Nos. 23-235, 23-236

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C.,
Petitioner,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

ON WRITS OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF OF *AMICI CURIAE* LOCAL GOVERNMENTS AND LOCAL GOVERNMENT LEADERS IN SUPPORT OF PETITIONERS

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STATEMENT OF INTEREST

Over the last two decades, the Food and Drug Administration ("FDA") has reviewed robust scientific evidence and repeatedly determined that mifepristone is safe and effective under the approved conditions of use. Since its initial approval, mifepristone has provided meaningful therapeutic benefits over other treatments for reproductive health conditions. It has been used widely for miscarriage management and the treatment of other reproductive health conditions, and approximately six million pregnant people in the United States have used mifepristone and a companion medication, misoprostol, to safely terminate early pregnancies. The decision below, if allowed to stand, would significantly impair access to mifepristone, run counter to decades of clear scientific evidence, and contradict established precedent of this Court. Any reversal of FDA authorization would immediately disrupt essential healthcare across the United States, including in *amici*'s jurisdictions, without basis in law or fact.

Amici are cities, counties, local government leaders, and public entities from across the country.[1] We file this brief in furtherance of our shared interest in and responsibility for protecting the health and safety of our diverse populations, including preserving access to essential healthcare such as reproductive healthcare. Some *amici* are large cities administering public health systems that depend on the availability

[1] No counsel for a party authored this brief in whole or in part. No person other than *amici* or *amici*'s counsel made a monetary contribution to the preparation or submission of this brief. A list of all *amici* is available at Appendix A.

of a range of devices and medicines, including access to mifepristone, that are subject to FDA approval. Other *amici* are smaller cities, counties, and their elected leaders, including some in remote and difficult to access parts of our country. All *amici* represent populations that are low-income and medically underserved.

The 2016 and 2021 REMS have advanced crucial interests in healthcare access. Eliminating in-person visits that do not improve outcomes has preserved precious resources for public health systems. Telemedicine has an especially important role to play in ensuring people who live in more rural areas have access to safe, effective care. On the other hand, imposing unnecessary restrictions on this medication will overburden health systems. Pregnant people who are unable to access mifepristone because of such restrictions may face worse health outcomes. Without access to mifepristone, those who seek to terminate a pregnancy may delay care, face additional barriers, terminate their pregnancies using alternative means that present additional risks, or may be forced to carry to term unwanted or unviable pregnancies or those that threaten their health. Pregnant people who would rely on mifepristone for treating miscarriages could instead be forced to endure more pain and health risks at an already challenging time. If the decision below is affirmed, there will be significant economic, health, and social consequences for *amici*.

SUMMARY OF ARGUMENT

Under well-established precedent, Respondents lack Article III standing to challenge the FDA's 2016 and 2021 actions relating to mifepristone, because those actions do not require Respondents to do anything or refrain from doing anything. Respondents' alleged injuries—which rely on an indirect theory of harm—are simply too attenuated and speculative to constitute an injury-in-fact. Closer examination of their claims make clear that Respondents' theories for standing are not supported by the record in this case and are foreclosed by established precedent about the probability of future harm. Additionally, Respondents' claims are not traceable to the FDA's decisions and cannot be redressed by this case either. In fact, making mifepristone less available could produce more health complications of the type that Respondents fear will land in their emergency rooms and hospitals. Because the Fifth Circuit committed clear errors of law by ignoring or misconstruing precedent, and by incorrectly applying Article III's standing requirements when it comes to injury-in-fact, traceability, and redressability, this Court should reverse the decision below on jurisdictional grounds and enter judgment for Petitioners. *See TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021).

Should this Court move to the merits of the case, *amici* underscore two reasons for reversal. To start, the Fifth Circuit improperly substituted its own judgment for the FDA's expert agency analysis. The decision to override the 2016 and 2021 REMS is contrary to the clear weight of the evidence that was before FDA at the time of decision-making. In

addition, the injunction should be reversed for running counter to the public interest, given the far-ranging and disruptive impacts of the Fifth Circuit's ruling.

ARGUMENT

I. RESPONDENTS HAVE NOT SUFFERED AN INJURY-IN-FACT

A showing of injury-in-fact requires "an invasion of a legally protected interest" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (citation omitted). Respondents lack standing because they are not directly regulated by the agency action at issue. They do not administer or prescribe mifepristone, and the FDA's approval of the drug does not require them to do or refrain from doing anything. They are not "the object of the government action or inaction [they] challenge[]." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992).

To establish their standing, Respondents offer several indirect theories for their injuries. They all fail. These theories are not legally cognizable, illogical, too speculative, and not substantiated either by the record before the Court or by a general understanding of how medical professionals operate. *Amici* local governments focus principally on the issue of standing herein, because (i) the analysis is dispositive to the case; and (ii) the Fifth Circuit's analysis, if affirmed, would enable actors with no direct connection to a law or regulation to sue if they come into contact with third parties affected in some way by said regulation,

thus burdening local governments with the costs of defending such a flood of lawsuits.[2]

A. Respondents' Diversion of Resources Theory of Standing Suffers from Multiple Fatal Flaws

Respondents' main contention for standing is that FDA authorization of mifepristone requires member physicians who practice in emergency rooms to divert their time and attention away from other patients. Implied in this argument is that these "other patients" are preferred, because they have not chosen to terminate a pregnancy through medication. Respondents' diversion of resources theory fails for at least three reasons: (1) seeing patients in an emergency room is not an injury; (2) probabilistic theories of standing have been rejected by this Court; and (3) there is no limiting principle for their contention, which would convert physicians into super-plaintiffs given all of the policies and decisions that influence the number of patients presenting for care at hospitals.

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[2] *Amici* agree with the Fifth Circuit in so far as it concluded that Respondents' assertion of stress and emotional distress "does not provide a separate basis for Article III standing." Pet. App. 35a. Accordingly, it is not addressed directly herein. *See also* FDA Br. 26 ("Endorsing [Respondents'] novel theory would open the courthouse doors to an endless parade of suits. Doctors could sue to challenge virtually any policy that allegedly increased the risk that they would be presented with patients whose cases they find distressing.").

1. Seeing Patients Is What Doctors Do

Respondents' assertion that the availability of mifepristone forces a diversion of their resources is not cognizable harm. Caring for patients is what doctors do. It is the principal purpose of the profession. At the very least, the argument that treating Patient A versus Patient B constitutes harm is too abstract to meet the concreteness requirements of Article III. *Spokeo*, 578 U.S. at 340 ("When we have used the adjective 'concrete,' we have meant to convey the usual meaning of the term—'real,' and not 'abstract.'"). The record does not indicate that Respondents' members are required to provide different *types* or *scopes* of care for patients experiencing complications from mifepristone compared to patients who are experiencing a spontaneous miscarriage. In fact, the treatment is generally the same. In both circumstances, doctors will treat bleeding and fluid loss. In both circumstances, doctors will monitor for and, if needed, treat infection and remove products of conception from the uterus. And, in both circumstances, doctors will support patients experiencing emotional distress.[3]

Digging deeper into Respondents' theory of harm, their contention is really about worthiness of care. Respondents' theory is effectively an expression of a preference to care for certain types of patients. *See,*

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[3] Clark Alves, et al., *Early pregnancy loss (spontaneous abortion)*, NATIONAL LIBRARY OF MEDICINE (2023), https://www.ncbi.nlm.nih.gov/books/NBK560521/; Julia S. Marcus, et al., *Complications of elective medical abortions*, Emergency Medicine Residents' Association (2022), https://www.emra.org/emresident/article/abortion-complications.

e.g., J.A. 198 (Decl. Dr. Shaun Jester) (describing harm as "los[ing] the opportunity to provide these obstetrical and medical services to care for the woman and child through pregnancy"). That theory cannot be credited. This is particularly true for physicians like Respondents' members who have chosen to treat all incoming patients in a hospital or emergency setting. Such doctors do not get to choose which patients they treat and which complications they like or dislike. They may not approve of the choices their patients make, but their obligation to provide care exists nonetheless.[4] It is common for patients to smoke, not exercise, not take their medications appropriately, abuse alcohol or other substances, or make choices about their lives and exhibit behaviors that a doctor might not agree with. But when a patient arrives seeking care in an emergency room setting, care must be provided. *See, e.g.*, 42 U.S.C. § 1395dd (requiring the provision of appropriate screening and stabilizing treatment when *any* patient arrives at an emergency department and requests treatment) (emphasis added). Otherwise, Respondents' theory of standing is effectively a license to sanction discrimination against particular patients.

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[4] American Medical Association, *Principles of Medical Ethics*, 1.1.2 PROSPECTIVE PATIENTS, https://www.ama-assn.org/system/files/code-of-medical-ethics-chapter-1.pdf. ("Physicians must also uphold ethical responsibilities not to discriminate against a prospective patient on the basis of… other personal or social characteristics that are not clinically relevant to the individual's care.").

Moreover, there is no limiting principle to Respondents' assertion here. All patients require resources that could otherwise be directed to other patients, and all patients make choices that might impact a physicians' perception of their worthiness for care. Any particular patient may engage in behavior, take medication, or make choices that impact their care. None of that should give rise to a theory for Article III standing. *See also* FDA Br. 26.

2. Probabilistic Standing Is Not Cognizable

This Court's precedent demands that standing be denied where the alleged anticipated injury results from "a highly attenuated chain of possibilities." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013). The Fifth Circuit incorrectly relied on probabilistic speculation that Respondents would be impacted given that "millions of women take mifepristone" and a "number of them experience complications" and "a large number of association members [ ] are emergency room doctors." Pet. App. 17a. Among other errors, this reasoning clearly runs afoul of the standing analysis in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009).

Here, Respondents say that they have treated people with mifepristone complications on some occasions in the past and say that they or members of their association will need to do so again in the future. That assertion of statistical likelihood is not enough for injunctive relief. *Cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 101–02 (1983). Standing for prospective relief cannot be based on past injury. An "imminent future injury" must be shown. *Summers*, 555 U.S. at

495. And it cannot be based on "a statistical probability that some of those members are threatened with concrete injury. . . . This novel approach to the law of organizational standing would make a mockery" of Supreme Court precedent. *Id.* at 497–98.

The Fifth Circuit found that "evidence of prior injury is especially probative," and "where the causes that produced the first injury remain in place, past-injury evidence bears strongly on whether there is a real and immediate threat of repeated injury." Pet. App. 16a (internal quotation omitted). That is the exact type of probabilistic approach soundly rejected by this Court. *See Clapper*, 568 U.S. at 410 ("[O]bjectively reasonable likelihood standard is inconsistent with our requirement that threatened injury must be certainly impending to constitute injury in fact.") (internal quotations omitted). Seeking to distinguish *Summers*, the Fifth Circuit posited that this Court's "bigger concern was that plaintiffs failed to *prove* their claims: they lacked evidence of the number of association members who intended to visit the parks, and when." Pet. App. 29a (emphasis in original). That is the precise problem here. No individual can claim that they will be injured in the future with any certainty. Instead, Respondents rely on the assertion that "it is highly likely that one or more" of the organizations' members "will be required to provide emergency care to a mifepristone patient in the near future." Pet. App. 23a–24a.

Respondents' theory also "rest[s] on speculation about the decisions of independent actors," *Clapper*, 568 U.S. at 414, which this Court has been "reluctan[t]

to endorse." *Id.* Among the attenuated circumstances involved are the following chain of events:

- a pregnant person chooses to use mifepristone to terminate a pregnancy;
- the usage falls outside of initial authorization, and is connected to the 2016 and 2021 REMS—mifepristone was prescribed based on a telemedicine interaction, mailed to the patient, or prescribed by an APC;
- the person experiences significant complications;
- the person does not or cannot seek care from the prescribing physician;
- the person goes to a hospital emergency room, among all others available, where a physician within Respondents' membership works;
- the person needs medical attention from a doctor at that hospital;
- a physician within Respondents' membership is working at the hospital or on-call at that time;
- that particular physician is an appropriate medical specialty to see and care for the person;[5] and

[5] Danco's argument about the range of medical specialties and practices within Respondents' membership groups further undercuts Respondents' standing contention along these same lines. *See* Danco Br. 26.

- none of the other doctors at the hospital see this person.

See also FDA Br. 21 (listing "contingencies [that] would have to occur" for Respondents to suffer alleged injury); Brief *Amici Curiae* of Profs. Cohen & Rebouché at 10 ("[C]ausal chain via which the Alliance seeks to link its injury to the FDA's actions is lengthy and attenuated at best, filled with 'pure speculation.'"). Given this chain of events required for Respondents' theory to come to fruition, it is clear that their standing is "all too dependent on conjecture." *Dep't of Educ. v. Brown*, 600 U.S. 551, 567 (2023) (internal quotation omitted).

One more point here warrants analysis. Respondents appear to claim that the 2016 and 2021 REMS make their future injury *more probable* because they perceive that they are seeing more patients with complications from mifepristone in recent years. *See, e.g.*, J.A. 153 (Decl. of Dr. Christina Francis). Respondents offer no clinical data to support these anecdotes, and there is no reason to credit these cursory observations. Recent data has shown that telehealth-only visits where mifepristone is prescribed produce similarly strong results for patient safety.[6] These recent findings are *in addition to* the studies before the FDA at the time of its decision-making. The weight of this scientific research undermines the

[6] *See, e.g.*, Ushma D. Upadhyay, Leah R. Koenig & Karen R. Meckstroth, *Safety And Efficacy Of Telehealth Medication Abortions In The US During The Covid-19 Pandemic,* JAMA NETWORK (2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2783451.

credibility of Respondents' highly speculative assertions and offers further basis to defeat standing.

3. Respondents' Theory Turns Physicians and Other Actors Into Super-Plaintiffs

Under the standing theory Respondents advance, many parties would enjoy Article III standing so long as they could conjure up some downstream effect (however speculative) that might affect them at some point. Physicians, in particular, would enjoy a special status under Article III to bring lawsuits.

A cursory review of medical literature and other scholarship reveals the wide array of issues that could be opened to federal litigation by individual physicians or their membership groups. Numerous studies have shown correlation between policy changes, public events, or natural occurrences and emergency room visits.

Under Respondents' theory of standing, any one of these changes or decisions could be challenged by doctors required to shoulder an increased or more challenging patient load.

- A change in a health plan's copayment by as few as $10 has been shown to impact the frequency of emergency room visits.[7]
- Temporary changes in emissions and localized pollution can result in more emergency room

[7] Joe V. Selby, Bruce H. Fireman, and Bix E. Swain, *Effect of a Copayment on Use of the Emergency Department in a Health Maintenance Organization*, 334 NEW ENGLAND JOURNAL OF MEDICINE 635-642 (1996).

visits due to pneumonia and respiratory disease.[8]

- Daylight savings time changes are associated with more vehicle accidents and trips to the hospital.[9]
- Power outages increase carbon monoxide poisoning, also resulting in more trips to the hospital.[10]
- Alcohol consumption during sporting events, at concerts, and even on holidays results in more patient trips to the emergency department.[11]
- Road closures due to major-city marathons delay and divert care, which can result in patients arriving at the hospital in worse condition.[12]

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[8] Jennifer L. Peel, et al., *Ambient Air Pollution and Respiratory Emergency Department Visits*, 16 EPIDEMIOLOGY, 164-174 (2005).

[9] Ruihong Zhou and Yingfeng Li, *Traffic Crash Changes Following Transitions between Daylight Saving Time and Standard Time in the United States: New Evidence for Public Policy Making,* 83 JOURNAL OF SAFETY RESEARCH, 119-127 (2022).

[10] Christopher M. Worsham, et al., *Carbon Monoxide Poisoning during Major U.S. Power Outages*, 386 NEW ENGLAND JOURNAL OF MEDICINE 191-192 (2022).

[11] Stephanie Rae Hagan, et al. *Alcohol-Related Presentations to Emergency Departments on Days with Holidays, Social, and Sporting Events: An Integrative Literature Review,* 38 PREHOSPITAL AND DISASTER MEDICINE 764–773 (2023). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10694469/.

[12] Anupam B. Jena, *Delays in Emergency Care and Mortality during Major U.S. Marathons*, 376 NEW ENGLAND JOURNAL OF

- Increased availability of cell phones and other portable devices increases serious patient injuries from falls and accidents arriving at hospitals.[13]

The examples of studies are extensive and the possibility for litigation are almost limitless. Many decisions, activities, and policies impact patient visits to hospitals. In fact, many of the scenarios set forth above are more specific and localized than the facts at issue in this case, making the standing arguments stronger for those physician-plaintiffs. To agree with Respondents' view of standing would be to transform emergency room physicians and other hospital-based doctors into super-plaintiffs under Article III.

B. Respondents' Supposed Conscience Violations Are Not Supported by the Record

Respondents also assert that "treatment violates their conscience rights, putting them in a position where they must perform or complete an abortion even though doing so is contrary to their moral beliefs." Pet. App. 24a. This argument is not supported by the testimony in the record. As the parties required to meet the burden of proof and persuasion to satisfy standing, a lack of sufficient evidence at this stage eliminates Article III jurisdiction. *Lujan*, 504 U.S. at

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MEDICINE 1441-1450 (2017), https://www.nejm.org/doi/full/10.1056/nejmsa1614073.

[13] William M. McLaughlin, *An Epidemiological Study of Cell Phone-Related Injuries of the Hand and Wrist Reported in United States Emergency Departments From 2011 to 2020*, 5 JOURNAL OF HAND SURGERY 184-188 (2023), https://www.sciencedirect.com/science/article/pii/S2589514122001785.

561. Mere allegations are not enough; "the specific facts set forth by the plaintiff to support standing must be supported adequately by the evidence." *TransUnion*, 594 U.S. at 431 (internal quotation and citation omitted). A closer examination of the record shows that claims of a conscience violation are unsubstantiated.

Dr. Christina Francis, for example, recounts an episode when a patient experienced complications and "*my partner* felt as though she was forced to participate in something that she did not want to be a part of—completing the abortion." J.A. 154 (emphasis added). The partner is not identified, and Dr. Francis did not allege a conscience violation of her own. In a second episode involving a patient who received medication from India and experienced complications, Dr. Francis does not identify the drug as mifepristone and clearly it was not. J.A. 153. Moreover, Dr. Francis does not allege any kind of conscience violation—she merely says she saw the patient in the emergency room.

Testimony from Dr. Ingrid Skop does not fare better on close evaluation. Dr. Skop's declaration states that she has "cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion" J.A. 163, but no assertion that she herself had to perform the surgery against her conscience. In a specific example, Dr. Skop described in-office treatment she provided for a woman: "I performed a sonogram, identified a significant amount of pregnancy tissue remaining in her uterus, and performed a suction aspiration procedure to resolve her complication." J.A. 164. This

example cannot be treated as a conscience violation: Dr. Skop saw the patient in her office after two follow-up appointments at Planned Parenthood and Dr. Skop could have referred this patient to someone else, if she had an objection, which she fails to assert in the declaration. Dr. Skop concludes her declaration with a speculative assertion that FDA approval of mifepristone "could force" her to "surgically finish an incomplete elective chemical abortion," J.A. 167, but offers no explanation of why or how that could happen.

Dr. Nancy Goodwin-Wozniak describes an episode involving a patient who had been advised against a medication abortion, had one, and suffered complications. J.A. 173. Even in this example, Dr. Goodwin-Wozniak asserts no action that violates her conscience: she advised the patient not to take misoprostol, instructed an internist, and describes the actions taken by other medical providers. J.A. 174.

No other declarant offers examples or specifics regarding the conscience claim. Notably, the only declarant who is an emergency room physician, Dr. Tyler Johnson, made no mention of a possible conscience violation. J.A. 177–181. That is consistent with the scope of emergency medicine. If a patient needed a procedure, such as a dilation and curettage (D&C), following the use of mifepristone, an emergency physician would refer the case to an OB-GYN.[14] There would be no obligation to "complete" an

[14] Training for emergency room physicians requires that they perform certain key procedures a minimum number of times before they graduate from their residency programs. This includes delivering a baby. Procedures such as D&C and manual vacuum aspiration (MVA) are not on that mandate. *See* The

abortion. In sum, none of the declarations relied upon by the Fifth Circuit states that the physicians conscientiously objected to providing care in the particular instance, explain why the doctor chose to proceed without invoking conscience protections, or state that they could not otherwise pass the care to another doctor.

Additionally, federal law currently offers significant conscience protections, yet none of the declarants explain why these provisions are inadequate. *See, e.g.*, 42 U.S.C. §§ 238n, 300a-7(c) & (d) (federal conscience protections). These statutes prohibit health care facilities from discriminating against physicians who refuse to provide an abortion or to force such physicians to provide an abortion against their will. *Id.* §§ 238n, 300a-7(b), (c), & (d). Currently enjoined federal guidance about emergency treatment does not change this conclusion, either. *See* U.S. Br. 23. Among other things, EMTALA creates obligations for hospitals, not individual providers, 42 U.S.C. § 1395dd(b)(1), and the federal government has taken the position that EMTALA would not compel individuals to perform an abortion against their sincerely held beliefs. Gov't C.A. Reply Br. at 25, *Texas v. Becerra*, No. 23-10246 (5th Cir. Aug. 4, 2023).

Accreditation Council for Graduate Medical Education, *Program Requirements for Graduate Medical Education in Emergency Medicine* (effective July 1, 2023), at 27–28, https://www.acgme.org/globalassets/pfassets/programrequirements/110_emergencymedicine_2023.pdf.

C. Respondents' Frustration of Mission Claim Does Not Create an Injury-in-Fact

Respondents also seek to establish standing by asserting that the FDA's decisions on mifepristone have frustrated their organizational missions. Agency decisions that do not align with the viewpoints of an organization are not enough to establish standing. For Respondents to have standing, the challenged conduct must impact the organizations' activities specifically, not merely frustrate the achievement of their mission in a general sense. *See Havens Realty Corp. v. Coleman,* 455 U.S. 363, 379 (1982). Additionally, the organization cannot undertake these activities solely with an eye toward litigation.

Respondents have failed to substantiate how any action by the FDA has directly impeded their ability to do work to achieve their mission. At the *certiorari* stage, for example, Respondents argued based on outreach efforts to membership, public education, and new studies and analysis. AFHM Opp. Br. 37-38. But Respondents' declarations are critically devoid of any assertions how the FDA's actions on mifepristone specifically impacted their ability to operate. Instead, Respondents simply state that the FDA's 2021 decisions "perceptibly impaired" their missions. AFHM Opp. Br. 38.

Even a cursory review of the cases relied upon by Respondents show this is not nearly enough. For example, in *OCA-Greater Houston v. Texas*, 867 F.3d 604 (5th Cir. 2017), a community-based organization challenged a state law claiming it was preempted by the federal Voting Rights Act. "The membership

consists of people with limited English proficiency," *id.* at 610, and the state law restricted the use of interpreters at the polls. Of course, the plaintiff organization disagreed with the state law. But its standing was based on actual operational impact. More specifically, the Fifth Circuit relied on testimony about the fact that "in-depth conversations take more time than merely explaining the requirements of the VRA, and therefore OCA must spend more time on each call (and reach fewer people in the same amount of time) because of Texas's law." *Id.* The 2016 and 2021 REMS do not interact with Respondents' operations in a similar manner. *See also Fort Lauderdale Food Not Bombs v. City of Fort Lauderdale*, 11 F.4th 1266, 1287 (11th Cir. 2021) (city ordinance blocked organization from traditional meeting following demonstration in public park).

Respondents similarly failed to identify any Article III injury that their alleged diversion of resources is necessary to avoid. Respondents assert that FDA's 2016 actions caused them to "expend[] 'considerable time, energy and resources' on their 26-page citizen petition challenging" those actions. AFHM Opp. Br. 38 (citation omitted). In *Clapper,* this Court rejected arguments regarding costly and burdensome measures allegedly incurred to protect their communications with foreign contacts. 568 U.S. at 415. The Court's reasoning that "Plaintiffs cannot manufacture standing merely by inflicting harm on themselves," *id*. applies with equal force to this case.

D. None of the Other Purported Harms Gives Respondents Standing

Respondents hint at several other types of harms in their declarations. None of them has received much attention at prior stages of this litigation. That is for good reason. Further inspection of these assertions demonstrate that they are unsubstantiated or not cognizable.

First, some of the testifying physicians claim greater exposure to liability and increased insurance premiums because of expanded access to mifepristone. Pet. App. 31a. But they failed to make a requisite showing to establish standing. *See TransUnion*, 594 U.S. at 431. All Respondents do is vaguely suggest that physicians will see higher insurance costs because of the perceived increased liability exposure. *See, e.g.*, J.A. 142 (Decl. of Dr. Jeffrey Barrows). No one testified that their insurance premiums increased or that they paid more money out of pocket directly as a result of the FDA rules on mifepristone. In addition, past injury is not enough for prospective relief, and Respondents offer no facts showing such an increase is imminently coming. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 108 (1998) (because injunctive relief "cannot conceivably remedy any past wrong," past harm is not enough for standing).

Beyond their vague and bald assertions, the testimony on its face strains credulity. For example, Dr. Tyler Johnson's testimony asserts that because some people present at the emergency department and are reluctant to share that they have taken mifepristone, "[t]he FDA's actions have created a culture of chaos for emergency room physicians." J.A.

180. As a result, "[t]his culture puts us in increasingly higher risk situations, which increases our exposure to claims of malpractice and liability." J.A. 180. Emergency room physicians, in particular, regularly work in high-pressure situations. Patients are not always forthcoming about a host of information, some of which may be highly relevant to the course of care. Some patients may not be able to communicate information about their condition. Even taking Dr. Johnson's testimony at face value, he has not described anything distinct from the type of care these physicians typically provide, whether for pregnancy loss or other medical interventions.

Second, some of the declarants assert injury because of loss of income derived from patients who would otherwise carry their pregnancies to term. *See, e.g.*, J.A. 198 (Decl. of Shaun Jester). This theory is clearly foreclosed by Supreme Court precedent. In *Diamond v. Charles*, 476 U.S. 54 (1986), this Court rejected a physician's attempt to defend a state law restricting abortions. The physician asserted that fewer abortions would lead to more paying patients, but this Court rejected the argument as "unadorned speculation" and insufficient to meet the requirements of Article III. *Id.* at 66. Even without *Diamond* on point, first principles of standing dictate a quick dismissal of this theory. At the very least, it requires the Court to accept the speculation that the patients who would otherwise take mifepristone would choose Respondents' members as their treating physicians as opposed to terminating the pregnancy through a surgical abortion, a misoprostol-only medication abortion, or by other means.

II. RESPONDENTS' ALLEGED INJURIES ARE NOT FAIRLY TRACEABLE TO THE FDA'S 2016 AND 2021 ACTIONS

The FDA initially approved mifepristone in 2000, but that approval cannot be challenged at this late date, as the Fifth Circuit correctly concluded. As a result, Respondents are left to explain how the more recent changes connect directly to the harms they allege. *See, e.g.*, *California v. Texas*, 141 S. Ct. 2104, 2119 (2021) (injury must be "fairly traceable to enforcement of the allegedly unlawful provision of which the plaintiffs complain") (internal quotations omitted). They cannot do so, which thwarts any possible standing assertions under Article III's traceability requirements.

In 2016, the FDA allowed advanced practice clinicians, such as nurse practitioners and physician assistants, to become certified prescribers under the mifepristone REMS, where permitted under state law. FDA Br. 5. Also in 2016, the FDA modified adverse event reporting requirements to align with what is required for the vast majority of other drugs. FDA Br. 5-6. In 2019, the FDA approved an application from GenBioPro to market a generic version of mifepristone. FDA Br. 6. In 2021, the FDA determined that the in-person dispensing requirement was not necessary to ensure mifepristone's safe use. FDA Br. 7.

Focusing almost exclusively on alleged injuries caused by the availability of mifepristone in general, Respondents did not specify the impacts to them from the 2016 and 2021 actions. Respondents offered no evidence that the 2016 and 2021 FDA actions

increased the number of people who will suffer complications of sufficient severity to require emergency room care by Respondents or their members. Nor did the Fifth Circuit point to any such substantiated evidence. The record shows that serious adverse events remain extremely infrequent with the relevant actions in place. *See*, *e.g.*, C.A. Add. 658–59 (reporting adverse events received by FDA through June 30, 2021).

III. RESPONDENTS' CLAIMS ARE NOT REDRESSABLE IN THIS LITIGATION.

The Fifth Circuit failed to analyze how Respondents' claims are redressable or explain how enjoining the FDA's 2016 and 2021 actions in particular would cause fewer injuries to Respondents. Here, there are at least three core flaws in any conclusion that Respondents' claims are redressable.

First, eliminating or impairing access to mifepristone will not end medication abortions. A two-medicine regimen comprising of mifepristone and misoprostol is safe, effective, and the most common means of providing a medication abortion in the United States. But patients can also terminate pregnancies by taking misoprostol alone. The availability of a misoprostol-only abortion protocol undercuts Respondents' assertion that their "injury" can be redressed by limiting patients' access to mifepristone. Put simply: if Respondents prevail in this lawsuit, it likely will result in many more misoprostol-only medication abortions. And, while still very infrequent, side effects from misoprostol-only abortions could lead patients to seek medical care of the same kind that plaintiffs speculate they will seek

under the two-drug regimen.[15] A "win" for Respondents in this lawsuit therefore will not redress their asserted "injury" of caring for patients experiencing the effects of medication-abortion.

Second, Respondents' diversion-of-resources theory is undercut by the fact that carrying a pregnancy to term is far riskier than any method of abortion.[16] Mifepristone is eminently safe and used by millions of people across the country. Respondents may *prefer* to help patients who are experiencing complications from childbirth (or other medical issues). But that is not about diversion of resources. The restricted use of mifepristone will not change Respondents' need to treat patients, nor will it reduce the number of patients experiencing pregnancy-related complications.

Third, as Danco contends, the FDA's 2016 and 2021 actions made mifepristone more effective and reduced adverse events. Danco Br. 33. By requiring Danco to return to pre-2016 labeling, Respondents would make it more likely that people using the drug need additional, medical intervention. J.A. 450 (92% need no intervention under original labeling); J.A. 449 (96.1% and 97.4% of women need no intervention

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[15] *See, e.g.*, Elizabeth G. Raymond, et al., *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, Obstet Gynecol. 2019 Jan; 133(1): 137–147, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6309472/.

[16] *See, e.g.*, Elizabeth Raymond, et al., *The comparative safety of legal induced abortion and childbirth in the United States*, Obstet. Gynecol., Feb. 2012; 119(2): 215–19, http://unmfamilyplanning.pbworks.com/w/file/fetch/119312553/Raymond%2520et%2520al-Comparative%2520Safety.pdf.

under 2016 changes). *See also* Brief of Cohen & Rebouché at 22–24.

IV. THE FIFTH CIRCUIT IMPROPERLY SUBSTITUTED ITS JUDGMENT FOR THE SCIENTIFIC EVALUATIONS OF AN EXPERT AGENCY

The Fifth Circuit improperly substituted its own judgment for both the scientific evaluation of an expert agency and an established track record. This is not just disfavored but constitutes reversible error. *See, e.g.*, *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 579 (2021) ("[C]ourts owe significant deference to the politically accountable entities with the 'background, competence, and expertise to assess public health.'") (Roberts, C.J., concurring); *Cytori Therapeutics, Inc. v. FDA*, 715 F.3d 922, 927 (D.C. Cir. 2013) ("A court is ill-equipped to second-guess that kind of agency scientific judgment under the guise of the APA's arbitrary and capricious standard.") (Kavanaugh, J.); *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375, 403 (D.D.C. 2016) ("To begin with, the FDA is an expert agency charged with making precisely these sorts of highly technical determinations, and its interpretation of romanette iv is premised on 'the agency's evaluations of scientific data within its area of expertise.'") (Jackson, J.), *aff'd sub nom. Otsuka Pharm. Co. v. Price*, 869 F.3d 987 (D.C. Cir. 2017).

The Fifth Circuit substituted its judgment in the place of thorough agency review because of a purported failure to cite to a study that evaluated the effects of those changes "as a whole." Pet. App. 53a. To the contrary, it was not arbitrary or capricious for the

FDA to "rel[y] on the data it had (and the absence of any countervailing evidence) to predict" that the individual changes also would be safe as a whole. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 425 (2021). The Fifth Circuit's judgment of how evidence-based scientific review should proceed is not enough to override years-long, deliberative and expert decision-making. *See Cytori Therapeutics*, 715 F.3d at 923. Moreover, the Fifth Circuit was wrong that the FDA only studied the changes individually and not cumulatively. The FDA made clear it relied on data from several studies "to support multiple changes." FDA Br. 38–39 (citing J.A. 299).

This Court criticized such a lack of judicial restraint before. *See, e.g.*, *FDA v. Am. Coll. of Obstetricians and Gynecologists*, 141 S. Ct. 10, 12 (2020) ("Nevertheless, a District Court Judge in Maryland took it upon himself to overrule the FDA on a question of drug safety.") (Alito, J., dissenting from holding of request for stay in abeyance). Here, the Fifth Circuit, demonstrating little regard for science or evidence, in fact substituted its own policy judgment for that of an expert agency, imperiling the lives and health of our residents by limiting the availability of mifepristone and potentially many other drugs in medicine cabinets.

V. THE INJUNCTION CONTRAVENES THE PUBLIC INTEREST

Returning to the pre-2016 restrictive conditions will eliminate or impair access to mifepristone for abortion, miscarriage management, and the treatment of other reproductive health conditions. None of this serves patients, and it imposes higher

burdens on our local healthcare systems. The Fifth Circuit in fact conceded that eliminating access to mifepristone, even temporarily as the result of its order, "may pose health risks to women, including those who use the drug to manage miscarriage," and will burden state and local health care systems. Pet. App. 69a-70a. Disruption and restrictions in accessing mifepristone will certainly be devastating, particularly for those of *amici*'s residents living in rural areas or otherwise underserved by medical facilities and doctors.

Some of *amici*'s communities that already lack access to adequate medical care are also home to populations with maternal mortality rates twice those of other communities. Access to timely, high-quality, effective therapeutic care like mifepristone is essential in these communities to treat miscarriage, to reduce bleeding and life-threatening hemorrhaging, and to treat other serious pregnancy and reproductive health complications.[17] One community is so remote and has such high rates of life-threatening hemorrhage from miscarriages that it requires, on average, one medevac a week. Mifepristone is frequently administered in that community for miscarriage management and

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[17] *See* Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and its Effects on Coagulation Function*, 13 INT. J. CLIN. EXP. MED. 2234 (Apr. 30, 2020); Mara Gordon & Sarah McCammon, *A Drug that Eases Miscarriages is Difficult for Women to Get*, NPR (Jan. 10, 2019), https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.

remains an essential tool for keeping emergency incident numbers down.[18]

Barriers to accessing mifepristone will also cause some of the millions who wish to end unwanted or unviable pregnancies with safe and effective mifepristone to turn to alternatives outside the medical system, some of which may be dangerous. Some will be pushed toward more invasive and later-gestational age procedural abortions, which can carry higher risks. Others will delay care, leading to *more* complications, *worse* health outcomes, and *greater* strain on local governments and medical providers. The impediments to accessing mifepristone for miscarriage management and various other reproductive health conditions will strain provider availability, exacting enormous costs on *amici*'s understaffed and underfunded medical facilities.

The FDA's most recent evidence-based decisions to allow non-physician health care providers to be certified prescribers of mifepristone and to permit remote prescription and by-mail delivery of the drug have the potential to reduce great disparities in healthcare delivery. These recent changes are particularly meaningful to the rural, medically underserved, and lower-income people in *amici*'s jurisdictions. The Fifth Circuit's decision would take us back in time and further entrench us in a two-tiered medical system, where necessary medical care is

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[18] Honor Macnaughton et al., *Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion*, 103 AM. FAM. PHYSICIAN 473 (2021); Marike Lemmers et al., *Medical Treatment for Early Fetal Death (Less Than 24 Weeks)*, COCHRANE DATABASE SYSTEMATIC REVIEWS 25 (June 17, 2019).

accessible only to those with the geography or means to access healthcare despite higher burdens. All of those harms to pregnant people and communities should be enough to command this Court's attention. But the harms threatened by the Fifth Circuit's order extend further—to industry.

The pharmaceutical industry has warned that the lower courts' approach would "result in a seismic shift in the clinical development and drug approval processes, erecting unnecessary and unscientific barriers to the approval of lifesaving medicines, chilling drug development and investment, threatening patient access, and destabilizing the rigorous, well-established, and long-standing drug approval process." Pharmaceutical Companies Amicus Br. at 18, *FDA v. Alliance for Hippocratic Medicine*, No. 22A902 (Apr. 14, 2023). The industry will be significantly disrupted "[i]f every FDA drug approval decision is subject to an appreciable risk of being upended by a court based on flawed assessments of studies, reliance on anecdotes, and judicially added requirements." *Id.* at 26. The Fifth Circuit's ruling undermines "the durability of FDA drug approvals" and "diminish[es] the incentives for biopharmaceutical companies to invest in new medications." *Id.* at 20-21.

More specifically, Danco explains that the Fifth Circuit's decision will have the effect of removing its brand-name drug Mifeprex from the market for an extended period of time (first while Danco prepares, and the FDA approves, an application to revert to the 2011 labeling and REMS, and then longer while Danco relabels Mifeprex, implements the modified REMS,

recertifies prescribers, and updates its distribution model). Danco Pet. 35; Danco Br. 53. This type of disruption in the availability of safe care does not promote the public interest.

CONCLUSION

For the foregoing reasons and for the reasons provided by the Petitioners and their other *amici,* the judgment of the Fifth Circuit should be reversed.

Respectfully submitted,

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APPENDIX

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City of Austin, Texas
City of Baltimore, Maryland
City of Bethel, Alaska
City of Boston, Massachusetts
Bucks County, Pennsylvania
City of Chicago, Illinois
City of Cincinnati, Ohio
City of Cleveland, Ohio
City of Columbus, Ohio
City and County of Denver, Colorado
City of Kansas City, Missouri
City of Los Angeles, California
City of Madison, Wisconsin
Marin County, California
Milwaukee County, Wisconsin
City of Minneapolis, Minnesota
Monterey County, California
Montgomery County, Maryland
City of Oakland, California
City of Pittsburgh, Pennsylvania
City of Portland, Oregon
City of St. Paul, Minnesota
City of San Diego, California
Travis County, Texas
City of Tucson, Arizona

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