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

JOHN DOE #1-#14 and JANE DOE #1-#2,

Plaintiffs,

v. **Case No. 3:21-cv-1211-AW-HTC**

LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, et al.,

Defendants.

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ORDER DENYING PRELIMINARY INJUNCTION MOTIONS

In August, Secretary of Defense Lloyd Austin issued a mandate requiring all military personnel to become vaccinated against COVID-19. Seven weeks later, sixteen servicemembers sued the Secretary and others, challenging the mandate. They then filed two separate preliminary injunction motions, one raising statutory claims and the other raising constitutional claims. ECF Nos. 3, 10. The government defendants responded, the plaintiffs replied, and there was a telephonic hearing. ECF Nos. 31, 33, 45. Having carefully considered all the arguments, I now deny the motions.

It is worth saying at the outset what this case is not about. For one, it is not about vaccine mandates generally. The plaintiffs argue that the military's vaccine mandate should be viewed "as part of a larger effort by federal administrative agencies and the Executive Branch to impose unconstitutional vaccination mandates

for essentially all Americans," ECF No. 11 at 8; *see also* ECF No. 10 at 2-3 (requesting "that this Court address the larger questions raised by federal vaccine mandates"); ECF No. 3-2 at 23, but challenges to other mandates in other contexts are not at issue here.[1] This case addresses only the Secretary's mandate, which relates only to the affected servicemembers. Second, this case is not about the wisdom of the Secretary's decision—or whether the Secretary *should* mandate vaccines. The plaintiffs argue that the mandate is imprudent and unwise—even contrary to national security interests. Although those arguments relate to certain legal points (like arbitrariness under the APA), the issues presented here are not that broad. Courts don't serve to review the wisdom of the other branches' policy decisions. *See Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978) (explaining that a court's "individual appraisal of the wisdom or unwisdom" of a policy "is to be put aside" and that "[o]nce the meaning of an enactment is discerned and its constitutionality determined, the judicial process comes to an end").

The issue in this case is whether the mandate fails based on the specific APA or constitutional claims these plaintiffs present. And the issue at this early stage of

[1] For example, there is a recent OSHA requirement, *see* COVID-19 Vaccination and Testing, Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021) (to be codified at 29 C.F.R. pts. 1910, 1915, 1917, 1918, 1926, and 1928). That rule, which the Fifth Circuit stayed pending review, *see BST Holdings, LLC v. OSHA*, No. 21-60845 (5th Cir. filed Nov. 6, 2021), is not at issue here.

the case is whether the plaintiffs have shown they are entitled to preliminary injunctive relief.

I.

A preliminary injunction is no small thing. It is "an extraordinary and drastic remedy" and should never be granted unless the party seeking it "clearly establishe[s]" entitlement. *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (quoting *McDonald's Corp. v. Robertson*, 147 F.3d 1301, 1306 (11th Cir. 1998)); *see also Texas v. Seatrain Int'l, S.A.*, 518 F.2d 175, 179 (5th Cir. 1975) ("[W]e must remember that granting a preliminary injunction is the exception rather than the rule."). To secure an injunction, the plaintiffs must clearly establish four factors: (1) that they have "a substantial likelihood of success on the merits"; (2) that they will suffer irreparable injury without an injunction; (3) that they face a threatened injury that "outweighs whatever damage the proposed injunction may cause" the government; and (4) that "the injunction would not be adverse to the public interest." *Siegel*, 234 F.3d at 1176. They must clearly establish all four; a failure on even one prong dooms their motion. *ACLU of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009).[2]

[2] The plaintiffs also seek an administrative stay under the APA, 5 U.S.C. § 705. *See* ECF No. 3-2 at 40. A similar analysis applies for administrative stays and preliminary injunctions. *Nken v. Holder*, 556 U.S. 418, 434 (2009).

II.

I will first consider plaintiffs' APA claims against the FDA[3] and DOD. In plaintiffs' view, those entities acted unlawfully—the FDA by approving the vaccines, and the DOD by mandating their use. Before turning to those claims, though, it is helpful to cover some relevant background.

The parties do not agree on all the facts, but neither side requested an evidentiary hearing. Regardless, many of the pertinent facts are essentially undisputed.

Pfizer developed a COVID-19 vaccine, for which the FDA issued an Emergency Use Authorization ("EUA"). This allowed Pfizer to distribute the vaccine starting in December 2020. ECF No. 1-6 at 2-3. An EUA is not a full FDA license. It instead represents the FDA's conclusion that a product may be effective against a disease in a public health emergency where there is no "adequate, approved, and available alternative." *See generally* 21 U.S.C. § 360bbb-3(a)-(c). EUA drugs must include labeling and package inserts telling patients "of the option to accept or refuse administration of the product." *Id.* § 360bbb-3(e)(1)(A)(ii)(III).

[3] The plaintiffs also include a claim against the Secretary of the Department of Health and Human Services. ECF No. 3-2 at 14; *see also* ECF No. 1. But it is unclear why HHS is an appropriate party. The FDA is part of HHS, but an order against HHS is not necessary to effect the relief plaintiffs seek against the FDA.

On August 23, 2021—roughly eight months after the EUA first became effective—the FDA approved a Biologics License Application ("BLA") and issued a full FDA license to produce and distribute the vaccine and label it with its proprietary name, "Comirnaty." ECF No. 1-4 at 2-3. The BLA approval requires that Pfizer produce Comirnaty only at approved locations, subject to specific manufacturing, packaging, and labeling requirements. *Id.* at 2

During the administrative process, several scientists filed a Citizens' Petition challenging the approval on various grounds. *See generally* ECF No. 1-12. But the FDA denied that petition, explaining why the FDA felt evidence justified approving the Comirnaty BLA. *See generally* ECF No. 1-13.

In addition, the FDA concluded Comirnaty's BLA approval did not eliminate the grounds for extending the vaccine's EUA. ECF No. 1-6 at 3. The FDA explained that the EUA allows some third doses and use in children under 16, neither of which the BLA approval allows. *Id.* at 5-6. The FDA also concluded that "there is not sufficient approved vaccine available for distribution to [the approved] population in its entirety." *Id.* at 6 n.9. Thus, Pfizer continues to produce vials of vaccine that are labeled as an EUA drug with packaging material saying, "This product has not been approved or licensed by the FDA . . . ." *Id.* at 12-13. And there "remains . . . a significant amount of [Pfizer COVID-19 vaccine] that was manufactured and labeled in accordance with [the EUA]." *Id.* at 12.

In the Summary Basis for Regulatory Action regarding Pfizer's BLA approval, the FDA explained that some vials of EUA-labeled vaccine are still considered BLA-compliant—and are thus essentially Comirnaty—because they have the BLA-approved chemical composition and were produced at a BLA-approved facility. *See* ECF No. 1-5 at 28. For those lots, the FDA maintains that the EUA informed-consent provision, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), is inapplicable for the BLA-approved use: the two-dose regimen for those over 16. ECF No. 31-13 ¶ 13. (A batch produced in a non-BLA-approved facility can exist as an EUA drug but is not BLA-compliant and cannot be labeled Comirnaty. ECF No. 1-5 at 28.) To keep it all straight, FDA requires Pfizer to identify which lots it considers BLA compliant and list them on the Internet. ECF No. 1-5 at 28.[4]

In short, what people think of as the Pfizer vaccine has two distinct FDA-approval statuses. It is licensed—that is, fully approved—for the two-dose application in those 16 and older. But it is unlicensed and operating under an EUA—that is, an emergency use authorization—for other applications, like for children under 16 and for certain third shots. Nonetheless, the FDA describes the two as the

[4] *See RE: Pfizer-BioNTech COVID-19 IMPORTANT PRODUCT INFORMATION*, Pfizer (Aug. 23, 2021), https://webfiles.pfizer.com/half-lot-number-letter-v3.

"same formulation" and "interchangeabl[e]" for medical purposes. *See* ECF No. 1-6 at 3 n.8.[5]

On August 9, two weeks before the FDA approved Pfizer's Comirnaty BLA, the Secretary of Defense issued a memorandum announcing his intent to require vaccination against COVID-19 either "immediately" upon FDA licensure or "no

[5] The plaintiffs question whether the two products are, in fact, chemically identical. *See, e.g.*, ECF No. 45 at 16:17-19. Indeed, the Summary Basis for Regulatory Action lists a redacted excipient for BLA-approved Comirnaty that does not appear on the ingredient list in the EUA letter. *Compare* ECF No. 1-5 at 9 (listing 11 components, including .450 ml per vial of a redacted excipient), *with* ECF No. 1-6 at 7 (listing 10 components, all of which also appear on the Summary Basis list). Excipients are "inactive" ingredients like "coatings, binders, and capsules," but they sometimes "may affect the safety and effectiveness of drug products." *United States v. Generix Drug Corp.*, 460 U.S. 453, 454-55 (1983). In *Generix*, the Supreme Court held that two products with the same active ingredients were nonetheless not the same "drug" under the FDCA where the district court had found that their different excipients created a reasonable possibility that the unlicensed drug was "less safe and effective" than the licensed one. *Id.* at 455-57. But the Court expressly declined to decide "whether two demonstrably bioequivalent products, containing the same ingredients but different excipients, might under some circumstances be the same 'drug.'" *Id.* at 461. Because an excipient is, by definition, an inactive ingredient—and because the plaintiffs haven't shown a "reasonable possibility" that excluding .450 ml of the redacted excipient from a vial of the EUA vaccine makes it any "less safe and effective" than Comirnaty, *Generix*, 460 U.S. at 455—I do not discount the FDA's conclusion that the two vaccines are medically interchangeable. *See* ECF No. 1-6 at 3 n.8; ECF No. 31-13 at ¶¶ 7-9. Of course, that does not mean the two vaccines are *legally* indistinguishable—the FDA concedes they are not. *See* ECF No. 1-6 at 3 n.8. Still, EUA-labeled vials that Pfizer and the FDA "consider[] BLA compliant," ECF No. 1-5 at 28, presumably must include the redacted excipient to meet Comirnaty's licensing requirements. *Cf.* ECF No. 1-4 at 4 ("You must submit information to your BLA for our review and written approval under 21 C.F.R. 601.12 for *any* changes in . . . the manufacturing [of Comirnaty]." (emphasis added)).

later than mid-September, . . . whichever [came] first." ECF No. 31-1 at 2. Then, the day after Comirnaty's approval, the Secretary of Defense issued another memorandum that announced the DOD-wide vaccination mandate. ECF No. 31-2 at 2. The memorandum advised Pentagon leadership that "[m]andatory vaccination . . . will only use COVID-19 vaccines that receive full licensure from the Food and Drug Administration (FDA), in accordance with FDA-approved labeling and guidance." *Id.*

With that background in mind, I now turn to the plaintiffs' specific statutory claims.

A.

1. First, the plaintiffs contend the DOD mandate is invalid because it did not go through notice-and-comment rulemaking. ECF No. 3-2 at 17. Long before the DOD mandate issued, an existing regulation—Army Reg. 40-562—set out the military's vaccine policy. That regulation allows medical exemptions for, among other things, a "medical contraindication relevant to a specific vaccine or other medication." Army Reg. 40-562 ¶ 2-6(a). As an example of what might justify a medical exemption, it includes "[e]vidence of immunity based on serologic tests, documented infection or similar circumstances," *id.* ¶ 2-6(a)(1)(b), along with many

other "exemption codes," *see* Army Reg. 40-562 app'x C-1.[6] The new mandate, notwithstanding Army Reg. 40-562, includes no exception for natural immunity. Indeed, the DOD has explicitly stated that even those who already recovered from COVID-19 must be vaccinated.

The plaintiffs contend that because the mandate contradicts Army Reg. 40-562, it essentially amends it. And, the plaintiffs argue, the Secretary cannot amend Army Reg. 40-562 without notice-and-comment rulemaking. ECF No. 3-2 at 17-19; *see also* 5 U.S.C. § 553 (setting out notice-and-comment procedures for rulemaking); *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995) (noting that APA rulemaking is required when an agency "adopt[s] a new position inconsistent with any of the Secretary's existing regulations.").

The problem for the plaintiffs is that the statute they rely on—5 U.S.C. § 553—is inapplicable "to the extent that there is involved . . . a military or foreign affairs function of the United States." *Id.* § 553(a)(1). The plaintiffs insist the mandate is not really related to a "military function," that the mandate is instead "one piece in the larger federal administrative scheme to impose nearly universal federal vaccine mandates (affecting 100 million Americans) as a condition of

[6] The regulation also allows servicemembers to submit religious exemption requests. *See* Army Reg. 40-562 ¶ 2-6(b)(3). The plaintiffs here do not present any claims based on religion. *See* ECF No. 1 at 2 n.1.

employment." ECF No. 33 at 16. But regardless of any broader federal administrative scheme, the military's decision to inoculate servicemembers plainly involves a military function. The Ninth Circuit's decision in *Independent Guard Association of Nevada, Local No. 1 v. O'Leary*, on which plaintiffs rely, does not suggest otherwise. ECF No. 33 at 15-16 (citing 57 F.3d 766 (9th Cir. 1995)). The issue in that case was whether certain civilian contract guards were performing a "military function." *O'Leary*, 57 F.3d at 770. The military-function test is easily satisfied here as to the plaintiffs, each of whom is an active-duty servicemember. The plaintiffs have not shown a likelihood of success as to their notice-and-comment-rulemaking claim.[7]

2. The plaintiffs next argue that the mandate is arbitrary and capricious because it lacks any legitimate basis. ECF No. 3-2 at 19-20. They point to the fact that the mandate issued the day after the FDA's Comirnaty approval, which they say shows a lack of meaningful consideration of the mandate. They also contend that DOD did not support its decision with 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,

[7] In a footnote, the defendants argue a second statutory exception for "matter[s] relating to agency management or personnel." 5 U.S.C. § 553(a)(2) (cited in ECF No. 31 at 23 n.9). Because the military-function exception applies, I need not address this separate argument.

without exemption of service members whit natural immunity or pregnancy." ECF No. 3-2 at 20.

This argument is a difficult one because of the substantial deference afforded to administrative decisions. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2569 (2019). There is substantial deference with most any agency decision, but this case involves military affairs, where "the lack of competence on the part of the courts is marked." *Rostker v. Goldberg*, 453 U.S. 57, 65 (1981); *accord id*. at 66 ("The operation of a healthy deference to legislative and executive judgments in the area of military affairs is evident in several recent decisions of [the Supreme] Court.").

Parties must show far more than that the agency made the wrong decision. As noted at the outset, a federal court's role is not to determine whether agencies made the best or most prudent choice. The question is "whether the Secretary examined the relevant data and articulated a satisfactory explanation for his decision, including a rational connection between the facts found and the choice made." *Dep't of Com.*, 139 S. Ct. at 2569. At this stage, the plaintiffs have not shown that they are likely to succeed on this point.

Next, to the extent plaintiffs rely on the administrative record to support their claim (*e.g.*, ECF No. 3-2 at 20 ("[T]here is no indication in the record . . . .")), I note that the administrative record is not before the court. Finally, the plaintiffs' argument that the mandate is arbitrary and capricious because it "relied on facially unlawful

FDA actions" (ECF No. 3-2 at 20) cannot succeed because plaintiffs have not shown those actions were facially unlawful. *See infra*. This is not to say that the plaintiffs' challenge cannot ultimately succeed, but at this stage, they have not shown enough.

3. The plaintiffs next argue that the mandate violates their statutory right to refuse an EUA vaccine. ECF No. 3-2 at 20-21. Under the EUA statute, recipients of EUA drugs must be "informed . . . of the option to accept or refuse administration of the product." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III); *see also* 5 U.S.C. § 706(2)(C) (APA provision prohibiting agency action taken "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"). And under 10 U.S.C. § 1107a, "[i]n the case of the administration of [an EUA] product . . . to members of the armed forces," that statutory right to refuse "may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1). The DOD acknowledges that the President has not executed a wavier under this section, ECF No. 45 at 52:8-9, so as things now stand, the DOD cannot mandate vaccines that only have an EUA. 10 U.S.C. § 1107a(a)(1).

One problem with this argument is that the DOD's guidance documents explicitly say only FDA-licensed COVID-19 vaccines are mandated. *See, e.g.*, ECF No. 1-3 at 2 (DOD mandate memorandum) ("Mandatory vaccination against COVID-19 will only use COVID-19 vaccines that receive full licensure from the

[FDA] in accordance with FDA-approved labeling and guidance."); *and* ECF No. 1-7 at 11 (Air Force guidance) ("Only an FDA-licensed vaccine may be mandated . . . ."). The plaintiffs present a facial challenge, ECF No. 33 at 10 ("Plaintiffs' claims are facial challenges to a generally applicable military regulation . . . ."), and on its face, the mandate does not require anyone to take an EUA vaccine.

Notably, though, the plaintiffs have shown that the DOD is requiring injections from vials not labeled "Comirnaty." Indeed, defense counsel could not even say whether vaccines labeled "Comirnaty" exist at all. ECF No. 45 at 48:5-7. (Although the DOD's response said it had an adequate Comirnaty supply, it later clarified that it was mandating vaccines from EUA-labeled vials. *See id*. at 46:22-47:3.) In the DOD's view, this is fine because the contents of EUA-labeled vials are chemically identical to the contents of vials labeled "Comirnaty" (if there are any such vials). According to the DOD's argument, this means servicemembers are not required to accept "a *product* authorized for emergency use." 10 U.S.C. § 1107a(a)(1). Rather, the DOD argues that once the FDA licensed Comirnaty, all EUA-labeled vials essentially became Comirnaty, even if not so labeled. ECF No. 45 at 60:1-3. Thus, the DOD argues, the "product" injected is a chemical formulation

that has received full FDA licensure—not merely an EUA—so § 1107a does not apply. *Id.* at 65:1-6.[8]

The DOD's interpretation of § 1107a is unconvincing. For starters, FDA licensure does not retroactively apply to vials shipped before BLA approval. *See* 21 U.S.C. § 355(a) ("No person shall introduce . . . into interstate commerce any new drug, unless an approval of an application [for FDA licensure] *is effective* with respect to such drug." (emphasis added)). Thus, as a legal matter, vaccines sent before August 23—and vaccines produced after August 23 in unapproved facilities—remain "product[s] authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act." § 1107a(a)(1).[9] Section 1107a's explicit cross-reference to the EUA provisions suggests a concern that drugs mandated for military personnel be actually BLA-approved, not merely chemically similar to a BLA-approved drug. And the distinction is more than mere labeling: to be BLA compliant, the drug must be produced at approved facilities, *see* ECF No. 1-4 at 2; 21 C.F.R. §§ 600.11, 600.20-.21, and there is no indication that all EUA-labeled

[8] The plaintiffs also cite 10 U.S.C. § 1107, but the defendants correctly note it does not apply. That statute covers "an investigational new drug or a drug unapproved for its applied use," and this vaccine (either under the EUA or the BLA) is neither.

[9] This distinction is the basis for the FDA's comment that the BLA-compliant vials and the EUA-compliant vials are "legally distinct," even though their chemical formulation is identical. *See* ECF No. 1-6 at 3 n.8. Thus, the DOD cannot rely on the FDA to find that the two drugs are legally identical for § 1107a purposes.

vials are from BLA-approved facilities.[10] Moreover, the DOD concedes that some of its current vials are not BLA-compliant, and that there is no policy to ensure that servicemembers get only BLA-compliant vaccines. *See* ECF No. 45 at 61:10-12. It is difficult to see how vials that the DOD admits are not BLA-compliant—and thus could only be EUA products—could fall outside § 1107a's prohibition on mandatory administration.

Notwithstanding all of this, the plaintiffs have not shown a substantial likelihood of success on this APA claim. The FDA's Summary Basis for Regulatory Action approving Comirnaty explains that certain lots of EUA-labeled vials are nonetheless "BLA-compliant," and that healthcare providers may disregard the EUA-specific labeling when administering doses from those vials. ECF No. 1-5 at 28. The DOD claims it possesses "hundreds of thousands of BLA-compliant vaccine doses that are EUA-labeled, and is using them." ECF No. 30-14 ¶ 18. If the DOD is, in fact, administering Comirnaty (albeit EUA-labeled Comirnaty), the plaintiffs' § 1107a issue disappears. Although there is apparently no DOD policy in place to ensure that servicemembers receive BLA-compliant vaccines, *see* ECF No. 45 at

[10] The FDA's Comirnaty approval letter redacts the approved manufacturing locations, *see* ECF No. 1-4 at 2, and the EUA extension letter does not identify which facilities were "identified and agreed upon" in Pfizer's EUA application, ECF No. 1-6 at 8. The Summary Basis for Regulatory Action suggests that not all Pfizer facilities are BLA compliant, because it contemplates that not all EUA-labeled lots will contain BLA-compliant vials. *See* ECF No. 1-5 at 28.

61:10-12, no plaintiff claims he or she was specifically denied a BLA-compliant dose or offered only a dose from a non-BLA-compliant vial. Because the plaintiffs have not shown they are (or will be) required to receive an EUA-labeled, non-BLA-compliant vaccine, the plaintiffs have not shown a likelihood of success.[11]

B.

The plaintiffs' APA claims against the FDA do not fare better. These claims break down into three categories. First, plaintiffs contend the FDA's Comirnaty approval is invalid because the FDA did not follow the Food, Drug & Cosmetic Act (FDCA) and the Public Health Service Act (PHSA). Second, the plaintiffs argue that the FDA wrongfully determined that EUA drugs and Comirnaty are interchangeable.

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[11] The plaintiffs argue that the FDA cannot allow BLA-compliant vaccine doses to bear an EUA label. ECF No. 33 at 24-25. But they cite no legal authority for this proposition, and they do not dispute that the FDA's Summary Basis for Regulatory Action specifically included certain EUA-labeled lots under the BLA approval. Regardless, the plaintiffs do not present this claim against the FDA.

Still, the statutes leave unclear what FDA labeling decisions are discretionary. The FDA's Comirnaty approval letter says that the labeling on Comirnaty vials "must be identical" to what Pfizer submitted in its application, ECF No. 1-4 at 4, but this label does not appear to be identical to an EUA label, *see* ECF No. 1-5 at 28. And federal regulations require the FDA commissioner to initiate license revocation proceedings if he determines that a licensed product is "misbranded with respect to any [of its intended uses]" or "fails to conform to the applicable standards established in the license . . . designed to ensure the continued safety, purity, and potency" of the product. 21 C.F.R. § 601.5(b)(1)(iv), (vi). These provisions could be read to prohibit distributing a fully licensed drug with an EUA-specific label and package insert rather than those its BLA approval require.

Third, the plaintiffs argue that the FDA illegally extended the EUA for the vaccine while simultaneously licensing the same product as Comirnaty.[12]

1. First, the government's papers argued with some force that plaintiffs lacked standing to challenge the FDA's approval. ECF No. 31 at 32-33. The plaintiffs would have standing only if relief against the FDA would redress their injury, and the government argued that any injury was "not caused by FDA's actions, but by DoD's independent decision to require vaccination." ECF No. 31 at 32-33. In fact, the government argued, the DOD was going to impose a vaccine requirement with or without Comirnaty's full licensure. *Id.* at 33. But at the hearing, the government's counsel acknowledged 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 a Presidential approval, *see* 10 U.S.C. § 1107a(a)(1), which has not happened. Thus, at this stage, the plaintiffs have shown enough as to standing. But they still have not shown enough for preliminary injunctive relief.

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[12] Although based on alleged FDCA and PHSA violations, the plaintiffs' claims are APA claims. The plaintiffs have not identified a private cause of action under the FDCA or PHSA. *Cf. Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002). But the APA provides that a court may set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C); *see also* ECF No. 1 ¶¶ 126, 131. Here, the plaintiffs have not shown a likelihood of success on their APA claim because they have not shown a likelihood the FDA violated the FDCA or PHSA.

For one thing, there are procedural hurdles the plaintiffs have not overcome. There is the "record rule," which generally provides that courts reviewing agency action should limit their review to "the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *accord Pres. Endangered Areas of Cobb's History, Inc. v. U.S. Army Corps of Engineers*, 87 F.3d 1242, 1246 (11th Cir. 1996) ("The role of the court is not to conduct its own investigation and substitute its own judgment for the administrative agency's decision. Rather, the task of the reviewing court is to apply the appropriate standard of review to the agency decision based on the record the agency presents to the reviewing court." (cleaned up)); *see also Dep't of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019) ("In reviewing agency action, a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record. That principle reflects the recognition that further judicial inquiry into executive motivation represents a substantial intrusion into the workings of another branch of Government and should normally be avoided." (cleaned up)). Yet plaintiffs rely on extra-record evidence, including expert affidavits.

The plaintiffs' extra-record evidence does not appear to fall within the narrow exceptions to the record rule. While the FDA's decisions ordinarily may be challenged "solely on the basis of the administrative record," citizens who "wish[]

to rely on information or views not included in the administrative record" may submit a citizen petition asking the FDA "Commissioner . . . to modify the action." 21 C.F.R. § 10.45(f). In their filings, the plaintiffs introduce materials that the FDA did not receive for consideration as part of the citizen petition challenging Comirnaty's licensure. *See generally* ECF No. 1-12 (citizen petition that does not incorporate the rest of plaintiffs' exhibits). Thus, the plaintiffs have not pursued an available administrative route available to force the FDA to consider the materials they submit here. As the defendants point out, ECF No. 31 at 36, "[u]nder ordinary principles of administrative law, a reviewing court will not consider arguments that a party failed to raise in a timely fashion before an administrative agency." *Mahon v. USDA*, 485 F.3d 1247, 1254-55 (11th Cir. 2007) (quoting *Sims v. Apfel*, 530 U.S. 103, 114 (2000) (Breyer, J., dissenting)). The plaintiffs respond by assuring the court that their experts are well-qualified, *see* ECF No. 33 at 26-27, but they do not explain how they can clear the procedural hurdles to challenge FDA action on the basis of this expert testimony or their other exhibits.

On the merits, the plaintiffs haven't made a substantial showing that the FDA acted without a reasonable scientific basis. The FDA is entitled to substantial deference because drug licensing decisions involve "scientific determination[s]" within the FDA's "area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983). Thus, even if the plaintiffs' expert

declarations were properly before the court, they would need to overcome "an extreme degree of deference" to the FDA. *Nat'l Mining Ass'n v. Sec'y, U.S. Dep't of Lab.*, 812 F.3d 843, 866 (11th Cir. 2016) (quoting *Kennecott Greens Creek Mining Co. v. Mine Safety & Health Admin.*, 476 F.3d 946, 954 (D.C. Cir. 2007)). The defendants have submitted their own expert declaration contesting many of the plaintiffs' scientific claims, ECF No. 31-13 ¶ 25, and the FDA also responded in detail to the citizen petition challenging Comirnaty's licensure, *see* ECF No. 1-13. At most, the plaintiffs have shown that some experts disagree with the FDA's conclusions about Comirnaty's safety and efficacy. But that does not create a substantial likelihood of success on their APA claim. *See Marsh v. Oregon Nat. Res. Council*, 490 US. 360, 378 (1989) ("When specialists express conflicting views, an agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive.").

The plaintiffs also argue that the FDA had improper motivations in approving Comirnaty as quickly as it did. ECF No. 3-2 at 30-32. Normally, "a court may not reject an agency's stated reasons for acting simply because the agency might also have had other unstated reasons," including "political considerations" or "an Administration's priorities." *Dep't of Com.*, 139 S. Ct. at 2573. To get around this principle, the plaintiffs must provide a "strong showing of bad faith or improper

behavior," *id.* (quoting *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 420 (1971)). They rely on the FDA's short timeframe, and they claim the license was a pretext to allow for vaccine mandates. ECF No. 3-2 at 30-31. But the timeframe is of course susceptible to other explanations, and it is not itself evidence of bad faith—even if it shows that "political considerations" influenced the approval, *Dep't of Com.*, 139 S. Ct. at 2573. And the claims of pretext are supported at this stage only by conjecture.

2. The plaintiffs also argue that the FDA acted unlawfully when it issued guidance saying Pfizer's EUA vaccine may be used "interchangeably" with Comirnaty "to provide the vaccination series without presenting any safety or effectiveness concerns." ECF No. 1-6 at 3 n.8; *see also* ECF No. 3-2 at 36. In the plaintiffs' view, the FDA determined that the two were "interchangeable" under 42 U.S.C. § 262(i)(3) without requiring Pfizer to go through the proper channels. ECF No. 3-2 at 36. In their view, the EUA letter was an "attempt to retroactively license the EUA vaccine, solely for the purpose of enabling the mandate." *Id.* at 38.

The plaintiffs have serious standing issues challenging the interchangeability determination. If the FDA's goal were to "retroactively license" the EUA vaccine, it had an odd way of doing so—in the same footnote describing the EUA vaccine and Comirnaty as "interchangeabl[e]," the FDA clarifies that the two products are "legally distinct." ECF No. 1-6 at 3 n.8. More to the point, the FDA nowhere claims

that EUA vaccine had been *licensed* as "interchangeable" with Comirnaty, the process described in the statute the plaintiffs rely on. *See* 42 U.S.C. § 262(k)(4); ECF No. 3-2 at 37. And because the DOD hasn't mandated that the plaintiffs receive anything other than "COVID-19 vaccines that receive full licensure from the Food and Drug Administration," ECF No. 1-3 at 2, the plaintiffs cannot show that they are harmed by an interchangeability determination that does not purport to grant formal licensure to the EUA vaccines.

Even if the plaintiffs could show injury from the FDA's interchangeability determination, they still have not shown a substantial likelihood that the FDA acted unlawfully. The plaintiffs insist that the FDA "must be presumed" to have used the word "interchangeably" in the sense that 41 U.S.C. § 262(i)(3) defines it. ECF No. 3-2 at 37. But, the plaintiffs argue, the FDA may only make a statutory interchangeability determination after a drug manufacturer submits an application for licensure on the basis that its drug is "biosimilar" to an already-licensed drug. *See id.* n. 14 (citing 41 U.S.C. § 262(k)(4)).

What the plaintiffs overlook is that the FDA used the word "interchangeably" in a practical sense, not a legal one. The EUA letter explains that the EUA drug and Comirnaty "can be used interchangeably . . . *without presenting any safety or effectiveness concerns*," but clarifies that they are "legally distinct." ECF No. 1-6 at 3 n.8. That is most plausibly interpreted as a factual, medical claim rather than a

regulatory claim.[13] The best evidence of this is that, as noted above, the FDA was not considering whether to grant full approval to the EUA product on the basis that it was "interchangeable" with Comirnaty in the statutory sense. Rather, the FDA was extending an EUA authorization, a completely different regulatory classification, that expressly requires Pfizer to indicate that EUA vaccines "ha[ve] not been approved or licensed by the FDA." ECF No. 1-6 at 13.

3. In addition, the plaintiffs contend it is unlawful for the FDA Secretary to issue an EUA for a drug that is chemically identical to a drug with full FDA approval (like Comirnaty), because the existence of an approved drug entails the existence of an "available alternative" to the EUA drug. ECF No. 3-2 at 27. But the plaintiffs have not shown at this stage that EUA decisions are even reviewable. *Cf. Ass'n of Am. Physicians & Surgeons v. USDA*, 2020 WL 5745974, at *3 (6th Cir.

[13] At any rate, the PHSA's definition of "interchangeable" describes a drug that can be substituted for a licensed "reference product without the intervention of the healthcare provider who prescribed the reference product," 42 U.S.C. § 262(i)(3), because it is "biosimilar" and "can be expected to produce the same clinical result as the reference product," 42 U.S.C. § 262(k)(4). For example, a pharmacy might fill a doctor's prescription for a name-brand drug with an alternative the FDA has determined is "interchangeable," even though the pharmacy does not seek reapproval from the prescribing physician. *Cf., e.g., Greentech, Inc. v. Immunex R.H. Corp.*, 964 F.3d 1109 (Fed Cir. 2020) (addressing dispute between cancer treatment manufacturer and competitor who submitted a biosimilar product for licensure under § 262). But because healthcare providers administer COVID-19 vaccines directly, there is no scenario in which a patient would receive an EUA vaccine as substitute to Comirnaty without his healthcare provider's intervention or approval.

Sept. 24, 2020) ("[E]mergency-use authorizations are exempt from review under the APA."); *and compare* 5 U.S.C. § 701(a)(2) (APA does not apply to agency actions "committed to agency discretion by law") *with* 21 U.S.C. § 360bbb-3(i) (establishing EUA framework) ("Actions under the authority of this section . . . are committed to agency discretion."). The plaintiffs argue that 5 U.S.C. § 701(a)(2) doesn't apply because the FDCA provides "meaningful standards of review" for EUA approvals. ECF No. 34 at 13 (citing *Weyerhauser Co. v. U.S. Fish & Wildlife Servs*., 139 S. Ct. 361, 370 (2018)). But the statute at issue here—unlike the statute in *Weyerhauser*—explicitly says that EUA decisions "are committed to agency discretion." 21 U.S.C. § 360bbb-3(i).

Regardless, even if the EUA decision were reviewable, the plaintiffs have not shown a substantial likelihood of success on this claim. For one, they are not required to take an EUA-only drug, so even without the EUA determination, the Comirnaty decision would survive. Second, given the applicable deference and the absence of the full administrative record here, they have not shown a likelihood of success on the merits anyway. Finally, the plaintiffs have not shown that the FDCA itself envisions "availability" as a binary category. In fact, patients receiving EUA drugs must be informed "of alternatives to the product that are available." 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III), suggesting that mere existence of some alternative does not mandate immediate withdrawal of EUA determinations.

* * *

The plaintiffs have not shown a likelihood of success on any of their statutory claims.

III.

Beyond their statutory arguments, the plaintiffs present three constitutional claims: Substantive Due Process, the unconstitutional conditions doctrine, and Equal Protection. ECF No. 11 at 21, 26, 27 . (The constitutional claims are against the military defendants only, not the FDA.) But they have not shown a substantial likelihood of success on any of them.

A.

The parties contest the applicable standard of review. The plaintiffs want strict scrutiny, ECF No. 11 at 24-25, while the DOD urges rational-basis review, ECF No. 31 at 48. To justify strict scrutiny, the plaintiffs must show that the case involves a suspect class or some fundamental right. *Panama City Med. Diagnostic, Ltd. v. Williams*, 13 F.3d 1541, 1545 (11th Cir. 1994) (considering equal protection claim); *see also Doe v. Moore*, 410 F.3d 1337, 1343 (11th Cir. 2005) (explaining that substantive due process challenges merit strict scrutiny only if the plaintiff identifies

a fundamental right). There is no suspect class here,[14] so the question is whether there is a fundamental right at stake.

To allege a successful substantive due process claim, a plaintiff must give a "careful description of the fundamental interest at issue" and show that the interest is "deeply rooted in this Nation's history and tradition, and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed." *Doe v. Moore*, 410 F.3d 1337, 1344 (11th Cir. 2005) (quoting *Williams v. King*, 543 U.S. 1152, 1239 (2005)). Because substantive due process involves unenumerated rights, courts must be "reluctant to expand the concept." *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997) (quoting *Collins v. City of Harker Heights*, 503 U.S. 115, 125 (1992)).

[14] The plaintiffs claim that mandating vaccines for servicemembers but not for illegal immigrants constitutes alienage-based discrimination, ECF No. 11 at 28, but they do not get far with this argument. Equal Protection "keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike." *Nordlinger v. Hahn*, 505 U.S. 1, 10 (1992). (The Fourteenth Amendment's Equal Protection Clause refers only to the States, but it "has been 'reverse-incorporated' into the Fifth Amendment's Due Process Clause" to apply against the federal government too. *Nat'l Parks Conservation Ass'n v. Norton*, 324 F.3d 1229, 1241 n.4 (11th Cir. 2003) (citing *Bolling v. Sharpe*, 347 U.S. 497, 499-500 (1954)).) It is true that alienage can trigger strict scrutiny in an Equal Protection analysis. *See Graham v. Richardson*, 403 U.S. 365, 376 (1971). But the DOD mandate—the only policy at issue in this case—doesn't differentiate based on alienage. It applies to all servicemembers, regardless of alienage.

Here, the plaintiffs struggle to identify the specific fundamental interest at issue. They explicitly disclaim any general constitutional right to refuse vaccinations or other medications.[15] ECF No. 11 at 23. And although they point to end-of-life and assisted-suicide cases, *id.* at 21-22 (citing *Cruzan v. Dir., Mo. Dep't of Health*, 197 U.S. 261, 278 (1990), *and Glucksberg*, 521 U.S. at 722 n.17), they have not asserted the specific rights identified in those inapposite decisions. The plaintiffs' best effort at specificity is their argument that the Constitution protects military personnel from being forced to accept "an unwanted, unnecessary, and unproven experimental vaccine." ECF No. 45 at 69:17-18. But they have not pointed to any legal authority showing that such a right is "deeply rooted in this Nation's history and tradition." *Glucksberg*, 521 U.S. at 721 (quoting *Moore v City of E. Cleveland*, 431 U.S. 494, 503 (1977) (plurality op.)). Even if they had, now that Comirnaty is FDA-approved, it is not "experimental" in any legally relevant sense. And—Comirnaty's approval aside—if Pfizer's vaccines existed only under an EUA, there would only be a procedural barrier preventing the mandate. *See* 10 U.S.C. § 1107a(a)(1).[16] (The plaintiffs have not asserted that § 1107a(a)(1) is unconstitutional.)

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[15] That framing distinguishes the legal issues here from *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905) (holding that state smallpox vaccine mandate did not violate constitutional liberty interests).

[16] Once a drug receives an EUA, it is no longer considered under "clinical investigation" under the PHSA or the FDCA. 21 U.S.C. § 360bbb-3(k). The

As to whether Comirnaty is "unnecessary," ECF No. 45 at 69:18, that is a policy question left for the military to decide as a personnel matter, not for a court to declare as a matter of fundamental right. *Cf Gilligan v. Morgan*, 413 U.S. 1, 10 (1973) ("It would be difficult to think of a clearer example [than military affairs] of the type of governmental action that was intended by the Constitution to be left to the political branches . . . [or one] in which the courts have less competence."). Because the plaintiffs have identified no clearly defined fundamental right "deeply rooted in this Nation's history and tradition," they have not triggered heightened scrutiny. *Moore*, 410 F.3d at 1134. Nor have they cited a single case applying strict scrutiny to a vaccine mandate. *See contra Klassen v. Tr. of Ind. Univ.*, 7 F.4th 592, 593 (7th Cir. 2021), *emergency application for relief denied*, No. 21A15 (Barrett, J., in chambers) (Aug. 12, 2021) (applying rational-basis review to university vaccine mandate)).[17]

B.

Because strict scrutiny doesn't apply, we are left with rational-basis review. This is a "highly deferential" review, under which plaintiffs have the burden of

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plaintiffs have offered no other judicially manageable way to determine whether a drug is "experimental" under their asserted substantive due process right.

[17] The plaintiffs cite *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020), which they contend shows strict scrutiny applies. That case did apply strict scrutiny to a COVID-19 restriction, but it did so in the context of a Free Exercise claim. *Id.* There is no such claim here.

"negat[ing] every conceivable basis that might support [the DOD mandate], even if that basis has no foundation in the record." *Leib v. Hillsborough Cnty. Pub. Transp. Comm'n*, 558 F.3d 1301, 1306 (11th Cir. 2009). In other words, there must be no "reasonably conceivable state of facts that could provide a rational basis for the" mandate. *Williams v. Pryor*, 240 F.3d 944, 948 (11th Cir. 2001) (quoting *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 314 (1993)) (cleaned up). And "[a] statute survives rational basis review even if it seems unwise or if the rationale for it seems tenuous." *Locke v. Shore*, 634 F.3d 1185, 1196 (11th Cir. 2011) (quoting *Romer v. Evans*, 517 U.S. 620, 632 (1996)) (cleaned up).

The plaintiffs have not met their extraordinary burden of showing the mandate lacks any rationality. They note the absence of certain vaccine justifications in the record, but the defendants have no evidentiary burden in this regard; they can base their mandate "on rational speculation unsupported by evidence or empirical data." *Beach Commc'ns*, 508 U.S. at 315. And it matters not that the defendant's decision may be the wrong one, so long as there is at least some arguable basis for it.

The plaintiffs also argue that "[t]he DOD mandate also violates equal protection insofar as it singles out, and discriminates against, Plaintiffs based on their medical history, disabilities and/or medical conditions." ECF No. 11 at 22. They do not fully develop this argument, but it apparently relates to their complaint that military personnel previously infected with COVID-19 will not receive exemptions

from the vaccine mandate. *See* ECF No. 11 at 18, ECF No. 3-2 at 10-11. To the extent they argue that the mandate is irrational because it treats servicemembers with natural immunity the same as those without—it requires vaccination even for those who have recovered from a COVID-19 infection—plaintiffs could not succeed because this is a facial challenge. They have to show more than an unconstitutional application as to some; they "must demonstrate that no possible application" of the mandate is constitutional. *Doe v. Sullivan*, 938 F.2d 1370, 1383 (D.C. Cir. 1991). So although the plaintiffs point to the medical consensus that natural immunity provides greater protection than vaccination alone, that is insufficient to sustain their facial challenge. Relatedly, policies survive this standard even when they are "significantly over-inclusive or under-inclusive," so long as they bear some rational connection to the policy's goal. *Williams*, 240 F.3d at 948.

At bottom, the plaintiffs have not met the heavy burden of showing facial irrationality.

C.

Finally, the plaintiffs have not shown any likelihood of success on their unconstitutional conditions claim. It is true that "the government may not deny a benefit to a person because he exercises a constitutional right." *Koontz v. St. Johns Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013) (quoting *Regan v. Tax'n With Representation of Wash.*, 461 U.S. 540, 545 (1983)). But there is no conditioned

benefit in this case; the whole basis of the plaintiffs' lawsuit is that the DOD requires them to be vaccinated, not that the DOD is "coercing [the plaintiffs] into giving [] up" a constitutional right in exchange for extra benefits. *Id.* Even if continued employment in the military were a conditional benefit for the purposes of the doctrine, the plaintiffs would still fail because a "condition cannot be unconstitutional if it could be constitutionally imposed directly," *Rumsfeld v. F. for Acad. & Inst. Rts., Inc.*, 547 U.S. 47, 59-60 (2006). As discussed above, plaintiffs have not shown a likelihood of success on their claim that the DOD mandate cannot constitutionally be imposed directly.

IV.

In conclusion, the plaintiffs have not shown they are entitled to the preliminary injunctive relief they seek.[18] Because they have not shown a likelihood

[18] The defendants have raised certain alternative arguments that need not be addressed. Their ripeness argument is jurisdictional, but in denying preliminary injunctive relief, I have not determined that the court does have jurisdiction. It is plaintiffs' burden to show the court has jurisdiction, and the nature of their burden depends on the stage of the proceedings. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Because we are still at the pleading stage, and because the complaint itself does not show any lack of ripeness, I have proceeded to consider the motion. *Cf. id*. Of course, if the plaintiffs could not establish a likelihood that their claims are ripe, they could not show a likelihood of success on the merits. *Cf. Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) ("[A] party who seeks a preliminary injunction must show a substantial likelihood of standing."). But if they did not, that would only be a basis for denying preliminary injunctive relief—not dismissing the case at this stage. And because I am denying preliminary injunctive relief on other grounds, I have not further addressed ripeness.

of success on the merits, I need not evaluate the other preliminary injunction factors. The motions (ECF Nos. 3, 10) are DENIED.

An initial scheduling order and an order addressing the plaintiffs request to proceed anonymously (ECF No. 4) will issue separately.

SO ORDERED on November 12, 2021.

s/ *Allen Winsor*
United States District Judge