No. 26-30203

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

THE STATE OF LOUISIANA, BY AND THROUGH ITS ATTORNEY GENERAL, LIZ MURRILL, AND ROSALIE MARKEZICH,

Plaintiffs-Appellants

v.

U.S. FOOD AND DRUG ADMINISTRATION, ET AL,

***Defendants-Appellees*.**

On Appeal from the United States District Court
for the Western District of Louisiana,
No. 6:25-cv-01491

BRIEF OF PHARMACEUTICAL AND BIOTECH COMPANIES, EXECUTIVES, AND INVESTORS AS *AMICI CURIAE* IN SUPPORT OF APPELLEES

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SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

State of Louisiana et al. v. Food and Drug Administration et al., No. 26-30203

Pursuant to Fifth Circuit Rules 28.2.1 and 29.2, the undersigned counsel of record certifies that, in addition to the persons and entities listed in the briefs of the parties, the following listed persons and entities as described in the fourth sentence of Fifth Circuit 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. Further, pursuant to Federal Rules of Appellate Procedure 26.1 and 29 (a)(4)(A), the undersigned counsel certifies the following corporate disclosures for the amici curiae organizations.

Amici Curiae Organizations

- Adventris Pharmaceuticals, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Adventris Pharmaceuticals, Inc.
- Aera Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Aera Therapeutics, Inc.
- Allay Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Allay Therapeutics, Inc.
- Amasa Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Amasa Therapeutics, Inc.
- Arsenal Biosciences, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Arsenal Biosciences, Inc.

- AuGC Partners LLC has no parent corporation. No publicly held corporation owns 10% or more of AuGC Partners LLC.

- AustinPx, LLC has no parent corporation. No publicly held corporation owns 10% or more of AustinPx, LLC.

- Banks Advisory L.L.C. has no parent corporation. No publicly held corporation owns 10% or more of Banks Advisory L.L.C.

- BioBrit, LLC has no parent corporation. No publicly held corporation owns 10% or more of BioBrit, LLC.

- Biocom California has no parent corporation. No publicly held corporation owns 10% or more of Biocom California.

- BioNJ Inc. has no parent corporation. No publicly held corporation owns 10% or more of BioNJ Inc.

- Bonum Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Bonum Therapeutics, Inc.

- C4 Therapeutics, Inc. (NASDAQ: CCCC) has no parent corporation. No publicly held corporation owns 10% or more of C4 Therapeutics, Inc.'s stock.

- Coffin and Shawver, LLC has no parent corporation. No publicly held corporation owns 10% or more of Coffin and Shawver, LLC.

- Daré Bioscience, Inc. (NASDAQ: DARE) has no parent corporation. No publicly held corporation owns 10% or more of Daré Bioscience, Inc.'s stock.

- Delix Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Delix Therapeutics, Inc.

- Digital Oxygen LLC has no parent corporation. No publicly held corporation owns 10% or more of Digital Oxygen LLC.

- Disruptive Biomedical, LLC has no parent corporation. No publicly held corporation owns 10% or more of Disruptive Biomedical, LLC.

- Dunad Therapeutics US, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Dunad Therapeutics US, Inc.

- Facet Life Sciences LLC has no parent corporation. No publicly held corporation owns 10% or more of Facet Life Sciences LLC.

- Foghorn Therapeutics, Inc. (NASDAQ: FHTX) has no parent corporation. No publicly held corporation owns 10% or more of Foghorn Therapeutics, Inc.'s stock.

- Glya Health Inc. has no parent corporation. No publicly held corporation owns 10% or more of Glya Health Inc.

- HealthCare Institute of New Jersey has no parent corporation. No publicly held corporation owns 10% or more of HealthCare Institute of New Jersey.

- Immunitas Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Immunitas Therapeutics, Inc.

- insitro, Inc. has no parent corporation. No publicly held corporation owns 10% or more of insitro, Inc.

- Kapis Biosciences, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Kapis Biosciences, Inc.

- Katogen LLC has no parent corporation. No publicly held corporation owns 10% or more of Katogen LLC.

- Katrina Rogers Consulting LLC has no parent corporation. No publicly held corporation owns 10% or more of Katrina Rogers Consulting LLC.

- KNI Health Consultants, LLC has no parent corporation. No publicly held corporation owns 10% or more of KNI Health Consultants, LLC.

- Lisata Therapeutics, Inc. (NASDAQ: LSTA) has no parent corporation. No publicly held corporation owns 10% or more of Lisata Therapeutics, Inc.'s stock.

- Lorien Advisors LLC has no parent corporation. No publicly held corporation owns 10% or more of Lorien Advisors LLC.

- Lucius Partners, LLC has no parent corporation. No publicly held corporation owns 10% or more of Lucius Partners, LLC.

- Luvantas, Inc. is the wholly owned subsidiary of Medytox, Inc. Medytox, Inc. is a publicly traded company (Korea Exchange).

- Matrix Biomed, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Matrix Biomed, Inc.

- Michigan Biosciences Industry Association (MichBio) has no parent corporation. No publicly held corporation owns 10% or more of Michigan Biosciences Industry Association.

- Nkarta Inc. (NASDAQ: NKTX) has no parent corporation. No publicly held corporation owns 10% or more of Nkarta Inc.'s stock.

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- PeriphaGen, Inc. has no parent corporation. No publicly held corporation owns 10% or more of PeriphaGen, Inc.

- Phoenix Molecular Designs Ltd. has no parent corporation. No publicly held corporation owns 10% or more of Phoenix Molecular Designs Ltd.

- Princeton Biomedical Communications LLC has no parent corporation. No publicly held corporation owns 10% or more of Princeton Biomedical Communications LLC.

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- ReCode Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of ReCode Therapeutics, Inc.

- Rhythm Pharmaceuticals, Inc. (NASDAQ: RYTM) has no parent corporation. No publicly held corporation owns 10% or more of Rhythm Pharmaceuticals, Inc.'s stock.

- Samsara Biocapital, LLC has no parent corporation. No publicly held corporation owns 10% or more of Samsara Biocapital, LLC.

- Science Futures Management Co. LLC has no parent corporation. No publicly held corporation owns 10% or more of Science Futures Management Co. LLC.

- Selectin Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Selectin Therapeutics, Inc.

- Siolta Therapeutics, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Siolta Therapeutics, Inc.

- Trace Neuroscience, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Trace Neuroscience, Inc.

- Vedanta Biosciences, Inc. has no parent corporation. No publicly held corporation owns 10% or more of Vedanta Biosciences, Inc.

- Xencor, Inc. (NASDAQ: XNCR) has no parent corporation. BlackRock, Inc. (NYSE: BLK) owns more than 10% of Xencor, Inc.'s stock.

- Zola Therapeutics Inc. has no parent corporation. No publicly held corporation owns 10% or more of Zola Therapeutics Inc.

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Pursuant to Fed. R. App. P. 29(a)(2), counsel for Plaintiffs-Appellees and Defendants-Appellants have consented to the filing of this brief.

STATEMENT OF INTEREST OF AMICUS CURIAE[1]

Amici curiae are pharmaceutical and biotech companies and executives and pharmaceutical-industry associations and investors from across the United States. A full list of *Amici* appears above in the Supplemental Certificate of Interested Persons. As pharmaceutical and biotech companies, executives, and participants *Amici* are deeply familiar with the high costs associated with drug development and improvement. *Amici* are also acutely aware of the need for clarity, certainty, and stability in the regulatory framework governing drug approval and post-approval changes. As a result, they are well positioned to explain to this Court how staying the 2023 REMS will not only undermine market participants' ability to rely on FDA's scientific and evidence-based approval decisions and chill drug development, but will also negatively impact patients by reducing access and increasing drug costs.

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

INTRODUCTION AND SUMMARY OF ARGUMENT

FDA-approved drugs should not be subject to judicial recall. When FDA determines that a drug is safe and effective, clinicians and patients should have access on those terms. Courts should not pull drugs from patients' hands because they disagree with FDA's scientific and evidence-based judgment. Plaintiffs' attack on FDA's well-founded scientific judgment would wreak havoc on the American pharmaceutical and biotech industry.

Pharmaceutical and biotech developers and investors pour billions of dollars and years of effort to develop new drugs, bring them to market, and improve them. They do so on the promise of a predictable, science-based regulatory process: if the evidence shows a drug is safe and effective, FDA will approve it, and apply appropriate restrictions based on the existing scientific evidence. This promise has made the United States the global leader in pharmaceutical and biotech innovation and saved countless lives. This is the system Congress designed, and it serves as the foundation for investment in new drugs. This system depends on the pharmaceutical and biotech industry's trust that drug regulation will be driven by science, not by litigants seeking to restrict the availability of safe and effective medications based on their own ideological objections.

Plaintiffs attack FDA's determination that mifepristone is safe when not dispensed in person. FDA's determination is backed by ample evidence and thorough analysis. Plaintiffs urge this Court to supplant FDA's evidence-based, scientific judgment with Plaintiffs' own non-expert views.

If Plaintiffs succeed, the consequences will not be confined to mifepristone. Every drug will rest on a shakier foundation. FDA's ability to rely on the kinds of evidence that once justified greater patient access will now be in doubt. Reliance on FDA's approval decisions will be undermined. Investment in new drug development will falter. Drug costs will rise. Patients will suffer.

Amici are pharmaceutical and biotech companies, executives, and investors who depend on regulatory stability to bring life-saving drugs to market. They urge this Court to reject Plaintiffs' invitation to upend that system.

ARGUMENT

I. Congress authorized science-based regulation of drug safety and effectiveness.

With each drug introduced to the American pharmaceutical and biotech market there is a complex, capital-intensive, multi-step, multi-year process of scientific discovery, research, testing, application, review, approval, and monitoring. This requires the pharmaceutical and biotech industry to undertake enormous investment and risk. Approximately 12 percent of drugs that begin clinical trials are

ultimately approved by FDA.[2] On average it costs around $2 billion to develop each new drug that is brought to market.[3] These costs have risen over the last ten years due to numerous factors including the costs associated with "meeting evolving regulatory standards."[4] While specific costs associated with changing regulatory burdens are difficult to determine, studies indicate that drugmakers incur significant additional research and development expenses to navigate expanded regulatory review.[5] Even repurposed drugs carry significant costs due to complex and time-consuming regulatory review.[6]

Regulatory approval is rooted in scientific rigor. Drug developers and investors submit to this process because they trust that drug approvals and regulations will be based on science.

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[2] Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 2 (Apr. 2021), https://www.cbo.gov/system/files/2021-04/57025-Rx-RnD.pdf.

[3] Joseph A. DiMasi, et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 27, 31 (2016); Karen Taylor et al., *Be Brave, Be Bold: Measuring the Return from Pharmaceutical Innovation* 6 (15th ed., Deloitte Ctr. for Health Sols., Mar. 2025), https://www.deloitte.com/content/dam/assets-shared/docs/industries/life-sciences-health-care/2025/deloitte-measuring-return-from-pharmaceutical-innovation-2025.pdf.

[4] Taylor, *supra* note 3, at 6; Cong. Budget Off., *supra* note 2, at 2, 4.

[5] DiMasi, *supra* note 3 at 32 (2016).

[6] K. Saranraj & P. Usha Kiran, *Drug Repurposing: Clinical Practices and Regulatory Pathways*, 16 Persps. in Clinical Rsch. 61, 65 (2025).

Congress designed just such an evidence-based regulatory scheme with FDA at the helm. Pursuant to the federal Food, Drug, and Cosmetic Act ("FDCA"), Congress tasked FDA with determining that all drugs introduced into interstate commerce in the United States are safe and effective under the conditions of use described in each drug's labeling. 21 U.S.C. § 355. In accordance with the FDCA, FDA's primary mandate is to ensure that the United States' drug approval and review regime is evidence-based. 21 U.S.C. § 393(b). "FDA's biggest contribution to health has been through its progress in evidence-based medicine."[7]

At every step of drug approval and review, Congress charged FDA with using evidence-based medicine to ensure patients have access to safe, effective drugs.[8] Drug sponsors must begin with the new drug application ("NDA") process. FDA employs one of the most rigorous NDA processes in the world, requiring new drug

[7] Michelle Meadows, *Promoting Safe & Effective Drugs for 100 Years*, FDA Consumer Mag. 1 (Jan.-Feb. 2006), https://www.fda.gov/media/110482/download?attachment (quoting Steven Galson, M.D., former director of FDA's Center for Drug Evaluation and Research).

[8] *See, e.g.*, Federal Food, Drug and Cosmetic Act, Pub. L. No. 75-717, § 201(p), 52 Stat. 1040, 1041-42 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*) (requiring FDA to determine a new drug is safe before it can be marketed); Drug Amendments Act of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781–82 (1962) (codified as amended at various sections of 21 U.S.C. § 301 *et seq.*) (requiring FDA determine that a drug is effective before it can be marketed); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (codified as amended at various sections of 21 U.S.C. § 301 *et seq*) (requiring FDA determine that a drug is effective before it can be marketed); Food and Drug Administration Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993 (2012) (codified as amended at various sections of 21 U.S.C. § 301 *et seq*) (affirming FDA's role in determining the conditions under which a drug should be made available to the public); *see also* 21 U.S.C. § 355(c)-(d).

sponsors to demonstrate, after initial trials, that the drug is safe and effective for its intended use(s) and that the benefits of the drug outweigh the risks.[9] Only then will a proposed new drug be approved for sale in the United States. By reviewing NDAs and trial results, FDA "ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks."[10] Inherent in this approval structure is the Congressional acknowledgement that no drug is risk free. *See, e.g.*, 21 U.S.C. § 355-1(a)(1).

Congress also authorized FDA to impose additional restrictions (either at approval or after) on certain drugs via a Risk Evaluation and Mitigation Strategy ("REMS"). 21 U.S.C. § 355-1. A REMS may be imposed only if FDA determines it is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." *Id.* § 355-1(a)(1). In making a REMS determination FDA must consider, among other things, the benefits of the drug, the size of the population that would benefit from the drug, and the seriousness of known or potential adverse events. *Id.* As part of a REMS, Elements to Assure Safe Use ("ETASU") may be imposed because of a drug's "inherent toxicity or potential harmfulness" if the drug "has been shown to

[9] *New Drug Application (NDA)*, U.S. FDA, https://www.fda.gov/drugs/types-applications/new-drug-application-nda (last visited Apr. 22, 2026).

[10] *Development & Approval Process | Drugs*, U.S. FDA, https://www.fda.gov/drugs/development-approval-process-drugs (last visited Apr. 22, 2026).

be effective, but is associated with a serious adverse drug experience" that can only be mitigated by ETASU. *Id.* § 355-1(f)(1). ETASU can include requiring prescribers to have specific training or certification; limiting the settings in which a drug can be dispensed (*e.g.*, hospitals only); or requiring the patients receiving the medicine to be subject to monitoring. *Id.* § 355-1(f)(3).

Congress required that REMS and ETASU distribution restrictions must be carefully calibrated to minimize interference with patient access. If REMS and ETASU distribution restrictions are necessary, they must be "commensurate with" the drug's identified risks; "not be unduly burdensome on patient access;" and must be designed to "minimize the burden on the health care delivery system." 21 U.S.C. § 355-1(f)(2). When considering the burdens of REMS restrictions, FDA must consider "in particular" burdens placed on "patients with serious or life-threatening diseases or conditions"; "patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)"; and "patients with functional limitations." 21 U.S.C. § 355-1(f)(2)(c). In imposing REMS restrictions FDA must "seek input from patients, physicians, pharmacists, and other healthcare providers" to reduce burdens on the health care delivery system. *Id.* § 355-1(f)(5)(A).

The statute acknowledges that a new drug's safety profile may evolve over time, and requires FDA to continuously review the REMS and remove restrictions

that are no longer necessary. *See* 21 U.S.C. § 355-1(f)(5), (g). "FDA may release a REMS or remove certain components of a REMS, if, after review of REMS assessments or other information, [FDA] determine[s] that the extra measures in a REMS are no longer necessary to ensure a medication's benefits outweigh its risks."[11]

The information FDA considers in determining whether to modify a REMS can come from many sources. After approval for sale, FDA continues to monitor the safety of the drug. For nearly all FDA-approved drugs, drug sponsors are required to develop programs to monitor, and submit information on, adverse events through the FDA Adverse Event Reporting System Database ("FAERS").[12] FAERS is FDA's official post-marketing safety surveillance program. It is designed so that drug manufacturers are *required*, under 21 C.F.R. § 314.80, to monitor for and report to FDA any adverse drug events. Specifically, drug manufacturers have a duty to (i) "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse[13] drug experiences to FDA"; (ii) "promptly

[11] *Frequently Asked Questions (FAQs) about REMS*, U.S. FDA, http://fda.gov/drugs/risk-evaluation-and-mitigation-strategies-rems/frequently-asked-questions-faqs-about-rems (last visited Apr. 22, 2026).

[12] Most drugs are not subject to an additional physician reporting requirement.

[13] 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

review all adverse drug experience information" obtained; and (iii) report adverse drug experience information to FDA, either on a 15-day or quarterly basis, depending on the severity of the experience. 21 C.F.R. § 314.80(b)-(c). Other participants in the market, such as consumers and healthcare professionals, may also submit adverse events they identify to the FAERS database, although they are not required to do so by statute.[14] While FAERS data—like all data sources—is not perfect, its mandatory nature and broad scope make it a useful and reliable tool that FDA relies upon for all approved drugs.[15]

When reviewing the safety of approved drugs and any REMS or ETASU, in addition to the FAERS data, FDA can and does consider safety information from other sources, including science-based literature and safety studies based on usage

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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.

[14] *See FDA Adverse Event Reporting System (FAERS) Database*, U.S. FDA, https://www.fda.gov/drugs/drug-approvals-and-databases/fda-adverse-event-reporting-system-faers-database (last visited Apr. 22, 2026).

[15] C. Lee Ventola, *Big Data and Parmacovigilance: Data Mining for Adverse Drug Events and Interactions*, 43 Pharmacy & Therapeutics 340, 343, 347 (2018) ("SRS report databases, such as FAERS, provide a valuable source of data for drug safety surveillance efforts"); Emeri Potter, et al., *FDA Adverse Event Reporting System (FAERS) Essentials: A Guide to Understanding, Applying, and Interpreting Adverse Event Data Reported to FAERS*, 118 Clinical Pharmacology & Therapeutics 567, 579 (2025) ("FAERS is a powerful tool for drug safety surveillance and assessment, as evidenced by the fact that FAERS data are often used to make safety labeling changes. [] Understanding the structure, strengths, and limitations of the FAERS database is necessary for drawing scientifically and medically accurate conclusions.") (footnotes omitted).

data, not just from the United States, but also from around the world. It is FDA's job to take all the scientific information available to it—from clinical studies to FAERS data—and evaluate that information according to its scientific reliability to determine whether the burden of the REMS is commensurate with the known risks, while not burdening patient access. *See* 21 U.S.C. § 355-1(f)(2).

The regulatory framework that Congress designed requires science to form the cornerstone of FDA's NDA, REMS, and ETASU decisions. An evidence-based foundation for regulation, which evolves as new information is learned and gathered from reliable sources, protects both patients and the pharmaceutical and biotech industry.

II. The 2023 REMS modification to remove the in-person dispensing requirement is a science-backed determination that should not be displaced by Plaintiffs' unscientific second-guessing.

The best scientific evidence supports the 2023 REMS modification regarding in-person dispensing of mifepristone. Consistent with the congressionally mandated REMS framework, in approving the 2023 REMS modification lifting the in-person dispensing requirement, FDA examined extensive evidence and reached an evidence-based determination implementing precisely what the statute requires: targeted measures necessary to ensure that a drug's benefits outweigh its risks, while

ensuring patient access. FDA's science-backed determination should not be supplanted by Plaintiffs' unscientific second-guessing.

Context as to the timeline of FDA's decisions is helpful here. In April 2021, FDA made the evidence-based decision that it would not enforce the in-person dispensing requirement for mifepristone during the COVID-19 pandemic. ROA.259-60. Based on a review of additional safety data during the COVID-19 pandemic, FDA then announced on December 16, 2021, that it would permanently remove the in-person dispensing requirement for mifepristone, which was memorialized in the formal modification to the mifepristone REMS in January 2023. ROA.372, ROA.985.

FDA exercised evidence-based scientific judgment when it removed the in-person dispensing requirement. It canvassed a comprehensive scientific record—including pharmacovigilance data (from FAERS and elsewhere), peer-reviewed studies, and the broad range of information captured by the REMS program ("healthcare provider certification data, program utilization data, compliance data, audit results, and patient exposure data"). ROA.1022-45. It specifically examined the effect of in-person dispensing in multiple ways, including by parsing adverse-event data from periods when the in-person requirement was and was not enforced, and analyzing peer-reviewed studies of non-in-person dispensing models. *Id.* It found no difference in adverse events attributable to non-enforcement of the in-person

dispensing requirement. ROA.984, ROA.1022-27. It found no new safety concerns under real-world use. *Id.* And it found—from an extensive literature review of 646 publications—that non-in-person delivery models maintain efficacy without a meaningful increase in serious adverse events. ROA.1027-39, ROA.1041-43.

FDA's approach to the in-person dispensing requirement bears the hallmarks of quality science. Its data was objective. Its literature was peer-reviewed. It examined multiple sources of evidence and considered the limitations of each. That rigorous approach is exactly what Congress entrusted FDA to carry out.

Plaintiffs' critiques provide no basis for overriding this considered scientific judgment. If accepted, these critiques would upend safety surveillance and drug development—wreaking havoc far beyond this case.

Plaintiffs contend FDA should not rely on FAERS data to assess safety. *See* Opening Br. 54-57. If this rule were adopted, it would devastate drug development. FAERS is the very system Congress created to facilitate drug-safety decisions. 21 U.S.C. § 355(k). FDA, drug manufacturers, and others rely on FAERS data to assess drug safety and effectiveness for *all* of the more than 20,000 drugs that FDA has approved.[16] Barring reliance on FAERS would not only cast aside Congress's

[16] *See* U.S. FDA, Off. of the Comm'r, *Regulated Products and Facilities* (Nov. 2020), https://www.fda.gov/media/143704/download; *see also* 21 C.F.R. § 314.80.

judgment, but it would also hamstring FDA's scientific decision making by depriving it of a crucial data source.

Plaintiffs' attack on the FAERS data with respect to mifepristone is also misplaced. Contrary to Plaintiffs' suggestion (Opening Br. 54-57), the FAERS data on mifepristone is not unusually thin. Just the opposite: mifepristone has *more* adverse-event reporting requirements than the vast majority of other drugs, even after the 2016 REMS modification. What actually happened in 2016 is that after fifteen years of intensive, enhanced monitoring, FDA pared back *some* of the *heightened* reporting requirements it had imposed on prescribers of mifepristone—as it was required to do, *see* 21 U.S.C. § 355-1(f), (g). But, even after doing so, FDA continued to impose a mifepristone reporting requirement on prescribers that does not exist for over 99% of other FDA-approved drugs. ROA.391-2, ROA.414-15; 21 C.F.R. § 314.80(c). Moreover, even the baseline FAERS reporting requirements required for all drugs are extensive and allow FDA to capture a comprehensive set of data after a drug's approval. A drug sponsor must "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." 21 C.F.R. § 314.80(b). And it must review "*all* adverse drug experience information" received from "*any* source." *Id.* (emphases added). This includes reports the sponsor receives from clinicians and patients, "information

derived from commercial marketing experience," "reports in the scientific literature," and even "unpublished scientific papers." *Id.* In addition, patients and healthcare providers routinely submit voluntary reports directly to FDA.

FAERS data is a key part of the evidentiary puzzle for any scientific judgment about drug safety, and FDA properly relied on it—as one among several sources—when removing the in-person dispensing requirement. To deem FDA's reliance arbitrary or capricious would cast a pall of uncertainty over drug development and post-approval modifications. It would threaten to prevent the agency from *ever* loosening REMS reporting requirements—no matter how unnecessary and burdensome on patient access—thus frustrating FDA's ability to comply with the statutory requirements that Congress has imposed. And it would erect an unjustified and unscientific barrier to updating approved drugs to keep pace with science.

Plaintiffs also take issue with FDA's reliance on published literature because it was "not inconsistent with" the conclusion that mifepristone is safe without in-person dispensing. *See* Opening Br. 58. But considering all quality evidence, including published literature, is a hallmark of science-backed decision making. Congress itself expressly contemplated leveraging published literature to support approval decisions. *See* 21 U.S.C. § 355(b)(2). FDA did exactly what it should: it analyzed the studies, identified their specific limitations, and accounted for those

limitations in reaching its scientific conclusion. ROA.1078-90, ROA.1092-94. This evaluation (and FDA's conclusions, first in 2021, and then in the 2023 REMS) is especially appropriate given that more than twenty years of data and millions of patient uses of mifepristone conclusively establish it is safe and serious adverse events are very rare. ROA.399-400.

Plaintiffs would replace all this evidence with decidedly unscientific sources. They cite, for example, a "study"[17] that is neither reproducible, unbiased, peer reviewed, nor free from conflicts of interest.[18] This paper does not meet FDA's

[17] *See* ROA.91 at n.18) (citing Ex. 13, Jamie Bryan Hall & Ryan T. Anderson, *The Abortion Pill Harms Women: Insurance Data Reveals One in Ten Patients Experiences a Serious Adverse Event*, Ethics & Pub. Pol'y Ctr. at 1 (Apr. 28, 2025)).

[18] *See, e.g.*, UCLA Sch. of L. Ctr. on Reprod. Health, L., & Pol'y, Comment Letter in Support of Pending Mifepristone Citizen Petitions 7-19 (Aug. 27, 2025), https://downloads .regulations.gov/FDA-2025-P-0377-0230/attachment_1.pdf. (explaining in detail how the Ethics and Public Policy Center paper is "not verifiable or reproducible and suffers multiple methodological flaws" (capitalization altered)); *see also, e.g.*, Brief of Amici Curiae 360 Reproductive Health Researchers in Support of Applications by Danco and GenBioPro to Stay or Vacate the Fifth Circuit's Stay Pending Appeal, *Danco Lab'ys, LLC*, No. 25A1207, 25A1208, at 20-25 (S. Ct. May 6, 2026) (citing Kessler, Digging Into the Math of a Study Attacking the Safety of the Abortion Pill, Wash. Post (May 12, 2025), https://www.washingtonpost.com/politics/2025 /05/12/abortion-pill-medication-abortion-study-mifepristone; Landman, A Convenient Piece of Junk Science, The Atlantic, (May 24, 2025), https://www.theatlantic.com/health/archive /2025/05/mifepristone-abortion-rfk-fda/682939); *and* Ian Lopez, *RFK Jr. Says Biden 'Twisted the Data' on Abortion Pill Safety,* Bloomberg L. (Sep. 4, 2025, at 12:45 ET), https://news.bloomberglaw.com/health-law-and-business/rfk-jr-says-biden-twisted-the-data-on-abortion-pill-safety, (cited at ROA.2596 (W.D. La. No. 6:25-cv-1491, ECF No. 20-26 at 15). As the FDA Staff Manual Guide states, "[n]o concern is more central to the proper functioning of FDA than the need to ensure that the science underlying agency decisions is sound." U.S. FDA, *FDA Staff Manual Guides, Volume IV Agency Program Directives*, at 1 (Aug. 15, 2025) https://www.fda.gov/files/about%20fda/published/9001_internet_ 08.15.2025.pdf.

promise to consider only "Gold Standard Science" when evaluating the safety and effectiveness of drugs, which is science that is "reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of its findings and assumptions; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest."[19]

In sum, in criticizing the 2023 REMS modification removing the in-person dispensing requirement, Plaintiffs advocate for (1) the *rejection* of FAERS data, on which the entire pharmaceutical industry has long relied, and (2) the *acceptance* of an unverifiable and non-reproducible "study" that is not "Gold Standard Science." This non-scientific approach would upend the regulatory system Congress designed to evolve with science, ossifying outdated regulations and diminishing patient access by depriving patients of modern care pathways.

III. Uncertainty in drug approval and regulation threatens to upend the pharmaceutical and biotech industry.

The American pharmaceutical and biotech industry relies on a consistent, evidence-based drug approval process that new drug makers can reliably navigate. Unscientific second-guessing would inject uncertainty, increasing research and

[19] U.S. FDA, *FDA Staff Manual Guides, Volume IV, supra* note 18, at 2. Nor does it satisfy the standards of "Gold Standard Science" recently set forth by Executive Order. *See* Exec. Order No. 14,303, 90 Fed. Reg. 22601 (May 29, 2025).

development costs, increasing ongoing compliance costs, and decreasing productivity.

Drug approval and distribution is *already* subject to access restrictions that Congress has entrusted FDA to determine through evidence-based review by medical and scientific experts. Plaintiffs' claims, if successful, would create uncertainty in the drug regulation process that would limit drug innovation and development, depriving the public of critical life- and health-preserving medications. Companies that invest in drug research and development must be able to rely on the science-based approval processes that Congress designed, and that FDA has executed for the last 50 years.

a. Uncertainty in drug regulations will chill investment in drug development and innovation.

Scientific innovation in the pharmaceutical and biotech industry is a key driver of American economic growth. New and improved drug offerings not only save lives but also power the American economy. For example, of the $47.49 billion the National Institutes of Health ("NIH") invested in scientific research in 2025, every $1 generated $2.57 in economic activity.[20] This economic activity extends

[20] United for Med. Rsch., *NIH's Role in Sustaining the U.S. Economy: Creating Jobs and Strengthening Local Economies* 2 (2026), https://www.unitedformedicalresearch.org/wp-content/uploads/2026/03/UMR_2026-Annual-Economic-Report-FY2025.pdf.

nationwide, including supporting more than 390,000 jobs in 2025 alone.[21] The billions of dollars invested annually in government-funded scientific research are complemented by private investment. Pharmaceutical and biotech companies devoted approximately $116 billion to research and development in 2022.[22] This spending supported 172,000 domestic research and development jobs and 664,000 total domestic jobs.[23]

This investment depends on regulatory predictability, including the expectation of a reliable revenue stream after FDA approval. FDA's established regulatory framework, including the strict statutory standards for REMS and ETASU, provides critical stability and assurance to companies and investors who fund the development of drugs and seek a return on their investment. If FDA's evidence-based processes become subject to override by unscientific and ideologically driven sources, the economic returns on drug development would become less predictable and more risky. That increased risk threatens to deter

[21] *Id.*

[22] Letter from Philip L. Swagel, Dir., Cong. Budget Office, to the Honorable Jeffrey A. Merkley et al., Ranking Members, Committee on the Budget, U.S. Senate 3 (July 18, 2025), https://www.cbo.gov/system/files/2025-07/61373-Drugs.pdf; Arthur Hughes, *Business R&D Performance in the United States nears $700 Billion in 2022,* Nat'l Ctr. for Sci. & Eng'g Stats., (Sept. 30, 2024), https://ncses.nsf.gov/pubs/nsf24334.

[23] Hughes, *supra* note 22.

investment in research and development of new drugs, depriving the public of new drug offerings and the economic benefits of drug development.

b. Uncertainty in drug regulation will increase drug costs.

Regulatory uncertainty will drive up drug costs. While multiple factors contribute to high drug prices in the United States, slow and uncertain regulatory processes are chief among them. For example, FDA approval delays contribute to higher consumer drug prices by raising the barriers to entry, thereby reducing marketplace competition.[24] Drug makers must also price in both the chances a new drug will work and the chances the regulator agrees that the new drug works.[25]

By contrast, timely resolution of drug applications and regulatory clarity reduce drug prices. As recent efforts from across the political spectrum demonstrate, there is widespread recognition that reducing unnecessary regulatory barriers is critical to increasing competition and patient access.[26] For example, research shows

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[24] David A. Hyman & Charles Silver, *Why Are We Being Overcharged for Pharmaceuticals: What Should We Do about It*, 39 J. Legal Med. 137, 141-42 (2019).

[25] Stephanie Rennane et al., *Estimating the Cost of Industry Investment in Drug Research & Development: a Review of Methods and Results*, 58 J. Health Care Org., Provision, & Fin. 1, 9-10 (2021) (noting research and development costs cited as basis for not regulating drug prices); Ariel Dora Stern, *Innovation under Regulatory Uncertainty: Evidence from Medical Technology*, 145 J. Pub. Econ. 181, 183, 193-94 (2017) (discussing regulatory uncertainty in the context of medical device applications).

[26] *See, e.g.*, U.S. Dep't Health & Hum. Servs., Off. of the Assistant Sec'y for Plan. & Evaluation, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy* 20 (2021), https://aspe.hhs.gov /sites/default/files/2021-

that when drug makers have greater clarity regarding the regulatory process for a new drug, the time needed for FDA approval is likely to decrease.[27] A regulatory regime untethered from evidence-based decision-making will increase drug prices as a result of the greater uncertainty.

c. An unstable drug-regulation regime burdens the entire healthcare delivery system.

The consequences of an unstable drug regulation regime extend beyond increased patient costs. Congress designed drug regulation to evolve with science through structured, evidence-based procedures administered by FDA. That foundation begins to crumble when ideologically motivated litigants attempt to override FDA's authority based on mere disagreement with the agency's science-backed conclusion. The resulting instability and regulatory burdens for clinicians and patients will make it impossible for the healthcare system to plan or operate effectively.

Reporting requirements are a good example. FDA may impose heightened

09/Drug_Pricing_Plan_9-9-2021.pdf ("Bringing greater transparency to the generic drug review process, as well as removing barriers to generic drug development and market entry, supports patients' access to the medicines they need at affordable prices."); Katherine L. Gudiksen & Jaime S. King, *The Burden of Federalism: Challenges to State Attempts at Controlling Prescription Drug Costs*, 39 J. Legal Med. 95, 96 (2019) (describing Trump administration plan to improve competition in drug market in response to public outcry regarding rising drug prices).

[27] Stern, *supra* note 25 at 192-94 (discussing effects of regulatory clarity in context of medical device applications).

reporting requirements on healthcare providers if necessary to assure safe use of a particular drug. *See* 21 U.S.C. § 355-1(f)(3). For example, reporting requirements on mifepristone are heightened under both the 2016 and 2023 REMS.[28] FDA must periodically reassess those requirements to confirm they remain necessary, modifying them as needed to reduce the burden on the healthcare system. 21 U.S.C. §§ 355-1(f)(5), (g)(4)(B)(ii). This framework ensures changes to reporting requirements are evidence-based, carefully calibrated, and *predictable*.

Reporting requirements for mifepristone have evolved according to that framework. The original approval of mifepristone in 2000 imposed heightened reporting requirements on physicians. In the more than twenty years since original approval, FDA removed certain unnecessary and burdensome reporting over time as it accumulated additional safety data (though certain heightened reporting requirements remain).

Yet Plaintiffs would prefer to bypass the statutory framework based on a fiction that FAERS data is incomplete and unreliable. Plaintiffs' position would upend routine FDA reliance on FAERS data, which is not designed to capture all adverse events. *See* ROA.6563. But FDA does not take FAERS data at face value and

[28] *See* ROA.389-416, ROA.963-1054.

instead evaluates it with its limitations in mind.[29] FDA need not impose additional reporting requirements that are not warranted by historical data, scientific analysis, or agency expertise. That would force providers to divert significant time and resources from patient care to heightened reporting requirements that do not serve patient health or safety. IT and compliance teams will similarly be pulled from patient-centered duties to develop new reporting procedures and systems.[30] The result is not better care. It is more paperwork, more expense, fewer resources for patients, and greater strain on a healthcare delivery system that is already stretched thin.

Plaintiffs' claims also threaten telehealth, which has become an integral part of modern healthcare. The benefits of telehealth are extensive: increased patient access, decreased strain on in-person resources, greater access to critical medications, and lower costs. Healthcare providers have invested heavily in telehealth infrastructure to reap those benefits. And, in our modern world, patients

[29] Potter, et al., *supra* note 15, at 574, 576-79 (describing FDA practices for evaluating, using, and supplementing FAERS data based on its limitations).

[30] *See generally* Am. Hosp. Ass'n, *Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals and Post-acute Care Providers* 4, 24 (Oct. 2017), https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf.

have come to rely on it.[31] As both the practical and scientific case for telehealth strengthened, FDA modified mifepristone's in-person requirements—over years, through the evidence-based process Congress prescribed. These changes have increased patient satisfaction and accessibility without undermining safety. *See, e.g.*, ROA.6731-36.

Plaintiffs seek to pull from patients and providers what science indicates is safe and effective. A system that removes telehealth access on an *ad hoc* basis—untethered from science, agency expertise, or congressionally mandated processes—causes demonstrable harm to both providers and patients. In a system where mifepristone can only be dispensed at physical clinics and no longer through mail or from a pharmacy, patients prescribed mifepristone will tax the capacities of physical clinics and patients in "rural or medically underserved areas"—whose access Congress mandated must be considered (21 U.S.C. § 355-1(f)(2)(c)(ii))—will be disproportionately burdened. The emergency nationwide relief sought in this case provides a stark example of the regulatory whiplash that can occur through court intervention to block patient access to scientifically approved drugs. Here, patients lost access to mifepristone dispensed by mail or at a pharmacy on a Friday, only to

[31] *See, e.g.*, Am. Med. Assoc., *Issue Brief: The Case for Permanent Telehealth Policy and Expanded Access to Virtual Care* (Dec. 2025), https://www.ama-assn.org/system/files/issue-brief-telehealth-policy-expanded-access-to-virtual-care.pdf; Rhea E. Powell, et al., *Patient Perceptions of Telehealth Primary Care Video Visits*, 15 Annals Fam. Med. 225, 227 (2017).

have it restored (provisionally) on a Monday. *See Louisiana v. FDA*, 175 F.4th 310, 314 (5th Cir. 2026); *Danco Lab'ys, LLC v. Louisiana*, 146 S. Ct. 1192, 1192 (2026). As a result, patients bear the greatest burden.

A similar pattern repeats whenever a court sidesteps FDA's evidence-based regulatory decision. Providers must divert resources from patient care to comply with scientifically unsupported mandates, and patients lose access to the medications and treatment they need. That system fails everyone involved. This Court should reject regulatory whiplash in favor of the deliberative and scientific process Congress required FDA to perform by denying Plaintiffs' request for a stay of the 2023 REMS.

CONCLUSION

For the reasons set forth above, this Court should affirm the denial of a stay of the 2023 REMS.

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Respectfully submitted,

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I hereby certify that:

This brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(a)(7) because it contains 4,076 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Fifth Circuit Rule 32.2, which is less than 50 percent of that allotted for the Appellee's brief.

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I hereby certify that on this 21st day of July, 2026, a copy of the above document has been served on counsel for all parties to this proceeding through the court's electronic filing system.

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