FILED
2021 Sep-16 PM 05:12
U.S. DISTRICT COURT
N.D. OF ALABAMA

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

AMERICA'S FRONTLINE DOCTORS, *et al.*, Plaintiffs, v. XAVIER BECERRA, *et al.*, Defendants.	CIVIL ACTION NO. 2:21-CV-702-CLM **OPPOSED**

COMBINED MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS FOR LACK OF JURISDICTION, IMPROPER VENUE, AND FAILURE TO STATE A CLAIM, AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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INTRODUCTION

Since the COVID-19 pandemic began in the United States in early 2020, over 40.5 million Americans have been infected, over 2.8 million Americans have been hospitalized, and over 652,000 Americans have died. These numbers continue to rise: over the past week, there was an average of over 136,000 new infections per day, over 11,700 hospital admissions per day, and over 1000 deaths per day. COVID-19 affects both children and adults: over 4.4 million children age 17 and under have been infected, over 57,600 have been hospitalized, and over 500 have died.[1]

To protect themselves from COVID-19, millions of Americans have chosen to receive one of the COVID-19 vaccines manufactured by Pfizer, Inc. ("Pfizer"), ModernaTX, Inc. ("Moderna"), or Johnson & Johnson/Janssen Biotech, Inc. ("Janssen") (collectively, the "COVID-19 vaccines"), which received Emergency Use Authorizations ("EUAs") from the U.S. Food and Drug Administration ("FDA"). The Pfizer vaccine was recently approved by FDA for persons ages 16 and older.[2]

Over 210 million Americans have received at least one dose of a COVID-19 vaccine (over 63% of Americans), and over 179 million Americans are now fully vaccinated (over 54% of Americans).[3] Nonetheless, millions of Americans have not

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[1] Centers for Disease Control and Prevention ("CDC"), COVID Data Tracker Weekly Review: Interpretive Summary for Sept. 10, 2021, https://go.usa.gov/xFU9U; CDC, Demographic Trends of COVID-19 Cases and Deaths in the US Reported to CDC, https://go.usa.gov/xFU9t (posted Sept. 15, 2021); CDC, New Hospital Admissions, https://go.usa.gov/xFU9K (last updated Sept. 15, 2021).

[2] Comirnaty BLA Approval (Aug. 23, 2021), https://go.usa.gov/xM3nZ.

[3] CDC, COVID-19 Vaccinations in the United States, https://go.usa.gov/xFQXD (posted Sept. 15, 2021). Americans ages 12 and older are eligible to receive at least one of the COVID-19 vaccines.

yet received a vaccine, and more than half a million vaccine doses were administered in the last week alone. Plaintiffs America's Frontline Doctors ("AFLDS")—a not-for-profit healthcare advocacy organization comprising "hundreds of member physicians that come from across the country," Compl. ¶ 12—and 24 individuals seek to deprive Americans of the opportunity to get vaccinated.

Plaintiffs oppose the vaccines and dispute that the country is even in a public health emergency. AFLDS members and the individual Plaintiffs allegedly do not want to be vaccinated themselves, do not want their families to be vaccinated, and do not want others to receive the vaccines. The Complaint does not allege, though, that they or their families will imminently be required to receive the vaccines or that they will imminently be required to encourage others to receive them, let alone that such a requirement is traceable to any challenged action of Defendants. Plaintiffs can avoid any purported injury by refusing the vaccines for themselves and their families and declining to encourage others to receive them.

Not content to avoid injury to themselves, Plaintiffs ask the Court to invalidate the vaccine EUAs nationwide and prohibit FDA from fully approving the vaccines. This relief would prevent millions of Americans who have not yet received a vaccine and who are not parties to this litigation from receiving one. Every week, hundreds of thousands of Americans are choosing to receive a vaccine to protect themselves from COVID-19,[4] and Plaintiffs seek to take this choice away from them.

See Vaccine Information Fact Sheet for Recipients and Caregivers About Comirnaty (COVID-19 Vaccine, mRNA) and Pfizer-BioNtech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19), at 1, https://go.usa.gov/xFvry (last revised Aug. 23, 2021).

[4] COVID Data Tracker Weekly Review: Interpretive Summary for Sept. 10, 2021.

Plaintiffs undoubtedly may advocate against the vaccines and submit their arguments in a Citizen Petition to FDA. But to obtain an order from this Court invalidating the vaccine EUAs and blocking the vaccines' approval, Plaintiffs must plausibly allege that this Court has subject matter jurisdiction. Plaintiffs have failed to meet this burden for three reasons.

First, Plaintiffs have not set forth allegations sufficient to establish Article III standing to seek injunctive relief. Plaintiffs have not alleged, as they must, that they are subject to any actual or imminent vaccine mandate traceable to Defendants' challenged conduct. Moreover, the only potential bases for venue in this District are the claims by the eight Plaintiffs who reside in Alabama—Lyle and Julie Bloom, Greenslade, McFarlane, Miller, Roth, and Jody and Deborah Sobczak (the "Alabama Plaintiffs")—but each of these Plaintiffs lacks standing, so this case can be dismissed for improper venue without reaching the standing of the other Plaintiffs.

Second, the EUAs and related Public Health Emergency Declaration ("Emergency Declaration") are unreviewable under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, because 21 U.S.C. § 360bbb-3(a)(1) (the "EUA statute") expressly commits decisions under its authority to agency discretion. *Finally*, the Court does not have jurisdiction over Plaintiffs' mandamus claim because Defendants do not have a clear duty to act and Plaintiffs have an alternative remedy in the form of a Citizen Petition.

Even if the Court reached the merits, Plaintiffs have failed to state plausible claims for relief. Plaintiffs' APA claims (Counts I–III) rely on allegations that are beyond the scope of the existing administrative record and were never presented to

FDA before filing suit. These allegations thus cannot show that the decisions to issue the Emergency Declaration and EUAs were arbitrary and capricious. Plaintiffs' claim for a violation of customary international law (Count IV) fails for lack of a private right of action. Finally, Plaintiffs fail to state a claim under 45 C.F.R. Part 46 (Count V) because the use of the vaccines for clinical care under the EUAs is not a clinical investigation, and Plaintiffs fail to state a mandamus claim (Count VI) because Defendants do not have a clear duty to act and Plaintiffs have an alternative Citizen Petition remedy.

Plaintiffs have also failed to show they are entitled to the extraordinary remedy of a mandatory preliminary injunction. They are not likely to succeed on the merits because they have not established the Court's subject matter jurisdiction and they failed to state a plausible claim for relief. Nor can they assert new claims and seek new relief in their preliminary injunction motion. Plaintiffs have not shown irreparable harm because they do not face an imminent risk of future harm; indeed, they delayed for months before seeking a preliminary injunction. Finally, the balance of equities and the public interest oppose an injunction: whereas Plaintiffs do not face imminent irreparable harm absent an injunction, the public would be severely harmed by the requested relief, which would deprive millions of Americans of the opportunity to be vaccinated against COVID-19.

BACKGROUND

I. Statutory and Regulatory Background

A. In Public Health Emergencies, FDA Has Discretion to Permit the Distribution of Unapproved Products Through EUAs.

The Public Health Service Act governs the approval and marketing of "biological product[s]," which include vaccines. 42 U.S.C. § 262(i)(1). Normally, a "manufacturer of a biologic may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in [section] 262" of the Public Health Service Act. *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670 (2017). But in certain cases of "an actual or potential emergency," Congress empowered FDA to authorize the marketing of biological products (and other FDA-regulated products) "intended for use" in responding to the emergency. 21 U.S.C. § 360bbb-3(a)(1).

The EUA process begins when the Secretary declares that an EUA is justified based on a determination of emergency or threat, such as the Secretary's determination that "there is a public health emergency." *Id.* § 360bbb-3(b). Once the Secretary makes such a declaration, FDA may issue an EUA for use of an FDA-regulated product if certain criteria are met. *First*, the biological or other agent underlying the emergency declaration "can cause a serious or life-threatening disease or condition." *Id.* § 360bbb-3(c)(1). *Second*, "based on the totality of scientific evidence available to the Secretary, . . . it is reasonable to believe" that (1) the authorized product "may be effective in diagnosing, treating, or preventing" that "disease or condition" and (2) "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the

known and potential risks of the product." *Id.* § 360bbb-3(c)(2). *Third*, "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." *Id.* § 360bbb-3(c)(3).

The issuance of an EUA does not constitute approval of the product. *See id*. § 360bbb-3(a)(3). However, the individual use of a product under an EUA "shall not be considered to constitute a clinical investigation" for purposes of specified statutes governing clinical investigations. *Id.* § 360bbb-3(k).

For an emergency use of an unapproved product, such as the COVID-19 vaccines[5] (except the Pfizer vaccine administered to persons ages 16 and older, which has been approved), FDA shall, "to the extent practicable given the applicable circumstances," establish "[a]ppropriate conditions," as FDA finds "necessary or appropriate to protect the public health," for the use of EUA products. *Id.* § 360bbb-3(e)(1)(A). These include conditions designed to ensure that the people administering and receiving the product are informed "(I) that [FDA] has authorized the emergency use of the product; (II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and (III) of the alternatives to the product that are available, and of their benefits and risks." *Id.* § 360bbb-3(e)(1)(A)(i). They also include conditions to ensure that the product's recipients are informed "of the option to accept or refuse administration of the product." *Id.* § 360bbb-3(e)(1)(A)(ii). And

[5] Letter of Authorization from FDA to Pfizer Inc. (May 10, 2021), ECF No. 24-3, at 3, 11; Letter of Authorization from FDA to ModernaTX, Inc. (Feb. 25, 2021), ECF No. 24-8, at 2, 10; Letter of Authorization from FDA to Janssen Biotech, Inc. (June 10, 2021), ECF No. 24-12, at 2, 10.

they include "conditions for the monitoring and reporting of adverse events associated with the emergency use of the product." *Id.* § 360bbb-3(e)(1)(A)(iii).

The EUA statute provides that all "[a]ctions under [its] authority . . . are committed to agency discretion." *Id.* § 360bbb-3(i).

B. After Reviewing Extensive Scientific Data, FDA Exercised Its Discretion to Issue EUAs for the COVID-19 Vaccines.

In February 2020, the Secretary determined that a public health emergency existed involving COVID-19. Determination of Public Health Emergency, 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). In March 2020, the Secretary issued an additional declaration based on his February 2020 determination, declaring 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).[6]

In December 2020, FDA issued EUAs for the Pfizer and Moderna vaccines. *See* ECF Nos. 24-3, 24-8.[7] The Pfizer EUA was initially for persons ages 16 and older, and in May 2021, the EUA was extended to persons ages 12 and older. *See* ECF No. 24-3, at 2–5. The Moderna EUA is for persons ages 18 and older. *See* ECF

[6] Count I of the Complaint challenges the Secretary's February 2020 declaration, but not his March 2020 declaration. *See* Compl. ¶ 258. This brief will refer to the Secretary's February 2020 declaration as the "Emergency Declaration."

[7] Because "standing must be determined as of the time at which the plaintiff's complaint is filed," *Focus on the Fam. v. Pinellas Suncoast Transit Auth.*, 344 F.3d 1263, 1275 (11th Cir. 2003), through the Burk Declaration, ECF No. 24, this brief cites the versions of the relevant documents that were in effect when Plaintiffs filed the Complaint on June 10, 2021. For this motion to dismiss, the Court may take judicial notice of these exhibits—all of which were "publicly available on FDA's website," ECF No. 24, at ¶ 6— and other information available on government websites. *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).

No. 24-8, at 2–4. In February 2021, FDA issued an EUA for the Janssen vaccine for persons ages 18 and older. *See* ECF No. 24-12, at 2–4.

The EUAs were based on FDA's review of extensive safety and efficacy data. The Pfizer EUA was based on a clinical trial with approximately 46,000 participants, including 2,260 participants ages 12 to 15. ECF No. 24-3, at 3–4. The Moderna EUA was based on a clinical trial with approximately 30,000 participants; Janssen involved a clinical trial with approximately 43,000 participants. ECF Nos. 24-8, at 3; 24-12, at 3. After reviewing the data from these trials, FDA concluded 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. 24-3, at 3; 24-8, at 2; 24-12, at 2.

The EUAs require vaccination providers to give each vaccine recipient a "Fact Sheet for Recipients and Caregivers" (collectively, the "Fact Sheets"), either in hardcopy or online, and to communicate information from the Fact Sheets.[8] ECF Nos. 24-3, at 6, 10; 24-8, at 5, 9; 24-12, at 5, 9; *see* Pfizer Provider Fact Sheet, ECF No. 24-2, at 9; Moderna Provider Fact Sheet, ECF No. 24-7, at 5–6; Janssen Provider Fact Sheet, ECF No. 24-11, at 5. The Fact Sheets advise potential recipients that "[i]t is your choice to receive or not receive" the vaccine. Pfizer Recipient Fact Sheet,

[8] The EUAs also require vaccination providers to "participate [in] and comply with the terms and training required by CDC's COVID-19 Vaccination Program," which mandates that vaccination providers give a Fact Sheet to each vaccine recipient. ECF No. 24-3, at 10; ECF No. 8, at 9; ECF No. 12, at 9; CDC, COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets for Recipients and Caregivers, https://go.usa.gov/xFQ9A (last reviewed Aug. 6, 2021).

ECF No. 24-1, at 5; Moderna Recipient Fact Sheet, ECF No. 24-6, at 5; Janssen Recipient Fact Sheet, ECF No. 24-10, at 5.[9] They 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 or cleared product" and is authorized based on a determination that it "may be effective to prevent COVID-19." ECF Nos. 24-1, at 2–4, 7; 24-6, at 2–3, 6; 24-10, at 2–3, 7.

The Fact Sheets disclose the potential side effects of the vaccines. For example, they disclose that the vaccines "could cause a severe allergic reaction," manifesting in symptoms such as "[d]ifficulty breathing," "[d]izziness and weakness," and that other side effects may include "fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever." ECF Nos. 24-1, at 4; 24-6, at 4; 24-10, at 4–5. They warn that other "[s]erious and unexpected side effects may occur." ECF Nos. 24-1, at 4; 24-6, at 3; 24-10, at 4. The Pfizer and Moderna Fact Sheets also disclose that the vaccines include "messenger ribonucleic acid (mRNA)." ECF Nos. 24-1, at 3; 24-6, at 3. Finally, all the Fact Sheets provide websites and telephone numbers to obtain more information about the vaccines. ECF Nos. 24-1, at 6; 24-6, at 5–6; 24-10, at 5.

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." U.S. Dep't of Health & Human Servs., About VAERS,

[9] This brief will cite the Fact Sheets that were in effect when Plaintiffs filed the Complaint. *See Focus on the Fam.*, 344 F.3d at 1275.

https://go.usa.gov/xFEc6 (last visited Sept. 16, 2021); *see* ECF Nos. 24-3, at 8, 10; 24-8, at 7, 9; 24-12, at 7, 9. 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 (last updated Sept. 3, 2021); *see also* Compl. ¶ 270(e).

C. FDA Approved 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. Comirnaty BLA Approval (Aug. 23, 2021), https://go.usa.gov/xM3nZ. FDA determined that the vaccine was over 91% effective in preventing COVID-19 disease and between 95% and 100% effective in preventing severe COVID-19 disease, based on effectiveness data from approximately 20,000 vaccine recipients and 20,000 placebo recipients. Comirnaty Approved Prescribing Information, at 15–18, https://go.usa.gov/xM3nG (last revised 8/2021). FDA also determined that the product was safe based on data from approximately 12,000 vaccine recipients, each of whom was monitored for at least six months. *Id.* at 12. Although the Pfizer vaccine is now approved for individuals ages 16 and older to receive the standard two-dose series, the Pfizer EUA remains in effect for individuals ages 12 and older and to provide a third dose to certain immune-compromised individuals. *See* Re-issued Pfizer EUA Letter of Authorization (Aug. 23, 2021), https://go.usa.gov/xMBXr .[10]

[10] Although Comirnaty is approved to prevent COVID-19 in individuals 16 years of age and older, FDA has not revoked the Pfizer EUA because the agency found that "there is not sufficient approved vaccine available for distribution to this population in its entirety" at the time of Comirnaty's approval, and because the Pfizer EUA covers individuals age 12 through 15 and the provision of an additional dose to the immunocompromised population. *Id.* at 5 n.9.

II. Procedural History

On May 19, 2021, Plaintiffs filed a motion for a Temporary Restraining Order against Xavier Becerra, Secretary of Health and Human Services, and the U.S. Department of Health and Human Services to enjoin the extension of the COVID-19 vaccine EUAs to children under the age of 16. ECF No. 1. On May 24, the Court denied Plaintiffs' motion because it found "no specific facts in the motion or attached affidavits that 'clearly show that immediate and irreparable injury, loss, or damage will result to the [Plaintiffs] before [the Government Defendants] can be heard in opposition.'" ECF No. 3 (quoting Fed. R. Civ. P. 65(b)(1)(A)).

On June 10, 2021, Plaintiffs filed their Complaint, seeking invalidation of the Emergency Declaration and COVID-19 vaccine EUAs based on the APA, customary international law, 45 C.F.R. Part 46, and 28 U.S.C § 1361. *See* Compl., ECF No. 10, at ¶¶ 257–85. These claims are asserted against the U.S. Department of Health and Human Services; FDA; CDC; the National Institutes of Health; the National Institute of Allergies and Infectious Diseases ("NIAID"); and, in their official capacities, Secretary Becerra; Dr. Anthony Fauci, Director of NIAID; and Dr. Janet Woodcock, Acting Commissioner of Food and Drugs (collectively, "HHS").[11]

[11] Plaintiffs' "claims for injunctive or declaratory relief . . . are considered to be official capacity claims against" HHS. *Edwards v. Wallace Cmty. Coll.*, 49 F.3d 1517, 1524 n.9 (11th Cir. 1995). The Complaint also asserts a claim for money damages against Secretary Becerra, Dr. Fauci, and Dr. Woodcock in their individual capacities (Count VII). *See* Compl. ¶¶ 286–96. On August 28, 2021, Plaintiffs filed a Notice of Voluntary Dismissal of Count VII pursuant to Fed. R. Civ. P. 41(a). ECF No. 21. On September 3, 2021, the Court rejected Plaintiffs' Notice on the grounds that "Rule 41(a) is not an appropriate vehicle to dismiss a single claim without dismissing the entire lawsuit," and it "invite[d]" Plaintiffs to "seek leave to amend their Complaint under Rule 15." ECF No. 22. Although Plaintiffs have not yet sought leave to amend their Complaint, it is HHS's understanding that Plaintiffs still intend not to pursue Count VII.

On July 19, 2021, Plaintiffs moved for a preliminary injunction to invalidate the vaccine EUAs and enjoin FDA from approving the vaccines. PI Mot., ECF No. 15. HHS now moves to dismiss the Complaint under Federal Rules of Civil Procedure 12(b)(1), (3), and (6), and opposes the preliminary injunction motion.

ARGUMENT

I. This Case Must 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). When "a federal court concludes that it lacks subject-matter jurisdiction, the court must dismiss the complaint in its entirety." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998) (subject matter jurisdiction must "be established as a threshold matter"). The Court "presume[s]" to "lack [subject matter] jurisdiction" unless the plaintiff meets its "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (internal quotation marks omitted)). If a plaintiff cannot meet this burden, then the Court has "no business deciding" the case. *Id.* at 341, 342 n.3.

Where, as here, defendants assert a "facial attack" on subject matter jurisdiction, the Court must "look and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction." *Stalley ex rel. U.S. v. Orlando Reg'l Healthcare Sys., Inc.*, 524 F.3d 1229, 1232 (11th Cir. 2008). A plaintiff "must plausibly allege

all jurisdictional elements." *Brownback v. King*, 141 S. Ct. 740, 749 (2021); *see also City of Pembroke Pines, Fla. v. Fed. Emergency Mgmt. Agency*, 494 F. Supp. 3d 1272, 1281–82 (S.D. Fla. 2020). The complaint's factual allegations "are taken as true for the purposes of the motion," but conclusory statements and legal conclusions are not. *Stalley*, 524 F.3d at 1232–33.

Here, the Court lacks subject matter jurisdiction for three reasons. First, Plaintiffs lack standing. Second, Plaintiffs' claims are unreviewable under the APA. Finally, Plaintiffs have not plausibly alleged the Court's jurisdiction over their mandamus claim. The Complaint must therefore be dismissed.

B. Plaintiffs Lack Standing.

For standing, a plaintiff must establish (1) an injury in fact that is "concrete, particularized, and actual or imminent"; (2) "fairly traceable to the challenged action" of the defendant; and (3) likely "redressable by a favorable ruling." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013); *see TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203–07 (2021). At the pleading stage, a plaintiff "must clearly allege . . . facts demonstrating each element" of standing. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Because "standing is not dispensed in gross," a plaintiff "must demonstrate standing for each claim . . . and for each form of relief." *TransUnion*, 141 S. Ct. at 2208.

To seek "injunctive or declaratory relief," which is all that Plaintiffs seek against HHS, a plaintiff must plausibly allege a "material" risk of future injury. *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 927 (11th Cir. 2020) (en banc); *see also Malowney v. Fed. Collection Deposit Grp.*, 193 F.3d 1342, 1346 (11th Cir.

1999) ("a plaintiff must allege facts from which it appears there is a substantial likelihood that he will suffer injury in the future"). The plaintiff's threatened injury must be "certainly impending." *Jacobson v. Fla. Sec'y of State*, 974 F.3d 1236, 1245–46 (11th Cir. 2020) (quoting *Clapper*, 568 U.S. at).

Here, the Alabama Plaintiffs have not plausibly alleged standing, and thus the Complaint can be dismissed for improper venue without reaching the standing of the remaining individual Plaintiffs and AFLDS. But even if the Court considers those other Plaintiffs, they have also failed to plausibly allege standing.

1. The Alabama Plaintiffs Lack Standing, and Thus This Entire Case Should Be Dismissed for Improper Venue.

A court "shall dismiss" a case filed in the wrong venue unless "the interest of justice" requires transfer "to any district or division in which [the case] could have been brought." 28 U.S.C. § 1406(a); *see* Fed. R. Civ. P. 12(b)(3). Here, the only potential bases for venue in this District are the claims by the Alabama Plaintiffs. *See* Compl. ¶ 144 (asserting venue under 28 U.S.C. § 1391(e)(1) because "at least one Plaintiff resides in this District"). But all Alabama Plaintiffs lack standing, so this case should be dismissed in its entirety for improper venue.

Plaintiffs Lyle and Julie Bloom (*id.* ¶¶ 116–18), Greenslade (*id.* ¶¶ 120–21), McFarlane (*id.* ¶ 119), Miller (*id.* ¶ 58), and Jody and Deborah Sobczak (*id.* ¶¶ 65–66) fear that they, their children, or their grandchildren will be required to receive a vaccine and will suffer side effects. But the Complaint does not clearly allege facts demonstrating that any Plaintiffs, their children, or their grandchildren are currently required to receive the vaccines or will imminently be required to do so. Indeed,

Alabama enacted legislation in May 2021 that prohibits state and local government entities, including schools, from requiring COVID-19 vaccinations as a condition of receiving government services or entry into a government building. *See* Ala. SB267 (Act No. 2021-493), §§ 1(b)–(c).[12]

Although the Complaint alleges that certain unnamed local governments have "eliminate[d] the requirement for parental consent, and even parental knowledge, of medical treatments administered to children," Compl. ¶ 239, it does not allege that Plaintiffs' children or grandchildren live in such a jurisdiction. There is thus no indication that Plaintiffs' children or grandchildren face any risk, let alone a material risk, of being vaccinated over Plaintiffs' objections. *See Clapper*, 568 U.S. at 420 (no standing based on "mere conjecture about possible governmental actions"); *Muransky*, 979 F.3d at 927.

Moreover, those hypothetical injuries would not be traceable to the challenged actions of HHS here; rather, they would be "the independent action of some third party not before the court." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); *see also Clapper*, 568 U.S. at 414 n.5. Indeed, the Complaint does not allege that the challenged actions will require or pressure anyone to get vaccinated, but instead that children will face "social and school pressure" to get vaccinated, Compl. ¶ 119; *see id.* ¶ 65, or pressure from "friends, parents of friends, sports organizations, summer camps, schools and colleges," *id.* ¶ 58. Similarly, "just because the federal government approved [the] vaccine as safe for human" use, any state or local

[12] *Available at* http://alisondb.legislature.state.al.us/ALISON/SearchableInstruments/2021RS/PrintFiles/SB267-enr.pdf.

vaccination requirement would be an "action independently taken by a separate sovereign" and not traceable to HHS' conduct challenged here. *Null v. FDA*, No. CV 09-1924 (RBW), 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009).[13]

Finally, Dr. Roth alleges that he is afraid the vaccines could harm his young patients. Compl. ¶¶ 122–27.[14] But to bring a claim on behalf of a third party, Dr. Roth (1) "must have suffered an injury in fact, thus giving [him] a sufficiently concrete interest in the outcome of the issue in dispute"; (2) "must have a close relation to the third party"; and (3) "there must exist some hindrance to the third party's ability to protect his or her own interests." *Powers v. Ohio*, 499 U.S. 400, 411 (1991). Here, Roth has not alleged an injury in fact; at most he has an "abstract concern" about the vaccines that is not cognizable under Article III. *See Diamond v. Charles*, 476 U.S. 54, 66–67 (1986); *see also infra* § I.B.2.a. Furthermore, Roth has not alleged any hindrance to his patients' ability to protect their own interests, even assuming he could demonstrate his patients opposed the vaccine and were being compelled to get vaccinated. Thus, he cannot assert standing on his patients' behalf.

In sum, the Alabama Plaintiffs have not plausibly alleged standing. The Complaint should therefore be dismissed for improper venue. *See Atl. Marine Const. Co. v. U.S. Dist.* Ct. *for W. Dist. of Texas*, 571 U.S. 49, 55–56 (2013); *Ga. Republican Party v. Sec. & Exch. Comm'n*, 888 F.3d 1198, 1205 (11th Cir. 2018).

[13] Plaintiffs' citation to *Simon v. Eastern Kentucky Welfare Rights Organization*, 426 U.S. 26, 45 n.25 (1976), PI Mot. at 43–44, is inapposite here because the Emergency Declaration, EUAs, and any vaccine approvals do not themselves authorize any third parties to require anyone to get vaccinated or to permit children to get vaccinated over their parents' objection.

[14] The Complaint does not state where in Alabama Dr. Roth resides. Compl. ¶ 122. But even if he resides in the Northern District, venue remains improper because Dr. Roth lacks standing.

2. The Remaining Individual Plaintiffs Lack Standing.

The individual Plaintiffs who reside outside Alabama allege abstract objections to the vaccines, past injuries, and feared future injuries. None of these is sufficient for standing.

a. The Individual Plaintiffs Do Not Have Standing Based on Their Abstract Objections to the Vaccines.

The individual Plaintiffs allege several abstract objections to the administration of the vaccines. For example, Geyer "has strong objections to the experimental COVID-19 Vaccine for children," Compl. ¶ 94, and McCrae is concerned that vaccination sites are not ensuring that recipients give informed consent, *id.* ¶¶ 70–72. But those "abstract concern[s]," "claim[s] of conscientious objection," and "nonconcrete interest[s] in the proper administration of the laws" do "not provide a judicially cognizable interest." *Diamond*, 476 U.S. at 66–67; *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009).

b. The Individual Plaintiffs' Alleged Past Injuries Do Not Confer Standing to Seek Their Requested Injunctive Relief.

"[P]ast exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief . . . if unaccompanied by any continuing, present adverse effects." *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983). The requirement of future injury implicates both the injury-in-fact element—the plaintiff must be "likely to suffer future injury"—and the redressability element—the relief sought must "likely prevent such injury from occurring." *Cone Corp. v. Fla. Dep't of Transp.*, 921 F.2d 1190, 1203–04 (11th Cir. 1991). When a plaintiff "alleges only past infractions" and "not a continuing violation or the likelihood of a future

violation, injunctive relief will not redress its injury." *Steel Co.*, 523 U.S. at 109; *see also Malowney*, 193 F.3d at 1346.

Although several Plaintiffs allegedly suffered past physical or economic injuries, they have not plausibly alleged a likelihood of suffering *future* injury and that the requested relief would prevent such injury. *See Cone*, 921 F.2d at 1203–04. Plaintiffs Deselle (Compl. ¶ 78), Simmonds (*id.* ¶¶ 82–85), Vidiella (*id.* ¶ 92), and Wood (*id.* ¶ 40) allegedly lost their jobs because of vaccine side effects or because they refused to give the vaccines to children. But these past injuries are not likely to recur or be redressable by the requested injunctive relief. *See Clapper*, 568 U.S. at 409. For instance, Plaintiffs do not contend they would be rehired if the Emergency Declaration and EUAs were invalidated. *See Cone*, 921 F.2d at 1203–04.

Plaintiffs Boone (Compl. ¶¶ 60–64), Deselle (*id.* ¶¶ 73–80), Galvin (*id.* ¶¶ 46–56), Estate of Dovi Sanders Kennedy (*id.* ¶¶ 109, 115), Mills (*id.* ¶¶ 67–68), Simmonds (*id.* ¶¶ 81–85), and Vidiella (*id.* ¶¶ 87–90) allegedly suffered side effects from the vaccines. As a threshold matter, the Countermeasures Injury Compensation Program provides the exclusive remedy for all claims of loss related to administration of a COVID-19 vaccine licensed or authorized by the EUAs, other than willful misconduct. 42 U.S.C. §§ 247d-6d(a), 247d-6e(d)(4).[15] Congress has made the United States otherwise "immune from suit" on these claims, thereby divesting the Court of subject matter jurisdiction and rendering these alleged injuries

[15] These statutes apply here because the Secretary issued the declaration required by 42 U.S.C. § 247d-6d(b). *See* Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19, 85 Fed. Reg. 15,198 (Mar. 17, 2020), as amended. The Secretary's declaration is not subject to judicial review. 42 U.S.C. § 247d-6d(b)(7).

inadequate to support standing. *Id.* § 247d-6d(a), (d), (i)(2). Moreover, these alleged past injuries are not likely to recur or be redressable by the requested injunctive relief. *See Clapper*, 568 U.S. at 409; *Cone*, 921 F.2d at 1203–04. The Complaint does not plausibly allege any material risk that these Plaintiffs, who now vehemently oppose the vaccines, will imminently receive another vaccine dose. *Muransky*, 979 F.3d at 927; *see, e.g.*, Compl. ¶ 57.

Finally, the Complaint alleges that the vaccines were administered to these Plaintiffs without their receiving adequate information about the products. *See, e.g.*, Compl. ¶¶ 56, 62, 176, 270. But the information Plaintiffs allege they should have received is all in the Recipient Fact Sheets. The Fact Sheets disclose that "[i]t is your choice to receive or not receive" the vaccines. ECF Nos. 24-1, at 5; 24-6, at 5; 24-10, at 5. They explain that the vaccines are "unapproved" and authorized under "Emergency Use Authorization[s]," which means they have "not undergone the same type of review as an FDA-approved or cleared product" and are authorized based on a determination that they "may be effective" to prevent COVID-19. ECF Nos. 24-1, at 2–4, 7; 24-6, at 2–3, 6; 24-10, at 2–3, 7. The Fact Sheets also disclose that the vaccines can have a variety of potentially serious side effects, such as "severe allergic reaction[s]" manifesting in symptoms such as "[d]ifficulty breathing," "[d]izziness and weakness." ECF Nos. 24-1, at 4; 24-6, at 4; 24-10, at 4–5. Finally, the Pfizer and Moderna Fact Sheets disclose that the vaccines include messenger ribonucleic acid (mRNA). ECF Nos. 24-1, at 3; 24-6, at 3, 5–6.

The EUAs and CDC's COVID-19 Vaccination Program require vaccination providers to give a Fact Sheet to each vaccine recipient, either in hardcopy or online.

ECF Nos. 24-2, at 9; 24-7, at 5–6; 24-11, at 5. If Plaintiffs' vaccination providers furnished the information in the Recipient Fact Sheets, Plaintiffs did not "lack access to information to which [they were] legally entitled" and thus cannot show a "constitutionally cognizable informational injury." *Stacy v. Dollar Tree Stores, Inc.*, 274 F. Supp. 3d 1355, 1363 (S.D. Fla. 2017). If Plaintiffs' vaccination providers did not disseminate the Fact Sheet information as required, those are "the independent action of some third party not before the court" and not traceable to HHS. *Lujan*, 504 U.S. at 560–61; *see also Clapper*, 568 U.S. at 414 n.5.

The Complaint itself illustrates how third parties—not HHS—were responsible for any failure to give Plaintiffs the Fact Sheets. For example, DeSelle alleges that her employer provided her a consent form that appeared to be a standard influenza consent form "with the word 'influenza' replaced with 'COVID-19.'" Compl. ¶ 80. Similarly, Simmonds alleges that the "local health department" failed to provide the requisite Fact Sheet, *id.* ¶ 81, and Mills alleges that CVS failed to provide adequate information about the vaccine, *id.* ¶¶ 67, 69. The alleged failure of these providers to comply with the EUAs and CDC's COVID-19 Vaccination Program is not traceable to HHS. Moreover, far from denying Plaintiffs "access to [vaccine] information to which [they were] legally entitled," *Stacy*, 274 F. Supp. 3d at 1363, FDA posted the Fact Sheets on its website, ECF No. 24, ¶¶ 5–6.

Finally, Plaintiffs cannot have been injured by any purported failure to comply with the informed consent requirements in 45 C.F.R. Part 46 because that regulation is inapplicable here. It applies to "research involving human subjects," 45 C.F.R. § 46.101(a), but the administration of an EUA-authorized vaccine for clinical care

does not meet the regulation's definition of "research." 45 C.F.R. § 46.102(*l*). Removing any doubt, the EUA statute prescribes that 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). Additionally, although the VAERS and V-safe systems conduct vaccine surveillance and facilitate adverse event reporting, "[p]ublic health surveillance activities" are specifically excluded from the definition of "research." 45 C.F.R. § 46.102(*l*)(2).

c. The Individual Plaintiffs' Alleged Future Injuries Do Not Establish Standing.

Plaintiff MacFarlane fears losing her job because she will refuse to receive or administer the vaccine. Compl. ¶ 119. But this alleged injury is neither concrete nor imminent because it is speculative whether MacFarlane's employer will fire her.

Plaintiffs Boone (*id.* ¶¶ 60–64), Geyer (*id.* ¶¶ 94–95), Hibbard (*id.* ¶ 99), Hunt (*id.* ¶ 107), Meyers (*id.* ¶ 96), Roberts (*id.* ¶ 102), and Schweder (*id.* ¶¶ 128–29) fear that they, their children, or their grandchildren will be required to receive a vaccine and will suffer side effects. For the reasons discussed above with respect to the Alabama Plaintiffs, however, these Plaintiffs have not plausibly alleged standing because they have not alleged a material risk of future injury, nor any injury that is traceable to the challenged actions of HHS. *See Clapper*, 568 U.S. at 409; *supra* § I.B.1. Indeed, the Complaint does not allege that HHS' challenged actions require anyone to get vaccinated, but instead that the actions of third parties such as "public school[s]," Compl. ¶ 99, or "summer camp," *id.* ¶ 107, will do so, *see Clapper*, 568 U.S. at 409, 414 n.5; *Lujan*, 504 U.S. at 560–61.

3. AFLDS Lacks Standing.

An organization can have standing under two theories: (1) organizational standing, in which the organization sues on its own behalf, and (2) representational standing, in which the organization sues on behalf of its members. *See Ga. Republican Party*, 888 F.3d at 1201–05. AFLDS does not have standing under either.

a. AFLDS Lacks Organizational Standing.

Organizational standing is governed by "the same inquiry as in the case of an individual." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378–79 (1982). It is insufficient for an organizational plaintiff to have an "abstract concern" with an issue in the litigation or "a desire to vindicate value interests," and a "claim of conscientious objection to [particular conduct] does not provide a judicially cognizable interest." *Diamond*, 476 U.S. at 66–67. Similarly, a "nonconcrete interest in the proper administration of the laws" is not a cognizable injury. *Summers*, 555 U.S. at 497.

AFLDS's objections to the Emergency Declaration and the EUAs, *e.g.*, Compl. ¶ 16, are at most "abstract concern[s]" or "claim[s] of conscientious objection" that "do[] not provide a judicially cognizable interest," *Diamond*, 476 U.S. at 66–67. And its concern with ensuring compliance with the EUA statute and informed consent laws, *e.g.*, Compl. ¶¶ 230–49, is a "nonconcrete interest in the proper administration of the laws" that also does not amount to injury in fact, *Summers*, 555 U.S. at 497. The Complaint does not allege that AFLDS will suffer any concrete, imminent injury from the Emergency Declaration or EUAs, such as the need to divert its resources from other projects "to counteract those [allegedly]

illegal acts." *Ga. Republican Party*, 888 F.3d at 1203. Thus, AFLDS has not plausibly alleged organizational standing.

b. AFLDS Lacks Representational Standing.

"An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)). An organization must "make specific allegations establishing that at least one identified member ha[s] suffered or [will] suffer harm," and its "self-descriptions of [its] membership" are insufficient. *Id.* (quoting *Summers*, 555 U.S. at 498–99); *see also Jacobson*, 974 F.3d at 1249.

The Complaint does not identify any member of AFLDS, let alone "make specific allegations establishing that at least one identified member ha[s] suffered or [will] suffer harm." *Ga. Republican Party*, 888 F.3d at 1203. Although the Complaint describes AFLDS's members generally, these "self-descriptions of [its] membership" are insufficient. *Id.*

Furthermore, the abstract objections to the vaccine of AFLDS members, *e.g.*, Compl. ¶ 16 (claiming "it is unethical even to advocate for Covid-19 vaccine administration to persons under the age of 50"), are not cognizable under Article III. Also unavailing are the allegations that unidentified members fear losing their jobs because employers might follow an American Medical Association ethics opinion, which states that doctors "have an ethical responsibility to encourage patients to

accept immunization when the patient can do so safely" and health care "institutions' responsibility may extend to requiring immunization of staff." *Id.* ¶ 22; *see also id.* ¶¶ 18–23. These allegations rely on an impermissible "speculative chain of possibilities," *Clapper*, 568 U.S. at 414: the members' employers would have to (1) adopt the AMA's ethics opinion; (2) require their employees to receive or encourage their patients to receive the vaccines; and (3) discipline or terminate AFLDS's members for failing to do so rather than, for example, making an accommodation for their beliefs. Similarly deficient is the alleged fear of job loss based on anonymous reports to the National Physician's Database, Compl. ¶¶ 26, 28, because it "rest[s] on mere speculation about the decisions of third parties," *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019), *i.e.*, the decisions of unknown parties to file anonymous reports to the database and the decisions of employers to take adverse action in response to those reports.[16]

Even if the threat of being disciplined or fired was a cognizable injury to AFLDS members, "the independent action[s] of" employers, which are "third part[ies] not before the court," are not plausibly traceable to HHS' challenged conduct. *Lujan*, 504 U.S. at 560–61; *see also Clapper*, 568 U.S. at 414 n.5; *Ass'n of Am. Physicians & Surgeons v. FDA*, 2021 WL 4097325, at *11 (6th Cir. Sept. 9, 2021) (rejecting standing theory that "rests on pure guesswork about the decisions

[16] Although the Complaint alleges that unnamed doctors have lost their jobs because they refused to support the administration of the vaccines, Compl. ¶ 18, it does not allege those doctors are AFLDS members or even have the same employers as AFLDS members. Thus, there is no indication that AFLDS members face a material risk of imminently losing their jobs.

of parties not before the court"). Thus, AFLDS has not met its burden to plausibly allege standing.

In sum, none of the Plaintiffs have plausibly alleged standing. The Complaint should therefore be dismissed for lack of subject matter jurisdiction.

C. The Emergency Declaration and EUAs Are Unreviewable Under the APA.

Even if Plaintiffs had standing, they still failed to plausibly allege subject matter jurisdiction over their APA claims. Agency action is unreviewable under the APA when it "is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This provision is jurisdictional. *Lenis v. U.S. Att'y Gen.*, 525 F.3d 1291, 1294 (11th Cir. 2008).

The EUA statute provides that HHS's "[a]ctions under the authority of this section . . . are committed to agency discretion." 21 U.S.C. § 360bbb-3(i). Following this plain statutory language, the Sixth Circuit has held that "emergency-use authorizations 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); 21 U.S.C. § 360bbb-3(i)); *see Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) ("when the statute's language is plain," courts should enforce the statute "according to its terms" (internal quotation marks omitted)).

The Emergency Declaration and vaccine EUAs state that they were issued under the authority of the EUA statute. Emergency Declaration, 85 Fed. Reg. at 7317; ECF Nos. 24-3, at 2, 4; 24-8, at 2–3; 24-12, at 1–2. Thus, these actions are committed to agency discretion and unreviewable under the APA.

Although the plain meaning of 21 U.S.C. § 360bbb-3(i) is dispositive, the statute's purpose and structure confirm that HHS's actions related to an EUA are committed to agency discretion. *See Webster v. Doe*, 486 U.S. 592, 600–01 (1988) (considering statute's purpose and structure in finding actions were committed to agency discretion). The EUA statute was part of the Project BioShield Act of 2004. Pub. L. No. 108-276, 118 Stat. 835. That Act provided for the development and acquisition of new medical countermeasures against chemical, biological, radiological, or nuclear agents that might be used against the United States, and included various new authorities to protect the United States from harm caused by such agents. *Id.* at 835. Congress provided EUA authority to FDA specifically to "streamlin[e] . . . the approval process of countermeasures." *Id.*

The EUA statute grants discretion to HHS at key steps of the authorization process. The Secretary "may" declare "that the circumstances exist justifying" an EUA, 21 U.S.C. § 360bbb-3(b)(1); "may" issue an EUA, *id.* §§ 360bbb-3(a)(1), (c); "may" place "conditions on an authorization" that are "necessary and appropriate to protect the public health," *id.* § 360bbb-3(e)(1)(B); and "may revise or revoke" an EUA, *id.* § 360bbb-3(g)(2); *see Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016) (noting that "the word 'may' . . . implies discretion"). Thus, the EUA statute "fairly exudes deference to" HHS, *Webster*, 486 U.S. at 600, and reflects Congress's desire to make HHS's substantive decisions unreviewable. The EUA statute's purpose and structure, therefore, confirm what is clear from its plain text: The Emergency Declaration and vaccine EUAs are committed to agency discretion and unreviewable under the APA.

D. The Court Lacks Jurisdiction over Plaintiffs' Mandamus Claim (Count VI).

"The test for jurisdiction is whether mandamus would be an appropriate means of relief. Mandamus relief is only appropriate when: (1) the plaintiff has a clear right to the relief requested; (2) the defendant has a clear duty to act; and (3) no other adequate remedy is available." *Cash v. Barnhart*, 327 F.3d 1252, 1257–58 (11th Cir. 2003) (citations omitted) (cleaned up). In other words, a writ of mandamus "is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." *Id.* (quoting *Heckler v. Ringer,* 466 U.S. 602, 616 (1984)). "[M]andamus is an extraordinary remedy which should be utilized only in the clearest and most compelling of cases." *Id.*

HHS does not owe Plaintiffs "a clear nondiscretionary duty" to act. *Cash*, 327 F.3d at 1257–58 (quoting *Heckler,* 466 U.S. at 616). To the contrary, the decisions to issue an emergency declaration or an EUA are expressly "committed to agency discretion." 21 U.S.C. § 360bbb-3(i). Indeed, the duty to "ensure the faithful implementation" of the EUA statute and 45 C.F.R. Part 46, Compl. ¶ 283, is not the sort of "clear nondiscretionary duty" that a writ of mandamus may compel. Furthermore, 45 C.F.R. Part 46 does not apply here because the clinical use of a product within the scope of an EUA is not a clinical investigation, and the clinical use of such a product and the accompanying adverse event reporting systems are not "research." *See* 21 U.S.C. § 360bbb-3(k); 45 C.F.R. § 46.102(l)(2); *supra* § I.B.2.b.

Plaintiffs also have not "exhausted all other avenues of relief" because another "adequate remedy is available." *Cash*, 327 F.3d at 1257–58 (quoting *Heckler,* 466 U.S. at 616). FDA regulations set out an administrative Citizen Petition process and require that challenges to FDA action be brought through that process before being asserted in court.[17] 21 C.F.R. §§ 10.25(a), 10.45; *see infra* § II.B.1..

Contrary to Plaintiffs' argument, PI Mot. at 49–54, Plaintiffs are not excused from filing a Citizen Petition. "Exhaustion may be excused if a litigant can show: (1) that requiring exhaustion will result in irreparable harm; (2) that the administrative remedy is wholly inadequate; or (3) that the administrative body is biased, making recourse to the agency futile." *Ga. by & through Ga. Vocational Rehab. Agency v. U.S. by & through Shanahan*, 398 F. Supp. 3d 1330, 1343 (S.D. Ga. 2019). First, Plaintiffs are not at risk of imminent irreparable harm. *See infra* § III.C. Second, a Citizen Petition would not be "wholly inadequate" because, in response to such a petition, FDA could revoke the vaccine EUAs or the Pfizer vaccine approval. Finally, Plaintiffs' speculation about the prospects of any citizen petition they file, *see* PI Mot. at 49–54, is insufficient to show the futility of undertaking that administrative process.[18] *See Lanfear v. Home Depot, Inc.*, 536 F.3d

[17] 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.

[18] Notably, FDA continues to evaluate and respond to Citizen Petitions regarding the COVID-19 vaccines. *See, e.g.*, Citizen Petition Response, Dkt. No. FDA-2020-P-1770-0037 (Dec. 14, 2020), https://go.usa.gov/xMDyP (responding to requests for FDA to take certain actions prior to issuing EUAs for COVID-19 vaccines); Citizen Petition Responses, Dkt. Nos. FDA-2021-P-0460-30085 (Aug. 23, 2021), https://go.usa.gov/xMDVY (responding to request for FDA to take certain actions prior to approving a BLA for a COVID-19 vaccine); FDA-2021-P-0529-1077 (Aug. 23, 2021), https://go.usa.gov/xMDV8 (same).

1217, 1225 (11th Cir. 2008) ("[T]he futility exception is about meaningful access to administrative proceedings, not a potential conflict of interest of the decisionmakers."); *Bickley v. Caremark RX, Inc.*, 461 F.3d 1325, 1330 (11th Cir. 2006) (plaintiff's "claim of futility is merely speculative because he did not even attempt to pursue the administrative procedure available," and thus exhaustion was required).[19] As the Eleventh Circuit has emphasized, mandamus must "remain[] an extraordinary form of relief and not a strategy for avoiding administrative exhaustion." *Lifestar Ambulance Serv., Inc. v. United States*, 365 F.3d 1293, 1298 (11th Cir. 2004).[20]

In sum, none of the three requirements for mandamus are met. This case is plainly not among "the clearest and most compelling of cases" that warrant the "extraordinary remedy" of mandamus. *Cash*, 327 F.3d at 1257–58.

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

A. Legal Standard

The Court must dismiss the Complaint under Rule 12(b)(6) unless Plaintiffs have "state[d] a plausible claim for relief." *Iqbal*, 556 U.S. at 679. They must plead sufficient "factual content that allows the court to draw the reasonable inference that

[19] If the Court were to find the Emergency Declaration and the EUAs are reviewable under the APA, it would provide an adequate remedy for Plaintiffs and defeat their mandamus claim. *See Hollywood Mobile Ests. Ltd. v. Seminole Tribe of Fla.*, 641 F.3d 1259, 1267–68 (11th Cir. 2011).

[20] Plaintiffs' citation of 21 U.S.C. § 355(q)(1)(A), PI Mot. at 48–50, is inapposite because that provision regulates when the Secretary may "delay approval of a pending application" for new drug approval or biological product licensure. It is also irrelevant that 21 C.F.R. § 10.30 and the EUA statute do not expressly reference each other. PI Mot. at 50. FDA regulations require that "request[s] that the Commissioner take or refrain from taking any form of administrative action," including action under the EUA statute, be brought through the Citizen Petition process before being asserted in court. 21 C.F.R. § 10.45(b).

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 the Complaint's "well-pleaded factual allegations," but it need not accept as true "conclusory statements" or "legal conclusions." *Id.* at 678–79.

B. Counts I–III Fail to State a Claim that the Emergency Declaration and EUAs Are Unlawful Under the APA.

Counts I–III assert APA claims challenging, respectively, the Emergency Declaration, the alleged failure to satisfy the criteria for issuance of the vaccine EUAs, and the alleged failure to satisfy the required conditions of the EUAs. Even if the Court had jurisdiction over these claims, *see supra* §§ I.B. and I.C., Counts I–III still must be dismissed for failure to state a claim. The Complaint does not challenge HHS's contemporaneous explanations for the Emergency Declaration and EUAs in light of the existing administrative record; instead, it impermissibly relies on alleged evidence that postdates those actions and that was never presented to HHS. The Complaint thus fails to plausibly allege that those actions were arbitrary and capricious. Plaintiffs' remaining arguments are no more convincing.

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

"To state a proper claim under the APA," Plaintiffs "must allege facts that, if true, plausibly establish that the agency action is arbitrary and capricious." *Blanchett*

v. DeVos, 490 F. Supp. 3d 26, 32 (D.D.C. 2020); *see* 5 U.S.C. § 706(2). The Court's review of agency action under 5 U.S.C. § 706(2)(A) is "deferential" and "narrow." *Dep't of Commerce*, 139 S. Ct. at 2569 (quoting *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court "may not substitute its own policy judgment for that of the agency," but "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The Court's review here is "at its most deferential" because the challenged actions involve "scientific determination[s]" that are "within [HHS's] area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983). Moreover, "courts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'" *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) (Roberts, C.J., concurring in grant of application for stay).

The "focal point for judicial 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 "[a]n interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new [Citizen Petition] to modify the action." 21 C.F.R. § 10.45(f).

"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 protect the orderly operation of administrative processes, "to permit the agency to exercise its discretion or apply its expertise," and to "conserve scarce judicial resources." *Mahon*, 485 F.3d at 1255.

Here, Counts I–III 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 Decision Memoranda, which discuss the extensive data supporting FDA's conclusions. *See* Pfizer-BioNTech COVID-19 Vaccine EUA Amendment Review Memorandum (May 10, 2021), ECF No. 24-5; Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Review Memorandum (Dec. 11, 2020), ECF No. 24-4; Moderna COVID-19 Vaccine Emergency Use Authorization Review

Memorandum (Dec. 18, 2020), ECF No. 24-9; Janssen COVID-19 Vaccine Emergency Use Authorization Review Memorandum (Feb. 27, 2021), ECF No. 24-13. These contemporaneous explanations, based on "scientific determination[s]" that are "within [HHS's] area of special expertise," are entitled to a high degree of deference. *Balt. Gas & Elec. Co.*, 462 U.S. at 103.

The Complaint does not plausibly allege that HHS's "contemporaneous explanations" were unreasonable "in light of the existing administrative record." *Dep't of Commerce*, 139 S. Ct. at 2573. Instead, it attacks the Emergency Declaration and EUAs based on evidence that is *not* in the administrative record. For Count I, the Complaint challenges the Emergency Declaration based on evidence dating from after it was issued in February 2020, *see, e.g.*, Compl. ¶¶ 154 & n.7, 163–64, or based on undated studies, *see, e.g.*, *id.* ¶¶ 157, 161. And it vaguely asserts that Plaintiffs "have accumulated and will present expert medical and scientific evidence further supporting" their contentions, without alleging when this purported evidence is from or whether it was ever presented to HHS. *Id.* ¶ 264.

For Count II, which challenges the issuance of the EUAs, the Complaint again relies on evidence generated after the EUAs were issued, *see, e.g.*, *id.* ¶¶ 167–68, or on undated studies, *see, e.g.*, *id.* ¶¶ 168–72. It also summarizes the purported findings of "AFLDS medico-legal researchers [who] have analyzed the accumulated COVID-19 Vaccine risk data," *id.* ¶ 181, though it does not allege that these findings predate the issuance of the EUAs or that they were ever presented to HHS.

Finally, Count III challenges whether the EUAs met the required conditions to ensure that vaccination providers and recipients are appropriately informed about

the vaccines. *See* 21 U.S.C. § 360bbb-3(e)(1)(A). But Plaintiffs do not contest FDA's contemporaneous explanation (*i.e.*, at the time the EUAs were issued) for why these conditions were met. Instead, the Complaint disputes whether, in fact, vaccination providers and recipients "are being informed" of the information they must be provided under the EUA statute. Compl. ¶¶ 269–71. These allegations necessarily postdate the issuance of the EUAs and do not disturb HHS's contemporaneous explanation for how the required conditions were met. The Complaint also does not allege that its allegations were ever presented to HHS.

Because the Complaint does not plausibly allege that HHS's "contemporaneous explanations" for the Emergency Declaration and EUAs were unreasonable "in light of the existing administrative record," Plaintiffs fail to state APA claims for Counts I–III. *Dep't of Commerce*, 139 S. Ct. at 2573; *see also Velez-Duenas v. Swacina*, 875 F. Supp. 2d 1372, 1379 (S.D. Fla. 2012) (dismissing complaint for failure to state a claim because plaintiff "ask[ed] th[e] Court to consider documents that were not a part of the administrative record," which "would be improper"). Plaintiffs also do not allege that they ever presented their allegations to HHS, which confirms that they may not rely on these allegations to support Counts I–III. *See Mahon*, 485 F.3d at 1254–55. This Court cannot excuse Plaintiffs' failure to present their allegations to HHS by conducting a "*de novo* inquiry" and creating a new record. *Fla. Power & Light Co.*, 470 U.S. at 744; *Camp*, 411 U.S. at 142.

2. Plaintiffs' Remaining Arguments Are Unconvincing.

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, Compl. ¶¶ 257–65. 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, 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 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.[21]

Regarding Count II, even if Plaintiffs' allegations were properly before the Court, they still do not plausibly show the 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." Compl. ¶ 267(a). But apart from the known risk of death from COVID-19, Plaintiffs fail to address the risks of other serious conditions that FDA found to support the EUAs, *see* ECF Nos. 24-5, at 7–8, 39–42; 24-4, at 9, 50–

[21] 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 (b)(2)(A).

56; 24-9, at 9–10, 56–61; 24-13, at 9–10, 60–66. Additionally, Plaintiffs allege that there are "adequate, approved, and available alternative[s]" to the vaccines, 21 U.S.C. § 360bbb-3(c)(3); *see* Compl. ¶ 267(e), but they misinterpret this standard. It is immaterial that alternatives have allegedly been "approved by physicians as meeting the standard of care among similarly situated medical professionals," *id.* ¶ 267, because alternative treatments are only "approved" when approved by FDA, 21 U.S.C. § 360bbb-3(a)(2).[22] When FDA issued the EUAs, there was no adequate, approved, and available alternative to the vaccines. *See* ECF Nos. 24-4, at 9–10; 24-9, at 10; 24-13, at 9. (That remains true today. *See* Re-issued Pfizer EUA Letter of Authorization, at 5 n.9, https://go.usa.gov/xMBXr.).

In Count III, Plaintiffs' allegations (even if cognizable under the APA) that vaccination providers and recipients received inadequate information about the vaccines, Compl. ¶ 270, 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. 24-2, at 9; 24-3, at 6, 10; 24-7, at 5–6; 24-8, at 5, 9; 24-11, at 5; 24-12, at 5, 9. These Fact

[22] 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.

Sheets disclose all the information that must be provided to vaccination providers and recipients, respectively, under the EUAs. *See id.*

Plaintiffs do not dispute this, but instead allege that vaccination providers and recipients "are not," in fact, being informed of the information they must be given. Compl. ¶¶ 269–71. 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' efficacy and risks and that "psychological[] manipulat[ion]" and coercive "rewards and penalties" render "the 'option to [] refuse' meaningless." Compl. ¶¶ 153, 246–49, 270. But the Complaint does not plausibly allege that HHS is responsible for such censorship, manipulation, or coercion, which it alternately attributes to "the media," *id.* ¶¶ 153, 247; state or foreign governments, *id.* ¶¶ 247–48; and private businesses and employers, *id.* ¶ 248. As with their prior claims, Plaintiffs fail to plausibly allege any arbitrary or capricious decision or statutory violation by HHS.

Finally, Plaintiffs allege that "only a fraction (as low as 1%) of adverse events are reported to VAERS by physicians fearing liability." Compl. ¶ 270(e). But this alleged underreporting is not plausibly linked to any challenged action of HHS, 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,

Compl. ¶ 270(e), because the EUA statute does not require public access to the adverse event reporting system. Instead, the EUAs establish "[a]ppropriate conditions for the monitoring and reporting of adverse events," 21 U.S.C. § 360bbb-3(e)(1)(A)(iii), and FDA's actions in establishing those conditions are "committed to agency discretion," *id.* § 360bbb-3(i). Plaintiffs have not plausibly alleged any APA violation related to the monitoring or reporting of adverse events.

C. Count IV Fails to State a Claim Under Customary International Law.

Count IV alleges that HHS has violated the customary international law norm requiring informed consent for human medical experimentation, as expressed in the Declaration of Helsinki and the Nuremberg Code. But "there is no private right of action for an alleged violation of international law for the protection of human research subjects under the Declaration of Helsinki and the Nuremberg Code." *Robertson ex rel. Robertson v. McGee*, No. 01CV60, 2002 WL 535045, at *3 (N.D. Okla. Jan. 28, 2002); *see Hoover v. W. Va. Dep't of Health & Hum. Res.*, 984 F. Supp. 978, 980 (S.D.W. Va.), *aff'd*, 129 F.3d 1259 (4th Cir. 1997). Customary international law is controlling only "where there is no treaty and no controlling executive or legislative act or judicial decision." *Garcia-Mir v. Meese*, 788 F.2d 1446, 1453 (11th Cir. 1986) (quoting *The Paquete Habana,* 175 U.S. 677, 700 (1900)) (internal quotation marks omitted); *see also Lee-Lewis v. Kerry*, No. 2:13-CV-80, 2017 WL 498717, at *1 (S.D. Ga. Feb. 6, 2017). As Plaintiffs concede, Compl. ¶ 235, the norm against medical experimentation on non-consenting human subjects is implemented by 45 C.F.R. Part 46, *see, e.g.*, 45 C.F.R. § 46.116 ("General Requirements for Informed Consent"). It is "unnecessary to look to international law when human

research standards have been effectively promulgated here in the Code of Federal [Regulations]." *Keller v. Strauss*, No. 1:10-CV-3282-RWS, 2011 WL 2470631, at *6 (N.D. Ga. June 17, 2011), *aff'd*, 480 F. App'x 552 (11th Cir. 2012) (citing 45 C.F.R §§ 46.116 *et seq.*); *see Robertson*, 2002 WL 535045, at *3.

The only case about customary international law cited in the Complaint, *Abdullahi v. Pfizer, Inc.*, 562 F.3d 163 (2d Cir. 2009), is inapposite because it addressed the Alien Tort Statute, which creates jurisdiction over "any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." 28 U.S.C. § 1350; *see Abdullahi*, 562 F.3d at 172–89. Here, Plaintiffs do not assert a claim under the Alien Tort Statute.

D. Count V Fails to State a Claim Under 45 C.F.R. Part 46.

Count V alleges that HHS violated 45 C.F.R. Part 46, which implements the customary international law norm requiring informed consent for human medical experimentation. As discussed above, however, that regulation is inapplicable here because the use of a product for clinical care within the scope of an EUA and the accompanying adverse event reporting systems are not a "clinical investigation" or "research." 21 U.S.C. § 360bbb-3(k); *see supra* § I.B.2.b.

E. Count VI Fails to State a Mandamus Claim.

As discussed above in the context of jurisdiction, mandamus would not "be an appropriate means of relief." *Cash*, 327 F.3d at 1257–58; *supra* § I.D. Thus, Plaintiffs have failed to state a mandamus claim.

III. Plaintiffs' Motion for a Preliminary Injunction Should Be Denied.

A. Legal Standard

"A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "[A] preliminary injunction is an extraordinary and drastic remedy not to be granted unless the movant 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); *see also Brown v. Sec'y, U.S. Dep't of Health & Hum. Servs.*, 4 F.4th 1220, 1224 (11th Cir. 2021) (a preliminary injunction is "the exception rather than the rule"). "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 (internal quotation marks omitted).

Plaintiffs seek the mandatory relief of invalidating the EUAs and prohibiting vaccine approval. "[W]hen a plaintiff applies for a mandatory preliminary injunction, such relief should not be granted except in rare instances in which the facts and law are clearly in favor of the moving party." *Exhibitors Poster Exch., Inc. v. Nat'l Screen Serv. Corp.,* 441 F.2d 560, 561–62 (5th Cir. 1971) (internal quotation marks omitted).[23] Plaintiffs have not met their burden of persuasion on any of the prerequisites for a preliminary injunction. *See Siegel*, 234 F.3d at 1176.

[23] *See Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir. 1981) (en banc) (adopting as precedent all decisions of the former Fifth Circuit that were issued up to September 30, 1981).

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

As discussed above, the Complaint must be dismissed because Plaintiffs have not met their burden of plausibly alleging subject matter jurisdiction and 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)."). And like the Complaint, Plaintiffs' motion relies on evidence that is beyond the scope of "the existing administrative record," *Dep't of Commerce*, 139 S. Ct. at 2573, and that Plaintiffs "failed to raise" before HHS, *Mahon*, 485 F.3d at 1254–55; *see Velez-Duenas*, 875 F. Supp. 2d at 1379.

Plaintiffs' motion also impermissibly asserts new claims against HHS that are not rooted in the Complaint. To obtain a preliminary injunction, a plaintiff must show "it has a substantial likelihood of success on the merits of the underlying case when the case is ultimately tried." *Alabama v. U.S. Army Corps of Eng'rs*, 424 F.3d 1117, 1128 (11th Cir. 2005); *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).

Here, Plaintiffs seek a preliminary injunction to protect the "constitutional right[s] to personal autonomy and bodily integrity." PI Mot. at 61. But the Complaint

asserts those rights only in Count VII, which seeks money damages against Secretary Becerra, Dr. Fauci, and Dr. Woodcock in their individual capacities, *see* Compl. ¶¶ 286–96—a count Plaintiffs intend to abandon. The Complaint does not assert those rights as a basis for injunctive relief against HHS, and thus Plaintiffs cannot show "a substantial likelihood of success on the merits of the underlying case." *U.S. Army Corps of Eng'rs*, 424 F.3d at 1128.

Plaintiffs' motion also impermissibly seeks relief that is not requested in the Complaint. "[I]njunctive 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." *Id.* at 1134 (citing *Klay*, 376 F.3d at 1097–98; *Kaimowitz,* 122 F.3d at 43). Here, Plaintiffs ask the Court to bar FDA from approving the vaccines, PI Mot. at 65–66, but the Complaint does not request this relief; instead, it focuses on the Emergency Declaration and vaccine EUAs. FDA approvals of vaccines are new agency actions governed by a different statutory standard than EUAs, *see* 42 U.S.C. § 262(a); 21 C.F.R. § 601.2, and would need to be challenged through new APA claims. Moreover, because FDA has already approved Pfizer's vaccine, Plaintiffs' request to enjoin such approval is moot. Plaintiffs would need to plead a separate claim that FDA was required to revoke Pfizer's license, which is governed by a different statutory standard than granting a license in the first instance. *See* 42 U.S.C. § 262(a)(2)(A); 21 C.F.R. § 601.5(b). Thus, Plaintiffs cannot show a substantial likelihood of success regarding their request to enjoin the vaccine approvals.

C. Plaintiffs Have Not Shown 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 also Brown v. Sec'y of Health & Hum. Servs.*, 4 F.4th 1220, 1225 (11th Cir. 2021). Preventing future irreparable harm is "the *sine qua non* of injunctive relief.'" *U.S. Army Corps of Eng'rs*, 424 F.3d at 1133.

Plaintiffs' irreparable harm argument is based on the alleged injuries of Boone, Deselle, the Estate of Dovi Sanders Kennedy, Galvin, Mills, Simmonds, and Vidiella. *See* PI Mot. at 61–64. These Plaintiffs allegedly suffered side effects from the vaccines and did not receive adequate information about them. *See id.* But they do not face irreparable harm in the future, let alone in the period between when they filed the preliminary injunction motion and when this case could be resolved on the merits. *See Wreal*, 840 F.3d at 1248.

Plaintiffs attempt to bootstrap irreparable harm through supposed "harm to the public." PI Mot. at 63. But this argument is foreclosed by the Supreme Court's admonition that a plaintiff must show "*he* is likely to suffer irreparable harm" absent an injunction. *Winter*, 555 U.S. at 20 (emphasis added); *see also Siegel*, 234 F.3d at 1176 n.9. For the same reason, Plaintiffs cannot show irreparable harm based on alleged harm to Diana Hallmark, a non-party. *See* PI Mot. at 61–64.

Finally, courts "have found that a party's failure to act with speed or urgency in moving for a preliminary injunction necessarily undermines a finding of irreparable harm." *Wreal*, 840 F.3d at 1248. A delay of "even only a few

months . . . militates against a finding of irreparable harm" because "[a] preliminary injunction requires showing 'imminent' irreparable harm." *Id.* (quoting *Siegel*, 234 F.3d at 1176–77). Here, Plaintiffs delayed almost two months after the Court denied their TRO motion on May 24 before requesting a preliminary injunction on July 19. This delay "necessarily undermines a finding of irreparable harm." *Id.*

D. Plaintiffs Have Not Shown that the Balance of Equities Favors Them or that an Injunction Is in the Public Interest.

The balance of equities and the public interest strongly favor HHS because Plaintiffs' requested relief would greatly harm the public. "Stemming the spread of COVID-19 is unquestionably a compelling interest." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020). COVID-19 has already infected over 40.5 million Americans, hospitalized over 2.8 million, and killed over 652,000. The vaccines have been shown to be effective at protecting people from COVID-19, especially severe illness and death, and at reducing the risk of spreading the virus that causes COVID-19. So far, over 210 million Americans have received at least one dose of a COVID-19 vaccine, and over the past week, an average of over half a million Americans per day received a vaccine.[24] There is a compelling public interest in ensuring that Americans who want to get vaccinated continue to have access to the vaccine.

[24] COVID Data Tracker Weekly Review: Interpretive Summary for Sept. 10, 2021, https://go.usa.gov/xFU9U; New Hospital Admissions, https://go.usa.gov/xFU9K (last updated Sept. 15, 2021); CDC, Benefits of Getting a COVID-19 Vaccine, https://go.usa.gov/xFPes (last updated Aug. 16, 2021); COVID-19 Vaccinations in the United States, https://go.usa.gov/xFQXD (posted Sept. 15, 2021).

Although several Plaintiffs have decided not to get vaccinated, they do not ask merely to be exempt from a hypothetical vaccine mandate. Instead, they seek to invalidate the EUAs and prevent FDA from approving the vaccines, which would deprive millions of Americans of the opportunity to get vaccinated against COVID-19 and would interfere with HHS's efforts to combat the pandemic. The balance of equities and the public interest strongly oppose the requested injunction.

CONCLUSION

For the foregoing reasons, the Court should dismiss all of Plaintiffs' claims pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(3), and 12(b)(6), and should deny Plaintiffs' motion for a preliminary injunction.

Dated: September 16, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 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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