No. 23-10362

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; AMERICAN COLLEGE OF PEDIATRICIANS; CHRISTIAN MEDICAL & DENTAL ASSOCIATIONS; SHAUN JESTER, D.O.; REGINA FROST-CLARK, M.D.; TYLER JOHNSON, D.O.; GEORGE DELGADO, M.D.,

Plaintiffs-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, Commissioner of Food and Drugs; JANET WOODCOCK, M.D., in her official capacity as Principal Deputy Commissioner, U.S. Food and Drug Administration; PATRIZIA CAVAZZONI, M.D., in her official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services,

Defendants-Appellants,

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant

On Appeal from the United States District Court
for the Northern District of Texas

UNOPPOSED MOTION OF LOCAL GOVERNMENTS TO FILE BRIEF AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS AND INTERVENOR-APPELLANT

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

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Cities, counties, and local governmental entities from across the country move this Court for leave to file the enclosed brief as *amici curiae* in support of the Government's and Intervenor's appeal of the district court's April 7, 2023 order staying the effective date of the U.S. Food and Drug Administration's September 28, 2000 approval of mifepristone. The brief includes material that is "relevant to the disposition" of the stay applications, and which would be "desirable" for the Court to consider. Fed. R. App. P. 29(a)(3)(B).

The brief explains the devastating forthcoming impacts of the order in *amici*'s jurisdictions, including major health and economic costs as well as an extraordinary strain on public health and emergency medical systems. The brief also explains how the order below will be challenging to implement both because it is an immediate and widespread change and because it conflicts with another federal district court order. At a minimum, the district court's decision creates significant confusion in *amici*'s jurisdictions.

The brief argues that the district court's opinion upends precedent governing Article III standing and the preliminary injunction standard. The brief also argues that the decision's errors include overlooking many

procedural infirmities in the plaintiffs' lawsuit and providing a remedy that upends the status quo rather than preserving it.

Although all parties have consented to this filing of the proposed *amici curiae* brief, the Court on April 19, 2023 directed all *amici* to "seek leave before filing an amicus brief." *Amici* Local Governments therefore respectfully move for leave to file. The proposed brief complies with the type-volume limitations for an amicus brief on a motion because it uses fewer than 6,500 words permitted for a motion or response. *See* Fed. R. App. P. 27(d)(2(A); *id.* 29(a)(5).

CONCLUSION

The Court should grant amici curiae local governments leave to file the enclosed brief in support of the appeals of the Government and Intervenor-Appellant Danco Laboratories.

Respectfully submitted,

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Dated: May 1, 2023

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CERTIFICATE OF COMPLIANCE

Pursuant to Rules 27 and 32 of the Federal Rules of Appellate Procedure, Joshua Rosenthal, an attorney for Public Rights Project, hereby certifies that according to the word count feature of the word processing program used to prepare this document, the document contains 315 words and complies with the typeface requirements and length limits of Rules 27(d) and 32(a)(5)-(6) and applicable local rules.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed electronically with the Court's CM/ECF system on May 1, 2023. Service will be effectuated by the Court's electronic notification system upon all parties and counsel of record.

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Defendants-Appellants,

DANCO LABORATORIES, L.L.C.,

Intervenor-Appellant

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division, Case No. 2:22-cv-00223-Z, Judge Matthew J. Kacsmaryk

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BRIEF OF LOCAL GOVERNMENTS AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS AND INTERVENOR-APPELLANT

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STATEMENT OF INTEREST

Over the last two decades, the Food and Drug Administration has reviewed robust scientific evidence and determined that mifepristone is safe and effective under the approved conditions of use. Since its approval, mifepristone has provided meaningful therapeutic benefits over other treatments. It has been used for miscarriage management and the treatment of other maternal health conditions, and more than five million pregnant people in the United States have used mifepristone and a companion medication, misoprostol, to safely terminate early pregnancies. The district court's order runs counter to decades of clear scientific evidence and would upend legal precedent and the status quo. The order will disrupt essential healthcare across the United States, including in *amici*'s jurisdictions, since mifepristone has legal uses in every state.

Amici are cities, counties, local government leaders, and public entities from across the country.[1] We file this brief to highlight the shared

[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. A list of all *Amici* is available at Appendix A.

interest and responsibility of local governments in 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 of healthcare, 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.

Without access to mifepristone, all *amici* will bear heightened health and economic costs. Restrictions on this medication will overburden health systems; access to this safe medicine does not. Pregnant people who are unable to access mifepristone will have worse outcomes. If denied access to mifepristone, pregnant people will undergo invasive procedural abortion, delay abortion care, terminate their pregnancies using alternative means that present additional risks or side effects or complications, or may be forced to carry unwanted or unviable pregnancies to term against their will. Others, 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, bleeding, or even life-threatening hemorrhaging at an already devastating and terrifying time.

In all instances, there will be grave consequences for *amici*. With an increase in procedural abortions, clinics will become even more overwhelmed with individuals traveling to access care. Abortions that are performed later in pregnancy also increase cost and risk. And medication abortions that are performed without mifepristone carry increased risk of side effects, harming *amici*'s residents and increasing the strain on local governments.

What is more, the decision below is at odds with bedrock precedent governing Article III standing and the preliminary injunction standard, and threatens to undermine *amici*'s trust in the federal court system. Putting aside the facts of the case, which are in and of themselves consequential, *amici* fear significant disruption to litigation across the country if the reasoning on these issues is allowed to stand.

SUMMARY OF ARGUMENT

Just nine months ago, the U.S. Supreme Court overruled 50 years of precedent to "return the issue of abortion to the people's elected representatives." *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228,

2243 (2022). *Amici* local government leaders and entities do not agree with the conclusion in *Dobbs* but take the decision's words at face value. Now, the ink barely dry, that admonition rings hollow as a result of the decision below and the threat it poses to reproductive healthcare access nationwide. In rewriting standing jurisprudence, overlooking other procedural infirmities in plaintiffs' lawsuit, and disregarding decades of scientific research, the decision contains many grievous errors that warrant reversal. The outcome is an overreach of judicial authority, wrong as a matter of law, and clearly unjustified on the merits.[2]

But even if the ruling below, as a matter of law, presented a closer call, the specific context of this decision, coming nearly 23 years after FDA approval of mifepristone, necessitates reversal. The supposed limitations imposed by the stay panel are not modest either, and provide further indication of the broad sweep and impacts of the decision below.

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[2] By *amici*'s count, the district court's decision included at least seven clear errors of law. Among other things, plaintiffs lack standing (injury in fact, causation, and redressability), the claims are time-barred, plaintiffs failed to administratively exhaust, the FDA's decision was legally sound, a preliminary injunction is not warranted because of plaintiffs' delay, and—given the FDA's specific authority to unwind approval through its own processes—the remedy is wrong under federal law. Any of these would be sufficient for reversal. The stay panel made similar errors, particularly on standing.

As the government has explained, existing doses of mifepristone would immediately become misbranded, the generic version of the drug would cease to be approved, and the branded version could not be marketed until FDA and the sponsor sort through the current uncertainty. Gov. Br. at 2-3. Not to mention the fact that the FDA is currently subject to a conflicting injunction given a separate ruling in Washington. Thus, for the reasons that follow and for the reasons provided by Appellants and Intervenor, the district court's order should be reversed.

ARGUMENT

The standard for granting a preliminary injunction or a stay under 5 U.S.C. § 705 is "the same." *Cronin v. USDA*, 919 F.2d 439, 446 (7th Cir. 1990). This Court "review[s] a preliminary injunction for abuse of discretion, reviewing findings of fact for clear error and conclusions of law de novo." *Texans for Free Enter. v. Tex. Ethics Comm'n*, 732 F.3d 535, 573 (5th Cir. 2013). "When a district court applies incorrect legal principles, it abuses its discretion." *Planned Parenthood of Greater Tex. Family Planning & Preventative Health Servs., Inc. v. Kauffman*, 981 F.3d 347, 354 (5th Cir. 2020) (en banc).

To obtain a preliminary injunction, "a movant must establish (1) a likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest." *Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir. 2015) (quoting *Trottie v. Livingston,* 766 F.3d 450, 452 (5th Cir. 2014)). The district court clearly erred in concluding that plaintiffs had met their burden on each factor.

I. PLAINTIFFS LACK ARTICLE III STANDING

The district court abused its discretion and committed clear errors of law by ignoring or misconstruing precedent, and by incorrectly applying Article III's requirements when it comes to injuries-in-fact, causation, and redressability. *Amici* governments are concerned that such a precedent, if affirmed, would enable actors with no direct connection to the law or regulation to sue if they come into contact with third parties affected in some way by said regulation.

A. Plaintiffs Have Not Suffered An Injury-In-Fact.

The decision below failed to identify harm cognizable under Article III for four distinct reasons.

1. Plaintiffs are not directly regulated by the agency action at issue in the case.

Plaintiffs lack standing because they are not directly regulated by the agency action at issue. They do not administer or prescribe mifepristone. By contrast, in other abortion-related litigation, the providers (asserting the rights of their patients) are often subject to the very criminal sanction being challenged. *See, e.g.*, *June Med. Services L.L.C. v. Russo*, 140 S. Ct. 2103, 2118–19 (2020), *abrogated by Dobbs*, 142 S. Ct. 2228 (The Supreme Court has "generally permitted plaintiffs to assert third-party rights in cases where the enforcement of the challenged restriction against the litigant would result indirectly in the violation of third parties' right.") (internal citations omitted). Here, there is no "threatened imposition of governmental sanctions for noncompliance." *Id.* Nor do plaintiffs enjoy some type of connection to their yet-to-be-ascertained patients, *Kowalski v. Tesmer*, 543 U.S. 125, 130-31 (2004), such that they are in privity with them or in some other position to assert claims on their behalf. Any assertion of their patients' rights, even if available to them, is illogical, because plaintiffs seek to limit access to the drug those patients used to terminate a pregnancy. Thus, the district court's analysis erroneously ignored the principle that

"the party seeking review be himself among the injured." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 563 (1992).

2. Plaintiffs' alleged future injuries are not sufficiently imminent.

Any future injury needed to warrant the issuance of an injunction is not sufficiently imminent. This Court—duty-bound by Supreme Court precedent—consistently denies standing where the alleged anticipated injury has not been shown to be more than an uncertain eventuality. *See, e.g.*, *Prestage Farms, Inc. v. Bd. of Sup'rs of Noxubee Cnty.*, Miss., 205 F.3d 265, 268 (5th Cir. 2000). (The injury "depends on the occurrence of a number of uncertain events…future injury under these circumstances is too conjectural and hypothetical to provide Article III standing."). "Allegations of only a possible future injury similarly will not suffice." *Abdullah v. Paxton*, --- F.4th ----, 2023 WL 2889273, at *2 (5th Cir. Apr. 11, 2023) (internal citations omitted). Put another way, plaintiffs rely too much on the speculative and independent actions of third parties for their supposed injuries to arise. *See, e.g.*, *Continental Automotive Systems, Inc. v. Avanci, L.L.C.*, 27 F.4th 326, 332–33 (5th Cir. 2022).

The district court failed to identify an injury with sufficient imminence. Instead, it relied implicitly on probabilistic speculation that

plaintiffs would be "overwhelm[ed]" and subject to "enormous pressure and stress" because of patients experiencing complications from mifepristone. ROA 4313. Based on this theory, *Lujan* itself requires reversal. There, the Supreme Court rejected the claims of environmentalists who had previously traveled to impacted regions (and who intended to return) as "simply not enough. Such 'some day' intentions—without any description of concrete plans, or indeed even any specification of when the some day will be—do not support a finding of the 'actual or imminent' injury that our cases require." 504 U.S. at 564.

This Court has likewise made clear that "the concept of probabilistic standing based on non-particularized increased risk" is not recognized as an injury-in-fact. *Shrimpers & Fishermen of RGV v. Texas Comm'n on Env't Quality*, 968 F.3d 419, 424 (5th Cir. 2020) (quoting *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 127 n.3 (2014)). There, association members failed to demonstrate an injury-in-fact because they did not identify specific health risks directly tied to a proposed natural gas liquefaction facility. *Id.*[3] Here, plaintiffs have

[3] Similarly, this Court concluded that health risks from possible COVID-19 exposure in schools were not sufficiently imminent to warrant an

offered that, because they have treated people with mifepristone complications in the past, they will need to do so again in the future. That is not enough for injunctive relief. *Cf. City of Los Angeles v. Lyons*, 461 U.S. 95, 101–102 (1983).

Under the analysis of the district court, any parties would enjoy Article III standing if 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 in order 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

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injury-in-fact. *E.T. v. Paxton*, 41 F.4th 709, 716 (5th Cir. 2022). While acknowledging that imminence "is a somewhat elastic concept," the court concluded that "it 'has been stretched beyond the breaking point where, as here, the plaintiff alleges only an injury at some indefinite future time.'" *Id.* (quoting *Lujan*, 504 U.S. at 564 n.2). That logic and conclusion apply with equal force here.

standing theory is indistinguishable from plaintiffs' theory here. By allowing such suits to proceed, the district court's logic would not just open the standing floodgates, it would eliminate them entirely.[4]

The stay panel made the same mistake, and in so doing ran headlong into clear Supreme Court precedent. The stay panel concluded "these doctors quite reasonably know with statistical certainty . . . that women will continue needing plaintiffs' 'emergency care.'" ROA 4394. To start, plaintiffs cannot know this with "certainty." And there is a specific reason why the stay panel used "certainty" as opposed to "probability": precedent. In *Summers v. Earth Island Institute*, the Supreme Court squarely rejected a statistical probability theory of standing that relied on the likelihood that "some of [the Sierra Club's 700,000] members are

[4] The district court's standing analysis would effectively provide doctors with an atextual exception to Article III's case-or-controversy requirements. *See* Gov. Br. at 28-29 (highlighting that an association of doctors could challenge licensing of federal firearms dealers). 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.

threatened with concrete injury." 555 U.S. 488, 497 (2009). In fact, the Court stated that such a concept "would make a mockery of our prior cases, which have required plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm." *Id.* The stay panel's sleight of hand cannot avoid clear precedent foreclosing this theory of standing.[5]

3. Facts relied upon are clearly erroneous.

Key facts relied upon to find standing were clearly erroneous. *See Sepulvado v. Jindal*, 729 F.3d 413, 417 (5th Cir. 2013) ("[T]he district court's findings of fact are subject to a clearly-erroneous standard of review.") (internal quotation omitted). Relying principally on the testimony of Dr. Ingrid Skop, the stay panel concluded that the availability of mifepristone requires an "irreconcilable choice between performing their jobs and abiding by their consciences." ROA 4393. But

[5] The stay panel's analysis also lacks statistical sense. Arguing that "it's inevitable that one of the thousands of doctors in plaintiff associations will," ROA 4395, see a patient with complications from mifepristone, the stay panel did not interrogate the underlying facts. One of the plaintiff organizations has 7,000 members worldwide, but not all of its members are necessarily practicing physicians and not all of them are in the United States. The Stay Panel overcounted both the extent of complications requiring physician intervention and the physicians currently practicing in the U.S. and represented in this litigation.

Dr. Skop—or any other doctor—does not need to violate her conscience. *See, e.g.*, 42 U.S.C. §§ 238n, 300a-7(c) & (d) (federal conscience protections). She is not required to perform an abortion against her will, and her testimony shows just that. The closest her testimony comes to that contention is that once she performed a "suction aspiration procedure" to remove "pregnancy tissue." ROA 4393. But this procedure was needed only to "resolve [the patient's] complications," *id.*, and that is a procedure commonly used after a miscarriage. Certainly, Dr. Skop does not object to treating patients who experience spontaneous miscarriages.[6]

The district court relied on discredited research to assert that psychological harm from abortions made these patients less likely to assert their interests in court. ROA 4317. The district court's reliance on Priscilla Coleman was clearly erroneous, as her research falls outside of the mainstream of the scientific academy and her opinions have been found to be unreliable by both state and federal courts. *See, e.g.*, *Adams & Boyle, P.C. v. Slatery*, 494 F. Supp. 3d 488, 538 (M.D. Tenn. 2020);

[6] The district court reached a similar conclusion that members of the plaintiffs' associations would be forced to perform an abortion. ROA 4313-4. This is both unsupported by the record and not factually accurate.

Planned Parenthood of Indiana & Kentucky, Inc. v. Comm'r, Indiana State Dep't of Health, 273 F. Supp. 3d 1013, 1036 (S.D. Ind. 2017). Based on another study, the district court made assertions about lack of informed consent. Yet that entire sample consists of anonymous blog posts on a website designed for women who regret their abortions. ROA 4314. In fact, longitudinal studies have found that people who are *denied* abortions—including access to medication abortion—are more likely to experience psychological harms.[7]

4. Plaintiffs' chief complaint is not cognizable.

Plaintiffs' chief complaint—avoiding care for certain types of patients—is not cognizable. Caring for patients is what doctors do. They do not get to choose which complications they like or do not like. They may not care for the choices their patients make, but their obligation to provide care exists nonetheless.[8] Patients may be smokers, not exercise,

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[7] *See, e.g.*, Corinne H. Rocca et al., *Emotions and decision rightness over five years following an abortion: An examination of decision difficulty and abortion stigma*, Social Science and Medicine (2020); Antonia Biggs et al., *Perceived abortion stigma and psychological well-being over five years after receiving or being denied an abortion*, PLoS ONE (15)(1), (Jan. 29, 2020).

[8] American Medical Association, *Principles of Medical Ethics*, 1.1.2 Prospective Patients, https://www.ama-assn.org/system/files/code-of-

drink excessively, or make many other choices about their lives and their health that a doctor might not agree with. But when a patient arrives seeking care, it 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). Plaintiffs' assertion of "stress and pressure" in treating patients experiencing side-effects from mifepristone is not distinct from the stress and pressure they might experience in any other case.

B. Plaintiffs 'Claims Are Not Redressable In This Litigation.

The district court also clearly erred by concluding that plaintiffs' claims are redressable. *See* ROA 4322-23 ("Redressability is satisfied even if relief must filter downstream through third parties uncertain to comply with the result."). Plaintiffs have failed to establish "a substantial likelihood that the requested relief will remedy the alleged injury in fact." *Denning v. Bond Pharmacy, Inc.*, 50 F.4th 445, 451 (5th Cir. 2022)

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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.").

(concluding award of damages to the patient would not redress the insurer's injury of being subjected to unauthorized billing practices). Here, there are at least three core flaws in any assessment that plaintiffs' claims are redressable.

First, eliminating or impairing access to mifepristone will not end medication abortions—and may cause more patients to suffer 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 plaintiffs' assertion that their "injury" can be redressed by limiting patients' access to mifepristone. Put simply: if plaintiffs prevail in this lawsuit, it will result in many more misoprostol-only medication abortions. And side effects from misoprostol-only abortions that could lead to patients seeking additional medical care are (if anything) more frequent and severe than abortions that involve mifepristone (though still quite infrequent).[9]

[9] *See, e.g.*, Elizabeth G. Raymond, *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, Obstet Gynecol. 2019

Moreover, the harms about which plaintiffs complain are not fairly traceable to mifepristone itself—and they are certainly not specifically traceable to the FDA's post-2016 actions—but are connected to the small chance of complications from pregnancy termination generally. A "win" for plaintiffs in this lawsuit will therefore not redress plaintiffs' asserted "injury" of caring for patients with medication-abortion complications. To the contrary, it may exacerbate that injury. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 413 (2013) (injury must be fairly traceable to the complained-of conduct).

Second, the stay panel was mistaken when it asserted the REMS from 2016 and beyond "all empower non-doctors to prescribe mifepristone and thus shift the costs of the drug onto the plaintiff physicians who must manage the aftermath." ROA 4395. Relying on the testimony of Dr. Nancy Wozniak, the stay panel focused on the fact that patients receiving care from providers other than doctors causes more complications. Not so. In fact, in the specific example cited by the stay panel, Dr. Wozniak stated: "The woman was given mifepristone by the *doctor* at Planned

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Jan; 133(1): 137–147, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6309472/.

Parenthood." ROA 4392. (emphasis added). The distinction drawn by the stay panel was not grounded in science or the factual record. In fact, there is no evidence that a successful outcome in the case will result in fewer patients for plaintiffs to treat.

Third, plaintiffs' diversion-of-resources theory is undercut by the fact that more pregnant people experience complications as a result of childbirth than those who have abortions.[10] Mifepristone is eminently safe and used by millions of people across the country. Plaintiffs may *prefer* to help patients who are experiencing complications from childbirth (or other medical issues). But that is not about diversion of resources. The removal of mifepristone from the market (or its reduction in usage) will not change plaintiffs' need to treat patients, nor will it reduce the number of patients experiencing pregnancy-related complications. The district court's fundamental error in failing to analyze redressability is reason alone to reverse.

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

II. PLAINTIFFS DELAY IN SEEKING AN INJUNCTION UNDERMINES THE ISSUANCE OF A STAY AS A MATTER OF LAW

The district court abused its discretion by granting preliminary relief despite the two-decades-long delay between the initial approval of this drug and this litigation. Plaintiffs spent years waiting to take action. Delays by plaintiffs of far shorter duration have regularly undermined their requests for preliminary relief. *See, e.g.*, *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) ("a party requesting a preliminary injunction must generally show reasonable diligence"). Delays within the plaintiffs' control often eliminate the availability of this extraordinary remedy. *See Charles Alan Wright & Arthur R. Miller, et al.,* 11A Federal Practice & Procedure § 2948.1 (3d ed., Apr. 2017 update). Decisions from district courts across Texas repeatedly have reached a similar conclusion in far less extenuating circumstances. *See, e.g.*, *Crossover Mkt. LLC v. Newell*, A-21-CV-00640-JRN, 2022 WL 1797359, at 1-2 (W.D. Tex. Jan. 12, 2022) (collecting cases).

Moreover, preliminary relief is supposed to maintain the status quo—which, in this case, is the availability and general accessibility of mifepristone nationwide. *See Univ. of Texas v. Camenisch*, 451 U.S. 390,

395 (1981) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held."). Instead, plaintiffs seek to avail themselves of a change in legal circumstances—the overturning of *Roe v. Wade*—as the basis for this new relief on old government action. To the extent the complained-of harms relating to mifepristone exist (which they do not), they would have existed long before plaintiffs instituted suit. Nothing in the record excuses this delay or allows for the issuance of a preliminary relief.[11] By granting it, the district court abused its discretion.

III. THE DISTRICT COURT IMPROPERLY SUBSTITUTED ITS JUDGMENT FOR THE SCIENTIFIC EVALUATIONS OF AN EXPERT AGENCY

The district court 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

[11] In a recent order issued by the Supreme Court, Justice Alito (writing in dissent of the denial of a stay) noted that a lack of diligence can significantly undermine a request for emergency relief. *West Virginia v. B.P.J.*, 598 U. S. ____ (2023), No. 22A800 ("And it is a wise rule in general that a litigant whose claim of urgency is belied by its own conduct should not expect discretionary emergency relief from a court.") (Alito, J., dissenting).

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) (internal citations omitted); *Cytori Therapeutics, Inc. v. Food & Drug Admin.*, 715 F.3d 922, 927 (D.C. Cir. 2013) (Kavanaugh, J.) ("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."); *Otsuka Pharm. Co. v. Burwell*, 302 F. Supp. 3d 375, 403 (D.D.C. 2016) (Jackson, J.) ("To begin with, the FDA is an expert agency charged with making precisely these sorts of highly technical determinations, and its interpretation . . . is premised on 'the agency's evaluations of scientific data within its area of expertise.'"), *aff'd sub nom.*, *Otsuka Pharm. Co. v. Price*, 869 F.3d 987 (D.C. Cir. 2017). This Court has recently affirmed this exact point. *Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019) ("A reviewing court must be 'most deferential' to the agency where, as here, its decision is based upon its evaluation of complex scientific data within its technical expertise.").

The district court abused its discretion by failing to defer to the agency expert in evaluating the complex scientific data at issue here. To turn access to care on its head and create confusion in the marketplace requires far more than what the district court's analysis amounts to. Reliance on self-interested affidavit testimony, unscientific web postings, and spurious and discredited journal articles should not be enough to override years-long, deliberative, and expert decision-making. But those unreliable factual inputs are what the district court relied on when it replaced the FDA's nearly three decades of evidence-based scientific review with its own.

The Supreme Court has criticized such a lack of judicial modesty 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 district court, demonstrating little regard for science or evidence, has imperiled the lives and health of our residents by threatening approval of mifepristone and many other drugs in medicine cabinets as far away as Alaska.

The court's decision has also undermined *amici*'s confidence in the federal court system. This is significant. *Amici* rely on the courts as neutral arbiters of disputes—both large and small—covering a range of matters from employment to property to torts and contracts. We frequently litigate as both plaintiffs and defendants in courts, including the federal courts. Most of our cases do not receive significant attention, but they are important to us and the litigants, and to our broader communities. Having a court system that has public confidence is crucial to allowing us to conduct our business and resolve our disputes. The district court's raw exercise of power was an abuse of discretion that erodes *amici*'s faith in the federal judiciary.

IV. THE GRANT OF A STAY DISSERVES THE PUBLIC INTEREST

The district court's determinations, if upheld, will cause immeasurable harm to *amici* and our residents. Intervenor-Appellant manufacturer Danco explains that the district court has ordered mifepristone off the market while this case proceeds. And, later, once this case is finally resolved, the harms that will have flowed to Danco from its inability to distribute its sole product for this period of time will already

have led the company to close its doors, permanently eliminating access to the drug nationwide. Danco Br. 56-58.

Disruption in access to mifepristone will be devastating, particularly for those of our residents living in rural areas or otherwise underserved by medical facilities and doctors. Some of our communities not only lack access to adequate medical care, they are also home to populations with maternal mortality rates twice those in other communities. Access to timely, high-quality, effective therapeutic care like mifepristone is essential in these communities for treating miscarriage and reducing bleeding or life-threatening hemorrhaging or other serious pregnancy and reproductive health complications.[12] 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

[12] *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; Y. X. Zhang, Effect of Mifepristone in the Different Treatments of Endometriosis, CLIN. AND EXP. OBSTET. & GYNECOL. 350 (2016).

miscarriage management and is an essential tool for keeping emergency incident numbers down.[13]

Without mifepristone, the millions who wish to end unwanted or unviable pregnancies with safe and effective mifepristone may turn to drastic and more dangerous alternatives. Others will have to undergo more invasive, riskier, and later-gestational age procedural abortions, which can carry higher risks. Others still will delay care, leading to *more* complications, *worse* health outcomes, and greater strain on local governments and medical providers. The unavailability of mifepristone for various reproductive health conditions (or the greater burden in dispensing it) will strain provider availability, exacting enormous costs on *amici*'s healthcare systems.

The FDA's most recent evidence-based decisions to reduce the number of clinical visits from three to one and allow non-physician health

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[13] 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).

care providers to prescribe and dispense the drug had the potential to reduce great disparities in healthcare delivery. These recent changes were particularly meaningful to the rural, medically underserved, and lower-income people in *amici*'s jurisdictions. But the district court's and stay panel's orders would take us back in time and entrench us in a two-tiered medical system, accessible only to those with the geography or means to access healthcare despite higher burdens.

Traveling back in time with respect to the availability and dispensation of mifepristone will devastate reproductive healthcare in the future, but the confusion created by the district court's ruling has disrupted some sectors of the healthcare system now. Last month—and for almost 23 years prior—mifepristone was available for patient care. At some point in the future when this appeal is resolved, access may be disrupted or impaired. But maybe not, 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 that are party to that lawsuit and the District of Columbia. *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 district court's injunction, questions are proliferating. Appellant Danco explains that it has been inundated with questions from certified providers, questions it is unable to answer. Will access to mifepristone remain intact in some states and not others? In those 17 states that are party to the Washington case, and those with overlapping health systems (state, county, city, federal, tribal), will anything change at all for their residents' access to the drug? If the drug itself becomes unavailable in the future, should they stock up now?

In those 33 states that are not party to the Washington case, providers and pharmacies query whether doses of mifepristone that have already been acquired may be dispensed, and for how long. Health center staff wonder how to plan for the influx of many more patients if mifepristone cannot be obtained. FDA's drug regulatory regime is

designed to be national in scope. Upholding any part of the district court's opinion will result in incongruous implementation across *amici*'s jurisdictions. The confusion and harm caused by the district court's order cannot be overstated. Without question, the public interest is not served here by the issuance of an injunction.

CONCLUSION

For the foregoing reasons and for the reasons provided by the Appellants, Intervenor-Appellant, and their other *amici,* the Court should reverse the district court's order.

Respectfully submitted,

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Dated: May 1, 2023

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APPENDIX A — LIST OF *AMICI*

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City of Baltimore, Maryland
City of Birmingham, Alabama
City of Bethel, Alaska
City of Boston, Massachusetts
Bucks County, Pennsylvania
City of Cincinnati, Ohio
City of Cleveland, Ohio
City of Columbus, Ohio
Dallas County, Texas Judge Clay Lewis Jenkins
City and County of Denver, Colorado
City of Gary, Indiana
Harris County, Texas Attorney Christian Menefee
City of Kansas City, Missouri
Kansas City, Missouri Mayor Quinton D. Lucas
City of Little Rock, Arkansas
City of Los Angeles, California
County of Los Angeles, California
City of Madison, Wisconsin
County of Marin, California
Milwaukee County, Wisconsin
City of Minneapolis, Minnesota
Montgomery County, Maryland
City of Montgomery, Alabama
City of Newark, New Jersey
City of Northampton, Massachusetts
City of Oakland, California
Pima County Attorney's Office, Arizona
City of Philadelphia, Pennsylvania

City of Pittsburgh, Pennsylvania
City of Portland, Oregon
City of Providence, Rhode Island
City of Raleigh, North Carolina Mayor Mary-Ann Baldwin
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 Tallahassee, Florida Commissioners
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City of West Hollywood, California

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, Joshua A. Rosenthal, counsel of record, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 5,625 words and complies with the typeface requirements and length limits of Rules 27, 29, and 32(a)(5)-(7) and the corresponding local rules.

/s/ Joshua A. Rosenthal
Joshua A. Rosenthal

Dated: May 1, 2023