No. 21-6203

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

CHILDREN'S HEALTH DEFENSE; AMY MILLER,

Plaintiffs–Appellants,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; JANET WOODCOCK, MD,

Defendants–Appellees.

On Appeal from the United States District Court
for the Eastern District of Tennessee

BRIEF FOR APPELLEES

Of Counsel:

DANIEL J. BARRY
Acting General Counsel
U.S. Department of Health and Human Services

MARK J. RAZA
Chief Counsel

WENDY VICENTE
Acting Deputy Chief Counsel, Litigation

JAMES S. ALLRED
Associate Chief Counsel
U.S. Food & Drug Administration

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

FRANCIS M. HAMILTON III
Acting United States Attorney

SCOTT R. MCINTOSH
DENNIS FAN
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, DC 20530
(202) 514-2494
dennis.fan@usdoj.gov

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulation:

Other Authorities:

STATEMENT REGARDING ORAL ARGUMENT

The district court dismissed plaintiffs' amended complaint, concluding that they lack Article III standing to challenge the U.S. Food and Drug Administration's licensing and emergency use authorization of Pfizer's COVID-19 vaccine. The court held that plaintiffs had failed to demonstrate each of the three requirements for standing, as they had asserted no imminent harm to themselves from the vaccine and as any purported harm was the result of the actions of third parties rather than FDA. The government stands ready to present oral argument if it would be of assistance to this Court.

STATEMENT OF JURISDICTION

Plaintiffs' operative complaint asserts a claim under the Administrative Procedure Act and invokes the jurisdiction of the district court pursuant to 28 U.S.C. §§ 1331 and 1361. *See* Am. Compl., RE 19, Page ID # 857. On November 30, 2021, the court entered final judgment dismissing that complaint. *See* Judgment, RE 29, Page ID # 1088. On December 16, plaintiffs filed a timely notice of appeal. *See* Notice of Appeal, RE 30, Page ID # 1089.

STATEMENT OF THE ISSUE

Plaintiffs are a children's health organization that has attempted to represent adult military service members in this suit and one of the organization's members, who have asserted injuries based on the possible consequences of service members declining to follow the military's COVID-19 vaccination requirements. But rather than challenge those vaccination requirements, plaintiffs have sued the U.S. Food and Drug Administration (FDA), objecting to FDA's regulatory actions that have allowed the introduction into interstate commerce of a vaccine manufactured by Pfizer Inc. and BioNTech Manufacturing GmbH. The district court dismissed plaintiffs' amended complaint, holding that they had failed to satisfy all three requirements of Article III standing,

in large part because their suit was premised on the possible actions of third parties rather than FDA. 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.

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

A. FDA Vaccine Authorities

The Public Health Service Act generally prohibits the introduction of biological products such as vaccines into interstate commerce absent an approved biologics license application from FDA. *See* 42 U.S.C. § 262(a)(1)(A), (i)(1). To obtain a license, a manufacturer must submit an application to FDA, which the agency reviews to determine, among other things, whether the product is "safe, pure, and potent" and whether the product will be manufactured and processed in a facility designed to assure that it is "safe, pure, and potent." *Id.* § 262(a)(2)(C). FDA, in conducting that review, considers clinical studies as well as non-clinical laboratory studies. *See* 21 C.F.R. § 601.2(a).

Separately, the Federal Food, Drug, and Cosmetic Act provides that FDA may authorize biological products such as vaccines that are "intended for use

in an actual or potential emergency," "[n]otwithstanding" the Public Health Service Act's licensing provisions. 21 U.S.C. § 360bbb-3(a)(1). The Secretary of Health and Human Services may declare that circumstances justifying an emergency use authorization (EUA) exist if there is a current or impending public-health emergency. *Id.* § 360bbb-3(b)(1). FDA may then issue an EUA for vaccines or other products intended for use in diagnosing, treating, or preventing the serious or life-threatening disease or condition that caused the emergency. *Id.* § 360bbb-3(c)(1).

To issue an EUA, FDA must find that it is reasonable to believe that the vaccine is effective "based on the totality of scientific evidence … including data from adequate and well-controlled clinical trials, if available," and that the product's benefits outweigh its risks. 21 U.S.C. § 360bbb-3(c)(2). FDA also determines whether there is any "adequate, approved, and available alternative to the product." *Id.* § 360bbb-3(c)(3). The statute instructs FDA to "periodically review" the appropriateness of issued EUAs, and the agency "may" revoke an authorization if either the emergency or the conditions required for an EUA are no longer present. *Id.* § 360bbb-3(g)(1), (2); *see id.* § 360bbb-3(f)(1).

FDA's licensing authority under 42 U.S.C. § 262 and its EUA authority under 21 U.S.C. § 360bbb-3 are independent of each other. FDA's licensing

authority does not affect the agency's EUA authority, *see* 21 U.S.C. § 360bbb-3(a)(1); 42 U.S.C. § 262(g)—and vice versa, *see* 21 U.S.C. § 360bbb-3(*l*); *see also id.* § 360bbb-3(k).

B. FDA License and EUA for the Pfizer Vaccine

In response to the COVID-19 pandemic, FDA has permitted the distribution of a vaccine manufactured by Pfizer and BioNTech, first pursuant to an EUA and then (under the tradename Comirnaty) pursuant to an approved biologics license application. For ease, this brief refers to the products as the Pfizer vaccine.

1. In February 2020, the Secretary of Health and Human Services made a determination of a "public health emergency … that involves a novel (new) coronavirus … first detected in Wuhan City, Hubei Province, China in 2019," known as SARS-CoV-2, the virus that causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). Then, in March 2020, the Secretary declared that "circumstances exist justifying the authorization of emergency use of drugs and biological products." 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020). The Secretary's determination and declaration remain in effect.

In December 2020, after a thorough evaluation of the available scientific data, FDA issued an EUA for the then-unlicensed Pfizer vaccine for the prevention of COVID-19 in individuals who are 16 years of age and older. *See* FDA, *Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum* (Dec. 11, 2020), https://go.usa.gov/xzpzn. FDA has since reissued the EUA multiple times to update the vaccine's labeling with information on any safety issues and to incorporate EUA amendments. *See* FDA, *Emergency Use Authorization* (updated Apr. 11, 2022), https://go.usa.gov/xzpuX (FDA EUAs). Those amendments have, for instance, extended the authorization first to children who are 12 to 15 years of age and then to children who are 5 to 11 years of age, and also authorized the administration of booster doses in certain populations. *Id.*

2. On August 23, 2021, FDA approved a license for the Pfizer vaccine, for individuals who are 16 years of age and older. *See* Pfizer License, RE 19-1, Page ID # 964. The license was based on clinical studies of safety and effectiveness and on additional data, which encompassed safety information from the use of the vaccine manufactured pursuant to the EUA. *See* FDA, *Summary Basis for Regulatory Action* 22–23 (Nov. 8, 2021), https://go.usa.gov/xzdcg. FDA thus determined that the vaccine met the "high standards for safety, effectiveness,

and manufacturing quality that FDA requires of an approved product." FDA, Press Release, *FDA Approves First COVID-19 Vaccine* (Aug. 23, 2021), https://go.usa.gov/xugMS.

When it licensed the Pfizer vaccine, FDA contemporaneously reissued an EUA for the product. *See* Aug. 2021 Pfizer EUA, RE 19-1, Page ID # 896. FDA explained that the licensed vaccines have "the same formulation" as the corresponding EUA-authorized vaccines and that they can be substituted for one another in a series of vaccine doses "without presenting any safety or effectiveness concerns." *Id.*, RE 19-1, Page ID # 897 n.8. But a licensed vaccine and EUA vaccine are "legally distinct," in that they are subject to separate statutory regimes (which affects, for instance, standards governing labeling and the testing of vaccine lots). *Id.*; *see* FDA, *Q&A for Comirnaty (COVID-19 Vaccine mRNA)* (updated Feb. 8, 2022), https://go.usa.gov/xucdP (FDA Pfizer Q&A) (detailing distinctions between licensed and EUA vaccine).

As noted above, FDA may issue an EUA if, among other things, there is "no adequate, approved, and available alternative to the product." 21 U.S.C. § 360bbb-3(c)(3). FDA thus explained that it was maintaining the EUA here because there was "no adequate, approved, and available alternative" to the EUA product. Aug. 2021 Pfizer EUA, RE 19-1 Page ID # 900 (footnote omitted).

Specifically, there was "not sufficient approved vaccine" manufactured pursuant to the new license "available for distribution to [the target] population in its entirety at the time," and the licensed vaccine also had not been approved for children who are 5 to 15 years of age or for administering booster doses. *Id.*, RE 19-1, Page ID # 900 n.9.

3. Separately, FDA has issued an EUA and approved a license for the COVID-19 vaccine manufactured by ModernaTX, Inc. (under the tradename Spikevax), and issued an EUA for the vaccine manufactured by Janssen Biotech, Inc., a subsidiary of Johnson & Johnson (J&J). *See* FDA EUAs, *supra*.

C. Military Vaccine Policies

The U.S. Department of Defense has long relied on mandatory immunization to further military preparedness, and service members may be required to be vaccinated even when a vaccine is available only pursuant to an EUA. *See* 10 U.S.C. § 1107a; *see also* Stanley M. Lemon, *et al.*, *Protecting Our Forces: Improving Vaccine Acquisition and Availability in the U.S. Military* 12 (2002), https://perma.cc/E545-TQ9G (recounting George Washington's instruction to inoculate the Continental Army against smallpox). The Federal Food, Drug,

and Cosmetic Act states that nothing in its EUA provisions "impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces." 21 U.S.C. § 360bbb-3(j)(2).

In August 2021, after FDA had issued the Pfizer EUA but before the FDA had approved the Pfizer license, Secretary of Defense Lloyd Austin announced that he would "seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the [FDA] licensure, whichever comes first." Lloyd F. Austin, *Message to the Force* (Aug. 9, 2021), https://go.usa.gov/ xzw9b (Austin Message). On August 24, after FDA licensed the Pfizer vaccine, Secretary Austin added COVID-19 vaccination to the required list of vaccines for active-duty and reserve service members. *See* Lloyd F. Austin, *Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members* (Aug. 24, 2021), https://go.usa.gov/xzwXT. As with any other vaccination requirement, service members may seek medical exemptions and administrative exemptions (including to accommodate religious objections) from the Defense Department's COVID-19 policy. *See generally* U.S. Dep't of Def., Instruction 6205.02, DoD Immunization Program § 1.2.c (July 23, 2019), https://go.usa.gov/xucPe.

II. FACTUAL AND PROCEDURAL BACKGROUND

1. In May 2021, before the Pfizer vaccine had been licensed, plaintiff Children's Health Defense submitted a petition to FDA, asserting that safety concerns required the agency to revoke its EUAs for the Pfizer, Moderna, and J&J vaccines and to refrain from licensing any vaccine for the prevention of COVID-19. *See* Petition, RE 19-1, Page ID # 871. FDA denied the petition after detailing the robust scientific record that supported the safety and effectiveness of the vaccines. *See* Denial Letter, RE 19-1, Page ID ## 910–52.

On August 31, 2021, plaintiffs Children's Health Defense and Amy Miller (a member of the organization) brought suit under the Administrative Procedure Act against defendants FDA and its Commissioner. *See* Compl. RE 1, Page ID # 1. Plaintiffs contended that FDA could not license the Pfizer vaccine while "simultaneously" reissuing an EUA for the vaccine. *Id.*, RE 1, Page ID ## 5, 8, 9. In that regard, as plaintiffs confirm on appeal (Br. 12), they challenge *either* the license or the EUA, in the "alternative." Plaintiffs sought an immediate temporary restraining order and preliminary injunction against FDA (styled as a stay of agency action under 5 U.S.C. § 705). *See Ex Parte* Stay Mot., RE 8, Page ID # 546; Stay Mot., RE 9, Page ID # 564.

2. The district court first denied a temporary restraining order. *See* TRO Order, RE 10, Page ID # 593 (denying *Ex Parte* Stay Mot., RE 8, Page ID # 546). The court concluded that plaintiffs' "allegations of harm"—based on a purported "false impression" that FDA created about the Pfizer vaccine by both licensing and reissuing an EUA—were "speculative at best." *Id.*, RE 10, Page ID ## 596–97 (quotation omitted). Plaintiffs had also asserted that military vaccination requirements harmed service members, but the court explained that plaintiffs "fail to identify any military member" with injuries. *Id.*, RE 10, Page ID # 597.

Prompted by the district court's ruling, plaintiffs amended their complaint in an attempt to allege harm. *See* Am. Compl., RE 19, Page ID # 856. According to the amended complaint, Children's Health Defense sued "on behalf of its members" and alleged harms to fifteen individual service members who belonged to the organization. *Id.*, RE 19, Page ID ## 857, 859. That complaint alleges that FDA's license for the Pfizer vaccine "triggered employer, military, educational and institutional mandates across the country, coercing millions of healthy individuals to take unwanted, risky medical interventions." *Id.*, RE 19, Page ID # 865.

Children's Health Defense also brought suit "in its own capacity," but the complaint alleges no injury to the organization other than the fact that FDA "responded to" its petition. Am. Compl., RE 19, Page ID ## 857, 860. And individual plaintiff Miller alleged only that she was "at imminent risk of immediate harm from FDA's actions," without specifying the risk or harm, or the factual basis for its imminence. *Id.*, RE 19, Page ID # 857.

3. The district court again denied injunctive relief and also dismissed plaintiffs' amended complaint, concluding that they had failed to demonstrate each of the three requirements of Article III standing—injury-in-fact, causation, and redressability. *See* Op., RE 28, Page ID # 1075.

The district court first determined that plaintiffs' allegations had not established an actual or imminent harm, as required for an injury-in-fact. The court noted that a generalized grievance that "FDA is failing to carry out its mission" by licensing and reissuing an EUA for the Pfizer vaccine was insufficient to constitute an injury for Article III purposes. Op., RE 28, Page ID # 1082 (quotation omitted). Children's Health Defense had also failed to demonstrate associational standing on behalf of its members who serve in the military, as those individuals either did not state that they were yet required to take the Pfizer vaccine or did not assert that their requests for a medical or religious

exemption had been denied. *Id.*, RE 28, Page ID # 1083 & n.3. FDA's denial of the organization's petition also could not confer standing, as there was no allegation that any harm stemmed from the denial. *Id.*, RE 28, Page ID # 1084. And Miller had not included any specific allegations of harm. *Id.*, RE 28, Page ID # 1083.

The district court also held that, even if the plaintiffs had adequately alleged injuries, any harms would not have been caused by FDA's actions. The court pointed out that a plaintiff's injury must be "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." Op., RE 28, Page ID # 1084 (cleaned up) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Plaintiffs asserted harms from military vaccination requirements, and the service members purportedly "face[d] court martial, less than an honorable discharge, and exclusion from dining halls and gyms" if they refused to be vaccinated. *Id.*, RE 28, Page ID # 1083. But those harms were "not fairly traceable to the specific actions of the FDA," which did not require vaccination. *Id.*, RE 28, Page ID # 1084. Instead, the requirements were attributable to "the various branches of the United States military," and "not the FDA." *Id.*

Last, the district court confirmed that relief against FDA would not redress plaintiffs' purported injuries. As the court held, even if it invalidated the Pfizer license, the "EUA remains in place." Op., RE 28, Page ID # 1086. And "the third parties instituting the vaccine mandates" could continue to require vaccination, as confirmed by Secretary of Defense Austin's statement that he would seek to require vaccination for the military before a vaccine was licensed, by choosing to rely on the EUA instead if no license was approved by mid-September 2021. *Id.* (citing Austin Message, *supra*).

SUMMARY OF ARGUMENT

By issuing an EUA and then approving a license for the Pfizer vaccine, FDA has permitted the introduction into interstate commerce of a product that combats the COVID-19 pandemic. FDA's decisions do not require anyone to be vaccinated, however. Instead, third parties, such as the military, have independently chosen to require vaccination, pursuant to their own policies. Plaintiffs claim that they face harm from those vaccination requirements. But rather than requesting relief against the Department of Defense, whose policies are the source of those asserted harms, plaintiffs seek to leverage the Defense Department's COVID-19 vaccination requirement for service members as a basis to challenge FDA's license and EUA for the Pfizer vaccine.

The district court properly concluded that plaintiffs had failed to satisfy each of the three requirements of Article III standing. To establish an injury-in-fact, Children's Health Defense attempted to assert associational standing on behalf of a number of service members who belong to the organization. But the service members' allegations do not show any actual or imminent injury: they do not claim to have been vaccinated over their objections; instead, they almost uniformly had requested or intended to request medical or religious exemptions from the military's vaccination requirements. Nor is Children's Health Defense—an organization that advocates for *children's* health—an appropriate plaintiff to assert an injury to adult service members from military vaccination requirements, especially when the organization has no apparent stake in the litigation other than its litigating costs. As for individual plaintiff Miller, the complaint does not specify any injury at all.

Even if plaintiffs could establish an injury-in-fact from the military's vaccination requirements, their failure to satisfy the causation and redressability requirements of Article III standing precludes their suit. Those two requirements are "ordinarily substantially more difficult to establish" where, as here, the asserted injury stems from the actions of third parties. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992) (quotation omitted). The allegations of

harm on which plaintiffs rely involve the potential consequences of the Defense Department's vaccination policy. 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. Moreover, the military's continued discretion is underscored by the fact that the Pfizer vaccine will remain available in some form even if plaintiffs were to prevail in this action: plaintiffs request (Br. 12) relief in the "alternative"—demanding that FDA rescind the EUA *or* the license, but not both. Thus, plaintiffs' injuries are not caused by FDA and, in any event, would not be redressed by their suit.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's order dismissing a complaint for lack of Article III standing. *See Association of Am. Physicians & Surgeons v. FDA*, 13 F.4th 531, 535 (6th Cir. 2021) (*AAPS*).

ARGUMENT

THE DISTRICT COURT CORRECTLY CONCLUDED THAT PLAINTIFFS LACK ARTICLE III STANDING TO CHALLENGE FDA'S LICENSE AND EUA FOR THE PFIZER COVID-19 VACCINE

The district court properly dismissed plaintiffs Children's Health Defense and Miller's misdirected challenge to FDA's regulatory actions, correctly concluding that they lack Article III standing to sue the agency. The court held that the amended complaint failed to support each standing requirement, because plaintiffs had not pled with specificity that they "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of [FDA], and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016); *see Wuliger v. Manufacturers Life Ins. Co.*, 567 F.3d 787, 793 (6th Cir. 2009). Despite plaintiffs' stated dissatisfaction with FDA, "[f]ederal courts do not exercise general legal oversight of the Legislative and Executive Branches" and "may resolve only a real controversy with real impact on real persons." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021) (quotation omitted). These plaintiffs have not asserted such a controversy.

A. Plaintiffs' Speculation Concerning Actions that a Third Party Might Take Is Insufficient to Establish an Actual or Imminent Injury-in-Fact

The district court properly concluded, as an initial matter, that plaintiffs had failed to demonstrate an injury-in-fact. *See* Op., RE 28, Page ID ## 1081–84. As this Court has instructed, a plaintiff's general "belief that the FDA has engaged in wrongdoing does not prove its standing because its 'disagreement' with the FDA is not an injury, no matter how 'sharp and acrimonious' it may be." *AAPS v. FDA*, 13 F.4th 531, 537 (6th Cir. 2021) (quoting *Hollingsworth v. Perry*, 570 U.S. 693, 704 (2013)). Instead, in demanding an injury-in-fact, the Court requires suit by an appropriate plaintiff with a "personal stake in the outcome," to assure a "concrete adverseness which sharpens the presentation of issues." *City of Los Angeles v. Lyons*, 461 U.S. 95, 101 (1983) (quotation omitted). A plaintiff must suffer a harm in a "personal and individual way" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, 578 U.S. at 339 (quotation omitted). And where the injury has not occurred, the threatened injury must be "certainly impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 401 (2013). The district court correctly held that plaintiffs' allegations do not satisfy these requirements.

1. Children's Health Defense has not satisfied the requirements for associational standing

The district court properly rejected Children's Health Defense's principal basis for an injury-in-fact—its reliance on the supposed injuries of service members who belong to the organization. *See* Op., RE 28, Page ID # 1083. To establish associational standing, an organization must show that: "(1) its members would otherwise have standing to sue in their own right; (2) the interests that the suit seeks to protect 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." *AAPS*, 13 F.4th at 537 (quotation omitted). The first and second requirements are missing here.

1. As the district court recognized, the identified service members who are members of Children's Health Defense had alleged only "speculative" injuries, and their allegations did not establish any "'certainly impending'" harm that qualified as an injury-in-fact. Op., RE 28, Page ID # 1083 (quoting *Clapper*, 568 U.S. at 401). None of them claimed that they had been vaccinated by the military over their objections. Though plaintiffs stated that the military could impose adverse consequences if service members elected not to be vaccinated, the service members had only asserted a "belie[f]" that "court martial, less than an honorable discharge, and exclusion from dining halls and gyms"

"might occur in the future." *Id.* Such speculation about "mere possibilit[ies]" is insufficient. *Id.* (quoting *AAPS*, 13 F.4th at 545).

The district court's careful review of the fifteen service members' individual declarations revealed only further degrees of speculation. *See* Op., RE 28, Page ID # 1083 & n.3. As the court surveyed, twelve of the service members had requested or intended to request a medical or religious exemption from the military's COVID-19 vaccination requirement. *See* Craymer Decl., RE 15, Page ID # 637; Eschmann Decl., RE 15, Page ID # 649; Hastriter Decl., RE 15, Page ID # 658; Hollowell Decl., RE 15, Page ID # 668; Mason Decl., RE 15, Page ID # 673; Meacham Decl., RE 15, Page ID # 682; Nuss Decl., RE 15, Page ID # 715; Perez Decl., RE 15, Page ID # 720; Raethel Decl., RE 15, Page ID # 755; Santos Decl., RE 15, Page ID # 760; Sweger Decl., RE 15, Page ID # 804; Am. Zito Decl., RE 20, Page ID # 986. One other service member requested an opportunity to see a healthcare provider first, *see* Shour Decl., RE 15, Page ID # 766, while another was apparently willing to take a licensed vaccine (rather than an EUA vaccine), *see* Stanzione Decl., RE 15, Page ID # 784. The final declarant—a former service member who writes for Children's Health Defense's newsletter—asserted no harms to herself at all. *See* Long Decl., RE 15,

Page ID # 631. None of these allegations established that the service members were facing any "certainly impending" injury. *Clapper*, 568 U.S. at 401.

Plaintiffs only highlight their suit's deficiencies in selecting (Br. 27–28) two exemplars among these service members. Officer Robert Perez stated that the military had directed him to be vaccinated, but plaintiffs' brief altogether omits that he apparently already holds a "long-standing Religious Accommodation" and his commanding officer therefore instructed him "to bring [religious-exemption] documentation" to the vaccination site. Perez Decl., RE 15, Page ID ## 720, 723; *see id.*, RE 15, Page ID # 724 (religious-exemption documentation). Sergeant Steven Raethel wrote that he fears losing his career if he refuses to be vaccinated, but plaintiffs' brief fails to mention that he is "currently pursuing a religious exemption for this vaccine." Raethel Decl., RE 15, Page ID # 755.

Plaintiffs nonetheless assert (Br. 31–32) that it does not matter that the service members' threatened injuries are "contingent" on future events, such as the service members applying for a medical or religious exemption and the military considering and denying the exemption. But a "threatened injury must be certainly impending," *Clapper*, 568 U.S. at 410, rather than be uncertain, as it is here. And when future harm is contingent on uncertain events that

may or may not transpire, a plaintiff must demonstrate that the mere possibility of future injury "immediately and directly" causes *present* financial or other harms. *Clinton v. City of New York*, 524 U.S. 417, 431 (1998) (finding injury-in-fact where "a substantial contingent liability immediately and directly affects the borrowing power, financial strength, and fiscal planning of the potential obligor"). Plaintiffs have made no such demonstration here.

Unable to marshal any actual or imminent consequences from declining to be vaccinated, plaintiffs argue (Br. 27, 30, 32) that it is enough that service members have felt "pressur[ed]" or faced "coercive measures" or suffered "emotional distress." But an injury-in-fact cannot be supported by a "fear" or apprehension that, based on some agency policy, "the agency might in the future take some *other* and additional action detrimental to that individual." *Clapper*, 568 U.S. at 418 (quotation omitted). Mere "emotional consequences" from observing the government engage in regulatory action are insufficient "absent a real and immediate threat of future injury." *Lyons*, 461 U.S. at 107 n.8. Though plaintiffs cite (Br. 32) this Court's precedents that accept extreme psychological distress in specific contexts, the service members have never given content to the nature, degree, and objective basis for that specific sort of mental injury. *See Gerber v. Herskovitz*, 14 F.4th 500, 507 (6th Cir. 2021) (finding injury-in-

fact based on "extreme" distress from allegedly unconstitutional actions that specifically "target[ed]" the plaintiffs).

Nor is it enough for plaintiffs to claim (Br. 11, 27) an abstract harm from FDA's allegedly "misleading representations" or supposed "bait-and-switch." This Court has confirmed that a plaintiff's "belief that the FDA has engaged in wrongdoing does not prove its standing because its 'disagreement' with the FDA is not an injury." *AAPS*, 13 F.4th at 537 (quotation omitted). In any case, there is nothing misleading about FDA's actions, such that plaintiffs' confusion could amount to an injury-in-fact. As FDA explained, the agency has licensed the Pfizer vaccine but has also maintained an EUA for the Pfizer vaccine because there have not been sufficient doses of licensed vaccines available for distribution to the target population of the vaccine. *See* Aug. 2021 Pfizer EUA, RE 19-1 Page ID # 900 & n.9. The licensed vaccines thus share "the same formulation" with the corresponding EUA vaccines, but are governed by different statutory regimes (which affects, for instance, the standards concerning labeling and the testing of vaccine lots). *Id.*, RE 19-1, Page ID # 897; *see supra* at 2–4 (describing Public Health Service Act and Federal Food, Drug and Cosmetic Act). Though it is regrettable when any member of the public finds FDA's ac-

tions confusing, that generalized confusion does not establish standing, particularly where FDA has issued public guidance concerning the licensed vaccine and the EUA vaccine. *See* FDA Pfizer Q&A, *supra*.

2. Even if some service members who are members of Children's Health Defense could demonstrate an injury-in-fact, plaintiffs cannot establish that those interests are "'germane' to [the] purpose" of Children's Health Defense in particular. *AAPS*, 13 F.4th at 542. Children's Health Defense is not the appropriate plaintiff to assert standing on behalf of service members' interests unless it has been "organized for [that] purpose." *United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 545 (1996).

Children's Health Defense cannot coopt the interests of service members here. Children's Health Defense—as one might expect from the organization's name—is organized to advocate for children's health. As told by its President, the organization advocates against a number of "public health policies" in order to "end the *childhood* health epidemics." Holland Decl., RE 26, Page ID # 1057 (emphasis added) (quotation omitted). Children's Health Defense engages in "multiple legal initiatives in an effort to defend the health of our children and obtain justice for those already injured." Children's Health Defense, *The Mission of Children's Health Defense*, https://perma.cc/FM8J-BS5S; *see* Br. 34 n.8

(directing the Court to organization's website). Those efforts encompass advocacy against policies such as "university student vaccine mandates." Holland Decl., RE 26, Page ID # 1057. The connection between the organization's advocacy focused on children or students and the interests of adult members of the military, however, is tenuous at best. At a minimum, nothing in the complaint explains how the vaccination of adult service members has a natural relationship to the health of children. Thus, even assuming that service members (or perhaps a military organization) might be "in a position to serve as [FDA's] natural adversary" in litigation, Children's Health Defense lacks an adequate "stake in the resolution of the dispute" to assert those interests. *Brown Grp.*, 517 U.S. at 555–56.

2. Children's Health Defense has not satisfied the requirements for organizational standing

The district court also correctly held that Children's Health Defense had not alleged an injury-in-fact to itself, such that it had organizational standing. *See* Op., RE 28, Page ID ## 1082–83. As the court sensibly explained, it was not enough for Children's Health Defense to rely on the generalized assertion that FDA had "flagrantly violated federal law" or "fail[ed] to carry out its mission." Op., RE 28, Page ID # 1082 (quotation omitted). Nor is it enough for the organization to profess its opposition to particular "vaccine mandates." Holland

Decl., RE 26, Page ID # 1057. An organization must show "that its ability to further its goals has been 'perceptibly impaired' so as to constitute far more than simply a setback to the organization's abstract social interests." *Greater Cincinnati Coal. for the Homeless v. City of Cincinnati*, 56 F.3d 710, 716–17 (6th Cir. 1995) (cleaned up) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)).

Plaintiffs fail to specify a relevant organizational mission that has been harmed, and instead contend (Br. 21–22) that Children's Health Defense's "pre-litigation efforts" and "expenses associated with litigation" relating to the Pfizer vaccine are the source of its injury. But an organization "must demonstrate that the purportedly illegal action increases the resources the group must devote to programs *independent of its suit* challenging the action." *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 547 (6th Cir. 2021) (emphasis added) (quotation omitted). As this Court has recognized, even if an organization has "significantly shifted [its] operations, activities, and strategies in response to the COVID-19 pandemic" and its aftereffects, courts still should not permit an organization to "spend its way into standing." *Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 389 (6th Cir. 2020) (quotation omitted).

Contrary to plaintiffs' view (Br. 21–22), this Court's decisions do not endorse the circular proposition that an organization's litigation costs are themselves an injury-in-fact. Those decisions instead hold that, for purposes of organizational standing, the challenged action must in some manner first hamper an organization's mission such that the organization is necessarily called upon to invest resources (through litigation or otherwise). *See Online Merchs.*, 995 F.3d at 548 (finding that organizational expenditures "fall within its mission to advocate for the interests of online merchants"); *Hooker v. Weathers*, 990 F.2d 913, 915 (6th Cir. 1993) (finding that organizational expenditures advance its mission "to eliminate discriminatory housing practices"). As plaintiffs seemingly recognize (Br. 24 n.6), their complaint does not pinpoint a harm to Children's Health Defense's mission from the military's vaccination requirement, other than to assert that they have spent resources litigating against FDA. Plaintiffs cannot bootstrap their way into standing by bringing suit and by then complaining that the cost of suing is itself an Article III injury.

Insofar as plaintiffs claim (Br. 18–19, 35) an injury because FDA denied Children's Health Defense's petition, the contention fails. That administrative

denial produces an injury-in-fact only if it "impair[s] a *separate* concrete interest," which is missing here, as discussed above. *Lujan*, 504 U.S. at 572 (emphasis added); *see Pfizer v. Shalala*, 182 F.3d 975, 979–80 (D.C. Cir. 1999) (finding FDA's denial of a petition alone insufficient for standing purposes).

3. Miller has not demonstrated an injury-in-fact

As to individual plaintiff Miller, the district court properly held that she had not alleged an injury-in-fact either. *See* Op., RE 28, Page ID ## 1082–83. The amended complaint makes only a conclusory allegation that she faces an "imminent risk of immediate harm from FDA's actions," without identifying the risk or harm, or how the injury is imminent. Am. Compl. RE 19, Page ID # 857. These "[g]eneralized allegations" are insufficient without "specific, concrete facts showing a demonstrable injury." *Turaani v. Wray*, 988 F.3d 313, 317–18 (6th Cir. 2021) (quotation omitted). And by offering no basis to disturb the dismissal of Miller's claim, plaintiffs on appeal have "abandoned any such challenge." *Hih v. Lynch*, 812 F.3d 551, 556 (6th Cir. 2016); *see AAPS*, 13 F.4th at 537.

B. Plaintiffs' Asserted Injuries Are Traceable to Third Parties' Vaccine Policies Rather than to FDA's Actions

Even if this Court finds that Children's Health Defense's members (or plaintiffs' themselves) have been injured by vaccine requirements, the district court properly concluded that they cannot satisfy the causation requirement,

as plaintiffs' injuries were not the result of the specific FDA action that they challenge. *See* Op., RE 28, Page ID ## 1084–86. FDA does not require the general public to be vaccinated. Instead, as the court recognized, the specific FDA action that plaintiffs challenge has been the agency's decision to both "license" the Pfizer vaccine and "reauthorize" its EUA at the same time, rather than engage in only one regulatory action (as plaintiffs would prefer). *Id.*, RE 28, Page ID # 1084. But any claimed injuries do not arise from that action. Any injuries here arise from "vaccine mandates" by the military—which do not hinge on FDA's challenged action—and thus are "tied to the actions of … military leadership and not … FDA." *Id.*, RE 28, Page ID # 1085.

As the Supreme Court has held, a plaintiff's injury must be "fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *Lujan*, 504 U.S. at 560–61 (cleaned up). The Supreme Court has admonished that, in pleading causation, "much more is needed" when an injury "depends on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Id.* at 562 (quotation omitted). This Court has elaborated that, "unless the defendant's actions had a 'determinative or coercive effect' upon the

third party, the claimant's quarrel is with the third party, not the defendant." *Turaani*, 988 F.3d at 316 (quoting *Bennett v. Spear*, 520 U.S. 154, 169 (1997)). Here, unless the military has been "compelled" to require the use of a vaccine permitted by FDA, "then its decision (whether to use the [vaccine] or not) is an independent act breaking the chain of causation." *City of Detroit v. Franklin*, 4 F.3d 1367, 1373 (6th Cir. 1993).

The district court's decision faithfully applies these principles. The Department of Defense has ample, independent discretion to decide when and whether to require COVID-19 vaccination of service members. As a statutory matter, service members may be required to be vaccinated even when only an EUA vaccine is available. *See* 10 U.S.C. § 1107a. And nothing in FDA's EUA authorities "impairs" the Secretary of Defense's discretion in that respect. 21 U.S.C. § 360bbb-3(j)(2). As Secretary Austin announced prior to FDA's challenged action of simultaneously licensing and reissuing an EUA for the Pfizer vaccine, the military would seek to require COVID-19 vaccination, regardless whether FDA licensed the vaccine. *See* Austin Message, *supra*. Plaintiffs' injuries are thus hardly traceable to the specific FDA action of permitting the vaccine under *both* a license and an EUA at the same time, as service members could be required to be vaccinated if FDA had issued *either* a license or an EUA

(as opposed to both), as plaintiffs would prefer. Indeed, plaintiffs' references (Br. 33) to pandemic-related suits against the Defense Department only confirm that its dispute is with the military, not with FDA.

This Court's decision in *AAPS*, 13 F.4th 531, is particularly instructive. There, a physicians' organization challenged FDA's restricted EUA that permitted certain uses of hydroxychloroquine to treat COVID-19, contending that the EUA should be expanded. *Id.* at 535. But FDA's hydroxychloroquine EUA did not require physicians to use the drug, nor did it prohibit "off-label use" for COVID-19 that departed from the EUA. *Id.* at 544. Instead, the organization alleged that state medical boards had required physicians to follow the EUA and would punish departures from the EUA, thus imposing consequences beyond the EUA itself. *Id.* at 546. Even though FDA's actions and the state boards' actions touched on the same EUA, this Court held that a theory of causation that linked FDA's EUA to the state boards' requirements was "rank speculation," based on "guesswork" that the state boards had "fail[ed] to exercise independent judgment" in imposing their own requirements. *Id.* (quotation omitted). The same lesson holds here. Just as it was within the state boards' independent judgment to require strict adherence to an EUA, it was within the military's discretion to require vaccination.

Plaintiffs incorrectly contend (Br. 38) that the military's independent discretion is immaterial because FDA and the Defense Department are both in "the same Executive Branch." Third-party causation principles are no less applicable in this situation, as the Supreme Court has confirmed. In *Bennett*, plaintiffs injured by the operation of an irrigation project of the Bureau of Reclamation brought suit to challenge a biological opinion regarding the project that the Fish and Wildlife Service had issued. *See* 520 U.S. at 159–60. Notwithstanding that both agencies belonged to the Executive Branch (and were indeed both part of the Department of the Interior), the Supreme Court applied a traditional third-party causation analysis, requiring a causal connection between the Service's biological opinion and the plaintiffs' injuries. The Court found such a connection only because the Service's actions had a "determinative or coercive effect" on the third-party Bureau's operation of the project. *Id.* at 169–71. Here, by contrast, FDA "do[es] not control" the military. *United States v. Carroll*, 667 F.3d 742, 745 (6th Cir. 2012). And its decision to license and reissue an EUA for the Pfizer vaccine does not have a "powerful coercive effect," *Bennett*, 520 U.S. at 169, or indeed any coercive effect at all, on the vaccination policies of the Defense Department.

Plaintiffs miss the mark in contending (Br. 36) that something "less than but-for" causation is enough. *See Parsons v. U.S. Dep't of Justice*, 801 F.3d 701, 714 (6th Cir. 2015). Plaintiffs must, at a minimum, establish that FDA's challenged action was a sufficient "motivating factor"—for example, by demonstrating that Defense Department "officials themselves acknowledged that [FDA's challenged action] had caused them" to *require* vaccination. *Id.* But here, Secretary Austin stated that, even absent FDA's challenged action to simultaneously license and reissue an EUA for the Pfizer vaccine, he would seek to require vaccination. *See* Austin Message, *supra*. That is, though plaintiffs challenge the specific FDA action of permitting the Pfizer vaccine under a license and EUA at once, service members could still be required to be vaccinated if FDA had selected just one of those authorities, as plaintiffs would prefer.

It is not altogether clear what significance plaintiffs attach (Br. 36–37) to instances where military officers have informed individual service members that Pfizer's licensed vaccine and EUA vaccine can be substituted for one another. *See generally* Aug. 2021 Pfizer EUA, RE 19-1, Page ID # 897 n.8 (stating that corresponding licensed and EUA products have "the same formulation"). Plaintiffs appear to suggest (Br. 37) that FDA has planted "misrepresentations" about the relationship between the license and EUA, which then sprouted into

the military's vaccination requirement. The speculation is baseless. Even before FDA licensed the Pfizer vaccine, Secretary Austin had explained that he would seek to require COVID-19 vaccination regardless of whether the license was approved. The military's choice to proceed with requiring vaccination was thus made prior to, and independent of, FDA's decision to license and reissue an EUA for the Pfizer vaccine. If anything, the statements that plaintiffs reference merely reflect responsible efforts by military officers to educate service members about the vaccine, rather than an insidious effort by FDA to pull the Defense Department's strings.

C. Plaintiffs Cannot Redress Any Injuries from Third-Party Actions Through Relief Against FDA

Consistent with its conclusion on causation, the district court correctly held that judicial relief against FDA also would not redress plaintiffs' purported injuries from any vaccination requirements. *See* Op., RE 28, Page ID # 1086. As with causation, when the purported injury arises from the actions of third parties, redressability is also "ordinarily substantially more difficult to establish." *Lujan*, 504 U.S. at 562 (quotation omitted).

The district court properly recognized that the redressability problem here stemmed from the relief that plaintiffs had sought. As mentioned, plaintiffs had requested (Br. 12) only "alternative" relief against FDA: namely, that

the court should *either* revoke the Pfizer vaccine's license or revoke the Pfizer vaccine's EUA. *See* Am. Compl., RE 19, Page ID # 865 (demanding that the vaccine not be "both licensed and authorized simultaneously"); *see also id.*, RE 19, Page ID ## 861, 863. If plaintiffs prevailed on their first request, the EUA would remain in place; if plaintiffs prevailed on their second request, the license would remain in place. But "even if, consistent with the relief sought in plaintiffs' complaint, [the] court invalidated" either the license or the EUA, the relief "would not redress plaintiffs' injury," because the vaccine "still would" be able to be manufactured and distributed under the other, still-valid authority. *Midwest Media Prop., L.L.C. v. Symmes Township*, 503 F.3d 456, 461–62 (6th Cir. 2007).[1]

As the district court thus correctly held, regardless of the relief it issued, the Pfizer vaccine would still be available and "the third parties instituting the vaccine mandates, here the various branches of the military, can continue requiring servicemembers to get vaccinated." Op., RE 28, Page ID # 1086. And

[1] Plaintiffs unsurprisingly have not brought a standalone challenge to the Pfizer vaccine's EUA. Plaintiffs presumably recognize that Congress has expressly provided that FDA's actions pursuant to its EUA authority are "committed to agency discretion," 21 U.S.C. § 360bbb-3(i); *see* 5 U.S.C. § 701(a)(2); *Association of Am. Physicians & Surgeons v. FDA*, No. 20-1784, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020) (recognizing that "emergency-use authorizations are exempt from review" under the EUA statutory provisions).

Secretary Austin indicated as much in announcing that he would seek to require vaccination even if FDA had not issued a license. *Id.* (citing Austin Message, *supra*).

Plaintiffs altogether fail to grapple with the deficiencies in their pleadings, the fact that the military has independently required vaccination, or Secretary Austin's stated position. Plaintiffs instead hinge (Br. 39) their case on a speculative "possibility that the requested relief" against FDA "will prompt the injury-causing party"—here the Defense Department—"to reconsider the decision that allegedly harmed" them. *Massachusetts v. EPA*, 549 U.S. 497, 517–18 (2007). It is difficult to see how that would be the case, if the Pfizer vaccine remains available regardless of the outcome of this suit and if the military may seek to require vaccination regardless whether the vaccine is distributed pursuant to a license or an EUA.[2]

D. In All Events, the District Court Was Not Required to *Sua Sponte* Grant Plaintiffs Leave to Amend Their Amended Complaint

Plaintiffs last fault (Br. 40–42) the district court for not providing them leave to amend their amended complaint. That assertion fails at the outset, as

[2] The Department of Defense would also remain able to administer other COVID-19 vaccines manufactured by Moderna or J&J, the respective licenses and EUAs for which plaintiffs have not challenged.

plaintiffs "never moved for leave to file a second amended complaint." *Crosby v. Twitter, Inc.*, 921 F.3d 617, 628 (6th Cir. 2019). The contention that the court "should have rescued [them] by *sua sponte* offering leave to amend the complaint is simply misplaced." *Total Benefits Planning Agency, Inc. v. Anthem Blue Cross & Blue Shield*, 552 F.3d 430, 438 (6th Cir. 2008). That conclusion is particularly appropriate in this case. In denying a temporary restraining order, the district court provided plaintiffs with full notice that their original complaint had failed to allege harm, including harm to military members. *See* TRO Order, RE 10, Page ID ## 596–97. Plaintiffs then had "ample opportunities" to amend their complaint to establish the basic elements of standing, and indeed filed the amended complaint that the court decided here. *Stewart v. IHT Ins. Agency Grp., LLC*, 990 F.3d 455, 457 n.* (6th Cir. 2021). Plaintiffs are not entitled yet another opportunity, particularly when nothing in their brief (Br. 40–42) "explain[s] how a second amended complaint would resolve the problems in the [current] amended complaint." *Crosby*, 921 F.3d at 628.

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

FRANCIS M. HAMILTON III
United States Attorney

SCOTT R. McINTOSH

/s/ Dennis Fan
DENNIS FAN
Civil Division, Appellate Staff
U.S. Department of Justice
950 Pennsylvania Ave. NW
Washington, DC 20530
(202) 514-2494
dennis.fan@usdoj.gov

Of Counsel:

DANIEL J. BARRY
Acting General Counsel
U.S. Department of Health and Human Services

MARK J. RAZA
Chief Counsel

WENDY VICENTE
Acting Deputy Chief Counsel, Litigation

JAMES S. ALLRED
Associate Chief Counsel
U.S. Food & Drug Administration

APRIL 2022

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 7,630 words. The brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it was prepared using Microsoft Word 2016 in Constantia 14-point font, a proportionally spaced typeface.

/s/ Dennis Fan
DENNIS FAN

DESIGNATION OF RELEVANT DISTRICT COURT DOCUMENTS

Pursuant to Sixth Circuit Rule 28(b)(1)(A)(i), the government designates the following district court documents as relevant:

Record	Description	Page ID #
RE 1	Complaint	1–12
RE 8	Plaintiffs' *Ex Parte* Stay Motion	546–560
RE 9	Plaintiffs' Stay Motion	564–592
RE 10	Order Denying Temporary Restraining Order	593–597
RE 15	Declaration of Pam Long	631–633
RE 15	Declaration of Samuel Craymer	635–646
RE 15	Declaration of John Eschmann	647–654
RE 15	Declaration of Wayne Hastriter	655–665
RE 15	Declaration of Cassidy Hollowell	666–671
RE 15	Declaration of Nathaniel Mason	672–679
RE 15	Declaration of Thomas Meacham	680–711
RE 15	Declaration of Jake Nuss	712–716
RE 15	Declaration of Robert Perez	717–753
RE 15	Declaration of Steven Raethel	754–757
RE 15	Declaration of Christopher Santos	758–762
RE 15	Declaration of Jonathan Shour	763–781

Record	Description	Page ID #
RE 15	Declaration of John Stanzione	782–791
RE 15	Declaration of Joseph Sweger	802–810
RE 19	Amended Complaint	856–868
RE 19-1	Children's Health Defense Citizen Petition	870–888
RE 19-1	August 2021 Pfizer Vaccine Emergency Use Authorization	896–908
RE 19-1	Letter Denying Citizen Petition	910–962
RE 19-1	Pfizer Vaccine Biologics License Application Approval	964–974
RE 20	Amended Declaration of Mark Zito	985–994
RE 26	Declaration of Mary Holland	1056–1057
RE 28	Memorandum Opinion and Order	1075–1087
RE 29	Judgment	1088
RE 30	Notice of Appeal	1089