

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

**REPLY IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE AMENDED COMPLAINT**

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INTRODUCTION

Plaintiffs’ Opposition to Defendants’ Motion to Dismiss is notable more for what it does *not* say than for what it does. Plaintiffs opted not to defend the standing of five of the eight Plaintiffs. Likewise, they conceded that 15 of the 20 Defendants are not proper parties. Right off the bat, 20 parties should be dismissed from the case.

The three remaining Plaintiffs lack standing. Defendants showed that none of these Plaintiffs faces an imminent injury that is fairly traceable to the challenged actions, and the concessions in Plaintiffs’ brief confirm that. Plaintiffs concede that Makowski, the sole remaining federal-contractor Plaintiff, received a medical accommodation¹ that exempts him from any vaccination requirement based on Executive Order (“EO”) 14042. Makowski may fear a hypothetical, future vaccine mandate, but such fear is both speculative and beyond the allegations in the Amended Complaint.² As to Nelson and Leahy, the two remaining federal-employee Plaintiffs, Plaintiffs concede that their accommodation requests remain pending. Unless and until those requests are denied and they suffer adverse employment consequences, their feared injuries are speculative and may never come to pass.

Plaintiffs’ brief also fails to overcome the Amended Complaint’s many other jurisdictional defects. Regarding Counts I and III–VI, Defendants showed that actions taken under the emergency use authorization (“EUA”) statute, 21 U.S.C.

¹ The parties’ prior briefing referred to both “accommodations” and “exemptions” from vaccination requirements, but for clarity, this brief will refer to “accommodations” throughout.

² Even if the Opposition had defended the standing of the other federal-contractor Plaintiffs (Millen, Bloom, and Sobczak), they lack an imminent injury that is fairly traceable to EO 14042.

§ 360bbb-3, are exempt from review under the Administrative Procedure Act (“APA”) based on the EUA statute’s and APA’s plain language. Plaintiffs cannot show otherwise, and in fact concede that these actions “are subject to [Defendants’] discretion” and “are not subject to judicial review.” Pls.’ Opp’n, ECF No. 43, at 25.³ Plaintiffs also have no response to Defendants’ explanation of why jurisdiction does not lie under the mandamus statute (28 U.S.C. § 1361) or the Declaratory Judgment Act (28 U.S.C. §§ 2201–02). Finally, Plaintiffs do not dispute Defendants’ argument that this Court lacks jurisdiction over Counts II and VI because Nelson and Leahy must follow the Civil Service Reform Act’s (“CSRA”) review process to challenge potential adverse employment action reviewable under that statute, including termination.

Even if the Court reached the merits, Plaintiffs have failed to rebut Defendants’ showing that the Amended Complaint fails to state a claim for relief. Defendants explained that the APA claims in Counts I, III, and IV are not plausibly alleged because they do not purport to challenge the Emergency Declaration and EUAs in light of the agencies’ contemporaneous explanations and the existing administrative record. Plaintiffs cannot state viable APA claims based on new arguments and evidence that were never presented to the U.S. Department of Health and Human Services (“HHS”). Plaintiffs’ brief provides no reason to doubt that these critical deficiencies are fatal to Counts I, III, and IV.

³ The citations to Defendants’ opening brief, ECF No. 42, and Plaintiffs’ Opposition, ECF No. 43, refer to the page numbers at the bottom of each page. The citations to exhibits, *e.g.*, ECF No. 43-1, refer to the ECF page numbers at the top of each page.

Regarding Counts II and VI, Plaintiffs have no response to Defendants’ argument that EOs 14042 and 14043 (collectively, the “Executive Orders”) are not reviewable under the APA because the President is not an “agency.” They also ignore numerous cases cited by Defendants showing that the Executive Orders do not deprive Plaintiffs of substantive due process. Finally, Plaintiffs fail to show that the Executive Orders exceed the President’s statutory authority. They rely on decisions that address vaccine mandates not at issue here, including injunctions that have since been stayed by the Supreme Court. More fundamentally, they fail to rebut Defendants’ explanation of why the *text* of the relevant statutes authorizes the Executive Orders.⁴

It is Plaintiffs’ burden to establish this Court’s jurisdiction, and their Amended Complaint must state plausible claims for relief. Plaintiffs have failed on both accounts. This case should therefore be dismissed.

⁴ Defendants acknowledge that the Southern District of Texas has issued a nationwide preliminary injunction enjoining enforcement of EO 14043, though this decision has been appealed. *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). This decision provides an additional reason why Plaintiffs’ preliminary injunction motion should be denied, since Plaintiffs cannot show that they would suffer imminent, irreparable harm from EO 14043 before this case can be resolved on the merits. *See Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016). Similarly, Defendants explained that Plaintiffs cannot show that they would suffer imminent, irreparable harm from EO 14042 before this case can be resolved on the merits in light of the nationwide preliminary injunction enjoining enforcement of EO 14042 issued in *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). ECF No. 42, at 42 (citing *Wreal*, 840 F.3d at 1248); *see Feds for Med. Freedom*, 2022 WL 188329, at *1 (denying motion to preliminarily enjoin enforcement of EO 14042 because that Executive Order “is already the subject of a nationwide injunction” that “protects the plaintiffs from imminent harm”).

ARGUMENT

I. Numerous Plaintiffs and Defendants should be dismissed at the outset.

Defendants expressly challenged the standing of all eight Plaintiffs. *See* Defs.’ Mem., ECF No. 42, at 11–14, 18, 21–23. “[W]hen standing is questioned by . . . an opposing party, . . . the litigant must explain how the elements essential to standing are met.” *Va. House of Delegates v. Bethune-Hill*, 139 S. Ct. 1945, 1951 (2019). Rather than satisfy that obligation for all Plaintiffs, Plaintiffs’ brief “addresses just the circumstances of three of the Plaintiffs, Joseph Makowski . . . , Michael Nelson and Joseph Leahy.” Pls.’ Opp’n 2. Plaintiffs’ choice was deliberate and unaffected by space or time constraints (for example, Plaintiffs used only 28 of their allotted 45 pages).

By failing to defend the standing of America’s Frontline Doctors (“AFLDS”), Dr. Calderwood, Lyle Bloom, Ellen Millen, and Jody Sobczak, Plaintiffs concede these parties lack standing. *See, e.g., Ctr. for Biological Diversity v. EPA*, 937 F.3d 533, 542 (5th Cir. 2019) (“Arguments in favor of standing, like all arguments in favor of jurisdiction, can be forfeited or waived.” (collecting cases)); *Eternal World Television Network, Inc. v. Burwell*, No. CIV.A. 13-0521-CG-C, 2014 WL 2738546, at *2 (S.D. Ala. June 17, 2014); *Payne v. Gail Pittman, Inc.*, No. CV 06-B-0565-S, 2006 WL 8437754, at *1–2 (N.D. Ala. Nov. 14, 2006) (“The court finds that plaintiffs have abandoned their claims against [defendant] because they failed to address these arguments for dismissal of their claims.”). Because Plaintiffs’ failure to show standing cannot be remedied by the Court, *see Whitmore v. Arkansas*, 495 U.S. 149, 155–56 (1990), AFLDS, Dr. Calderwood, Lyle Bloom, Ellen Millen,

and Jody Sobczak should be dismissed for lack of standing, *see Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 475–76 (1982) (“Those who do not possess Art. III standing may not litigate as suitors in the courts of the United States.”).

Regarding the named Defendants, Plaintiffs “do not object to releasing the President as a defendant.” Pls.’ Opp’n 18. Plaintiffs also do not respond to Defendants’ argument that Dr. Anthony Fauci, Centers for Disease Control and Prevention (“CDC”), National Institutes of Health (“NIH”), National Institute of Allergy and Infectious Diseases (“NIAID”), and Does I–X are untethered to any claim for relief and should be dismissed from this action. Defs.’ Mem. 24. Plaintiffs thus concede that these Defendants should be dismissed. *See Eternal World Television Network*, 2014 WL 2738546, at *2; *Payne*, 2006 WL 8437754, at *1–2.

II. Plaintiffs still have not met their burden of establishing this Court’s jurisdiction.

Plaintiffs fail to rebut Defendants’ arguments for why they have not established jurisdiction over any of their claims. Defs.’ Mem. 10–23. The Court does not have jurisdiction over Plaintiffs’ challenges to Defendants’ actions under the EUA statute (Counts I, III–VI) because Plaintiffs lack standing; Counts I, III, and IV are unreviewable under the APA based on the EUA statute’s and the APA’s plain language; and the mandamus statute (Count V) and the Declaratory Judgment Act (Count VI) indisputably do not supply jurisdiction. The Court also does not have jurisdiction over Plaintiffs’ claims related to the Executive Orders (Counts II, VI) because Plaintiffs have not shown standing or ripeness. Moreover, Nelson and Leahy

must follow the CSRA’s review process to challenge potential adverse employment action reviewable under that statute, including termination, and this Court lacks jurisdiction.

A. Several jurisdictional hurdles bar Plaintiffs’ challenges to Defendants’ actions under the EUA statute (Counts I, III–VI).

1. Standing

Defendants explained why no Plaintiff has standing to challenge the existence of the Emergency Declaration or EUAs. Defs.’ Mem. 13–14. Plaintiffs respond only that “they have engaged in self-avoidance of imminent harm they fear can be caused by the vaccines.” Pls.’ Opp’n 12. But this argument skips several links in the “chain of possibilities” that would need to occur before Plaintiffs could actually be injured. *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 410 (2013). Plaintiffs must show that they face an *imminent* risk of suffering a “personal injury” that is “fairly traceable to the . . . allegedly unlawful” issuance of the Emergency Declaration and EUAs. *California v. Texas*, 141 S. Ct. 2104, 2113 (2021) (quotations omitted).

The Emergency Declaration and EUAs “neither require nor forbid any action on the part of” Plaintiffs, *Summers v. Earth Island Inst.*, 555 U.S. 488, 493–94 (2009), so standing is “substantially more difficult to establish,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992) (quotation omitted). The EUA “Fact Sheets advise that ‘[i]t is your choice to receive or not receive’ the vaccine.” Defs.’ Mem. 5 (quoting ECF No. 40-1, at 7). And as Defendants observed—without rebuttal—Plaintiffs “do not claim that they intend to receive [an EUA vaccine] in the future.” Defs.’ Mem. 13 (quoting *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275,

1280 (D.C. Cir. 2012)). The imminence requirement “has been stretched beyond the breaking point when, as here, the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff’s own control.” *Lujan*, 504 U.S. at 564 n.2.

To manufacture standing, Plaintiffs extend the “chain of possibilities” further still, relying on their potential encounter with an EUA vaccine due to EOs 14042 or 14043. *Clapper*, 568 U.S. at 410. But there is no imminent risk that EOs 14042 or 14043 will force Makowski, Nelson, and Leahy to receive any COVID-19 vaccine, let alone one issued under an EUA. Makowski’s medical accommodation request was granted, so he need not be vaccinated. Pls.’ Opp’n 2, 13. Nelson’s and Leahy’s accommodation requests remain pending,⁵ *id.* at 7, but even if they are denied, the Court can only speculate whether Nelson and Leahy would choose to be vaccinated. And even if one of them receives a COVID-19 vaccine in the future, they would not necessarily need to receive an *EUA* vaccine. The U.S. Food and Drug Administration (“FDA”) has approved the COVID-19 vaccine Comirnaty, and Plaintiffs do not challenge that approval. *See* Defs.’ Mem. 13–14. All of these contingencies preclude

⁵ In compliance with the nationwide preliminary injunction enjoining enforcement of EO 14043 issued in *Feds for Med. Freedom v. Biden*, 2022 WL 188329, the Safer Federal Workforce Task Force has instructed federal agencies to “take no action to implement or enforce the COVID-19 vaccination requirement pursuant to [EO] 14043,” and specifically to pause the processing of pending accommodation requests and not to “ask employees for additional information that may be required to process” those requests. Safer Federal Workforce Task Force, Frequently Asked Questions Related to Compliance with the Applicable Preliminary Nationwide Injunction on Implementation and Enforcement of the Vaccination Requirement Pursuant to Executive Order (E.O.) 14043: Guidance to Agencies as of January 24, 2022, at 1–2, <https://go.usa.gov/xtNPR>. Consistent with those instructions, the National Aeronautics and Space Administration (“NASA”) has paused the processing of Nelson’s and Leahy’s accommodation requests.

Plaintiffs from satisfying the “high standard” of an imminent injury traceable to the Emergency Declaration and EUAs. Defs.’ Mem. 14 (quoting *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 927 (11th Cir. 2020) (en banc)).⁶

Plaintiffs cite *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), Pls.’ Opp’n 12, which held that a plaintiff in a patent dispute had standing to assert a declaratory-judgment claim despite continuing to pay disputed royalties under a patent license to avoid potentially catastrophic liability. *MedImmune*, 549 U.S. at 137.⁷ But whereas the *MedImmune* plaintiff risked liability if it ever stopped paying the disputed royalties, here the accommodation process either already has prevented or may in the future prevent Plaintiffs from ever suffering the injury required for standing. Makowski’s medical accommodation request was granted, so he need not be vaccinated and will never suffer the requisite injury. Pls.’ Opp’n 2, 13. Nelson’s and Leahy’s accommodation requests remain pending. *Id.* at 7. If those requests are granted, then (like Makowski) Nelson and Leahy will not need to be vaccinated and will never suffer the requisite injury. If their accommodation requests are denied,

⁶ Moreover, because the Executive Orders were issued by the President, any potential injuries to Plaintiffs from the Executive Orders would not be fairly traceable to the challenged actions of Defendants Secretary Becerra, Dr. Fauci, Acting Commissioner Woodcock, HHS, FDA, CDC, NIH, NIAID, or Does I–X. See *Children’s Health Def. v. Food & Drug Admin.*, No. 1:21-CV-00200-DCLC-CHS, 2021 WL 5756085, at *5–6 (E.D. Tenn. Nov. 30, 2021), *appeal filed*, No. 21-6203 (6th Cir. Dec. 17, 2021) (“The [military] vaccine mandates, and the potential consequences for refusing those mandates, are not fairly traceable to the specific actions of the FDA” because they “result[ed] from the independent action of” the military—a “third party not before the court[.]” (quoting *Allen v. Wright*, 468 U.S. 737, 757 (1984)) (internal quotation marks omitted)).

⁷ The Court explained that the traditional standing inquiry continued to apply: “whether plaintiff is threatened with ‘imminent’ injury in fact ‘fairly . . . trace[able] to the challenged action of the defendant.’” *MedImmune*, 549 U.S. at 128 n.8 (quoting *Lujan*, 504 U.S. at 560).

they still might never suffer the requisite injury because they might choose to be vaccinated and might receive Comirnaty rather than an EUA vaccine. *See* Defs.’ Mem. 13–14. *MedImmune* is thus inapposite.⁸

2. Plaintiffs cannot overcome the statutory language rendering Counts I, III, and IV unreviewable under the APA.

Defendants explained that even if any Plaintiff had standing to challenge the Emergency Declaration and EUAs, this Court still lacks jurisdiction because those actions are “committed to agency discretion by law.” 5 U.S.C. § 701(a)(2); *see* Defs.’ Mem. 14–15. Plaintiffs appear to agree. They concede that “[a]ctions taken by agency officials pursuant to [21 U.S.C. § 360bbb-3] are subject to the discretion of these officials” and “are not subject to judicial review.” Pls.’ Opp’n 25.⁹

For Count I, however, Plaintiffs baldly contend that “whether an emergency exists is not a matter committed to the discretion of any agency, and is a matter that a court can determine at any time when raised in litigation.” Pls.’ Opp’n 18. But Plaintiffs cannot reconcile that position with Congress’s express statement that “[a]ctions under the authority of” the EUA statute, such as the Emergency

⁸ Plaintiffs present a hypothetical in which a man is about to be wrongfully executed, and they assert that, under Defendants’ arguments, “an injunction could not be granted to stop the execution” and that “the only remedy” would be a “wrongful death” lawsuit. Pls.’ Opp’n 3–4. This assertion blatantly misrepresents Defendants’ position. Defendants acknowledged that standing can be based on a future injury, but they explained that the future injury must be “concrete, particularized, and imminent rather than conjectural or hypothetical.” *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam) (quotation omitted). Plaintiffs have not plausibly alleged any such injury. Defs.’ Mem 11–14.

⁹ Because the Emergency Declaration and EUAs are unreviewable under the APA, Plaintiffs’ quotations from *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413–14 (1971), and *FCC v. Nextwave Personal Communications Inc.*, 537 U.S. 293, 300 (2003), for the APA’s standard of review, *see* Pls.’ Opp’n 26, are inapplicable.

Declaration and EUAs, “are committed to agency discretion.” 21 U.S.C. § 360bbb-3(i).

Plaintiffs again cite *Chastleton Corp. v. Sinclair*, 264 U.S. 543 (1924), and *Home Building and Loan Association v. Blaisdell*, 290 U.S. 398 (1934). Pls.’ Opp’n 18. But they do not dispute Defendants’ arguments for why those cases are inapposite. Defs.’ Mem. 26–27. As Defendants explained, both cases pre-dated the APA and addressed only a court’s review of emergency laws for compliance with the Constitution. *See id.* Count I does not challenge the Emergency Declaration based on the Constitution; instead, it asserts an APA challenge under the EUA statute, in the face of Congress’s express direction that no APA cause of action is available. Similarly inapposite is *Sterling v. Constantin*, 287 U.S. 378 (1932), *see* Pls.’ Opp’n 18, which held that “[w]hen there is a substantial showing that the exertion of state power has overridden private rights secured by th[e] Constitution, the subject is necessarily one for judicial inquiry.” *Sterling*, 287 U.S. at 398. Count I, again, presents no constitutional question.

Finally, in a last-ditch appeal to avoid dismissal, Plaintiffs assert that “the possibility that serious wrongs have likely been committed” means judicial review should not be “foreclosed.” Pls.’ Opp’n 28. But Congress declared that agency actions “committed to agency discretion by law” are unreviewable under the APA, 5 U.S.C. § 701(a)(2), and it included within that category actions under the EUA statute, 21 U.S.C. § 360bbb-3(i). Plaintiffs cannot manufacture an exception to Congress’s command by merely arguing that “serious wrongs have likely been committed”—an exception that would render 5 U.S.C. § 701(a)(2) a dead letter.

3. Plaintiffs concede the mandamus statute (Count V) and the Declaratory Judgment Act (Count VI) do not supply jurisdiction.

Defendants explained why jurisdiction does not lie under the mandamus statute (28 U.S.C. § 1361) or the Declaratory Judgment Act (28 U.S.C. §§ 2201–02). Defs.’ Mem. 15–16. Plaintiffs have no response and therefore concede the point. *See Ctr. for Biological Diversity*, 937 F.3d at 542; *Eternal World Television Network*, 2014 WL 2738546, at *2; *Payne*, 2006 WL 8437754, at *1–2.

B. Plaintiffs have not established the Court’s jurisdiction over their claims related to the Executive Orders (Counts II, VI).

1. Standing and ripeness

Defendants demonstrated that no Plaintiff has standing or ripe claims to challenge EOs 14042 or 14043. *See* Defs.’ Mem. 18–23. Of the three Plaintiffs whose standing is defended in the Opposition, only Makowski is allegedly a federal contractor covered by EO 14042. But Makowski has received a medical accommodation, Pls.’ Opp’n 2, 13, so he no longer “fac[es] a COVID vaccine mandate,” ECF No. 32-1, at ¶ 1. Thus, he cannot show the injury necessary for standing to challenge EO 14042 in Counts II and VI. *See Carney v. Adams*, 141 S. Ct. 493, 499 (2020) (plaintiff “bears the burden of establishing standing as of the time he brought this lawsuit and maintaining it thereafter”).

Plaintiffs attach as Exhibit 1 an FAQ page from Raytheon Technologies. ECF No. 43-1. On its face, the exhibit appears to be a document fragment. *See id.* at 3 (cutting off answer to Question 8 and possibly more FAQs). In any event, only Plaintiff Millen works for Raytheon, Pls.’ Opp’n 10, and Plaintiffs chose not to defend her standing, *id.* at 2. Moreover, no clearly alleged facts show that Millen is

a “covered contractor employee” for purposes of EO 14042, *see* Defs.’ Mem. 22, that she could not avail herself of the accommodation process, or that an accommodation request was denied, *see* ECF No. 43-1, at 3 (discussing “accommodation for medical or religious reasons”).

Plaintiffs’ argument that the federal-contractor Plaintiffs’ standing “is not affected when the harm they suffer has been caused by third parties such as [their] employers,” Pls.’ Opp’n 9, falls short. Defendants explained that, if the federal-contractor Plaintiffs’ accommodation requests were wrongfully denied under a workplace policy adopted due to EO 14042 (which, at least for Makowski, did not happen), those denials would be traceable to (and redressable by) their employers—not Defendants—because it is the employers’ responsibility to “review and consider what, if any, [religious or medical] accommodation [they] must offer.” Defs.’ Mem. 23 (quoting 86 Fed. Reg. 63,418, 63,420 (Nov. 16, 2021)). Accommodation denials would be an employer’s “independent action” and not fairly traceable to the Executive Orders. *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976). Moreover, Plaintiffs have not shown that an accommodation denial “would have been illegal without” Defendants’ challenged actions. *Id.* at 45 n.25; Pls.’ Opp’n 9 n.5; *see* Defs.’ Mem. 7–8.

Turning to EO 14043, Plaintiffs concede that Nelson’s and Leahy’s accommodation requests remain pending before NASA. Pls.’ Opp’n 7, 13–14. They do not dispute that “while their requests remain pending, they face no adverse employment action.” Defs.’ Mem. 18 (citing ECF No. 39, at ¶¶ 8, 11). And they ignore the numerous cases cited by Defendants holding that employees’ claims are

not justiciable when their accommodation requests remain pending. *See* Defs.’ Mem. 18–22; *see also* *Donovan v. Vance*, No. 4:21-CV-5148-TOR, 2021 WL 5979250, at *4–5 (E.D. Wash. Dec. 17, 2021) (where plaintiffs challenging EOs 14042 and 14043 were “in various stages of the exemption and accommodations process,” their claims were “unripe for judicial review because [p]laintiffs’ fears [of termination] may never come into fruition, and because delaying review will not unduly burden the parties”); *Am. Fed’n of Gov’t Emps. Loc. 501 v. Biden*, No. 21-23828-CIV, 2021 WL 6551602, at *7–8 (S.D. Fla. Dec. 22, 2021) (associational plaintiffs challenging EO 14043 lacked standing because “it is entirely speculative as to whether any of [their] members would be disciplined for failure to become vaccinated because, for example, they may choose to become vaccinated or receive an exemption”); *Robert v. Austin*, No. 21-CV-02228-RM-STV, 2022 WL 103374, at *3 (D. Colo. Jan. 11, 2022) (dismissing challenge to military vaccine mandate for lack of jurisdiction where plaintiffs’ exemption requests had been granted or were pending, and thus where “[p]laintiffs’ contention that they may be subject to discipline for refusing to take a vaccine appears to be based on nothing more than speculation”).

Plaintiffs cite *U.S. Navy SEALs 1–26 v. Biden*, No. 4:21-CV-01236-O, 2022 WL 34443 (N.D. Tex. Jan. 3, 2022), *appeal filed*, No. 22-10077 (5th Cir. Jan. 21, 2022), *see* Pls.’ Opp’n 14, but that decision, which reviewed the military’s vaccination policy, did not address Article III standing at all. Rather, it examined the justiciability of servicemembers’ Religious Freedom Restoration Act claims under a Fifth Circuit-specific “test to determine whether a given military issue is

justiciable.” 2022 WL 34443, at *4. That legal framework is inapplicable here. Moreover, although the court in *U.S. Navy Seals* found that “the record” in that case indicated that “the denial of each [religious accommodation] request is predetermined” such that the exhaustion of administrative remedies was futile, *id.*, no similar facts are alleged here. Under the ordinary principles of Article III standing and ripeness, Nelson’s and Leahy’s claims should be dismissed. *See* Defs.’ Mem. 18–19.

Finally, Plaintiffs’ brief inappropriately raises new theories of injury, including that Makowski finds mask-wearing “bothersome” and that Nelson spent time submitting his accommodation request. *See* Pls.’ Opp’n 13–15. “It is axiomatic that a plaintiff cannot amend the complaint by arguments of counsel made in opposition to a motion to dismiss.” *Kuhn v. Thompson*, 304 F. Supp. 2d 1313, 1321 (M.D. Ala. 2004). The only injuries alleged in the Amended Complaint are threats to Plaintiffs’ employment and to their bodily integrity from “COVID-19 vaccine mandate[s].” Am. Compl. ¶¶ 1, 15–19, 32. Likewise, in Counts II and VI, Plaintiffs challenge only those provisions of EOs 14042 and 14043 relating “to the mandate of the COVID-19 vaccines.” *Id.* ¶¶ 181, 192. Because the only injuries alleged in the Amended Complaint are Plaintiffs’ alleged injuries from the vaccine mandates, Plaintiffs lack standing to challenge any other provisions of the Executive Orders. *See CAMP Legal Def. Fund, Inc. v. City of Atlanta*, 451 F.3d 1257, 1273 (11th Cir. 2006) (plaintiffs must show injury-in-fact “as to each challenged [statutory] provision”).

Despite having filed an original complaint, an amended complaint, and a corrected amended complaint, Plaintiffs suggest they could file a fourth complaint with new allegations. *See* Pls.’ Opp’n 15. Further amendment, however, would be “futile” because “the complaint as amended [would] still [be] subject to dismissal.” *Archie v. Covington Cty.*, No. 2:19CV508-MHT, 2021 WL 4227027, at *1 (M.D. Ala. Sept. 16, 2021) (quoting *Bryant v. Dupree*, 252 F.3d 1161, 1163 (11th Cir. 2001)); *Hall v. United Ins. Co. of Am.*, 367 F.3d 1255, 1262–63 (11th Cir. 2004) (internal quotations omitted); *see also* Fed. R. Civ. P. 15(a)(2). Specifically, Plaintiffs’ newfound injuries would no more support standing than their presently alleged ones.

Makowski fears a hypothetical vaccine mandate “in the future,” Pls.’ Opp’n 13, but “unadorned speculation will not suffice to invoke the federal judicial power,” *Simon*, 426 U.S. at 44. Although Makowski finds masks “bothersome,” Pls.’ Opp’n 13, that kind of “psychic injury” does not satisfy standing’s requirement of concreteness, *Gardner v. Mutz*, 962 F.3d 1329, 1341 (11th Cir. 2020). Lastly, Makowski’s objection to “weekly testing,” Pls.’ Opp’n 13, cannot be fairly traced to EO 14042 or to the Safer Federal Workforce Guidance implementing EO 14042, which do not mention testing, *see* 86 Fed. Reg. 50,985 (Sept. 9, 2021); Safer Federal Workforce Task Force, *COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors*, <https://go.usa.gov/xtDVu> (updated Nov. 10, 2021); *see also* Pls.’ Opp’n 5 & n.1 (referencing Guidance).

Nelson’s concerns that his accommodation request “may be denied” and that “he may very well lose his job,” Pls.’ Opp’n 14, are simply “allegations of possible

future injury” that “are not sufficient” for standing, *Clapper*, 568 U.S. at 409. Moreover, the time Nelson spent preparing his accommodation request is not “a real and immediate threat of *future* harm,” as required for injunctive or declaratory relief, *Elend v. Basham*, 471 F.3d 1199, 1207 (11th Cir. 2006) (emphasis added), and is not redressable by such relief, see *Kawa Orthodontics, LLP v. Sec’y, U.S. Dep’t of the Treasury*, 773 F.3d 243, 247–48 (11th Cir. 2014).¹⁰ Finally, Nelson’s purported “ostraci[sm]” by his coworkers, Pls.’ Opp’n 14, results from his coworkers’ “independent action,” *Simon*, 426 U.S. at 41–42, and is not fairly traceable to Defendants’ challenged actions.

2. The CSRA precludes this Court from hearing any challenge by Nelson and Leahy to potential adverse employment actions reviewable under that statute.

Defendants explained that the Amended Complaint faces a further jurisdictional infirmity: preclusion under the CSRA. Defs.’ Mem. 20. Nelson and Leahy—the only Plaintiffs allegedly subject to EO 14043—are both covered by the CSRA. ECF No. 39, at ¶¶ 6, 9; see *Elgin v. Dep’t of Treasury*, 567 U.S. 1, 5 (2012). To challenge potential adverse employment action reviewable under the CSRA, including termination, they must follow the CSRA’s review process, and this Court lacks jurisdiction. See *Elgin*, 567 U.S. at 5–6 (citing 5 U.S.C. § 7512); *Rydie v. Biden*, No. CV DKC 21-2696, 2021 WL 5416545, at *2 (D. Md. Nov. 19, 2021), *appeal filed*, No. 21-2359 (4th Cir. Dec. 7, 2021); Defs.’ Mem. 20–21. *But see Feds*

¹⁰ For this reason, Plaintiffs’ reference to *Losch v. Nationstar Mortgage LLC*, 995 F.3d 937 (11th Cir. 2021), is inapposite. Pls.’ Opp’n 14–15. Whereas the *Losch* plaintiff sought only damages, 995 F.3d at 941–42, Plaintiffs here seek declaratory and injunctive relief and thus must show a material risk of future injury.

for Med. Freedom, 2022 WL 188329, at *2–3. Plaintiffs ignore this argument and thus concede it. *See Ctr. for Biological Diversity*, 937 F.3d at 542; *Eternal World Television Network*, 2014 WL 2738546, at *2; *Payne*, 2006 WL 8437754, at *1–2.

III. Plaintiffs’ claims for relief remain implausible on the merits.

Even if the Court reaches the merits, Defendants showed that the Amended Complaint should still be dismissed for failure to state a claim, Defs.’ Mem. 23–37, and Plaintiffs have not shown otherwise. Plaintiffs have not plausibly pleaded that the Emergency Declaration and EUAs violate the APA (Counts I, III, IV). Nor have they plausibly pleaded that the Executive Orders are unconstitutional or that they exceed the President’s statutory authority (Counts II, VI).

A. Counts I, III, and IV fail to state a claim that the Emergency Declaration and EUAs are unlawful under the APA.

Defendants explained that, even assuming jurisdiction over the APA claims in Counts I, III, and IV, they still are not plausibly alleged. Defs.’ Mem. 24–30. The APA requires plaintiffs to show that the agency’s contemporaneous explanations were unreasonable “in light of the existing administrative record,” *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2573 (2019), and courts “will not consider arguments that a party failed to raise in timely fashion before an administrative agency,” such as by filing a citizen petition with FDA, *Mahon v. U.S. Dep’t of Agric.*, 485 F.3d 1247, 1254–55 (11th Cir. 2007); *see* 21 C.F.R. §§ 10.25(a), 10.30, 10.45. The Amended Complaint, however, attacks the Emergency Declaration and EUAs based on evidence that is *not* alleged to be in the administrative record or to have been presented to HHS. Defs.’ Mem. 24–26. Plaintiffs’ brief confirms this deficiency,

identifying nothing in “the existing administrative record” that shows the contemporaneous explanations for the Emergency Declaration and EUAs were unreasonable, and nowhere suggesting that Plaintiffs presented their arguments to HHS before filing suit. *See* Pls.’ Opp’n 18, 25–27.¹¹

Instead, Plaintiffs argue that the vaccine manufacturers misbranded the vaccines, and they insinuate, without specificity or support, that Defendants were aware of “some problem.” Pls.’ Opp’n 26–28. Such speculation does not state a plausible APA claim, which would require Plaintiffs to identify evidence in the existing administrative record showing the vaccines are “dangerous to health when used” according to the FDA-approved labeling. Defs.’ Mem. 39; *see Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009). Neither the Amended Complaint nor Plaintiffs’ brief meets that burden.

In support of their misbranding argument, Plaintiffs improperly attach the Ealy Declaration, which suggests that the COVID-19 vaccines may have killed over 427,000 Americans—more than all Americans who died in World War II.¹² Pls.’ Opp’n 27–28; ECF No. 43-5, at ¶ 25. This assertion defies common sense, and Plaintiffs’ baseless speculation that Defendants were aware of this information and did not act on it cannot overcome the presumption of regularity to which federal officials are entitled. *See U.S. Postal Serv. v. Gregory*, 534 U.S. 1, 10 (2001). The

¹¹ Contrary to Plaintiffs’ belief, *see* Pls.’ Opp’n 25–26, Defendants did not purport to file the complete administrative record as an exhibit to the motion to dismiss. Rather, Defendants filed certain publicly available materials to demonstrate Plaintiffs’ complete failure to engage with the scientific evidence that was actually before the agency. *See* Defs.’ Mem. 25–26.

¹² Approximately 405,000 Americans died in military service during World War II. *See* Department of Veterans Affairs, America’s Wars, <https://go.usa.gov/xtB8s>.

Ealy Declaration is also improper because Plaintiffs may not defeat a Rule 12(b)(6) motion by adding new allegations in their brief. *See Lee v. Sec. Check, LLC*, No. 3:09-CV-421-J-12TEM, 2009 WL 3790455, at *2 (M.D. Fla. Nov. 9, 2009) (striking “the exhibits and new factual assertions contained in [p]laintiff’s response to [defendant]’s Motion to Dismiss” because “they attempt to insert new facts not contained in [p]laintiff’s Second Amended Complaint” and thus “cannot support denial of [defendant]’s Motion to Dismiss” (citations omitted)). Moreover, even if the Ealy Declaration reflected the allegations in the Amended Complaint, it still would not support an APA claim because its contents are untethered to the contemporaneous administrative record and were never presented to the agency. *See Dep’t of Com.*, 139 S. Ct. at 2573; *Mahon*, 485 F.3d at 1254–55; 21 C.F.R. §§ 10.25, 10.30, 10.45.

B. Counts II and VI fail to state a claim that the Executive Orders are unlawful.

Defendants explained that the Executive Orders “are not reviewable under the APA” because “the President is not an ‘agency.’” *Dalton v. Specter*, 511 U.S. 462, 470 (1994); Defs.’ Mem. 30. Plaintiffs ignore this argument and thus concede it. *See Eternal World Television Network*, 2014 WL 2738546, at *2; *Payne*, 2006 WL 8437754, at *1–2. But even if the Executive Orders were reviewable, Counts II and VI still fail to state plausible claims for relief.

1. Plaintiffs fail to show that the Executive Orders are unconstitutional.

Defendants explained that the Executive Orders do not deprive Plaintiffs of substantive due process, citing numerous cases that Plaintiffs completely ignore.

Defs.’ Mem. 30–34. Plaintiffs respond by simply invoking the “unconstitutional conditions doctrine,” Pls.’ Opp’n 15–16, under which “the government may not deny a benefit to a person on a basis that infringes his constitutionally protected” rights, *United States v. Am. Libr. Ass’n*, 539 U.S. 194, 210 (2003) (quotation omitted).

As an initial matter, Plaintiffs ignore that the only Plaintiffs whose standing they defend—Makowski, Nelson, and Leahy—are not being “forced to choose between” being vaccinated “or being terminated from their employment.” Pls.’ Opp’n 15. Makowski was granted an accommodation, and Nelson’s and Leahy’s accommodation requests are pending. But even if Nelson’s and Leahy’s accommodation requests are denied, the unconstitutional conditions doctrine does not apply here because the Executive Orders do not “infringe[] [Plaintiffs’] constitutionally protected” rights. *Am. Libr. Ass’n*, 539 U.S. at 210; *see* Defs.’ Mem. 30–34; *Burcham v. City of Los Angeles*, No. 221CV07296RGKJPR, 2022 WL 99863, at *8 n.4 (C.D. Cal. Jan. 7, 2022); *Troogstad v. City of Chicago*, No. 21 C 5600, 2021 WL 5505542, at *10 (N.D. Ill. Nov. 24, 2021), *appeal filed*, No. 21-3371 (7th Cir. Dec. 23, 2021); *Doe v. Zucker*, 520 F. Supp. 3d 217, 268 (N.D.N.Y. 2021), *appeal filed*, No. 21-537 (2d Cir. Mar. 5, 2021).

2. Plaintiffs fail to show that the Executive Orders exceed the President’s statutory authority.

Defendants explained why both Executive Orders are within the President’s statutory authority. Defs.’ Mem. 34–37. In opposition, Plaintiffs cite decisions preliminarily enjoining enforcement of the vaccine policies imposed by the Centers for Medicare and Medicaid Services (“CMS”) and the Occupational Safety and

Health Administration (“OSHA”),¹³ but those decisions are inapposite because they did not address EOs 14042 or 14043. *See Donovan*, 2021 WL 5979250, at *4 (decision regarding OSHA vaccine policy was not “persuasive or even instructive” in challenge to EOs 14042 and 14043). Moreover, the Supreme Court recently stayed the preliminary injunctions enjoining enforcement of the CMS policy on the basis that “the Secretary’s rule falls within the authorities that Congress has conferred upon him.” *Biden v. Missouri*, 142 S. Ct. 647, 652, 654–55 (2022).

Regarding EO 14043, Plaintiffs trace the history of 5 U.S.C. §§ 3301, 3302, and 7301, Pls.’ Opp’n 23–25, but fail to respond to Defendants’ explanation for why the text of those statutes authorizes EO 14043, *see* Defs.’ Mem. 36; *Rydie*, 2021 WL 5416545, at *3 (explaining that 5 U.S.C. §§ 3301, 7301, and 7513 authorize EO 14043); *Oklahoma v. Biden*, No. CIV-21-1136-F, 2021 WL 6126230, at *10 (W.D. Okla. Dec. 28, 2021) (“the court concludes that [EO 14043] is a permissible exercise of executive authority . . . substantially for the reasons stated in *Rydie v. Biden*”); *see also Bostock v. Clayton Cty.*, 140 S. Ct. 1731, 1749 (2020) (“when the meaning of the statute’s terms is plain,” a court’s “job is at an end”).¹⁴ Furthermore, EO 14043

¹³ Pls.’ Opp’n 19–21 (citing *BST Holdings, LLC v. Occupational Safety and Health Admin.*, 17 F.4th 604 (5th Cir. 2021); *Louisiana v. Becerra*, No. 21-30734, 2021 U.S. App. LEXIS 37035 (5th Cir. Dec. 15, 2021); *Louisiana v. Becerra*, No. 3:21-CV-03970, 2021 U.S. Dist. LEXIS 229949 (W.D. La. Nov. 30, 2021); *Missouri v. Biden*, No. 4:21-cv-01329-MTS, 2021 U.S. Dist. LEXIS 227410 (E.D. Mo. Nov. 29, 2021)).

¹⁴ The Southern District of Texas recently determined, in the preliminary injunction context, that “the President was without statutory authority to issue” EO 14043. *Feds for Med. Freedom*, 2022 WL 188329, at *6. The government’s appeal of the district court’s decision in *Feds for Med. Freedom* is pending. Defendants respectfully submit that this case was wrongly decided because it is contrary to the text of 5 U.S.C. §§ 3301, 3302, and 7301 and the case law interpreting those provisions, as explained in Defendants’ opening brief. *See* Defs.’ Mem. 36.

is within the President’s authority because the President has independent constitutional authority to act as CEO of the Executive Branch, even absent confirming statutory authority from Congress. *See* U.S. Const. Art. II, § 1; *Rydie*, 2021 WL 5416545, at *3; *Oklahoma*, 2021 WL 6126230, at *10.

Regarding EO 14042, Plaintiffs likewise trace the history of 3 U.S.C. § 301 and the Federal Property and Administrative Services Act (“Procurement Act”), 40 U.S.C. § 101, *et seq.*, Pls.’ Opp’n 21–23, but fail to respond to Defendants’ explanation for why the text of those statutes authorizes EO 14042, *see* Defs.’ Mem. 35–36; *see also Donovan*, 2021 WL 5979250, at *6 (EO 14042 “easily satisfies” the “lenient standard” for authorization under the Procurement Act). Although Plaintiffs cite several cases (each of which has been appealed) finding in the preliminary injunction context that EO 14042 likely exceeds the President’s authority under the Procurement Act,¹⁵ they do not discuss those cases’ reasoning. For the reasons explained in their opening brief, Defendants respectfully submit that those cases were wrongly decided and that the Procurement Act authorizes EO 14042.

In any event, the Eleventh Circuit has scheduled oral argument for the week of April 4, 2022, in one appeal of a decision preliminarily enjoining enforcement of EO 14042. *Georgia v. President of the United States*, No. 21-14269 (11th Cir.).

¹⁵ Pls.’ Opp’n 19–20 (citing *Georgia v. Biden*, No. 1:21-cv-163, 2021 U.S. Dist. LEXIS 234032 (S.D. Ga. Dec. 7, 2021), *appeal filed*, No. 21-14269 (11th Cir. Dec. 10, 2021); *Florida v. Nelson*, No. 8:21-cv-2524-SDM-TGW, 2021 U.S. Dist. LEXIS 246185 (M.D. Fla. Dec. 22, 2021), *appeal filed*, No. 22-10165 (11th Cir. Jan. 13, 2022); *Kentucky v. Biden*, No. 3:21-cv-00055-GFVT, 2021 U.S. Dist. LEXIS 228316 (E.D. Ky. Nov. 30, 2021)), *appeal filed*, No. 21-6147 (6th Cir. Dec. 6, 2021)).

Thus, this Court should defer any ruling on the merits of Plaintiffs' statutory challenge to EO 14042 until the Eleventh Circuit issues its decision in *Georgia*.

CONCLUSION

For the foregoing reasons, and those stated in Defendants' opening brief, the Court should dismiss Plaintiffs' Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and (b)(6).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 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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