No. 26-30203

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

v.

U.S. FOOD & DRUG ADMINISTRATION; KYLE DIAMANTAS, Acting Commissioner, U.S. Food & Drug Administration; MICHAEL DAVIS, in his official capacity as Director, Center for Drug Evaluation & Research, U.S. Food & 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,

v.

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, No. 25-cv-1491, Hon. David C. Joseph

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Amici curiae are U.S. food and drug law scholars and professors from academic institutions across the United States.[1] A full list of the *amici* is included as an Appendix to this brief. *Amici* have expertise in food and drug law, including the drug approval process and regulation of pharmaceuticals under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq*. Amici have a strong interest in the proper interpretation of food and drug law. They submit this brief to address important issues raised by this case concerning the authority of the U.S. Food & Drug Administration (FDA or the Agency) to regulate prescription drugs.

SUMMARY OF ARGUMENT

The FDCA sets out a comprehensive process under which FDA reviews and approves new drugs, and major changes to approved applications, before such products may be introduced into interstate commerce. FDA will approve a new drug application (NDA) only if it determines, based on the full record before the Agency, that the product is safe and effective for the proposed conditions of use. That

[1] This brief is submitted pursuant to Federal Rule of Appellate Procedure 29(a) with the consent of all parties. Undersigned counsel for *amici curiae* certify that this brief was not authored in whole or part by counsel for any of the parties, that no party or party's counsel contributed money for this brief, and that no one other than *amici* and their counsel have contributed money for this brief. The views expressed in this brief are those of the *amici* in their individual capacities and do not represent the views of their respective institutions.

determination requires the review of scientific evidence that sponsors[2] submit in support of their applications. In limited, specified circumstances, the FDCA authorizes FDA to impose distribution and use restrictions to assure that a drug's benefits outweigh its risks. But the statute requires the Agency to minimize the burdens of such restrictions on patient access to the drug and, to the extent practicable, the health care delivery system.

Ever since FDA approved mifepristone in 2000 it has been subject to distribution and use restrictions, first through a regulatory pathway known as Subpart H and later through a statutory process known as a Risk Evaluation and Mitigation Strategy (REMS) with elements to assure safe use (ETASU).[3] In 2021, FDA concluded that a requirement that mifepristone be dispensed in a clinic or doctor's office was no longer necessary. FDA reached this conclusion after more than 20 years of experience with the approved use of mifepristone and following a six-month period when the in-person dispensing requirement was not enforced due to the COVID-19 pandemic. FDA approved a modified REMS in January 2023 to replace the in-person dispensing requirement with a pharmacy certification

[2] In this brief, the term "sponsors" refers to marketing applicants and marketing application holders.

[3] This brief uses "mifepristone" to refer to both the branded and generic forms of this drug that are approved for the medical termination of intrauterine pregnancy.

requirement that continued to limit access to the drug. FDA preserved the other elements of the REMS including the prescriber certification and the patient form.

Louisiana's claims about FDA's 2023 REMS modification—which are credited in orders of the U.S. District Court for the Western District of Louisiana (the "district court") and the May 1 panel of this Court (the "stay panel")—rest on critical misunderstandings of federal food and drug law, the regulatory history of mifepristone, and the evidence relied on by FDA. FDA's decision to remove the in-person dispensing requirement was science-based, well-documented, and consistent with the statute's mandate to periodically review REMS and to minimize burdens on patients and the health care delivery system. The Comstock Act has no bearing on FDA's rationale or ultimate determination.

This Court should affirm the district court's denial of preliminary relief to the Plaintiffs, reverse the District Court's denial of intervenor-appellees' motion to dismiss, and remand with instructions to dismiss Plaintiffs' complaint.

ARGUMENT

I. Congress Has Directed FDA to Impose REMS with ETASU Only in Limited Circumstances, and Only in Ways that Minimize Burdens on Patient Access.

In the Food and Drug Administration Amendments Act of 2007 (FDAAA), Congress amended the FDCA to grant FDA express authority to impose "risk evaluation and mitigation strategies" on prescription drugs if necessary to address

specific safety concerns. Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926–49 (2007) (codified at 21 U.S.C. § 355-1).[4] FDA may impose a REMS *only* if the Agency determines that a REMS is "*necessary* to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1) (emphasis added). The components of a REMS may include, among other things, ETASU, such as requirements that health care providers who prescribe the drug be certified or that the drug be dispensed to patients only in certain settings.

Congress instructed FDA to use REMS with ETASU sparingly. They are appropriate only if "required as part of [a] strategy to mitigate a specific serious risk listed in the labeling of the drug," and they must be "commensurate" with this risk. 21 U.S.C. § 355-1(f)(1)(A), (f)(2)(A). Of the thousands of prescription drugs FDA has approved, currently there are only 62 REMS with ETASU.[5] To the extent practicable, ETASU must be designed "so as to minimize the burden on the health care delivery system." *Id.* § 355-1(f)(2)(D). And critically, the Act mandates that ETASU "not be unduly burdensome on patient access to the drug,

[4] Prior to the passage of FDAAA, FDA had established a mechanism to impose distribution and use restrictions through regulation at 21 C.F.R. § 314.520, "Approval with restrictions to assure safe use." FDAAA codified and expanded that regulation by creating a statutory REMS framework.

[5] *See* FDA, *Risk Evaluation & Mitigation Strategy (REMS) Public Dashboard: ETASU*, https://tinyurl.com/33p3whx7 (accessed July 21, 2026). Certain REMS are applicable to multiple applications. *See id.*

considering in particular . . . patients who have difficulty accessing health care (such as patients in rural or medically underserved areas) . . . and . . . patients with functional limitations." *Id.* § 355-1(f)(2)(C)(ii), (iii). In other words, ETASU must be the *least restrictive necessary* to ensure that the drug's benefits outweigh its risks, considering patients' ability to access the product and the impact on the health care delivery system.

Additionally, Congress did not intend REMS to be static or set in stone. All REMS require sponsors to submit "assessments" at regular intervals, and FDA may require additional assessments at any time. 21 U.S.C. § 355-1(d), (g)(2)(B), (g)(2)(C). Moreover, a sponsor may voluntarily submit a REMS assessment and propose to modify the REMS at any time. *Id.* § 355-1(g)(1), (g)(4)(A). An assessment must include, "with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether 1 or more such goals or such elements should be modified." *Id.* § 355-1(g)(3). FDA can also, at any time, require the submission of a proposed modification to the strategy, including if necessary to "ensure the benefits of the drug outweigh the risks of the drug" or to "minimize the burden on the health care delivery system of complying with the strategy." *Id.* § 355-1(g)(4)(B).

FDA expects REMS assessments to be based on "a combination of qualitative and quantitative information about the REMS" derived from sources such as company databases, stakeholder surveys, drug utilization data, post-marketing adverse event data, observational data, epidemiological data, and "stakeholder outreach." FDA, *Draft Guidance for Industry, REMS Assessment: Planning and Reporting*, at 7–12 (Jan. 2019), https://www.fda.gov/media/119790/download. Such data are to be used both to assess the effectiveness of the REMS and "the impact of the program on the healthcare delivery system and on patient access to the drug." *Id.* at 12.

Since the establishment of the statutory REMS framework in 2007, FDA has fully removed 219 REMS—including 20 REMS that contained ETASU.[6] In numerous other instances, the Agency has loosened ETASU restrictions without removing the REMS altogether. *See e.g.*, FDA, *Modification to Isotretinoin iPLEDGE Shared System REMS* (Feb. 9, 2026), https://tinyurl.com/3y5pt9ze; FDA, *Modification to Filspari (sparsentan) REMS* (Aug. 27, 2025), https://tinyurl.com/43xkwbey. Periodic REMS assessments and modifications are necessary to implement Congress's mandate that ETASU be maintained only when they are necessary to ensure a positive benefit-risk profile for the drug.

[6] *See* FDA, *Risk Evaluation & Mitigation Strategy (REMS) Public Dashboard: REMS Released*, https://tinyurl.com/nm63a4jm (accessed July 21, 2026).

II. FDA Had a Strong Basis to Determine that the In-Person Dispensing Requirement Should Be Removed and Was Obligated to Remove That Requirement Upon Concluding It Was Not Necessary.

Louisiana incorrectly casts FDA's decision to remove the in-person dispensing requirement as an attempt to undermine post-*Dobbs* state abortion restrictions. Br. 1, 9–11; *see also* ROA.9103-104; ROA.9141. That characterization is inaccurate as a matter of both chronology and substance. In reality, FDA made an evidence-based decision that adhered to the Congressional mandate that ETASU be the least restrictive necessary to ensure a drug's benefits outweigh its risks. And the Agency did so through a process that began well before *Dobbs* was issued.

A. The Process of Removing the In-Person Dispensing Requirement Adhered to the FDCA and Began pre-*Dobbs*.

It is incorrect to reframe FDA's decision to remove the in-person dispensing requirement as a response to *Dobbs*. The in-person dispensing requirement was first lifted for six months in response to a federal court injunction issued in July 2020. *See Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. July 13, 2020), *order clarified*, 2020 WL 8167535 (D. Md. Aug. 19, 2020) (preliminarily enjoining FDA from enforcing the in-person dispensing requirement and any other in-person requirements of the REMS); *FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578 (Jan. 12, 2021) (Mem.) (staying the preliminary injunction imposed by the District Court). In April 2021—more

than a year before *Dobbs*—FDA announced that it would not enforce the in-person dispensing requirement for mifepristone during the COVID-19 public health emergency if the other requirements of the REMS were met. *See* ROA.259.

By December 2021, FDA was on record concluding that "the [mifepristone] REMS *must* be modified to remove the in-person dispensing requirement" so as to "render the REMS less burdensome to healthcare providers and patients." ROA.382 (emphasis added). Consistent with the FDCA, FDA directed Danco Laboratories, LLC (Danco) and GenBioPro, Inc. (GenBioPro) to initiate the process of modifying the REMS by submitting a prior approval supplement within 120 days. 21 U.S.C. § 355-1(g)(4)(B).

In January 2023, FDA approved the sponsors' supplemental New Drug Applications (sNDAs) to remove the in-person dispensing requirement from the REMS. ROA.967–72. FDA did not simply remove the in-person dispensing requirement from the REMS; it also added a new REMS element that requires pharmacies dispensing the drug to satisfy a special certification process. *Id.* This was an incremental approach that frustrated some advocates who wanted the drug to be dispensed without special requirements.

In short, the process of revising the mifepristone REMS began well before *Dobbs* and was conducted pursuant to statutory requirements, not political whims. *See* Sophie Dilek et al., *The U.S. Food & Drug Administration's Regulation of*

Mifepristone, 335 JAMA 619, 619–25 (2026) (assessing 264 documents from FDA regarding the changes to the mifepristone REMS between 2011 and 2023 and not identifying any instances of political intervention in favor of loosening the REMS restrictions).

B. FDA's Decision to Remove the In-Person Dispensing Requirement was Grounded in Robust Evidence.

Louisiana incorrectly characterizes the evidence that FDA reviewed. Citing prior rulings of this Court, Louisiana contends that FDA erred by (1) giving "dispositive weight" to adverse event data in the FDA Adverse Event Reporting System (FAERS) database after previously removing a REMS requirement that obligated mifepristone prescribers to report non-fatal adverse events, and (2) improperly relying on "literature [that] did not affirmatively support [FDA's] position." Br. 54 (citing ROA.9144–45 and quoting *All. For Hippocratic Med. v. FDA*, 78 F.4th 210, 226 (5th Cir. 2023), *rev'd on other grounds*, 602 U.S. 367 (2024)). These contentions are incorrect. FDA's determination to modify the REMS by removing the in-person dispensing ETASU was both lawful and well-supported. Indeed, given the undeniable burdens on patients and the health care delivery system associated with in-person dispensing, once FDA concluded that in-person dispensing was not necessary to mitigate a specific risk, the FDCA required the Agency to amend the REMS and remove that requirement.

1. FDA Appropriately Considered FAERS Data.

As an initial matter, FDA did not give "dispositive weight" to the data in the FAERS database. FDA also reviewed other sources of postmarketing safety data, including data published in the medical literature and additional data FDA solicited from sponsors. ROA.374–75. The Agency used these data to compare time periods when in-person dispensing was and was not enforced, concluding that "there have not been any new safety concerns with the use of mifepristone for medical termination of pregnancy through 70 days gestation, including during the time when in-person dispensing was not enforced." ROA.374.

Following the 2016 removal of the REMS requirement that prescribers report non-fatal adverse events to sponsors, FDA continued to receive the same extensive scope of fatal and non-fatal adverse event reports required of any marketed drug. Louisiana alleges that "FDA had previously eliminated the requirement to report mifepristone's adverse events to FAERS" and implies that this change makes the FAERS data unreliable. Br. 51 (citing ROA.9144). In fact, under FDA regulations, *all* sponsors must review and report to FDA all adverse drug experiences of any level of severity associated with the use of a drug in humans, whether or not considered drug related, that they learn about from any

source, foreign or domestic. 21 C.F.R. § 314.80(b), (c); *see also id.* § 314.80(a).[7] Moreover, FDA maintains an extensive infrastructure called MedWatch for voluntary reporting of adverse drug events to the Agency by others, including health care professionals and patients. *See* FDA, *Reporting Serious Problems to FDA* (Sept. 26, 2025), https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda. All of these data, including mandatory reports from manufacturers and voluntary reports submitted by others through MedWatch, are captured within FAERS.

When FDA released the REMS requirement that mifepristone prescribers report non-fatal adverse events to the sponsor in 2016,[8] the Agency explained: "This information is being submitted to the Agency through other pathways including spontaneous adverse event reporting and the annual report." FDA,

[7] For adverse drug experiences that are both serious and unexpected, FDA requires the sponsor to submit a report to the Agency "as soon as possible but no later than 15 calendar days from initial receipt of the information by the applicant." 21 C.F.R. § 314.80(c)(1)(i). The sponsor must then "promptly investigate all adverse drug experiences that are the subject of these postmarketing 15-day Alert reports" and must submit follow-up reports to the Agency. *Id.* § 314.80(c)(1)(ii).

[8] At no time was there a separate REMS requirement to "report mifepristone's adverse events *to FAERS*." ROA.9144 (emphasis added). Until 2016, the mifepristone REMS required prescribers to report non-fatal adverse events to the *sponsor*. The adverse events reported by prescribers were entered into FAERS only after sponsors reported them to FDA in accordance with regulations requiring sponsors to submit adverse drug experiences obtained from any source to the Agency.

REMS Modification Review, at 10 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf. In other words, FDA's standard adverse event reporting system, applicable to all FDA-approved drugs, was *already* capturing the non-fatal adverse events the heightened reporting requirements were designed to ascertain. Indeed, while Louisiana focuses on purported gaps in the FAERS data that rendered the data unreliable, the opposite may be true. When FDA asked Danco and GenBioPro each to submit a summary of postmarketing safety information collected following the 2016 REMS changes, this information mirrored precisely the cases already identified in the FAERS database during that same period. ROA.374. This alignment reinforces the soundness of FDA's standard safety reporting requirements and the utility of FAERS data.

Louisiana emphasizes FDA's supposed concession that FAERS data "are not an indicator of the safety profile of a drug" and "cannot be used to calculate the incidence of an adverse event." Br. 55–56 (quoting ROA.1106–1108). In fact, FDA stated that FAERS data "*by themselves* are not an indicator of the safety profile of the drug." ROA.1106 (emphasis added). As FDA recognizes, FAERS data have limitations. First, FDA does not receive a report for every adverse event that occurs with a product. *See* FDA, *FDA Adverse Event Monitoring System (AEMS) Public Dashboard: Frequently Asked Questions* (accessed July 21, 2026),

https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html ("Does AEMS data have limitations?").[9] Second, as noted above, the mandatory sponsor-provided adverse event reports in FAERS include "[a]ny adverse event associated with the use of a drug in humans, *whether or not considered drug related* . . . ." 21 C.F.R. § 314.80(a) (emphasis added). If an adverse event occurs "in the course of the use of a drug product in professional practice," the sponsor must report it, regardless of any causal relationship.[10] For these reasons, FAERS data cannot be used to precisely calculate the incidence of drug-induced adverse events. But FAERS can be used as a *signal* of potential safety concerns. As FDA explains, "If a potential safety concern is identified in [FAERS], further evaluation is performed." *FDA Adverse Event Monitoring System (AEMS) Public Dashboard: Frequently Asked Questions* (accessed July 21, 2026) ("How does FDA use the information in AEMS?").

[9] In March 2026, FDA announced the transition from FAERS to the FDA Adverse Event Monitoring System (AEMS) Public Dashboard. Although the name and functionality of the adverse event reporting system have changed, the regulatory reporting requirements have not.

[10] According to Agency regulations, "A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect." 21 C.F.R. § 314.80(l).

Taken to its logical conclusion, Louisiana's reasoning would preclude FDA from ever relying on the FAERS database to modify or release a REMS in the absence of a requirement for prescriber reporting. Yet FDA frequently uses its evaluation of data from FAERS to inform regulatory decisions. For example, in 2023, FDA removed a REMS for Lotronex (alosetron hydrochloride), since reporting of adverse events in FAERS "has been stable since 2002 and an increase in severe outcomes has not been observed." FDA, *Lotronex (alosetron hydrochloride) Information* (Sept. 8, 2023), https://tinyurl.com/mppnxkrc.[11]

Finally, even after the 2023 REMS modification, mifepristone remains subject to a more rigorous adverse event reporting regime than the vast majority of other drugs. The prescriber agreement continues to state that prescribers must report any patient deaths to the sponsor. According to FDA regulations, the sponsor is in turn obligated to report these deaths to FDA. Of the thousands of drugs currently marketed in the United States, mifepristone is one of fewer than 40 requiring additional adverse event reporting.

[11] FDA likewise routinely uses its evaluation of FAERS data to support a host of regulatory actions, including updating a product's labeling information, communicating new safety information to the public, and even requesting that a company remove a product from the market. *See* Chisato Fukazawa et al., *Factors Influencing Regulatory Decision-Making in Signal Management: Analysis Based on the Signals Identified from the FAERS*, 55 THERAPEUTIC INNOVATION & REGUL. SCI. 685, 685–95 (2021) (analyzing regulatory actions taken based on signals FDA identified from FAERS, including labeling changes, REMS modifications, product recall, and withdrawal).

2. The Published Literature Supported FDA's Decisionmaking.

The FDCA does not require *any* clinical study data to modify a REMS under section 505-1 (21 U.S.C. § 355-1). Here, however, FDA *did* consider clinical study data, including data from three studies evaluating retail pharmacy dispensing, three studies evaluating mail order dispensing, five studies evaluating clinic dispensing by mail, and one study evaluating clinic dispensing by courier, among others. ROA.376–83.[12]

Louisiana incorrectly asserts that FDA acted arbitrarily by "relying" on this extensive published literature to support the removal of the in-person dispensing requirement. Br. 54. Although FDA acknowledged limitations in the published studies, it appropriately gave weight to the fact that none of them identified new or increased risks associated with dispensing mifepristone without an in-person visit to a health care setting. Moreover, FDA did not consider the published literature in isolation. Rather, FDA's review was comprehensive, encompassing "multiple different sources of information, including published literature, safety information

[12] When FDA initially announced that it would not enforce the in-person dispensing requirement during the COVID-19 public health emergency, it cited four of these studies. FDA stated that "[t]he overall findings from these studies do not appear to show increases in serious safety concerns (such as hemorrhage, ectopic pregnancy, or surgical interventions) occurring with medical abortion as a result of modifying the in-person dispensing requirement during the COVID-19 pandemic." ROA.259–60.

submitted to the Agency during the COVID-19 [Public Health Emergency] [and] FAERS reports," as well as information submitted by sponsors and other stakeholders. ROA.353, 369. Based on its analysis of the totality of the information before it, FDA concluded that mifepristone would remain safe if the in-person dispensing requirement was removed and a pharmacy certification requirement was added. *See* ROA.382.

3. Consistent with the Congressionally Mandated Framework, FDA Considered the Burdens Imposed by the In-Person Dispensing Requirement.

Perhaps most importantly, Louisiana ignores key statutory requirements guiding FDA's review of the mifepristone REMS: the ETASU must not be unduly burdensome on patient access and its burdens on the health care delivery system must be minimized. The in-person dispensing requirement prevented patients from meeting with providers remotely from their homes, thereby imposing on patients the financial costs and logistical burdens associated with travel. *See* Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 648, 691 (2022). It also forced prescribers to dispense mifepristone themselves instead of relying on pharmacies, creating logistical barriers associated with establishing and managing drug inventories. *See id.* at 645. Given these burdens, if FDA concluded the in-person dispensing requirement was unnecessary to assure the safe use of mifepristone—which it did—the Agency was *obligated* to remove the requirement.

That FDA carefully weighed the product's safety and burdens on patients and the health care delivery system when it modified the mifepristone REMS in 2023 is apparent not just in the Agency's removal of the in-person dispensing requirement, but also in the requirement the Agency adopted in conjunction with that removal—that pharmacies be specially certified to dispense mifepristone. Pursuant to this certification scheme, pharmacies have training, verification, recordkeeping, and reporting obligations, among others. *See* FDA, *Risk Evaluation and Mitigation Strategy Single Shared System for Mifepristone 200 mg* (Sept. 2025), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2025_09_30_REMS_Full.pdf.[13] FDA thus adopted a measured approach that adhered to the FDCA's mandate to protect patient safety in a manner that does not unduly burden patient access. *See* 21 U.S.C. § 355-1(f)(2)(D). In other words, FDA's well-supported determination was consistent with the statute.

III. FDA's Authority to Approve and Regulate Mifepristone is Not Limited by the Comstock Act.

FDA's removal of the in-person dispensing requirement is not limited by the Comstock Act, 18 U.S.C. §§ 1461–62. The FDCA authorizes FDA to approve "*any* new drug" for "introduc[tion] into interstate commerce" and makes no exception to

[13] It is notable that pharmacy certification is a burdensome requirement applicable to only 57 drugs on the market today. *See* FDA, *Risk Evaluation & Mitigation Strategy (REMS) Public Dashboard: ETASU*, https://tinyurl.com/33p3whx7 (accessed July 21, 2026).

this authority for abortifacients. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (creating 21 U.S.C. § 355(a)) (emphasis added). Courts frequently explain that the word "any" means "all" or "every." *See, e.g.*, *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1353 (2018); *Regions Bank v. Legal Outsource PA*, 936 F.3d 1184, 1194 (11th Cir. 2019) ("[W]hen Congress uses the word 'any' without 'language limiting the breadth of that word, 'any' means all.'" (citation omitted)). The Comstock Act places restrictions on use of the U.S. mails or common carriers for transporting certain items, but it does not limit FDA's authority to approve any drug shown to be safe and effective pursuant to the FDCA. *See* 18 U.S.C. § 1461–62.

In accordance with the statutory language, FDA has approved drugs despite their inclusion in the Comstock Act. For example, in 1960 FDA approved Enovid, the first oral contraceptive, despite the facts that contraceptives were Comstock-listed articles at the time and the sale of contraceptives remained illegal in much of the nation.[14] *See* Martha Bailey, *"Momma's Got the Pill": How Anthony Comstock and Griswold v. Connecticut Shaped US Childbearing*, 100 Am. Econ. R. 98, 105-06 (2010). Two years after Enovid's approval, Congress enacted the Kefauver-Harris Amendments to the FDCA, which strengthened FDA's authority to regulate

[14] The Supreme Court had not yet decided *Griswold v. Connecticut*, 381 U.S. 479 (1965).

drugs, including contraceptives. *See* Pub. L. No. 87-781, 76 Stat. 780 (1962). And although a pending marketing application for an oral contraceptive was discussed during floor debate on the legislation, there was no suggestion that approval of the application would violate the Comstock Act or exceed FDA's authority. *See* 108 Cong. Rec. 21088 (Sept. 27, 1962). By December 1965—while contraceptives were still Comstock-listed articles—FDA had approved no fewer than seven oral contraceptives for introduction into interstate commerce. *See* FDA, *Fact Sheet: Oral Contraceptives* (Dec. 1965) (hereinafter FDA Contraceptive Fact Sheet).[15]

Since FDA approved mifepristone in 2000, Congress has amended Section 505 of the FDCA (21 U.S.C. § 355)—which sets forth FDA's authority to approve and regulate new drugs—no fewer than 18 times, including post-*Dobbs*. It has also enacted the section authorizing REMS (21 U.S.C. § 355-1) and amended it seven

[15] When Congress amended the Comstock Act in 1971 to remove contraceptives from coverage under that Act, the House report noted that the FDCA would "still" (i.e., would continue to) regulate the "interstate transportation of drugs, medicines, and other articles for the prevention of conception." H.R. Rep. No. 91-1105, at 3 (1970) (quoting the Department of Health, Education, and Welfare's conclusion); *id.* (quoting the Department of Labor's conclusion that the FDCA "would continue to apply to imports and shipments" of contraceptives). Congress thus confirmed its understanding that FDA regulates all drugs in interstate commerce, including Comstock-listed drugs.

times during this period, including post-*Dobbs*. Yet Congress has never amended the FDCA to curtail FDA's authority to approve abortifacients.[16]

In sum, Congress has assigned FDA the task of ensuring that drugs submitted to it for approval are safe and effective for their intended use, including implementation of certain restrictions FDA determines are necessary. The Comstock Act has no bearing on that decision. *See* 21 U.S.C. § 355(d) (listing grounds on which FDA may refuse to approve an application for a new drug); *see also* FDA Contraceptive Fact Sheet ("New drugs must be proved both *safe* and *effective* if used as directed, before clearance can be granted. But if the product *is* established as safe and effective, FDA *must* grant the clearance.") (emphasis in original)). By Congress's design, the Comstock Act has no role in FDA's product approval processes, including its decision to remove the in-person dispensing requirement for mifepristone.

[16] *See, e.g.*, Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002); Pediatric Research Equity Act of 2003, Pub. L. No. 108-155, 117 Stat. 1936 (2003); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012); Consolidated Appropriations Act, Pub. L. No. 117-328, §§ 3001-3631 (2022) ("Food and Drug Omnibus Reform Act of 2022").

CONCLUSION

This Court should affirm the district court's denial of preliminary relief to the Plaintiffs, reverse the District Court's denial of intervenor-appellees' motion to dismiss, and remand with instructions to dismiss Plaintiffs' complaint.

Respectfully submitted,

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I certify that on July 22, 2026, the foregoing document was served on all parties or their counsel of record through the CM/ECF system.

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No. 26-30203 State of Louisiana v. FDA
USDC No. 6:25-CV-1491

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