No. 23-395

IN THE

Supreme Court of the United States

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Petitioners,

v.

FOOD AND DRUG ADMINISTRATION, ET AL.,
Respondents.

On Conditional Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR MISSISSIPPI AND 18 OTHER STATES AS AMICI CURIAE IN SUPPORT OF CROSS-PETITIONERS AND CONDITIONAL CROSS-PETITION

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INTRODUCTION AND INTEREST OF AMICI CURIAE*

This case challenges the U.S. Food and Drug Administration's efforts to impose a nationwide elective-abortion policy that could not be achieved through the democratic process.

For two decades, the FDA has acted to establish a 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. That approval was legally flawed, but it at least included measures to account for mifepristone's risks to life and health. The approval extended only through 49 days of pregnancy; allowed mifepristone to be dispensed only in clinics, medical offices, or hospitals (all under a certified prescriber's supervision); mandated three in-person office visits; and required providers to report all adverse events from the drug. Yet over time the FDA cast those measures aside. In 2016, it rolled back many safety requirements—allowing mifepristone to be prescribed through 70 days of pregnancy, by non-doctors, and with only one in-person visit—and stopped requiring prescribers to report non-fatal adverse events from the drug. And in 2021, the agency abandoned the in-person-dispensing requirement. The FDA now condones a broad mail-order abortion-drug regime. None of this would have been possible if the FDA had not unlawfully approved mifepristone in the first place.

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* Counsel of record for all parties received notice of undersigned counsel's intent to file this brief at least ten days before the brief's due date. S. Ct. R. 37.2(a).

The district court in this case held that the FDA's core actions on mifepristone are flawed and stayed them. The Fifth Circuit upheld that ruling in part: it held that the FDA's 2016 and 2021 actions were likely unlawful but that challenges to the FDA's 2000 approval were likely untimely. The FDA and Danco Laboratories, a mifepristone distributor, have sought this Court's review on the FDA's 2016 and 2021 actions. Nos. 23-235, 23-236. Cross-petitioners have conditionally sought this Court's review on the FDA's 2000 approval.

Amici curiae are the States of Mississippi, Alabama, Arkansas, Florida, Georgia, Indiana, Iowa, Kentucky, Louisiana, Montana, Nebraska, North Dakota, Oklahoma, South Carolina, South Dakota, 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, result from hard-fought democratic processes, and embody the considered judgments of "the people and their elected representatives." *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228, 2284 (2022). The FDA's actions on mifepristone undermine the considered judgments of the elected representatives of States like amici. Those actions all trace back to the FDA's approval of mifepristone in 2000.

SUMMARY OF ARGUMENT

If this Court grants the FDA's or Danco's petition for certiorari, it should also grant certiorari to review the 2000 approval of mifepristone. That approval contravenes federal law. It has poisoned the FDA's later actions on the drug. And it has resulted in a nationwide mail-order abortion-drug regime that violates

the FDA's regulations and federal criminal law, defies the public-interest determinations that the amici States have properly made, and undermines amici's enforcement of their laws. The FDA's original approval of mifepristone is thus central to this case and to the sound consideration of the equities it raises. If the Court takes this case then it should take the full case by granting the conditional cross-petition.

REASONS FOR GRANTING THE CONDITIONAL CROSS-PETITION

A. The FDA's Flawed Approval Of Mifepristone Has Created An Unlawful Nationwide Abortion-Drug Regime.

The conditional cross-petition explains how the FDA's 2000 approval of mifepristone violated the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act. Cross-Pet. 28-31; *see* FDA Petition Appendix (App.) 172a-184a (No. 23-235) (district-court opinion). This brief focus on two specific flaws with the approval: it violates the agency's regulations and it has given rise to a mail-order abortion regime that violates federal criminal law. If this Court takes this case, it should go back to the beginning and examine the approval underlying this unlawful regime and all the actions challenged in this case.

1. The FDA's 2000 approval of mifepristone defied the agency's own regulations. The agency relied on Subpart H of its regulations when it approved mifepristone. 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 the preamble to its rulemaking "explained that Subpart H was available for drugs that treat serious or life-threatening *conditions*"—regardless of whether they are *illnesses*. FDA BIO 22 (emphasis added). But a clear regulation—not the agency's aspirational gloss on it—controls. *E.g.*, *Fort Stewart Schools v. FLRA*, 495 U.S. 641, 654 (1990) ("[A]n agency must abide by its own regulations."). 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.

The FDA has claimed that Congress "incorporated mifepristone's distribution restrictions" (and thus endorsed the FDA's approach to mifepristone), FDA BIO 22, when it enacted the Food and Drug Administration Amendments Act in 2007. Pub. L. No. 110-85, 121 Stat. 823 (2007). That argument fails. That 2007 law directed the FDA 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 2007 law temporarily "deemed [a drug] to have in effect an approved risk evaluation and mitigation strategy" pending formal adoption of a REMS 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. Congress thus "deemed" preexisting safety requirements to be sufficient REMS programs until a new strategy was approved. But Congress's actions 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. Congress did not blot out the FDA's defiance of its own regulation.

2. The FDA's unlawful approval of mifepristone provided the foundation for a mail-order abortion regime that violates 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 the 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. To provide cover for the Administration's actions, the Justice Department issued a memo reading into the statutes the very 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* App.150a-159a (district-court opinion).

In sum, the FDA's actions on mifepristone defy the agency's regulatory authority and longstanding federal criminal law. All those actions trace back to the FDA's initial flawed approval. If this Court reviews any of those actions, it should review (and reject) all of them. Those actions were flawed from the start.

B. Allowing The FDA's Unlawful Regime To Stand Would Undermine The Public-Interest Determinations Properly Made By States.

Elected representatives—not unelected officials in federal agencies—are responsible for balancing the "competing interests" on abortion. *Dobbs*, 142 S. Ct. at 2268. But in approving mifepristone, expanding its use, and now condoning a broad mail-order abortion regime, the FDA has undermined the balance properly struck by States. Granting the conditional cross-petition and rejecting the FDA's actions would

halt the FDA's overreach from continuing to harm the public interest reflected in state laws.

1. States have the "primar[y]" authority 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.* (exception for 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 elective abortions, elective chemical abortions are generally unlawful in several 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 imposed 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 and the agency's own regulations. 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. States have that authority. And they have balanced these interests in laws that reflect the views of their citizens.

State laws on chemical abortion 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 misuse of the agency's regulatory authority in approving mifepristone, the absence of authority for the FDA to establish a mail-order abortion regime, and States' retained authority to act (*see* U.S. Const. amend. X), the public interest weighs against the FDA's efforts to override state laws.

2. The federal government 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. *E.g.*, Memorandum on Further Efforts to Protect Access to Reproductive Healthcare Services, The White House (Jan. 22, 2023), http://bit.ly/3kEZrPl (Biden Memorandum) (spotlighting the Administration's efforts to "evaluat[e] and monitor[ ]" state laws "that threaten to infringe" claimed "Federal legal protections" for abortion). 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). 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. States are thus entitled to enforce their laws against those involved in sending or receiving such drugs by mail.

Yet the FDA's actions—going back to its original approval of mifepristone—undermine States' laws, undercut States' efforts to enforce them, and 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. Indeed, the Administration's recent actions encourage evasion of those laws. *See* Blue-State Doctors Launch Abortion Pill Pipeline Into States With Bans, Wash. Post (July 19, 2023), https://wapo.st/3M29JUq ("The result is a new pipeline of legally prescribed abortion pills flowing into states with abortion bans."); 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."). Such evasion—particularly when coupled with the FDA's abandonment of safeguards on mifepristone's use—will harm amici's citizens. That harm defies the public interest.

Second, the FDA's actions force States to divert scarce resources to address violations of their laws. As the FDA continues a campaign that will harm amici's citizens, amici will 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. *E.g.*, Blue-State Doctors (describing how one "small group" of out-of-state providers "mailed 3,500 doses of abortion pills" to recipients in States with chemical-abortion restrictions "[i]n less than a month," a pace that will "facilitate at least 42,000 abortions" per year). 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*). The federal Administration's approach will force States to divert resources to investigate and address the harms that this lawbreaking will inflict on women, children, and the public interest. *See supra* pp. 7-8 (summarizing harms that States' laws address). That is tragic on its own. It is all the more tragic when placed alongside the reality that those resources will no longer be available for maternal, prenatal, and neonatal care—and the many other uses that amici wish to put them toward in order to promote the wellbeing of women and children.

All of this confirms that the district court was right to order relief against the FDA's actions on mifepristone. And it confirms that if this Court takes this case, it should address all the FDA's challenged actions, because the harms those actions inflict go back to the beginning, when the FDA approved mifepristone.

CONCLUSION

If the Court grants the FDA's or Danco's petition, it should grant the conditional cross-petition.

Respectfully submitted.

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