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 Petitions for Writ 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 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 6 million pregnant people in the United States have used mifepristone and a companion medication, misoprostol, to safely terminate early pregnancies. The decision below would significantly impair access to mifepristone, runs counter to decades of clear scientific evidence, and violates established precedent of this Court. If allowed to stand, the lower court's order will 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 to highlight the shared interest and responsibility of local governments in protecting the health and safety of our diverse populations, including preserving access to essential healthcare such as

[1] No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund its preparation or submission. No person other than *amici* or *amici*'s counsel made a monetary contribution to the preparation or submission of this brief. *Amici* provided timely notice of their intent to file this amicus brief to all the parties in the case. A list of all *amici* is available at Appendix A.

reproductive healthcare. Some *amici* are large cities administering public health systems that depend on the availability of healthcare options, including access to mifepristone. Other *amici* are smaller cities, counties, and other public entities, including some in remote and difficult to access parts of our country. All *amici* represent populations that are low-income and medically underserved.

Impaired access to mifepristone will cause all *amici*—in fact, all local governments—to bear heightened health and economic costs. Restrictions on this medication will overburden health systems; continuing to allow FDA-approved access to this safe medicine would not. Pregnant people who are unable to access mifepristone will have worse outcomes. Without access to mifepristone, those who seek to terminate a pregnancy will undergo invasive procedural abortion, delay abortion care, or terminate their pregnancies using alternative means that present additional risks, side effects, or complications. Some may be forced to carry to term unviable pregnancies or those that threaten their health. Pregnant people who would rely on mifepristone for treating miscarriages, or for the treatment of other pregnancy or health complications, will instead be forced to endure more pain and health risks at an already devastating and terrifying time. In all instances, there will be significant economic, health, and social consequences for *amici*.

SUMMARY OF ARGUMENT

The clear errors of the decision below warrant this Court's review. 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 are simply too attenuated and speculative to constitute an injury-in-fact. Their claims are not traceable to the FDA's 2016 and 2021 decisions and cannot be redressed by this case either. In fact, making mifepristone less available will increase the number of pregnancy complications and produce more health complications of the type that Respondents fear will land in their emergency rooms.

Vacating the FDA's recent actions based on Respondents' speculation upends fundamental legal principles, improperly substitutes the judgment of a court for that of an expert agency, and destabilizes drug development and the pharmaceutical industry. The decision below was incorrect, threatens serious harm to the healthcare system, patients, and *amici* governments, and warrants review by this Court.

ARGUMENT

I. THE FIFTH CIRCUIT ERRED BY CONCLUDING THAT RESPONDENTS HAVE ARTICLE III STANDING.

The Fifth Circuit committed clear errors of law by ignoring or misconstruing precedent and incorrectly applying Article III's requirements when it

comes to injury-in-fact, traceability, and redressability. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). *Amici* governments are concerned that such a precedent, 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. Given the potential wide-ranging implications of the Fifth Circuit's decision on standing alone, review or summary reversal by this Court is warranted.

A. 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). The decision below failed to identify harm cognizable under Article III because it is neither particularized nor imminent.

1. No concrete and particularized harm has been established.

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). Instead, Respondents offer several

indirect theories for their injuries, none of which is substantiated in the record.[2]

First, they 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. But nothing in the record actually substantiates such a claim. 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." Pet. App. 20a (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 cannot identify whether the drug was in fact mifepristone and does not allege any kind of conscience violation—she merely says she saw the patient in the emergency room.

Testimony from Dr. Ingrid Skop and Dr. Nancy Wozniak do not fare better on close evaluation. Dr. Skop's declaration includes that she has "cared for at least a dozen women who have required surgery to remove retained pregnancy tissue after a chemical abortion," Pet. App. 20a, but no assertion that she herself had to perform the surgery against her conscience. In a specific example, Dr. Skop described

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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.

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." Pet. App. 21a. 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. Wozniak describes an episode involving a patient who had been advised against a medication abortion, had one, and suffered significant complications. Even in this example, Dr. 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. Pet. App. 22a.

None of the declarations relied upon by the Fifth Circuit states that the physicians conscientiously objected to providing care in the particular instance. They fail to explain why the doctor chose to proceed without invoking conscience protections or otherwise pass the care to another doctor. That is because none of the Respondents nor any other doctor needs to violate her conscience. *See, e.g.*, 42 U.S.C. §§ 238n, 300a-7(c) & (d) (federal conscience protections). Currently enjoined federal guidance about emergency treatment does not change this conclusion, either. U.S. Pet. 17 n.2 (quoting Gov't C.A. Reply Br. at 25, *Texas v. Becerra*, No. 23-10246 (5th Cir. Aug. 4, 2023) (EMTALA "does not purport to displace the Religious Freedom Restoration Act,"

which would "inform EMTALA's application to individual providers.")).

Second, Respondents' assertion that the availability of mifepristone forces a diversion of their resources is not cognizable here. Caring for patients is what doctors do. That is particularly true for those like Respondents who have chosen to treat all incoming patients in an emergency setting and do not have regular patients from whom they must divert their attention. Such doctors do not get to choose which complications they like or dislike. They may not approve of the choices their patients make, but their obligation to provide care exists nonetheless.[3] Patients may be smokers, not exercise, struggle with substance abuse, or make choices about their lives and exhibit behaviors that a doctor might not agree with. But when a patient arrives seeking care, care must be provided, absent a conscience objection. *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). Moreover, there is no limiting principle to Respondents' assertion here. All patients require resources that could otherwise be directed to other patients.

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[3] 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.").

Third, Respondents claim greater exposure to liability and increased insurance premiums because of expanded access to mifepristone. Pet. App. 31a. But they have failed to make a requisite showing to establish standing. *See TransUnion*, 141 S. Ct. at 2208 (quoting *Lujan*, 504 U.S. at 561) ("A plaintiff must demonstrate standing 'with the manner and degree of evidence required at the successive stages of the litigation.'"). All Respondents do is vaguely suggest that physicians will see higher insurance costs because of the perceived increased liability exposure. *See, e.g.*, Alliance App. 276-277 (5th Cir.) (Decl. of Dr. Jeffrey Barrows). No one testifies that their insurance premiums have increased or that they have paid more money out of pocket as a result of the 2016 and 2021 FDA rules on mifepristone. Nor could they. Beyond their vague and bald assertions, the testimony on its face strains credulity. For example, Dr. Tyler Johnson's testimony includes the assertion 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." Alliance App. 092 (emphasis added). As a result, "[t]his culture puts us in increasingly higher risk situations, which increases our exposure to claims of malpractice and liability." Alliance App. 092.[4]

[4] Respondents' third-party standing claims likewise fail. They do not enjoy some type of connection to their yet-to-be-ascertained patients, *Kowalski v. Tesmer*, 543 U.S. 125, 130–131 (2004), such that they are in privity with them or some other position to assert claims on their behalf. Additionally, any assertion of their patients' rights, even if available to them, is illogical.

2. Future injuries are not sufficiently imminent.

Any future injury needed for the issuance of an injunction must be sufficiently imminent. This Court's precedent demands that standing be denied where the alleged anticipated injury results only with "a highly attenuated chain of possibilities." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013). The Fifth Circuit 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 clear errors, this reasoning runs afoul of the standing analysis in *Summers v. Earth Island Institute*, 555 U.S. 488 (2009).

Here, Respondents have offered that, because they have treated people with mifepristone complications on some occasions in the past, they or members of their association will need to do so again in the future. That statistical likelihood is not enough for injunctive relief. *Cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 101–102 (1983). Standing for prospective relief cannot be based on such 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

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Respondents seek to limit access to the drug those patients sought out and chose for their healthcare.

make a mockery" of Supreme Court precedent. *Id.* at 497-498.

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 certainty. Instead, Respondents rely on the fact 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.

This analysis is clearly erroneous and could have wide implications. 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. Imagine, for example, that a municipality exercises eminent domain over an

undeveloped parcel of land to build a public playground. The property owner declines to bring a Fifth Amendment takings claim. Nevertheless, a doctor who lives nearby—and opposes the construction of a park near her home—files a lawsuit asserting an unconstitutional taking. She asserts that she fears (1) the playground will lead to children being injured; (2) those injured will seek care from her; and (3) she will have to divert time and resources from other patients. That doctor's standing theory is indistinguishable from Respondents' theory here. Allowing such suits to proceed would not just open the standing floodgates, it would eliminate them entirely.

The Fifth Circuit's standing analysis would effectively provide associations of doctors with an atextual exception to Article III case-or-controversy requirements. For example, it would allow an association of doctors to challenge regulations that loosened access to firearms, removed safety restrictions for kitchen appliances, or changed car safety law. But the misguided logic is not limited to claims asserted by medical professionals. Assume a school district issues a set of procedures around pupil suspensions and expulsions. No students (or their parents) challenge those procedures on due process grounds. Nevertheless, a group of schoolteachers from a *neighboring* school district files a lawsuit alleging due process violations, asserting that they fear (1) more students will be suspended or expelled from the nearby school district; (2) students will then enroll in their school district; and (3) the teachers will then need to divert time and resources away from other

students. Much more is required to meet the injury-in-fact demands of Article III.

B. 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 for provision of medication abortion by advance practice clinicians, such as nurses or midwives. FDA Pet. 5. Also in 2016, FDA modified adverse event reporting requirements to align with what is required for the vast majority of other drugs. In 2019, FDA approved an application from GenBioPro to market a generic version of mifepristone. FDA Pet. 6. In 2021, FDA determined that the in-person dispensing requirement was not necessary to ensure mifepristone's safe use.

The Fifth Circuit concluded that Respondents' challenge to the 2000 approval of mifepristone is likely time-barred and that Respondents could not show that they were separately injured by the 2019 approval of the generic version of mifepristone. As a result,

Respondents can challenge only the FDA's 2016 and 2021 actions regarding mifepristone's terms of use. We concur that this Court's precedent requires such a limitation, at the very least. *TransUnion*, 141 S. Ct. at 2208 ("[P]laintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek.").

But Respondents, focusing almost exclusively on alleged injuries caused by the availability of mifepristone in general, did not specify the impacts to them of the 2016 and 2021 actions. Respondents offered no evidence that the 2016 and 2021 FDA actions specifically increased the number of people who 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. 658-659 (reporting adverse events received by FDA through June 30, 2021); *see also* Mifepristone U.S. PostMarketing Adverse Events Summary through 12/31/2022, https://www.fda.gov/media/164331/download?attachment.

C. Respondents' Claims Are Not Redressable in this Litigation.

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

First, eliminating or impairing access to mifepristone will not end medication abortions; instead, it will cause more patients to suffer pregnancy complications. 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 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 more often than abortions involving mifepristone.[5] A "win" for Respondents in this lawsuit therefore will not redress their asserted "injury" of caring for patients with medication-abortion complications.

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.[6] Mifepristone is eminently safe and used by

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[5] *See, e.g.*, Elizabeth G. Raymond, *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/.

[6] *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.

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. The Fifth Circuit's fundamental error in failing to analyze redressability is reason alone to grant certiorari.

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

The Fifth Circuit substituted its own judgment for the scientific evaluation of an expert agency, as well as an established track record of safety for mifepristone. This is not just disfavored but constitutes reversible error. *See, e.g.*, *Food & Drug Admin. 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. Food & Drug Admin.*, 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) (quoting *Actavis Elizabeth LLC v. FDA*, 625 F.3d 760, 766 (D.C. Cir. 2010)) ("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 failed to defer to the agency expertise in evaluating the complex scientific data at issue here. Turning access to care on its head and creating confusion in the marketplace requires far more than what the Fifth Circuit's analysis amounts to.

The Fifth Circuit substituted its judgment for 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*, 141 S. Ct. 1150, 1159 (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 did not "fail[] to address the cumulative effect at all." Pet. App. 54a. The FDA expressly considered the work of Sanhueza Smith et al. 2015 (cited at C.A. Add. 782 n.3); Winikoff et al. 2012 (cited at C.A. Add. 782 n.1); and Olavarietta 2015 (cited at C.A. Add. 782 n.4) (evaluating prescription by nurses versus physicians). The FDA made clear it was relying on data from these and other studies "to

support multiple changes." FDA Pet. 23 (citing C.A. Add. 781); *see also* ROA.2142-2243 (showing that Section 1 of FDA's Medical Review document explains why FDA approvers recommended approval after detailing dozens of studies that address various combinations of the changes).

The FDA's 2021 removal of the in-person dispensing requirement was based on adverse event reports, data from the drug's sponsors, and an extensive review of studies that "examined replacing in-person dispensing in certain healthcare settings" with "dispensing at retail pharmacies" and "by mail." C.A. Add. 864. The Fifth Circuit cited no legal authority requiring the FDA to do anything more or different. Nor did the panel explain why the FDA should have continued mandatory prescriber reporting of all adverse events—instead of using the prescriber reporting system used for *every other* FDA approved drug.

This Court has criticized such a lack of judicial restraint before. *See, e.g.*, *Food and Drug Administration v. American College 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, has in fact substituted its own policy judgment for that of an expert agency, imperiling the lives and health of our residents by the availability of mifepristone and many other drugs in medicine cabinets as far away as Alaska.

III. THE IMPORTANCE OF THIS CASE DEMANDS REVIEW.

The Fifth Circuit's ruling, if upheld, will cause immeasurable harm to pregnant people nationwide in addition to *amici* and our residents, and it will destabilize the pharmaceutical industry. 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 our residents living in rural areas or otherwise underserved by medical facilities and doctors.

Some of our 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.[7] One community is so remote and has

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[7] *See* Yanxia Cao et al., Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and its Effects on

such high rates of life-threatening hemorrhage from miscarriages that it routinely requires medevacs. Mifepristone is frequently administered in that community for miscarriage management and remains an essential tool for keeping emergency incident numbers down.[8]

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

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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-hots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get; Y. X. Zhang, Effect of Mifepristone in the Different Treatments of Endometriosis, CLIN. AND EXP. OBSTET. & GYNECOL. 350 (2016).

[8] Honor Macnaughton, Melissa Nothnagle & Jessica Early, Mifepristone and Misoprostol for Early Pregnancy Loss and Medication Abortion, 103 AM. FAM. PHYSICIAN 473 (2021); ACOG and the Society for Maternal-Fetal Medicine, Practice Bulletin No. 10, 135(3) Obstetric Care Consensus e110, e122 (2020); Marike Lemmers et al., Medical Treatment for Early Fetal Death (Less Than 24 Weeks), COCHRANE DATABASE SYSTEMATIC REVIEWS 25 (June 17, 2019); American College of Obstetricians and Gynecologists, Practice Bulletin No. 200, Early Pregnancy Loss (Nov. 2018).

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 has 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 entrench us in a two-tiered medical system, where necessary medical care is 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 upended "[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.

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 (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. Additionally, and as discussed above, allowing such a seismic shift and disruption in the drug development and approval process at the behest of those with such a strained claim of standing would enshrine serious legal errors. *Amici* worry that Respondents' theory of standing could open the floodgates for suits against any local government action that might incidentally affect someone.

Finally, there is considerable confusion as a result of the lower court decisions in this case. Earlier this year—and for almost 23 years prior—mifepristone was available for patient care. At some point in the future if certiorari is not granted, access may be disrupted or impaired. But maybe not everywhere, given that there is a conflicting decision from a federal court in Washington that commands the FDA to preserve the status quo on mifepristone—at least in the 17 states and the District of Columbia

that are party to that lawsuit. *See Washington v. FDA*, No. 23-3026 (E.D. Wash. Apr. 7, 2023), ECF No. 80 (order granting in part plaintiffs' motion for preliminary injunction). Another order issued by that same court makes clear that its injunction remains in effect "irrespective of the Northern District of Texas Court ruling or the Fifth Circuit's anticipated ruling." *Washington v. FDA*, No. 23-3026, (E.D. Wash. Apr. 13, 2023), ECF No. 91 (order granting motion for clarification).

Beside the point that the FDA cannot comply with both the Washington order and the Fifth Circuit's order at the same time, questions are proliferating. The FDA's drug regulatory regime is designed to be national in scope. Upholding any part of the Fifth Circuit's opinion will result in incongruous implementation across *amici*'s jurisdictions. The confusion and harm caused by the Fifth Circuit's order cannot be overstated.

CONCLUSION

For the foregoing reasons and for the reasons provided by the Petitioners and their other *amici,* this Court should grant the petitions for a writ of certiorari or, in the alternative, should summarily reverse the judgment below.

Respectfully submitted,

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APPENDIX

APPENDIX — LIST OF *AMICI CURIAE*

Local Governments

City of Albuquerque, New Mexico

City of Alexandria, Virginia

City of Austin, Texas

City of Baltimore, Maryland

City of Bethel, Alaska

City of Birmingham, Alabama

City of Boston, Massachusetts

Bucks County, Pennsylvania

City of Chicago, Illinois

City of Cincinnati, Ohio

City of Cleveland, Ohio

City of Columbus, Ohio

City of Denver, Colorado

County of Denver, Colorado

City of Gary, Indiana

City of Kansas City, Missouri

City of Los Angeles, California

City of Madison, Wisconsin

Milwaukee County, Wisconsin

City of Minneapolis, Minnesota

City of Montgomery, Alabama

Montgomery County, Maryland

Multnomah County, Oregon

City of Newark, New Jersey

City of Northampton, Massachusetts

City of Oakland, California

City of Philadelphia, Pennsylvania

City of Pittsburgh, Pennsylvania

City of Portland, Oregon

City of Providence, Rhode Island

City of Sacramento, California

City of San Diego, California

City of Santa Cruz, California

City of Santa Monica, California

City of St. Paul, Minnesota

City of Tucson, Arizona

Washtenaw County Prosecuting Att'y's Office, Michigan

City of West Hollywood, California

Local Government Leaders

Elizabeth Alcantar
Council Member, City of Cudahy, California

Mary-Ann Baldwin
Mayor for City of Raleigh, North Carolina

Brian Beck
Councilor & Mayor Pro Tem, City of Denton, Texas

John Bonitz
Commissioner, Town of Pittsboro, North Carolina

Nancy Bowen
Commissioner, City of Coral Springs, Florida

Xouhoa Bowen
City Council Member, City of San Leandro, California

Andy Brown
Travis County Judge, Texas

Michael Chameides
Supervisor, Columbia County, New York

John Clark
Mayor, Town of Ridgway, Colorado

Laura Conover
County Attorney, Pima County, Arizona

Jorge DeFendini
Alderperson, City of Ithaca, New York

Kara Davis
District Attorney, Gilliam County, Oregon

Robyn Denson
Councilmember, Pierce County, Washington

Olgy Diaz
Council Member, City of Tacoma, Washington

Rosalba Dominguez
Council Member, Murray City, Utah

Matt Ellis
District Attorney. Wasco County, Oregon

Carrie Evans
Council Member, City of Minot, North Dakota

Obi Ezeadi
Councilor, City of Westminster, Colorado

Vanessa Fuentes
Councilwoman, City of Austin, Texas

Delia Garza
County Attorney, Travis County, Texas

Juan Geracaris
Council Member, City of Evanston, Illinois

Megan Green
President of the Board of Aldermen, City of St. Louis, Missouri

Marion Greene
Commissioner, Hennepin County, Minnesota

Beau Harbin
Legislator, Cortland County, New York

Michele Hirsch
Alderwoman, City of Kingston, New York

Jani Hitchen
Council Member, Pierce County, Washington

Carolyn Delvecchio Hoffman
Legislator, Monroe County, New York

Susan Hughes-Smith
Legislator, Monroe County, New York

Lisa Kaplan
Councilwoman, City of Sacramento, California

Timothy Keller
Mayor, City of Albuquerque, New Mexico

Nick Komives
Council Member, City of Toledo, Ohio

Andrea Jenkins
Council President, City of Minneapolis, Minnesota

Clay Lewis Jenkins
Judge, Dallas, Texas

Quinton D. Lucas
Mayor, Kansas City, Missouri

Caity Maple
Councilmember, City of Sacramento, California

Yasmine-Imani McMorrin
Vice Mayor, Culver City, California

Ryan Mello
Council Chair, Pierce County, Washington

Christian Menefee
County Attorney, Harris County, Texas

Marcelia Nicholson
Chairwoman for the Board of Supervisors, Milwaukee County, Wisconsin

Isabel Piedmont-Smith
Council Member, City of Bloomington, Indiana

Jacqueline Porter
Commissioner, City of Tallahassee, Florida

Delishia Porterfield
Councilwoman, Metropolitan Government of Nashville and Davidson County, Tennessee

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