UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT
NO. 21-6203

CHILDREN'S HEALTH DEFENSE, AMY MILLER
Plaintiffs-Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION;
JANET WOODCOCK, M.D., Acting Commissioner of
Food & Drugs, in her official capacity;
Defendants-Appellees.

Appeal from the United States District Court
for the Eastern District of Tennessee (Chattanooga)
District Judge Clifton L Corker District Judge
Case No.: 1:21-cv-00200-DCLC-CHS

REPLY BRIEF FOR THE APPELLANTS CHILDREN'S HEALTH DEFENSE and AMY MILLER

Robert E. Barnes, Esq.
Email: robertbarnes@barneslawllp.com
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211

Ray L. Flores II
Email: rayfloreslaw@gmail.com
11622 El Camino Real Suite 100
San Diego, CA 92130
Telephone: (858) 367-0397

Counsel for Plaintiffs-Appellants

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I. INTRODUCTION

Appellees' Brief[1] obstinately maintains the FDA's[2] claim that its decisions are effectively immune from review under the Administrative Procedures Act ("APA"). Appellees' principal contention is that Appellants are barred from suit for lack of standing, because any injury to Appellants was inflicted by an entirely independent third-party actor, the Department of Defense ("DoD"). This very argument has been tried by government agencies time and time again, and soundly rejected by nearly every court. Even more so here, as the Department of Defense is FDA's Operation Warp Speed partner, who as alleged in the Amended Complaint, openly and explicitly engaged in a joint drive to authorize and implement mass vaccinations of members of the U.S. military.[3]

At the end of the day, Emergency Use Authorization ("EUA")[4] products and vaccines may not be authorized or mandated to military personnel such as the

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[1] "Appellees' Brief" refers herein to the Brief For Appellees filed in this appeal on April 15, 2022 as ECF Doc No. 16.

[2] "FDA" refers herein to the United States Food and Drug Administration and the acting commissioner of Food & Drugs collectively, defendants and appellees in this appeal.

[3] Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges: https://www.gao.gov/products/gao-21-319 Last accessed 4/22/22

[4] 21 U.S.C. § 360bbb-3, authorizes the FDA to issue an Emergency Use Authorization for a vaccine under certain emergency circumstances, allowing a vaccine to be introduced and administered to the public even when the product has not gone through the review process necessary for approval and licensure.

service member Appellants, absent a Presidential Order[5]. Not by the FDA, not by DoD, not by any other governmental authority or entity. The FDA is the ultimate arbiter of drugs and biologics, including vaccines. These products may prevent harm, but they can also result in deaths, serious injuries, and unspeakable tragedy. Appellants are precisely a class of plaintiffs having Article III standing to file suit under the APA, in order to grant the courts an opportunity to review and insure that FDA complies with the APA standards and procedures that Congress authorized.

II. APPELLEES' BRIEF FAILS TO REFUTE THAT APPELLANTS' PLEADING SUFFICIENTLY ALLEGES ORGANIZATIONAL STANDING IN ITS OWN RIGHT

An organization or association 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, 332-333 (6th Cir. 2002). Organizational standing in its own right exists at the pleading stage, if the plaintiff alleges injury to its organizational activities and a consequent drain on its resources. *Havens Realty Corp. v. Coleman,* 455 U.S. 363, 378 (1982) ["drain on the organization's resources"]; *El Rescate Legal Services, Inc. v. Executive Office of Immigration Review,* 959 F.2d 742, 748 (9th Cir. 1991) ["frustra[tion] [of the organization's]

[5] *Doe #1 v. Rumsfeld,* 297 F.Supp.2d 119 (D.D.C. 2003); 10 U.S.C. §1107a.

goals and requir[ing] the organization[] to expend resources … they otherwise would spend in other ways …"]; *Online Merchants Guild v. Cameron,* 995 F.3d 540, 548 (6th Cir. 2021) ("*Online Merchants*") ["'expend[ing] organizational resources in response to the … investigation' by working with members on how best to respond …"]; *see generally* Appellants' Brief, at pp. 20-25.

Appellants' Brief details the drain on CHD's resources and frustration of the organization's goals caused solely and exclusively by the acts of FDA. Namely, the 19-page Citizen Petition CHD submitted to FDA on May 16, 2021 ("Citizen Petition"), requesting that FDA refrain from licensing COVID-19 vaccines, and to revoke EUAs for three existing vaccines. Appellants' Brief, at pp. 22-25; Amended Complaint, RE 19, Page ID #859, ¶ 17; Amended Complaint – Attachment #1, Exhibit 1, RE 19-1, Page ID # 869-888. CHD's resource expenditures also included the man hours required to review FDA's 52-page response to CHD's Citizen Petition. *Ibid., see also* Amended Complaint – Attachment #1, Exhibit 4, RE 19-1, Page ID # 909-962. Appellees' Brief does not contest that CHD in fact prepared and drafted the Citizen Petition, and in fact received and reviewed FDA's response on August 23, 2021[6]. Nor does, or can, Appellees' Brief dispute that those hours expended by CHD were separate and independent of the underlying

[6] As set forth in Appellees' Brief, FDA issued its 52-page response to CHD's Citizen Petition: "after detailing the robust scientific record that supported the safety and effectiveness of the vaccines." Appellees' Brief, pg. 9.

civil action which was filed on August 31, 2021 (and that those man hours included no active participation by DoD). As such, and contrary to the Appellees' Brief's contentions otherwise, the organizational drain on CHD's resources caused by the actions of FDA, and the FDA alone, were: "independent of the suit challenging the action" and thereby "separate concrete interest[s]". Appellees' Brief, at pg. 25 and pg. 27 (citing *Online Merchants, supra,* 995 F.3d at 547 and *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 572 (1992) ("*Lujan*")).

Appellee's Brief barely even addresses the issue of CHD's organizational standing. Appellees' Brief, pg. 26 [arguing merely "the contention fails"]. Nor do the two cases cited in Appellees' Brief support that Appellants' Amended Complaint fails to plead organizational standing. Appellees' Brief, pg. 27. The case of *Lujan, supra,*182 F.3d at 975, actually supports Appellants' standing as set forth in Appellants' Brief (at pg. 35 and 39). The other case cited in Appellees' Brief, *Pfizer v. Shalala,* 182 F.3d 975, 979-980 (D.C. Cir. 1999) does not even contain the word "standing" in the opinion, but rather holds that particular plaintiff's citizens petition to FDA failed to satisfy judicial ripeness principles in that case.

Finally, the suggestion in Appellees' Brief that Appellants' pleading must "pinpoint a harm to Children's Health Defense's mission from the military's vaccination requirement …" yet again misses the operative issue. The sole issue for organizational standing, is whether Appellants' pleading alleges that FDA's

conduct relating to CHD's Citizen's Petition, and CHD's review of FDA's response to the Citizen's Petition, drained CHD's resources and frustrated its goals. The undisputed answer is it did. As such, Appellants' pleading sufficiently pleads Article III standing as an organization.

III. APPELLEES' BRIEF FAILS TO REFUTE ASSOCIATIONAL STANDING ON THE THEORY THAT THE FDA'S ACTIONS ARE ENTIRELY DISTINCT FROM THOSE OF THE DEPARTMENT OF DEFENSE

According to Appellees' Brief: "The issue presented is: Whether the district court correctly concluded that plaintiffs lack Article III standing to sue FDA, where their particular alleged injuries would arise, if at all, from possible actions of third parties rather than FDA." Appellees' Brief, pg. 2. Appellees' Brief goes on to contend that Appellants' pleading failed to allege the injury-in-fact, causation and redressability elements of associational standing because:

> "It is presumed that the Defense Department exercises independent judgment in deciding whether to vaccinate the armed forces, and the Secretary of Defense confirmed as much by announcing that he would seek to require vaccination, whether or not FDA approved the Pfizer vaccine's license." Appellees' Brief, pg. 15.

In other words, go sue the Department of Defense, not us.

FDA's argument here fails because it entirely misframes the operative issue. The singular issue for purposes of this appeal, is whether Article III standing was sufficiently alleged in Appellants' pleading, due to FDA's authorization of Pfizer's Emergency Use Authorization ("EUA") and Comirnaty vaccines in violation of the

APA, thereby causing legal harm to the zone of interests belonging to CHD and its members.

Appellants' Amended Complaint alleges a single cause of action under the APA. Amended Complaint, RE 19, Page ID # 866. The APA sets forth in relevant part: "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702. The APA goes on to state: "[T]he reviewing court shall - ¶ (2) hold unlawful and set aside agency action, findings, and conclusion found to be - ¶ (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;" 5 U.S.C. § 706(2)(A); *see also* Amended Complaint, RE 19, Page ID # 866.

As such, the conduct at issue for injury-in-fact standing analysis, is whether the FDA in authorizing Pfizer's EUA and licensing its Comirnaty vaccine, did so in a manner that was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" 5 U.S.C. § 706(2)(A). Appellees' Brief does not dispute whether or not Appellants' Amended Complaint sufficiently alleges this element (nor did the District Court below for that matter)[7]. Moreover, Appellees do not dispute that the FDA publically represented that the Pfizer EUA and Comirnaty

[7] Rather, Appellees' Brief assumes that even if its EUA and licensing related actions violated the APA, it was DoD that is responsible for any injury-in-fact to Appellants.

license were "'the same formulation'" and "can be substituted for one another". Appellees' Brief, pg. 6.[8] Nor do Appellees dispute that DoD mandated the vaccine in question "after FDA licensed the Pfizer vaccine" on August 24, 2021. *Id.,* at pg. 8.

Ostensibly however, Appellees' Brief argues that any responsibility for Appellants' injuries, is upon DoD. Appellees' Brief, pg. 15 ["It is presumed that the Defense Department exercises independent judgment in deciding whether to vaccinate the armed forces, …."]. Appellees' "sue them not us" argument misunderstands the nature of the remedy afforded by the APA, which focuses upon: "A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action …" 5 U.S.C. § 702; *see also Lexmark Int'l, Inc. v. Static Control Components, Inc.,* 572 U.S. 118, 129 (2014) [the APA extends to any plaintiff whose interests "fall within the zone of interests protected by the law invoked."].

[8] If, as contended in Appellees' Brief, the Pfizer-BioNTech EUA and licensure of Pfizer's Comirnaty vaccine are "[f]or ease [of reference]" purposes one and the same "Pfizer vaccine" (Appellees' Brief, pg. 4, ¶2), how can that "Pfizer vaccine" be both experimental and safe and effective at the same time? If the "Pfizer vaccine" is identical, why doesn't the FDA grant both Pfizer-BioNTech and Comirnaty vaccines a biologics license instead of granting it only to Comirnaty? Indeed, in a confusingly contradictory part of Appellees' Brief, it is stated: "But a licensed vaccine and EUA vaccine are 'legally distinct,' in that they are subject to separate statutory regimes." (Appellee's Brief, at pg. 6, ¶ 2.).

The recent decision in *Booth v. Bowser,* 2022 WL 823068 (D.C. March 18, 2022) ("*Booth*") involved COVID-19 vaccine mandates with circumstances parallel to those at issue here. In *Booth*, parents filed various constitutional challenges to the District of Columbia's Minor Consent for Vaccinations Act Amendment of 2020 ("MCA"), which was passed by the Council of the District of Columbia. The MCA permitted certain minor children to receive a vaccine without parental consent. One of the parents in *Booth* had a 13-year-old child that attended Kipp Academy, a D.C. public charter school, who had not submitted to the COVID-19 vaccine permitted by the MCA. The *Booth* parents alleged that, despite the fact their child had not yet submitted to a vaccination, that the District had nevertheless created: "[a] pressure-cooker environment, enticing and psychologically manipulating [their minor children] to defy their parents and take vaccinations against their parents' wills." *Booth, supra,* at *4. The District argued that the *Booth* parents' alleged injury "depends on 'pure speculation' that [their child] will receive the vaccine", and further "The District argues that because Booth's alleged injuries depend on the independent actions of third parties – both [their child] and healthcare providers – his claims are too speculative to constitute an imminent injury." *Id.,* at *5.

The *Booth* court held the plaintiff parents nevertheless had Article III standing: "To be sure, Booth engages in some hypothesizing about what [their

child] will do. … But here [the child] has made it clear that he is on the cusp of getting vaccinated." *Id.,* at *6. The *Booth* court concluded by holding that the parents had sufficiently pleaded that the "'threatened injury" was "certainly impending to constitute injury in fact,'" *Ibid.* (quoting *Clapper v. Amnesty Int'l USA,* 568 U.S. 398, 409 (2013) ("*Clapper*").) The *Booth* court thus ruled that the plaintiff parents had pled injury-in-fact despite that the imminent threat of vaccination absent their consent would have been administered by a third party, Kipp Academy public charter school, and not the Council of the District of Columbia that actually passed the MCA. *Booth, supra,* at *5.

As Appellees' Brief itself states, the District Court below ruled that the Appellant service members who are members of CHD "had alleged only 'speculative' injuries, and their allegations did not establish any 'certainly impending' harm that qualified as an injury-in-fact. [citations]" Appellees' Brief, pg. 18 (citing *Clapper, supra,* 568 U.S. at 401). The District Court's ruling was erroneous however, under the *Booth* decision's finding of "certainly impending" injury in fact under the very *Clapper* decision relied upon by the District Court.

The District Court's ruling in this regard was also incongruous with the text of the APA, which grants a cause of action for administrative review to any person "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action" 5 U.S.C. § 702. Judicial precedent has applied a broad

standard to the "suffering legal wrong" and "adversely affected or aggrieved" language of 5 U.S.C. § 702.

For example, in *National Collegiate Athletic Ass'n v. Califano,* 622 F.2d 1382 (10th Cir. 1980) ("*Califano*"), the Tenth Circuit held that members of an intercollegiate athletic association bringing suit under the APA had standing in their own right to challenge regulations promulgated by the Department of Health and Human Services ("DHHS"). Specifically, the *Califano* court held that sufficient "legal wrong" under the APA was alleged, and a cause-and-effect relation appeared between the challenged DHHS regulations and the changing operation of intercollegiate athletics programs. In so holding, the *Califano* court applied a broad interpretation of "legal wrong" set forth I 5 U.S.C. § 702: "It is [] clear, in our view, that the members of the NCAA would have standing to sue on their own under the Administrative Procedure Act. This is so whether the question is of 'legal wrongs' or of 'zones of interests'. *Califano, supra,* 622 F.2d at 1389.

Similarly, in *Scenic America, Inc. v. United States Department of Transportation,* 983 F.Supp.2d 170 (D.D.C. 2013) ("*Scenic America*"), the court held that a nonprofit organization whose goal was to preserve and improve the visual character of America's countryside communities, had organizational standing to challenge a "Guidance document" issued by the Federal Highway Administration's (FHA's) under the APA. The Guidance document at issue in

Scenic America permitted construction of digital billboards along interstate highways, subject to the FHA's guidance on the size, lighting, spacing and other digital billboard features. The *Scenic America* court held that the plaintiff organization's injury was fairly traceable to the FHA's Guidance document for Article III standing purposes, even though it was the states' individual decisions whether and how to amend their own regulations on digital billboards that caused the organization's harm:

> "Of course, as this theory of the case makes clear, it is the *States'* decision to amend their regulations to permit the construction of digital billboards that causes Scenic America's harm, not the 2007 Guidance that merely allowed them to do so. Although the burden is formidable, [citation omitted], a plaintiff may establish standing based on the actions of third parties, so long as there is 'substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation.' (citing *Americans for Safe Access v. Drug Enforcement Admin.,* 706 F.3d 438, 446 (D.C. Cir. 2013)." *Scenic America, supra,* 983 F.Supp.2d at 179 (emphasis original).

The *Scenic America* court further held that a favorable court decision vacating the FHA's Guidance document, would redress the organization's injuries: "At the very least, vacating the Guidance would return the FHWA to agnosticism on the question [of digital billboard regulation], leaving Division Offices free to draw their own conclusions." *Id.,* at 181.

What is germane here, is that in the *Califano* and *Scenic America* decisions, the actions of one government agency (the DHHS in *Califano,* and the FHA in

Scenic America), were followed by a separate third-party entity (intercollegiate athletics programs in *Califano,* and individual states in *Scenic America*), and yet the *Califano* and *Scenic America* courts held that the elements of sufficient legal wrong as defined by the APA (i.e. injury-in-fact), causation and judicial redressibility existed between the actions of the government actor defendant on the one hand, and the third party that directly inflicted the plaintiff's harm on the other. The circumstances in *Califano* and *Scenic America* are indistinguishable from the case at bar, which involves acts by a government agency (the FDA) that are followed by another government agency (the DoD). In sum, Appellees' argument that DoD, and not the FDA, is responsible for the injury alleged in the Amended Complaint for purposes of Article III standing – fails.

In addition, as set forth in more detail in Appellants' Amended Complaint and Brief, the FDA and DoD collaborated to such an extent as to render them one and the same executive agency actor, for purposes of the release of the subject Pfizer EUA and Comirnaty vaccines[9]. Specifically, DoD is FDA's Operation Warp Speed partner, and as such is inextricably linked for purposes of the injury-in-fact and causation elements under Article III standing principles[10].

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[9] The FDA works with DoD under a Memorandum of Understanding issued December 12, 2017: https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001

[10] Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges:

In the FDA and DoD's December 11, 2020 joint announcement (the day the subject EUA was granted, and before safety and efficacy were determined by licensure) the DoD stated:

> "The massive logistical planning our military has contributed to Operation Warp Speed gives me even more pride in the talent and dedication of our service members. They have been crucial in bringing a safe and effective vaccine to the American people and in restoring the health of our country." - Acting Secretary of Defense Christopher C. Miller[11]

This joint collaboration began on December 12, 2017 when the President signed into law Public Law No. 115-92 (P.L. 115-92), an Act to amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to:

> "enhance[] collaborations and communication between the U.S. Department of Defense (DoD) and the U.S. Food and Drug Administration (FDA) on DoD's medical product priorities (MPPs) for military emergencies. This Memorandum of Understanding (MOU) implements the framework for this Congressionally-directed collaboration between DoD and FDA."[12]

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https://www.gao.gov/products/gao-21-319 ["Operation Warp Speed (OWS)—a partnership between the Departments of Health and Human Services (HHS) and Defense (DOD)—aimed to help accelerate the development of a COVID-19 vaccine. … FDA issued specific guidance that identified ways that vaccine development may be accelerated during the pandemic."]

[11] Statement From HHS and DOD on FDA Emergency Use Authorization of a COVID-19 Vaccine Candidate December 11, 2020: https://www.defense.gov/News/Releases/Release/Article/2445116/statement-from-hhs-and-dod-on-fda-emergency-use-authorization-of-a-covid-19-vac/

[12] Memorandum of Understanding Concerning Coordination With The Food and Drug Administration Regarding Department of Defense Medical Product Development and Assessment information current as of 3.2.22: https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001

Finally, Appellees' Brief asserts that none of the Appellant service members can demonstrate injury in fact sufficient to plead Article III standing, because: "None of them claimed that they had been vaccinated by the military over their objections." Appellees' Brief, pg. 18. Appellees go on to contend that each and every one of the fifteen Appellant service members sought religious exemptions to getting the COVID-19 vaccines the FDA authorized, because those exemptions had not been denied by DoD yet. Appellees' Brief, pp. 18-20. First, even assuming *arguendo* that each and every Appellant service member did in fact submit religious exemption requests to DoD that had neither been granted nor denied (which is not the case, as Appellants' Brief discusses, at pp. 26-28[13]), that circumstance would be irrelevant. As discussed in more detail in Appellants' Brief, injury-in-fact for Article III standing purposes, is not restricted to injuries that have already occurred, as the District Court erroneously held. *See* Appellants' Brief, pp. 30-32 [citing authority supporting that a credible threat of enforcement by a government agency is sufficient, and even entirely contingent liability and emotional distress can support the injury in fact element]. Second, DoD's religious exemption procedure has already been adjudicated as questionable at a minimum, and potentially a complete ruse:

[13] *See also* Affidavit In Support of Plaintiffs' Motion to Stay, RE 15, Page ID # 631-827.

> "[T]he plaintiffs' contention is – based on current data – quite plausible that each branch's procedure for requesting a religious exemption is a ruse that will result inevitably in the undifferentiated … denial of each service member's request. Particularly, the data produced by the defendants show that more than 16,643 requests for a religious exemption pend. The military has granted no exemptions but has denied hundreds. This disparity, although susceptible to a benign explanation is, as well, susceptible to an explanation actionable and remediable under the [Religious Freedom Restoration Act]." *Navy Seal 1 v. Biden,* 2021 WL 5448970 (M.D. Fla 2021); *see also* Appellants' Brief, at pp. 32-34,

In sum, Appellees' contention that certain Appellant service members submitted religious exemption requests that had not yet been affirmatively denied, is unsupported by the record as well as of no consequence for purposes of Appellants' Article III standing in any event.

IV. APPELLEES' BRIEF FAILS TO REFUTE THAT THE DISTRICT COURT ERRED AS A MATTER OF LAW BY NOT GRANTING APPELLANTS LEAVE TO AMEND THEIR PLEADING

Finally, Appellees' Brief contends that the District Court's refusal to grant Appellants' leave to amend their pleading was not reversible error, because it was not required to do so *sua sponte*. Appellees' Brief, pp. 35-37. This argument is controverted by the applicable case law.

In *Alston v. Parker,* 363 F.3d 229 (3rd Cir. 2004) ("*Alston*")[14], the Third Circuit held:

[14] The *Alston* case is cited in Appellants' Brief (at pg. 41). *Alston* is not cited or discussed in Appellee's Brief (*see* pp. 35-37).

> "We have held that even when a plaintiff does not seek leave to amend, if a complaint is vulnerable to 12(b)(6) dismissal, a District Court must permit a curative amendment, unless an amendment would be inequitable or futile. *Grayson v. Mayview State Hosp.,* 293 F.3d 103, 108 (3d Cir.2002) (citing *Shane v. Fauver,* 213 F.3d 113, 116 (3d Cir.2000)). In *Shane,* we held that this aspect should be considered and noted in dismissing a claim for failure to state a claim:
> '[W]e suggest that district judges expressly state, where appropriate, that the plaintiff has leave to amend within a specified period of time, and that application for dismissal of the action may be made if a timely amendment is not forthcoming within that time. If the plaintiff does not desire to amend, he may file an appropriate notice with the district court asserting his intent to stand on the complaint, at which time an order to dismiss the action would be appropriate.'
> *Id.* at 116 (quoting *Borelli v. City of Reading,* 532 F.2d 950, 951 n. 1 (3d Cir.1976)). … Dismissal without leave to amend is justified only on the grounds of bad faith, undue delay, prejudice, or futility. *Id.* at 115 (citing *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1434 (3d Cir.1997))." *Alston, supra,* 363 F.3d at 235-236.

As a result, the District Court's failure to expressly grant Appellants leave to amend within a specified amount of time, or at a minimum hold that any amendment would be inequitable or futile, was itself reversible error.

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CONCLUSION

For the reasons discussed above, the District Court's granting of Appellees' Motion to Dismiss should be reversed, the Judgment of Dismissal should be vacated, and the action remanded to the District Court to consider the merits of Appellants' Motions to Stay.

Dated: May 6, 2022

/s/ Robert E. Barnes, Esq.
Robert E. Barnes, Esq.
Email: robertbarnes@barneslawllp.com
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211

Ray L. Flores II
Email: rayfloreslaw@gmail.com
11622 El Camino Real Suite 100
San Diego, CA 92130
Telephone: (858) 367-0397

Counsel for Plaintiffs-Appellants

CERTIFICATE OF COMPLIANCE

[FRAP, Rule 32]

This brief complies with the 13,000 word type-volume limit of FRAP 32(a)(7)(B)(ii) and 6 Cir. 32(a) because, excluding the parts of the document exempted by FRAP 32(f), this document contains 4,322 words.

This brief complies with the typeface requirements of FRAP 32(a)(5) and the type style requirements of FRAP 32(a)(6) because this document has been prepared in a proportionally spaced typeface using 14-point Times New Roman style font.

Dated: May 6, 2022

/s/ Robert E. Barnes, Esq.
Robert E. Barnes, Esq.
Email: robertbarnes@barneslawllp.com
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211

Ray L. Flores II
Email: rayfloreslaw@gmail.com
11622 El Camino Real Suite 100
San Diego, CA 92130
Telephone: (858) 367-0397

Counsel for Plaintiffs-Appellants

CERTIFICATE OF SERVICE

I certify that on May 6, 2022, the foregoing Reply Brief For Appellants Children's Health Defense and Amy Miller, was served on all parties or their counsel of record through the CM/ECF system if they are registered users or, if they are not, by placing a true and correct copy in the United States mail, postage prepaid, to their address of record as follows:

Food & Drug Administration Food & Drug Administration
c/o U.S. Attorney's Office
1110 Market Street, Suite 515
Chattanooga, TN 37402

Food & Drug Administration Food & Drug Administration
c/o U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Janet Woodcock,
acting commissioner of Food & Drugs
Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

/s/ Robert E. Barnes, Esq.
Robert E. Barnes, Esq.
Email: robertbarnes@barneslawllp.com
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211

Counsel for Plaintiffs-Appellants