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**

COMBINED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINT, AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

The United States remains in the midst of a serious public health crisis. To date, the virus that causes COVID-19 has infected more than 50 million Americans, hospitalized more than 3.5 million, and killed over 800,000.[1] Fortunately, a key tool for ending this crisis is readily available: vaccination. Beginning in December 2020, the U.S. Food and Drug Administration ("FDA") issued Emergency Use Authorizations ("EUAs") to COVID-19 vaccines manufactured by Pfizer, Inc. and BioNTech Manufacturing GmbH ("Pfizer"), ModernaTX, Inc. ("Moderna"), and Johnson & Johnson/Janssen Biotech, Inc. ("Janssen"). In August 2021, FDA approved the Pfizer vaccine.

In September 2021, the President sought to mitigate the impact of COVID-19 on federal operations through two executive orders ("EOs"). In EO 14043, the President "determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service" required "COVID-19 vaccination for all Federal employees, subject to such exceptions as required by law." 86 Fed. Reg. 50,989 (Sept. 14, 2021). EO 14042 sought to "promote[] economy and efficiency in Federal procurement" by directing agencies to include a clause in certain contracts requiring federal contractors to comply with "workplace safety guidance" regarding COVID-19, provided that the guidance is approved by the Director of the Office of Management and Budget ("OMB"). 86 Fed. Reg. 50,985 (Sept. 14, 2021).

[1] *See* Centers for Disease Control and Prevention ("CDC"), COVID Data Tracker Weekly Review (updated Dec. 17, 2021), https://go.usa.gov/xFU9U.

Plaintiffs object to these sound measures to protect the health and safety of federal employees and contractors. Their objections verge on the conspiratorial—*e.g.*, that there is no public health emergency and that the American people have been psychologically manipulated. To resolve this motion to dismiss, however, the Court need not engage with those objections, but need only apply well-established jurisdictional principles and pleading standards.

Plaintiffs' six claims may be grouped into two categories. *First*, Counts I, III, IV, V, and VI challenge actions taken under the EUA statute, 21 U.S.C. § 360bbb-3, specifically the Secretary of Health and Human Services' (the "HHS Secretary") declaration of a public health emergency and FDA's issuance of EUAs for COVID-19 vaccines. But Plaintiffs do not have standing to assert these claims, and Congress expressly exempted actions under the EUA statute from review under the Administrative Procedure Act ("APA"). Even if the Court reaches the merits, Plaintiffs have not stated plausible APA claims.

Second, Counts II and VI challenge EOs 14042 and 14043 (collectively, the "Executive Orders"). But Plaintiffs have not established standing or that their claims are ripe. No Plaintiff is threatened with forcible vaccination or imminent adverse employment action from refusing vaccination. The federal-employee Plaintiffs (Leahy and Nelson) have accommodation requests pending with their employer. If they were subjected to an adverse action, the Civil Service Reform Act would deprive this Court of jurisdiction. The federal-contractor Plaintiffs (Makowski, Millen, Bloom, and Sobczak) have not even shown that EO 14042 applies to them, let alone that their employers denied any accommodation requests.

Even if the Court reaches the merits, the Amended Complaint does not plausibly allege that the Executive Orders are unlawful. They do not deprive Plaintiffs of substantive due process, and they fall within the President's statutory authority over federal employment and the federal procurement process.[2]

At a minimum, Plaintiffs are not entitled to the extraordinary relief of preliminarily enjoining the Executive Orders. Besides no likelihood of success on the merits, Plaintiffs have not shown they will suffer any imminent, irreparable harm before this case is resolved on the merits. Any employment-related injuries are generally redressable through back pay and reinstatement. Finally, given the federal government's compelling interest in stemming the spread of COVID-19 and the public interest in effective government administration, the balance of hardships and the public interest weigh heavily against the requested injunction.

BACKGROUND

I. The Federal Government's Responses to the COVID-19 Pandemic

A. HHS Secretary's Emergency Declaration

In the EUA statute, Congress authorized the HHS Secretary to determine that a "public health emergency . . . affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad." 21 U.S.C. § 360bbb-3(b)(1)(C). The Secretary may then further declare that circumstances exist justifying the marketing of FDA-regulated products "intended

[2] Defendants acknowledge that the Southern District of Georgia has issued a nationwide preliminary injunction enjoining enforcement of EO 14042, though this decision has been appealed. *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).

for use" in responding to the emergency. *Id.* § 360bbb-3(a)(1), (b). Congress expressly committed these decisions to the Secretary's discretion. *Id.* § 360bbb-3(i).

Under that authority, the HHS Secretary determined on February 4, 2020 that a public health emergency existed involving the virus SARS-CoV-2, which causes COVID-19. Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020) ("Emergency Declaration"). On March 27, 2020, the Secretary declared that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic." Emergency Use Authorization Declaration, 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020).

B. FDA's Issuance of EUAs for COVID-19 Vaccines

Normally, a manufacturer of a biological product, such as a vaccine, may market it "only if the FDA has licensed it" pursuant to the Public Health Service Act. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017); *see* 42 U.S.C. § 262(i)(1). But when the Secretary has made the required declarations under the EUA statute, FDA may issue an EUA for a vaccine intended for use in responding to the emergency. 21 U.S.C. § 360bbb-3(c). FDA's decision to issue an EUA is committed to agency discretion. *Id.* § 360bbb-3(i).[3]

FDA has issued EUAs for COVID-19 vaccines manufactured by Pfizer, Moderna, and Janssen. *See* ECF Nos. 40-6; 40-14; 40-20.[4] Based on its review of

[3] Issuance of an EUA does not constitute approval of the product. *See* 21 U.S.C. § 360bbb-3(a)(3).

[4] Subject matter jurisdiction is determined as of the time at which the Amended Complaint was filed. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473–74 (2007). For that reason, this brief cites the FDA documents that were in effect when the Court permitted the corrected Amended Complaint to be filed on November 5, 2021. *See* ECF No. 33. Like other information on government websites cited herein, these exhibits were "publicly available on FDA's website," ECF

extensive safety and efficacy data, including clinical trials with tens of thousands of participants, *see* ECF Nos. 40-7; 40-8; 40-9; 40-10; 40-11; 40-15; 40-16; 40-17; 40-21; 40-22; *see also* 21 U.S.C. § 360bbb-3(c), FDA found that "it is reasonable to believe that [the vaccines] may be effective in preventing COVID-19, and that, when used under the conditions described in [the EUAs], the known and potential benefits of [the vaccines] when used to prevent COVID-19 outweigh [their] known and potential risks." ECF Nos. 40-6, at 9; 40-14, at 6; 40-20, at 4–5.

The EUAs require vaccination providers to give recipients a "Fact Sheet for Recipients and Caregivers" (collectively, the "Fact Sheets"), either in hardcopy or online. ECF Nos. 40-6, at 13–14, 17; 40-14, at 8, 12; 40-20, at 6–7, 10; *see, e.g.*, ECF No. 40-3, at 15–16.[5] The Fact Sheets advise that "[i]t is your choice to receive or not receive" the vaccine. *E.g.*, ECF No. 40-1, at 7. The Moderna and Janssen Fact Sheets explain that the vaccine is "unapproved" and is authorized "under an Emergency Use Authorization," meaning it "has not undergone the same type of review as an FDA-approved" product and is authorized based on a determination that it "may be effective to prevent COVID-19." *E.g.*, ECF No. 40-12, at 3–4, 7. The Fact Sheets disclose the vaccines' potential side effects and warn that other "[s]erious and unexpected side effects may occur." *E.g.*, ECF No. 40-1, at 5–6.

No. 40, at ¶ 6, and are subject to judicial notice, *see Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322–23 (2007); *Eternal Word Television Network, Inc. v. Sebelius*, 935 F. Supp. 2d 1196, 1209 n.12 (N.D. Ala. 2013). The exhibits also are central to Plaintiffs' claims, and their authenticity is indisputable. *See U.S. ex rel. Osheroff v. Humana Inc.*, 776 F.3d 805, 811 (11th Cir. 2015); *see also* Fed. R. Evid. 201(b).

[5] This paragraph cites the Pfizer fact sheets, but except as otherwise noted, the same information is also in the Moderna and Janssen fact sheets. *See* ECF Nos. 40-12; 40-13; 40-18; 40-19.

The EUAs also require vaccine manufacturers and providers to report serious adverse events to the Vaccine Adverse Event Reporting System ("VAERS")—"a national early warning system to detect possible safety problems in U.S.-licensed vaccines." HHS, About VAERS, https://go.usa.gov/xFEc6 (last visited Dec. 17, 2021); *see* ECF Nos. 40-6, at 15–18; 40-14, at 10, 12; 40-20, at 8, 10. CDC has also developed a second reporting system known as V-safe, which "is a smartphone-based tool" for vaccine recipients to report side effects. CDC, V-safe After Vaccination Health Checker, https://go.usa.gov/xFvgR (updated Nov. 9, 2021).

C. FDA's Approval of the Pfizer COVID-19 Vaccine.

On August 23, 2021, FDA approved Pfizer's Biologics License Application ("BLA") for its COVID-19 vaccine, named Comirnaty, for persons ages 16 and older. ECF No. 41-1. FDA's decision was based on effectiveness data from approximately 20,000 vaccine recipients and 20,000 placebo recipients, which showed that the vaccine was over 91% effective in preventing COVID-19 and between 95% and 100% effective in preventing severe COVID-19. *See* ECF Nos. 41, at ¶ 16; 41-7, at 7–14. FDA also relied on safety data from approximately 12,000 vaccine recipients monitored for at least six months and from the millions of vaccine doses administered under the EUA, which showed that the product was safe. ECF No. 41-7, at 13. Although Comirnaty is now approved for individuals ages 16 and older to receive the standard two-dose series, the Pfizer EUA remains in effect, including for individuals ages 5 and older and to provide a third dose to certain individuals. *See* ECF No. 41-2.

On December 16, 2021, FDA approved a second formulation of Comirnaty. Notably, the two formulations of Comirnaty are the same as the two formulations authorized under the Pfizer EUA. ECF No. 41, at ¶ 11–12. Although the approved and EUA-authorized products are legally distinct with certain differences, such as in labeling, the products are "medically interchangeable." *Id.* ¶ 13. For individuals ages 12 and older, FDA has determined that both formulations of Comirnaty and the EUA-authorized Pfizer vaccine, "when prepared according to their respective instructions for use, can be used interchangeably without presenting any safety or effectiveness concerns." *Id.* ¶ 12.

D. President Biden Orders COVID-19 Safety Measures for Federal Employees and Contractors.

On September 9, 2021, President Biden issued EOs 14042 and 14043, addressing COVID-19 safety measures for federal civilian employees and contractors. Neither Executive Order is self-effectuating; rather, both require additional implementing actions from federal agencies.

In EO 14043, the President "determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service" requires "COVID-19 vaccination for all Federal employees, subject to such exceptions as required by law." 86 Fed. Reg. at 50,989. Accordingly, EO 14043 directs each federal agency to implement a COVID-19 vaccination program for its employees, and directs the Safer Federal Workforce Task Force ("Task Force") to issue guidance to agencies on the implementation of EO 14043. *Id.* at 50,990.

The Task Force guidance, like EO 14043, recognizes that federal employees may be eligible for "a reasonable accommodation" if they "communicate to the agency that they are not vaccinated against COVID-19 because of a disability or because of a sincerely held religious belief, practice, or observance." *See* Task Force, Vaccinations Frequently Asked Questions, https://go.usa.gov/xe9CV (last visited Dec. 17, 2021) ("Employee FAQs"). The guidance advises each agency to "follow its ordinary process to review and consider what, if any, accommodation it must offer." *Id.* Although federal employees should have been vaccinated by November 22, 2021, the guidance advises that they should not face discipline if they have "received an exception" or if the agency is considering their exception request. *Id.*

EO 14042 "promotes economy and efficiency in Federal procurement by ensuring that the parties that contract with the Federal Government provide adequate COVID-19 safeguards to their workers performing on or in connection with a Federal Government contract." 86 Fed. Reg. at 50,985. The order instructs Executive departments and agencies, "to the extent permitted by law," to incorporate a COVID-19 safety clause into certain new contracts. *Id*. That clause requires that contractors and subcontractors comply with guidance developed by the Task Force and approved by the OMB Director after she concludes that adherence to the provisions "will promote economy and efficiency in Federal contracting." *Id.* The clause would be included in new contracts executed after October 15, 2021, and in existing contracts upon an extension or modification event. *Id.* at 50,987.

On November 10, 2021, the Acting OMB Director approved the issuance of the Task Force's current guidance based on "OMB's expert opinion that the

[g]uidance will promote economy and efficiency in Federal Government procurement." OMB Determination, 86 Fed. Reg. 63,418, 63,423 (Nov. 16, 2021).[6] The guidance provides that "covered contractor employees" must be fully vaccinated by January 18, 2022, unless they are "legally entitled to an accommodation." *Id.* at 63,420; *see id.* at 63,419. Contractors "may be required to provide an accommodation" if an employee communicates that she is not vaccinated "because of a disability (which would include medical conditions) or because of a sincerely held religious belief, practice, or observance." *Id.* The contractor must "review and consider what, if any, accommodation it must offer." *Id.*

II. Procedural History

On May 19, 2021, Plaintiffs filed a motion for a Temporary Restraining Order to enjoin the extension of the EUAs to children under the age of 16, ECF No. 1, which the Court denied *sua sponte*, ECF No. 3. Plaintiffs later filed their initial complaint, seeking invalidation of the Emergency Declaration and EUAs. *See* ECF No. 10. They then moved for a preliminary injunction to invalidate the EUAs and enjoin FDA from approving the vaccines. ECF No. 15. On September 16, 2021, Defendants opposed Plaintiffs' preliminary injunction motion and moved to dismiss the complaint under Federal Rule of Civil Procedure 12(b)(1), (b)(3), and (b)(6). *See* ECF Nos. 23–25. Plaintiffs then withdrew their preliminary injunction motion and received an extension of time to amend their complaint. *See* ECF Nos. 27, 29.

[6] This OMB determination "rescind[ed] and supersede[d]" a prior determination by the OMB Acting Director. 86 Fed. Reg. at 63,418.

On November 5, 2021, the Court allowed Plaintiffs to file the operative Amended Complaint. Am. Compl., ECF No. 32-1; *see* ECF No. 33. Plaintiffs raise claims regarding the Emergency Declaration, EUAs, and Executive Orders under the APA, substantive due process, 28 U.S.C. § 1361 (mandamus), and the Declaratory Judgment Act. Am. Compl. ¶¶ 169–92. On November 19, 2021, Plaintiffs filed a new motion for a preliminary injunction. PI Mot., ECF No. 37. Defendants now move to dismiss the Amended Complaint under Federal Rule of Civil Procedure 12(b)(1) and (b)(6), and oppose the preliminary injunction motion.

ARGUMENT

I. This Case Should Be Dismissed for Lack of Subject Matter Jurisdiction.

A. Legal Standard

"Article III of the Constitution limits the jurisdiction of federal courts to 'Cases' and 'Controversies.'" *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 157 (2014) (quoting U.S. Const., Art. III, § 2). Subject matter jurisdiction must "be established as a threshold matter." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The Court "presume[s]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotations omitted)); *see Brownback v. King*, 141 S. Ct. 740, 749 (2021) (plaintiff "must plausibly allege all jurisdictional elements").

Where, as here, Defendants factually attack subject matter jurisdiction, the Court does not "presum[e] the truthfulness of the plaintiff's allegations." *Makro Cap. of Am., Inc. v. UBS AG*, 543 F.3d 1254, 1258 (11th Cir. 2008) (quotation

omitted). Rather, it "may consider extrinsic evidence," including declarations, and "weigh the evidence" to determine whether it has jurisdiction. *Id.*

B. The Court Lacks Jurisdiction to Review the Actions Taken Under the EUA Statute (Counts I, III–VI).

Counts I, III, IV, V, and VI challenge actions taken under the EUA statute. For several reasons, however, the Court lacks jurisdiction over each count.

1. Standing

To show standing, Plaintiffs "must clearly allege . . . facts demonstrating" (1) an injury in fact that is "concrete, particularized, and actual or imminent"; (2) "fairly traceable" to Defendants' challenged actions; and (3) likely "redressable by a favorable ruling." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Plaintiffs "must demonstrate standing for each claim . . . and for each form of relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2208 (2021). Here, Plaintiffs lack standing for all claims and requested relief related to the Emergency Declaration or EUAs.

America's Frontline Doctors ("AFLDS") alleges no concrete injury to itself from the mere existence of the Emergency Declaration and EUAs. *See Jacobson v. Fla. Sec'y of State*, 974 F.3d 1236, 1249–50 (11th Cir. 2020). Likewise, AFLDS lacks standing "to bring suit on behalf of its members" because it has not shown any member "would otherwise have standing to sue in their own right." *Ga. Republican Party v. SEC*, 888 F.3d 1198, 1203 (11th Cir. 2018) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)); *see* Am. Compl. ¶ 13. AFLDS must, among other things, "make specific allegations establishing that

at least one identified member has suffered or will suffer harm," and "self-descriptions of its membership" are insufficient. *Ga. Republican Party*, 888 F.3d at 1203 (cleaned up); *see Jacobson*, 974 F.3d at 1249.

AFLDS does not identify a member who suffered a "concrete, particularized, and actual or imminent" injury. *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 925 (11th Cir. 2020) (en banc). It alleges only that unidentified members object to (1) an American Medical Association ("AMA") "ethical opinion"; (2) the possibility that their unknown employers will adopt the AMA's view; (3) unspecified vaccine mandates by unknown employers; and (4) hypothetical complaints in the National Physicians Database. Am. Compl. ¶¶ 7–9, 11. These allegations impermissibly rely on a "speculative chain of possibilities," *Clapper*, 568 U.S. at 414, before any injury could become "real," *Muransky*, 979 F.3d at 925. And none are "fairly traceable" to Defendants' conduct, which is entirely separate from the independent actions of the AMA, AFLDS members' employers, or the database complainants. *Clapper*, 568 U.S. at 409; *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) (injury must not result from "the independent action of some third party not before the court" (quotations omitted)). Accordingly, AFLDS lacks standing.

Dr. Calderwood also lacks standing to represent his patient Makowski. Absent an "injury in fact" to himself, Dr. Calderwood lacks "a sufficiently concrete interest in the outcome of the issue in dispute" for third-party standing. *Powers v. Ohio*, 499 U.S. 400, 411 (1991) (quotations omitted); *see* Am. Comp. ¶ 14. And Makowski—a plaintiff himself—is not hindered in his "ability to protect" his "own interests." *Powers*, 499 U.S. at 411.

The remaining individual Plaintiffs also have not suffered an injury traceable to the mere existence of the Emergency Declaration or EUAs. *Muransky*, 979 F.3d at 925–26, 928; *see Children's Health Defense v. FDA*, No. 1:21-cv-00200-DCLC-CHS, 2021 WL 5756085, at *4 (E.D. Tenn. Nov. 30, 2021) (no standing to challenge FDA's procedures in approving Comirnaty and reissuing EUA). For example, no individual Plaintiff was injured by an EUA vaccine.[7] Rather, the Amended Complaint implies (without explanation) that they might fear a future injury.

Plaintiffs, though, cannot meet the "high standard," subject to "robust judicial" scrutiny, of showing "a material risk of harm" traceable to the challenged actions. *Muransky*, 979 F.3d at 927–28; *see Elend v. Basham*, 471 F.3d 1199, 1207 (11th Cir. 2006) ("a real and immediate threat of future harm" is necessary for "injunctive and declaratory relief"). At most, Plaintiffs may fear future exposure to an EUA vaccine, but they "do not claim that *they* intend to receive [an EUA vaccine] in the future." *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012). And the Court may not "create jurisdiction by embellishing a deficient allegation of injury." *DiMaio v. Democratic Nat. Comm.*, 520 F.3d 1299, 1301 (11th Cir. 2008) (quotation omitted).

Moreover, even if Plaintiffs received a COVID-19 vaccine in the future, it could be the Pfizer vaccine from lots that were "manufactured in compliance with the BLA" and that are "not subject to the EUA requirements when used for the approved indication." ECF No. 41, at ¶ 15; *see Coal. for Mercury-Free Drugs*, 671

[7] Although Plaintiffs' preliminary injunction motion states that certain individuals have been injured by vaccines, PI Mot. 5–6, none of those individuals is currently a plaintiff.

F.3d at 1280 (no standing to challenge "thimerosal-preserved vaccines" when "thimerosal-free" version available); *Norris v. Stanley*, No. 1:21-CV-756, 2021 WL 3891615, at *2 (W.D. Mich. Aug. 31, 2021) ("should Plaintiff be offered the FDA-approved Pfizer Comirnaty vaccine, her argument under the EUA statute would be moot"). Thus, the individual Plaintiffs have not satisfied the "high standard," *Muransky*, 979 F.3d at 927, to show an "injury they will suffer" that "is 'fairly traceable'" to the Emergency Declaration or EUAs, *California v. Texas*, 141 S. Ct. 2104, 2113 (2021).

At bottom, Plaintiffs raise only an impermissible "generally available grievance" challenging the wisdom of the Emergency Declaration and EUAs. *Lujan*, 504 U.S. at 573–74; *see Diamond v. Charles*, 476 U.S. 54, 66–67 (1986). But "Article III standing is not to be placed in the hands of concerned bystanders, who will use it simply as a vehicle for the vindication of value interests." *Hollingsworth v. Perry*, 570 U.S. 693, 707 (2013) (quotations omitted). And federal courts lack "a general authority to conduct oversight of" the Executive Branch. *California*, 141 S. Ct. at 2116. Thus, Counts I, III, IV, V, and VI must be dismissed for lack of standing.

2. Counts I, III, and IV Are Unreviewable Under the APA.

Even if Plaintiffs had standing, the Court lacks jurisdiction over the APA claims in Counts I, III, and IV because the Emergency Declaration and EUAs are "committed to agency discretion by law." 5 U.S.C. § 701(a)(2); *see Lenis v. U.S. Att'y Gen.*, 525 F.3d 1291, 1293–94 (11th Cir. 2008). The EUA statute states that HHS's "[a]ctions under the authority of this section . . . are committed to agency discretion." 21 U.S.C. § 360bbb-3(i). The Emergency Declaration and EUAs were

issued expressly under the EUA statute's authority. *See* 85 Fed. Reg. at 7317; ECF Nos. 40-6, at 2–4, 9–10; 40-14, at 2–3, 5–6; 40-20, at 2, 4–5. Thus, the Sixth Circuit has recognized that EUAs "are exempt from review under the APA." *Ass'n of Am. Physicians & Surgeons v. FDA*, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (citing 5 U.S.C. § 701(a)(2)); *see also Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) ("[W]hen the statute's language is plain," courts should enforce the statute "according to its terms." (quotations omitted)). The Emergency Declaration and EUAs are committed to agency discretion and unreviewable under the APA.

3. Neither the Mandamus Statute (Count V) nor the Declaratory Judgment Act (Count VI) Supplies Jurisdiction.

Regarding Count V, "[t]he test for jurisdiction is whether mandamus would be an appropriate means of relief," which requires that "the defendant owes [the plaintiff] a clear nondiscretionary duty" and that the plaintiff "exhausted all other avenues of relief." *Cash v. Barnhart*, 327 F.3d 1252, 1257–58 (11th Cir. 2003) (quotations omitted). Despite Plaintiffs' bare allegation of a duty "to ensure the faithful implementation of" the EUA statute, Am. Compl. ¶ 188, HHS does not owe Plaintiffs "a clear nondiscretionary duty" to act, *Cash*, 327 F.3d at 1257–58. Rather, all of HHS's "[a]ctions under the authority of" the EUA statute, including issuing an emergency declaration or an EUA or imposing conditions on an EUA, are "committed to agency discretion." 21 U.S.C. § 360bbb-3(i). The operative provisions of the EUA statute reinforce this point. For example, the Secretary "may" declare "that the circumstances exist justifying" an EUA and "may" issue an EUA. 21 U.S.C. §§ 360bbb-3(a)(1), (b)(1), (c); *see Kingdomware Techs., Inc. v. United*

States, 136 S. Ct. 1969, 1977 (2016) ("the word 'may' . . . implies discretion"). HHS's decisions under the EUA statute, moreover, involve weighing scientific evidence to make complex judgments about the safety and efficacy of medical products. *See* 21 U.S.C. § 360bbb-3(c). Such decisions are the opposite of "clear nondiscretionary dut[ies]." *Cash*, 327 F.3d at 1257–58.

Plaintiffs also have not "exhausted all other avenues of relief." *Id.* FDA regulations require parties to follow an administrative citizen petition process before challenging FDA's action in court.[8] *See* 21 C.F.R. §§ 10.25(a), 10.45; *see also Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21 (D.D.C. 2008), *aff'd*, 358 F. App'x 179 (D.C. Cir. 2009) (per curiam). Plaintiffs have not done so. For all these reasons, this case is not among "the clearest and most compelling of cases" warranting the "extraordinary remedy" of mandamus, and the Court therefore lacks jurisdiction over Count V. *Cash*, 327 F.3d at 1257–58.

Regarding Count VI, the Declaratory Judgment Act "does not enlarge the jurisdiction of the federal courts." *Wendy's Int'l, Inc. v. City of Birmingham*, 868 F.2d 433, 435 (11th Cir. 1989). A "party seeking declaratory relief must satisfy" the standard jurisdictional requirements, including standing. *Id.*; *DiMaio*, 520 F.3d at 1301. For the same reasons Plaintiffs cannot establish jurisdiction over their other claims related to the EUA statute, they also cannot establish the Court's jurisdiction to issue the declaratory relief requested in Count VI regarding the EUA statute.

[8] Although the Emergency Declaration was issued by the Secretary, not FDA, Plaintiffs could still challenge it in a Citizen Petition, such as by arguing that the EUAs are improper because the Emergency Declaration is improper. *See* 21 C.F.R. §§ 10.25(a), 10.30.

C. The Court Lacks Jurisdiction over the Claims Related to the Executive Orders (Counts II, VI).

Count II seeks to enjoin "any mandate or action that would lead to the mandate of [EUA-authorized] COVID-19 vaccines" on substantive due process grounds. Am. Compl. ¶¶ 179–81. Count VI further requests a "declaration that EOs 14042 and 14043 are invalid to authorize compulsory EUA vaccinations." *Id.* ¶ 192. Like the other counts, these counts have numerous jurisdictional defects.

1. The President Should Be Dismissed as a Defendant.

Plaintiffs sue the President, but the Court may not issue either injunctive or declaratory relief against him. In 1866, the Supreme Court disclaimed jurisdiction "to enjoin the President in the performance of his" non-ministerial, "official duties." *Mississippi v. Johnson*, 71 U.S. 475, 501 (1866). The Court reaffirmed that principle in *Franklin v. Massachusetts*, 505 U.S. 788 (1992); *see id.* at 802–03 (plurality opinion); *id.* at 829 (Scalia, J., concurring) ("we have no power" to "order[] declaratory or injunctive relief against appellant President Bush"); *Made in the USA Found. v. United States*, 242 F.3d 1300, 1310 n.25 (11th Cir. 2001). The D.C. Circuit has applied this principle to declaratory relief, *Swan v. Clinton*, 100 F.3d 973, 976–77 n.1 (D.C. Cir. 1996), and explained that "courts do not have jurisdiction to enjoin [the President], and have never submitted the President to declaratory relief," *Newdow v. Roberts*, 603 F.3d 1002, 1013 (D.C. Cir. 2010). Indeed, the Executive Orders at issue here "are discretionary," not "ministerial," and thus the Court lacks jurisdiction to issue injunctive or declaratory relief against President Biden. *McCray v. Biden*, No. CV 21-2882 (RDM), 2021 WL 5823801, at *7 (D.D.C. Dec. 7, 2021);

see Navy Seal 1 v. Biden, No. 8:21-CV-2429-SDM-TGW, 2021 WL 5448970, at *2 (M.D. Fla. Nov. 22, 2021); *Rydie v. Biden*, No. CV DKC 21-2696, 2021 WL 5416545, at *3 (D. Md. Nov. 19, 2021); *see also Ctr. for Democracy & Tech. v. Trump*, 507 F. Supp. 3d 213, 226 (D.D.C. 2020). The President must therefore be dismissed as a defendant.

2. Standing, Ripeness, and the Civil Service Reform Act Bar Plaintiffs' Challenge to EO 14043.

Only Plaintiffs Leahy and Nelson allegedly fall within the ambit of EO 14043. *See* Am. Compl. ¶ 19. But "[t]wo related doctrines of justiciability"—standing and ripeness—deprive the Court of jurisdiction over their claims. *Trump v. New York*, 141 S. Ct. 530, 535 (2020) (per curiam).

To show standing, Leahy and Nelson must demonstrate "an injury that is concrete, particularized, and imminent rather than conjectural or hypothetical." *Id.* (quotation omitted). But Nelson has conceded that his and Leahy's religious accommodation requests remain "pending." ECF No. 37-4; *see* ECF No. 39, at ¶¶ 7, 10. And while their requests remain pending, they face no adverse employment action. ECF No. 39, at ¶¶ 8, 11. Nor is any action imminent under NASA's process, which involves evaluation of the request by the Vaccine Exception Agency Review Team, advice to senior NASA officials, a decision by those officials, as well as the option for reconsideration by a different senior official. *Id.* ¶ 12. Thus, Leahy and Nelson have not shown the actual or imminent injury necessary for standing. *See Children's Health Def.*, 2021 WL 5756085 at *4 (no standing when plaintiff's religious accommodation request remained pending).

Leahy's and Nelson's claims are also not ripe, because they depend on "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump*, 141 S. Ct. at 535 (quotation omitted). Ripeness is a "threshold jurisdictional question," *Elend*, 471 F.3d at 1204, and it is Plaintiffs' burden to establish it. *Ralston v. LM Gen. Ins. Co.*, No. 616CV1723ORL37DCI, 2016 WL 6623728, at *3 (M.D. Fla. Nov. 9, 2016). "Any prediction how" NASA will resolve Leahy's and Nelson's religious accommodation requests "is no more than conjecture at this time." *Trump*, 141 S. Ct. at 535 (quotation omitted). Even if their accommodation requests are denied, it is uncertain how these Plaintiffs would respond; they might decide to get vaccinated. *See* ECF No. 39, at ¶ 4 (discussing employee counseling period). Thus, these Plaintiffs' claims are "riddled with contingencies and speculation that impede judicial review." *Trump*, 141 S. Ct. at 535; *see McCray*, 2021 WL 5823801, at *8 (plaintiff's challenge to the Executive Orders was not ripe because his "purported injury is contingent upon his employers denying his application for a medical exemption").

Furthermore, "[w]hen a court is asked to review decisions of administrative agencies, it is hornbook law that courts must exercise patience and permit the administrative agenc[ies] the proper time and deference for those agencies to consider the case fully." *Nat'l Advert. Co. v. City of Miami,* 402 F.3d 1335, 1339 (11th Cir. 2005); *see Elend*, 471 F.3d at 1211. When, as here, employees' "exemption requests are still under consideration by the agencies," the issues are "unfit for judicial review." *Church v. Biden*, No. CV 21-2815 (CKK), 2021 WL 5179215, at *9 (D.D.C. Nov. 8, 2021).

Meanwhile, "withholding adjudication at this time" will cause Leahy and Nelson no hardship. *Pittman v. Cole*, 267 F.3d 1269, 1280 (11th Cir. 2001). The "source of any injury to the plaintiffs is the action that" NASA "*might* take in the future" to implement EO 14043, *not* the Executive Order "itself in the abstract." *Trump*, 141 S. Ct. at 536 (quotation omitted). And NASA will not take any adverse action while their exception requests are pending. *See* ECF No. 39, at ¶¶ 8, 11. Thus, Nelson and Leahy have not shown why adjudication of their claims may not be "withheld until a more mature case can be presented." *Pittman*, 267 F.3d at 1281; *see Church*, 2021 WL 5179215, at *10 (no "immediate and significant hardship" to federal employee by allowing agency process to conclude).

In addition to these standing and ripeness problems, another jurisdictional infirmity looms on the horizon: preclusion under the Civil Service Reform Act ("CSRA"), which "established a comprehensive system for reviewing personnel action taken against federal employees." *Elgin v. Dep't of Treasury*, 567 U.S. 1, 5 (2012) (quotations omitted). "When a covered employee appeals a covered adverse action," the Merit Systems Protection Board ("MSPB") has initial "jurisdiction over the appeal," and the Federal Circuit has "exclusive jurisdiction over appeals from a final decision of the MSPB." *Id.* at 6, 20 (citing 5 U.S.C. § 7703). This review framework is exclusive, with no "additional avenue of review in district court," including for constitutional claims. *Elgin*, 567 U.S. at 12, 21; *see Stephens v. Dep't of Health & Hum. Servs.*, 901 F.2d 1571, 1575–76 (11th Cir. 1990); *Rydie*, 2021 WL 5416545, at *2 (federal employees challenging "future terminations" related to EO

14043 "likely have to proceed through the CSRA process, even though they assert constitutional challenges").

Both Nelson and Leahy are covered by the CSRA. ECF No. 39, at ¶¶ 6, 9; *see Elgin*, 567 U.S. at 5. Thus, if they faced a "reviewable action," including termination, they would need to follow the CSRA's review process, and this Court would not have jurisdiction. *See Elgin*, 567 U.S. at 5–6 (citing 5 U.S.C. § 7512).[9]

3. No Plaintiff Properly Challenges EO 14042.

Plaintiffs Makowski, Millen, Bloom, and Sobczak allege that, due to EO 14042, they "confront[] the vaccine mandate in November, 2021." Am. Compl. ¶¶ 15-18.[10] But beyond an abstract "confront[ation]," these Plaintiffs allege no "real" or particularized injury that they have incurred or will imminently incur. *Muransky*, 979 F.3d at 925–26. Makowski has conceded that his request for "medical and/or religious exemptions" remains pending, ECF No. 37-3, at 2, and the other federal-contractor Plaintiffs have not plausibly shown their accommodation requests were denied. *Cf. Makro Cap.*, 543 F.3d at 1258. Thus, the federal-contractor Plaintiffs' claims are not justiciable because any injury is "dependent on contingent future events that may not occur as anticipated, or indeed may not occur at all." *Trump*, 141 S. Ct. at 535 (quotation omitted); *see Children's Health Def.*, 2021 WL 5756085.[11]

[9] The CSRA also sets forth "prohibited personnel practices," 5 U.S.C. § 2302, and any challenge to such practices must be submitted "in the first instance to the [Office of Special Counsel] for review," *Ferry v. Hayden*, 954 F.2d 658, 661 (11th Cir. 1992). A failure to do so "precludes judicial review" of any allegedly "improper agency action." *Id.*

[10] AFLDS vaguely alludes to members "currently facing COVID vaccine mandates," Am. Compl. ¶ 9, but does not tie those supposed mandates to EOs 14042 or 14043.

[11] As noted above, EO 14042 is currently enjoined by a nationwide preliminary injunction, which has been appealed. *See Georgia*, 2021 WL 5779939, at *12.

Moreover, the federal-contractor Plaintiffs have not established that EO 14042 even applies to them. EO 14042 provides that "new contracts" after October 15, 2021, as well as "extensions or renewals of existing contracts," shall include a clause requiring the contractor to follow Task Force guidance about COVID-19 workplace safety. 86 Fed. Reg. at 50,987. Contractors can choose whether to accept the term or decline to perform. *See* 86 Fed. Reg. at 63,419. If the clause has been incorporated into a contract, the guidance applies only to "covered contractor employees." 86 Fed. Reg. at 63,419. To plausibly allege an injury traceable to EO 14042, therefore, the federal-contractor Plaintiffs must "clearly allege facts" showing that they are "covered contractor employees." *Spokeo*, 578 U.S. at 338 (cleaned up).

They have failed to do so. Although Makowski alleges that his employer has required him to "receive a COVID vaccine by December 8, 2021, if [he is] not granted a medical and/or religious exemption," and that "[t]his requirement is imposed because of [EO] 14042," he acknowledges that he will not imminently be required to be vaccinated because "[t]he dates are currently fluid and dependent upon the guidance from the government customer." ECF No. 37-3; *see Hollis v. Biden*, No. 1:21-CV-163-GHD-RP, 2021 WL 5500500, at *4 (N.D. Miss. Nov. 23, 2021) (dismissing for lack of standing plaintiffs who "have not adequately demonstrated that they are currently or imminently will be subject to the vaccine requirement set forth in E.O. 14042"); *McCray*, 2021 WL 5823801, at *9.

Finally, even if Plaintiffs had shown their accommodation requests were denied under a workplace policy adopted due to EO 14042, those denials still would be traceable to (and redressable by) their employers, not Defendants. It is the

responsibility of contractor-employers, not Defendants, to "review and consider what, if any, [religious or medical] accommodation [they] must offer." 86 Fed. Reg. at 63,420; *cf. Hollis*, 2021 WL 5500500, at *5. Thus, if the federal-contractor Plaintiffs' employers deny their accommodation requests, Am. Compl. ¶¶ 16–18, their recourse would be against those employers, not against Defendants. *See Lewis v. Governor of Ala.*, 944 F.3d 1287, 1301 (11th Cir. 2019); *Navy Seal 1*, 2021 WL 5448970, at *2.[12]

II. The Amended Complaint Should Be Dismissed for Failure to State a Claim.

A. Legal Standard

The Court must dismiss the Amended Complaint under Rule 12(b)(6) unless Plaintiffs have "state[d] a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). They must plead sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("Factual allegations must be enough to raise a right to relief above the speculative level."). "Threadbare recitals of the elements of a cause of action" or "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" do not suffice. *Iqbal*, 556 U.S. at 678. The Court accepts as true Plaintiffs' "well-pleaded factual allegations," but it need not accept as true "conclusory statements" or "legal conclusions." *Id.* at 678–79.

[12] Even if the Court finds that any Plaintiff has standing to challenge one of the Executive Orders, that Plaintiff would still lack standing to challenge the Public Health Emergency Declaration and the EUAs. *See TransUnion*, 141 S. Ct. at 2208 (plaintiffs "must demonstrate standing for each claim . . . and for each form of relief").

B. Defendants Untethered to Any Count Must Be Dismissed.

A plaintiff must plausibly allege "that the *defendant* is liable for the misconduct alleged." *Id.* at 678 (emphasis added). But Dr. Fauci, CDC, NIH, NIAID, and Does I-X are untethered to any claim for relief. *See* Am. Compl. ¶¶ 169–92. Thus, these Defendants must be dismissed.

C. Counts I, III, and IV Fail to State a Claim that the Emergency Declaration and EUAs Are Unlawful Under the APA.

Counts I, III, and IV assert APA claims challenging the Emergency Declaration and HHS's alleged failure to satisfy the EUA issuance criteria and the EUAs' required conditions. Even if the Court had jurisdiction over these claims, they should be dismissed for failure to state a claim.

1. Plaintiffs Do Not Challenge HHS's Contemporaneous Explanations in Light of the Existing Administrative Record.

The "focal point" for arbitrary-and-capricious review under the APA "should be 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) (per curiam); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry."); *Pres. Endangered Areas of Cobb's Hist., Inc. v. U.S. Army Corps of Eng'rs*, 87 F.3d 1242, 1246 (11th Cir. 1996). This Court is therefore "limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Dep't of Commerce*, 139 S. Ct. at 2573. FDA regulations reflect this principle, providing that "the validity of [an administrative] action must be determined solely on the basis

of the administrative record" and that "information or views not included in the administrative record shall" be submitted "to the Commissioner with a new [Citizen Petition] to modify the action." 21 C.F.R. § 10.45(f); *see id.* §§ 10.25, 10.30.

"Under ordinary principles of administrative law," moreover, "a reviewing court will not consider arguments that a party failed to raise in timely fashion before an administrative agency." *Mahon v. U.S. Dep't of Agric.*, 485 F.3d 1247, 1254–55 (11th Cir. 2007); *see also Drummond Co., Inc. v. Dir., OWCP*, 650 F. App'x 690, 693–94 (11th Cir. 2016). This issue-exhaustion requirement serves numerous important policies, including "to permit the agency to exercise its discretion or apply its expertise" and to "conserve scarce judicial resources." *Mahon*, 485 F.3d at 1255. FDA's regulations allow any "interested person [to] petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action" by filing "a citizen petition." 21 C.F.R. § 10.25(a); *see id.* § 10.30.

Here, Counts I, III, and IV assert APA challenges to the Emergency Declaration and EUAs. HHS's contemporaneous explanations for these actions are contained in the Secretary's February 2020 and March 2020 declarations, the EUAs, and the related FDA Review Memoranda, which discuss the extensive data supporting FDA's conclusions.[13]

The Amended Complaint does not plausibly allege that HHS's contemporaneous explanations were unreasonable "in light of the existing

[13] *See* 85 Fed. Reg. 7316; 85 Fed. Reg. 18,250; ECF Nos. 40-6; 40-7; 40-8; 40-9; 40-10; 40-11; 40-14; 40-15; 40-16; 40-17; 40-20; 40-21; 40-22.

administrative record." *Dep't of Commerce*, 139 S. Ct. at 2573. Nor does it allege that Plaintiffs ever presented their allegations to HHS, such as by filing a citizen petition. *See Mahon*, 485 F.3d at 1254–55; 21 C.F.R. §§ 10.25(a), 10.30. Instead, it 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. For example, the Amended Complaint vaguely asserts that Plaintiffs "have accumulated and will present expert medical and scientific evidence" supporting their contentions, without alleging whether such evidence was ever presented to HHS. Am. Compl. ¶ 176; *see also id.* ¶ 79–116. And for Count IV, Plaintiffs dispute whether vaccination providers and recipients "are being informed" of the information described in the EUA statute, *id.* ¶¶ 185–87, but do not contest FDA's contemporaneous explanation (*i.e.*, at the time the EUAs were issued) for why the content of the Fact Sheets satisfied appropriate conditions designed to ensure that vaccination providers and recipients are informed about the vaccines, *see* 21 U.S.C. § 360bbb-3(e)(1)(A). Thus, Plaintiffs fail to state APA claims for Counts I, III, and IV. *See Dep't of Commerce*, 139 S. Ct. at 2573; *Mahon*, 485 F.3d at 1254–55; *see also Velez-Duenas v. Swacina*, 875 F. Supp. 2d 1372, 1379 (S.D. Fla. 2012) (dismissing complaint because plaintiff asked the Court "to consider documents that were not a part of the administrative record," which "would be improper").

2. Plaintiffs' Remaining Arguments Fail.

In Count I, Plaintiffs argue that *Home Building & Loan Association v. Blaisdell*, 290 U.S. 398 (1934), and *Chastleton Corp. v. Sinclair*, 264 U.S. 543 (1924), support their reliance on facts postdating the issuance of the Emergency

Declaration, Am. Compl. ¶¶ 169–77. But those cases are inapposite because they addressed a court's duty to determine whether an emergency still exists when evaluating whether emergency laws violate the Constitution. *See Blaisdell*, 290 U.S. at 415–16; *Chastleton*, 264 U.S. at 546. Count I does not assert a constitutional violation, but only an APA challenge to the Emergency Declaration under the EUA statute. Moreover, the APA, which postdates both *Blaisdell* and *Chastleton*, provides the operative framework for an aggrieved party to challenge a final agency action, emergency and non-emergency alike. And the APA requires Plaintiffs to show that HHS's "contemporaneous explanation" for the Emergency Declaration was unreasonable "in light of the existing administrative record," *Dep't of Commerce*, 139 S. Ct. at 2573, not based on a new record they attempt to create before the Court, *see Fla. Power & Light Co.*, 470 U.S. at 744. Plaintiffs have not done so.[14]

Regarding Count III, even if Plaintiffs' allegations were properly before the Court, they do not plausibly show the EUA issuance criteria were not met. Plaintiffs allege that COVID-19 is "not 'a serious or life-threatening disease or condition' for 99% of the population." Am. Compl. ¶ 183. But over 800,000 Americans, of all ages, have died from COVID-19. And Plaintiffs fail to address the risks of other serious conditions, short of death, that FDA found to support the EUAs, *see, e.g.*, ECF Nos. 40-7, at 9, 50–56; 40-8, at 7–8, 39–42; 40-15, at 9–10, 56–61; 40-21, at 9–10, 60–

[14] Although Plaintiffs may not challenge the issuance of the Emergency Declaration under the APA by alleging that a public health emergency no longer exists, the EUA statute expressly accounts for when circumstances change and there is no longer a public health emergency. It provides that an emergency declaration terminates, *inter alia*, upon "a determination by the Secretary . . . that the [public health emergency] ha[s] ceased to exist." 21 U.S.C. § 360bbb-3(b)(2)(A). Plaintiffs have not alleged, however, that that the Secretary was required to make a determination under section 360bbb-3(b)(2)(A).

66. Additionally, Plaintiffs allege there are "adequate, approved, and available alternative[s]" to the vaccines, 21 U.S.C. § 360bbb-3(c)(3); Am. Compl. ¶ 183, but they misinterpret this standard. It is immaterial that alternatives have been "approved by physicians as meeting the standard of care among similarly situated medical professionals," *id.* ¶ 183, because alternative treatments are only "approved" when approved by FDA, 21 U.S.C. § 360bbb-3(a)(2).[15] When FDA issued the EUAs, the vaccines had no adequate, approved, and available alternatives. *See* ECF Nos. 40-7, at 9–10; 40-15, at 10; 40-21, at 10.[16]

In Count IV, Plaintiffs' allegations that vaccination providers and recipients received inadequate information about the vaccines, Am. Compl. ¶ 186—even if cognizable under the APA—do not show that HHS violated the EUA statute. Consistent with the EUA statute, FDA has established "appropriate conditions designed to ensure" that vaccination providers and recipients are informed of the specified information. 21 U.S.C. § 360bbb-3(e)(I)(A)(i)–(ii). The EUAs require local health authorities to give vaccination providers a Fact Sheet for Healthcare Providers Administering Vaccine, and require vaccination providers to give vaccine recipients a Fact Sheet for Recipients and Caregivers, in hardcopy or online. ECF Nos. 40-6, at 13–14, 17; 40-14, at 8, 12; 40-20, at 6–7, 10; *see, e.g.*, ECF Nos. 40-3, at 15–16. These Fact Sheets disclose all the information that must be provided to

[15] FDA has clarified that the term "approved" in the EUA statute refers solely to FDA approval. *See* Response Letter to Citizen Petition from FDA CBER to Children's Health Defense, FDA-2021-P-0460-30085, at 29 & n.83 (Aug. 23, 2021), https://go.usa.gov/xMZNu; FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* at 3 n.7 (Jan. 2017), https://go.usa.gov/xMaKg.

[16] That remains true today for all three vaccines. *See* ECF No. 41-2, at 10 & n.18.

vaccination providers and recipients, respectively, under the EUAs. *See* ECF Nos. 40-1; 40-2; 40-3; 40-4; 40-5; 40-12; 40-13; 40-18; 40-19.

Plaintiffs do not dispute this, but instead allege that vaccination providers and recipients "are not," in fact, being informed of the information that they claim must be given. Am. Compl. ¶ 186. This allegation is irrelevant, however, to the question of whether FDA has established "appropriate conditions *designed* to ensure" that vaccination providers and recipients are informed of the specified information. 21 U.S.C. § 360bbb-3(e)(I)(A)(i)–(ii) (emphasis added).

Plaintiffs also make conclusory allegations that there is an "effort to censor information" about the vaccines and that "psychological[] manipulat[ion]" and coercive "rewards and penalties" render "the 'option to [] refuse' meaningless." Am. Compl. ¶¶ 50, 140-44, 186. But Plaintiffs do not plausibly allege that HHS is responsible for the alleged censorship, manipulation, or coercion, which it attributes to "the media," *id.* ¶¶ 50, 142; state or foreign governments, *id.* ¶¶ 142–43; or private businesses and employers, *id.* ¶ 143. As with their prior claims, Plaintiffs fail to plausibly allege any arbitrary or capricious decision or statutory violation by HHS.[17]

Finally, Plaintiffs allege that "only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability." Am. Compl. ¶ 186. But this doubtful allegation of underreporting, *see* ECF No. 41, at ¶ 17, is not plausibly linked

[17] The Amended Complaint alleges that the vaccine recipients "are participants in a large scale, ongoing non-consensual human experiment." Am. Compl. ¶ 144; *see id.* ¶¶ 128–44. But the use of a product within the scope of an EUA "shall not be considered to constitute a clinical investigation" for purposes of the statutes governing such investigations. 21 U.S.C. § 360bbb-3(k). Moreover, the informed consent requirements in 45 C.F.R. Part 46 are inapplicable because they apply only to "research involving human subjects." 45 C.F.R. § 46.101(a). Administration of an EUA-authorized vaccine for clinical care is not "research." 45 C.F.R. § 46.102(*l*).

to any challenged HHS action, and it does not show that HHS failed to establish "[a]ppropriate conditions for the monitoring and reporting of adverse events," 21 U.S.C. § 360bbb-3(e)(1)(A)(iii). Similarly, it is irrelevant that the public allegedly cannot access reports to V-safe, Am. Compl. ¶ 186, because the EUA statute does not require that. Instead, FDA's actions in establishing "[a]ppropriate conditions for the monitoring and reporting of adverse events" are "committed to agency discretion." 21 U.S.C. § 360bbb-3(e)(1)(A)(iii), (i). Plaintiffs have not plausibly alleged any APA violation related to the monitoring or reporting of adverse events.

D. Counts II and VI Fail to State a Claim that the Executive Orders Are Unlawful.

Counts II and VI challenge the issuance of EOs 14042 and 14043. Plaintiffs stated that "[a]ll counts in the amended complaint," including Counts II and VI, "are predicated on 5 U.S.C. §702"—the APA. PI Mot. 41. But Executive Orders "are not reviewable under the APA" because "the President is not an 'agency.'" *Dalton v. Specter*, 511 U.S. 462, 470 (1994). Even assuming the Executive Orders were reviewable, Plaintiffs have not plausibly alleged that they are inconsistent with the Constitution or the President's statutory authority.

1. Plaintiffs Have Not Plausibly Alleged that the Executive Orders Are Unconstitutional.

Count II alleges that the Executive Orders violate Plaintiffs' "fundamental right to bodily integrity" and thus deprive them of substantive due process. Am. Compl. ¶ 179; *see also id.* ¶ 192 (Count VI). But courts have repeatedly held that

vaccine mandates do not violate the fundamental right to bodily integrity, that they are subject to rational basis review, and that they easily pass this test.

Courts "must analyze a substantive due process claim by first crafting a 'careful description of the asserted right.'"[18] *Doe v. Moore*, 410 F.3d 1337, 1343 (11th Cir. 2005) (quoting *Reno v. Flores*, 507 U.S. 292, 302 (1993)). Although Plaintiffs allege that the Executive Orders violate their "fundamental right to bodily integrity," courts have repeatedly held that this is not an accurate description of the interest implicated by COVID-19 vaccine mandates. For example, in *Bauer v. Summey*, No. 2:21-CV-02952-DCN, 2021 WL 4900922 (D.S.C. Oct. 21, 2021), the court held that the challenged vaccine mandate did not violate the plaintiff's right to "bodily integrity," and that "a more appropriate description is plaintiffs' interest in continued employment with defendants while unvaccinated for COVID-19." *Id.* at *9–10; *see also Kheriaty v. Regents of Univ. of Cal.*, No. SACV 21-1367 JVS (KESx), 2021 WL 5238586, at *5 (C.D. Cal. Sept. 29, 2021). Here, similarly, what is at stake is Plaintiffs' interest in holding federal or federal-contractor employment while refusing to be vaccinated against a highly contagious virus.

The Executive Orders contrast sharply with the government actions that the Supreme Court has discussed as implicating the "fundamental right to bodily integrity": "forced administration of life-sustaining medical treatment," *Cruzan ex rel. Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 279 (1990), and "forced

[18] Different substantive due process analyses apply depending on whether the challenged action is executive or legislative in character. *See McKinney v. Pate*, 20 F.3d 1550, 1557 n.9 (11th Cir. 1994) (en banc). The Executive Orders are "broad-ranging executive regulations" and are thus legislative in character. *Id.*

administration of antipsychotic drugs," *Washington v. Harper*, 494 U.S. 210, 236 (1990). Unlike these actions, the Executive Orders do not *force* anyone to receive medical care, but instead allow federal employees and contractors to seek medical and religious exemptions or pursue other employment. *See, e.g.*, *Klaassen v. Trs. of Ind. Univ.*, 2021 WL 3073926, at *25 (N.D. Ind. July 18, 2021) (public university's COVID-19 vaccination requirement was "a far cry" from forcible provision of medical care); *Bridges*, 2021 WL 2399994, at *2 (similar).

After crafting a "careful description of the asserted right," the Court "must determine whether the asserted right is one of those fundamental rights and liberties which are, objectively, 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 they were sacrificed." *Doe*, 410 F.3d at 1343 (quotations omitted). The interest at stake here is not such a fundamental right. As the court explained in *Bauer*, the Supreme Court "expressly rejected the idea of a fundamental right to refuse vaccination" in *Jacobson v. Massachusetts*, 197 U.S. 11, 26–27 (1905), which "upheld a state law allowing cities and towns to implement vaccine mandates in order to contain smallpox outbreaks," *Bauer*, 2021 WL 4900922, at *9; *see also Prince v. Massachusetts*, 321 U.S. 158, 166–67 (1944) (the Constitution does not provide "freedom from compulsory vaccination").[19] Accordingly, within the past

[19] Plaintiffs argue that *Planned Parenthood v. Casey,* 505 U.S. 833 (1992), "largely overturned *Jacobson*." Am. Compl. ¶ 2. Not so. *Casey* cited *Jacobson* with approval. *Casey*, 505 U.S. at 857. Since then, courts have continued to cite *Jacobson*. *See, e.g.*, *Klaasen*, 7 F.4th at 593; *Phillips v. City of N.Y.*, 775 F.3d 538, 542 (2d Cir. 2015); *Bauer*, 2021 WL 4900922, at *9 n.6 ("[T]he majority of courts considering challenges to state and local COVID-19 restrictions have respected *Jacobson*'s precedential value, and the court follows suit today.").

several months, federal courts have repeatedly held that vaccine mandates do not violate a fundamental right. *See Bauer*, 2021 WL 4900922, at *10.[20]

"When a challenged law does not infringe upon a fundamental right, [courts] review substantive due process challenges under the rational basis standard." *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 945 (11th Cir. 2013).[21] "The rational basis test is highly deferential to government action, and the regulation can only be invalidated if it is so unrelated to the achievement of any combination of legitimate purposes that we can only conclude that the legislature's actions were irrational.'" *Ga. Elec. Life Safety & Sys. Ass'n*, 965 F.3d at 1275 (quotations omitted). "[T]hese requirements are generally easily met." *Id.* (quotations omitted).

The Executive Orders easily survive rational basis review. "Stemming the spread of COVID-19 is unquestionably a compelling interest." *Roman Cath. Diocese of Brooklyn*, 141 S. Ct. at 67; *see Florida v. Dep't of Health & Hum. Servs.*, No. 21-14098-JJ, 2021 WL 5768796, at *17 (11th Cir. Dec. 6, 2021). The Executive Orders are rationally related to that compelling interest.[22] *See Rydie*, 2021 WL 5416545, at *4 ("There is a long tradition of upholding *mandatory* vaccination laws under rational basis scrutiny because they were necessary to the public health."); *Bauer*,

[20] *See, e.g.*, *Klaassen*, 7 F.4th 592; *Smith v. Biden*, No. 1:21-cv-19457, 2021 WL 5195688 (D.N.J. Nov. 8, 2021); *Rodriguez-Vélez v. Pierluisi-Urrutia*, No. 21-1366, 2021 WL 5072017, at *15 (D.P.R. Nov. 1, 2021); *Johnson v. Brown*, No. 3:21-CV-1494-SI, 2021 WL 4846060, at *13 (D. Or. Oct. 18, 2021); *Dixon v. De Blasio*, 2021 WL 4750187, at *8 (E.D.N.Y. Oct. 12, 2021); *Norris v. Stanley*, No. 1:21-CV-756, 2021 WL 4738827, at *2 (W.D. Mich. Oct. 8, 2021); *Kheriaty*, 2021 WL 5238586, at *6; *Valdez v. Grisham*, No. 21-CV-783 MV/JHR, 2021 WL 4145746, at *5 (D.N.M. Sept. 13, 2021).

[21] Justice Gorsuch explained that "[a]lthough *Jacobson* pre-dated the modern tiers of scrutiny," the Supreme Court "essentially applied rational basis review" to a government-imposed vaccination requirement. *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 70 (2020) (Gorsuch, J., concurring).

[22] Indeed, Plaintiffs have not argued that the Executive Orders lack a rational basis.

2021 WL 4900922, at *10–11 ("numerous courts have recognized that preventing the spread of COVID-19 provides a rational justification for vaccine mandates"). Moreover, "the Government has a much freer hand in dealing with citizen employees than it does when it brings its sovereign power to bear on citizens at large." *NASA v. Nelson*, 562 U.S. 134, 148 (2011) (quotations omitted). "Like private individuals and businesses, the Government enjoys the unrestricted power . . . to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Perkins v. Lukens Steel Co.*, 310 U.S. 113, 127 (1940). Thus, Plaintiffs have failed to state a substantive due process claim.

2. Plaintiffs Have Not Plausibly Alleged that the Executive Orders Exceed the President's Statutory Authority.

The Amended Complaint alleges that EO 14042 is not authorized by the Federal Property and Administrative Services Act ("Procurement Act"), 40 U.S.C. § 101, *et seq.*; that EO 14043 is not authorized by 5 U.S.C. §§ 3301, 3302 and 7301; and that both Executive Orders violate the EUA statute. Am. Compl. ¶¶ 159, 166, 192. But none of these statutes waive the federal government's sovereign immunity or authorize a private right of action here. *See, e.g.*, *Guilfoyle v. Beutner*, No. 2:21-cv-5009, 2021 WL 4594780, at *27 (C.D. Cal. Sept. 14, 2021). Although *Larson v. Domestic and Foreign Commerce Corp.*, 337 U.S. 682 (1949), may permit an action against a government official who acts outside his statutory authority, *id.* at 689–90, *Larson* is a doctrine "of last resort intended to be of extremely limited scope." *Terveer v. Billington*, 34 F. Supp. 3d 100, 123 (D.D.C. 2014) (quoting *Griffith v. Fed. Labor Relations Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988)). An officer acts *ultra*

vires "only when he acts 'without any authority whatever.'" *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 101–02 n.11 (1984) (citation omitted). As explained below, this standard is not satisfied for either of the Executive Orders.

EO 14042 is authorized by the Procurement Act, which broadly empowers the President to "prescribe policies and directives that the President considers necessary to carry out" the Act's provisions, so long as they are "consistent" with the Act. 40 U.S.C. § 121(a). This requires that they be "reasonably related to the Procurement Act's purpose of ensuring efficiency and economy in government procurement." *Liberty Mut. Ins. Co. v. Friedman*, 639 F.2d 164, 170 (4th Cir. 1981). "Efficiency" and "economy" are "not narrow terms," *AFL-CIO v. Kahn*, 618 F.2d 784, 789 (D.C. Cir. 1979) (en banc), and the statute gives the President "necessary flexibility and 'broad-ranging authority'" to carry out its goals, *UAW-Labor Emp. & Training Corp. v. Chao*, 325 F.3d 360, 366 (D.C. Cir. 2003); *see also Chamber of Com. v. Reich*, 74 F.3d 1322, 1333 (D.C. Cir. 1996) (providing examples of Executive Orders authorized by the Procurement Act); *Kahn*, 618 F.2d at 788.

EO 14042 easily satisfies this "lenient" standard. *See Chao*, 325 F.3d at 367. As a proprietor like "private individuals and businesses," the federal government may "determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases." *Perkins*, 310 U.S. at 127. The President, as ultimate manager of procurement operations, determined that workplace safeguards aimed at preventing the spread of COVID-19 will "decrease worker absence, reduce labor costs, and improve the efficiency of contractors and subcontractors at sites where they are performing work for the Federal Government."

86 Fed. Reg. at 50,985. Slowing the spread of COVID-19 promotes efficiency and economy for the simple reason that federal procurement—like any other business endeavor—suffers when the employees of entities the government contracts with get sick and miss work. *See Florida*, 2021 WL 5768796, at *12 (explaining, in the context of a healthcare worker COVID-19 vaccine mandate, that it is "highly inefficient for facility employees to be out sick with COVID-19"). Thus, EO 14042 is within the President's authority under the Procurement Act.[23]

EO 14043 is authorized by 5 U.S.C. §§ 3301, 3302 and 7301. Am. Compl. ¶ 166. Section 3301 broadly authorizes the President to "prescribe such regulations for the admission of individuals into the civil service in the executive branch as will best promote the efficiency of that service." Section 3302 authorizes the President to "prescribe rules governing the competitive service," and section 7301 authorizes him to "prescribe regulations for the conduct of employees in the executive branch." *See Clarry v. United States*, 85 F.3d 1041, 1047 (2d Cir. 1996) ("The President has broad authority pursuant to 5 U.S.C. §§ 3301 and 7301 to regulate employment matters . . . ."). These statutes authorize EO 14043, which is based on the President's "determin[ation] that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID-19 vaccination for all Federal employees, subject to [required] exceptions." 86 Fed. Reg. at 50,989.

[23] Two district courts have found to the contrary in the preliminary injunction context. *Georgia*, 2021 WL 5779939; *Kentucky v. Biden*, No. 3:21-CV-00055-GFVT, 2021 WL 5587446 (E.D. Ky. Nov. 30, 2021), *appeal filed*, No. 21-6147 (6th Cir. Dec. 6, 2021). But those decisions are inconsistent with longstanding precedent holding that the Procurement Act gives the President "necessary flexibility and 'broad-ranging authority,'" *Chao*, 325 F.3d at 366, to carry out its goals of "ensuring efficiency and economy in government procurement," *Liberty Mut. Ins. Co.*, 639 F.2d at 170.

Finally, Plaintiffs have not plausibly alleged that the Executive Orders violate the provisions of the EUA statute directing FDA to establish "[a]ppropriate conditions designed to ensure that [vaccine recipients] are informed" of certain information, including "the option to accept or refuse administration of the" vaccine. 21 U.S.C. § 360bbb-3(e)(1)(A)(ii); Am. Compl. ¶ 167. Federal employees and contractors might receive the Pfizer vaccine from lots that were "manufactured in compliance with the [BLA]" and that are "not subject to the EUA requirements" because they are "used for the approved indication." ECF No. 41 ¶ 15. Any dispute regarding the EUA statute is therefore moot. *See Norris v. Stanley*, No. 1:21-cv-756, 2021 WL 3891615, at *2 (W.D. Mich. Aug. 31, 2021). Moreover, the EUA statute does not prohibit the government from requiring vaccination with an EUA product as a condition of continued employment. Instead, it directs HHS to establish "[a]ppropriate conditions designed to ensure that [vaccine recipients] are informed" of certain information, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii), which is satisfied by the Fact Sheets. As numerous courts have held, this informational requirement does not prevent any entity (including the government) from imposing workplace discipline, including termination, on employees who choose not to receive an EUA vaccine.[24]

[24] *See Bridges*, 2021 WL 2399994, at *2; *Valdez*, 2021 WL 4145746, at *4; *Norris v. Stanley*, No. 1:21-cv-756, 2021 WL 4738827, at *3 (W.D. Mich. Oct. 8, 2021); *Johnson v. Brown*, No. 3:21-cv-1494, 2021 WL 4846060, at *18 (D. Or. Oct. 18, 2021); *Pelekai v. Hawaii*, No. 1:21-cv-343, 2021 WL 4944804, at *6 n.9 (D. Haw. Oct. 22, 2021).

III. Plaintiffs' Preliminary Injunction Motion Should Be Denied.

A. Legal Standard

A preliminary injunction is "the exception rather than the rule." *Brown v. Sec'y, U.S. Dep't of Health & Hum. Servs.*, 4 F.4th 1220, 1224 (11th Cir. 2021). Plaintiffs must establish that (1) they are "likely to succeed on the merits," (2) they are "likely to suffer irreparable harm in the absence of preliminary relief," (3) "the balance of equities tips in [their] favor," and (4) "an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Court may not grant this "extraordinary and drastic remedy" unless Plaintiffs "clearly established the 'burden of persuasion' as to each of the four prerequisites." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc) (per curiam). Plaintiffs have not met their burden on any of these factors.

B. Plaintiffs Are Not Likely to Succeed on the Merits.

As discussed above, the Amended Complaint must be dismissed because Plaintiffs have not plausibly alleged subject matter jurisdiction or stated claims upon which relief can be granted. For the same reasons, Plaintiffs have not shown a likelihood of success on the merits. *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).").

Additionally, Plaintiffs seek "a preliminary injunction enjoining enforcement of EOs 14042 and 14043, and every rule, directive, and guidance based thereon." PI Mot. 43. Yet "injunctive relief must relate in some fashion to the relief requested in

the complaint" and must be "of the same character as that which may be granted finally." *Alabama v. U.S. Army Corps of Eng'rs*, 424 F.3d 1117, 1134 (11th Cir. 2005). Because the Amended Complaint does not challenge any "rule, directive, [or] guidance based" on the Executive Orders, those actions may not be the subject of a preliminary injunction.

Properly construed, Plaintiffs' motion seeks to enjoin only the Executive Orders. But Plaintiffs stated that "[a]ll counts in the amended complaint are predicated on 5 U.S.C. § 702," PI Mot. 41, and Executive Orders "are not reviewable under the APA" because "the President is not an 'agency.'" *Dalton*, 511 U.S. at 470. Thus, Plaintiffs cannot show a likelihood of success on the merits.

Plaintiffs argue that the issuance of the EUAs violated the misbranding statute, 21 U.S.C. § 352(j). PI Mot. 34–37. But Plaintiffs' motion does not seek to enjoin the EUAs. Moreover, Plaintiffs fail to identify any evidence in "the existing administrative record," *Dep't of Commerce*, 139 S. Ct. at 2573; *see Mahon*, 485 F.3d at 1254–55, showing the vaccines are "dangerous to health when used" according to the FDA-approved labeling, 21 U.S.C. § 352(j).

Plaintiffs' motion also impermissibly asserts new claims that were not alleged in the Amended Complaint. For example, Plaintiffs' motion argues for the first time that the Executive Orders violate the separation of powers and the nondelegation doctrine[25] and that the federal government has infringed on the states' prerogative to

[25] In support of this new argument, Plaintiffs cite *Alabama Association of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021); PI Mot. 31–32, which addressed whether the Public Health Service Act, 42 U.S.C. § 264(a), authorized CDC's eviction moratorium due to the COVID-19 pandemic. That case is inapposite because it addressed whether a different government action was authorized under a different statute. Unlike the Executive Orders,

regulate the practice of medicine. PI Mot. 25–37. To obtain a preliminary injunction, however, a plaintiff must show "it has a substantial likelihood of success on the merits of the underlying case when the case is ultimately tried." *U.S. Army Corps of Eng'rs*, 424 F.3d at 1128; *see id.* at 1134 (plaintiff "must demonstrate a substantial likelihood of prevailing on at least one of the causes of action he has asserted"). "A district court should not issue an injunction" that "is not of the same character, and deals with 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); *see also Bruce v. Reese*, 431 F. App'x 805, 806 n.1 (11th Cir. 2011). Plaintiffs here cannot show a likelihood of success on the merits based on the claims they raise for the first time in their preliminary injunction motion.

Even if the Court reached the merits of these new arguments, they would fail. To show an impermissible delegation of legislative authority, Plaintiffs must show that Congress failed to "lay down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001) (quotations omitted). But the Supreme Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law," and it has even "found an 'intelligible principle' in various statutes authorizing regulation in the 'public interest.'" *Id.* at 474–75 (quotations

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moreover, CDC's eviction moratorium did not implicate the federal government's "much freer hand in dealing with citizen employees," *Nelson*, 562 U.S. at 148, and its "unrestricted power . . . to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases," *Perkins*, 310 U.S. at 127.

omitted). The statutes authorizing the Executive Orders provide at least as much of an "intelligible principle" as regulation in the "public interest." Plaintiffs also cannot succeed on their claim that the federal government has intruded on the states' prerogative to regulate the practice of medicine because neither the Executive Orders, nor the EUAs, nor any liability protections for entities involved in vaccine administration regulate the practice of medicine.

Finally, Exhibits 5 and 6 to Plaintiffs' motion do not show a likelihood of success on the merits. Relying on Exhibit 5, Plaintiffs contend that FDA and manufacturers "ignored" several "probable harms" of the EUA vaccines. PI Mot. 35. But this argument blatantly misconstrues the public record. Exhibit 5 is an excerpt from a slide deck used at an October 22, 2020, public meeting of FDA's vaccines advisory committee, during which CDC and FDA discussed plans to monitor for "possible adverse event outcomes of interest" for "any new COVID-19 vaccine." Mtg. Tr. at 122, https://go.usa.gov/xemdx; *see id.* at 96–99, 121. The agencies also shared draft working lists of possible surveillance events, which would be refined after reviewing "sponsor safety data submitted to FDA," "the literature and regulatory experience with these vaccines," and "other relevant data." *Id.* at 121; *see* CDC Presentation, https://go.usa.gov/xemdp (slides 31–32); FDA Presentation, https://go.usa.gov/xemdP (slide 16). Accordingly, the slide in Exhibit 5 is titled, "FDA Safety Surveillance of COVID-19 Vaccines: Draft Working list of possible adverse event outcomes ***Subject to change***." Far from a conspiracy to suppress information, Exhibit 5 simply reflects FDA's transparent process to devise a useful surveillance system for vaccine adverse events.

Exhibit 6 purports to provide "Data from [the] Medicare System" showing that "51,100 beneficiaries died within 14 days after the COVID-19 vaccine." *See* PI Mot. 14. The exhibit does not identify where Plaintiffs obtained these data, and Plaintiffs did not respond to Defendants' November 29, 2021, email requesting this information. There is thus no way to verify or evaluate the data. Even taking Exhibit 6 on face value, it does not identify the Medicare beneficiaries' cause of death, let alone show that they died because of the vaccine. As Dr. Marks explained, VAERS "reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness" because "vaccination providers are required to report to VAERS serious adverse events following vaccination with the COVID-19 vaccines 'irrespective of attribution to vaccination.'" ECF No. 41, at ¶ 17. In short, Plaintiffs have not met their burden of showing a likelihood of success on the merits.

C. Plaintiffs Have Not Shown Imminent, Irreparable Harm.

A preliminary injunction is designed to protect a plaintiff from future irreparable harm it would suffer "before a case can be resolved on its merits." *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016); *see Brown*, 4 F.4th at 1225. Preventing future irreparable harm is "the *sine qua non* of injunctive relief." *U.S. Army Corps of Eng'rs*, 424 F.3d at 1133.

As an initial matter, the Southern District of Georgia has issued a nationwide preliminary injunction enjoining enforcement of EO 14042. *Georgia*, 2021 WL 5779939, at *12. Plaintiffs therefore cannot show that they would suffer future imminent, irreparable harm from EO 14042 before this case can be resolved on the merits. *See Wreal*, 840 F.3d at 1248.

Plaintiffs' irreparable harm argument is based entirely on their contention that the Executive Orders deprive them of substantive due process by violating their fundamental right to bodily integrity. PI Mot. 37–38. But this contention fails. *See supra* pp. 30–34. Even looking beyond Plaintiffs' erroneous framing of their argument, Plaintiffs still fail to show irreparable harm. They argue that they will be forced "to take a shot against their will." PI Mot. 38. But *no one* has been—or will be—vaccinated "against their will" under the Executive Orders. The individual Plaintiffs face no imminent risk of *any* harm, moreover, because they may request medical or religious accommodations and avoid any adverse employment actions while their requests are pending. *See* ECF No. 39, at ¶¶ 8, 11; *Church*, 2021 WL 5179215, at *13. An injunction is thus unnecessary to protect them from harm "before [this] case can be resolved on its merits." *Wreal*, 840 F.3d at 1248; *see Rodden v. Fauci*, No. 3:21-CV-317, 2021 WL 5545234, at *2 (S.D. Tex. Nov. 27, 2021) (finding it "too speculative to say that the plaintiffs who have claimed an exemption [from EO 14043] are in imminent danger of irreparable harm" because "[t]here is little to suggest either how soon the exemption claims will be resolved or how likely the claimants are to prevail"); *Church*, 2021 WL 5179215, at *13.[26]

No more irreparable are any adverse employment consequences, including termination, that Plaintiffs may face if their accommodation requests are denied and they choose to remain unvaccinated. The loss of employment does not normally

[26] Plaintiffs also baselessly assert that "the vaccines as first developed and tested were more dangerous than those being used today." PI Mot. 25. But even if true, it would undermine Plaintiffs' irreparable harm argument because Plaintiffs' purported evidence of past harms from the vaccines would not be probative of future harms. *See U.S. Army Corps of Eng'rs*, 424 F.3d at 1133 (preventing future irreparable harm is "the *sine qua non* of injunctive relief'").

constitute irreparable harm. *See Sampson v. Murray*, 415 U.S. 61, 90, 92 n.68 (1974). If Plaintiffs are right on the merits, they may seek appropriate relief, such as back pay and reinstatement, for any unlawful workplace discipline. *See id.* at 90–91; *Rydie*, 2021 WL 5416545, at *5 (no irreparable harm to federal employees challenging EO 14043); *Church*, 2021 WL 5179215, at *15 (same).

D. Neither the Equities nor the Public Interest Favors an Injunction.

"Because the government is the party opposing a preliminary injunction here, its interest and harm merge with the public interest, so [the Court] may consider the third and fourth factors together." *Brown*, 4 F.4th at 1224 (quotations omitted).

The balance of equities and the public interest strongly favor Defendants because enjoining the Executive Orders would greatly harm the public. COVID-19 has already infected over 50 million Americans, hospitalized over 3.5 million, and killed over 800,000.[27] "Stemming the spread of COVID-19 is unquestionably a compelling interest." *Roman Cath. Diocese of Brooklyn*, 141 S. Ct. at 67. As President Biden observed, CDC "has determined that the best way to slow the spread of COVID-19 and to prevent infection by the Delta variant or other variants is to be vaccinated." 86 Fed. Reg. 50989. Any "injunction affecting the Pfizer-BioNTech vaccine EUA would greatly harm the public," "call into question" FDA's scientific determination that Pfizer's EUA vaccine and Comirnaty "are safe and effective," create "considerable public and administrative confusion" given that Pfizer's EUA vaccine and Comirnaty are "medically interchangeable," and exacerbate "vaccine hesitancy." ECF No. 41, at ¶ 19. Accordingly, the federal government's compelling

[27] CDC, COVID Data Tracker Weekly Review, https://go.usa.gov/xFU9U.

interest in stemming the spread of COVID-19 "would be impeded by [the requested] injunction." *Rydie*, 2021 WL 5416545, at *5.

Furthermore, "[t]he effective administration of the federal government, in which Defendants and the public have a deep and abiding interest, would likely be hampered by an injunction." *Id.* As President Biden reasonably determined, the Executive Orders are necessary "to promote the health and safety of the Federal workforce and the efficiency of the civil service" and to promote "economy and efficiency in Federal procurement." 86 Fed. Reg. 50989; 86 Fed. Reg. 50985.

Notably, the Executive Orders do not *force* anyone to receive a vaccine, but instead allow federal employees and contractors to seek medical and religious exemptions or pursue other employment. Thus, the Executive Orders strike a careful balance between the federal government's compelling interest in stemming the spread of COVID-19 and certain individuals' medical or religious reasons for declining vaccination. The balance of equities and the public interest, therefore, strongly oppose the requested injunction.

Finally, if an injunction is granted, it should be limited to the Executive Orders as applied to Plaintiffs. *See Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018) ("A plaintiff's remedy must be tailored to redress the plaintiff's particular injury.").

CONCLUSION

For the foregoing reasons, 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.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 17, 2021, 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/ James W. Harlow
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