No. 26-30203

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 AND DRUG ADMINISTRATION; MARTY MAKARY, COMMISSIONER, U.S. FOOD AND DRUG ADMINISTRATION; RICHARD PAZDUR, 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,

v.

GENBIOPRO, INC.,
Intervenor-Appellee/Cross-Appellant,

v.

DANCO LABORATORIES, LLC,
Intervenor-Appellee/Cross-Appellant.

On Appeal from the United States District Court
for the Western District of Louisiana
Case No. 25-cv-1491, Hon. David C. Joseph

BRIEF OF FORMER U.S. FOOD AND DRUG ADMINISTRATION COMMISSIONERS AND ACTING COMMISSIONERS AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS-APPELLEES

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CERTIFICATE OF INTERESTED PERSONS

In addition to the persons and entities listed in the Defendants-Appellees and Intervenor-Appellees' Certificates of Interested Persons, 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.

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INTERESTS OF *AMICI CURIAE*[1]

Amici served as commissioners and acting commissioners of the U.S. Food and Drug Administration (FDA or the Agency) and place a high value on the regulatory framework that provides patients access to critical drugs and vaccines. During their time leading the Agency, *Amici* oversaw the complex, evidence-based drug approval process that led to the approval of mifepristone, its "risk evaluation and mitigation strategy" (REMS), subsequent modifications of the mifepristone REMS, and the regulation of mifepristone after it was approved. As experts in the drug approval process, *Amici* are qualified to explain (i) how the Agency's close examination of mifepristone's safety profile informed each action it has taken with respect to the drug from 2000 through the 2023 REMS modification and was consistent with sound science, and (ii) how the FDA Adverse Event Reporting System (FAERS) operates to ensure the safety of a drug and that adopting Plaintiffs-Appellants' incorrect arguments and this Court's erroneous conclusions with respect to FAERS data would create serious consequences that would affect the entire drug approval system.

[1] Pursuant to Federal Rule of Appellate Procedure 29, undersigned counsel for *Amici* certify that: no party's counsel authored this *amicus* brief in whole or in part; no party or party's counsel contributed money that was intended to fund preparing or submitting this *amicus* brief; and no person or entity, other than *Amici* or their counsel, contributed money intended to fund the preparation or submission of this *amicus* brief. All parties have consented to the filing of this *amicus* brief in this litigation. This brief represents the views of the individual *Amici* and not necessarily of their organizations.

Amici are:

- **David A. Kessler, M.D.**, FDA Commissioner (1990–1997)
- **Jane E. Henney, M.D.**, FDA Commissioner (1999–2001)
- **Margaret Hamburg, M.D.**, FDA Commissioner (2009–2015)
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- **Joshua M. Sharfstein, M.D.**, FDA Acting Commissioner (2009)
- **Stephen Ostroff, M.D.**, FDA Acting Commissioner (2015–2016, 2017)
- **Norman E. "Ned" Sharpless, M.D.**, FDA Acting Commissioner (2019)
- **Janet Woodcock, M.D.**, FDA Acting Commissioner (2021–2022)

SUMMARY OF ARGUMENT

Despite FDA's request for a stay of this litigation to accommodate the Agency's new review of Agency decisions pertaining to mifepristone, which the district court granted, this Court stayed the 2023 REMS, which codified evidence-based decisions that FDA made in 2021. The record demonstrates, however, that FDA was extremely thorough and careful in approving mifepristone and subsequently modifying its REMS, and that the Agency's adjustments to the drug's postmarketing restrictions in 2021 and 2023 were based on 20 years of adverse event reporting and a thorough review of the data and the literature.

Granting Plaintiffs-Appellants' request for a stay under § 705 of the Administrative Procedure Act would upend FDA's gold-standard, science-based drug approval system and create a roadmap for attacks on science-based drug regulatory decisions.

Amici respectfully request that the Court affirm the district court's denial of Plaintiffs-Appellants' motion for a preliminary injunction.

BACKGROUND

A. Congress Granted FDA Authority to Engage in an Evidence-Based Process to Approve Drugs.

FDA is the agency that Congress has tasked with reviewing and approving drugs according to established scientific principles. FDA reviewers include physicians, pharmacologists, chemists, biologists, and statisticians—all with advanced degrees in their respective disciplines—who review every aspect of a New Drug Application (NDA) submitted by a sponsor. Through FDA's consideration of each NDA, its reviewers make hundreds of scientific judgments that lead the Agency to an ultimate decision whether to approve or deny the application. Further, once an NDA is approved, the Agency continues to monitor the drug's safety and efficacy.

The Agency's drug approval process requires rigorous review of available scientific evidence. In order for a new drug to be approved, the Federal Food, Drug, and Cosmetic Act (FDCA) directs FDA to determine whether the sponsor's application contains evidence demonstrating that the drug is safe and effective for its intended use, based on "adequate and well-controlled investigations." 21 U.S.C. § 355(d); *see* 21 C.F.R. §§ 314.50, 314.105(c). FDA has promulgated regulations describing the requirements for clinical investigations that meet the statutory standard and the labeling requirements for approved drugs. *See* 21 C.F.R. §§ 201.56,

201.57, 314.50, 314.126. Congress requires that FDA conduct a careful risk-benefit analysis in considering each NDA "to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decisionmaking, and the communication of the benefits and risks of new drugs." 21 U.S.C. § 355(d)(7); *see also Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 476 (2013) ("In order for the FDA to consider a drug safe, the drug's 'probable therapeutic benefits must outweigh its risk of harm.'") (internal citation omitted).

FDA imposes complex, rigorous standards in its review of NDAs and requires drug sponsors to demonstrate the drug's safety and efficacy through rigorous scientific studies, including laboratory and pre-clinical testing as well as three separate phases of clinical studies (with the later phase studies usually including several thousand patients). Further, drug sponsors must demonstrate that the methods used in, and the facilities used for, the manufacturing, processing, and packaging of the drug are adequate to "preserve its identity, strength, quality, and purity." 21 U.S.C. § 355(d)(3). FDA's scientific and medical experts receive information from and confer with the drug sponsor throughout the development and approval process. Because of the meticulous statutory standard, many NDAs are never approved. Industry members and consumers around the world regard FDA's

rigorous review of NDAs as the "gold standard" in ensuring drug safety and efficacy.[2] For this reason, FDA's approval of a new drug promotes its uptake and acceptance. Moreover, drug companies look to the consistency, clarity, and predictability of FDA's drug review and approval processes to inform future investments in developing new drugs and vaccines.

B. FDA May and Does Modify Applicable Postmarketing Restrictions, Including By Removing Restrictions, When a Product's Safety Profile Changes.

After a product is approved and used by a large number of people, FDA analyzes more data on its use, and its safety profile may change. Accordingly, the NDA sponsor is required to monitor the drug's safety and report adverse events to FDA. *See* 21 C.F.R. § 314.80.[3] Specifically, the drug sponsor "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, . . . reports in the scientific literature, and unpublished scientific papers." *Id.* § 314.80(b). Further, the regulation requires that the drug sponsor "develop written procedures for

[2] *See* Rachel Roubein, Laurie McGinley & David Ovalle, *Abortion Pill Fight May Have Broader Implications for FDA Drug Approval*, Wash. Post (Mar. 15, 2023), https://perma.cc/YVH8-2GGJ.

[3] FDA defines "adverse event" as "any untoward medical occurrence associated with the use of a drug product in humans, whether or not it is considered related to the drug product. An adverse event can occur in the course of the use of a drug product; from overdose of a drug product, whether accidental or intentional; from abuse of a drug product; from discontinuation of the drug product (e.g., physiological withdrawal); and it includes any failure of expected pharmacological action." 21 C.F.R. § 251.2.

the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." *Id.* The regulation also requires that sponsors, manufacturers, packers, and distributors report serious, unexpected adverse experiences to FDA within 15 days and submit quarterly adverse drug experience reports. *Id.* § 314.80(c). Thus, the law places considerable responsibility on manufacturers to assure the continued safety of their drugs. *See, e.g.*, 21 C.F.R. § 314.70(c)(6)(iii)(A); *Wyeth v. Levine*, 555 U.S. 555, 562 (2009).

After a drug's approval, FDA continues to monitor safety data and retains the authority to restrict its distribution through REMS. In addition, FDA regularly evaluates the safety reports it receives. Sometimes after reviewing new safety data, FDA requires that a drug be withdrawn from the market. Sometimes (as with mifepristone) the data demonstrates that the drug is safer than initially estimated, and when appropriate FDA will change labeling or relax restrictions initially placed on the drug's marketing and distribution.[4]

In 1992, FDA promulgated regulations (21 C.F.R. § 314.500, Subpart H) to impose conditions needed "to assure safe use" of drugs, including distribution

[4] *See* Rachel K. Jones & Heather D. Boonstra, *The Public Health Implications of the FDA Update to the Medication Abortion Label*, Guttmacher Inst. (June 30, 2016), https://perma.cc/X57B-DG27 (explaining that FDA's 2016 changes to mifepristone's conditions of use were supported by substantial evidence gathered since the drug's initial approval in 2000); *see generally* Br. of Over 300 Reproductive Health Researchers as *Amici Curiae* In Support of Petitioners, *FDA v. All. for Hippocratic Med.*, Nos. 23-235 & 23-236 (Jan. 30, 2024).

restrictions.[5] In 2007, Congress ratified and expanded on Subpart H. Food and Drug Administration Amendments Act (FDAAA) of 2007, 21 U.S.C. § 355-1; *see* FDAAA, Pub. L. No. 110-85, Tit. IX, § 901, 121 Stat. 922. These amendments authorized the Agency to require a Risk Evaluation and Mitigation Strategy or REMS when it finds that restrictions on use are necessary to meet FDA's safety and efficacy standards, which apply to every drug. *Id.* A REMS may impose Elements to Assure Safe Use (ETASU) such as requiring prescribing providers to have specific training or experience to prescribe the drug; mandating that a drug may only be dispensed in certain settings, for example, hospitals; or subjecting all patients of a drug to monitoring, subject to certain statutory constraints, including that an ETASU not be "unduly burdensome on patient access" and the ETASU must be designed to "minimize the burden on the health care delivery system . . . to the extent practicable."[6] *See* 21 U.S.C. § 355-1(f).

Under the FDAAA, any conditions needed "to assure safe use" established under Subpart H were automatically converted to a REMS with the same restrictions. *Id.* § 909(b), 121 Stat. at 950-51 (21 U.S.C. § 331 note). When FDA determines that new requirements are needed to assure safe use or that existing requirements are no

[5] Final Rule: New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval, 57 Fed. Reg. 58942, 58958 (Dec. 11, 1992) (codified at 21 C.F.R. §§ 314.500, 314.520).

[6] U.S. Food & Drug Admin., *What's in a REMS?*, https://www.fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/whats-rems.

longer necessary or should be modified to reduce the burdens of an ETASU, FDA may modify a drug's approved REMS. 21 U.S.C. §§ 355-1(f), (g), (h).

ARGUMENT

A. FDA Was Extremely Cautious In Approving Mifepristone And Subsequently Modifying Its REMS.

1. After Careful Review Confirming the Safety and Efficacy of Mifepristone, FDA Approved the Drug in 2000.

In 2000—after an intensive review spanning more than four years, at least 92 submissions by the drug sponsor, and a unanimous advisory committee vote in favor of approval—FDA approved mifepristone (under the brand name Mifeprex®) when used in combination with misoprostol as safe and effective to terminate pregnancy through the first seven weeks of gestation. *See* ROA.603–606. Pursuant to its authority under Subpart H, FDA placed restrictions on the drug's distribution, including a requirement that mifepristone be dispensed in person by or under the supervision of a physician with specified qualifications. *Id.*

Mifepristone's approval complied with the statute's evidentiary standard. FDA scientific and medical experts comprehensively reviewed the totality of scientific evidence and concluded that, with those distribution restrictions in place, the benefits of mifepristone clearly outweighed its risks. In reaching this conclusion, FDA experts performed an exhaustive review of large volumes of clinical trial data

across three rounds of review over the course of more than four years.[7] If anything, the external pressure and sensitivity surrounding the approval of mifepristone resulted in FDA taking particular care because the Agency knew that the drug's approval would face scrutiny. FDA was correct to assume that its approval of mifepristone would be scrutinized. Immediately after the 2000 Approval, several groups filed a citizen petition seeking reversal of the decision. ROA.485–576. In 2006, there was a Congressional hearing on the approval.[8] In 2008, the U.S. Government Accountability Office (GAO) confirmed that FDA's review and approval of mifepristone was consistent with the processes for other Subpart H drugs, recognizing that the details of FDA's approval depended on the unique risks and benefits of each drug.[9]

In its initial review, FDA compared the results of three mifepristone clinical trials—two from France and one from the United States—to reliable, well-

[7] *See generally* ROA.4465–519.

[8] *See* U.S. Gov't Publ'g Off., *RU-486: Demonstrating a Low Standard for Women's Health?: Hearing Before the Subcomm. on Crim. Just., Drug Pol'y, & Hum. Res. of the H. Comm. on Gov't Reform*, 109th Cong. (2006).

[9] ROA.4474.

documented data on pregnancy, including rates of miscarriage.[10] These trials included more than 4,000 patients across the different studies.[11]

FDA also convened an advisory committee of reproductive health drug experts to evaluate the data on mifepristone.[12] That committee voted six to zero, with two abstentions, that the benefits of mifepristone outweigh its risks and seven to zero, with one abstention, that mifepristone is safe.[13]

As is often the case, FDA did not approve mifepristone after the sponsor's initial submission. Instead, FDA denied approval twice to require and evaluate additional data and information from the drug sponsor. After completing those evaluations, FDA concluded, based on its own comprehensive review of the data and the advisory committee's recommendations, that mifepristone was safe and effective for use in terminating early-stage pregnancies subject to certain distribution restrictions.

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[10] ROA.4483–84. In evaluating new drug applications, FDA routinely considers studies conducted in other countries. By the time FDA approved mifepristone in 2000, the drug had already been approved for use in many other countries. Mifepristone had been approved in France, China, and the United Kingdom in the late 1980s and early 1990s, and by 1999, nearly a dozen more countries had followed suit. Today, mifepristone is available in at least 95 other countries. *See* Gilda Sedgh & Irum Taqi, *Mifepristone for Abortion in a Global Context: Safe, Effective and Approved in Nearly 100 Countries*, Guttmacher Inst., https://perma.cc/F9N8-2GVE.

[11] ROA.4483.

[12] ROA.4484–85.

[13] *Id.*

2. Consistent With the FDCA, FDA Regulations, and Mifepristone's Improved Safety Profile, FDA Amended the Drug's Postmarketing Restrictions in 2016.

The subsequent modifications to mifepristone's approved conditions of use were also driven by a straightforward and thorough application of the expert scientific review process that Congress entrusted to FDA. In May 2015, Danco Laboratories, L.L.C. (Danco), the drug's sponsor, submitted a supplemental new drug application proposing changes to mifepristone's conditions of use. In March 2016, following a comprehensive scientific review by numerous FDA scientific and medical experts who examined 16 years of experience with mifepristone, guidelines from professional organizations here and abroad, and clinical trials that had been published in the peer-reviewed medical literature since the drug's approval, FDA approved those changes. ROA.388–416.

Relying on safety and efficacy data from more than 20 studies, FDA increased the approved gestational age from seven to ten weeks. ROA.391, 395. Relying on additional studies, FDA also reduced the number of in-person clinical visits from three to one. ROA.395. Based on four studies including more than 3,000 patients, in 2016 FDA also modified the REMS to allow the sponsors to distribute the drug to a broader set of healthcare providers, rather than only physicians, to prescribe and dispense mifepristone (as the FDA permits for most drugs). ROA.412.

Finally, in that same year, FDA modified the requirement that prescribers of mifepristone report certain non-fatal adverse events such as hospitalizations and blood transfusions to mifepristone's manufacturers. ROA.415. After considering 15 years of adverse event reporting across more than 2.5 million patients since mifepristone's approval in 2000, which consistently demonstrated the drug's safety, FDA found that the reporting by prescribers of serious adverse events other than death could instead be collected in the periodic safety update reports and annual reports submitted by the drug's sponsor to FDA, which is the Agency's usual practice for prescription drugs. *Id.* FDA based its conclusion on studies showing that serious adverse events occurred very rarely, in less than 1% of cases. ROA.399–400. Although this change eliminated some, but not all, of the reporting requirements for prescribers, which typically are not required for prescription drugs, *infra* Part B. it did not impact reporting requirements for mifepristone's manufacturers, which remain the same. *Supra* Part A.

3. Based On 20 Years of Adverse Event Reporting and a Thorough Review of the Literature, FDA Adjusted the Drug's Postmarketing Restrictions in 2021 and 2023 to Remove the In-Person Dispensing Requirement.

In April 2021, during the COVID-19 pandemic public health emergency, after conducting a thorough review of the relevant data, FDA exercised its enforcement discretion with respect to the in-person dispensing requirement in mifepristone's REMS. FDA determined that the available data and information, including studies

regarding the use of telehealth, supported modification of the REMS to reduce the burden on the health care delivery system and to ensure that the benefits of the product outweighed its risks.[14]

Then, on January 3, 2023, following another thorough review by multiple scientists completed in December 2021, *see* ROA.1055, FDA amended mifepristone's REMS to remove the in-person dispensing requirement.[15] To support the 2023 REMS modification, FDA undertook a thorough assessment of the relevant evidence, including a literature review of 646 unique publications from the period from March 29, 2016 to July 26, 2021. ROA.1027–43. Of those publications, 15 assessed safety outcomes from various mifepristone delivery models in countries around the world, including prescribers sending mifepristone by mail; prescribers delivering mifepristone by courier; and pharmacies dispensing mifepristone in person or through the mail. *Id.* FDA found that these studies confirmed that no significant safety concerns would result from removal of the in-person dispensing requirement.

FDA also considered drug safety information collected during the COVID-19 Public Health Emergency, FAERS reports, REMS assessments, and information provided by advocacy groups, individuals, the plaintiffs in ongoing litigation, and

[14] ROA.6566–68.

[15] ROA.2893–905.

the manufacturers of mifepristone and its generic equivalent. *Id.* In its analysis of U.S. postmarketing data, FDA divided the FAERS data into time periods when FDA enforced the in-person dispensing requirement versus when FDA did not enforce the in-person dispensing requirement. FDA analyzed the eight cases of reported adverse events from January 2020 to April 2021. Based on its analysis of the postmarketing data and those cases, FDA determined that there was no difference in adverse events resulting from the removal of the in-person dispensing requirement.[16]

Plaintiffs-Appellants erroneously argue that FDA has conceded that "the studies [it] reviewed are *not adequate on their own* to establish safety of the model of dispensing mifepristone by mail," which "conclusively establishes that FDA's reliance on the studies was unreasonable." Pls.-Appellants' Br. at 58 (emphasis in original). But FDA did not rely on these studies "*on their own*," and instead considered the studies, which were largely consistent with the safety and efficacy outcome ranges in mifepristone's labeling, alongside other evidence, including "REMS assessment data, FAERS data from the time period when the in-person dispensing requirement was not being enforced, [their] review of the literature, *and* information provided by advocacy groups, individuals, [mifepristone's manufacturers], and the plaintiffs in the *Chelius v. Becerra* litigation." ROA.1093 (emphasis added).

[16] ROA.1055–1103.

B. Disregarding FAERS Data Would Upend FDA's Gold-Standard, Science-Based Drug Approval System.

Plaintiffs-Appellants argue that FDA wrongly gave dispositive weight to the lack of adverse event data in FAERS in the safety review, which according to Plaintiffs-Appellants is unreliable because FAERS relies (in part) on voluntary reporting by providers. Pls.-Appellants' Br. at 55. If accepted, this argument would undermine FDA's regulation of drugs since the Agency uses FAERS as the sole method of adverse event reporting for virtually all drugs after approval. Although, as FDA has long acknowledged, FAERS is not designed to capture every single adverse event, this is a feature that FDA takes into account as it makes decisions based on FAERS data. In any event, FDA requires greater monitoring of mifepristone's safety than it requires for most drugs. Like all other FDA-approved drugs, pursuant to FDA regulations, mifepristone's REMS continues to require mandatory reporting of adverse events by the manufacturers. But unlike most prescription drugs, for mifepristone FDA also requires mandatory reporting by prescribers when a fatality occurs, regardless of any evidence of causality. 21 C.F.R. §§ 314.80, 314.81. FDA routinely relies on data reported through the FAERS system to support its decision to modify or remove REMS or labels of other drugs, including those with Black Box warnings, like mifepristone.[17]

[17] *See, e.g.*, U.S. Food & Drug Admin., Lotronex sNDA Approval 2 (Sept. 8, 2023), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/021107s030ltr.pdf.

If accepted, Plaintiffs-Appellants' position that FDA is not entitled to rely on the lack of adverse-event data regarding mifepristone from FAERS because FAERS relies on voluntary physician reporting—as it does for virtually all other approved drugs—would upend FDA's rigorous, well-established system for drug approvals and other regulatory decisions. FDA has used adverse event reporting data in some form to inform its assessments of drug safety for over half a century.[18] In its expert judgment, FDA has determined that it is appropriate to only require mandatory reporting from manufacturers—not physicians—for the vast majority of approved drugs because this system generates sufficient data to inform the Agency about the safety profile of approved drugs. The orderly system that Congress and FDA have established would screech to a halt if litigants could weaponize the widely accepted limitations of FAERS data to support successful challenges to drug approvals. It would also be contrary to widely accepted legal principles. *See*, *e.g.*, *FCC v. Prometheus Radio Project*, 592 U.S. 414, 427 (2021) (explaining that an agency need not have perfect data to support its decisions).

[18] FAERS was launched in 2012 to succeed the legacy Adverse Event Reporting System, which had been established in 1969. Archived Reports | Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS) (formerly AERS), https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/archived-reports-potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event#:~:text=Reporting%20System%20(FAERS)-,Archived%20Reports%20%7C%20Potential%20Signals%20of%20Serious%20Risks/New%20Safety%20Information,(FAERS)%20(formerly%20AERS)&text=The%20following%20reports%20list%20potential,archived%20reports%20on%20this%20page.

Plaintiffs-Appellants point out that FDA has stated that "FAERS data *cannot* be used to indicate drug safety." Pls.-Appellants' Br. at 54–55 (emphasis in original). They also note that FDA has stated that FAERS data cannot be used to establish "rates of occurrence" for an adverse event and that "FAERS should not be used to determine the likelihood of a side effect occurring." *Id.* at 55. It is of course true that FAERS data is no substitute for the rigorous safety studies that are a prerequisite to the approval of a drug and that FAERS data alone are not sufficient for calculating the actual likelihood of an event occurring. But that was never the purpose of FAERS, and FDA's use of FAERS data in modifying the mifepristone REMS is consistent with these recognized limitations. Instead, the FAERS system is used to monitor information about a drug's safety after its approval by assessing any changes in the number of reported events. Based on this data, articles in the literature, FDA's scientific expertise, and other information, FDA may decide to increase or relax restrictions on using or marketing a drug after a drug is approved. This system has successfully protected the public health during the modern era of drug regulation while ensuring that important drugs are available. The Court should not permit Plaintiffs-Appellants to undermine that system by allowing parties that disagree with FDA's scientific judgment to challenge those decisions by arguing that the Agency's adverse reporting system is imperfect.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court affirm the district court's order denying Plaintiffs-Appellants' motion for a preliminary injunction.

Dated: July 21, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 21, 2026, the foregoing Brief of Former U.S. Food and Drug Administration Commissioners and Acting Commissioners as *Amici Curiae* in Support of Defendants-Appellees and Intervenor-Appellees was filed electronically and has been served via the Court's ECF filing system in compliance with Rule 25(b) and (c) of the Federal Rules of Appellate Procedure on all registered counsel of record.

/s/ William B. Schultz
Counsel for Amici Curiae

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 3,913 words, as counted by Microsoft Word, excluding the parts of the brief excluded by Federal Rule of Appellate Procedure 32(f). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word in 14-point Times New Roman font.

I further certify that (1) any required privacy redactions have been made, 5th Cir. R. 25.2.13; and (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1.

/s/ William B. Schultz
Counsel for Amici Curiae