No. 26-30203

In the United States Court of Appeals for the Fifth Circuit

STATE OF LOUISIANA, BY & THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL; ROSALIE MARKEZICH,
Plaintiffs-Appellants/Cross-Appellees,

v.

FOOD & DRUG ADMINISTRATION; MARTY MAKARY, *Commissioner, U.S. Food and Drug Administration*; RICHARD PADZUR, *in his official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROBERT F. KENNEDY, JR., *Secretary, U.S. Department of Health and Human Services*,
Defendants-Appellees,

GENBIOPRO, INCORPORATED,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, L.L.C.,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana, Lafayette Division
No. 6:25-CV-1491

BRIEF OF AMICI CURIAE SENATOR BILL CASSIDY, M.D., REPRESENTATIVE CHRISTOPHER H. SMITH, AND 89 MEMBERS OF CONGRESS, IN SUPPORT OF APPELLANTS/CROSS-APPELLEES

Heather Gebelin Hacker
HACKER STEPHENS LLP
108 Wild Basin Road South
Suite 250
Austin, Texas 78746
(512) 399-3022 (phone)
heather@hackerstephens.com

Counsel for Amici Curiae

Certificate of Interested Persons

No. 26-30203

STATE OF LOUISIANA, ET AL.,
Plaintiffs-Appellants/Cross-Appellees,

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FOOD AND DRUG ADMININISTRATION, ET AL.,
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Intervenor-Appellee/Cross-Appellant.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

Plaintiffs-Appellants/Cross-Appellees	**Former or present counsel**
• State of Louisiana, by & through its Attorney General, Liz Murrill • Rosalie Markezich	Louisiana Department of Justice • Jorge Benjamin Aguinaga • Caitlin Ann Huettemann Alliance Defending Freedom • Erik C. Baptist • Julie M. Blake • Erin M. Hawley • Gabriella McIntyre Johnson Siebeneicher & Ingram • Michael T. Johnson
Defendants-Appellees	**Former or present counsel**
• Food and Drug Administration • U.S. Department of Health and Human Services • Marty Makary, Commissioner of Food and Drugs • Richard Padzur, in his official capacity as Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration • Robert F. Kennedy, Jr., Secretary, U.S. Department of Health and Human Services	U.S. Department of Justice • Daniel Winik • Andrew Marshall Bernie • Noah T. Katzen
Intervenor-Appellees/Cross-Appellants	**Former or present counsel**

• GenBioPro, Incorporated • Danco Laboratories, L.L.C.	Arnold & Porter Kaye Scholer, LLP • John Patrick Elwood • John N. Adcock • Robert J. Katerberg • Daphne O'Connor Democracy Forward Foundation • Carrie Yvette Flaxman • Lisa Newman Hogan Lovells LLP • Jessica L. Ellsworth • Katherine McKay • William Brock Most • Dana A. Raphael • Jo-Ann Tamila Sagar • Danielle Desaulniers Stempel
Amici Curiae	**Former or present counsel**
• Senator Bill Cassidy, M.D. • Congressman Christopher H. Smith • Additional 89 Members of Congress listed in Appendix	Hacker Stephens LLP • Heather Gebelin Hacker

/s/ Heather Gebelin Hacker
HEATHER GEBELIN HACKER
Counsel for Amici Curiae

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Introduction and Interest of Amici Curiae

Amici curiae[1] are 90 Members of the United States Congress. A complete list of Amici is found in the Appendix to this brief. Congress delegates power to the U.S. Food and Drug Administration (FDA) to approve drugs and regulate their safety and efficacy within the parameters set by federal law. But Congress specifically prohibited the mailing of "[e]very article or thing designed, adapted, or intended for producing abortion." 18 U.S.C. § 1461.

By deregulating chemical abortion drugs and permitting them to be sent through the mail, the Biden FDA violated that longstanding federal law. Unelected, unaccountable bureaucrats in Biden's FDA therefore overrode the will of the American people as expressed through their elected representatives in Congress and in state legislatures and subverted Congress's critical public policy interests in upholding patient welfare. The lawless actions of the Biden FDA have also caused real harm and continue to endanger women and girls undergoing chemical abortions, warranting preliminary relief. As pro-life elected representatives, Amici are committed to protecting women and girls from the harms of the abortion industry. Amici are also committed to upholding the rule of law and the proper separation of powers outlined in our Constitution.

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[1] Pursuant to Rule 29(a)(2), no motion for leave to file is necessary as all parties have consented to the filing of this brief. Pursuant to Rule 29(a)(4)(E), undersigned counsel affirms that no counsel for any party authored this brief in whole or in part and that no person or entity other than amici or their counsel made a monetary contribution intended to fund the preparation and submission of this brief.

Summary of the Argument

Congress has conferred regulatory power on federal agencies like the FDA, but that power is also circumscribed by Congress. The Administrative Procedure Act (APA) prohibits agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory . . . authority, or limitations, or short of statutory right," and requires federal courts to "hold unlawful and set aside" such actions. 5 U.S.C. § 706(2)(A), (C). In passing the Comstock Act, Congress decided that chemical abortion drugs are "nonmailable matter" by the United States Postal Service (USPS) and private carriers, protecting women and girls from the heightened risks of mail-order chemical abortion drugs. 18 U.S.C. §§ 1461–62. To further its expressly stated goal of subverting state abortion prohibitions authorized by *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), and in direct violation of the Comstock Act, the Biden administration in 2023 lifted a key safety requirement in the FDA's Risk Evaluation and Mitigation Strategy (REMS)—the requirement of in-person dispensing of mifepristone, one of two drugs that are used to chemically induce abortion. The change was made precisely so that abortionists in pro-abortion states could prescribe and mail abortion drugs to women or girls in pro-life states with tighter regulations on these drugs.[2] Former President Biden admitted as much when he issued an Executive Order directly challenging

[2] In Louisiana, for example, even when a state licensed physician may lawfully administer a chemical abortion drug to a pregnant woman under one of the exceptions to the State's abortion prohibition, the drug must be administered to the pregnant woman *in person*. *See* La. R.S. §§ 14:87.1, 14:87.9.

"the continued advancement of restrictive abortion laws in States across the country."[3] This action contravenes federal laws passed by the elected representatives of the American people. It also contravenes state laws prohibiting abortion, such as Louisiana's, even though "the authority to regulate abortion" belongs to "the people and their elected representatives," not unelected bureaucrats. *Dobbs*, 597 U.S. at 292.

Further, the Biden FDA's lawless action also carries serious risks that were not properly analyzed. The Biden FDA did not have a sufficient evidentiary basis to conclude that eliminating the in-person dispensing requirement was safe. And because no in-person visit is required now, women cannot be meaningfully screened for serious contraindications for the use of this drug, such as ectopic pregnancy.[4] It also increases the likelihood that some women are being coerced into taking these drugs against their will, as the heartbreaking story of Plaintiff Rosalie Markezich illustrates. As delegated by Congress, the FDA's job is to ensure drug safety, not to encourage the risky use of drugs just to further former President Biden's pro-abortion agenda. Exceeding its mandate is illegal and also harmful, both to the separation of powers

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[3] Executive Order No. 14,079 of Aug. 3, 2022, *Securing Access to Reproductive and Other Healthcare Services*, 87 Fed. Reg. 49505 (Aug. 11, 2022), *available at* https://www.federalregister.gov/documents/2022/08/11/2022-17420/securing-access-to-reproductive-and-other-healthcare-services.

[4] FDA's label for mifepristone warns that "if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected," a provider should "[a]ssess the pregnancy by ultrasonographic scan." FDA, *Mifeprex Label* at 2, https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf. Providers cannot assess a pregnancy by ultrasonographic scan without an in-person visit.

and to women taking mifepristone. The Court should reverse the district court's order and grant preliminary relief.

ARGUMENT

I. The Biden FDA's 2023 Mifepristone REMS Is Contrary to Law Because It Fails to Meet the Statutory Requirement to Demonstrate Safety and the Fifth Circuit's Ruling is Justified.

A. The Biden FDA relied on insufficient data to establish the safety of foregoing the in-person requirement.

The Biden FDA's justification for eliminating the in-person dispensing requirement is arbitrary and capricious and not in accordance with law, and thus violates the APA, because it failed to support its conclusion with sufficient studies or evidence to meet the statutory requirement to demonstrate the safety and effectiveness of the drug under the new conditions. The FDA's conclusion heavily relies on adverse events collected from the drug manufacturers and the FDA's Adverse Event Reporting System (FAERS) during periods when the in-person dispensing requirement was not being enforced to conclude that eliminating the in-person requirement would not affect safety.[5] But this is not evidence of safety. The Biden FDA admitted that "[r]ates of occurrence [for an adverse event] cannot be established with [FAERS] reports." D. Ct. Doc. 1-52 at 5. Thus, as the Fifth Circuit has explained, "FDA's

[5] *See* Ctr. for Drug Eval. & Research, *Mifepristone REMS Modification Rationale Review* at 23, https://www.accessdata.fda.gov/drugsatfda_docs/summary_review/2023/020687Orig1s025SumR.pdf#page=75 (comparison between FAERS data before 2020 and after, when in-person requirement was not being enforced, "suggests that mifepristone may be safely used without an in-person dispensing requirement.").

decision to rely so heavily on data from FAERS 'runs counter to' the critical limitations associated with that data." *All. for Hippocratic Med. v. FDA*, 78 F.4th 210, 250 (5th Cir. 2023), *rev'd and remanded sub nom. FDA v. All. for Hippocratic Med.*, 602 U.S. 367 (2024) (citation omitted). And the lack of data is the logical consequence of the FDA's action in 2016 to remove the requirement for providers who prescribe abortion drugs to report non-fatal adverse events. Because of this, FAERS data on the safety of chemical abortion drugs significantly understates the risk. As the Fifth Circuit has already pointed out, "[a]fter eliminating that adverse-event reporting requirement, FDA turned around in 2021 and declared the absence of non-fatal adverse-event reports means mifepristone is 'safe.'" *All. for Hippocratic Med. V. FDA*, No. 23-10362, 2023 WL 2913725, at *17 (5th Cir. Apr. 12, 2023) (per curiam). "It's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the absence of data to support its decision." *Id.* Thus, the Biden FDA's "actions are well 'outside the zone of reasonableness,'" *id.* (quoting *FCC v. Prometheus Radio Project*, 592 U.S. 414, 428 (2021)), and violate the APA.

On top of its reliance on the insufficient FAERS data, the Biden FDA also relied on other scientific literature that did not support the removal of the in-person dispensing requirement, again in violation of the APA. The Biden FDA admitted that "the studies [it] reviewed are not adequate on their own to establish the safety of the model of dispensing mifepristone by mail." D. Ct. Doc. 1-10 at 36. The Biden FDA also acknowledged that "the studies neither confirmed nor rejected the idea that mifepristone would be safe if the in-person dispensing requirement were removed." *All. for Hippocratic Med.*, 78 F.4th at 250. This admission makes it clear that the Biden

FDA got its legal responsibilities backward. The FDA has the burden of establishing safety *before* weakening safety standards. In fact, as Plaintiffs argued in their Motion for Preliminary Relief, "the studies actually showed *increased* risk of harm from removing the in-person dispensing requirement." D. Ct. Doc. 20-26 at 18 n. 2. When looking at the full administrative record, it becomes clear that rather than letting science and evidence drive its decision making, the Biden FDA reached a predetermined and politically motivated conclusion to expand access to abortion drugs despite lacking enough evidence to show the change would be safe. This is a clear violation of FDA's legal responsibilities and a fact acknowledged by current Secretary of Health and Human Services Robert F. Kennedy, Jr., and FDA Commissioner Martin A. Makary, who both stated in September 2025 that there was a "lack of adequate consideration" of the safety risks "underlying the prior REMS approvals," including the Biden FDA's decision to "remov[e] the in-person dispensing requirement." D. Ct. Doc. 1-110 at 2.

B. The Fifth Circuit's ruling is warranted because the 2023 REMS endangers women's health and safety and increases the risk of coercion.

1. The 2023 REMS endangers women's health and safety.

A federal agency contravening federal law is bad enough, but by expressly authorizing mail-order chemical abortion drugs, the FDA is endangering women's health and safety by eliminating a medically necessary in-person examination to screen for contraindications. The FDA admits that a number of medical conditions make a woman ineligible to take chemical abortion drugs, including potentially

having a dangerous ectopic pregnancy (a pregnancy outside of the uterus) or having an intrauterine device (IUD) in place.[6] A physician can only diagnose an ectopic pregnancy by blood tests and an ultrasound, which means a physician cannot determine via telemedicine whether a pregnancy is ectopic.[7]

Chemical abortion drugs also should not be used after the first seventy days of pregnancy due to heightened risk to the woman's health, as the FDA acknowledges.[8] Ultrasound is the most accurate method to establish or confirm gestational age in the first trimester.[9] Dating a pregnancy by using a woman's last menstrual period (LMP) is far less accurate. In one study, forty percent of women had more than a five-day discrepancy between their LMP dating and the ultrasound dating.[10] Thus, relying solely on LMP, as occurs in mail-order abortion, will not produce an accurate measurement of gestational age, which is required to show that a woman is a candidate for

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[6] FDA, *Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (current through Feb. 11, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[7] Mayo Clinic, *Ectopic Pregnancy*, https://www.mayoclinic.org/diseases-conditions/ectopic-pregnancy/diagnosis-treatment/drc-20372093 (last accessed Feb. 2, 2026).

[8] *See Questions and Answers*, n. 6 *supra*.

[9] Comm. on Obstetric Practice, Am. Coll. of Obstetricians & Gynecologists et al., Methods for Estimating the Due Date, Comm. Op. No. 700, at 1 (reaffirmed 2025), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.

[10] *Id.*

a chemical abortion. Further, a delay in the mail or cold feet upon receipt of the drugs may significantly worsen a woman's risk profile even if the prescription was sent within the seventy-day window.

An additional known problem is that without an in-person evaluation, a woman cannot be tested for Rh negative blood type. During pregnancy, if a woman has Rh negative blood while her fetus is Rh positive, the woman's body may produce antibodies after exposure to fetal red blood cells.[11] Without an Rh immune globulin injection, the Rh antibodies can endanger future pregnancies by creating life-threatening anemia in fetal red blood cells.[12] But if a physician has not tested for Rh factor, a physician cannot provide this critical treatment, and a woman will be unaware she has a condition that could endanger her future children. The American College of Obstetricians and Gynecologists agrees: "Rh testing is recommended in patients with unknown Rh status before medication abortion, and Rh D immunoglobulin should be administered if indicated."[13]

2. The 2023 REMS increases the risk of coercion.

The 2023 REMS also opens the door for those who seek to coerce a woman into having an abortion because it removes the ability of a doctor to ensure a woman

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[11] Mayo Clinic, *Rh factor blood test*, https://www.mayoclinic.org/tests-procedures/rh-factor/about/pac-20394960 (last accessed Feb. 2, 2026).

[12] *Id.*

[13] ACOG, Comm. On Practice Bulletins – Gynecology and the Soc'y of Family Planning, *Medication Abortion Up to 70 Days of Gestation*, Comm. Op. 225, at 40 (reaffirmed 2023), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

receiving chemical abortion drugs actually wishes to take them. A woman seeking an abortion may be facing coercion or intimate partner violence (IPV), and without an in-person evaluation, a provider's ability to discern that is limited. There are "[h]igh rates of physical, sexual, and emotional IPV . . . among women seeking a[n abortion]."[14] For women seeking abortion, the prevalence of IPV is nearly three times greater than women continuing a pregnancy.[15] Post-abortive IPV victims also have a "significant association" with "psychosocial problems including depression . . . , suicidal ideation . . . , stress . . . , and disturbing thoughts."[16] Medical professionals must "[s]creen for IPV in a private and safe setting with the woman alone and not with her partner, friends, family, or caregiver."[17] But mail-order abortions administered online cannot ensure that a coercive partner, friend, family member, or caregiver is not in the room with a woman seeking a chemical abortion. In other words, domestic violence screening by telehealth "may not allow individuals the privacy or

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[14] Megan Hall et al., *Associations Between Intimate Partner Violence and Termination of Pregnancy: A Systematic Review and Meta-Analysis*, PLOS Med., Jan. 7, 2014, at 1, 15, https://pmc.ncbi.nlm.nih.gov/articles/PMC3883805/pdf/pmed.1001581.pdf.

[15] Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Reproductive and Sexual Coercion*, Comm. Op. No. 554, at 2 (Feb. 2013), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/02/reproductive-and-sexual-coercion.

[16] Hall, n. 14 *supra*, at 11.

[17] Comm. on Health Care for Underserved Women, Am. Coll. of Obstetricians & Gynecologists, *Intimate Partner Violence*, Comm. Op. No. 518, at 3 (reaffirmed 2022), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2012/02/intimate-partner-violence.

safety needed to disclose abuse."[18] Thus, telehealth ineffectively screens women seeking chemical abortions for domestic violence or coercion, subjecting those women to increased harm. Even worse, some mail-order abortionists are choosing not to even confirm whether the recipient is a pregnant adult woman who desires an abortion.[19]

This is not abstract. Plaintiff Rosalie Markezich experienced this harm personally. D. Ct. Doc. 1-92. A doctor did not examine Ms. Markezich nor detect the coercion she experienced. Her boyfriend ordered mifepristone from a California doctor and coerced Ms. Markezich to take it, resulting in her great distress and the loss of her baby. *Id.* at ¶¶ 7-9, 11-13, 16, 18-19. The only contact she had with a doctor throughout the process was sending a payment to a doctor in California. *Id.* at ¶ 8. Had she visited a doctor in person, her "boyfriend would never have been able to obtain the drugs he made [her] take," and she "would have told the doctor that [she]

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[18] *Id.*

[19] For example, when investigating an online abortion provider for unlawful sales or advertising practices, the North Dakota Attorney General found two websites selling chemical abortion drugs did not require "any information outside of a name, email, phone number, billing and shipping address to complete the purchase" and that "[a] purchaser is not asked to answer any health questions, provide a prescription, verify identity, or disclose their age . . . [t]here was no age or identity verification during the entire purchasing process for either website." Cease and Desist Order, Notice of Civil Penalty and Notice of Right to Request a Hearing, *State of North Dakota v. Prairie Abortion Fund*, CPAT 250164.001 (Jan. 16, 2026), *available at* https://attorneygeneral.nd.gov/wp-content/uploads/2026/01/Prairie-Abortion-Fund-CD-color.pdf.

wanted to keep [her] baby." *Id.* at ¶ 19. The Biden FDA's lawless action caused this harm to Ms. Markezich, and other women like her.

Tragically, Ms. Markezich's case is not the only case of its kind to happen since the 2023 REMS was enacted. In January 2025, a Baton Rouge-area grand jury indicted a New York doctor and a Louisiana mother on felony charges after the mother allegedly ordered chemical abortion drugs online from the doctor and forced her pregnant teenage daughter to take them.[20] Her daughter then experienced a severe medical emergency, prompting a 911 call and hospitalization, and her baby did not survive. The mother allegedly obtained the drugs by simply filling out an online questionnaire and there was no consultation between the doctor and the teenage daughter.[21] In November 2025, the State Medical Board of Ohio suspended the license of a medical resident after he admitted to purchasing chemical abortion drugs online using his estranged wife's name, birth date, and driver's license number without her knowledge or consent and had the drugs shipped to his address.[22] He admitted to crushing the pills up to adjust the dosage and make them dissolve faster, and then

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[20] *See Louisiana woman pleads not guilty to felony after allegedly giving abortion pills from N.Y. doctor to her teen,* CBS News (Mar. 12, 2025), https://www.cbsnews.com/news/louisiana-woman-pleads-not-guilty-abortion-case-pills-doctor-teen/.

[21] *Id.*

[22] *See* Melissa Andrews, *Ohio suspends UTMC doctor's license amid allegations he secretly gave abortion drugs to patient*, WTOL11 (Nov. 10, 2025), https://www.wtol.com/article/news/investigates/11-investigates/utmc-doctor-license-suspended-abortion-drug-allegations/512-2ec091b0-552a-4f67-bc25-3c44a063798e.

the victim reportedly awoke to find him holding her down and forcing the crushed abortion pills inside her mouth.[23] When she managed to escape, she drove to the emergency room where she was diagnosed with vaginal bleeding, and her baby did not survive.[24]

These stories, and many others—both publicly reported and not—demonstrate the real-world impact of the Biden administration's unlawful decision to eliminate the in-person dispensing requirement in the 2023 REMS. The Fifth Circuit was correct to grant a stay because it is needed to prevent this deep injustice from continuing to plague other women in Louisiana and across the country.

II. The Biden FDA's 2023 Mifepristone REMS Violates Federal Law.

A. The 2023 REMS directly conflicts with the Comstock Act, which prohibits mailing abortion drugs.

As numerous Members of Congress already told the Biden FDA in response to the 2023 REMS,[25] eliminating the in-person dispensing requirement for mifepristone and authorizing the dispensing of mifepristone "through the mail," D. Ct. Doc. 1-50 at 81, "is not in accordance with" federal criminal law, 5 U.S.C. § 706(2)(A).

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[23] *Id.*

[24] Patrick Reilly, *Surgeon allegedly shoved crushed abortion pills into pregnant girlfriend's mouth while she slept*, N.Y. Post (Dec. 9, 2025), https://nypost.com/2025/12/09/us-news/surgeon-allegedly-shoved-crushed-abortion-pills-into-pregnant-girlfriends-mouth-while-she-slept/.

[25] Letter from Sen. Cindy Hyde-Smith, et al., to Robert Califf, FDA Commissioner (Jan. 26, 2023), https://www.hydesmith.senate.gov/sites/default/files/2023-01/012623%20Bicameral%20Letter%20to%20FDA%20re%20Abortion%20Drugs.pdf.

The Comstock Act imposes felony criminal liability on the mailing of "[e]very article or thing designed, adapted, or intended for producing abortion" and "[e]very article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion." 18 U.S.C. § 1461. It also applies similar criminal penalties for importing and using a "common carrier" (like FedEx) or "interactive computer service" "for carriage in interstate or foreign commerce . . . any drug, medicine, article, or thing designed, adapted, or intended for producing abortion." 18 U.S.C. § 1462. Violations are serious—anyone who violates the Comstock Act "shall be fined . . . or imprisoned not more than five years, or both, for the first such offense," and "fined . . . or imprisoned not more than ten years, or both, for each such offense thereafter." *Id.* Violations of the Comstock Act are also predicate offenses under the Racketeer Influenced and Corrupt Organizations Act (RICO), which provides for extended criminal penalties and a civil cause of action. 18 U.S.C. § 1961(1).

B. The Biden FDA's attempt to authorize conduct prohibited under federal law exceeds its statutory authority and violates the separation of powers.

Federal agency action that rewrites, contradicts, or ignores a federal statute violates the separation of powers. "When the Government is called upon to perform a function that requires an exercise of legislative, executive, or judicial power, only the vested recipient of that power can perform it." *DOT v. Ass'n of Am. Railroads*, 575 U.S. 43, 68 (2015) (Thomas, J., concurring in judgment). Because the Constitution gives the executive branch only "[t]he executive Power," executive agencies may

only constitutionally exercise that power. U.S. Const. art. II, § 1, cl. 1. Legislative power is reserved for Congress. U.S. Const. art. I, § 1. An agency action that contradicts or encourages violation of a federal statute exceeds the agency's constitutional authority and usurps Congress's legislative power. Violating the separation of powers is nothing less than antithetical to our system of government, as "the separation of powers is the defining feature and virtue of our Constitution." *Cochran v. SEC*, 20 F.4th 194, 214 (5th Cir. 2021) (Oldham, J., concurring, joined by Smith, Willett, Duncan, Englehardt, and Wilson, JJ.).

The FDA cannot purport to authorize conduct criminalized under federal law—that would exceed its constitutional authority. A federal agency "lacks the authority to 'rewrite clear statutory terms to suit its own sense of how the statute should operate,' particularly in a way that undercuts a statute's purpose." *Texas v. Cardona*, 743 F. Supp. 3d 824, 870 (N.D. Tex. 2024) (quoting *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014)). Nothing in the law "remotely authorizes an agency to modify unambiguous requirements imposed by a federal statute." *Util. Air Regul. Grp.*, 573 U.S. at 327. Nor does the executive power "include a power to revise clear statutory terms," even if those terms "turn out not to work in practice." *Id.* "When a regulation attempts to override statutory text, the regulation loses every time—regulations can't punch holes in the rules Congress has laid down." *Djie v. Garland*, 39 F.4th 280, 285 (5th Cir. 2022).

Thus, while it is true that Congress has delegated authority for drug approval and the imposition of REMS requirements to the FDA within the guardrails set up by statute, *see* 21 U.S.C. §§ 355, 355-1, that authority does not extend to unilaterally

deciding all conditions related to the use or distribution of any drug, nor does anything in those statutes grant FDA a permission slip to override or ignore all other federal laws. The USPS, another federal agency, acknowledged in 2021 in the context of a final rule pertaining to e-cigarettes, that "FDA authorization of a [product] for introduction or delivery into interstate commerce does not absolve an actor from other Federal requirements that govern the manufacture and distribution of [such products]: Rather, all overlapping requirements must be complied with in order to offer the product in interstate commerce." *Treatment of E-Cigarettes in the Mail*, 86 Fed. Reg. 58398, 58403 n. 5 (Oct. 21, 2021) (to be codified at 39 C.F.R. pts. 111, 211).

C. The Biden administration's attempts to evade the plain text of the Comstock Act do not stand up to legal scrutiny.

In defending the 2023 REMS against legal challenges contending the action was inconsistent with the Comstock Act and advising federal agencies to flout the law, the Biden Department of Justice argued that the Comstock Act essentially does not really mean what it says, or "that judicial gloss and lax enforcement over the past century act to graft relevant exceptions onto it." *All. for Hippocratic Med.*, 2023 WL 2913725, at *21. But the language is plain, and as Judge Ho has explained, the Biden administration's contentions to the contrary are "atextual." *All. for Hippocratic Med.* 78 F.4th at 268–70 (5th Cir. 2023) (Ho, J., concurring in part). No consensus judicial construction contradicting the relevant plain text exists, but even if it did, judicial "gloss" cannot change the unambiguous text of a statute nor create exceptions where Congress did not.

1. There is no "longstanding judicial construction" of the Comstock Act which limits its applicability to situations where the sender "intends" that the pills be used unlawfully.

In response to an inquiry by the USPS as to the legality of mailing abortion drugs, the Biden Office of Legal Counsel (OLC) released an opinion in December 2022, claiming that despite its plain terms, the Comstock Act does not prohibit sending abortion drugs through the mail when the sender "lacks the intent" that the recipient will use them in violation of state law.[26] Of course, OLC opinions are not binding anywhere outside the executive branch, and even there only by custom. *See, e.g., Campaign for Accountability v. DOJ*, 155 F.4th 724, 727 (D.C. Cir. 2025). Nor may an OLC opinion override federal statutes, as that would exceed the constitutional authority of the executive branch. *Util. Air Regul. Grp.*, 573 U.S. at 327 ("Under our system of government, Congress makes laws and the President, acting at all times through agencies . . . ., 'faithfully execute[s]' them." (quoting U.S. Const. art. II, § 3)). While the Comstock Act does have an intent requirement, it has nothing to do with knowledge of a violation of state law. "The plain text does not require that a user of the mails or common interstate carriage intend that an abortion actually occur. Rather, a user of those shipping channels violates the plain text merely by knowingly making use of the mail for a prohibited abortion item." *All. for Hippocratic Med.,* 2023 WL 2913725, at *20. The Biden OLC attempted to sidestep the unambiguous text of the statute by arguing that its favored interpretation is "based upon a

[26] *Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions*, 46 Op. O.L.C. ----, ---- (Dec. 23, 2022) at 1-2, https://www.justice.gov/olc/opinion/file/1560596/dl?inline ("OLC Opinion").

longstanding judicial construction of the Comstock Act, which Congress ratified." OLC Opinion at 2. This claim is wrong, as numerous Members of Congress explained to former Attorney General Merrick Garland.[27]

To start, just as the executive branch cannot purport to change or override the plain text of a statute consistent with the Constitution, the judicial branch generally may not either. "'[O]nly the words on the page constitute the law adopted by Congress and approved by the President,'" and "if 'judges could add to, remodel, update, or detract from old statutory terms inspired only by extratextual sources and our own imaginations, we would risk amending statutes outside the legislative process reserved for the people's representatives.'" *Clements v. Florida*, 59 F.4th 1204, 1222 (11th Cir. 2023) (Newsom, J., concurring) (quoting *Bostock v. Clayton Cnty.*, 590 U.S. 644, 654-55 (2020)). Thus, a court's "inquiry begins with the statutory text, and ends there as well as if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004).

OLC does not explain how the Act is ambiguous, necessitating a judicial spin on the "words on the page" in the first place. *See generally* OLC Opinion. Regardless, OLC's claim of a "longstanding judicial construction" contradicting the statute's plain text does not hold up to scrutiny. In support of this contention, OLC relied on a smattering of decisions from the Second Circuit, along with one each from the Sixth, Seventh, and D.C. Circuits. *See* OLC Opinion at 5-10 (citing *Bours v. United*

[27] Letter from Sen. James Lankford, et al., to Attorney General Merrick B. Garland, (Jan. 25, 2023), https://www.lankford.senate.gov/wp-content/uploads/media/doc/dojletterabortionmail.pdf.

States, 229 F. 960 (7th Cir. 1915); *Youngs Rubber Corp. v. C.I. Lee & Co.*, 45 F.2d 103 (2d Cir. 1930); *Davis v. United States*, 62 F.2d 473 (6th Cir. 1933); *United States v. One Package*, 86 F.2d 737 (2d Cir. 1936); *United States v. Nicholas*, 97 F.2d 510 (2d Cir. 1938); *Consumers Union U.S., Inc. v. Walker*, 145 F.2d 33 (D.C. Cir. 1944)). The issue in all these cases except *Bours* was the mailing of contraceptives,[28] which was also originally prohibited by the Act but was later repealed by Congress (in contrast to the mailing of chemical abortion drugs). The decisions concluded that because state law allowed lawful uses of contraceptives in some circumstances, Congress must have really meant to say, "*illegal* contraception or abortion or for indecent or immoral purposes." *See One Package*, 86 F.2d at 738 (emphasis added). But using "illegal" to modify "abortion" in that clause wouldn't have been necessary for the same reason because abortion, as conceptualized by the Biden administration, was illegal in all 50 states at this time, under both federal and state law. And as *Bours* explains, the statute was aimed at prohibiting the mailing of items that "*destroy*[ ] life." 229 F. at 964. Even though states allowed abortions to *save* the mother's life, and *Bours* agreed that the Act's definition of "abortion" excludes "operation[s]" that are necessary to "save [the mother's] life," *id.*, *Bours* also held that "it is immaterial what the local statutory definition of abortion is, what acts of abortion are included, or what excluded," *id.* Rather, "the word 'abortion' in the national statute

[28] *Youngs* was a trademark infringement case and OLC admits that the court's conclusion that mailing contraceptives was only illegal if the contraceptives were illegal under state law was dicta (which was later adopted by the other Second Circuit decisions cited). OLC Opinion at 6.

must be taken in its general medical sense." *Id.* And "[i]ts inclusion in the statute governing the use of the mails indicates a national policy of discountenancing abortion as inimical to the national life." *Id.* In short, *Bours* contradicts OLC's argument, undermining OLC's claim of a "longstanding judicial construction."

OLC's claim of judicial consensus on this point rapidly disintegrates. It is doubtful that every other circuit would presume that it knows better and Congress didn't "underst[an]d" what it was doing, as the Second Circuit did:

> [W]e are satisfied that this statute, as well as all the acts we have referred to, embraced only such articles as Congress would have denounced as immoral if it had understood all the conditions under which they were to be used. Its design, in our opinion, was not to prevent the importation, sale, or carriage by mail of things which might intelligently be employed by conscientious and competent physicians for the purpose of saving life or promoting the well being of their patients.

One Package, 86 F.2d at 739. In fact, other circuits, including this one, have applied the statute with respect to abortion without the same modification. *See, e.g., Lee v. United States*, 156 F. 948, 949 (9th Cir. 1907); *Clark v. United States*, 202 F. 740, 741 (8th Cir. 1912); *Weathers v. United States*, 126 F.2d 118 (5th Cir. 1942). OLC's claim of consensus amounts to a few strident opinions from the Second Circuit in a different context that were followed by two other circuits. This is "neither a settled judicial construction nor one which [the Court] would be justified in presuming Congress, by its silence, impliedly approved." *United States v. Powell*, 379 U.S. 48, 55, n. 13 (1964).

2. Congress did not "ratify" the Biden administration's preferred construction of the Comstock Act.

Neither of the requirements to assume that Congress ratified a settled judicial construction are present here. As discussed above, the "supposed judicial consensus" is not "so broad and unquestioned that [the Court] must presume Congress knew of and endorsed it." *Jama v. Immigr. & Customs Enf't*, 543 U.S. 335, 349 (2005). And as OLC's cited authority (at 11) acknowledges, only where a statute is "given a *uniform interpretation* by inferior courts" will "a later version of that act perpetuating the wording [be] presumed to carry forward that interpretation." *Tex. Dep't of Hous. & Cmty. Affairs v. Inclusive Cmtys. Project, Inc.*, 576 U.S. 519, 536 (2015) (emphasis added) (quoting A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 322 (2012)).

Nor did Congress "simply reenact" §§ 1461-62 "without change," which is the second requirement to presume ratification. *Jama*, 543 U.S. at 349. Congress has amended the Act several times since the cases OLC relies on were decided, notably removing the provisions related to contraception altogether but leaving the prohibition on mailing chemical abortion drugs. *All. for Hippocratic Med.*, 78 F.4th at 269 (Ho., J., concurring in part) (citing Pub. L. No. 91-662, §§ 3–4, 84 Stat. 1973, 1973 (1971)). Further, in 1978, Congress considered—and rejected—amendments to the Act specifying that it applies only to "illegal abortions"—the exact amendment the Biden OLC wanted to read into the statute. *Id.* at 269 (Ho, J., concurring in part). And contrary to OLC's argument that the Court should presume that Congress knew about and accepted the judicial interpretation it claims, legislative history

shows the opposite. A House subcommittee report accompanying the proposed bill stated that

> under current law, the offender commits an offense whenever he 'knowingly' mails any of the designated abortion materials. [The proposed modification] requires proof that the offender specifically intended that the mailed materials be used to produce an illegal abortion. An abortion is 'illegal' if it is contrary to the laws of the state in which it is performed.[29]

This shows that when considering the exact change OLC argues to be adopted by judicial (and bureaucratic) fiat, Congress clearly understood the statute to mean just what it says and *kept that meaning*. Further, in 1996, Congress "had the opportunity to remove 'abortion' from the Comstock Act altogether," but it did not. *All. for Hippocratic Med.*, 78 F.4th at 269 (Ho., J., concurring in part).

Courts "do not lightly assume that Congress has omitted from its adopted text requirements that it nonetheless intends to apply, and our reluctance is even greater when Congress has shown . . . that it knows how to make such a requirement manifest." *Jama*, 543 U.S. at 341. There is no basis for the Court to ignore the plain text of the statute and assume that Congress ratified the decisions of a few isolated judicial opinions from over thirty years earlier when it declined to adopt the very modification the Biden administration claimed is law.

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[29] *Report of the Subcommittee on Criminal Justice on Recodification of Federal Criminal Law*, Committee on the Judiciary, H. Rpt. 95-29, at 42 (1979), *available at* https://www.ojp.gov/pdffiles1/Digitization/63344NCJRS.pdf (last accessed Feb. 2, 2026).

Conclusion

The district court's opinion should be reversed.

Respectfully submitted.

/s/Heather Gebelin Hacker
Heather Gebelin Hacker
Hacker Stephens LLP
108 Wild Basin Road South
Suite 250
Austin, Texas 78746
(512) 399-3022 (phone)
heather@hackerstephens.com

Counsel for Amici Curiae

Certificate of Service

On June 22, 2026, this brief was served via CM/ECF on all registered counsel and transmitted to the Clerk of the Court. Counsel further certifies that: (1) any required privacy redactions have been made in compliance with Fifth Circuit Rule 25.2.13; and (2) the electronic submission is an exact copy of the paper document in compliance with Fifth Circuit Rule 25.2.1.

/s/ Heather Gebelin Hacker
HEATHER GEBELIN HACKER

Certificate of Compliance

This brief complies with: (1) the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 5674 words, excluding the parts exempted by Rule 32(f); and (2) the typeface and type style requirements of Rule 32(a)(5) and (6) because it has been prepared in a proportionally spaced typeface (14-point Equity) using Microsoft Word (the program used for the word count).

/s/ Heather Gebelin Hacker
HEATHER GEBELIN HACKER

Appendix: List of Amici Curiae

22 U.S. Senators

Bill Cassidy, M.D. (LA)

Jim Banks (IN)

Marsha Blackburn (TN)

Katie Boyd Britt (AL)

Ted Budd (NC)

John Cornyn (TX)

Kevin Cramer (ND)

Mike Crapo (ID)

Ted Cruz (TX)

Steve Daines (MT)

Lindsey O. Graham (SC)

Josh Hawley (MO)

John Hoeven (ND)

Cindy Hyde-Smith (MS)

James Lankford (OK)

Roger Marshall, M.D. (KS)

Rand Paul, M.D. (KY)

Pete Ricketts (NE)

Jim Risch (ID)

Rick Scott (FL)

Tim Sheehy (MT)

Tommy Tuberville (AL)

69 U.S. Representatives

Christopher H. Smith (NJ)

Robert B. Aderholt (AL)

Mark Alford (MO)

Rick Allen (GA)

Brian Babin, D.D.S. (TX)

Sheri Biggs (SC)

Lauren Boebert (CO)

Mike Bost (IL)

Josh Brecheen (OK)

Eric Burlison (MO)

Ben Cline (VA)

Michael Cloud (TX)

Andrew S. Clyde (GA)

Jeff Crank (CO)

Eric A. "Rick" Crawford (AR)

Warren Davidson (OH)

Troy Downing (MT)

Ron Estes (KS)

Julie Fedorchak (ND)

Michelle Fischbach (MN)

Scott Fitzgerald (WI)

Chuck Fleishmann (TN)

Mike Flood (NE)

Vince Fong (CA)

Virginia Foxx (NC)

C. Scott Franklin (FL)

Russ Fulcher (ID)

Brandon Gill (TX)

H. Morgan Griffith (VA)

Michael Guest (MS)

Harriet M. Hageman (WY)

Andy Harris, M.D. (MD)

Mark Harris (NC)

Diana Harshbarger (TN)

Clay Higgins (LA)

Richard Hudson (NC)

Jim Jordan (OH)

Mike Kelly (PA)

Julia Letlow, Ph.D. (LA)

Tracey Mann (KS)

Addison P. McDowell (NC)

John J. McGuire III (VA)

Mark Messmer (IN)

Mary E. Miller (IL)

John Moolenaar (MI)

Blake D. Moore (UT)

Riley M. Moore (WV)

Nathaniel Moran (TX)

Ralph Norman (SC)

Andy Ogles (TN)

Robert F. Onder (MO)

Gary Palmer (AL)

Mike D. Rogers (AL)

David Rouzer (NC)

Chip Roy (TX)

John Rutherford (FL)

Keith Self (TX)

Pete Sessions (TX)

Michael K. Simpson (ID)

Adrian Smith (NE)

Pete Stauber (MN)

Marlin A. Stutzman (IN)

Claudia Tenney (NY)

Glenn "GT" Thompson (PA)

Matt Van Epps (TN)

Randy K. Weber (TX)

Daniel Webster (FL)

Joe Wilson (SC)

Rudy Yakym III (IN)