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

UNOPPOSED MOTION OF THE STATES OF MISSISSIPPI, ALABAMA, ARKANSAS, FLORIDA, GEORGIA, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MONTANA, NEBRASKA, OHIO, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, AND WYOMING FOR LEAVE TO FILE AN OVERLENGTH BRIEF AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES' OPPOSITION TO AN EMERGENCY STAY PENDING APPEAL

LYNN FITCH
Attorney General
WHITNEY H. LIPSCOMB
Deputy Attorney General
SCOTT G. STEWART
Solicitor General
JUSTIN L. MATHENY
ANTHONY M. SHULTS
Deputy Solicitors General
MISSISSIPPI ATTORNEY
GENERAL'S OFFICE
P.O. Box 220
Jackson, MS 39205-0220
Telephone: (601) 359-3680
E-mail: justin.matheny@ago.ms.gov
Counsel for Amici Curiae

CERTIFICATE OF INTERESTED PERSONS

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

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

UNOPPOSED MOTION FOR LEAVE TO FILE AN OVERLENGTH BRIEF AS AMICI CURIAE

Amici curiae—the States of Mississippi, Alabama, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Montana, Nebraska, Ohio, South Carolina, South Dakota, Tennessee, Texas, Utah, and Wyoming—respectfully move this Court for leave under Federal Rule of Appellate Procedure 27 to file the attached proposed amicus brief in support of the plaintiffs-appellees and in opposition to an emergency stay pending appeal on these consolidated appeals and state:

1. This lawsuit challenges the actions through which the U.S. Food and Drug Administration has approved the chemical-abortion drug mifepristone, made it widely accessible, and discarded measures to manage the risks that it presents when used to induce abortions. Agreeing with a wide range of plaintiffs' arguments, as well as arguments advanced by the amici States here, the district court stayed the FDA's approval of mifepristone. Op. 32-67, D. Ct. Dkt. 137. Defendants-appellants the U.S. Food and Drug Administration and Danco Laboratories, L.L.C., a lead distributor of mifepristone, have moved this Court for an emergency stay of the district court's ruling.

2. The amici States submit the attached proposed brief to emphasize why the public interest and equities support the district court's order and support denying stay relief. Amici filed a similar brief

in the district court. *See* D. Ct. Dkt. 100. The district court relied on that brief in granting relief to plaintiffs. *See* Op. 29, 58 n.63, 63.

3. Amici have important interests at stake in this litigation, and their brief will assist this Court in resolving defendants' motions.

4. 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.* 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.*

5. Rather than respect the Constitution, the Supreme Court, and the democratic process, the Biden Administration and its FDA have 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.

6. The amici States' attached proposed brief demonstrates that the public interest and equities strongly support denying emergency relief, for at least three reasons. 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.

7. Under Federal Rules of Appellate Procedure 29(a)(2) and (5), on this Court's initial consideration of a case on the merits, States may file an amicus brief, without the parties' consent or leave of court, that contains up to one-half the maximum length allowed for a party's principal brief. Because those rules do not expressly govern these proceedings on defendants' stay motions, amici request leave to appear as amici and file the attached proposed brief containing 4922 words.

8. Under Fifth Circuit Rule 27.4, counsel for the amici States has contacted counsel for the parties and been advised that counsel for plaintiffs-appellees consents to the relief sought in this motion; counsel

for defendants-appellants consents to the filing of an amicus brief but takes no position on the length of that brief; and counsel for intervenor-appellant consents to the relief sought in this motion.

REQUEST FOR RELIEF

The amici States respectfully request an order granting them leave to file the attached proposed amicus brief in support of plaintiffs-appellees and in opposition to an emergency stay pending appeal.

Dated: April 12, 2023

Respectfully submitted,

LYNN FITCH
Attorney General

s/ Justin L. Matheny

WHITNEY H. LIPSCOMB
Deputy Attorney General
SCOTT G. STEWART
Solicitor General
JUSTIN L. MATHENY
ANTHONY M. SHULTS
Deputy Solicitors General
MISSISSIPPI ATTORNEY
GENERAL'S OFFICE
P.O. Box 220
Jackson, MS 39205-0220
Telephone: (601) 359-3680
E-mail: justin.matheny@ago.ms.gov
Counsel for Amici Curiae

Counsel for Additional Amici States

Steve Marshall
Attorney General
State of Alabama

Austin Knudsen
Attorney General
State of Montana

Tim Griffin
Attorney General
State of Arkansas

Michael T. Hilgers
Attorney General
State of Nebraska

Ashley Moody
Attorney General
State of Florida

Dave Yost
Attorney General
State of Ohio

Christopher M. Carr
Attorney General
State of Georgia

Alan Wilson
Attorney General
State of South Carolina

Theodore E. Rokita
Attorney General
State of Indiana

Marty J. Jackley
Attorney General
State of South Dakota

Brenna Bird
Attorney General
State of Iowa

Jonathan Skrmetti
Attorney General
State of Tennessee

Kris W. Kobach
Attorney General
State of Kansas

Ken Paxton
Attorney General
State of Texas

Daniel Cameron
Attorney General
Commonwealth of Kentucky

Sean D. Reyes
Attorney General
State of Utah

Jeff Landry
Attorney General
State of Louisiana

Bridget Hill
Attorney General
State of Wyoming

CERTIFICATE OF SERVICE

I, Justin L. Matheny, hereby certify that the foregoing motion 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: April 12, 2023

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

CERTIFICATE OF COMPLIANCE

This motion complies with the word limitations of Fed. R. App. P. 27(d)(2)(A) because, excluding the exempted parts of the document, it contains 713 words. This motion 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: April 12, 2023

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

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, ARKANSAS, FLORIDA, GEORGIA, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA, MONTANA, NEBRASKA, OHIO, SOUTH CAROLINA, SOUTH DAKOTA, TENNESSEE, TEXAS, UTAH, AND WYOMING AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES' OPPOSITION TO AN EMERGENCY STAY PENDING APPEAL

LYNN FITCH
Attorney General
WHITNEY H. LIPSCOMB
Deputy Attorney General
SCOTT G. STEWART
Solicitor General
JUSTIN L. MATHENY
ANTHONY M. SHULTS
Deputy Solicitors General
MISSISSIPPI ATTORNEY
GENERAL'S OFFICE
P.O. Box 220
Jackson, MS 39205-0220
Telephone: (601) 359-3680
E-mail: justin.matheny@ago.ms.gov
Counsel for Amici Curiae

CERTIFICATE OF INTERESTED PERSONS

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

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

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provision

Statutes

Executive Order

Regulations

Rulemaking

Other Authorities

INTRODUCTION, INTEREST OF AMICI CURIAE, AND SUMMARY OF ARGUMENT

The public interest and equities overwhelmingly support the district court's order staying the FDA's actions on chemical abortion. That order details the FDA's decades-long defiance of federal law (Op. 32-48, D. Ct. Dkt. 137) that has inflicted harm (Op. 45-47, 51-52, 57-58, 61-63) on a scale we will never fully know because the FDA "systematically" concealed it (Op. 59; *see* Op. 29 n.22, 58)—all because the "political objective[s]" of "abortion advocates" were more important to the FDA than the safety of women (Op. 55, 57 (emphasis omitted)). The FDA and a lead purveyor of chemical abortion now ask this Court to grant them extraordinary equitable relief halting the district court's ruling. The equities doom that request—indeed it is rare that the equities are so one-sided. This Court should leave in place the district court's ruling restoring lawfulness and safety after a quarter century of harm.

Amici curiae submit this brief to drive home why the public interest and equities support the district court's order. Amici are the States of Mississippi, Alabama, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Montana, Nebraska, Ohio, South Carolina, South Dakota, Tennessee, Texas, Utah, and Wyoming. 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.* 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 tighter restrictions on abortion following *Dobbs*. Other States have embraced more permissive regimes. 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 and its FDA have 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). Earlier this year, 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. 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 cast even 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. 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.

The district court held that the FDA's core actions on mifepristone are profoundly flawed and stayed them. The FDA and a lead seller of chemical abortion ask this Court to halt that ruling.

The public interest and equities strongly support denying emergency relief and leaving in place the district court's stay of 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. The district court recognized these points in invalidating the FDA's actions. This Court should do the same.

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." FDA Addendum (Add.) 181, CA5 Dkt. 27. 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." Add.186 (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. Add.185. These risks increase later in pregnancy and for ectopic pregnancy. Add.181-88. The approval thus required 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." 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 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. Add.838-39.

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. Add.776-803, 839. 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. Add.840.

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, D. Ct. Dkt. 8. 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. Add.842. 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 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 a wide range of plaintiffs' arguments, as well as arguments advanced by the amici States here, the district court stayed the FDA's approval of mifepristone. Op. 32-67. The FDA and Danco Laboratories, a lead distributor of mifepristone, now ask this Court for emergency relief from that ruling.

REASONS TO DENY A STAY PENDING APPEAL

The Public Interest And Equities Strongly Support The Relief The District Court Ordered 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. The district court properly ordered relief against the agency's actions. There is no sound basis for staying that order.

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

Plaintiffs have explained why the FDA's and Danco's merits arguments fail. *See* Stay Opp. 15-25. Amici emphasize, as they did in the

district court, 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 strongly support upholding the district court's ruling and rejecting the requests for relief from that ruling.

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. *See* Op. 39-48. 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 drugs that treat serious or life-threatening *conditions*"—regardless of whether they are understood colloquially as *illnesses*. FDA Mot. 20 (citing New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942, 58946-48 (Dec. 11, 1992)) (emphasis added). 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 "[a]ny error from relying on Subpart H" is "harmless" because Congress "incorporated mifepristone's restrictions" when it "created the new REMS framework" in 2007. FDA Mot. 19, 20. This is not the argument of an agency that is confident in the legality of its actions. *See* Op. 58 n.63 (embracing the States' argument on this point). 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. *See* Op. 32-38. 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)(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. *See* Op. 32-38.

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 and Danco cannot claim any public interest in enforcing them. Indeed, upholding the district court's ruling requiring the FDA to "abide by" federal law promotes the public interest, *Biden*, 10 F.4th at 559—and disturbing the district court's ruling 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, consistent with the FDA's longstanding approach of favoring the "political objective[s]" of "abortion advocates" over the health and safety of women, Op. 55, 57 (emphasis omitted), the agency was acting at the behest of the Biden Administration and its allies who demanded political action after *Dobbs v. Jackson Women's Health*

Organization, 142 S. Ct. 2228 (2022). 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 mail-order abortion regime seeks to override the balance properly struck by States. The district court's order properly prevents those actions from continuing to 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(1)(a); "are associated with an increased risk of complications relative to surgical abortion" that heightens "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 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 (same); 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, in accordance with the Federal Food, Drug, and Cosmetic

Act. 21 C.F.R. §§ 314.2, 314.500. The agency has no authority to approve dangerous drugs in violation of federal law—much less 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 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 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. This too supports denying emergency relief.

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, if the district court's ruling is stayed, continue to undercut those efforts and thus harm the public interest. *See* Op. 63.

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 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); *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 undermine States' laws, undercut their 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-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. *Cf.* Op. 57-58, 61-63. That harm defies the public interest.

Second, the FDA's actions 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 if the district court's ruling is stayed, the FDA's actions will continue to make that task hard. The FDA—and the broader Administration—is encouraging lawbreaking on a mass scale. Without the relief ordered by the district court, that 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 the relief the district court issued—and confirms that this Court should deny emergency 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 the relief the district court ordered. 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. The district court's decisive action was warranted. And this Court's is too. This Court should deny any stay relief.

CONCLUSION

The public interest and equities support rejecting emergency stay relief from the district court's ruling against the FDA's actions.

Dated: April 12, 2023

Respectfully submitted,

LYNN FITCH
Attorney General

s/ Justin L. Matheny

WHITNEY H. LIPSCOMB
Deputy Attorney General
SCOTT G. STEWART
Solicitor General
JUSTIN L. MATHENY
ANTHONY M. SHULTS
Deputy Solicitors General
MISSISSIPPI ATTORNEY
GENERAL'S OFFICE
P.O. Box 220
Jackson, MS 39205-0220
Telephone: (601) 359-3680
E-mail: justin.matheny@ago.ms.gov
Counsel for Amici Curiae

Counsel for Additional Amici States

Steve Marshall
Attorney General
State of Alabama

Austin Knudsen
Attorney General
State of Montana

Tim Griffin
Attorney General
State of Arkansas

Michael T. Hilgers
Attorney General
State of Nebraska

Ashley Moody
Attorney General
State of Florida

Dave Yost
Attorney General
State of Ohio

Christopher M. Carr
Attorney General
State of Georgia

Alan Wilson
Attorney General
State of South Carolina

Theodore E. Rokita
Attorney General
State of Indiana

Marty J. Jackley
Attorney General
State of South Dakota

Brenna Bird
Attorney General
State of Iowa

Jonathan Skrmetti
Attorney General
State of Tennessee

Kris W. Kobach
Attorney General
State of Kansas

Ken Paxton
Attorney General
State of Texas

Daniel Cameron
Attorney General
Commonwealth of Kentucky

Sean D. Reyes
Attorney General
State of Utah

Jeff Landry
Attorney General
State of Louisiana

Bridget Hill
Attorney General
State of Wyoming

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: April 12, 2023

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

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 4922 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: April 12, 2023

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