IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE and AMY MILLER,	)	**Case No. 1:21-cv-00200**
Plaintiffs,	)	
v.	)	
FOOD and DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner of Food and Drug Administration,	)	
Defendants.	)	

PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR A STAY & OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TO THE HONORABLE JUDGE OF THE COURT:

COME NOW Plaintiffs Children's Health Defense ("CHD") and Amy Miller reply in support of their motion to stay as well as oppose herein to Defendants' U.S. Food and Drug Administration's ("FDA") and Janet Woodcock's ("Woodcock") (Collectively "FDA") motion to dismiss Plaintiffs' First Amended Complaint.

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INTRODUCTION

Defendants' defense is simple: they are above the law. Defendants claim no court has authority over them for their actions in this matter, that Congress' plain limits in its legislation do not apply to them, and that federal agencies can ignore the petitions of their own citizens and the injuries their actions inflict on those citizens. Of note, Defendants do not substantially defend the substance of their actions or substantially dispute the equitable grounds for an administrative stay under the APA. Hence, the stay should be granted, and the motion to dismiss denied.

FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs filed their Citizen Petition with the FDA on May 16, 2021 requesting the "FDA to refrain from licensing COVID vaccines and to revoke EUAs for the three existing COVID vaccines. Am. Compl. ¶ 17; Exh. 4. It received over 30,000 comments from a wide range of legally recognized interested persons, including scientists, public health experts, medical doctors, and ordinary citizens from all walks of life impacted directly by the FDA's decision on this precise issue. The FDA's decision took on increasing importance when many employers, including the Department of Defense ("DoD"), made clear they would not mandate people take an Emergency Use only authorized drug, as doing so would violate both federal law and the Nuremberg Code, which both enshrine informed consent as the governing medical ethic of experimental, investigatory drugs, which enjoy extraordinary immunity from lawsuits and are uncovered by good manufacturing policies essential to safety and efficacy. Then, on August 23, 2021, the FDA pulled their bait-and-switch. Am. Compl. ¶ 20. This bait-and-switch subjects millions of Americans, including members of the Plaintiff, CHD, to coerced injections of this drug.

News outlets around the world proclaimed the first FDA approval of a COVID-19 vaccine for individuals aged 16 and up as businesses, schools, and our own federal government poised their pens to draft mandates based precisely on this approval. However, FDA's little caveat was buried in footnote number 8 -- Comirnaty was unavailable to the public. (Ftn. 8 Exh. 19-1 Page 29 of 116) The "approved" drug was, and continues to be, unmanufactured and unable to be distributed to the populace en masse. According to the U.S. National Library of Medicine, as of September 13, 2021, "Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution."[1] As such, Pfizer is not currently producing Comirnaty or marketing it to the public and won't for some time. Rather, the EUA Pfizer-BioNTech vaccine, still only authorized under Emergency Use Authorization ("EUA"), and other EUA vaccines made by others, remain the only biologics available to be administered, under the smokescreen of licensure.

Defendants demand this Court accept the same fiction they propagated -- that two different vaccines are a single vaccine -- "identical" but "legally distinct," but ignore their own internal documents showing critical "certain differences," including different manufacturing rules, different labeling rules, different companies approved, and, critically, completely different legal status. The FDA licensed a vaccine as "safe and effective" when the FDA knew insufficient quantities were available for U.S. Distribution (Exhibit 19-1 Page 32 of 116). To solve that problem FDA took the unprecedented step of calling an experimental vaccine interchangeable with the approved safe and effective one. FDA can argue that it has free reign to revoke an EUA or not. But, in this instance, FDA re-issued the EUA for the BioNTech vaccine the same day it

[1] https://dailymed.nlm.nih.gov/dailymed/dailymed-announcements-details.cfm?date=2021-09-13

licensed the unavailable Comirnaty vaccine, abrogating the emergency use authorization laws and violating the Administrative Procedures Act ("APA"). The FDA's chicanery must be called out for what it is: unethical, illegal, and abusive. All the declarants who assert injuries in this case are members of CHD. Am. Compl. ¶ 18.

STANDARDS OF REVIEW

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.' " *Bell Atl. Corp v. Twombly,* 550 U.S. 544, 555 (2007) (citing *Conley* v. *Gibson*, 355 U.S. 41, 47, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)). Furthermore, the allegations of the complaint must be taken as true. *Jenkins v. McKeithen*, 395 U.S. 411, 421-422 (1969). "In passing on a motion to dismiss . . . for failure to state a cause of action, the allegations of the complaint should be construed favorably to the pleader." *Scheuer* v. *Rhodes*, 416 U.S. 232, 236, 94 S. Ct. 1683, 40 L. Ed. 2d 90 (1974).

In determining whether to issue a preliminary injunction, the Court must consider four factors: "(1) the likelihood that the party seeking the stay will prevail on the merits of the appeal; (2) the likelihood that the moving party will be irreparably harmed absent a stay; (3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting the stay." *Mich. Coal. of Radioactive Material Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991). "These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together." *Id*. "When a party seeks a preliminary injunction on the basis of a potential constitutional violation," however, "'the likelihood of success on the merits often will be the determinative factor.'" *City of Pontiac Retired Emps. Ass'n v. Schimmel*, 751 F.3d 427, 430 (6th Cir. 2014) (order) (en banc) (per curiam) (internal citation omitted).

ARGUMENT

Who does the FDA's rogue action injure? The Plaintiffs, who now suffer the risk of compelled bodily invasion with an experimental drug, because Defendants pretend it is the licensed drug.

The Constitutional question with standing is a simple one: is there a "case or controversy" here? Clearly, there is.

First, the APA expressly authorizes standing for citizen petitioners denied relief: "a person suffering legal wrong because of agency action…is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire point of the APA was to assure judicial review of agency action, specifically authorizing federal courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

Second, organizational standing here clearly exists. CHD must divert resources from its current activities due to the threat the FDA's bait-and-switch imposes on millions of Americans. Such resource diversion is, itself, grounds for standing. *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017).

Third, associational standing here equally exists. Indeed, it is "common ground that…organizations can assert the standing of their members." *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009). CHD's members would have standing to sue in their own right, because this bait-and-switch was aimed at, and did, injure their legal interests. Equally, CHD's interests are to protect Informed Consent in all cases, and this case is all about how the FDA's bait-and-switch precluded Informed Consent by mislabeling the drug being given people under a

mandate. Finally, CHD's claims do not require any individual members to participate directly in the suit.

In sum, if CHD lacks standing, nobody has standing. The Defendants' argument asks this court to declare itself impotent, the judiciary an empty chamber, the balance of powers permanently imbalanced, and the Constitutional check on executive power just words on paper without effect or consequence. That was never the law and is not the law. The FDA is not above the law, the courts, the Constitution, or the citizens its actions legally injure, as the court should so find, deny the motion to dismiss, and issue the requested remedial relief pending the remainder of the litigation, before millions of Americans, including those members of the CHD, from losing their Constitutional rights to Informed Consent, a right we considered so universal and sacred, as a jus cogens value, that we ordered the execution of those who violated it at Nuremberg in 1947. The FDA is not above the law, nor the courts, nor our citizens.

I. Defendants Are Not Above the Law: Plaintiffs Enjoy Standing

A. Plaintiffs' Associational Standing

Art. III § 2 of the United States Constitution only requires a "case" or "controversy." "The presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement." *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 53, n2 (2006). The Court construes this to mean that a plaintiff has a "personal interest at the commencement of the litigation." *Barry v. Lyon,* 834 F.3d 706; *see Lujan v. Defenders of Wildlife,* 504 U.S. 555, 560, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992). "To satisfy Article III's standing requirements, a plaintiff must show (1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed

to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.,* 528 U.S. 167, 181, 120 S. Ct. 693, 145 L.Ed. 2d 610 (2000) (quoting *Lujan*, 504 U.S. at 560-561). "It can scarcely be doubted that for a plaintiff who is injured or faces the threat of future injury due to illegal conduct ongoing at the time of suit, a sanction that effectively abates that conduct and prevents its recurrence provides a form of redress." *Laidlaw*, 528 U.S. at 185-186. "An . . . organization may assert standing in one of two ways: (1) on its own behalf because it has suffered a palpable injury as a result of the defendants' actions; or (2) as the representative of its members." *MX Grp., Inc. v. City of Covington,* 293 F.3d 326, 332-33 (6th Cir. 2002).

CHD clearly has organizational, associational and citizen petition' standing to bring this suit. *See e.g.*, 5 U.S.C. § 701-706; *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017); *Summers*, 555 U.S. at 494.

"An association has standing to bring suit on behalf of its members when [1] its members would otherwise have standing to sue in their own right, [2] the interests at stake are germane to the organization's purpose, and [3] neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Laidlaw*, 528 U.S. at 181; *see Hunt v. Washington State Apple Advertising Comm'n,* 432 U.S. 333, 343, 53 L.Ed. 2d 282, 97 S. Ct. 2434 (1977). Indeed, it is "common ground that…organizations can assert the standing of their members." *Summers*, 555 U.S. at 494. "This doctrine sometimes permits an entity to sue over injuries suffered by its members even when . . . the entity itself alleges no personal injury." *Ass'n of Am. Physicians & Surgs v. United States FDA*, No. 20-1784, 2021 U.S. App. LEXIS 27157 * 9 (6th Cir. Sep. 9, 2021); *see e.g. Summers v. Earth Island Inst.,* 555 U.S. 488, 129 S. Ct. 1142, 173 L.Ed.2d 1 (2009).

To satisfy the first element: "It generally suffices for an association to demonstrate 'at least one of [its] members would have standing to sue on his own.' "*Waskul v. Washtenaw Cty. Cmty. Mental Health*, 900 F.3d 250 (6th Cir. 2018) (quoting *Lewis v Casey,* 518 U.S. 343, 358 n.6, 116 S. Ct. 2174, 135 L.Ed. 2d 606 (1996)). Therefore, the organization must "show that one of its named members '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Waskul,* 900 F.3d at 255 (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547, 194 L. Ed. 2d 635 (2016)). "If in a proper case the association seeks a declaration, injunction, or some other form of prospective relief, it can reasonably be supposed that the remedy, if granted, will inure to the benefit of those members of the association actually injured." *Warth v. Seldin,* 422 U.S. 490, 515, 95 S. Ct. 2197, 45 L. Ed. 2d 343 (1975).

Defendants argue in their motion to dismiss that CHD does not satisfy the first two factors. *Motion to Dismiss* at 1-2. However, CHD's allegations give the organization associational standing for two reasons: (1) Plaintiffs identify numerous CHD members who have standing to sue in their own right and (2) the interests of the adult military members that CHD protects are clearly related to CHD's mission as an organization.

1. CHD has identified numerous members who have standing to sue in their own right

CHD's members would have standing to sue in their own right, because FDA's rogue bait-and-switch action was aimed at, and did, injure their legal interests. The Plaintiffs now suffer the risk of compelled bodily invasion with an experimental drug because Defendants pretend it is the licensed drug. Indeed, the entire reason for this bait-and-switch was to mislead employers and government agencies into thinking they are compelling a biologic licensed drug,

made consistent to Good Manufacturing policies and liable under the law like any other biologic licensed drug. The bleak reality is that they are administering an experimental drug, authorized only under an EUA, that requires informed consent before it can be administered, where good manufacturing policies have been waived in its production, and where no one can be liable for any injury it causes. This is the "legally distinct" admission by the FDA.

Plaintiffs have standing since they clearly allege personal injury to a number of their members in the First Amended Complaint. (See Decl. Mary Holland) The 14 declarations submitted by CHD members chronicle imminent and irreparable harm associated with dishonorable discharge, loss of status, loss of employment opportunities, etc., that have resulted from FDA's licensure and its consequences. CHD's military service members memorialize in gut-wrenching detail the harm and injuries imposed by a vaccine mandate by the Department of Defense and various military branches, that would not have occurred but for FDA's unlawful "approval" of Comirnaty.

CHD has demonstrated concrete, immediate, and specific harm directly linked to the actions of the FDA which approved an unavailable vaccine and intentionally misled the public through its bait-and-switch. This deceit confuses and harms Plaintiffs as well as the nation.

Defendants make the inconsequential accusation that Plaintiffs fail on standing because they are not suing the Department of Defense. FDA alone created the confusion with vague and clever language designed to obfuscate and confuse, and the problem can only be resolved at the source -- end the bait-and-switch and withdraw the biologic license for Comirnaty. At the same time, the FDA empowered the President and the DoD to implement mandates of experimental products, in the military and elsewhere, in clear violation of federal law and universally accepted

medical ethics, thus establishing an abhorrent precedent on the precipice of emergency use authorization of Pfizer vaccines for all individuals, including young children aged 5-11.

2. CHD aims to protect interests germane to its purpose

Plaintiff Children's Health Defense ("CHD") is a large organization that has over two million people associated with it and is growing. While their members boast tens of thousands, CHD reaches well over 5 million individuals every month through their publications and TV channels. CHD provides that its mission is to "end the childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and establish safeguards so this never happens again."[2] The organization goes on to state in its purpose statement that "the one thing we all share is our passionate belief that we have public health policies and practices that are harming our children. For the future good health of our children and planet, we call for more research and transparency."[3] These goals pertain not only to actions that directly affect children, but also those that will set long-lasting and dangerous precedents that will undoubtedly affect future generations of youth.

Furthermore, the organization fights to protect all citizens from various forms of public health harm: wireless radiation harms, glyphosate toxicity, and university student vaccine mandates, to name a few. (See Decl. Mary Holland) All ages are represented in CHD's advocacy. They are the voice for those oppressed by corporate capture of Federal agencies, as we have here.

The confusion as to licensure and EUA affects CHD's servicemen and women who are lifetime members. Am. Compl. ¶ 18. Indeed, FDA's questionable decision-making process is

[2] https://childrenshealthdefense.org/about-us/why-we-do-what-we-do/
[3] *Id.*

already influencing the health of children ages 12-16 who are eligible to receive EUA vaccines. Moreover, the White House released plans on October 20, 2021 to administer COVID-19 vaccines to children ages 5 to 11, pending FDA authorization.[4] During the briefing, COVID-19 response director Jeff Zients stated that, "We have secured vaccine supply to vaccine every child ages 5 through 11. And as soon as the vaccine is authorized by the FDA, we will begin shipping millions of doses worldwide."[5] The actions of the FDA regarding the approval and authorization of Pfizer's COVID-19 vaccine undoubtedly impact the mission of CHD. With potential authorization of EUA Pfizer vaccines for children aged 5-11 within days, the imminent impact of this case on children could hardly be greater. Some of the military members are quite young, and what happens in this case sets the precedent for all future mandates, including those for children, which are likely to be implemented in 2022.

3. The relief sought by CHD does not require the participation of individual members.

Finally, as the FDA does not contest in their motion, CHD's claims do not require any individual members to participate directly in the suit and thus the third factor of associational standing is satisfied.

B. Plaintiffs' Organizational Standing

Organizational standing here also clearly exists. CHD must divert resources from its current activities due to the threat the FDA's bait-and-switch imposes on millions of Americans. Such resource diversion is, itself, grounds for standing. *Bank of Am. Corp. v. City of Miami, Fla.*, 137 S. Ct. 1296, 1303 (2017).

[4]https://www.whitehouse.gov/briefing-room/press-briefings/2021/10/20/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-62/
[5] *Id.*

C. Plaintiffs' Petitioner Standing

1. CHD's Citizen Petition Authorizes Standing in This Case

Defendants allege that Plaintiff Amy Miller lacks standing. Motion to Dismiss, *7, fn.2. Plaintiff Amy Miller has shown that she has suffered an injury in fact, that is (a) concrete and particularized and (b) actual or imminent, the injury is fairly traceable to the actions of FDA; and injunctive relief in this case will redress her injury. *Lujan*, 504 U.S. at 560-561

Amy Miller is one of the many interested persons in the citizen petition process who faces imminent risk of vaccine mandates based on this bait-and-switch by the Defendants. Without the Defendants' bait-and-switch, no vaccine mandates would be occurring, due to the Informed Consent requirements of federal law for emergency authorized only medical products, and as such, she too, like other citizens facing loss of bodily autonomy to access employment, education, or other basic services, such as accommodations to places open to the public.

II. Plaintiffs State Cognizable Claims on Which This Court Can Grant Relief

Vaccines cannot be both licensed and experimental simultaneously. Either the vaccines are available or they aren't; licensed or they aren't. The FDA took the unprecedented step of calling an experimental vaccine "interchangeable" with the safe and effective one. In granting a biologic license simultaneously with re-issuing an EUA for two products that are "legally distinct," the FDA is actively deceiving the public, creating the illusion of safety and "approval" of a product that has not even been manufactured in the United States of America, to the detriment of millions of people. This is reason sufficient to grant the stay.

Plaintiffs ask for this Court to vacate and remand the FDA's decision to license Pfizer's Comirnaty vaccine and to extend its Pfizer-BioNTech EUA on the grounds that FDA's licensure violated the APA, 5 U.S.C. § 706(2)(A) and was arbitrary and capricious. Defendants claim that Plaintiffs do not have a valid claim for relief and that Plaintiffs' claims are unreviewable. Motion to Dismiss at 14-15.

Here CHD sufficiently detailed the FDA's wrongdoing, regardless of whether Defendants believe it is reviewable. Plaintiffs gave sufficient detail to give fair notice of the claim and CHD sufficiently cited 5 U.S.C § 701(2)(A), showing entitlement to relief for a single cause of action with facts, and verified, exhibit-supported harm. Not only are the facts true, they must be accepted as true – something Defendants refuse to acknowledge. FDA effectively admits the bait-and-switch they pulled, and do not dispute that the "approved" vaccine isn't actually available for administration in the United States, despite their misrepresentations to the people.

A. Plaintiffs' challenge to the EUA is reviewable

The APA expressly authorizes standing for citizen petitioners denied legal relief: "a person suffering legal wrong because of agency action…is entitled to judicial review thereof." 5 U.S.C. § 702. Indeed, the entire point of the APA was to assure judicial review of agency action, specifically authorizing federal courts to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). As the Supreme Court advised: a litigant to whom Congress has "accorded a procedural right to protect his concrete interests," *Lujan v. Defenders of Wildlife,* 504 U.S. at 572, n. 7—here, the right to challenge agency action unlawfully withheld, 42 U.S.C. §7607(b)(1)—"can assert that right without meeting all the normal standards for redressability and immediacy." *Ibid.* When a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-

causing party to reconsider the decision that allegedly harmed the litigant. *Ibid;* see also *Sugar Cane Growers Cooperative of Fla.* v. *Veneman*, 289 F. 3d 89, 94–95 (D.C. Cir. 2002) ("A [litigant] who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result")." *Massachusetts v. EPA*, 549 U.S. 497 (2007).

Defendants make an incorrect argument that their conduct is somehow beyond the scope of accountability under APA. Defendants claim *Ass'n of Am. Physicians & Surgeons v. United States FDA ("AAPS I")* as precedent to support Defendants' argument that its arbitrary and capricious conduct is beyond review. *Ass'n of Am. Physicians & Surgeons v. United States FDA*, No. 20-1784, 2020 U.S. App. LEXIS 30622 (6th Cir. Sep. 24, 2020). That case, still under appellate review, stands for no such proposition.

Exemptions from judicial review are rare and narrowly construed. In any event, "nothing in the subsequent enactment of the APA altered the [pre-existing] doctrine of review." *Chamber of Commerce of the United States v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996); see *Duncan v. Muzyn*, 833 F.3d 567, 578 (6th Cir. 2016) (recognizing the ongoing vitality of pre-APA review). As Prof. Davis put it shortly after the APA's enactment, when review is cut off under the Act (i.e., the APA), "[t]he result is that the pre-Act law continues." Kenneth Culp Davis, Nonreviewable Administrative Action, 96 U. PA. L.REV. 749, 776 (1948). Under that pre-APA review, "if an official acts solely on grounds which misapprehend the legal rights of the parties, an otherwise unreviewable discretion may become subject to correction." *Arenas v. United States*, 322 U.S. 419, 432 (1944).

B. FDA's decision to maintain the EUA runs afoul of 21 U.S.C. § 360bbb-3

FDA argues that it has a choice that it "may" revoke an EUA. However, FDA had no right to re-issue an EUA when it contemporaneously granted licensure on August 23, 2021 to a product that is unavailable – with insufficient quantity for distribution in the United States.

In addition, the Federal Food, Drug, and Cosmetic Act recognizes an exception for products distributed under an EUA. *See* 21 U.S.C. § 360bbb-3(a)(1).The Secretary of Health and Human Services (acting through FDA's Commissioner, *id*. § 393(d)(2)) may issue an EUA for an unlicensed vaccine if he declares a public emergency arising from a "disease or condition" attributable to a virus, id. §§ 360bbb-3(a)(1), (a)(2), (b)(1)(C). An authorization can be issued "only if . . . the Secretary concludes . . . that **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) (emphasis added).

The black letter law is clear. There can be no biologic license approved to a medical product for diagnosing, preventing or treating COVID-19 if there is also still an Emergency Use Authorization for the same medical product serving the same purpose. As the Defendants concede, the question of their biologic licensure is absolutely subject to judicial review, and it is that question posed to this court: that no biologic licensure can occur until, and unless, there is no Emergency Use Authorized medical products serving the same purpose as the biologic licensed medical product.

C. Plaintiffs successfully allege that Defendants violated the APA

1. FDA's arbitrary and capricious decision making

The APA affords Plaintiffs the right to challenge Defendants' Conduct which Plaintiffs' First-Amended Complaint properly does.

It is important to be aware of the scope of review a court has when examining an administrative exercise of discretion. The Supreme Court has indicated that a two-step procedure is required, entailing first, a determination whether the agency has acted within the scope of its statutory authority, and, second, whether the actual choice made was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). To make the latter finding, the Court must undertake a "searching and careful" inquiry into the facts. *Id*. An agency's action is "arbitrary and capricious" if it did not articulate any rational connection between the facts it found and the choices it made. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S. Ct. 239, 9 L.Ed.2d 207 (1962).

In their complaint, Plaintiffs successfully pleaded that the FDA's licensure of Pfizer's Comirnaty vaccine was arbitrary and capricious. In its approval, the FDA:

1. failed to examine relevant data;
2. failed to articulate its standard for assessing the issue at hand;
3. relied on factors not intended for it to consider;
4. failed to consider an important aspect of the problem;
5. offered an explanation that runs counter to the evidence; or
6. failed any aspect of reasoned decision-making in the process it utilized to come to its conclusions.

Defendants authorized the Comirnaty vaccine to give the misleading impression to the public that the vaccine that would be mandated if fully approved, when in fact what is available, according to the FDA's own admission is actually the EUA, liability-free, made without good manufacturing policies, product. Politics and industry pressure should play no role in the

approval and authorization process, yet they appear to have been central in the FDA's decision-making process.

Defendants acted arbitrarily and capriciously by failing to engage in a pluralistic, critical, open, transparent and scientific dialogue with the public and medical community based on careful, deliberative evaluation of all relevant research before rushing the approval of this vaccine. As a result, Defendants' actions warrant vacatur and remand. Am. Compl. ¶ 54-58

Furthermore, the Pfizer-BioNTech EUA was re-issued the same day Comirnaty vaccine was approved. While arguably the regulation did not require immediate revocation of the Pfizer-BioNTech, the corporation certainly should not have been reissued the EUA the same day. FDA cannot cite any authority it was granted to re-issue an EUA when a licensed alternative exists.

FDA's approval of the license during the continued extension of the EUA violated the requirement of reasoned decision making detailing all the areas under 5 U.S.C. § 701 that were not followed. Unlike rational-basis review, review of agency action is based on the record before the agency. Compare *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto Ins. Co.*, 463 U.S. 29, 50 (1983) (APA); *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (pre-APA) with *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993).

Defendants had no statutory authority to mislead the public in a classic bait-and-switch. In several respects, FDA's actions exceeded Defendants' statutory authority, which is reviewable under both the APA and pre-APA review.

CHD successfully pleads Defendant FDA exceeded its statutory authority in connection with reissuance of the EUAs. The APA's requirement of "reasoned decision making" is offended since the FDA "agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015) (citation omitted).

III. Plaintiffs Have Satisfied the Standard for a Preliminary Injunction

When determining the appropriateness of a preliminary injunction, a court must examine four factors. First, the court must determine "whether the plaintiff has established a substantial likelihood or probability of success on the merits" of his claim. *Winnett v. Caterpillar, Inc*., 609 F.3d 404, 408 (6th Cir. 2010) (internal quotation marks omitted). Second, the court will determine "whether the [plaintiff] would suffer irreparable injury" if a preliminary injunction is not issued. *Bays v. City of Fairborn*, 668 F.3d 814, 818-819 (6th Cir. 2012) (citing *Certified Restoration Dry Cleaning Network, L.L.C. v. Tenke Corp.*, 511 F.3d 535, 542 (6th Cir. 2007)). Third, the court determines "whether the injunction would cause substantial harm to others." *Id*. at 819. And finally, a court must consider "whether the public interest would be served" if the court were to grant the requested injunction. *Id*.; *Liberty Coins, LLC v. Goodman*, 748 F.3d 682, 689-690

Assuming that the court interprets Defendants' Motion to Dismiss as an opposition to Motion to Stay, Plaintiffs have shown irreparable injury, likelihood of success on the merits, the balance of harm tips in Plaintiffs' favor, and the requested relief is in the public interest.

A. Plaintiffs are substantially likely to succeed on the merits

As demonstrated above, Plaintiffs have successfully pleaded a valid cause of action against Defendants. Plaintiffs have shown Defendants did not properly follow APA rules, and arbitrarily and capriciously granted a biologic license for Pfizer's Comirnaty while simultaneously reissuing an EUA for an experimental vaccine that the FDA claims is both "identical" and "interchangeable."

B. Plaintiffs will suffer irreparable harm if a preliminary injunction is not granted

Constitutional injury is irreparable harm. *See Monsanto Co. v. Manning*, 841 F.2d 1126 (6th Cir. 1998). The First-Amended complaint referenced 14 affidavits attached to Plaintiffs' Amended Motion to Stay (ecf 15) a from CHD members who are service men and women in the US armed forces. Those declarations (ecf 15) detail the imminent and irreparable harm faced as a result of the FDA's bait-and-switch. Loss of bodily autonomy, forfeiture of conscience, no informed consent is irreparable harm. Dishonorable discharge, loss of rank, possible confinement, inability to see loved ones, being ostracized, is irreparable harm.

C. The balance of harm & the public interest weighs in favor of Plaintiffs

There is no harm to Defendants since all Plaintiffs are asking the court to make them follow the law and come clean with the American People, demonstrate honesty and make clear that the FDA is no longer above the law. This is in the public interest.

Defendants argue that granting the requested relief would make it more difficult for those who wish to receive the vaccine to have access to it; this is false. A stay would not alter the EUA for all three COVID-19 vaccines, which are the same products currently on the market for distribution. The requested relief would merely remove the false label of "approved" from the current Pfizer vaccine being administered, and prevent government agencies, schools, private businesses, etc., from mandating an unlicensed product based on the Defendants' bait-and-switch operation.

CONCLUSION

For the foregoing reasons, this Court should deny Defendants' Motion to Dismiss and grant Plaintiffs' motion to stay.

Dated: October 20, 2021

Respectfully submitted,

__/s/ Derek Jordan_____

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