

# United States Court of Appeals for the Fifth Circuit

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No. 23-50167

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United States Court of Appeals

Fifth Circuit

**FILED**

January 23, 2024

CHILDREN'S HEALTH DEFENSE; DEBORAH L. ELSE; SACHEL W. CAYCE  
DIETRICH; AIMEE VILLELLA MCBRIDE; JONATHAN SHOUR; Clerk  
REBECCA SHOUR,

*Plaintiffs—Appellants,*

*versus*

FOOD & DRUG ADMINISTRATION; ROBERT M. CALIFF,

*Defendants—Appellees.*

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Appeal from the United States District Court  
for the Western District of Texas  
USDC No. 6:22-CV-93

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Before JONES, HAYNES, and DOUGLAS, *Circuit Judges.*

PER CURIAM:\*

Five parents and one organization challenged the Food and Drug Administration's issuance of emergency use authorizations covering COVID-19 vaccines for children. Specifically, the parents allege fears of a third party vaccinating their children without parental consent, harassing or marginalizing their children for their unvaccinated status, and pushing pro-

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\* This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

No. 23-50167

vaccine messaging. After finding that Plaintiffs lacked standing, the district court dismissed the suit. For the reasons that follow, we AFFIRM.

## I. BACKGROUND

The Food and Drug Administration (“FDA”), an agency within the U.S. Department of Health and Human Services (“HHS”), and FDA Commissioner Califf are tasked with protecting the public’s health by ensuring the safety, efficacy, and security of drugs and biological products, among other things. In February 2020, the Secretary of HHS declared a “public health emergency . . . that involves a novel (new) coronavirus,” known as SARS-CoV-2, the virus that causes COVID-19. 85 Fed. Reg. 7316, 7317 (Feb. 7, 2020). Subsequently, the Secretary of HHS determined that the circumstances surrounding the COVID-19 pandemic justified “the authorization of emergency use of drugs and biological products.” 85 Fed. Reg. 18250, 18250—51 (Apr. 1, 2020); *see* 21 U.S.C. § 360bbb-3 (authorizing the use of medical products in emergencies and justified threats).

In December 2020, FDA issued two emergency use authorizations (“EUAs”) for administering COVID-19 vaccines to individuals over age 16.<sup>1</sup> In May 2021, October 2021, and June 2022, FDA revised the Pfizer EUA to expand the authorization to include additional age groups: first, individuals 12 through 15 years old; second, individuals 5 through 11 years old; and third, individuals 6 months through 4 years old. And in June 2022, FDA revised the

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<sup>1</sup> Specifically, the vaccines manufactured by Pfizer, Inc. and BioNTech Manufacturing GmbH were authorized for use in individuals 16 years of age and older and one manufactured by ModernaTX, Inc. was authorized for use in individuals 18 years of age and older. *See* 86 Fed. Reg. 5200, 5200, 5204, 5214 (Jan. 19, 2021) (providing notice of EUA issuance).

No. 23-50167

Moderna EUA to authorize administration of the vaccine to those between 6 months and 17 years old.<sup>2</sup>

In May 2021, Plaintiff Children’s Health Defense (“CHD”) filed a petition with FDA asking the agency to revoke the existing EUAs for the COVID-19 vaccines. The FDA denied the petition, and the instant lawsuit followed in January 2022.

CHD is a nonprofit “organization that has tasked itself with protecting and promoting the health and wellbeing of children.” The remaining Plaintiffs are parents that do not want their children to receive a COVID-19 vaccine. Some of the parents allege that they are at risk because their children may be coerced to receive the vaccine, may be forced to take the vaccine due to allegedly impending mandates, may receive the vaccine without parental consent, or may suffer adverse reactions should they be given the vaccine. Moreover, they complain of a “societal push toward vaccination” evidenced by, for example, “Sesame Workshop” which released a YouTube video announcing that Elmo had gotten the COVID-19 vaccine.<sup>3</sup> Plaintiffs claim that FDA failed to comply with the Administrative

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<sup>2</sup> See FDA, Emergency Use Authorization, <https://perma.cc/XKQ8-GUBN> (listing EUAs). While the FDA has issued EUAs for an updated bivalent formula of both the Pfizer-BioNTech and Moderna vaccines, the monovalent formulas remain licensed but are no longer authorized for emergency use in the United States; they are thus only approved for use in individuals 12 years and older (Pfizer) or 18 years and older (Moderna). See generally FDA, FDA COVID-19 Vaccine News and Updates, <https://perma.cc/E3VU-JDWF>; FDA News Release, Coronavirus (COVID-19) Update: FDA Authorizes Changes to Simplify Use of Bivalent mRNA COVID-19 Vaccines (Apr. 18, 2023), <https://perma.cc/WY2V-YLJU>.

<sup>3</sup> Plaintiffs allege that Elmo sent the message that children will “get sick if [they] don’t take the COVID-19 vaccine.” In doing so, Plaintiffs rely on a video that suggests otherwise. See Sesame Street: Elmo Gets the COVID-19 Vaccine, Sesame Street, available at <https://www.youtube.com/watch?v=bwimt9n2JEk>. In the video, Elmo’s father states that: “I had a lot of questions about Elmo getting the COVID vaccine. Was it safe? Was it the right decision? I talked to our pediatrician so I could make the right choice. I learned

No. 23-50167

Procedure Act's ("APA") reasoned decision making requirements when it approved the COVID-19 vaccine for children and, as a result, request a stay, vacatur, and remand. Plaintiffs also seek an injunction against the marketing or promotion of the vaccines.

The district court dismissed the initial complaint, which included only the plaintiff parents from Texas. Plaintiffs filed an amended complaint, adding the plaintiff parents from North Carolina and Florida, who likewise do not want their children to receive COVID-19 vaccines. The district court again dismissed Plaintiffs' complaint for lack of standing, concluding that no plaintiff had adequately pled an injury in fact. This appeal followed. "We have jurisdiction to determine our own jurisdiction." *Martin v. Halliburton*, 618 F.3d 476, 481 (5th Cir. 2010).

## II. DISCUSSION

We review standing de novo. *See Shemwell v. City of McKinney*, 63 F.4th 480, 483 (5th Cir. 2023). We may affirm a dismissal "'on any basis supported by the record.'" *Collins v. Dep't of the Treasury*, 83 F.4th 970, 978 (5th Cir. 2023) (quoting *Asadi v. G.E. Energy U.S., L.L.C.*, 720 F.3d 620, 622 (5th Cir. 2013)).

### A. Article III Standing

"'The law of Art. III standing is built on a single basic idea—the idea of separation of powers.'" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 422-23 (2021) (quoting *Raines v. Byrd*, 521 U.S. 811, 820 (1997)). "Under Article III, federal courts do not adjudicate hypothetical or abstract disputes" and

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that Elmo getting vaccinated is the best way to keep himself, our friends, neighbors and everyone else healthy and enjoying the things they love." *Id.* Further, the video explains that "it's okay to have questions about the COVID-19 vaccine for your kids. Get the latest facts by speaking with your pediatrician or healthcare provider." *Id.*

No. 23-50167

“do not exercise general legal oversight of the Legislative and Executive Branches.” *Id.*

Plaintiffs argue that the district court erred in its analysis of Article III standing on three grounds, including organizational standing, associational standing, and the APA. To begin, we must consider whether Plaintiffs satisfy the first requirement for Article III standing. Then, we consider whether CHD itself has standing.

#### *1. Injury in Fact*

“[T]o establish standing, a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief.” *TransUnion*, 594 U.S. at 423 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–561 (1992)).

For an injury to be “‘concrete,’” it must be “‘real, and not abstract.’” *Id.* at 424 (quoting *Spokeo, Inc. v. Robins*, 578 U. S. 330, 340 (2016)). When evaluating whether a harm is “concrete,” we consider “whether the alleged injury to the plaintiff has a ‘close relationship’ to a harm ‘traditionally’ recognized as providing a basis for a lawsuit in American courts.” *Id.* (quoting *Spokeo*, 578 U. S. at 340). To be “imminent,” “there must be at least a ‘substantial risk’ that the injury will occur.” *Stringer v. Whitley*, 942 F.3d 715, 721 (5th Cir. 2019) (quoting *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014)).

Moreover, “allegations of *possible* future injury are not sufficient.” *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). Instead, “to ensure that the alleged injury is not too speculative,” a plaintiff who wishes to rely on a threatened injury to establish standing must demonstrate that a concrete injury is “certainly impending.” *Id.*

No. 23-50167

Plaintiffs contend that the injury-in-fact element is satisfied because a third party might vaccinate their children over their objections, and that such vaccine could allegedly injure them and their children. Additionally, Plaintiffs argue that any alleged advertising or disseminated information regarding the vaccine constitutes harm. In doing so, Plaintiffs note that “general factual allegations of injury” “may suffice” where, as here, the district court granted a motion to dismiss based on the pleadings. Be that as it may, we agree with the district court that Plaintiffs fail to demonstrate an injury in fact because the alleged injury is neither concrete nor imminent. “The party invoking federal jurisdiction bears the burden of establishing” the elements of standing, which “are not mere pleading requirements but rather an indispensable part of the plaintiff’s case[.]” *Lujan*, 504 U.S. at 561.

Nothing in Plaintiffs’ amended complaint or briefs suggest that the alleged injuries are nonspeculative or “certainly impending.” *Clapper*, 568 U.S. at 409. To begin, it is insufficient that Plaintiffs allege that some hypothetical third party might, at some hypothetical point in the future and through some hypothetical means, will vaccinate their children against their wishes.

We are not persuaded by the out-of-circuit cases that Plaintiffs rely on to establish injury in fact. Take *Booth v. Bowser*, 597 F. Supp. 3d 1 (D.D.C. 2022), which concluded that two sets of parents had sufficiently alleged an impending injury to establish standing. The parents in *Booth* challenged the District of Columbia’s law permitting children at least eleven years old to get vaccinated without parental consent. *Id.* at \*9. To determine whether the parents had standing, the court considered whether the complaint detailed allegations regarding the likelihood that the parents’ children would soon seek vaccines. *Id.* For example, one child said he would take the vaccine if offered, and another child repeatedly told her parents that she needed the vaccine to participate in various school activities, so she wanted to get the

No. 23-50167

vaccine. *Id.* at \*6 (finding that the child “made it clear that he is on the cusp of getting vaccinated”). Thus, the imminent injury for the parents in *Booth* arose from the D.C. law allowing children to seek vaccines absent parental consent, particularly when D.C. mandated vaccines for most students. *Id.* at \*13.

In contrast, the parents in this case do not allege any facts establishing a similar likelihood that their children will seek or obtain a vaccine without parental consent. The parents do not allege that their children are or will be subject to any vaccine mandates that might be imposed by third parties. Nor do they allege that their children wish to receive a COVID-19 vaccine or have the means or opportunity to get it despite their parents’ wishes. The parents’ allegations are particularly speculative because there are no COVID-19 vaccine mandates, state or federal, and their states generally *prohibit* administering vaccines absent parental consent.<sup>4</sup> See e.g., *Biden v. Feds for Med. Freedom*, No. 23-60, 2023 WL 8531839, at \*1 (U.S. Dec. 11, 2023) (explaining that an order granting a preliminary injunction against a vaccine mandate is moot because such mandate does not exist). By extension, there is also no “impending injury” arising from the parents’ fear of moving to

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<sup>4</sup> State laws establish vaccination requirements for school children. See Fla. Stat. 1014.06(1); N.C. Gen. Stat. § 90-21.5(a1); Tex. Family Code Ann. § 151.001(a)(6); see also Tex. Family Code Ann. § 32.101(b) (permitting certain specified non-parents to consent to immunization in limited circumstances where, among other things, the parents are “not available.”). To be sure, the Texas-based parents have alleged fears of a third-party authorizing vaccines to their children but, as they have noted, this occurs in limited circumstances. The parents neither identify any specific third party able to provide that authorization, nor do they allege that a third party wants to vaccinate their children, or that their children would consent on their own. Even if they did, the claim still fails for lack of imminency. As the district court explained, under Texas and Florida law, vaccination cannot be mandatory. Tex. Executive Order GA-40 (Oct. 11, 2021); Fla. Stat. § 381.00319. Moreover, under North Carolina law, individuals other than parents are not permitted to vaccinate a child. N.C. Gen. Stat. § 90-21.5(a1).

No. 23-50167

another state that might have a vaccine mandate in the future, as such a mandate has not materialized.<sup>5</sup> *See e.g., TransUnion*, 594 U.S. at 437-38 (explaining that plaintiffs did not establish a concrete harm because “plaintiffs did not demonstrate that the risk of future harm materialized” and such risk was “too speculative”).

Moreover, information in the public domain related to vaccines and general “pressure to receive the COVID-19 [vaccine] . . . from the media and other children” do not constitute a concrete injury. Plaintiffs rely on cases that find standing on similar theories as *Booth*, such as where a government agency allegedly exposed the plaintiff to, or increased the risk that the plaintiff would be exposed to, harmful products or drugs;<sup>6</sup> where an agency allegedly increased health-related uncertainty;<sup>7</sup> and where a parent’s medical control over her children’s care was allegedly impaired.<sup>8</sup> As the district court explained, however, those cases are neither binding, nor persuasive. To illustrate, in *Baur*, the plaintiff described how the alleged threat of harm directly arose from the agency’s action. *See Baur*, 352 F.3d at 634 (finding that enhanced risks in the “context of food and drug safety suits . . . are cognizable for standing purposes, where the plaintiff alleges exposure to potentially

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<sup>5</sup> To be clear, Plaintiffs fail to point to any states that require COVID-19 vaccines for children or adults. Even if they did, nothing in the amended complaint suggests that a vaccine mandate would present a threat to the parent or child that chooses not to seek the vaccine. Further, if a mandate existed, plaintiffs would need to bring a cause of action against the mandating entity (i.e., schools, employers, businesses), not FDA.

<sup>6</sup> *See Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003); *Cutler v. Kennedy*, 475 F. Supp. 838 (D.D.C. 1979); *Center for Food Safety v. Price*, No. 17-cv-3833, 2018 WL4356730 (S.D.N.Y. Sept. 12, 2018).

<sup>7</sup> *See New York Public Interest Research Grp. v. Whitman*, 321 F.3d 316 (2d Cir. 2003).

<sup>8</sup> *See Tummino v. Torti*, 603 F. Supp. 2d 519 (E.D.N.Y. 2009) (explaining that under the challenged FDA action, parents are unable to legally obtain Plan B on behalf of their children).

No. 23-50167

harmful products.”). *Baur* clarifies that the injury must nonetheless be a “discrete, individual risk of personal harm from exposure[.]” *Id.* at 635.

Unlike the plaintiffs in *Baur*, the Plaintiffs do not have a concrete or particularized injury. Instead, Plaintiffs merely allege that a third party may vaccinate their children without their consent, that a third party might harass their children for being unvaccinated, and that their children may be exposed to pro-vaccine messaging. These hypothetical dangers are untethered to the law. Even if the alleged harms were plausible, each are the result of a third-party action, not the FDA. *See e.g., TransUnion*, 594 U.S. at 438 (finding that plaintiffs failed to establish a future risk of harm by not showing “a sufficient likelihood that their individual credit information would be requested by third-party businesses and provided by [defendant] . . . [or] that there was a sufficient likelihood that [defendant] would otherwise intentionally or accidentally release their information to third parties.”). In other words, the EUAs do not put the parents at an imminent risk of harm or exposure because the parents are free to choose whether to consent to their children receiving the COVID-19 vaccine, and whether to restrict their children’s access to information related to the vaccine.<sup>9</sup> Thus, the parents fail to display any nonspeculative risk of harm based on a “possible future injury.” *Clapper*, 568 U.S. at 409.

In addition, Plaintiffs fail to argue how being marginalized by society and media campaigns based on vaccination status constitutes an injury in fact

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<sup>9</sup> “Under the EUA, there is an option to accept or refuse receiving this vaccine. Should you decide for your child not to receive this vaccine, it will not change the standard medical care.” *See e.g.,* FOOD & DRUG ADMIN. Fact Sheet for Recipients and Caregivers about Pfizer-BioNTech COVID-19 Vaccine (2023 - 2024 Formula) which has Emergency Use Authorization (EUA) to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 6 Months through 11 Years of Age; 21 U.S.C. § 360bbb-3(c)(1)-(5). [www.covidvaxoption.com](http://www.covidvaxoption.com).

No. 23-50167

to sue FDA. Plaintiffs simply point to a Sesame Street video saying that Elmo received the COVID-19 vaccine.<sup>10</sup> Because they do not explain on appeal how media or even societal norms may constitute an injury-in-fact, they forfeit any challenge to the district court's conclusion that plaintiffs have not suffered an injury in fact at the hands of unidentified third parties or the media. *See Owens v. Circassia Pharm., Inc.*, 33 F.4th 814, 824 n.4 (5th Cir. 2022); *see also TransUnion*, 594 U.S. at 424 (“[U]nder Article III, a federal court may resolve only ‘a real controversy with real impact on real persons.’”)(quoting *American Legion v. American Humanist Assn.*, 139 S.Ct. 2067, 2103 (2019)). Even if challenged, the district court correctly explained that Plaintiffs have not suffered an injury in fact because they have merely alleged a “psychological consequence” “produced by observation of conduct with which one disagrees.” *Valley Forge Christian Coll. v. Am. United for Separation of Church & State, Inc.*, 454 U.S. 464, 485 (1982).

## 2. *Organizational and Associational Standing*

We next consider whether CHD, as an organization or association, establishes standing. CHD first suggests that it has spent resources working with its members, addressing societal pressures, and educating the public regarding alleged dangers of vaccines. Then CHD asserts that it spent resources investigating FDA's action to prepare for litigation and file a citizen petition.

Organizations can satisfy injury-in-fact for standing under two theories: organizational standing and associational. *OCA-Greater Houston v. Texas*, 867 F.3d 604, 610 (5th Cir. 2017). “[A]n organization may establish

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<sup>10</sup> Misleadingly, Plaintiffs also allege that a federal vaccine mandate for students exists. The falsity of that allegation is demonstrated by Plaintiffs failure to cite any legal or factual support. Indeed, Plaintiffs do not identify any specific factual allegations that would support their claim of harassment related to their vaccination status.

No. 23-50167

injury in fact by showing that it had diverted significant resources to counteract the defendant’s conduct.” *N.A.A.C.P. v. City of Kyle*, 626 F.3d 233, 238 (5th Cir. 2010). Thus, any diversion must be a specific response to the challenged law or action. It is not fairly traceable to defendants if the diversion responded not only to the defendants’ conduct but also to other forces. *Texas State LULAC v. Elfant*, 52 F.4th 248, 254 (5th Cir. 2022). “A “setback to [an] organization’s abstract social interests” is insufficient. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982).

Associational standing is derivative of an organization’s members. *OCA-Greater Houston*, 867 F.3d at 610. To have associational standing, the organization must show: (1) that its members independently possess Article III standing, (2) “the interests the association seeks to protect are germane to the purpose of the organization,” and (3) the claim and the relief requested does not require participation of the individual members. *Ctr. for Biological Diversity v. U.S. EPA*, 937 F.3d 533, 536 (5th Cir. 2019).

We find that CHD has not established standing as it has not “diverted significant resources to counteract” the FDA’s EUAs. *City of Kyle*, 626 F.3d at 238. In particular, CHD has failed to show how the diversion of resources in response to the EUAs has “concretely and ‘perceptibly impaired’” CHD’s ability to carry out its purpose. CHD “ha[s] not identified any specific projects that [it] had to put on hold or otherwise curtail in order to respond to” the EUAs; instead, it has “only conjectured that the resources that [it] had devoted to” the EUAs “could have been spent on other unspecified [CHD] activities.” *City of Kyle*, 626 F.3d at 238-39. Furthermore, an organizational plaintiff—like any other plaintiff—cannot spend its way to standing through a lawsuit; instead, the organization must show that the injury increases the resources devoted to programs, “independent of its suit challenging the action.” *Online Merchs. Guild v. Cameron*, 995 F.3d 540, 547 (6th Cir. 2021) (quotation omitted); see also *Steel*

No. 23-50167

*Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) (“Obviously, . . . a plaintiff cannot achieve standing to litigate a substantive issue by bringing suit for the cost of bringing suit.”). CHD fails to show how such previously incurred costs are redressable. Further, because the parents have not demonstrated an injury in fact, CHD has not established associational standing.

### **III. CONCLUSION**

Because Plaintiffs fail to show that they have standing, we AFFIRM the district court and DISMISS the suit for lack of jurisdiction.