

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 WOODCOOK, M.D., in her official capacity as Principal
Deputy Commissioner, U.S. Food and Drug Administration; PATRIZIA
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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.

**BRIEF OF LOCAL GOVERNMENTS AS *AMICI CURIAE* IN
SUPPORT OF THE GOVERNMENT'S AND INTERVENOR'S
REQUESTS FOR A STAY PENDING APPEAL**

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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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Case: 23-10362 Document: 20 Page: 7 Date Filed: 04/10/2023

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TABLE OF CONTENTS

TABLE OF AUTHORITIES xiv

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 2

ARGUMENT 4

 I. THE GOVERNMENT IS LIKELY TO SUCCEED ON
 THE MERITS BECAUSE PLAINTIFFS DO NOT
 HAVE STANDING 4

 A. Plaintiffs have not suffered an injury in fact. 4

 B. Plaintiffs’ claims are not redressable in this litigation. 8

 II. PLAINTIFFS’ DELAY IN SEEKING AN INJUNCTION
 AGAINST FDA APPROVAL UNDERMINES THE
 ISSUANCE OF A PRELIMINARY INJUNCTION AS A
 MATTER OF LAW 10

 III. COMPETING COURT RULINGS AND CONFUSION
 ABOUT IMPLEMENTATION OF AN IMMEDIATE
 INJUNCTION DEMONSTRATE THAT A STAY IS
 IMPERATIVE 12

 IV. THE PUBLIC INTEREST DEMANDS THE ISSUANCE
 OF A STAY 13

CONCLUSION 17

ADDITIONAL COUNSEL 18

APPENDIX A — LIST OF AMICI 21

CERTIFICATE OF COMPLIANCE 23

TABLE OF AUTHORITIES

CASES

<i>Adams & Boyle, P.C. v. Slatery,</i> 494 F. Supp. 3d 488 (M.D. Tenn. 2020)	6
<i>Alliance for Hippocratic Medicine, et al., v. U.S. Food and Drug Administration, et al.,</i> No. 2:22-CV-223 (N.D. Texas Apr. 7, 2023)	7
<i>Benisek v. Lamone,</i> 138 S. Ct. 1942 (2018)	10
<i>Clapper v. Amnesty Int’l USA,</i> 568 U.S. 398 (2013)	9
<i>Crossover Mkt. LLC v. Newell,</i> A-21-CV-00640-JRN, 2022 WL 1797359 (W.D. Tex. Jan. 12, 2022).....	10
<i>Dobbs v. Jackson Women’s Health Org.,</i> 142 S. Ct. 2228 (2022)	3, 5
<i>Food & Drug Admin. v. Am. Coll. of Obstetricians & Gynecologists,</i> 141 S. Ct. 578 (2021)	14
<i>In re Murchison,</i> 349 U.S. 133 (1955)	15
<i>June Med. Services L.L.C. v. Russo,</i> 140 S. Ct. 2103 (2020)	5
<i>Lujan v. Defs. of Wildlife,</i> 504 U.S. 555 (1992)	5
<i>Nken v. Holder,</i> 556 U.S. 418 (2009)	4
<i>Planned Parenthood of Indiana & Kentucky, Inc. v. Comm’r, Indiana State Dep’t of Health,</i> 273 F. Supp. 3d 1013 (S.D. Ind. 2017)	6

Roe v. Wade,
410 U.S. 113 (1973) 11

State of Washington v. U.S. Food and Drug Admin.,
No. 1:23-CV-3026-TOR (E.D. Wash. Apr. 7, 2023) 11

Steel Co. v. Citizens for a Better Env’t,
523 U.S. 83 (1998) 8

Univ. of Texas v. Camenisch,
451 U.S. 390 (1981) 10

Veasey v. Perry,
769 F.3d 890 (5th Cir. 2014)..... 4

West Virginia v. B.P.J.,
598 U. S. ____ (2023) 11

STATUTES

42 U.S.C. § 1395dd..... 7

OTHER AUTHORITIES

Biggs MA, Brown K, Foster DG, *Perceived abortion stigma and psychological well-being over five years after receiving or being denied an abortion*, PLoS ONE (15)(1), Jan. 29, 2020 7

Charles Alan Wright & Arthur R. Miller, et al., 11A Federal Practice & Procedure § 2948.1 (3d ed., Apr. 2017 update). 10

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) 7

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/119312553/Raymond%2520et%2520al-Comparative%2520Safety.pdf> 9

STATEMENT OF INTEREST

Over 20 years ago, the U.S. Food and Drug Administration (FDA) reviewed robust scientific evidence and determined that mifepristone is safe under the approved conditions of use. Since its approval, more than five million pregnant people in the United States have used mifepristone and a companion medication, misoprostol, to safely terminate their pregnancies. Indeed, over half of all abortions are now performed with this safe, effective medication. If allowed to take effect, the district court's order would run counter to decades of clear scientific evidence and upend legal precedent. The impacts of this order would be felt across the United States, including in *amici*'s jurisdictions, since mifepristone has legal uses in every state.

Amici are cities, counties, and local government 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 residents, including access to essential healthcare such as reproductive healthcare. Some *amici* administer public health systems that depend on the availability of healthcare, including access to mifepristone. Without access to mifepristone, *amici* will bear heightened health and

¹ All parties have consented to the filing of this brief. 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.

economic costs. Restrictions on medication abortion will overburden health systems. Pregnant people who are unable to access medication abortion care in a timely manner will have worse outcomes. If denied access to mifepristone, pregnant people will undergo procedural abortion, will delay abortion care, terminate their pregnancies using alternative means that present additional risks or side effects or complication, or may be forced to carry pregnancies to term against their will.

In all instances, there will be devastating consequences for *amici*. With an increase in procedural abortions, clinics will become overwhelmed with individuals traveling to access care. Abortions that are performed later in pregnancy 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 district court's opinion is at odds with bedrock precedent governing Article III standing and the preliminary injunction standard. 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 district court's 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 in order 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 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 district court’s order and the threat it poses to abortion access across the country. In rewriting standing jurisprudence and overlooking other procedural infirmities in the plaintiffs’ lawsuit, the decision contains many grievous errors that warrant a stay of the injunction. 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 decision below presented a closer call, the specific context of this decision, coming nearly 23 years after FDA approval of mifepristone, necessitates a stay pending appeal. There is too much uncertainty surrounding the order and too much abruptness for immediate implementation of the district court’s groundless order. Thus, for the reasons that follow and for the reasons provided by the Government and Intervenor, a stay should issue immediately.

² By *amici*’s count, the district court’s decision included at least seven clear errors of law. Among other things, plaintiffs lacked 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 errors would be sufficient for a stay. *Amici* local governments focus on only some of them given their particular interests at stake and that many are well-covered by parties and other *amici* in the case.

ARGUMENT

In deciding a motion to stay pending appeal, the Court considers the following factors: “(1) whether the stay applicant has made a strong showing that [they are] likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Veasey v. Perry*, 769 F.3d 890, 892 (5th Cir. 2014) (quoting *Nken v. Holder*, 556 U.S. 418, 426 (2009)). While the first two factors are often considered the most significant, all four factors fall in favor of the stay in these proceedings.

I. THE GOVERNMENT IS LIKELY TO SUCCEED ON THE MERITS BECAUSE PLAINTIFFS DO NOT HAVE STANDING

The district court clearly erred in its conclusion that the plaintiffs had standing in this suit. The decision rests on flawed logic, misconstruction of precedent, and a tortured understanding of Article III’s requirements when it comes to injuries in fact and redressability. *Amici* local 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 district court’s decision failed to identify harm cognizable under Article III. *First*, the court’s third-party standing analysis is illogical. Plaintiffs purport to

be suing to vindicate the rights of patients. But the remedy sought in this case would restrict patients' rights, by making unavailable a medication that they would otherwise have chosen to use. That hardly fits the mold of third-party standing. *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 quotation omitted).

Second, the district court’s logic effectively eliminates the principle that “the party seeking review be himself among the injured.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 563 (1992). Instead, under the analysis of the district court, any 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 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 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.³

Third, the district court relied upon discredited research to assert that psychological harm from abortions made these patients less likely to assert their interests in court. The 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); *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 upon 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

³ The district court’s standing analysis would effectively provide doctors with an atextual exception to Article III’s case-or-controversy requirements. *See* Gov’t Mot. for Stay at 7 (highlighting that an “association of doctors” could “challenge the licensing of federal firearms dealers” or “allegedly inadequate highway safety standards”). But the district court’s 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 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.

abortions. *See Alliance for Hippocratic Medicine, et al., v. U.S. Food and Drug Administration, et al.*, No. 2:22-CV-223, at 8, (N.D. Texas Apr. 7, 2023) (order granting in part plaintiffs’ motion for preliminary injunction). In fact, longitudinal studies have found that people who are *denied* abortions—including access to medication abortion—are more likely to experience psychological harms.⁴

Fourth, to the extent the harm that plaintiffs seek to remedy is having to see less of “these types of patients,” that 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. Patients may be smokers, obese, have a history of untreated disease in their families, not exercise, 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). To the extent plaintiffs have a religious objection to providing specific care to a particular patient,

⁴ *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); and Biggs MA, Brown K, Foster DG, *Perceived abortion stigma and psychological well-being over five years after receiving or being denied an abortion*, *PLoS ONE* (15)(1), Jan. 29, 2020.

the answer is not to take a sledgehammer and eliminate FDA-approval for safe and effective medicine to millions of people across the country.

B. Plaintiffs' claims are not redressable in this litigation.

The district court also failed to address a core component of the standing analysis—whether their claims were redressable. Redressability demands that a dispute be particular and that a remedy impact actual legal rights. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) (“Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement.”). Here, there are two core flaws in any assessment that plaintiffs’ claims are redressable.

First, making mifepristone unavailable will not end medication abortions—and may cause more patients to suffer complications. A two-medicine regimen comprising of mifepristone and misoprostol is the most common and effective, and least painful means of providing a medication abortion. 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. At bottom, the harms about which plaintiffs complain are not fairly traceable to mifepristone itself, but are connected to the small chance of complications from pregnancy termination overall. 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, 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.⁵ 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 will not change plaintiffs’ need to treat patients, nor will it reduce the number of patients experiencing pregnancy-related complications.

⁵ *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 AGAINST FDA APPROVAL UNDERMINES THE ISSUANCE OF A PRELIMINARY INJUNCTION AS A MATTER OF LAW

Amici local governments regularly respond to requests for preliminary injunctions. The district court's decision creates concern about broadening the availability of this remedy beyond what Rule 65 and this Court's jurisprudence require.

First, the two-decades-long delay between the initial approval and this litigation should end any possibility of a preliminary injunction. 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, a preliminary injunction is supposed to maintain the status quo—which, in this case, is the availability 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. The complained-of harms relating to mifepristone (if they existed at all) existed long before plaintiffs instituted suit. There is nothing in the record that excuses this delay or allows for the issuance of a preliminary injunction here.⁶

Second, modifications to the REMS and other approvals relating to mifepristone do not open the door to claims challenging the original approval. Challenges to more recent agency decisions—such as those at issue in Washington—are appropriate and timely. *See State of Washington v. U.S. Food and Drug Admin.*, No. 1:23-CV-3026-TOR (E.D. Wash. Apr. 7, 2023) (order granting in part plaintiffs’ motion for preliminary injunction). But the notion that a slight modification on a policy can re-open the entire history of related agency decisions to challenge is both contrary to logic and destabilizing. *Amici* local governments routinely make modifications and alterations to policies, some of which are

⁶ In a recent order issued by the U.S. 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).

longstanding. The most-recent amendment does not reopen all of those prior decisions to review.

III. COMPETING COURT RULINGS AND CONFUSION ABOUT IMPLEMENTATION OF AN IMMEDIATE INJUNCTION DEMONSTRATE THAT A STAY IS IMPERATIVE

Local governments and their public health systems must now account for this disruptive ruling that raises complex questions around implementation. The confusion is significant. Last week—and for almost 23 years prior—the availability of mifepristone was assured. Next week, access may be disrupted. 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.

Beside the point that the FDA may be unable to comply with both orders, questions are already proliferating. 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? What about when their residents (physicians, pharmacists) prescribe or dispense mifepristone to residents traveling from the other 33 states not party to the Washington case?

In those 33 states: can doses of mifepristone that have already been acquired be dispensed? Can licensed and certified physicians prescribe and administer

mifepristone for non-abortion purposes, such as for managing miscarriages? Can providers and pharmacists refer for mifepristone/medication abortion interstate, sending patients to the 17 states where access is presumably protected by the Washington order?⁷ A negative or unclear answer to any one of these questions may cause some local governments to radically alter staff and other resources on a dime—without knowing for how long—on the basis of the district court’s order. Other local governments will change nothing. Others still may risk harming their residents and their health and social services systems out of an abundance of caution to comply with the order. No matter the choices, there will be significant uncertainty, confusion, and inconsistency. FDA’s drug regulatory regime is designed to be national in scope. Failing to issue a stay here will result in incongruous implementation.

IV. THE PUBLIC INTEREST DEMANDS THE ISSUANCE OF A STAY

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,

⁷ Among other questions, providers have inquired whether FDA’s approval of mifepristone for Cushing’s disease allows for off-label prescribing for abortion. Off-label prescriptions are generally permissible, when supported by scientific data, under state licensure regimes.

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 where plaintiffs lack standing to invoke such power undermines confidence in the federal court system. For at least three reasons, a stay is required to ensure a considered and complete review of that flawed decision before its impacts are realized.

First, the district court substituted its own judgment for the considered evaluation of an expert agency, as well as an established track record of safety for mifepristone. This should be disfavored. *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). To turn access to care on its head and to create confusion in the marketplace with an immediately implemented order, especially without the benefit of a trial and consideration of tested evidence, sows doubt as to whether the court sits as a neutral rather than yet another political actor in our constitutional system. This district court's hasty, poorly informed decision should be reversed for a host of reasons. But at the very least, it should be stayed pending further consideration of its merits. Reliance on affidavit testimony, unscientific web

postings, and spurious and discredited journal articles should not be enough to override the expert decision-making authority on food and drug safety in America.

Second, the selection of venue orchestrated through an eleventh-hour formulation of a corporate entity undermines confidence in the impartiality of the judiciary. Plaintiffs registered the Alliance for Hippocratic Medicine in Amarillo a mere three months before filing suit. The location of this entity—which could be nearly anywhere, but happened to be in the Texas panhandle—appears purposefully designed to create venue in a particular division of the Northern District of Texas. More specifically, it appeared to be geared toward ensuring the assignment of Judge Kacsmayk (who has a well-known background as an anti-abortion litigator) to the case.

To be sure, all of this may fall within the bounds of what federal courts permit. But allowing a single, hand-picked judge to remove from the market a medication that has been safely used by millions undercuts confidence in the judiciary. “Justice must satisfy the appearance of justice.” *In re Murchison*, 349 U.S. 133, 136 (1955). The appearance of gamesmanship in this case—combined with the legal and factual infirmities in the district court’s ruling—warrant, at the very least, a stay.

Third, disruption in access to mifepristone will imperil the lives and health of pregnant people in our localities, causing immense harm to those individuals and to our public health, social services, and emergency medical services. Those who lose

access to mifepristone may undergo more expensive and invasive procedural abortion that requires more days off work for the procedure and recovery—potentially hundreds of miles from home. The district court’s decision will exacerbate the delays and overcrowding at clinics and hospitals in jurisdictions that are already managing an influx of patients seeking care. Many who lose access to mifepristone may turn to drastic and more dangerous alternatives to ending a pregnancy. Others who are experiencing miscarriages for which mifepristone would be otherwise prescribed will lose access to that care and will need to access less effective alternatives. And others still will delay abortion care, leading to *more* complications, *worse* health outcomes, and greater strain on medical providers and local governments alike.

CONCLUSION

For the foregoing reasons and for the reasons provided by the Government and Intervenor and their other *amici*, the request for an emergency stay pending appeal should be granted.

Respectfully submitted,

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APPENDIX A — LIST OF AMICI

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City of Baltimore, Maryland
City of Birmingham, Alabama
City of Boston, Massachusetts
Bucks County, Pennsylvania
City of Cincinnati, Ohio
City of Cleveland, Ohio
City of Columbus, Ohio
City and County of Denver, Colorado
Harris County, Texas Attorney Christian Menefee
County of Los Angeles, California
City of Madison, Wisconsin
Milwaukee County, Wisconsin
City of Minneapolis, Minnesota
Montgomery County, Maryland
City of Montgomery, Alabama
City of Newark, New Jersey
City of Oakland, California
Pima County Attorney's Office, Arizona
City of Pittsburgh, Pennsylvania
City of Portland, Oregon
City of Sacramento, California
City of Santa Cruz, California
City of St. Paul, Minnesota
City of Tucson, Arizona

Travis County Judge Andy Brown
Travis County Attorney Delia Garza
Washtenaw County Prosecuting Attorney's Office

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 3,851 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
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