

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

AMERICA'S FRONTLINE
DOCTORS, *et al.*,

Plaintiffs,

v.

UNITED STATES OF AMERICA, *et al.*,

Defendants.

CIVIL ACTION NO.
2:21-CV-702-CLM
OPPOSED

DEFENDANTS' RESPONSE TO PLAINTIFFS' SUPPLEMENT

The Court authorized Plaintiffs to submit a supplement, "the purpose of which is to explain the relevance and significance of the Excel file" they provided to the Court. ECF No. 46. Although Plaintiffs acknowledge their responsibility to establish "the relevance of the Excel file," ECF No. 47, at 1, they do not do so. Indeed, the Excel file is irrelevant to this case. What's more, the data it contains is incorrect. The Court should disregard Plaintiffs' supplement and dismiss this case.

According to Plaintiffs, the Excel file shows that "prior to the commencement of vaccination within the [Department of Defense ("DOD")] with the mRNA COVID-19 vaccines, the incidence of certain diseases and medical conditions among DOD personnel was predictable and constant at a certain level over a number of years from 2016 to 2020." ECF No. 47, ¶ 6. But Plaintiffs assert that "after the commencement of vaccination within the DOD with the mRNA COVID-19 vaccines

in 2021, the incidence of these diseases and medical conditions among DOD personnel spiked dramatically.” *Id.*

As Plaintiffs concede, DOD has already explained that the data in the Excel file is incorrect and is the product of a “glitch” in the Defense Medical Epidemiology Database (“DMED”) that “resulted in artificially low incidence numbers in the years 2016–2020.” ECF No. 47, ¶ 8.¹ Plaintiffs reject this explanation, however, and instead accuse the government of “alter[ing]” the data in DMED “to distort and hide the true extent of the harm caused to the US Armed Forces by the mRNA vaccines.” ECF No. 47, Ex. C. Plaintiffs’ unsupported speculation should not be countenanced by the Court.

More fundamentally, Plaintiffs’ supplement is improper because Plaintiffs failed to heed the Court’s direction to explain the Excel file’s “relevance and significance” to this case. ECF No. 46. Plaintiffs’ supplement does not reference any of the eight named Plaintiffs, nor does it cite any of the six counts in the Amended Complaint (ECF No. 32-1) or explain how the Excel file is relevant to them. The Amended Complaint, moreover, does not mention DMED, does not name as parties any members of the military, and does not assert any claims against the military. Plaintiffs’ supplement is entirely untethered to the Amended Complaint.

The supplement also makes no attempt to show the Excel file’s “relevance and significance” (ECF No. 46) to Plaintiffs’ pending preliminary injunction motion

¹ See Reuters, Fact Check-DoD says data error caused spike in numbers of medical diagnoses in their medical database for 2021, <https://www.reuters.com/article/factcheck-militarydatabase-error/fact-check-dod-says-data-error-caused-spike-in-numbers-of-medical-diagnoses-in-their-medical-database-for-2021-idUSL1N2UY1S2> (Feb. 23, 2022).

or Defendants’ pending motion to dismiss. Nor could Plaintiffs have met that burden had they tried. The supplement cannot overcome Defendants’ arguments that the Court lacks subject matter jurisdiction because (1) no plaintiff possesses standing or ripe claims; (2) the challenged actions taken under 21 U.S.C. § 360bbb-3 are not reviewable under the Administrative Procedure Act (“APA”); (3) no jurisdiction exists under the mandamus statute or the Declaratory Judgment Act; and (4) the Civil Service Reform Act precludes jurisdiction over any challenge by Plaintiffs Nelson and Leahy to potential adverse employment action reviewable under that statute.

The supplement also cannot rebut Defendants’ arguments that the Amended Complaint fails to state a plausible claim for relief because (1) Counts I, III, and IV do not purport to challenge the Emergency Declaration and Emergency Use Authorizations in light of Defendants’ contemporaneous explanations and the existing administrative record, as required for an APA claim; (2) Executive Orders 14042 and 14043 (collectively, the “Executive Orders”) are not reviewable under the APA because the President is not an “agency”; (3) the Executive Orders do not deprive Plaintiffs of substantive due process; and (4) the Executive Orders are within the President’s statutory authority. Moreover, the new allegations in Plaintiffs’ supplement could not defeat Defendants’ motion to dismiss because they are outside “the four corners of the [amended] complaint.” *St. George v. Pinellas Cty.*, 285 F.3d 1334, 1337 (11th Cir. 2002). And although “[a]ll counts in the amended complaint are predicated on” the APA, ECF No. 37, at 41, Plaintiffs’ supplement cannot support an APA claim because it presents new evidence that is outside “the existing administrative record,” *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019),

and it does not claim that its allegations were ever presented to Defendants, *Mahon v. U.S. Dep't of Agric.*, 485 F.3d 1247, 1254–55 (11th Cir. 2007); *see* 21 C.F.R. §§ 10.25, 10.30, 10.45.

Finally, Plaintiffs' supplement cannot support their preliminary injunction motion. It cannot show a likelihood of success on the merits because it cannot overcome Defendants' showing that the Amended Complaint should be dismissed for lack of subject matter jurisdiction and failure to state a claim. *See Klay v. United Healthgroup, Inc.*, 376 F.3d 1092, 1097–98 (11th Cir. 2004) (“For a traditional injunction to be even theoretically available, a plaintiff must be able to articulate a basis for relief that would withstand scrutiny under Fed. R. Civ. P. 12(b)(6).”). Moreover, the supplement cannot support preliminary relief because it addresses “a matter lying wholly outside the issues in the suit.” *Kaimowitz v. Orlando*, 122 F.3d 41, 43 (11th Cir. 1997), *opinion amended on reh'g*, 131 F.3d 950 (11th Cir. 1997).

Silent about any named Plaintiff, the supplement also cannot show that any Plaintiff would suffer irreparable harm “before [this] case can be resolved on its merits.” *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016). As Defendants explained in their reply brief, there is no imminent risk that the Executive Orders will force Plaintiffs Makowski, Nelson, and Leahy to receive any COVID-19 vaccine, let alone one authorized under an Emergency Use Authorization. Makowski's medical accommodation request was granted; Nelson's and Leahy's religious accommodation requests remain pending; and Nelson's and Leahy's employer has paused the processing of their religious accommodation requests in compliance with the nationwide preliminary injunction enjoining enforcement of

Executive Order 14043 issued in *Feds for Med. Freedom v. Biden*, No. 3:21-CV-356, 2022 WL 188329, at *7–8 (S.D. Tex. Jan. 21, 2022), *appeal filed*, No. 22-40043 (5th Cir. Jan. 26, 2022).² ECF No. 44, at 7–8 & n.5.

Instead of attempting to show a connection to this case, Plaintiffs’ supplement focuses on wholly unrelated conduct: the Department of Defense’s maintenance of DMED. Federal courts, however, “do not possess a roving commission,” and they do not “exercise general legal oversight of the Legislative and Executive Branches.” *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). Plaintiffs’ counsel may not use this lawsuit to pursue matters unrelated to the claims at issue in this case.

In sum, the Court should disregard Plaintiffs’ supplement because Plaintiffs have failed to show that it has any “relevance [or] significance” to this case. ECF No. 46. For the reasons stated in Defendants’ briefs, *see* ECF Nos. 42, 44, the Court should dismiss Plaintiffs’ Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (b)(6) and deny Plaintiffs’ motion for a preliminary injunction.

Dated: March 2, 2022

Respectfully submitted,

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² In addition, the Southern District of Georgia has issued a nationwide preliminary injunction enjoining enforcement of Executive Order 14042. *Georgia v. Biden*, No. 1:21-CV-163, 2021 WL 5779939, at *12 (S.D. Ga. Dec. 7, 2021), *appeal filed*, No. 21-14269 (11th Cir. Dec. 10, 2021); *see Feds for Med. Freedom*, 2022 WL 188329, at *1 (denying motion to preliminarily enjoin enforcement of Executive Order 14042 because that Executive Order “is already the subject of a nationwide injunction” that “protects the plaintiffs from imminent harm”).

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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2022, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to counsel of record.

/s/ Isaac C. Belfer
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