintiffs' injury from the FDA's Interchangeability determinations is directly and "fairly traceable to the FDA," ECF 65-1 at 19, and would be redressed

by a favorable decision.

II. PLAINTIFFS HAVE STATED CLAIMS AGAINST DEFENDANTS.

A. Plaintiffs Have Stated Multiple APA and *Ultra Vires* Claims Regarding DOD and Armed Services Violations.

1. The Court Cannot Rule on Motion to Dismiss without Complete Administrative Record.

Plaintiffs' claims against the DOD and Armed Services demonstrate why, in the absence of the administrative record, this Court cannot perform "meaningful judicial review," *Occidental Petroleum*, 873 F.2d at 339, or "properly evaluate Plaintiffs' claims" of APA violations. *Farrell*, 315 F.Supp.3d at 47. It appears that the totality of the DOD and Armed Services record materials before the Court consist of: (1) the two-page August 24, 2021 SECDEF Memo that justifies the DOD Mandate based on a single conclusory sentence that Secretary Austin had "determined that mandatory vaccination against coronavirus disease 2019 (COVID-19) is necessary to protect the Force and defend the American people," ECF 1-2 at 1; (2) a one-page memorandum from the Acting Assistant Secretary of Defense Memorandum to DOD Surgeons General directing that the EUA and licensed vaccines "should" (in place of the FDA's "can") be "used interchangeably," ECF 65-2; and (3) the Armed Services Guidance to implement the mandate. *See* ECF 65-8 to 65-12.

Notably, none of these record materials even use the term "BLA-compliant;" limit the mandate to "BLA-compliant," EUA-labeled doses, as Defendants claim; or acknowledge informed consent requirements. The limitation to BLA-compliant vaccines was first introduced in filings by Defendants' counsel to this Court.[35] "The district court may not," as Defendants urge, simply "rely on counsel's statements as to what was in the record." *Olenhouse*, 42 F.3d at 1576. This Court owes no deference to government defense counsel's *post hoc* rationalization for the agencies' actions. *See State Farm*, 463 U.S. at 50.

2. Plaintiffs' Claims Easily Satisfy *Twombly/Iqbal* Standard Facial Plausibility Standard.

Through their pleadings, declarations, exhibits, and documents incorporated therein by reference, Plaintiffs have "allege[d] the specific nature of the … obligation" Defendants "failed to satisfy," *Speaker*, 623 F.3d at 1381, pled sufficient factual content for the "court to draw the reasonable inference that the defendant[s] [are] liable for the misconduct alleged," *Iqbal*, 129 S.Ct. at 1949, and thereby

[35] Defendants' filings also include Declarations from an FDA official and at least one Air Force official that address BLA vaccines. *See* ECF 65-14, Decl. of Peter Marks, M.D., Ph.D. (FDA), ¶¶ 10-13 & 65-15, Decl. Colonel Tonya Rans (USAF), ¶ 18. But these declarations do not purport to be part of the record. Further, the Marks Declaration discusses only FDA's procedures, while the Rans Declaration provides no information whatsoever about the DOD or Armed Services decision-making process, or any policies or procedures adopted to ensure that only "BLA-compliant" doses are administered pursuant to the mandate.

"raise[d] a right to relief above the speculative level." *Twombly*, 550 U.S. at 556.

It is undisputed that Comirnaty is not available, and the DOD and Armed Services Defendants are instead "mandating vaccines from EUA-labeled vials." *Doe Ausin*, 2021 WL 5816632, at *5. Their action are facial violations of the Informed Consent Laws, and Plaintiffs' statutory "right to accept or refuse" expressly stated in the product's labeling. While Defendants' counsel has asserted that only BLA-compliant, EUA-labeled are mandated, there is no basis for this claim in the record. The record materials that are available acknowledge there "are certain differences" between the two versions, ECF 1-6, August 23 EUA Expansion Letter, and Plaintiffs have identified additional differences between the EUA and licensed products, in terms of formulation and manufacturing process and locations, which this Court found plausible in *Austin*, *see id.*, at *3 n.5, and have included additional expert testimony from Dr. Robert Malone explaining the distinctions between these two versions. *See* Declaration of Robert Malone, ¶¶20-24. The FDA has subsequently expanded the scope of interchangeability to cover products with admittedly different formulations that the FDA deems to be "analytically comparable." *See, e.g,* Ex. 3, January 3, 2021 EUA Expansion Letter at 12. This amounts to a tacit concession by Defendants (or at least the FDA) that different products may be interchangeable, and that Plaintiffs no longer need to show that the two versions have the "same formulation" to prove their claims. Finally, Plaintiffs have alleged that, whatever the

FDA's position may be, the DOD and Armed Services have applied the FDA's interchangeability determination to mean "legal," rather than merely "factual," interchangeability. *See* Dixon Decl., ¶14. Accordingly, Plaintiffs have pled sufficient factual content to create a reasonable inference that Defendants have violated the Informed Consent Laws, and they have provided numerous cognizable legal theories for their claims for relief. As such, they have easily exceeded the requirements to survive a Rule 12(b)(6) motion to dismiss.

While there is no support in the record for Defendants' claims regarding "BLA-compliant," EUA-labeled vaccines, Plaintiffs have nevertheless alleged and provided sufficient factual support to infer that neither Comirnaty nor BLA-compliant vaccines are available. Most inquired and were informed that Comirnaty and/or BLA-complaint vaccines were not available;[36] sought medical exemptions (code MS) for lack of supply, *see* Dixon Decl., ¶16 & Kupper Decl., ¶12; certain Plaintiffs stated that they would comply with a lawful order to take an FDA-approved vaccine, but not an EUA vaccine, or sought guidance on whether they were specifically required to take a non-BLA-compliant vaccine, *see* Dixon Decl., ¶¶8-15; and others filed Article 138 complaints or IG complaints questioning the legality

[36] *See* Ex. 1, Kupper Decl., ¶11 (no Comirnaty or BLA-approved lots available); Roberts Decl., ¶9; Connell Decl., ¶4 (no Comirnaty); Cossette Decl., ¶5 (same); Harwood Decl., ¶8 (same); Sigoloff Decl., ¶21 (same); Snow Decl., ¶5; Thompson Decl., ¶5.

of mandating injection of an EUA-labeled product. *See* Roberts Decl., ¶10 & SAC ¶23 (Kupper IG Complaint) & ¶29 (Stermer Article 138 complaint).

In this filing, Plaintiffs have provided additional information that supports the plausibility of their claims. First, the legal landscape has also shifted in Plaintiffs' favor since the filing of the SAC and that lends credence to their legal claims. In particular, Courts have recently stayed all five of the other federal vaccine mandates, based on same grounds as those asserted by Plaintiffs (*i.e.*, agency or President exceeded statutory or constitutional authority). *See supra* Background, Section I. Two courts have enjoined the DOD Mandate based on abuses of the exemption requests and an unwritten policy that amounted to a categorical elimination of existing exemptions. *See generally Navy SEALs 1-26* & *Navy SEAL 1* TRO Order. Second, Plaintiffs have provided a plausible explanation for why only EUA vaccines are available, namely, Pfizer's compliance with FDA's labeling requirement and desire to avoid prosecution for misbranding an unlicensed product as a licensed product, *see supra* Background, Section II & *infra* Argument, Section I.D.5. Defendants' theory, by contrast, would require Pfizer to have misbranded its products, or otherwise violated FDA requirements. In addition, the BLA-compliant procedures described by Defendants would be much more administratively, legally and logistically to implement than if the products were administered simply using the manufacturers' labeling. *See* Ex. 2, Normal Vaccination vs. FDA-DOD BLA-

Compliant Process. Finally, Plaintiffs have provided several examples where the DOD and Armed Services have ignored or circumvented informed consent requirements, frequently with the active support or cooperation of the FDA as alleged here. *See supra* Background, Section III (discussing DOD and FDA coordination to mandate investigational and experimental vaccines).

In short, Plaintiffs have alleged sufficient factual content not only to render their claims facially plausible, but that (1) demonstrate the need for Defendants to produce the complete administrative record and (2) to "raise a reasonable expectation that discovery will evidence" required to prove their claims. *Twombly*, 550 U.S. at 556.

3. Plaintiffs Have Stated Multiple APA Claims for DOD Violations of Informed Consent Laws.

It is undisputed that Plaintiffs' claims for violations of the Informed Consent Laws lie under the APA.[37] Defendants, however, erroneously assert that Plaintiffs

[37] *See, e.g., Austin*, at *2 & *7 n.12 (characterizing violations as "APA claims"); ECF 65-1 at 27 (*citing id.*); ECF 45, November 3, 2021 Oral Argument Transcript, at 57:2-3 ("if the mandate violates 1107a, then it is contrary to law under an APA."). It is well-settled that, where a statute does not provide a cause of action, plaintiffs "are nevertheless entitled to enforce [the statute's] substantive requirements through the judicial review provisions of the APA." *Int'l Brominated Solvents*, 393 F.Supp.2d at 1378.

have failed "to identify or describe an APA claim on this issue." ECF 65-1 at 27.[38] Defendants' statement is incorrect both with respect to its description of Plaintiffs' pleadings and the pleading requirements for APA claims.

***Ultra Vires* Claims.** To state an APA claim that the agency action violates the statute or exceeds its statutory authority, or that the agency failed to follow appliable procedural requirements, the plaintiff need only identify the law, regulation, rule or procedure violated and provide sufficient factual content to plausibly allege defendants' violation of its obligation(s) thereunder. *See supra* Legal Standard, Section I.C.

Plaintiffs specifically alleged that the DOD Mandate and the Armed Services Guidance violate the Informed Consent Laws, and Plaintiffs rights thereunder, and that Secretary Austin and the Secretaries of the Air Force, Army and Navy exceeded their statutory authority insofar as they sought to mandate an unlicensed, EUA vaccine, without Presidential Approval. *See* ECF 56, SAC ¶¶ 9, 111, 115-117; ECF

[38] Defendants also claim, in passing, that neither 10 U.S.C. § 1107a, nor 21 U.S.C. § 360bbb-3, provides a waiver of sovereign immunity. This is irrelevant because Congress waived sovereign immunity for APA claims like those made by Plaintiffs seeking injunctive and declaratory relief in its 1976 amendments to 5 U.S.C. § 702. *See generally* Charles H. Koch & Richard Murphy, 4 ADMIN. L. & PRAC. § 12:23 (3d ed. 2010) (discussing scope of sovereign immunity). Further, no waiver of sovereign immunity is required where, as here, plaintiffs assert that defendant agencies or officials acted *ultra vires* because the action is not one against the United States as sovereign. *See, e.g., Davis,* 2002 WL 31235735, at *4.

3-2, TRO Motion, at 13-15; ECF 33, Reply Brief, at 11-12; *see also supra* Argument, Section II.2.

It is undisputed that DOD and Armed Services require Plaintiffs, and all other service members, to take EUA-labeled vaccines, which the FDA-approved labeling and governing statutes expressly give recipients the option to reject or refuse. *See, e.g.,* ECF 1-14, Pfizer-BioNTech EUA Fact Sheet (Aug. 23, 2021) at 9 ("The recipient or their caregiver has the option to accept or refuse"). Mandating an EUA vaccine, as the DOD and Armed Services have done, is expressly prohibited by 10 U.S.C. § 1107a, in the absence of Presidential approval, which SECDEF has neither requested nor received.

Arbitrary and Capricious Claims. Plaintiffs also stated claims that these violations of the Informed Consent Laws were arbitrary and capricious, and otherwise not in accordance with law. Specifically, Plaintiffs alleged that the DOD and Armed Services failed to engage in reasoned decision-making required by the APA; failed to consider whether they had the legal authority to mandate an experimental EUA vaccine; relied on facially unlawful FDA Interchangeability determinations; and failed to provide any explanation, to consider or cite any relevant evidence apart from the conclusory statement that the Mandate was necessary. *See generally* ECF 56, SAC ¶¶ 111, 115-116; ECF 3-2, TRO Brief, at 13-15; ECF 33, Reply Brief, at 8-9.

First, the only records supporting DOD and Armed Services' actions are a two-page memo and orders or guidance materials that purport to implement SECDEF's directive; they provide no information whatsoever on their decision-making process, the procedures followed, or the evidence considered. Second, the DOD and Armed Services asserted defense—that only "BLA-compliant" vaccines are mandates—is made only by Defendants' counsel, and is contrary to the record materials before the Court, which state apply to all EUA vaccines, without regard to whether they are BLA-compliant or not. Third, the timing of the mandate—issued just one day after the licensure—could not have permitted reasoned decision-making or compliance with applicable procedures. Fourth, the DOD's is arbitrary and capricious because it runs counter to the DOD's position only the month before that EUA vaccines may not be mandated. *See* ECF 33-4, OLC Memo, at 16-18. Plaintiffs have therefore identified multiple grounds for this Court to find that the DOD and Armed Services' actions are arbitrary and capricious under *State Farm* and similar cases.

Finally, Plaintiffs have alleged that the DOD and Armed Services failed altogether to address an important aspect of the problem, namely, the complete unavailability of any FDA-licensed vaccines at the time it was issued—and continuing through the present, nearly six months later. Instead, the record materials available demonstrate that the DOD and Armed Services have adopted four

contradictory positions: (1) only vaccines with "full licensure" from the FDA with "FDA-approved labeling" may be vaccinated (DOD Mandate); (2) all EUA vaccines may be used "as if" they were the licensed vaccine (Armed Services Guidance); (3) only "BLA-compliant," EUA-labeled vaccines may be mandated (*post hoc* litigation position first announced by Defendants' counsel); and (4) instructing service members that the EUA-labeled vaccines "are" Comirnaty, Cossette Decl., ¶ 7, or that they are "legal[ly] interchangeab[le]." *Id.*, Dixon Decl., 14. These conflicting and incoherent positions are arbitrary and capricious because they are internally inconsistent, "run[] counter to the evidence before the agency," and fail to "articulate[] an explanation establishing a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation omitted).

Defendants claim that the DOD Mandate "cannot be arbitrary and capricious" because it relies on CDC recommendations. ECF 65-2 at 24. Yet the DOD and Armed Services have ignored the November 19, 2021 CDC/ACIP unanimous recommendation that ***all eligible adults*** receive the third shot of the booster.[39] Neither the DOD nor the Armed Services have provided any explanation for why they followed the CDC recommendation for a two-dose regimen, but ignored it for

[39] *See* CDC, *CDC Expands Eligibility for COVID-19 Booster Shots to All Adults,* CDC Media Statement (Nov. 19, 2021), available at: https://www.cdc.gov/media/releases/2021/s1119-booster-shots.html.

the third booster shot. Such selective picking and choosing is the essence of arbitrary and capricious decision making.

Failure to Observe Procedures Required by Law. DOD and Armed Services Defendants claim that all decisions regarding mandatory vaccination requirements are driven by the procedures in DODI 6205.02. *See, e.g.,* ECF 65-1 at 22. DODI 6205.02 sets forth a detailed set or roles and responsibilities for several DOD components and commands, as well as the Joint Chiefs and Armed Services commands to complete. As far as Plaintiffs are aware, there is no information in the public record currently available for this Court to review or for Plaintiffs to even comment on whether DOD and the Armed Services have in fact complied with these procedures.

Instead, Plaintiffs' allegations are based on the only information publicly available, which are: (1) the FDA's August 23 Comirnaty and Interchangeability determinations in a footnote to the EUA extension letter; (2) the August 24 SECDEF Memo, a two-page memo stating only that the DOD Mandate "will be implemented consistent with" DODI 6205.02, ECF 1-2 at 1; and (3) the Armed Services Guidance and Surgeons General Memo directed the services and HCPs to treat all EUA vaccines "as if" they were licensed vaccines. ECF 65-10, ¶ 1.2.1.2; ECF 65-13, Surgeons Generals Memo.

The factual allegations before the Court provide sufficient for the Court to

reasonably infer that that the DOD and Armed Services did not comply with these requirements. It is undisputed that SECDEF did not request or receive Presidential approval to mandate an EUA vaccine. The DOD and Armed Services appear to assert that the two-page SECDEF Memo announcing the DOD Mandate satisfied any applicable procedural requirements despite the fact that it was issued only a day after FDA licensure, and the fact that the use of future tense indicates that the August 24 SECDEF Memo represented the commencement of the DODI 6205.02 process, rather than consummation of that process. This inference is further supported by the fact that the SECDEF Memo refers only to vaccines with "full licensure" from the FDA, but does not mention EUA nor BLA-compliant vaccines

Defendants give great, but misplaced, weight on Secretary Austin's August 9, 2021 statement that that 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 would "seek the President's approval to make the vaccines mandatory no later than mid-September, or upon the [FDA] licensure, whichever comes first." *See* ECF 65-24 at 8 (*quoting* ECF 65-4).[40] Secretary

[40] Secretary Austin likely knew approval was imminent, based on his statement that "public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month," ECF 65-6, and because just the day before, Anthony Fauci expressed his hope that the Pfizer-BioNTech vaccine would be approved "within the next few weeks." *See* Associated Press, *Fauci is hopeful Covid vaccines*

Austin's stated intent to seek Presidential approval is irrelevant because he has neither requested nor obtained such approval. Further, this Court may not presume that such a request would have been granted because the Rule 12 requires the Court draw all reasonable inferences in a light most favorable to Plaintiffs.

4. Plaintiffs Have Stated Multiple APA Claims Regarding the DOD's Categorical Elimination of Existing Medical Exemptions under AR 40-562.

The August 24 SECDEF Memo, without explanation or discussion, categorically eliminated all existing categories of medical exemptions under AR 40-562. Whether or not these exemptions were "presumptive," ECF 65-1 at 20, these exemptions did exist and were available prior to August 24, 2021, but were eliminated after August 24, 2021.

In their pleadings, Plaintiffs have provided significant factual evidence that natural immunity from a previous documented infection is superior to that provided by the COVID-19 vaccines. *See* SAC, ¶¶ 98-102; ECF 33-1, McCullough Decl., ¶¶ 53-56. Moreover, the clinical trials on which Comirnaty's licensure was based expressly excluded individuals with previous documented infections, pregnant or lactating women, and those from other key "special populations" that may be at

---

will get full approval by the FDA within weeks (Aug. 8, 2021), available at: cnbc.com/2021/08/08/fauci-is-hopeful-covid-vaccines-will-get-full-approval-by-the-fda-within-weeks.html (last visited Feb. 4, 2022).

heightened risk of adverse effects. *See* SAC, ¶¶ 79-80; Ruby Aff., ¶¶ 13-15. Accordingly, there was no basis for the FDA or the DOD to determine whether the vaccines were safe or effective for these populations.

The DOD and Armed Services provided no rationale or explanation whatsoever for elimination of this pre-existing category of exemptions. As such, Plaintiffs have adequately pled that DOD and Armed Services categorical elimination of medical exemptions is arbitrary and capricious, and unsupported by substantial evidence, insofar as they "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. *See also Deese v. Esper*, 483 F.Supp.3d 290 (D. Md. 2020) (finding that DOD's "categorical bar" preventing graduates of the service academies with HIV to be commissioned was arbitrary and capricious).

To implement the elimination of these medical exemption categories, the DOD and Armed Services significantly altered the procedures and authority for granting such exemptions. Under AR 40-562, "[g]ranting medical exemptions is a medical function," ECF 65-4, AR 40-562, ¶ 2-6, and requests are evaluated and granted, in the first instance, by treating physicians and HCPs. *See* Sigoloff Decl., ¶7. After the adoption of the DOD Mandate, however, this authority was taken away from treating physicians and HCP. *Id.* Medical exemptions from COVID-19 vaccination granted by physicians under existing procedures were revoked. *See, e.g.,*

Ex. 1, Roberts Decl., ¶7; Sigoloff Decl., ¶¶10-18 (describing suspension, removal and other disciplinary actions for granting medical exemptions).

5. Plaintiffs Have Stated an APA Claim and/or a Non-Statutory Ultra Vires Claim Against the Armed Services.

Plaintiffs' third claim is not a "standalone claim" that the Armed Services violated the DOD Mandate, without an underlying cause of action. ECF 65-2 at 32. It is an APA claim that the Armed Services implementation was arbitrary and capricious and *ultra vires*, where the subject of review is compliance with the DOD Mandate requirement to use only FDA-licensed vaccines. The Armed Services Guidance may be deemed to unreviewable nonfinal agency action, though it is impossible to say in the absence of the record.

In that event, then Plaintiffs' claim should be construed as a non-statutory *ultra vires* claim. Plaintiffs have alleged that the Armed Services have interpreted the FDA's Interchangeability determination as meaning "legal interchangeability." *see, e.g.,* Dixon Decl., at ¶ 14, and to require all EUA vaccines to be treated as if they are licensed, without regard to BLA-compliance. In doing so, the Armed Services acted without statutory authority, as only the FDA has the authority to make such determinations or implement the PHSA. The Armed Services Guidance also violates 10 U.S.C. § 1107a, which prohibits EUA products to be mandated without Presidential approval. Further, if APA review is not available, then a non-statutory

claim would be the only means by which Plaintiffs may vindicate their rights under the Informed Consent Laws. *See Rhode Island*, 304 F.3d at 42.

D. Plaintiffs Have Stated APA and Non-Statutory *Ultra Vires* Claims Against FDA

1. Plaintiffs' Claims Against FDA Meet *Twombly/Iqbal* Facial Plausibility Standard.

Plaintiffs' assert four, connected claims against the FDA asserting that the FDA alone, or in coordination with the DOD and Armed Services, violated the statutes it administers, as well as its own regulations, rules, procedures, and policies, for the extra-statutory purpose of facilitating near universal and illegal federal vaccine mandates. Subsequent developments have confirmed that Plaintiffs' claims, are not only plausible, but highly probable, namely: (1) the FDA's "unprecedented" timeline for Comirnaty approval, *i.e.*, months rather than several years, and its similarly unprecedented blanket determination(s) finding that any EUA product may be used "interchangeably" with the (unavailable) licensed Comirnaty, *see* ECF 33, Reply Brief, 18 & n.16; (2) its decision not to enforce mandatory FDA labeling requirements, *see* ECF 65-14, ¶ 13; (3) DOD and Armed Services express reliance on the FDA's Interchangeability determinations to impose the DOD Mandate; (4) President Biden's announcement a little over two weeks later, on September 9, 2021, of five sweeping vaccine mandates in reliance on the FDA's licensure affecting 100 million Americans; (5) Chief Justice Roberts articulation of a theory,

nearly identical to Plaintiffs, of government-wide effort to impose nearly universal federal mandates, agency-by-agency; and (6) post-approval evidence of the vaccine's rapidly waning efficacy, and increased safety risks, that would have precluded approval if the FDA had followed the law and its own procedures.

2. Plaintiffs Have Cited the Correct Standard of Review and Statutory Provisions.

Defendants repeat their arguments that Plaintiffs' claims "fail[] as a matter of law" because they are "citing and quoting the wrong statute." ECF 65-1 at 35. First, the PHSA's substantive requirements for approval and clinical trials are largely identical to those under the FDCA. To be approved under the PHSA, a biological product must be shown to be "safe, pure and potent," 42 U.S.C. § 262(a)(1)(C)(i)(II), while the FDCA criteria are that a drug must be shown to be safe and effective. Thus, both the PHSA and FDCA require products to be safe, while "[t]he standard for licensure of a biological product as potent under 42 U.S.C. § 262 has long been interpreted by FDA to include effectiveness." *See* ECF No. 65-14, Marks Decl., ¶5 n.1. (Plaintiffs do not contest any FDA purity findings.) PHSA Section 351(j), 42 U.S.C. § 262(j), directs the FDA to apply the requirements of FDCA Section 505, 21 U.S.C. § 355, for approval of drugs to vaccines and other biologics. Both drugs and biological products are subject to the statutory provisions relied on by Plaintiffs, *see* SAC ¶¶ 125-126 (*citing* 21 U.S.C. §§ 355(d)-(e)), governing "substantial

evidence" and "adequate and well-controlled investigations." Second, FDA regulations governing clinical trials apply to both drugs and biological products. *See* 21 C.F.R. § 312.2(a).[41]

3. Plaintiffs Have Stated Multiple APA Claims Challenging the FDA's Unlawful Comirnaty Approval.

FDA Acted *Ultra Vires* and Contrary to Law. Plaintiffs identify several instances where the FDA violated applicable statutory or regulatory requirements in granting approval of Comirnaty. Plaintiffs allege that the FDA violated the PHSA by approving Comirnaty without the required demonstration that Comirnaty is safe and potent (which the FDA treats as equivalent to "effective" under the FDCA), and that this failure is due to the FDA several discrete, identifiable and factually supported violations of statutory, regulatory, procedural and evidentiary requirements.

First, the FDA approved Comirnaty based on an "unprecedented" timeline,

[41] Defendants conflate their Rule 12(b)(1) exhaustion arguments with their Rule 12(b)(6) arguments where they invoke the "record rule" as barring the Court from considering any factual allegations or arguments in Plaintiffs' complaint that were not submitted to the FDA. *See* ECF 65-1 at 34-35. The lone case cited by Defendants did not apply exhaustion arguments in the Rule 12(b)(6) context. *See* ECF 65-2 at 35 (*quoting Mahon*, 485 F.3d at 1254-55). Defendants' argument, if accepted, would bar entire categories of APA claims, particularly in non-adversarial proceedings like the one that resulted in the Comirnaty approval, where persons that may be harmed by the outcome do not have knowledge or ability to participate, and where the public relies on the FDA to comply with the law and follow its own procedures.

based on months of data, rather than the several years of clinical trial data required for other drugs or biologics. This compressed process could not possibly provide evidence of the long-term safety and efficacy of Comirnaty, or the Pfizer-BioNTech EUA Vaccine. At the time of approval, there existed strong evidence that the Pfizer-BioNTech vaccine caused unprecedented safety risks, as reported in VAERS, and that the efficacy declines dramatically over time.[42] This evidence has grown over time, leading Pfizer's CEO to admit that the two-dose regimen required by the DOD Mandate "offer[s] very limited protection, if any"[43] against the Omicron variant that accounts for over 99.9% of cases.[44] Just this week, Senator Ron Johnson held a roundtable with DOD whistleblowers, including Plaintiff SIGOLOFF, discussing data from the DOD databases showing that diagnoses of serious cardiovascular

[42] *See* SAC ¶¶89-90 (efficacy declined below 50% after six months) & 96 (VAERS data indicating that vaccine injuries and death for COVID vaccines exceeded those reported for all other vaccines combined since 1990); *see also* ECF 33-1, McCullough Decl., ¶¶24 (limited effectiveness in preventing infection), ¶¶27-28 (discussing COVID-19 vaccine injuries and deaths), ¶¶ 30-32 (specific risks to military age males of myocarditis and heart failure).

[43] *New COVID-19 Vaccine That Covers Omicron 'Will Be Ready in March,' Pfizer CEO Says* YAHOO!FINANCE (Jan. 10, 2022) (transcript of video interview with Pfizer CEO Albert Bourla), available at: https://finance.yahoo.com/video/covid-19-vaccine-covers-omicron-144553437.html (last visited Jan. 17, 2022). The decline in efficacy has been so severe, that Pfizer is developing a new version that purportedly will be ready in March, *see id.*, but like Comirnaty is currently unavailable

[44] *See* CDC, *COVID Data Tracker: Variant Proportions*, Chart: Week Ending January 29, 2022, available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions (last visited Feb. 4, 2022).

diseases, neurological disorders and certain cancers had increased anywhere from 300% (3x) to 2,000% (20x) in 2021, when vaccinations started, compared to the five-year average for 2016-2020. *See* Ex. 12, Sen. Ron Johnson Letter to Secretary of Defense Lloyd Austin, III (Feb. 1, 2022).

Second, the FDA violated express statutory requirements that proof of effectiveness requires an application to be supported by "substantial evidence," in particular, "adequate and well-controlled investigations, including clinical trials." 21 U.S.C. §§ 355(d)-(e). The FDA did so when it allowed Pfizer to convert a randomized, well-controlled trial into an uncontrolled or partially controlled trial by unblinding 93% of clinical trial participants. *See* SAC ¶¶ 81-83 & ECF 1-18, Ruby Aff., ¶ 12. Such uncontrolled trials cannot constitute substantial evidence of effectiveness required for approval. The FDA has cited no authority for its contention that it can simply waive a statutory requirement where it "reasonably determine[s]" it is not necessary. ECF 65-2 at 36. Accordingly, Plaintiffs "have alleged … facts," namely, the fact that unblinding eliminated the controls required for a "well-controlled" trial required by statute, that "should invalidate the approval." *Id.* at 37.

FDA Approval Was Arbitrary and Capricious. In approving Comirnaty, the FDA ignored or waived both its own generally applicable policies and procedures for clinical trials and supporting evidence, as well as the specific

guidelines for COVID-19 vaccine developed announced the year before. *See* ECF 1-10, June 2020 Industry Guidelines. These guidelines directed developers, among other things, to include key "special populations" like those with previous infections and pregnant women;[45] to conduct Phase III trials lasting at least one to two years; and indicated an intent to trial results to be reviewed by the Advisory Committee. *See* SAC ¶ 72. None of these COVID-19 vaccine specific-procedures were followed; the FDA instead chose to rely on partial, interim data from incomplete, uncontrolled or partially controlled Phase III trial that excluded key groups it had previously identified for inclusion. *See id.* ¶¶ 125-126. Nevertheless, in the absence of any meaningful data the FDA approved Comirnaty without any contraindications for these groups.

The FDA decisions not to convene an Advisory Committee, which would have provided an opportunity for public notice and comment, was also arbitrary and capricious. The FDA's claim that the Comirnaty application did not "raise concerns or controversial issues," ECF 65-2 at 39 (*citing* ECF 1-5, August 23 SBRA, at 27) is not plausible, as vaccine mandates are one of the most controversial issues since

[45] The Defendants assert that some members of these key "special populations" were included in the trials, *see* ECF 65-2 at 37, but this appears to have been accidental and reflects a screening failure by those conducting the trials. There is no evidence on the numbers included, how they were distributed among trial groups, whether the results were statistically significant, or if any differences were identified with respect to these groups and the general population of trial participants.

they were first adopted. The Comirnaty approval satisfied all the requirements for "high priority" Advisory Committee review. *See* SAC ¶ 148 (*discussing* 21 C.F.R. § 14.171(b)).

4. Plaintiffs Have Stated a Claim that FDA Relied on Extra-Statutory Criteria to Approve Comirnaty.

Plaintiffs have stated a claim that the FDA's action is *ultra vires* insofar as the FDA relied on extra-statutory criteria (*e.g.*, to facilitate federal vaccine mandate or to overcome vaccine hesitancy) and/or improper purposes or political interference from the White House. Plaintiffs have also stated a claim that the FDA's action was arbitrary and capricious because, by considering these extra-statutory factors, "the agency has relied on factors which Congress has not intended it to consider." *State Farm*, 463 U.S. at 34. Further, where there is significant evidence of improper political purposes or interference combined with significant departures from normal decision-making processes, this constitutes evidence of "the FDA's bad faith that renders its decision arbitrary and capricious." *Tummino*, 603 F.Supp.2d at 544.

5. Plaintiffs Have Stated APA and Ultra Vires Claim with Respect to Interchangeability.

As was the case for the DOD and Armed Services, the FDA's Interchangeability determinations apply to all EUA vaccines, and do not purport to limit interchangeability to "BLA-complaint," EUA-labeled vaccines. *See* ECF 1-6 at 2 n.8; *see also* Ex. 3, October 29, 2021 EUA Expansion Letter, at 3; Ex. 4, January

3, 2022 EUA Expansion Letter, at 12. The limitation to "BLA-complaint" vaccines was first announced in filings by Defendants' counsel and finds no support in the record.

While the initial basis for the FDA's Interchangeability determination was that Comirnaty and the Pfizer-BioNTech EUA Vaccine had the "same formulation," *see* ECF 1-6 at 2 n.8, the FDA has subsequently abandoned that standard. The FDA now deems products that are both "legally distinct" and that have different formulations to be interchangeable, based on its finding that the legally and chemically distinct products are "analytically comparable." *See* Ex. 3, October 29, 2021 EUA Expansion Letter, at 3 (finding that Comirnaty with PBS buffer "can be used interchangeably" with EUA vaccines with PBS buffer and Tris buffer) & n.14 (defining "analytical comparability"); Ex. 4, January 3, 2022 EUA Expansion Letter, at 12 (finding that Comirnaty with PBS or Tris buffers are interchangeable with EUA products with PBS or Tris buffer, *i.e.*, that four different products are mutually interchangeable).[46] Defendants' Motion does not acknowledge that the FDA has moved the goalposts of interchangeability from "same formulation" to "analytical comparability." Because the FDA has changed the basis for its Interchangeability

[46] The TRIS formulation was approved on December 16, 2021, *see* ECF 62-14, ¶ 10 n.4, a little over a week after Plaintiffs filed the SAC; Plaintiffs could not have challenged the TRIS formulation at that time. Because this approval relied on the August 23 approval, the SAC should be construed as challenging this one as well.

determination to embrace products with different formulation, it is no longer necessary for Plaintiffs to allege that the Comirnaty and the EUA product have different formulations, because that matter is no longer in dispute. Further, the FDA's unannounced and unexplained departure from its previous standard is necessary arbitrary and capricious where it "depart[s] from a prior policy *sub silentio*." *FCC v. Fox Television Stations, Inc.,* 556 U.S. 502, 515, 129 S. Ct. 1800, 173 L.Ed.2d 738 (2009).

Plaintiffs have previously identified the apparent differences between the EUA and licensed formulations, which the Court found plausible in *Austin.* In any case, the FDA documents severely understate the complexities of the novel mRNA vaccines and nanolipid delivery systems, which Pfizer has stated include "more than 280 materials," rather than 10 or 1l, "made by suppliers in 19 countries." Baker & Silver, *supra* note 13.[47] Plaintiffs have also included the testimony of Dr. Robert Malone, who explains the distinctions between these versions in more detail. *See* Ex.

[47] Defendants assert the "extra ingredient" in the August 23 SBRA is in fact "water." ECF No. 65-1 at 5 n.2. This argument does not hold water so to speak for several reasons. This is the one and only completely redacted ingredient in the entire August 23 SBRA. It is redacted as a trade secret under FOIA exemption (b)(4); adding water is not a trade secret, and the exact same ingredient – water – appears unredacted on the very same page of the SBRA. In addition, the volumes differ between the August 23 and the November 8 SBRAs, and Defendants provide no explanation of the reason for the difference. In any case, the FDA appears to have expanded Interchangeability determinations to products with different formulations, which may have eliminated a factual dispute between the parties.

12, Malone Decl., ¶¶ 20-26. As Dr. Malone has stated, "just focusing on the RNA, that alone has numerous ingredients involved in its manufacture and its final composition." Dr. Malone statement at 1:04:54, available at: https://youtu.be/prGAsGgByA4. The lots themselves are significant, as "the Pfizer-BioNTech emergency use authorization product is not even consistent from lot to lot in terms of the adverse events." *Id.* at 43:30.

Plaintiffs' *Ultra Vires* Claim. The FDA does not identify any statutory basis for evolving and expanding Interchangeability determination(s). In fact, the FDA denies that it is a "statutory interchangeability determination" at all, and claims that it is instead a "factual finding." ECF 65-2 at 42. Yet in the immediately preceding paragraph, they suggest that this "factual finding" is made pursuant to the FDA's unreviewable EUA authority, ECF 65-2 at 42, under 21 U.S.C. §§ 360bbb-3. But this statute makes no mention of "interchangeability," and cannot constitute the basis for any legal or factual determination. The only statutory basis for such a determination is 42 U.S.C. §§ 262(k) & (l), and it is undisputed that they the FDA has not satisfied the requirements under that statute.

Moreover, contrary to the Defendants' assertion, the FDA's Interchangeability determinations, in Defendants' view, "do … determine [the] rights and obligations" of Plaintiffs, ECF 65-2 at 42 (citation and quotation omitted), as well as those of Defendants, Pfizer-BioNTech, and other subjects of vaccine

mandates. First, the Interchangeability determination was made on the exact same day that the FDA formally licensed Comirnaty, and it extended the legal benefits of licensure to all EUA products. Because the Interchangeability determination extended the benefits of licensure to otherwise unlicensed products, these FDA actions should be treated as one and the same final agency action under review. Second, the FDA's Interchangeability determination, in Defendants' view, eliminated Plaintiffs' rights under the Informed Consent Laws, and obviated any need for the Secretary of Defense to obtain Presidential approval under 10 U.S.C. § 1107a. Third, the Interchangeability determination is the basis for the FDA's position that it can waive otherwise mandatory FDA labeling requirements, including statutory rights to informed consent, and the option to refuse, that are clearly stated in the FDA-required labeling for EUA products.

Plaintiffs Challenge FDA Labeling Non-Enforcement. To eliminate any doubt or ambiguity, *see Austin*, 2021 WL 5816632, at *6 n.11, Plaintiffs reiterate that they are challenging the FDA's apparent violations, or non-enforcement, of its mandatory labeling requirements. *See* ECF No. 65-14, Marks Decl., ¶13. The FDA's non-enforcement is an inseparable element of its Interchangeability determination, and as such is "but for" and proximate cause of the injuries they have suffered due to the DOD Mandate and the violation of their informed consent rights. In any case, Plaintiffs specifically alleged that the Interchangeability determination was

unlawful, among other things, insofar as it permitted EUA-labeled products to be treated as licensed products, in violation of FDA labeling requirements. *See* SAC ¶71 & n.38, ¶75 & n.40, ¶144.

The PHSA expressly prohibits the sale of any biologic product in interstate commerce unless the package is "plainly marked with" "the proper name of the biological product," (*i.e.*, Comirnaty) and "the name, address and applicable license number of the manufacturer." 42 U.S.C. § 262(a)(1)(B)(i)-(ii). These requirements are mandatory, not discretionary. *See* 21 C.F.R. § 610.60(a)(1)(2) (directing that the "proper name" and "license number" "shall appear on the label" of biological product); *see also* 21 C.F.R. § 207.37(a)(2) (a product is "deemed … misbranded" if labeling codes used to "denote or imply FDA approval of [an unapproved] drug"). While the FDA has discretion to make exceptions to labeling requirements, it may not waive any requirements "explicitly required by statute." *See, e.g.,* 21 C.F.R. § 610.68. Accordingly, the FDA does not have discretion not to enforce these labeling requirements for "BLA-compliant" products.

Plaintiffs Also State a Non-Statutory *Ultra Vires* Claim. To the extent that the Court determines that Plaintiffs do not have an APA claim regarding the FDA's Interchangeability determinations, *e.g.*, because it "not a final agency action at all," ECF 65-2 at 42, then Plaintiffs have stated a non-statutory *ultra vires*. The FDA has not identified any statutory basis for this action, and acknowledges that it is not a

statutory determination. Plaintiffs have alleged that FDA's nonfinal action "wholly deprives" Plaintiffs "of a meaningful and adequate means of vindicating" their rights under the Informed Consent Laws. *Rhode Island*, F.3d at 42 (citations omitted), and that FDA's actions are "plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory," *CBD*, 453 F. Supp. 3d at 47, namely the express prohibitions in the Informed Consent Laws and the PHSA's labeling requirements above.

CONCLUSION

For these reasons, the Court should deny Defendants' Motion. The Court should further direct Defendants to produce a certified index within seven (7) days (*i.e.*, February 11, 2022), and the complete administrative record within 21 days (*i.e.*, February 25, 2022).

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson
DC Bar No. 491370
/s/ Travis Miller
Travis Miller
Texas Bar No. 24072952
Defending the Republic
2911 Turtle Creek Blvd., Suite 300
Tel. (214) 707-1775
Email: bcj@defendingtherepublic.org
Email: traviswmiller@gmail.com

CERTIFICATE OF COMPLIANCE

I hereby certify that this submission contains 11,800 words or less 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 day e-filed the foregoing Plaintiffs' Opposition to Defendants' Motion using the CM/ECF system.

This 4th day of February, 2022.

Respectfully Submitted,

/s/ Brandon Johnson
Brandon Johnson