Nos. 25A1207 & 25A1208

IN THE

Supreme Court of the United States

DANCO LABORATORIES, L.L.C.,

Applicant,

v.

THE STATE OF LOUISIANA, ET. AL.

Respondents.

GENBIOPRO, INC.,

Applicant,

v.

THE STATE OF LOUISIANA, ET AL.

Respondents.

ON APPLICATION TO STAY OR VACATE THE FIFTH CIRCUIT'S STAY PENDING APPEAL

BRIEF OF FOOD AND DRUG LAW SCHOLARS AND PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF APPLICANTS' APPLICATIONS TO STAY OR VACATE THE FIFTH CIRCUIT'S STAY PENDING APPEAL

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INTEREST OF THE *AMICI CURIAE*

Amici curiae are U.S. food and drug law scholars and professors from academic institutions across the United States. A full list of the *amici* is included as an Appendix to this brief.[1] *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 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

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[1] No party or counsel for a party authored this brief in whole or in part, and no person other than *amici* or their counsel made a monetary contribution intended to fund the preparation or submission of 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.

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

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 on the market with 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—after more than 20 years of experience with the approved use of mifepristone, and after an extended period when the in-person dispensing requirement was not enforced due to the COVID-19 pandemic. FDA subsequently approved a modified REMS in January 2023 to remove the in-person dispensing requirement, replacing it with a pharmacy certification 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.

The Fifth Circuit's order rests on critical misunderstandings of federal food and drug law, the regulatory history of mifepristone, and the evidence relied on by FDA. FDA's determination to remove the in-person dispensing requirement was measured, science-based, well-documented, and consistent with the statute's mandate to periodically review REMS and to minimize burdens on patients and the health

[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.

care delivery system. The Court should grant the stay Applications and allow the 2023 REMS modification to remain in place.

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

[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.

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, 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

[5] *See* FDA, *Risk Evaluation & Mitigation Strategy (REMS) Public Dashboard*, https://perma.cc/H3UA-5BKG (archived May 6, 2026). Certain REMS are applicable to multiple applications. *See id.*

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);[7] FDA, *Modification to Filspari (sparsentan) REMS* (Aug. 28, 2025).[8] 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.

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[6] *See* FDA, *Risk Evaluation & Mitigation Strategy (REMS) Public Dashboard*, https://perma.cc/H3UA-5BKG (archived May 6, 2026).

[7] https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=24.

[8] https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=IndvRemsDetails.page&REMS=416.

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.

The Fifth Circuit incorrectly describes FDA's decision to remove the in-person dispensing requirement as an attempt to undermine post-*Dobbs* state abortion restrictions. Fifth Circuit Decision at 10. In reality, it was 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. Both on chronology and substance, the Fifth Circuit's analysis fails.

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

The Fifth Circuit's attempted reframing of FDA's decision to remove the in-person dispensing requirement is wrong as a matter of chronology. 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* Janet Woodcock,

Acting Comm'r, FDA, Letter to Am. Coll. of Obstetricians & Gynecologists and Soc'y for Maternal Fetal Med. (Apr. 12, 2021).

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." Response Letter from P. Cavazzoni, Dir., FDA, to D. Harrison, Exec. Dir., Am. Ass'n of Pro-Life Obstetricians & Gynecologists Denying Citizen Petition, at 35 (Dec. 16, 2021) (emphasis added) [hereinafter *FDA December 2021 Memorandum*]. 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.[9] *See* FDA, *Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 mg* (Jan. 2023).[10] 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.

[9] In staying the approval of the sNDA, the Fifth Circuit failed to consider potential downstream consequences of this decision, including the status of subsequently-approved sNDAs that build off of the 2023 approval and the associated impact on products currently on the market.

[10] https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf.

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.

The Fifth Circuit's ruling is also incorrect with respect to its characterization of the evidence FDA reviewed. Citing its opinion in *Alliance for Hippocratic Medicine* (*Alliance II*), the Fifth Circuit held that FDA's determination was likely arbitrary and capricious because FDA (1) "gave 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) the "literature did not affirmatively support [FDA's] position." Order at 13, *Louisiana v. FDA*, No. 26-30203 (5th Cir. May 1, 2026), ECF No. 119-1 (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)) [hereinafter *Fifth Circuit Order*]. These conclusions 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 it was not necessary to mitigate a

specific risk, the FDCA required the Agency to amend the REMS and remove that requirement.

1. FDA Did Not Inappropriately Rely on 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. *FDA December 2021 Memorandum* at 27–28. 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." *Id.* at 27.

Even after the 2016 removal of the REMS requirement that prescribers report non-fatal adverse events to sponsors, FDA still received the same extensive scope of fatal and non-fatal adverse event reports required of any marketed drug. The Fifth Circuit incorrectly states "FDA had previously eliminated the requirement to report mifepristone's adverse events to FAERS" and implies that this change makes the FAERS data unreliable. *Fifth Circuit Order* at 13.[11] 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.

[11] Until 2016, the mifepristone REMS required prescribers to report non-fatal adverse events to the *sponsor*, not to FAERS. These adverse events 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, as discussed above.

§ 314.80(b), (c); *see also id.* § 314.80(a).[12] 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 this 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,[13] the Agency explained: "This information is being submitted to the Agency through other pathways including spontaneous adverse event reporting and the annual report." FDA, *REMS Modification Review*, at 10 (Mar. 29, 2016).[14] 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 the Fifth Circuit focuses on purported gaps in the FAERS data that, in the court's view, rendered the data unreliable, the opposite may be

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[12] 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).

[13] There never existed a separate REMS requirement to "report mifepristone's adverse events *to FAERS*." Fifth Circuit Order at 13 (emphasis added). 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.

[14] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RiskR.pdf.

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. *FDA December 2021 Memorandum* at 27. This alignment reinforces the soundness of FDA's standard safety reporting requirements and the utility of FAERS data.

FAERS data has limitations, since FDA does not receive a report for every adverse event that occurs with a product. *See* FDA, *FDA Adverse Event Reporting System (FAERS) Public Dashboard: Frequently Asked Questions* (accessed May 6, 2026), https://fis.fda.gov/extensions/FPD-FAQ/FPD-FAQ.html ("Does FAERS data have limitations"). But FAERS data is an effective system for capturing adverse events, and FDA regularly uses it to make regulatory decisions.[15] Taken to its logical conclusion, the Fifth's Circuit'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 additional mandatory prescriber reporting. Yet, FDA does so frequently. 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)*

[15] In March, FDA announced the transition from FAERS to the FDA Adverse Event Monitoring System (AEMS) Public Dashboard. *See* FDA, *FDA Adverse Event Monitoring System (AEMS) Public Dashboard* (Mar. 11, 2026), https://www.fda.gov/drugs/fda-adverse-event-monitoring-system-aems/fda-adverse-event-monitoring-system-aems-public-dashboard. Although the name and functionality of the adverse event reporting system has changed, the regulatory reporting requirements have not changed.

Information (Sept. 8, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/lotronex-alosetron-hydrochloride-information.[16]

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.

2. The Published Literature Supported FDA's Decisionmaking.

The Fifth Circuit revives its prior view from *Alliance II* that the published literature—which described clinical studies evaluating different mifepristone dispensing models—was inadequate to support the removal of the in-person dispensing requirement. The FDCA does not require *any* clinical trials to modify a REMS under section 505-1 (21 U.S.C. § 355-1). Here, however, FDA *did* consider clinical data, including data from three studies evaluating retail pharmacy dispensing, three studies evaluating mail order dispensing, five studies evaluating clinic dispensing by

[16] FDA likewise routinely relies on 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).

mail, and one study evaluating clinic dispensing by courier, among others. *FDA December 2021 Memorandum* at 29–36.[17] FDA acknowledged limitations in the published studies, but none of the studies identified any new or increased risks associated with dispensing mifepristone outside of an in-person visit to a health care setting.

Even if, as the Fifth Circuit states, the published literature alone "did not affirmatively support [FDA's] position," *Fifth Circuit Order* at 13, FDA never considered the published literature in isolation. Rather, FDA's review was comprehensive, encompassing "multiple different sources of information, including published literature, safety information submitted to the Agency during the COVID-19 [Public Health Emergency] [and] FAERS reports," as well as information submitted by sponsors and other stakeholders. *FDA December 2021 Memorandum* at 6, 22. 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 id.* at 35.

[17] 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." Janet Woodcock, Acting Comm'r, FDA, Letter to Am. Coll. Of Obstetricians & Gynecologists and Soc'y for Maternal Fetal Med., at 1–2 (Apr. 12, 2021).

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

Perhaps most importantly, the Fifth Circuit 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 both 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 was carefully weighing 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* Risk Evaluation and Mitigation Strategy

Single Shared System for Mifepristone 200 mg (Jan. 2025).[18] These dual modifications removed one burdensome requirement (in-person dispensing), but not without adding another (pharmacy certification). FDA thus adopted a measured approach that lowered the burden on patients as much as possible while ensuring safe use. Therefore, this modified approach to prescribing and distributing the medication considered, and adhered to, the FDCA's mandate that FDA 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 determination was consistent with the statute and well-supported.

CONCLUSION

The Court should grant the Applications.

[18] https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2025_09_30_REMS_Full.pdf.

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