UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Case No. 2:22-cv-00223-Z

AMICUS CURIAE BRIEF OF MISSISSIPPI, ALABAMA, ALASKA, ARKANSAS, FLORIDA, GEORGIA, IDAHO, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MONTANA, NEBRASKA, OHIO, OKLAHOMA, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, AND WYOMING IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

INTRODUCTION, INTEREST OF AMICI CURIAE, AND SUMMARY OF ARGUMENT 1

BACKGROUND 4

ARGUMENT 7

The Public Interest And Equities Support Injunctive Relief Against The FDA's Actions On Mifepristone 7

A. The Public Interest And Equities Weigh Strongly Against The FDA's Actions Because Those Actions Defy Federal Law 8

B. The FDA's Actions Undermine The Public-Interest Determinations That States—Not Federal Agencies—Are Entitled To Make 11

C. The FDA's Actions Harm The Public Interest By Undermining States' Ability To Protect Their Citizens And Forcing States To Divert Scarce Resources To Investigating And Prosecuting Violations Of Their Laws 14

CONCLUSION 18

TABLE OF AUTHORITIES

Page(s)

Cases

Dobbs v. Jackson Women's Health Organization,
142 S. Ct. 2228 (2022) 1, 2, 11, 12, 13, 14, 17

Gonzales v. Oregon,
546 U.S. 243 (2006) 12

Hillsborough Cnty., Fla. v. Automated Med. Laboratories, Inc.,
471 U.S. 707 (1985) 12

Maine v. Taylor,
477 U.S. 131 (1986) 16

Metro. Life Ins. Co. v. Massachusetts,
471 U.S. 724 (1985) 12, 15

Rice v. Santa Fe Elevator Corp.,
331 U.S. 218 (1947) 15

Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engineers,
531 U.S. 159 (2001) 15

Texas v. Biden,
10 F.4th 538 (5th Cir. 2021) 8, 11

Texas v. United States,
787 F.3d 733 (5th Cir. 2015) 16-17

Valley v. Rapides Parish Sch. Bd.,
118 F.3d 1047 (5th Cir. 1997) 8, 11

Wages & White Lion Invs., LLC v. FDA,
16 F.4th 1130 (5th Cir. 2021) 8

Constitutional Provision

U.S. Const. amend. X 14

Statutes

18 U.S.C. § 1461 ..... 10, 11, 14

18 U.S.C. § 1462 ..... 10, 11

21 U.S.C. § 321 4

21 U.S.C. § 355 4

21 U.S.C. § 355-1 5

21 U.S.C. § 393 4

Food and Drug Administration Amendments Act,
Pub. L. No. 110-85, 121 Stat. 823 (2007) 5, 9

Ind. Code Ann. § 16-34-2-1 13

La. Stat. Ann. § 40:1061.11 13

Miss. Code Ann. § 41-41-45 ..... 12, 13

Miss. Code Ann. § 41-41-103 13

Miss. Code Ann. § 41-41-107 13

Okla. Stat. Ann. tit. 63, § 1-729.1 13

Pub. L. No. 91-662, 84 Stat. 1973 (1971) 10

Tex. Health & Safety Code Ann. § 171.063 13

Executive Order

Protecting Access to Reproductive Healthcare Services,
Exec. Order No. 14076,
87 Fed. Reg. 42053 (2022) 2, 11

Regulations

21 C.F.R. § 314.2 13-14

21 C.F.R. § 314.500 ..... 4, 8, 9, 10, 13-14

21 C.F.R. § 314.520 4

21 C.F.R. §§ 314.500-314.560 5

Rulemaking

New Drug, Antibiotic, and Biological Drug Product Regulations;
Accelerated Approval,
57 Fed. Reg. 58942 (Dec. 11, 1992) 9

Other Authorities

Abortion Pills Can Now Be Offered at Retail Pharmacies, F.D.A. Says,
N.Y. Times (Jan. 3, 2023) 16

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) 2

Fact Sheet: President Biden to Sign Presidential Memorandum
on Ensuring Safe Access to Medication Abortion,
The White House (Jan. 22, 2023) 2

H.R. 13959, 95th Cong. (1978) 10

H.R. Rep. No. 29 (1979) 10

Memorandum on Further Efforts to Protect Access to
Reproductive Healthcare Services,
The White House (Jan. 22, 2023) 2, 15, 17

NIH, Nat'l Library of Medicine 4

Remarks of President Joe Biden—State of the Union Address
as Prepared for Delivery,
The White House (Feb. 7, 2023) 17

Retail Pharmacies Can Now Offer Abortion Pill, FDA Says,
Politico (Jan. 3, 2023) 16

U.S. Food & Drug Admin.,
Information about Mifepristone for Medical Termination of
Pregnancy Through Ten Weeks Gestation 6-7

U.S. Food & Drug Admin.,
Risk Evaluation and Mitigation Strategies..... 5

INTRODUCTION, INTEREST OF AMICI CURIAE, AND SUMMARY OF ARGUMENT

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's integrity by regulating or restricting abortion. *Ibid.*

Amici curiae are the States of Mississippi, Alabama, Alaska, Arkansas, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Montana, Nebraska, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, and Wyoming. Like other States, amici have, consistent with the Constitution and the Supreme Court's decision in *Dobbs*, 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.* Some States have chosen to adopt or maintain tighter restrictions and more thorough regulations on abortion after *Dobbs*. Other States have continued or embraced more permissive regimes. All States have provisions in their abortion laws to protect a woman's life and commonly include exceptions in other circumstances. These choices reflect the approach the Constitution envisions for addressing complex issues that require "legislative bodies" to "draw lines that accommodate competing interests." *Id.* at 2268.

Rather than respect the Constitution, the Supreme Court, and the democratic process, the Biden Administration has attacked and worked to undermine the considered judgments of the elected representatives of States like amici. The Administration's actions on abortion drugs typify that effort. 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. The President 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). Just weeks ago, President Biden signed a memorandum spotlighting his Administration's efforts to "evaluat[e] and monitor[ ]" state laws "that threaten to infringe" on purported "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 also 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 Biden Administration has, following *Dobbs*, doubled down on its efforts to impose on the country an elective-abortion policy that it could never achieve through the democratic process, that goal is not new—especially with abortion drugs.

For two decades, the U.S. Food and Drug Administration has acted to establish a nationwide regime of on-demand abortion by licensing sweeping access to chemical abortion drugs—in defiance of federal and state laws protecting life, health, and safety. *See* Pls.' Mot. 2-6, Dkt. 7. In 2000, the FDA purported to approve the drug mifepristone for chemically induced abortions through 49 days of pregnancy. That approval had basic legal problems of its own, but it did include safety measures to account for mifepristone's serious risks to life and health. Yet over time the FDA has cast even those measures aside. In 2016, the FDA rolled back many safety requirements—allowing mifepristone to be prescribed later in pregnancy, by non-doctors, and with only one in-person visit. In 2021, the agency halted the remaining in-person dispensing requirements during the COVID-19 pandemic and later abandoned the requirements altogether. After decades of such efforts, the FDA now broadly condones a wide-ranging mail-order abortion-drug regime. Plaintiffs here have moved to preliminarily enjoin and set aside the FDA's actions.

This brief explains why the public interest and equities strongly support relief against the FDA's actions. First, the FDA's actions contravene federal law and so disserve the public interest. Second, the FDA's actions defy the public-interest determinations made by the amici States, which are entrusted with balancing the policy and equitable considerations in this area. Last, the FDA's actions threaten to undermine the amici States' enforcement of duly enacted laws and thus undercut the public interest that those laws promote. For these reasons, injunctive relief against the FDA's actions would promote the public interest.

BACKGROUND

The Federal Food, Drug, and Cosmetic Act directs the U.S. Food and Drug Administration to "protect the public health by ensuring that ... human and veterinary drugs are safe and effective." 21 U.S.C. § 393(b)(2)(B). Under the Act, the FDA is responsible for approving any "new drug" before it is marketed and distributed to the public. *Id.* § 321(p)(1). The Act bars anyone from "introduc[ing] or deliver[ing] for introduction into interstate commerce any new drug" without FDA "approval." *Id.* § 355(a). To obtain FDA approval, a new drug must undergo an extensive process with rigorous testing. The FDA's conclusion that a drug is safe and effective must be based on "substantial evidence" of expert consensus. *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." App.518, Dkt. 8. Mifepristone is a synthetic steroid that causes "menstrual bleeding, disruption of the endometrium [or uterine lining], and then termination" of a pregnancy. Mifepristone, NIH, Nat'l Library of Medicine, http://bit.ly/403EjSN. Mifepristone is generally followed by a dose of misoprostol, which causes the pregnant woman's uterus to contract and expel the detached embryo. *Id.*, Misoprostol, http://bit.ly/3DgTpKZ.

The FDA approved mifepristone under Subpart H of the agency's regulations, which implement the agency's general 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. To satisfy Subpart H, the FDA needed to—and did—deem

pregnancy a "serious or life-threatening illness[ ]" (even in the absence of complications) and conclude that mifepristone was "safe[ ]" and "provide[d] meaningful therapeutic benefit." App.523 (citing 21 C.F.R. §§ 314.500-314.560).

Despite approving mifepristone, the FDA recognized the serious risk of "urgent adverse event[s] associated with" the drug—including incomplete abortions or severe bleeding requiring surgery. App.522. These risks increase later in pregnancy and in cases of ectopic pregnancy. App.518-25, 607-09. The approval thus included requirements that the drug be provided only "by or under the supervision of a physician" with the ability to "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," "provide [or arrange 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." App.523.

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 new 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; *see ibid.* ("While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS."). Because of the serious safety concerns involved, the FDA established a REMS program for mifepristone in 2011 with various "elements to assure safe use," including a requirement that the

drug be dispensed only in certain healthcare settings—clinics, medical offices, and hospitals—under the supervision of a certified prescriber. App.731-32.

Despite the risks that the FDA itself recognized, over the next decade and beyond, the Obama and Biden Administrations expanded mifepristone's use and dropped the safety measures erected around it. In 2016, the FDA extended the approved use of mifepristone through 70 days (10 weeks) of pregnancy, allowed a broader set of persons to prescribe the drug, and reduced the number of required in-person patient visits from three to one. App.625-52, 732. But the agency maintained the requirement for at least one in-person visit so that the drug could be dispensed only in clinics, medical offices, and hospitals under the supervision of a certified healthcare provider. App.733.

In April 2021, however, the FDA stopped enforcing the in-person-dispensing requirements. The FDA attributed that decision to "COVID-related risks" of in-person dispensing. App.715. The agency added that it would "exercise enforcement discretion during the COVID-19 [public-health emergency] with respect to the dispensing of mifepristone through the mail." *Ibid.*

In December 2021, the FDA abandoned the in-person dispensing requirement altogether. App.735. It made this decision independent of any COVID-related risks and 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" and "ensure the benefits of mifepristone outweigh the risks." *Ibid.* On January 3, 2023, the FDA modified the

mifepristone REMS program to make clear the agency's position that the drug can now be dispensed by certified prescribers or retail pharmacies "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.

While the FDA is authorized to evaluate new drugs for safety and effectiveness, States are primarily responsible for protecting the health and welfare of their citizens. Many States, including several amici here, have thus enacted laws to regulate abortion-inducing drugs and account for their dangers. Such laws can include in-person examination and dispensing requirements, qualification requirements for prescribers, mandates for informed consent, bans on distribution by mailing, or some combination of these and other safety limitations. *See infra*.

The lawsuit here seeks to enjoin the panoply of agency actions through which the FDA has approved mifepristone, made it widely accessible, and discarded measures to manage the risks that it presents.

ARGUMENT

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

The FDA's challenged actions on mifepristone are deeply flawed. They defy federal law, flout the public-interest determinations that States have properly made, and undermine the public interest in the enforcement of validly enacted state laws. These features strongly support injunctive relief against the agency's actions.

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

Plaintiffs have demonstrated that the FDA's actions on mifepristone violate the Federal Food, Drug, and Cosmetic Act and related FDA regulations. *See* Pls.' Mot. 14-23. Amici emphasize that the FDA's actions defy both the agency's regulations and also federal laws restricting the mailing of abortion drugs. The public interest and equities thus favor injunctive relief against the FDA's actions.

An agency action defies the public interest if it is unlawful. "There is generally no public interest in the perpetuation of unlawful agency action." *Texas v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021) (brackets omitted); *see also Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1143 (5th Cir. 2021). Allowing illegal actions by government agencies to stand "undermine[s]" the public interest. *Valley v. Rapides Parish Sch. Bd.*, 118 F.3d 1047, 1056 (5th Cir. 1997). And there is a strong public interest "in having governmental agencies abide by the federal laws that govern their existence and operations." *Biden*, 10 F.4th at 559.

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

First, the FDA's approval of mifepristone defies the agency's own regulations. As noted, the agency relied on Subpart H of its regulations when it first 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 doubly 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 a condition that is "serious or life-threatening" or that requires the "treatment" mifepristone provides.

The FDA admits that pregnancy is not an illness but claims that its rulemaking "explained that Subpart H was available for serious or life-threatening 'conditions,' whether or not they were understood colloquially to be 'illnesses.'" Opp. 26, Dkt. 28 (quoting New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942, 58946 (Dec. 11, 1992)). But an unambiguous regulation—not the agency's aspirational gloss on it—controls. As explained, that clear regulatory text defeats the FDA's view and thus its approval of mifepristone. At most, the FDA's argument suggests that it could have approved mifepristone under Subpart H for cases in which 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 "any hypothetical error in the initial reliance on Subpart H" has "been overtaken by congressional action." Opp. 25, 26. This is not the argument of an agency that is confident in the legality of its actions. And the argument fails. When Congress established the REMS framework in 2007, it temporarily "deemed to have in effect an approved risk evaluation and mitigation strategy" any "drug that 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. This means

that Congress "deemed" preexisting safety requirements to be sufficient REMS programs under the new 2007 law 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-inducing drugs such as mifepristone. The statutes' restrictions on abortion have remained in place—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 from what is now section 1461). Congress has also considered narrowing those statutes with a targeted intent requirement. *See* H.R. 13959, 95th Cong. §§ 6701(a)(1)(2), 6702(1)(C)(i) (1978); *see also* H.R. Rep. No. 29, pt. 3, at 42 (1979) (explaining how bill would have "change[d] current law"). Those efforts failed. A late-breaking memo from the Biden Justice Department, *see* Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions,

46 Op. OLC __ (Dec. 23, 2022), reads into sections 1461 and 1462 the very intent requirement that Congress refused to enact. But that memo cannot paper over clear statutory language or the historical reality that Congress has not altered the relevant text.

The FDA's challenged actions on mifepristone thus defy the agency's regulatory authority and longstanding federal criminal law. Because those actions are at war with the law, the FDA cannot claim any public interest in enforcing them. Indeed, enjoining the FDA to "abide by" federal law would promote the public interest, *Biden*, 10 F.4th at 559—and not issuing injunctive relief would "undermine" the public interest, *Valley*, 118 F.3d at 1056.

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

The FDA was not responding to changed circumstances on the safety of mifepristone when it cast aside the longstanding requirements for in-person dispensing. Nor was the agency following any legislative mandate from Congress when promoting a new mail-order abortion regime. Rather, the agency was acting at the behest of the Biden Administration and its allies who demanded political action after *Dobbs*. After that decision the Administration swiftly declared that duly enacted state laws on abortion will have "devastating implications" for "public health" and that the federal government would act 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)—despite considered judgments by elected representatives on how to address the health interests at stake. But, as

the Supreme Court recognized, it is the responsibility of elected representatives in States—not unelected bureaucrats in federal agencies—to strike the balance between "competing interests" on abortion. *Dobbs*, 142 S. Ct. at 2268. The FDA's actions seek to override the balance properly struck by States. If allowed to stand, those actions will harm the public interest.

Under our Constitution, States have the primary authority to legislate to protect the health, safety, and welfare of their citizens. *Hillsborough Cnty., Fla. v. Automated Med. Laboratories, Inc.*, 471 U.S. 707, 719 (1985) ("[T]he regulation of health and safety matters is primarily, and historically, a matter of local concern."); *Metro. Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985) ("The States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons.") (internal quotation marks omitted). This power includes regulating the medical profession and setting standards of care. *Gonzales v. Oregon*, 546 U.S. 243, 270 (2006) ("[A] functioning medical profession [is] regulated under the States' police powers.").

Using this authority, States have adopted varying approaches to abortion that reflect the policy decisions of their constituent citizens. State laws restricting abortion ubiquitously include provisions to protect a woman's life. *E.g.*, Miss. Code Ann. § 41-41-45(2). They commonly include exceptions in other circumstances too. *E.g.*, *ibid.* (abortion permitted "where the pregnancy was caused by rape"). Many States have passed laws that address the particular 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(a); "are associated with an increased risk of complications relative to surgical abortion" that heightens "with increasing gestational age," *id.* § 41-41-103(b); and "are contraindicated in ectopic pregnancies," *id.* § 41-41-107(2). Given those risks, States have used their regulatory authority to direct (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 abortion drugs "must be administered in the same room and in the physical presence of the physician," ensuring that the pregnant woman is informed of risks and monitored for complications. *Id.* §§ 41-41-107(2), (3); *see, e.g.*, Ind. Code Ann. § 16-34-2-1 (requiring in-person exam and dispensing); La. Stat. Ann. § 40:1061.11 (requiring in-person 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-inducing 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").

In the actions at issue here, the FDA has sought to impose a federal mail-order abortion regime that disregards the protections for life, health, and safety adopted by numerous 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. 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, and state legislatures have balanced these interests and others in laws that reflect the views of constituent citizens. Insofar as the federal legislature has weighed in at all in this area, it has been to condemn 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 the benefit of democratic legitimacy (and legal authority). The FDA's actions can make no such claim. By obstructing the judgments of elected representatives, the agency has undermined the public interest. 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 strongly weighs against the FDA's effort to override duly enacted state laws.

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

Even if the FDA's approval of mifepristone harmonized with the agency's own regulations and federal criminal law, those actions would not simply displace state laws regulating abortion. The amici States are entitled to enforce their duly enacted

laws regulating chemical abortion in the interests of life, health, and safety. Yet the FDA's actions will undercut those efforts and thus harm the public interest.

The Biden Administration claims that it has the power to broadly make abortion drugs accessible despite contrary determinations by States and despite regulations that States may 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 manifests Congress's "clear and manifest purpose" to displace state law in this context. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also ibid.* (Courts should "start with the assumption that the historic police powers of the States [are] not to be superseded ... unless that was the clear and manifest purpose of Congress."). The need for a clear statement from Congress "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); *see also Metro. Life*, 471 U.S. at 740 (Courts "must presume that Congress did not intend to pre-empt areas of traditional state regulation."). As discussed above, the relevant federal statutes criminalize sending or receiving abortion drugs by mail and thus affirmatively condemn the FDA's actions. *Supra* Part B. States are thus entitled to enforce their laws—protecting life, health, and safety—against persons and businesses involved in distributing or receiving abortion drugs by mail.

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

First, the FDA's actions will undermine States' ability to protect their citizens. Those actions will lead to the widespread shipment and use of abortion-inducing 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 widespread use will often occur in defiance of 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 whole point of the Administration's recent actions is to encourage and achieve evasion of those state laws. Such evasion—particularly when coupled with the FDA's abandonment of key protections on mifepristone's use—will harm the citizens of the amici States. That harm defies the public interest.

Second, the FDA's actions will force States to devote scarce 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 will make that task hard. The FDA—and the broader Administration—is encouraging lawbreaking on a mass scale. The new regime will require States to divert scarce 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."); *Texas v.*

United States, 787 F.3d 733, 749 (5th Cir. 2015) ("[S]tates have a sovereign interest in the power to create and enforce a legal code.") (internal quotation marks omitted). Such enforcement will be especially hard in these circumstances, given the Administration's position that it will not enforce existing federal restrictions on abortion drugs, will treat state laws as "barriers" to be avoided, and can be expected to stymie and defy States' efforts to enforce their own 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 subverts the public interest and the equities represented by validly enacted state laws. It strongly supports injunctive relief.

* * *

The serious nature of the FDA's unlawful actions, and the agency's decision to invite lawbreaking by private parties and government actors across the country, favors broad relief. The FDA and the Administration as a whole have no intention to respect the Constitution, the Supreme Court, or the democratic process when it comes to abortion. This Court's decisive action is warranted.

CONCLUSION

The public interest and equities support relief against the FDA's actions.

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Respectfully submitted,

LYNN FITCH
Attorney General

/s/ *Justin L. Matheny*
SCOTT G. STEWART (MS Bar No. 106359)
Solicitor General
JUSTIN L. MATHENY (MS Bar No. 100754)
Deputy Solicitor General
MISSISSIPPI ATTORNEY GENERAL'S OFFICE
P.O. Box 220
Jackson, MS 39205-0220
Telephone: (601) 359-3680
Fax: (601) 359-2003
justin.matheny@ago.ms.gov
Counsel for Amici Curiae

On behalf of:

Steve Marshall
Attorney General
State of Alabama

Treg Taylor
Attorney General
State of Alaska

Tim Griffin
Attorney General
State of Arkansas

Ashley Moody
Attorney General
State of Florida

Christopher M. Carr
Attorney General
State of Georgia

Raúl R. Labrador
Attorney General
State of Idaho

Theodore E. Rokita
Attorney General
State of Indiana

Brenna Bird
Attorney General
State of Iowa

Kris W. Kobach
Attorney General
State of Kansas

Daniel Cameron
Attorney General
Commonwealth of Kentucky

Jeff Landry
Attorney General
State of Louisiana

Austin Knudsen
Attorney General
State of Montana

Michael T. Hilgers
Attorney General
State of Nebraska

Dave Yost
Attorney General
State of Ohio

Gentner F. Drummond
Attorney General
State of Oklahoma

Alan Wilson
Attorney General
State of South Carolina

Marty J. Jackley
Attorney General
State of South Dakota

Jonathan Skrmetti
Attorney General
State of Tennessee

Ken Paxton
Attorney General
State of Texas

Sean D. Reyes
Attorney General
State of Utah

Bridget Hill
Attorney General
State of Wyoming

CERTIFICATE OF SERVICE

I hereby certify that the foregoing brief has been served on all counsel of record by ECF.

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/s/ Justin L. Matheny
Justin L. Matheny
Counsel for Amici Curiae