Nos. 22A901 & 902

IN THE SUPREME COURT OF THE UNITED STATES

DANCO LABORATORIES, L.L.C.,
Applicant,
v.

ALLIANCE FOR HIPPOCRATIC MEDICINE; et al.,

U.S. FOOD AND DRUG ADMINISTRATION; et al.,
Applicants,
v.

ALLIANCE FOR HIPPOCRATIC MEDICINE; et al.,

BRIEF OF LOCAL GOVERNMENTS AS *AMICI CURIAE* IN SUPPORT OF THE GOVERNMENT'S AND DANCO'S APPLICATIONS TO STAY THE ORDER ENTERED BY THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS

To the Honorable Samuel A. Alito, Jr., Associate Justice of the Supreme Court of the United States and Circuit Justice for the Fifth Circuit

JOSHUA A. ROSENTHAL
AADIKA SINGH
HILARY BURKE CHAN
JONATHAN B. MILLER
Counsel of Record

Public Rights Project
490 43rd Street, Unit #115
Oakland, CA 94609
jon@publicrightsproject.org
646-831-6113

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

STATEMENT OF INTEREST

Over the last two decades, the Food and Drug Administration 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. *Every* part of the district court's order runs counter to decades of clear scientific evidence and would upend legal precedent. The Fifth Circuit's partial stay of the district court's order is erroneous as well. The order will disrupt healthcare and create chaos across the United States, including in *amici*'s jurisdictions, since mifepristone has legal uses in every state.

Amici are cities, counties, and local government leaders and 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 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. All *amici* represent populations that are low-income and medically underserved. Without access to mifepristone, all *amici* will

[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.

bear heightened health and economic costs. Restrictions on medication abortion overburden health systems; access to this safe medicine does not. 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 abortions, will delay abortion care, terminate their pregnancies using alternative means that present additional risks or side effects or complications, 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 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 decisions below are 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 reasoning on these issues is allowed to stand.

SUMMARY OF ARGUMENT

Just nine months ago, this 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 decisions below and the threat they pose to abortion access nationwide. In rewriting standing jurisprudence and overlooking other procedural infirmities in plaintiffs' lawsuit, the decisions contain 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 decisions below presented a closer call, the specific context of these decisions, coming nearly 23 years after FDA approval of mifepristone, necessitates a stay pending appeal. There is too much uncertainty surrounding the decisions (and their interaction) and too much abruptness for immediate implementation of the district court's groundless order. 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. App. 113a-116a. Not to mention the fact that the FDA is currently subject to conflicting injunctions. Thus, for the reasons that follow and for the reasons provided by the Applicants, 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 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 errors would be sufficient for a stay. The court of appeals made similar errors, particularly on standing and the merits. *Amici* local governments focus on only some of them given their interests at stake and that many are well-covered by parties and other *amici* in the case.

ARGUMENT

To prevail in an application for a stay pending appeal, applicants must show that they are likely to succeed on the merits, they will be irreparably injured absent a stay, a stay will not substantially injure other parties, and a stay serves the public interest. *Nken v. Holder*, 556 U.S. 418, 434 (2009). All factors fall in favor of immediate injunctive relief from this Court. *Amici* here focus on the merits and the public interest.

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

Both the district court and the court of appeals clearly erred in their conclusion that the plaintiffs have standing in this suit. The decisions rest on flawed logic, misconstruction of precedent, and a tortured understanding of 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. Additionally, the court of appeals seeks to revive theories of standing long rejected by this Court.

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

The decisions below failed to identify harm cognizable under Article III.

First, the district court's standing analysis is illogical. By nature of their practice and their personal views, plaintiffs are not regulated by the agency action at issue. They seek more regulation, not less. In other abortion-related litigation, the providers (asserting the rights of their patients) were often subject to criminal

sanction for violating the laws 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 quotation omitted).

Second, the lower courts' analysis 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 impact (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 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]

[3] Both lower courts' standing analysis would effectively provide doctors with an atextual exception to Article III's case-or-controversy requirements. *See* Gov't Br. at 23 (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

Third, the court of appeals failed to identify an injury with sufficient imminence to satisfy *Lujan* and its progeny. In that case, this 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." *Lujan* 504 U.S. at 564. Here, plaintiffs have 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).

Fourth, the court of appeals relied on a statistical probability theory of standing previously discredited by this Court. The Fifth Circuit concluded "these doctors quite reasonably know with statistical certainty . . . that women will continue needing plaintiffs' 'emergency care.'" Gov't App. at 43(a). To start, plaintiffs cannot know this with "certainty." And there is a specific reason why the court of appeals used "certainty" as opposed to "probability": precedent. In *Summers v. Earth Island Institute*, this 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 threatened with concrete injury." 555 U.S. 488, 497 (2009). In fact, the Court stated

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.

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 court of appeals' sleight of hand cannot avoid clear precedent foreclosing this theory of standing.[4]

Fifth, the facts relied upon by the court of appeals to reach its conclusion are flawed. Relying principally on the testimony of Dr. Ingrid Skop, the Fifth Circuit concluded that the availability of mifepristone requires an "irreconcilable choice between performing their jobs and abiding by their consciences." Gov't App. 16. But 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." PI. App. at 206. 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.

Sixth, the district court relied upon discredited research to assert that psychological harm from abortions made these patients less likely to assert their

[4] The court of appeals' probability analysis also lacks statistical sense. Arguing that "it's inevitable that one of the thousands of doctors in plaintiff associations will" see a patient with complications from mifepristone, the Fifth Circuit does not interrogate the underlying facts. Gov't App. 18. 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 U.S. The court of appeals overcounted both the extent of complications requiring physician intervention and the physicians currently practicing in the U.S. and represented in this litigation.

interests in court. 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); *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 abortions. *See* Gov't App. at 43(a). In fact, longitudinal studies have found that people who are *denied* abortions—including access to medication abortion—are more likely to experience psychological harms.[5]

Seventh, 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

[5] *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).

(requiring the provision of appropriate screening and stabilizing treatment when *any* patient arrives at an emergency department and requests treatment). 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 emergency.

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

The district court failed to address a core component of the standing analysis—whether their claims were redressable—and the courts of appeals gave it short-shrift. 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 at least three core flaws in any conclusion 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 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. 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 court of appeals is mistaken when it asserts 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." Gov't App. at 18. Relying on the testimony of Dr. Nancy Wozniak, the Fifth Circuit focuses 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 court of appeals, Dr. Wozniak stated: "The woman was given mifepristone by the *doctor* at Planned Parenthood." PI App. at 216-17 (emphasis added). The distinction drawn by the court of appeals is not grounded in science or the factual record.

Third, plaintiffs' diversion-of-resources theory is undercut by the fact that more pregnant people experience complications because of childbirth than those who

have abortions.[6] 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.

II. 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 the disruptive rulings below that raise complex questions around implementation. The confusion is significant. Last week—and for almost 23 years prior—mifepristone was available for patient care. Overnight, 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 State of Wash. 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). An order issued yesterday 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

[6] *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.

anticipated ruling." *State of Washington v. U.S. Food and Drug Admin.*, No. 1:23-CV-3026-TOR (E.D. Wash. Apr. 13, 2023) (order granting motion for clarification).

Beside the point that the FDA cannot comply with both orders, questions are already proliferating. Applicant manufacturer 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? In those 33 states that are not party to the Washington case, pharmacists query whether doses of mifepristone that have already been acquired may be dispensed in local pharmacies and by mail. Health center staff wonder how to plan for the influx of many more patients if mifepristone cannot be obtained via telehealth or mail or at all.

The uncertainty caused by two conflicting federal court rulings will force some providers, pharmacists, and ultimately local governments across the country to radically alter staff and other resources on a dime—without knowing for how long—on the basis of the lower courts' orders. 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 and harmful confusion. Already, several telehealth providers in *amici*'s jurisdictions have radically altered their regimens, or plan to do so as early as this weekend. FDA's drug regulatory regime is designed to be national

in scope. Failing to issue a stay here will result in incongruous implementation across *amici*'s jurisdictions.

III. PLAINTIFFS' DELAY IN BRINGING THIS LAWSUIT 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.

The two-decades-long delay between the initial approval and this litigation should end any possibility of a preliminary injunction. Even in considering the narrower scope of the order permitted to issue by the court of appeals, 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 a.,* 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 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. 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.[7]

IV. THE PUBLIC INTEREST DEMANDS THAT A STAY BE ISSUED

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 where plaintiffs lack standing to invoke such power undermines confidence in the federal court system. The court of

[7] In a recent order issued by this Court, Justice Alito (writing in dissent from 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).

appeals rushed attempt to solve those problems does little to mask those deep concerns. 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); *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[.]"), *aff'd sub nom. Otsuka Pharm. Co. v. Price*, 869 F.3d 987 (D.C. Cir. 2017).

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. The district court's hasty, poorly informed decision should be reversed for a host of reasons. But at the very least, it should be stayed in its entirety 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. Moreover, the court of appeals made numerous errors, including and especially in its misreading of mifepristone's labeling, in its haste to insulate the district court's decision. These compounded errors further underscore the need for a stay.

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 Kacsmaryk (who has a well-known background as an anti-abortion litigator).

To be sure, all of this may fall within the bounds of what federal courts permit. But allowing a single, hand-picked judge to restrict access to a medication that has been safely used by millions for more than two decades 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 complete stay of the underlying decision.

Third, the lower courts improperly substituted their own judgment for the FDA's nearly three decades of evidence-based scientific review. This 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 lower courts have imperiled the lives and health of our residents by threatening approvals for every drug in their medicine cabinets. Removal of mifepristone from the market, as the district court's ruling required, would certainly imperil life and health. But so would returning to the pre-2016 regulatory landscape the court of appeals' decision requires.

The disruption and chaos the Fifth Circuit's decision alone will engender for the provision and receipt of patient care will cause immeasurable harm to *amici* and our residents. Mifepristone may become functionally unavailable. The decision will cause confusion about what care can be offered, what is available, and where patients can access it. The decision may eliminate direct-to-patient medication abortion, critical for those of our residents living in rural areas or otherwise underserved by medical facilities and doctors. If allowed to stand, the decision could also eliminate access to the lower-cost generic drug. Applicant manufacturer Danco explains that, presently, under the preliminary injunction, it cannot legally market and distribute mifepristone at all. 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

may have already led the company to close its doors, permanently eliminating access to the drug nationwide.

The millions who will lose access to mifepristone may turn to drastic and more dangerous alternatives to ending a pregnancy. Others still will delay abortion care, leading to *more* complications, *worse* health outcomes, and *greater* strain on local governments and medical providers, including plaintiff-providers.

CONCLUSION

For the foregoing reasons and for the reasons provided by the Applicants and their other *amici,* the Court should stay the preliminary injunction pending appeal. Alternatively, the Court should grant certiorari before judgment and set this case for expedited briefing and argument.

Respectfully submitted,

Joshua A. Rosenthal
Aadika Singh
Hilary Burke Chan
Jonathan B. Miller*
PUBLIC RIGHTS PROJECT
490 43rd Street, #115
Oakland, CA 94609
jon@publicrightsproject.org
646-831-6113
* *Counsel of Record*

Dated: April 14, 2023

Counsel for Amici Curiae

ADDITIONAL COUNSEL

JOANNA C. ANDERSON
City Attorney
301 King Street, Suite 1300
Alexandria, VA 22314
Attorney for the City of Alexandria, Virginia

ANNE L. MORGAN
City Attorney
P.O. Box 1546
Austin, TX 78767
Attorney for the City of Austin, Texas

EBONY M. THOMPSON
Acting City Solicitor
Baltimore City Department of Law
100 N. Holliday Street
Baltimore, MD 21202
Attorney for the City of Baltimore, Maryland

ADAM CEDERBAUM
Corporation Counsel
City Hall, Room 615
Boston, MA 02201
Attorney for the City of Boston, Massachusetts

JOSEPH J. KHAN
County Solicitor
55 East Court Street
Doylestown, PA 18901
Counsel for the County of Bucks, Pennsylvania

EMILY SMART WOERNER
City Solicitor
801 Plum Street, Room 214
Cincinnati, OH 45202
Attorney for the City of Cincinnati, Ohio

MARK D. GRIFFIN
Chief Legal Officer and Law Director
601 Lakeside Ave., Room 106
Cleveland, OH 44114
Counsel for the City of Cleveland, Ohio

ZACHARY M. KLEIN
Columbus City Attorney
77 North Front Street, 4th Floor
Columbus, OH 43215
Attorney for the City of Columbus, Ohio

KERRY TIPPER
City Attorney
1437 Bannock Street, Room 353
Denver, CO 80202
Counsel for the City and County of Denver, Colorado

CHRISTIAN D. MENEFEE
County Attorney Harris
County Attorney's Office
1019 Congress Street
Houston, TX 77002
Office of the Harris County, Texas Attorney

MATTHEW GIGLIOTTI
City Attorney
414 E. 12th Street, 2300 City Hall
Kansas City, MO 64106
Attorney for Mayor Quinton D. Lucas and the City of Kansas City, Missouri

HYDEE FELDSTEIN SOTO
City Attorney
200 N. Main Street, 8th Floor
Los Angeles, CA 90012
Attorney for the City of Los Angeles, California

MICHAEL R. HAAS
City Attorney
210 Martin Luther King Jr. Blvd.
Room 401
Madison, WI 53703
Attorney for the City of Madison, Wisconsin

MARGARET C. DAUN
Corporation Counsel
901 North 9th Street, Room 303
Milwaukee, WI 53233
Counsel for Milwaukee County, Wisconsin

KRISTYN ANDERSON
City Attorney
City Hall, Room 210
350 South Fifth Street
Minneapolis, Minnesota 55415
Attorney for the City of Minneapolis, Minnesota

JOHN P. MARKOVS
County Attorney
Montgomery County, Maryland
101 Monroe Street, 3rd Floor
Rockville, Maryland 20850
Attorney for Montgomery County, Maryland

KENYATTA K. STEWART
Corporation Counsel
920 Broad Street
Newark, NJ 07102
Attorney for the City of Newark, New Jersey

ALAN SEEWALD
City Solicitor
One Roundhouse Plaza, Suite 304
Northampton, MA 01060
Attorney for the City of Northampton, Massachusetts

BARBARA J. PARKER
City Attorney
Oakland City Hall
1 Frank H. Ogawa Plaza
Oakland, CA 94612
Attorney for the City of Oakland, California

LAURA CONOVER
County Attorney
Pima County Attorney's Office
32 N. Stone Ave.
Tucson, AZ 85745
Pima County, Arizona Attorney

DIANA P. CORTES
City Solicitor
1515 Arch Street, 17th Floor
Philadelphia, PA 19102
Attorney for the City of Philadelphia, Pennsylvania

KRYSIA KUBIAK
City Solicitor and Chief Legal Officer
414 Grant Street
Pittsburgh, PA 15219
Attorney for the City of Pittsburgh, Pennsylvania

ROBERT TAYLOR
City Attorney
1221 SW Fourth Avenue
Room 430
Portland, OR 97204
Attorney for the City of Portland, Oregon

JEFFREY DANA
City Solicitor
444 Westminster Street, Suite 220
Providence, RI 02903
Attorney for the City of Providence, Rhode Island

SUSANA ALCALA WOOD
City Attorney
915 I Street, Fourth Floor
Sacramento, CA 95814
Attorney for City of Sacramento, California

MARA W. ELLIOTT
San Diego City Attorney
1200 Third Ave., Suite 1100
San Diego, CA 92101
Attorney for the City of San Diego, California

ANTHONY P. CONDOTTI
Atchison, Barisone & Condotti
P.O. Box 481
Santa Cruz, CA 95061
Attorney for the City of Santa Cruz, California

DOUGLAS T. SLOAN
City Attorney
1685 Main Street, Room 310
Santa Monica, CA 90401
Attorney for the City of Santa Monica, California

LYNDSEY M. OLSON
City Attorney
400 City Hall & Court House
15 West Kellogg Boulevard
St. Paul, MN 55102
Attorney for the City of St. Paul, Minnesota

CASSANDRA K. JACKSON
City Attorney
300 S. Adams Street
Tallahassee, FL 32301
Attorney for the City of Tallahassee, Florida

MIKE RANKIN
City Attorney
City of Tucson, Arizona
P.O. Box 27210
Tucson, AZ 85726-7210
Attorney for City of Tucson, Arizona

DELIA GARZA
Travis County Attorney
P.O. Box 1748
Austin, TX 78701
Attorney for Travis County, Texas

ELI SAVIT
Washtenaw County Prosecuting Attorney
200 N. Main Street, Suite 300
Ann Arbor, MI 48107
Washtenaw County, Michigan Prosecuting Attorney's Office

LAUREN LANGER
City Attorney
Best Best & Krieger LLP
300 South Grand Ave., 25th Floor
Los Angeles, CA 90071
Attorney for City of West Hollywood, California

APPENDIX A — LIST OF *AMICI*

City of Alexandria, Virginia

City of Austin, Texas

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

Dallas County, Texas Judge Clay Lewis Jenkins

City and County of Denver, Colorado

Harris County, Texas Attorney Christian Menefee

City of Kansas City, Missouri

Kansas City, Missouri Mayor Quinton D. Lucas

City 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 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

Jacqueline Porter, Curtis Richardson, and Diane Williams-Cox

City of Tucson, Arizona

Travis County, Texas Judge Andy Brown and Attorney Delia Garza

Washtenaw County, Michigan Prosecuting Attorney's Office

City of West Hollywood, California