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.
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
v.
DANCO LABORATORIES, L.L.C.
Intervenor-Appellant

On Appeal from the United States District Court
for the Northern District of Texas
No. 2:22-cv-00223-Z

BRIEF OF THE STATES OF MISSISSIPPI, ALABAMA, ALASKA, ARKANSAS, FLORIDA, GEORGIA, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO, OKLAHOMA, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, WEST VIRGINIA, AND WYOMING AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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CERTIFICATE OF INTERESTED PERSONS

Under this Court's Rule 28.2.1, governmental parties need not furnish a certificate of interested persons.

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INTRODUCTION AND INTEREST OF AMICI CURIAE

Last year, the Supreme Court held that abortion is a matter that is entrusted to "the people and their elected representatives" to address. *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022). Overruling precedent that took that authority away from the people, the Court returned the issue of "regulating or prohibiting abortion" to "the citizens of each State." *Ibid.* States may thus pursue their "legitimate interests" in protecting unborn life, women's health, and the medical profession by regulating or restricting abortion. *Ibid.*

Amici curiae are the States of Mississippi, Alabama, Alaska, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Like other States, amici have adopted laws regulating abortion—including chemical abortion. Those laws strike a balance among the competing interests, are the results of hard-fought democratic processes, and embody the considered judgments of "the people and their elected representatives." *Ibid.*

Yet the Administration and the FDA have attacked and worked to undermine the considered judgments of the elected representatives of States like amici. The day *Dobbs* was decided, President Biden directed his Administration to ensure that abortion drugs are "as widely accessible as possible," including "through telehealth and sent by mail."

Fact Sheet: President Biden Announces Actions In Light of Today's Supreme Court Decision on Dobbs v. Jackson Women's Health Organization, The White House (June 24, 2022), http://bit.ly/3DqTmwd. He soon signed an executive order lamenting States' regulation of abortion and directing federal agencies to "expand access to abortion care, including medication abortion." Protecting Access to Reproductive Healthcare Services, Exec. Order No. 14076, 87 Fed. Reg. 42053, 42053 (2022). He later signed a memorandum spotlighting his Administration's efforts to "evaluat[e] and monitor[ ]" state laws "that threaten to infringe" claimed "Federal legal protections [for abortion]." Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, The White House (Jan. 22, 2023), http://bit.ly/3kEZrPl. He expressed his intent to promote access to abortion drugs for patients and providers "no matter where they live." Fact Sheet: President Biden to Sign Presidential Memorandum on Ensuring Safe Access to Medication Abortion, The White House (Jan. 22, 2023), http://bit.ly/3I160Vn.

Although the Administration has, after *Dobbs*, sought to impose on the country an elective-abortion policy that it could not achieve through the democratic process, that goal is not new—especially with abortion drugs. For two decades, the FDA has acted to establish a nationwide regime of on-demand abortion by licensing sweeping access to chemical-abortion drugs. In 2000, the FDA approved the drug mifepristone for chemically induced abortions through 49 days of pregnancy. That

approval had basic legal flaws, but it did include safety measures to account for mifepristone's risks to life and health. Yet over time the FDA cast those measures aside. In 2016, it rolled back many safety requirements—allowing mifepristone to be prescribed later in pregnancy, by non-doctors, and with only one in-person visit—and stopped requiring prescribers to report non-fatal adverse events from the drug. In 2021, the agency abandoned the in-person-dispensing requirement. The FDA now condones a broad mail-order abortion-drug regime.

The district court held that the FDA's core actions on mifepristone are flawed and stayed them.

This brief explains why the public interest and equities strongly support that ruling. The FDA's actions contravene federal law, defy the public-interest determinations that the amici States have properly made, and undermine amici's enforcement of their duly enacted laws.

BACKGROUND

The Federal Food, Drug, and Cosmetic Act directs the U.S. Food and Drug Administration to "protect the public health" by ensuring that drugs are "safe and effective." 21 U.S.C. § 393(b)(2)(B). The FDA may approve a drug only if it is "safe for use under the conditions prescribed" and "will have the effect it purports or is represented to have." *Id.* § 355(d).

In 2000, the FDA approved the marketing and distribution of mifepristone for "the medical termination of intrauterine pregnancy

through 49 days' pregnancy." FDA Addendum (Add.) 181, CA5 Dkt. 27. The agency approved mifepristone under Subpart H of its regulations, which implements the agency's authority to approve new drugs that "have been studied for their safety and effectiveness in treating serious or life-threatening illnesses," 21 C.F.R. § 314.500, and "can be safely used only if distribution or use is restricted," *id.* § 314.520(a). To satisfy Subpart H, the FDA deemed pregnancy a "serious or life-threatening illness[ ]" (even in the absence of complications) and concluded that mifepristone was "safe[ ]" and "provide[d] meaningful therapeutic benefit." Add.186 (citing 21 C.F.R. §§ 314.500-314.560).

Despite approving mifepristone, the FDA recognized the "urgent adverse event[s] associated with" the drug—such as incomplete abortions and severe bleeding requiring surgery. Add.185. These risks increase later in pregnancy and for ectopic pregnancy. Add.181-88. The FDA thus required that the drug be provided only "by or under the supervision of a physician" who could "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," provide for "surgical intervention in cases of incomplete abortion or severe bleeding," and "assure patient access to medical facilities equipped to provide blood transfusions and resuscitation." Add.186.

In 2007, Congress enacted the Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007). That law affected FDA approvals under Subpart H. It directed the agency to adopt

a Risk Evaluation and Mitigation Strategy (REMS) for a drug when "necessary to ensure that the benefits of the drug outweigh the risks." 21 U.S.C. § 355-1(a)(1)-(2). A REMS operates as a "drug safety program" for medications that present "serious safety concerns." U.S. Food & Drug Admin., Risk Evaluation and Mitigation Strategies, http://bit.ly/3wKOwGp. The FDA established a REMS program for mifepristone in 2011, which required that the drug be dispensed only in certain healthcare settings—clinics, medical offices, and hospitals—under the supervision of a certified prescriber. Add.838-39.

Despite the risks the FDA recognized, in the coming years the Obama and Biden Administrations expanded mifepristone's use and dropped the safety measures around it. In 2016, the FDA extended the drug's approved use through 70 days of pregnancy, allowed more persons to prescribe it, reduced the number of required in-person patient visits from three to one, and stopped requiring prescribers to report non-fatal adverse events from the drug. Add.776-803, 839-40. The agency kept requiring at least one in-person visit so that the drug could be dispensed only in clinics, medical offices, and hospitals under a certified healthcare provider's supervision. Add.840.

In April 2021, however, the FDA stopped enforcing the in-person-dispensing requirement. The FDA attributed that decision to "COVID-related risks" of in-person dispensing. App.715, D. Ct. Dkt. 8.

In December 2021, the FDA abandoned the in-person-dispensing requirement altogether. Add.842. It did that despite recognizing that "certain elements of the Mifepristone REMS Program"—including "healthcare provider certification and dispensing of mifepristone to patients with evidence or other documentation of safe use conditions"—"remain necessary to assure the safe use of mifepristone." *Ibid.* In January 2023, the FDA modified the mifepristone REMS program to allow prescribers and pharmacies to dispense the drug "in-person or by mail." U.S. Food & Drug Admin., Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation, http://bit.ly/3kHmh8Q.

This lawsuit challenges the actions through which the FDA has approved mifepristone, made it widely accessible, and discarded measures to manage the risks that it presents. Agreeing with many of plaintiffs' arguments, as well as arguments made by the amici States here, the district court stayed the FDA's approval of mifepristone and later actions around it. This appeal followed.

SUMMARY OF ARGUMENT

The public interest and equities support the district court's order. The FDA's challenged actions defy federal law, flout the public-interest determinations that the amici States have properly made, and undermine the public interest in the enforcement of amici's valid laws.

ARGUMENT

The Public Interest And Equities Strongly Support Relief Against The FDA's Actions On Mifepristone.

A. The Public Interest And Equities Weigh Against The FDA's Actions Because Those Actions Defy Federal Law.

The FDA's actions defy the agency's regulations and federal laws restricting the mailing of abortion drugs. "There is generally no public interest in the perpetuation of unlawful agency action." *Texas v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) (per curiam) (brackets omitted). And there is a strong public interest "in having governmental agencies abide by the federal laws that govern" them. *Id.* at 559. The public interest and equities thus strongly support the district court's order.

The FDA's actions here have two basic legal flaws.

First, the FDA's approval of mifepristone defies the agency's own regulations. The agency relied on Subpart H of its regulations when it approved mifepristone in 2000. Subpart H permits the FDA to approve "certain new drug products that have been studied for their safety and effectiveness *in treating serious or life-threatening illnesses* and that provide meaningful therapeutic benefit to patients over existing treatments." 21 C.F.R. § 314.500 (emphasis added). That regulation forecloses the FDA's approval. Pregnancy is not an "illness[ ]." It is a natural state essential to perpetuating human life. And typical early-stage pregnancy without complications is not "serious or life-threatening" and does not require the "treatment" that mifepristone provides.

The FDA admits that pregnancy is not an illness but has said that its rulemaking "explained that Subpart H was available for drugs that treat serious or life-threatening *conditions*"—regardless of whether they are ordinarily understood as *illnesses*. FDA Br. 46, CA5 Dkt. 222 (emphasis added). But a clear regulation—not the agency's aspirational gloss on it—controls. The regulatory text defeats the FDA's view. At most, the FDA's argument suggests that it could have approved mifepristone under Subpart H for when a pregnant woman's life or health is seriously in danger. That is not what it did—and the FDA still would have been stuck with the reality that pregnancy is not an "illness[ ]." 21 C.F.R. § 314.500. Subpart H does not permit the agency to greenlight elective abortions on a wide scale.

The FDA also claims that Congress "incorporated mifepristone's distribution restrictions" when it "created the new REMS framework" in 2007. FDA Br. 45. That argument fails. In 2007, Congress temporarily "deemed [a drug] to have in effect an approved risk evaluation and mitigation strategy" if that drug "was [previously] approved" under Subpart H with "elements to assure safe use," Pub. L. No. 110-85, § 909(b)(1), 121 Stat. at 950, and required the sponsors of such drugs to "submit to the [FDA] a proposed risk evaluation and mitigation strategy" within 180 days, *id.* § 909(b)(3), 121 Stat. at 951. Congress thus "deemed" preexisting safety requirements to be sufficient REMS programs until a new strategy was approved. That law did not affect whether a drug was

properly authorized under Subpart H in the first place to treat "serious or life-threatening illnesses." 21 C.F.R. § 314.500. Congressional action did not blot out the FDA's defiance of its own regulation.

Second, the FDA's actions defy federal criminal law. Longstanding federal law provides that "[e]very article or thing designed, adapted, or intended for producing abortion ... [i]s declared to be nonmailable matter and shall not be conveyed in the mails or delivered from any post office or by any letter carrier." 18 U.S.C. § 1461. A related statute makes it a federal crime to "knowingly use[ ] any express company or other common carrier" to ship "in interstate or foreign commerce ... any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." *Id.* § 1462. Violations of either statute are punishable by five or more years of imprisonment. *Id.* §§ 1461, 1462. These statutes prohibit using the mail to send or receive abortion drugs such as mifepristone. The statutes' restrictions on abortion have remained even as Congress has repealed other parts of these laws. *See* Pub. L. No. 91-662, 84 Stat. 1973 (1971) (repealing certain restrictions on contraceptives). Congress has considered narrowing those statutes with a targeted intent requirement. *See* H.R. 13959, 95th Cong. §§ 6701(a)(2), 6702(1)(C)(i) (1978); *see also* H.R. Rep. No. 29, pt. 3, at 42 (1978) (explaining how bill would have "change[d] current law"). Those efforts failed. The Justice Department recently issued a memo reading into sections 1461 and 1462 the intent requirement that Congress refused to enact. *See* Application of the

Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. OLC __ (Dec. 23, 2022). But that memo cannot paper over clear statutory language or the historical reality that Congress has not altered the relevant text. *See* D. Ct. Op. 32-38.

The FDA's challenged actions on mifepristone defy the agency's regulatory authority and longstanding federal criminal law. Because those actions are at war with the law, the FDA cannot claim a public interest in enforcing them. The lower court's ruling requiring the FDA to abide by federal law promotes the public interest.

B. The FDA's Actions Undermine The Public-Interest Determinations That States—Not Federal Agencies—Are Entitled To Make.

The FDA was not following a congressional mandate or responding to changed circumstances on mifepristone's safety in promoting a new mail-order abortion regime. Rather, the agency was acting at the behest of the current Administration and its allies who demanded action after *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022). After that decision the Administration swiftly declared that state laws on abortion will have "devastating implications" for "public health" and that the Administration would "expand access to abortion care, including medication abortion," Protecting Access to Reproductive Healthcare Services, Exec. Order No. 14076, 87 Fed. Reg. 42053, 42053 (2022)—despite considered judgments by elected representatives on how to

address the health interests at stake. But it is the responsibility of elected representatives—not unelected bureaucrats in federal agencies—to balance the "competing interests" on abortion. *Dobbs*, 142 S. Ct. at 2268. The FDA's mail-order abortion regime seeks to override the balance struck by States. The district court's order properly prevents those actions from continuing to harm the public interest.

States have the "primar[y]" authority to legislate to protect health, safety, and welfare. *Hillsborough Cnty., Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 719 (1985). This power includes "regulat[ing]" the medical profession and setting standards of care. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006).

Using this authority, States have adopted varying approaches to abortion that reflect the policy views of their citizens. State laws restricting abortion ubiquitously protect a woman's life. *E.g.*, Miss. Code Ann. § 41-41-45(2). They commonly include exceptions in other circumstances. *E.g.*, *ibid.* (abortion permitted "where the pregnancy was caused by rape"). Many States have passed laws that address the risks presented by chemical abortions. Such laws recognize, for example, that "abortion-inducing drugs": "present[ ] significant medical risks to women," such as "uterine hemorrhage, viral infections, pelvic inflammatory disease, severe bacterial infection and death," *id.* § 41-41-103(1)(a); "are associated with an increased risk of complications relative to surgical abortion" that surge "with increasing gestational age," *id.*

§ 41-41-103(1)(b); and "are contraindicated in ectopic pregnancies," *id.* § 41-41-107(2). Given those risks, States have directed (for example) that only physicians may provide such drugs, that a physician may do so only after "physically examin[ing] the woman and document[ing] ... the gestational age and intrauterine location of the pregnancy," and that these drugs "must be administered in the same room and in the physical presence of the physician." *Id.* § 41-41-107(1)-(3); *see*, *e.g.*, Ind. Code Ann. § 16-34-2-1 (requiring in-person exam and dispensing); Okla. Stat. Ann. tit. 63, § 1-729.1 (requiring in-person dispensing); Tex. Health & Safety Code Ann. § 171.063(b-1) (prohibiting shipment of abortion drugs "by courier, delivery, or mail service"). Last, like all methods of elective abortion, elective chemical abortion is generally unlawful in numerous States. *E.g.*, Miss. Code Ann. § 41-41-45(2) (abortion unlawful except "where necessary for the preservation of the mother's life or where the pregnancy was caused by rape").

The FDA has sought to impose a mail-order elective-abortion regime that disregards the protections for life, health, and safety adopted by many States' elected representatives. But the authority to "regulat[e] or prohibit[ ] abortion" belongs to "the citizens of each State." *Dobbs*, 142 S. Ct. at 2284. The FDA may determine only whether mifepristone is "safe and effective" for its intended use, in line with the Federal Food, Drug, and Cosmetic Act. 21 C.F.R. §§ 314.2, 314.500. The agency has no authority to make broad policy judgments balancing the people's

interests in "prenatal life at all stages of development," "maternal health and safety," and "the integrity of the medical profession." *Dobbs*, 142 S. Ct. at 2284. Legislatures have that authority. State legislatures have balanced these interests in laws that reflect the views of their citizens. Insofar as the federal legislature has spoken in this area, it has condemned what the FDA has done. Congress has expressly declared that drugs "designed, adapted, or intended for producing abortion ... shall not be conveyed in the mails." 18 U.S.C. § 1461.

State laws on chemical abortion thus account for the public interests at issue—and they do so with democratic legitimacy (and legal authority). The FDA's actions can make no such claim. Given the absence of authority for the FDA to establish a mail-order abortion regime—and States' retained authority to act, U.S. Const. amend. X—the public interest weighs against the FDA's effort to override state laws.

C. The FDA's Actions Harm The Public Interest By Undermining States' Ability To Protect Their Citizens And Forcing States To Divert Resources To Address Violations Of Their Laws.

Even if the FDA's approval of mifepristone harmonized with the agency's regulations and federal criminal law, those actions would not simply displace state laws regulating abortion. The amici States are entitled to enforce their laws regulating chemical abortion in the interests of life, health, and safety. Disturbing the district court's order would undercut those efforts and harm the public interest.

The Administration claims that it has the power to make abortion drugs broadly accessible despite contrary determinations by States and despite laws that States have enacted to protect life, health, and safety in the use of those drugs. *See* Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, The White House (Jan. 22, 2023), http://bit.ly/3kEZrPl (Biden Memorandum). That claim is wrong. No federal law shows a "clear and manifest purpose" to displace state law in this context. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). The need for a clear statement "is heightened" where, as here, an "administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173 (2001). But federal law criminalizes sending or receiving abortion drugs by mail and so condemns the FDA's actions. *Supra* Part A. States are thus entitled to enforce their laws against those involved in sending or receiving such drugs by mail.

Yet the FDA's actions undermine States' laws, undercut States' efforts to enforce them, and—as a result—harm the public interest, in two overarching ways.

First, the FDA's actions undermine States' ability to protect their citizens. Those actions lead to the widespread shipment and use of abortion drugs. *See* Abortion Pills Can Now Be Offered at Retail Pharmacies, F.D.A. Says, N.Y. Times (Jan. 3, 2023),

http://bit.ly/3WFFxB0. That use will often defy state laws that protect life, health, and safety. *See* Retail Pharmacies Can Now Offer Abortion Pill, FDA Says, Politico (Jan. 3, 2023), http://bit.ly/3wCPl3V ("Telemedicine and mail delivery of the pills has allowed patients to circumvent state bans."). Indeed, the Administration's recent actions encourage evasion of those laws. Such evasion—particularly when coupled with the FDA's abandonment of safeguards on the drug's use—will harm amici's citizens. That harm defies the public interest.

Second, the FDA's actions force States to devote resources to investigating and prosecuting violations of their laws. As the FDA continues a campaign that will harm amici's citizens, amici will not sit by. Amici will enforce their laws to protect their citizens. But the FDA's actions on mifepristone make that task hard. The FDA—and the broader Administration—is encouraging lawbreaking on a mass scale. That regime will require States to divert resources to investigate and prosecute violations of their laws to vindicate the public interests that those laws represent. *Cf. Maine v. Taylor*, 477 U.S. 131, 137 (1986) ("[A] State clearly has a legitimate interest in the continued enforceability of its own statutes."). Such enforcement will be especially hard when the Administration will not enforce existing federal restrictions on abortion drugs, will treat state laws as "barriers" to be avoided, and can be expected to stymie States' efforts to enforce their laws. Biden Memorandum; *cf.* Remarks of President Joe Biden—State of the Union

Address as Prepared for Delivery, The White House (Feb. 7, 2023), http://bit.ly/3RHeAfn (reaffirming opposition to States that are protecting life and health after *Dobbs*). All of this confirms that the district court was right to order relief against the FDA's actions.

CONCLUSION

The public interest and equities support affirming the district court's ruling against the FDA's actions.

Dated: May 12, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Justin L. Matheny, hereby certify that the foregoing brief has been filed with the Clerk of Court using the Court's electronic filing system, which sent notification of such filing to all counsel of record.

Dated: May 12, 2023

s/ Justin L. Matheny
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CERTIFICATE OF COMPLIANCE

This brief complies with the content and form requirements of Fed. R. App. P. 29(a)(4) and 32(a) and Fifth Circuit Rule 29.2, and comports with the word-limitation requirements of those rules because leave of court has been granted to file the brief, which, excluding the parts of the document exempted by Fed. R. App. P. 32, contains 3525 words. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in proportionally spaced typeface, including serifs, using Microsoft Word 2016, in Century Schoolbook 14-point font.

Dated: May 12, 2023

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