

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

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

DEFENDANTS' RESPONSE TO PLAINTIFFS' SUPPLEMENTAL BRIEF

Pursuant to the Order dated April 15, 2022, ECF No. 78, Defendants submit this memorandum in response to Plaintiffs' supplemental memorandum, ECF No. 79 ("Pls.' Br."), which fails to counter Defendants' Motion to Dismiss.

1. **Status of the FDA Record.** With respect to the claims against FDA, Plaintiffs allege in a footnote that Defendants have not produced the complete FDA record. *See* Pls.' Br. at 1 n.1 The parties have initiated conferral about the proper scope of the record, and Defendants have produced an informal index, portions of the record containing no protected information, and a proposed protective order. As of today, May 2, 2022, Plaintiffs have not responded to the proposed protective order provided on April 1, 2022. No further portions of the record can be produced without a protective order in place (or in the alternative, review and redaction of potentially hundreds of thousands of pages. But this issue has no bearing on the Motion

to Dismiss, which can and should proceed on the basis of the complaint allegations and judicially noticeable documents already in the record. Dismissal is even more clearly appropriate now that there is an additional FDA-approved vaccine that Plaintiffs could take in lieu of the Pfizer vaccine. See Press Release: FDA Takes Key Action by Approving Second COVID-19 Vaccine (Jan. 31, 2022), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine> (explaining that FDA approved the Moderna COVID-19 vaccine). Plaintiffs have not objected to the approval of the Moderna vaccine, and as a result, they lack standing to pursue their challenge to the Pfizer vaccine. See *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280-83 (D.C. Cir. 2012) (Kavanaugh, J.) (explaining that availability of other vaccines eliminated plaintiffs' standing).

2. **DoD's Position on Interchangeability.** Plaintiffs argue that "no record materials support the . . . affirmative defense that the DoD Mandate and the scope of interchangeability are limited to EUA-labeled, 'BLA-compliant' vaccines or lots." Pls.' Br. at 2. Defendants never made any such argument, nor put it forth as an "affirmative defense." Defendants have explained consistently that the BLA-labelled Pfizer vaccine is exactly the same vaccine as the respective EUA-labelled Pfizer vaccine for those 16 and older, and according to FDA guidance, they may "use doses distributed under the EUA to administer the series as if the

doses were the licensed vaccine.” *See* Defs.’ MTD at 28, ECF No. 56-1; DOD000001. Accordingly, Plaintiffs are correct that Defendants consider the Pfizer EUA and BLA labelled vaccines to be interchangeable. *See* Pls.’ Br. at 3.¹

A subset of the EUA-labelled doses were manufactured in compliance with the BLA; these doses meet the BLA manufacturing requirements, and are not subject to requirements under the EUA. *See* Defs.’ MTD at 28-29; *see also* HCP Lot Letter & Additional Lot Details, <https://www.cvdvaccine-us.com/16-up-yearsold/resources> (under “Important Lot Information”). Because these BLA doses are available to Plaintiffs, (1) Plaintiffs lack standing to challenge the administration of other EUA doses, when they can request the BLA doses and have not been refused such doses; and (2) DoD has complied with any arguable additional requirements of Section 1107a of Title 10 by having these doses available.²

3. **Alternatives to Vaccination.** Finally, Plaintiffs argue that DoD failed to consider alternatives to vaccination. In fact, prior to the availability of vaccines, DoD had to rely on alternative measures to mandatory vaccination for over a year,

¹ Plaintiffs claim that the FDA says the vaccines “can be used interchangeably” whereas DoD says they “should be used interchangeably.” Pls.’ Br. at 3n.3. In other words, FDA explicitly permitted what DoD in fact does. DoD properly relied on FDA guidance in determining the scope of the mandate for service members and uses the vaccines interchangeably.

² Plaintiff Commander Furman is retired and not subject to the mandate, and Master Sergeant Lund is already vaccinated. Both Plaintiffs lack standing to seek any of the prospective relief identified in the Second Amended Complaint because they are not currently subject to the challenged requirements. SAC ¶¶ 19, 24, ECF No. 56.

and found them inadequate to protect the force. And the record shows the continuing impact of COVID-19 on the force as of July and August 2021, despite mitigation measures and despite voluntary vaccination rates. *See, e.g.*, DOD000007 (deaths and hospitalization totals); DOD000160-70 (COVID-19 Epidemiology Update); 173-75 (Recommendation of Joint Chiefs); 186-88 (memorandum describing measures to date), 280-84 (Risks to the Force of the Delta Variant); 357-58 (DepSec Mem). By contrast, the Secretary found that the military found mandatory vaccination to be safe, effective and consistent with historical practice. *See* DOD000005.

To the extent Plaintiffs are arguing that DoD did not adequately consider making exceptions to the mandate on an individualized basis, no such claim appears in the SAC, and in any event is mistaken as a matter of law and fact. In fact, the original vaccination mandate on its face explained that it was “subject to any identified contraindications and any administrative or other exemptions established in Military Department policy.” DOD000005. And DoD does in fact consider medical, religious, and administrative exemptions on an individualized basis. *See* Defs.’ MTD, at 8-9 (collecting exemption standards).

Plaintiffs also point to irrelevant religious freedom cases in an attempt to bolster their argument. Pls.’ Br. at 4-5. But Plaintiffs here do not make religious freedom arguments and have previously indicated that they do not intend to amend their complaint in order to do so. In those other cases, a few district courts have granted

preliminary injunctions to plaintiffs claiming they are entitled to an exception from the vaccine mandate based on their religious beliefs and claiming that alternative measures would be adequate to protect the military's interest in readiness with respect to them. Most courts, however, have rejected similar arguments.³ And Plaintiffs here have avoided arguing that they personally are entitled to exemptions, and cannot attempt to import such arguments now. Plaintiffs' further citation to a case about the transportation mask mandate (currently on appeal) is even farther afield, relying on a record from another agency, imposing a different policy based on different statutory authority and distinct policy concerns.

The Court should grant Defendants' Motion to Dismiss.

Dated: May 2, 2022

Respectfully submitted,

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³ See, e.g., *Church v. Biden*, 21-cv-2815-CKK, 2021 WL 5179215 (D.D.C. Nov. 8, 2021); *Robert v. Austin*, 21-cv-02228, 2022 WL 103374 (D. Colo. Jan. 11, 2022), appeal filed, No. 22-1032 (10th Cir. 2022); *Dunn v. Austin*, No. 2:22-cv-00288 (E.D. Cal. Feb. 22, 2022), appeal filed, 22-15286 (9th Cir. 2022); *Mark Short v. Berger*, No. 2:22-cv-01151, 2022 WL 1051852 (C.D. Cal. Mar. 3, 2022), appeal filed, No. 22-55339 (9th Cir. 2022); *Thomas Short v. Berger*, No. 22-cv-0444, 2022 WL 1203876 (D. Ariz. Apr. 22, 2022); *Vance v. Wormuth*, 3:21-cv-00730-CRS, 2022 WL 1094665 (W.D. Ky. Apr. 12, 2022); *Navy Seal I v. Austin*, 1:22-cv-00688-CKK (D.D.C. Apr. 29, 2022). In two matters that reached the Supreme Court on motions, the Supreme Court granted the Government's requested partial stay of one such injunction, and refused to impose another injunction pending appeal in another. See *Austin v. U.S. Navy SEALs I-26*, 142 S. Ct. 1301 (2022); *Dunn v. Austin*, No. 21A599, 2022 WL 1133402 (U.S. Apr. 18, 2022).

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